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Puberty Suppression

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Section:

Medical and Behavioral Health Coverage Policy

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Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	September 13, 2016

PUBERTAL SUPPRESSION WITH GONADOTROPIN-RELEASING HORMONE ANALOG AGENT FOR GENDER DYSPHORIA

LENGTH OF AUTHORIZATION: THREE MONTHS

CLINICAL CRITERIA:

Gender dysphoria is defined as distress or discomfort caused by a discrepancy between a person's assigned sex at birth and a person's gender identity. Unresolved, the distress or discomfort can manifest into a host of behavioral health problems including depression, anxiety, suicidal ideation and self-mutilation. The purpose of pubertal suppression is to alleviate suffering caused by the development of secondary sex characteristics, to provide time to make a balanced decision regarding the actual gender reassignment.¹

REVIEW CRITERIA:

- Comprehensive mental health evaluation required including the diagnosis of gender dysphoria, using the current Diagnostic and Statistical Manual of Mental Disorders-5 by a licensed qualified mental health provider (MHP) with experience in treating patients with gender dysphoria (supporting documentation required).²
- The diagnosis must be confirmed by an endocrinologist.²
- MHP clinical notes must conclude that not treating the patient is likely to be worse than the potential long-term consequences of the treatment. The treatment must be medically necessary (e.g. it is administered to protect life and/or prevent significant disability, such as to prevent suicide or self-mutilation), and must ensure that the pubertal suppression treatment approach presents as the best alternative given the patient's psychological state and presenting signs and symptoms (supporting documentation required).
- Patient must have been in psychotherapy for a minimum of six months since diagnosed with gender dysphoria prior to consideration for pubertal suppression therapy.
- Females and males must reach at least a Tanner stage 2 or Tanner stage 3 prior to consideration of pubertal suppression therapy and have confirmed pubertal levels of estradiol and testosterone, respectively.² If treatment is being prescribed for adolescents under the age of 12, additional documentation is required to support the request.
- MHP clinical notes must address the patient's readiness for pubertal suppression treatment and ensure psychotherapy will continue to be offered while on pubertal suppression therapy.³
- Parental consent is required during treatment for patients under the age of 18.4 The patient and the legal guardian/parents must demonstrate knowledge and understanding of the expected



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outcomes of suppression of pubertal hormones including the reversible and irreversible effects of pubertal suppression therapy (supporting documentation required).²

- Evidence that other psychiatric or medical comorbidities that may interfere with the diagnostic work-up or treatment have been ruled out.³
- Documentation of treatment adherence is required.

¹The Standards of Care for Gender Identity Disorders (5th Ed) Harry Benjamin International Gender Dysphoria Association, Inc. Available at: http://www.tc.umn.edu/~colem001/hbigda/hstndrd.htm Accessed September 9, 2016

²Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 2009; 94:3132-3154

³ Vance SR, Ehrensaft D, Rosenthal SM, et al. Psychological and Medical Care of Gender Nonconforming Youth Pediatrics 2014; 134:1184-1192

⁴ Cavanaugh T Cross-Sex Hormone Therapy. Available at: http://www.lgbthealtheducation.org/wp-content/uploads/Cross-Sex-Hormone-Therapy1.pdf Accessed September 9, 2016

RICK SCOTT GOVERNOR

ELIZABETH DUDEK SECRETARY

PUBERTY SUPPRESSION THERAPY GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS (GAPMS) DETERMINATION REPORT WITH RECOMMENDATION

Date:

April 11, 2022

To:

Justin Senior, Deputy Secretary for Medicaid

From:

Bureau of Medicaid Policy

Subject:

Puberty Suppression Therapy

PURPOSE

In order for the use of puberty suppression therapy to be covered under the Florida Medicaid program, it must meet medical necessity criteria as defined in Rule 59G-1.010, Florida Administrative Code (F.A.C.), and be funded through the General Appropriations Act of Chapter 216, Florida Statutes (F.S.).

Pursuant to the criteria set forth in Rule 59G-1.010, F.A.C., the use of puberty suppression therapy must be consistent with generally accepted professional medical standards (GAPMS) as determined by the Medicaid program, and not experimental or investigational.

In accordance with the determination process established in Rule 59G-1.035, F.A.C., the Deputy Secretary for Medicaid will make the final determination as to whether the use of puberty suppression therapy is consistent with generally accepted professional medical standards and not experimental or investigational.

If it is determined that puberty suppression therapy is consistent with generally accepted professional medical standards, this report will be supplemented with an addendum which analyzes additional factors to determine whether this health service should be covered under the Florida Medicaid program.

REPORT WITH RECOMMENDATION

This report with recommendation is presented as the summary assessment considering the factors identified in Rule 59G-1.035, F.A.C., based on the collection of information from credible sources of reliable evidence-based information. The intent is to provide a brief analysis with justification in support of the final recommendation.

The analysis described in this report includes:

- A high level review of relevant disease processes.
- An overview of the health service information.
- Clearance from the government regulatory body (e.g., Food and Drug Administration).

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- Evidence based clinical practice guidelines.
- A review of the literature considered by the relevant medical community or practitioner specialty associations from credible scientific evidence-based literature published in peer reviewed journals and consensus of coverage policy from commercial and other state Medicaid insurers.

HEALTH SERVICE SUMMARY

Hormones

Hormones are important chemical messengers in the body that effectively transfer signals and instructions from one set of cells to another. Hormones are secreted into the bloodstream by a collection of glands inside the body referred to as the endocrine system. A gland is a group of cells that produces and secretes chemicals into the body. The major glands that make up the endocrine system include the hypothalamus, pituitary gland, thyroid and parathyroid, adrenals, pineal body, and the ovaries and testes.

In a laboratory setting, hormones are produced synthetically and are prescribed by physicians to treat disease or hormone deficiencies. An instance where synthetic hormones may be needed is when an individual has their thyroid gland surgically removed; a practitioner may prescribe synthetic thyroid hormones to replace those that their body can no longer produce.

Over 50 different hormones have been identified in the human body, and more are still being discovered. Hormones influence and regulate practically every cell, tissue, organ, and function of the body, including growth, development, metabolism, homeostasis, and sexual and reproductive function.²⁰

Reproductive Hormones

The hormones commonly considered as reproductive hormones in the body are testosterone, estrogen, and progesterone. Testosterone is often referred to as a male hormone, and estrogen and progesterone are often referred to as female hormones. However, there are no exclusively male or female hormones that have been identified. The physical manifestations of gender result from differences in the amounts of individual hormones in the body and differences in their patterns of secretion, first in utero and then again during puberty. In other words, testosterone, estrogen, and progesterone are produced by men and women, but in differing amounts and in different patterns.²⁰

Reproductive Hormone Suppression Therapy

There are many disease processes in which increased levels of reproductive hormones are released. They include, but are not limited to, prostate cancer, breast cancer, severe endometriosis, and central precocious puberty. To address the over-secretion of reproductive hormones, several drugs have been developed to aid in reducing hormone levels, including those hormones released during puberty.

For the purposes of this report, an analysis is being performed on the use of hormone treatment to suppress puberty. Currently, there are a number of drugs used to suppress puberty, which all use gonadotropin-releasing hormone (GnRH) agonists. Agonists function to stop receptors from connecting with the appropriate transmitter. For a hormone to perform its primary function in the

brain and body it must find the correct receptor to transmit its response; the GnRH agonists prevent this natural cycle.²⁰

Government Regulatory Body Approval

The Food and Drug Administration (FDA) has approved three drugs for the use in children for the purpose of puberty suppression therapy, as follows:

- Lupron⁴⁴
 - o Indications for use: Palliative treatment of advanced prostatic cancer and central precocious puberty in children of both sexes.
- Synarel⁴⁷
 - o Indications for use: Central precocious puberty (gonadotropin-dependent precocious puberty) in children of both sexes and endometriosis.
- Supprelin⁴⁶
 - o Indications for use: Central precocious puberty in both sexes.

Each of these drugs has specific indications for use and dosing information. Additionally, these medications have approved off-label uses. This permits usage in other than the approved FDA indications. These approved off-label uses are compiled in three compendia: American Hospital Formulary Service Drug Information (AHFS), United States Pharmacopeia-Drug Information (or its successor publications), and DRUGDEX Information System.⁷ The drugs specified above are authorized in the respective compendia to treat the following conditions:

- Lupron:
 - o Breast cancer
 - In vitro fertilization
 - o Ovarian cancer
 - o Premenstrual syndrome
 - o Prostate cancer
 - Prostate cancer, Neoadjuvant treatment
 - o Uterine leiomyoma
- Synarel:
 - Benign prostatic hyperplasia
 - Contraception, Female; prophylaxis
 - o Contraception, Male; prophylaxis
 - o Crohn's disease
 - Hirsutism
 - In vitro fertilization
 - Uterine leiomyoma
- Supprelin:
 - Acute intermittent porphyria
 - o Endometriosis
 - Female infertility; Adjunct
 - Polycystic ovary syndrome
 - o Uterine leiomyoma

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While all of these drugs may be utilized to treat other conditions, as indicated above and specified in the compendia, none of them are authorized or specified in the compendia for use in treating individuals diagnosed with gender dysphoria.⁷

LITERATURE REVIEW

This analysis summarizes information obtained from scientific literature published in credible peer-reviewed journals related to the use of puberty suppression therapy. This section also briefly cites the positions from the relevant medical societies, and summarizes the key articles referenced in support of their positions.

Central Precocious Puberty

Central precocious puberty (CPP) develops due to premature pubertal changes and rapid bone development. CPP is associated with lower adult height and increased risk for development of psychological problems.

Reproductive hormone suppression therapy (also referred to as puberty suppression therapy in this document) has been the standard of care for CPP for the last 15-20 years. The standard treatment for CPP is GnRH analogs. Although there are many different analogs with different routes of administration, the primary agent in the United States for many years was depot intramuscular injections administered every four weeks, but in the last ten years, a subdermal or under the skin implant has been developed, which has been shown to be effective for up to two years. ^{17, 39, 41}

In a recent study, researchers explored the difference in cognitive function, behavior, emotional reactivity, and psychosocial problems between young females treated with GnRH and agematched controls. They concluded that young females treated with GnRH do not differ in their cognitive functioning, behavioral, and social problems from their same age peers. However, they did find a significant difference in heart rate that increased with treatment duration and suggested a follow-up study with an emphasis on cardiac health.⁵⁵

Gender Dysphoria

Gender dysphoria is an individual's affective or cognitive discontent with their assigned gender (gender at birth). Gender dysphoria refers to the distress that may accompany the incongruence between the individual's experienced or expressed gender and their assigned gender. Evidence of this distress is the hallmark of the disorder. The diagnostic criteria are divided into a category for children and a category for adolescents and adults. The disorder is manifested differently as an individual ages or enters different developmental stages. Both categories require marked incongruence between the individual's experienced or expressed gender and their assigned gender of at least a six months' duration and clinically significant distress or impairment in social, school (occupation for adults), or other important areas of functioning.

Diagnostic criteria in children include: a strong desire to be the other gender or an insistence that they are the other gender; a preference for wearing clothing associated with the other gender; preference for cross gender roles in simulated play; preference for toys games, or activities usually associated with the other gender; preference for playmates of the other gender; and the dislike of their sexual anatomy. The prevalence of this diagnosis among the general population ranges from 0.005% to 0.014% in males and 0.002% to 0.003% in females.¹⁴

Studies have shown that the majority of children (80%) diagnosed with gender dysphoria will not continue to be gender dysphoric after puberty.³¹

In adolescents and adults, diagnostic criteria include: a strong desire to be and to be treated as the other gender and a strong desire to have the sex characteristics of the other gender (or in the case of adolescents, the wish to prevent the development of their assigned gender's characteristics).¹⁴

Gender dysphoria is associated with high levels of stigmatization, discrimination, and victimization, leading to negative self-concept, increased rates of mental disorder comorbidity, school dropout, and economic marginalization.¹⁴ Adolescents that do not receive treatment during this already vulnerable period of development might engage in risky or self-harming behaviors, such as self-harm, self-mutilation, suicidal ideation, or suicide.²²

For the 20% of children who persist in their feelings of gender dysphoria, clinicians may begin to explore alternative treatment approaches beyond psychotherapy after the onset of puberty, including medical interventions such as the use of GnRH analogs to suppress puberty.³⁸ The use of puberty suppression therapy is used as a diagnostic aid in adolescents contending with gender dysphoria.^{6, 10, 11, 24, 31, 50} The use of GnRH analogs is generally prescribed in adolescents ages 12-16. In addition to puberty suppression therapy, a physician may also begin to prescribe cross-sex hormones, though the latter does not generally begin until the ages of 16-18.^{10, 11}

The use of GnRH analogs will delay reproductive development in this population. However, there remains a great deal of concern and lack of consensus in the medical community of the potential risks, including: misdiagnosis, sterilization, adverse medical effect on the metabolic and endocrine system, impaired bone mass and brain development, etc.^{51, 6} To date, there have been no randomized controlled clinical trials on the use of GnRH analogs in the treatment of gender dysphoria (on large cohorts) that have been shown to be efficacious with tolerable side effects. This is in large part due to the small number of patients diagnosed with gender dysphoria, which makes any statement on the general efficacy of a treatment approach challenging.³¹ However, there have been case-studies (qualitative) that have been conducted that review the outcomes on small cohorts. These studies have concluded that there are limited negative side effects from the use of puberty suppression drugs in adolescents contending with gender dysphoria.^{54, 55}

Clinicians who support the use of puberty suppression therapy in the treatment of gender dysphoria argue that the risks of misdiagnosis are significantly reduced if the treatment is delayed until the initiation of puberty. They also contend that this treatment may relieve emotional distress in the individual (including reducing suicidal ideation in severe cases) and may "buy time" for the child to explore their feelings of gender dysphoria without contending with physical changes that cannot be undone (e.g., breast development).²² Most treatment protocols recommend extensive psychological evaluations/assessments and psychotherapy by mental health professionals prior to the initiation of medical interventions. This is especially important given the changing thoughts and feelings of prepubescent children versus adolescents with persistent gender dysphoria and in adolescents presenting with co-morbid conditions.

It is important to note that most of the literature reviewed in development of this analysis concluded that more systematic research is required to determine the long-term efficacy of medical treatment for adolescents with gender dysphoria. ^{21, 24, 25, 28, 50, 51}

Evidence-Based Clinical Practice Guidelines

The American Academy of Pediatrics published a consensus statement on the use of GnRH analogs in children in March 2009. They concluded that GnRH use was undisputed in the treatment of CPP early-onset (less than six years old). However, the use of GnRH for conditions other than CPP requires additional investigation and cannot be suggested routinely. The consensus statement does not specifically address the use of GnRH in the treatment of gender dysphoria.

The Endocrine Society published guidelines for the endocrine treatment of transsexual persons. The Society concluded that transsexual persons seeking to develop the physical characteristics of the desired gender require safe, effective hormone regimen that will 1) suppress endogenous hormone secretion determined by the person's genetic/biological sex and 2) maintain sex hormone levels within the normal range for the person's desired gender. They recommend that a mental health professional make the referral and participate in ongoing care and an endocrinologist must confirm the diagnostic criteria. They do not recommend endocrine treatment of prepubertal children. The recommendations are as follows:

- Treatment of transsexual adolescents (Tanner stage two, generally achieved around the age of 12 years) by suppressing puberty with GnRH analogues until the age of 16 years.
- Initiation of cross-sex hormones at the age of 16 years with continued suppression of biological sex hormones.
- Maintaining physiologic levels of gender-appropriate sex hormones and monitoring for known risks throughout adulthood.^{19, 18, 32}

In making these recommendations, however, the Endocrine Society identified the strength of the evidence used to support its conclusions. For all of the recommendations listed above, the Society acknowledged the strength of the evidence as low or very low.

COVERAGE POLICY

Federal Regulations

Federal regulations for Medicaid specify that a state may limit coverage of a drug with respect to the treatment of a specific disease or condition for an identified population (if any) based on the drug's labeling, if it does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary. In addition, states may exclude a drug when the prescribed use of the drug is not for a medically accepted indication, either approved by the FDA or supported by information from the appropriate compendia. These guidelines apply to a state's administration of its Medicaid prescribed drug benefit in both managed care and non-managed care delivery systems.

States are also required to implement a drug use review program for covered outpatient drugs in order to assure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical results. The program is required to assess data on drug use against predetermined standards, consistent with the following:

- 1. Compendia, consisting of the following:
 - a. American Hospital Formulary Service Drug Information;
 - b. United States Pharmacopeia-Drug Information (or its successor publications); and
 - c. the DRUGDEX Information System; and
- 2. The peer-reviewed medical literature.

Federal law requires states to provide services to eligible recipients under the age of 21 years, if such services are medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness. This is known as the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit. Included are diagnostic services, treatment, equipment, supplies, and other measures described in section 1905(a) of the Social Security Act, codified in Title 42 of the United States Code 1396d (a). As such, services for recipients under the age of 21 years exceeding any coverage limitations specified within a state's policies maybe approved, if medically necessary.

Florida Medicaid

In order to be reimbursed by Florida Medicaid, a drug must be medically necessary and either (a) prescribed for medically accepted indications and dosages found in the drug labeling or drug compendia in accordance with section 1927(k) (6) of the Social Security Act, or (b) prior authorized by a qualified clinical specialist approved by the Agency for Health Care Administration (Agency).¹

The criteria that are utilized under the Florida Medicaid program in the authorization of drugs for off-label purposes are as follows:

- 1. Documentation submitted with trial and failure or intolerance to all FDA- approved medications for the indication **AND**
- 2. Phase III clinical studies published in peer review journals to support the non-FDA approved use **AND**
- 3. Usage supported by publications in peer reviewed medical literature **and** one or more citations in at least one of the following compendia:
 - a. American Hospital Formulary Service Drug Information (AHFS)
 - b. United States Pharmacopeia-Drug Information (or its successor publications)
 - c. DRUGDEX Information System¹

Florida Medicaid covers reproductive hormone suppression therapy (including puberty suppression therapy) for all FDA approved indications/uses or when the information in the appropriate compendium supports the use of the drug in the treatment of the specific disease state or condition. Since the use of GnRH agonists are not FDA approved or listed in the appropriate compendia for the treatment of gender dysphoria, Florida Medicaid does not authorize these drugs for such uses. However, children/adolescents diagnosed with gender dysphoria are eligible to receive an array of other medical and behavioral health interventions (e.g., individual and family therapy, psychological evaluations/assessments, other medical evaluation and management services) necessary to address their presenting signs and symptoms.

Health plans contracted to provide services under the Florida Medicaid Statewide Medicaid Managed Care program are required to cover all prescription drugs listed in the Agency's Medicaid Preferred Drug List (PDL). In addition, the health plan's prior authorization criteria and protocols may not be more restrictive than those used by the Agency as indicated in the Florida Statutes, the Florida Administrative Code, the Medicaid State Plan and those posted on the Agency website.

Florida Medicaid provides services to eligible recipients under the age of 21 years, if such services are medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness. Medical necessity in the State of Florida must meet the following conditions:

- 1. Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
- 2. Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs;
- 3. Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational:
- 4. Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide; and
- 5. Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

If a service exceeds the coverage described within a Florida Medicaid policy or the associated fee schedule, a request (along with all supporting documentation) may be submitted to the Agency or its designee for review.

Medicare

Medicare covers reproductive hormone suppression for all FDA approved use. The *Medicare Benefit Policy Manual*, Chapter 15, page 15, subsection 50.4.2, discusses the unlabeled use of a drug. The policy states that "FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice." However, because Medicare covers primarily elderly adults and disabled adults, its coverage policies have little or no application in this analysis.

State Medicaid Programs

All state Medicaid programs cover reproductive hormone suppression therapy for the approved FDA indications and when the criteria for off-label use are met. Some state Medicaid programs are also adopting coverage policies that allow for reimbursements of puberty suppression therapy in adolescents diagnosed with gender dysphoria. It appears at this time as though most states do not cover this service although that may change over time. This report highlights the coverage policies for four Medicaid programs that do cover the service, as follows:

- 1. Colorado Medicaid covers behavioral health services, GnRH analogs/agonists, cross-sex hormone therapy, gender confirmation surgery, and pre and post-operative care.
- 2. Maryland Medicaid covers GnRH treatment if the recipient has a diagnosis of gender dysphoria.
- 3. Rhode Island Medicaid covers behavioral health services, pharmacological and hormonal therapy to delay physical changes of puberty, and pharmacological and hormonal therapy that is non-reversible and produces masculinization or feminization. Some services require prior authorization.
- 4. Washington State Medicaid covers behavioral health services, puberty suppression therapy, hormonal therapy, and gender reassignment surgery.

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

Puberty suppression therapy is considered a health service that is consistent with generally accepted professional medical standards for the approved FDA indications (i.e., central precocious puberty) and for off-label use when supported by citations in at least one of the compendia. Since Florida Medicaid already provides coverage of puberty suppression therapy in the treatment of central precious puberty and for use in treating the conditions cited in the compendia, no further policy coverage analyses are needed to supplement this report on this point.

Based upon the available published literature, it is inconclusive whether puberty suppression therapy is considered a health service that is consistent with generally accepted professional medical standards in the treatment of gender dysphoria. Most of the studies published thus far on the use of puberty suppression in gender dysphoric children/adolescents have concluded that further systematic research is required to determine the long-term safety and efficacy of this approach and there remains a lack of consensus within the medical community on its appropriateness (both from an ethical and safety perspective). As the research on this topic continues to evolve, more conclusive evidence may emerge that supports the long-term efficacy and effectiveness of this treatment approach. At any time, a follow-up analysis can be performed that could change this recommendation.

EPSDT Considerations:

While the Agency cannot make a blanket determination on puberty suppression therapy for gender dysphoria, we also cannot categorically exclude this treatment for children. Clinical guidelines from the Endocrine Society do recommend this therapy for certain adolescents, albeit based upon a combination of weak and very weak evidence. In certain circumstances, the risks of not treating an adolescent may be worse than the potential long-term consequences of treatment. Moreover, it is noted extensively in the literature that adolescents contending with gender dysphoria often experience a myriad of emotional, physical, and societal challenges. Unresolved, the distress can manifest into a host of behavioral health problems including depression, anxiety, and suicidal ideation and self-mutilation. Florida pays for services for children when they protect life and /or prevent significant disability or harm, in accordance with the state's medical necessity definition.

Given these concerns, while it is not recommended that any further analyses be conducted to expand Florida Medicaid's coverage of puberty suppression therapy beyond those indications/uses approved by the FDA or authorized in the appropriate compendium, it is recommended that any individualized request for such therapy be reviewed as a part of the Agency's special services process. Consistent with EPSDT requirements, the request can be evaluated on an individualized basis to determine if the service is medically necessary (e.g. it is administered to protect life and/or prevent significant disability, such as to prevent suicide or self-mutilation) to ensure that all less invasive interventions have been exhausted, and to ensure that this treatment approach presents as the best alternative given the adolescent's psychological state and presenting signs and symptoms.

Concur	Do not Concur
Comments:	

	Puberty	Suppression	Therapy	10
Deputy Secretary for Medicaid (or designee			 Date	0

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Division: Pharmacy Policy	Subject: Prior Authorization Criteria		
Original Development Date:	September 20, 2016		
Original Effective Date:	September 18, 2017		
Revision Date:	November 17, 2017		
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SPECIAL SERVICES CRITERIA PUBERTAL SUPPRESSION WITH GONADOTROPIN-RELEASING HORMONE ANALOG AGENT FOR GENDER DYSPHORIA

LENGTH OF AUTHORIZATION: THREE MONTHS

CLINICAL CRITERIA:

Gender dysphoria is defined as distress or discomfort caused by a discrepancy between a person's assigned sex at birth and a person's gender identity. Unresolved, the distress or discomfort can manifest into a host of behavioral health problems including depression, anxiety, suicidal ideation and self-mutilation. The purpose of pubertal suppression is to alleviate suffering caused by the development of secondary sex characteristics, in order to provide time to make a balanced decision regarding the actual gender reassignment.¹

REVIEW CRITERIA:

- A comprehensive mental health evaluation is required and must include the diagnosis of gender dysphoria, using the current Diagnostic and Statistical Manual of Mental Disorders-5 by a mental health professional (MHP) licensed in accordance with s. 490 or s. 491, Florida Statutes (supporting documentation required).²
- The diagnosis must be confirmed by an endocrinologist.²
- The MHP clinical notes must reflect the MHP's professional judgment that not treating the patient is likely to be worse than the potential long-term consequences of the treatment. The treatment must be medically necessary (e.g. it is administered to protect life and/or prevent significant disability, such as to prevent suicide or self-mutilation), and must ensure that the pubertal suppression treatment approach presents as the best alternative given the patient's psychological state and presenting signs and symptoms (supporting documentation required).
- The patient must have been in psychotherapy for a minimum of six months since diagnosed with gender dysphoria prior to consideration for pubertal suppression therapy.
- Females and males must have reached a Tanner stage 2 or Tanner stage 3 prior to consideration of pubertal suppression therapy and have confirmed pubertal levels of estradiol and testosterone.
- If treatment is being prescribed for adolescents under the age of 12, additional documentation is required to support the request.
- The MHP clinical notes must address the patient's readiness for pubertal suppression treatment and ensure psychotherapy will continue to be offered while on pubertal suppression therapy.³
- Parental consent is required during treatment for patients under the age of 18.⁴ The patient and the legal guardian/parents must demonstrate knowledge and understanding of the expected



Division: Pharmacy Policy	Subject: Prior Authorization Criteria		
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outcomes of suppression of pubertal hormones including the reversible and irreversible effects of pubertal suppression therapy (supporting documentation required).²

- Documentation must include evidence that other psychiatric or medical comorbidities that may interfere with the diagnostic work-up or treatment have been ruled out.³
- Documentation of treatment adherence is required.

¹The Standards of Care for Gender Identity Disorders (5th Ed) Harry Benjamin International Gender Dysphoria Association, Inc. Available at: http://www.tc.umn.edu/~colem001/hbigda/hstndrd.htm Accessed September 9, 2016

²Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 2009; 94:3132-3154

³ Vance SR, Ehrensaft D, Rosenthal SM, et al. Psychological and Medical Care of Gender Nonconforming Youth Pediatrics 2014; 134:1184-1192

 $^{^4\,}Cavanaugh\,T\,Cross-Sex\,Hormone\,Therapy.\,\,Available\,at:\,\underline{http://www.lgbthealtheducation.org/wp-content/uploads/Cross-Sex-New Content/uploads/Cross-Sex-New Content/uploads/Cross-New Content/uploads/New Conte$ Hormone-Therapy1.pdf Accessed September 9, 2016

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RICK SCOTT GOVERNOR

JUSTIN M. SENIOR INTERIM SECRETARY

October 6, 2016

Melissa Vergeson, Director Florida Department of Health Children's Medical Services Managed Care Plan 4052 Bald Cypress Way, BIN A-06 Tallahassee, FL 32399-1707

Dear Ms. Verguson:

The purpose of this letter is to address the Children's Medical Services (CMS) Plan's determination of coverage under the Medicaid Act's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) requirements for medically necessary services to an enrollee under the age of 21 years. The CMS Plan must establish and maintain a utilization management system to monitor utilization of medically necessary services, including an automated service authorization system for denials, service limitations, and reductions of authorization. The CMS Plan must not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of the enrollee's diagnosis, type of illness, or condition. (Attachment I, Section II.D.20.)

In an authorization review dated January 7, 2016, the CMS Plan issued a Notice of Prior Authorization Determination (Notice) for coverage of Supprelin LA (request 0917477). The CMS Plan did not authorize coverage of Supprelin LA and did not issue a notice of action for the denied service as required by Attachment II, Section VII.G.6.a. of the contract. In its Notice, the CMS Plan stated, "Please be advised patient's age exceeds max age limit for this request. Please refer to web site for specific drug criteria and preferred alternatives." The enrollee filed a request for Medicaid Fair Hearing in response to the denied pharmacy claim. In its Statement of Matters filed in the Fair Hearing, the CMS Plan included several additional documents, including the Agency for Health Care Administration's (Agency) rules for experimental and investigational procedures and Rule 59G-1.035, Determining Generally Accepted Professional Medical Standards, Florida Administrative Code.

The Statement of Matters arises from several factual errors. For example, Supprelin LA is not an experimental drug; the Food and Drug Administration has approved Supprelin LA for treatment of central precocious puberty in both sexes. Supprelin LA is also approved to treat other conditions, as specified in the American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications), and DRUGDEX Information System. However, Supprelin LA is not authorized or specified in these compendia for use in treating individuals diagnosed with gender dysphoria. This means that the CMS Plan denied Supprelin LA based solely on the Agency's criteria, which were not developed for this particular application of the drug. Given that this medication was prescribed for purposes outside of the approved indications, referring the treating physician to the Agency Web site could not provide "preferred alternatives."

The CMS Plan must ensure that all decisions to deny a service authorization request or limit a service in amount, duration, or scope that is less than requested, must be determined using the acceptable standards of care, state and federal laws, the Agency's medical necessity definition,

2727 Mahan Drive • Mail Stop #50 Tallahassee, FL 32308 AHCA.MyFlorida.com



Facebook.com/AHCAFlorida Youtube.com/AHCAFlorida Twitter.com/AHCA_FL SlideShare.net/AHCAFlorida October 6, 2016 Re: Verguson Page 2 of 2

and clinical judgment of a licensed physician, psychiatrist, or dentist (as appropriate) or other professional as approved by the Agency. (Attachment I, Section VII.G.4.b.) The CMS Plan may utilize a national standardized set of criteria (e.g., Interqual*) or other evidence-based guidelines approved by the Agency to approve services. Such criteria and guidelines must not **solely** be used to deny, reduce, suspend or terminate a service; it may only be used as evidence of generally accepted medical practices which support the basis of a medical necessity determination.

The CMS Plan must develop a process for authorization of any medically necessary EPSDT service to enrollees under the age of 21 years when:

- (1) The service is not listed in the service-specific Medicaid Coverage and Limitations Handbook, Coverage Policy, or fee schedule, or is not a covered service of the plan; or
- (2) The amount, frequency, or duration of the service exceeds the limitations specified in the service-specific handbook or the corresponding fee schedule. (Attachment I, Section VII.G.1.d.)

The CMS Plan must notify the provider and give the enrollee written notice of any decision to deny a service authorization request, or to authorize a service in an amount, duration or scope that is less than requested. (Attachment I, Section VII.G.5.a.) In addition, the CMS Plan must mail the enrollee a written notice of action using the template provided by the Agency. (Attachment I, Section VII.G.6.a.) Finally, the CMS plan must provide the notice of action for standard service authorization decisions that deny or limit services no more than seven days following the request for service. (Attachment I, Section VII.G.6.b.(3))

Based on these facts, the CMS Plan must rescind the Notice of Prior Authorization Determination for request 0917477 and conduct a medical necessity review of the enrollee's request in compliance with the plan's contract with the Agency. For additional reference, the CMS Plan may use the Agency's Puberty Suppression Therapy - Generally Accepted Professional Medical Standards (GAPMS) Determination Report with Recommendation (attached to this letter). As a result of this review on puberty suppression therapy, the Agency has developed Drug Utilization Review Criteria for Pubertal Suppression with Gonadotropin-Releasing Hormone Analog Agent for Gender Dysphoria, which is also included with this letter.

Sincerely,

Lucinda Coverston Contract Manager

LC/dp Attachments; GAPMS Analysis

Generally Accepted Professional Medical Standard (GAPMS)- Agents Used to Suppress Puberty in Transgender Children

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Article#	Name/Article Identifier	Link to Article	Assigned to	Notes
L	Medscape-Care of the Child with the Desire to Change Gender–Part I	http://www.medscape.com/viewarticle/718619	Sara	
2	fallonhealth: Transgender Services Clinical Coverage Criteria	http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=20&ved =0ahUKEwjeharTGubOAhVH5iYKHZYfAlg4ChAWCF8wCQ&url=http%3A%2F%2F www.fchp.org%2Fproviders%2Fmedical- management%2F~%2Fmedia%2FFiles%2FProviderPDFs%2FMedicalPolicies%2F TransgenderServices.ashx&usg=AFQiCNHGumXLS82ivBfVGHDP6bXEeJOdbQ	Sara	
3	Aetna – Gender Reassignment Surgery	http://www.aetna.com/cpb/medical/data/600_699/0615.html		
4	Blue Regence – Transgender Services - Policy	http://blue.regence.com/trgmedpol/medicine/med153.pdf	Arlene Sara	Reassigned
5	The Journal of Clinical Endocrinology & Metabolism	http://press.endocrine.org/doi/full/10.1210/ic.20090345	Arlene	
6	TransYouth Family Allies Puberty Inhibitors	http://www.imatyfa.org/permanent_files/pubertyblockers101.html	Arlene	
7	Moda Health Plan, Inc Gender Reassignment Medically Necessity Criteria	https://www.modahealth.com/pdfs/med_criteria/GenderReassignment.pdf	Susan	
8	Oregon Health Plan Coverage of Gender Dysphoria – FAQs	http://www.basicrights.org/wp-content/uploads/2015/09/OHP FAQ for CommunityPartners Mar 2016.pdf	Kym	
9	Boston Medical Center Health Net Plan – Well Sense Health Plan – Gender Reassignment Surgery	http://www.bmchp.org/~/media/d86fcbe8c97f4312834b4975caf64c6f.pdf	Kym	
10	Washington Apple Health Transgender Health Coverage FAQs	http://www.genderjusticeleague.org/wp-content/uploads/2015/08/Apple Health-FAQ-Final.pdf	Kym	
11	AAAP Gateway Psychological and Medical Care of Gender Nonconforming Youth	http://pediatrics.aappublications.org/content/134/6/1184	Susan	
12	AAAP Gateway- Office-Based Care for Lesbian, Gay, Bisexual, Transgender, and Questioning Youth	http://pediatrics.aappublications.org/content/132/1/e297	Susan	
13	Cross-Sex Hormone Therapy for Transgender Male-to-Female (MtF) Patients Criteria for Use VA Pharmacy Benefits Management Services	http://www.pbm.va.gov/PBM/clinicalguidance/criteriaforuse/Transgender Cross Sex Hormone Therapy in MtF Male to Female CFU.pdf	Sara	
14	Testosterone Replacement Therapy in Adult Men Criteria for Use VA Pharmacy Benefits Management Services,	http://www.pbm.va.gov/clinicalguidance/criteriaforuse/Testosterone Replacement in Adult Males Criteria for Use.pdf	Susan	

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Generally Accepted Professional Medical Standard (GAPMS)- Agents Used to Suppress Puberty in Transgender Children Case 4:22-cv-00325-RH-MAPLISTING CERFREARCH STILLES Filed 04/27/23 Page 2 of 3

	Casc 4.22 CV 00323 KIT MAI	Document 101 20° Filed 04/21/20° Fi	age Z or o	
15	Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People	http://transhealth.ucsf.edu/protocols	Arlene	
16	Cross-Sex Hormone Therapy	http://www.lgbthealtheducation.org/wp-content/uploads/Cross-Sex- Hormone-Therapy1.pdf	Arlene	
17	Pediatric Growth Hormone Deficiency Treatment & Management	http://emedicine.medscape.com/article/923688treatment	Arlene	
18	When Transgender Kids Transition, Medical Risks are Both Known and Unknown	http://www.pbs.org/wgbh/frontline/article/when-transgender-kids-transition-medical-risks-are-both-known-and-unknown/	Kym	
19	US NATIONAL LIBRARY OF MEDICINE - Consecutive lynestrenol and cross- sex hormone treatment in biological female adolescents with gender dysphoria: a retrospective analysis.	http://www.ncbi.nlm.nih.gov/pubmed/26885361	Tiffany	
20	Gender dysphoria – Treatment - NHS Choices information Gov.UK	http://www.nhs.uk/Conditions/Gender-dysphoria/Pages/Treatment.aspx	Tiffany Susan	
21	SUMMARY OF CLINICAL EVIDENCE FOR GENDER REASSIGNMENT SURGERIES CMS	https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/ Kalra_comment_01022016_b.pdf	EVERYONE — CMS REPORT	Listed Wrong Article – disregard
22	US NATIONAL LIBRARY OF MEDICINE` The effect of cross-sex hormonal treatment on gender dysphoria individuals' mental health: a systematic review	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4977075/	Tiffany -Kym	Reassigned
23	Supporting Transgender Children: What Does The Evidence Say? University of Alberta	https://inclusivehealthconference.files.wordpress.com/2016/05/supportingtransgenderchildren.pdf	Sara	
24	AMERICAN FAMILY PHYSICIAN - Updated Recommendations from the World Professional Association for Transgender Health Standards of Care	http://www.aafp.org/afp/2013/0115/p89.html	Susan	
25	Largest Study to Date: Transgender Hormone Treatment Safe	http://www.medscape.com/viewarticle/827713	Arlene	
26	Hormone treatment of gender identity disorder in a cohort of children and adolescents THE MEDICAL JOURNAL OF AUSTRIA	https://www.mia.com.au/journal/2012/196/9/hormonetreatment-gender-identity-disorder-cohort-children-and-adolescents	Sara	
27	Hormone Therapy is Lifesaving — But Why is No One Studying Its Long- Term Effects? OUT - By Diana Tourjee Tue, 2016-09-20 09:38	http://www.out.com/out-exclusives/2016/9/20/hormone-therapy-lifesaving- why-no-one-studying-its-long-term-effects	Arlene	
28	University of California, San Francisco Overview of feminizing hormone therapy	http://transhealth.ucsf.edu/trans?page=guidelinesfeminizing-therapy	Tiffany	
29	BOSTON UNIVERSITY – SCHOOL OF MEDICIN ENDOCRINOLOGY, DIABETES & NUTRITION Practical Guidelines for Transgender Hormone Treatment	http://www.bumc.bu.edu/endo/clinics/transgendermedicine/guidelines/	Sara	

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Generally Accepted Professional Medical Standard (GAPMS)- Agents Used to Suppress Puberty in Transgender Children

Case 4:22-cv-00325-RH-MAP-INTING CERFEE ARCH STILLES Filed 04/27/23 Page 3 of 3

30	Clinical Study Prevalence of cardiovascular disease and cancer during cross-sex hormone therapy in a large cohort of trans persons: a case-control study	http://www.eje-online.org/content/169/4/471.long	Tiffany
31	International Journal of Transgenderism, 13:165-232, 2011 Copyright C World Professional Association for Transgender Health ISSN: 1553-2739 print / 1434-4599 online Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version	https://www.academia.edu/13190717/Standards of Care for the Health of Transsexual Transgender and GenderNonconforming People Version 7	Susan
32	A long-term follow-up study of mortality in transsexuals receiving treatment with cross-sex hormones	http://www.eje-online.org/content/164/4/635.full	Tiffany
33	HAYES- Hormone Therapy for the Treatment of Gender Dysphoria	https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=16619&searchStore=%24search_type%3Dall%24icd%3D%24keywords%3Dcros 5= 5ex%2Chormones%24status%3Dall%24page%3D1%24from_date%3D%24to_date%3D%24report_type_options%3D%24technology_type_options%3D%24or_gan_system_options%3D%24specialty_options%3D%24order%3DasearchRelev_ance	Kym

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Newsfeed	OneDrive	Brackett	

	Medi	icaid Policy R	outing and	d Tracking Fo	orm				
Date:	11/2/	2016							
Assignment Title:	Cross-	Cross-Sex Hormone Therapy GAPMS							
Assignment Type:	GAPM	APMS							
Final Due Date:	11/20	/2016							
Assignment Summar	y (brief): Cross-	Sex Hormone Therapy	GAPMS						
Attachment(s):	GAPMS I	II (004) to SH.docx							
Section:	Pharm	nacy Policy							
Prepared By:	Sara C	Craig							
Position:	Senior	Pharmacist							
Preparer Phone:	4157								
Preparer Room Numl	per: 4157								
		Reviewed	by and Routing Ti	meline(s):					
Name	Title	Start Date	End Date	Date Received	Todays Date an				
Arlene Elliott	AHC Administrator			10/31/2016	11/2/2016	AE			
Erica Floyd-Thomas	Interim Deputy Sec	cretary fo		11/2/2016	2/1/2018				
Notes:	2/1/20	018 received for Erica	's review. JB	ı	•	•			

From: Ryals, Christopher

Sent: Monday, December 19, 2016 9:28 AM EST

To: \"\"Elliott\"\",\"\" Arlene; \" \"Harris\"\",\"\" Shevaun; Arlene.Elliott@ahca.myflorida.com;

Shevaun.Harris@ahca.myflorida.com

CC: Sokoloski, Kristin

Subject: FOLLOW UP DUE COB 12/22: Legislative Inquiry: Pharmaceutical Compendia

Arlene and Shevaun – We received the follow up question below from the House.

Can you please provide a response?

Thanks,

Chris

Christa wanted me to follow up on the Compendia information and ask whether the compendia research regarding off-label cross-sex hormones for gender dysphoria was viewed as positive or negative?

From: Elliott, Arlene

Sent: Sunday, December 04, 2016 12:11 PM

To: Sokoloski, Kristin

Cc: Harris, Shevaun; Ryals, Christopher

Subject: Re: PLEASE REVIEW: DRAFT RESPONSE RE: DUE COB 11/29: Legislative Inquiry:

Pharmaceutical Compendia

Hi. The prior auth refers to all. I'd rather not add that sentence but keep if you must.

The prior response regarding off label still requires to be medically necessary and until the puberty suppression GAPMS was approved we would be not thought gender dysphoria use was medically necessary. Our reviews from that GAPMS on have to change because most of the research we did find the treatment of G D medically necessary. All of our conclusions say each review has to be individualized. Thanks.

Sent from my iPhone

On Dec 4, 2016, at 10:53 AM, Sokoloski, Kristin Kristin.Sokoloski@ahca.myflorida.com> wrote:

Shevaun and Arlene – Below is our prior response and the proposed response to the follow up question.

I have a question about our response to the follow up. Is the phrase "Some of the drugs mentioned above require prior authorization" intended to only go with the paragraph beginning "Testosterone cypoinate . . ." or with that AND the paragraph beginning with "Lupron Depot . . .". Please let me know and let me know if any changes are needed based on this so that I can move this forward. Thanks!

Prior Response;

Consistent with federal law, Florida Medicaid covers all medically necessary services for children under the age of 21 years (child) even if the service is not listed in the Medicaid coverage policy/handbook, fee schedule, or the Florida Medicaid State Plan. If a provider requests a service for a child that is not covered by Florida Medicaid, the Agency (and its contracted health plans) has a process in place for reviewing such requests to make an individualized medical necessity determination. The treating practitioner can submit the request to the Agency's prior authorization vendor (or the enrollee's health plan) for review. States are not required to have the same processes in place for adult Medicaid recipients.

Florida Medicaid does not cover the majority of the services in question for adults. Florida Medicaid covers reproductive hormone suppression therapy (including puberty suppression therapy) for all FDA approved indications/uses or when the information in the appropriate compendium supports the use of the drug in the treatment of the specific disease state or condition. Children/adolescents diagnosed with gender dysphoria are eligible to receive an array of other medical and behavioral health interventions (e.g., individual and family therapy, psychological evaluations/assessments, other medical evaluation and management services) necessary to address their presenting signs and symptoms. Florida Medicaid covers behavioral health assessments/evaluations and individual and group therapy services for adults.

Follow up request:

Per our telephone call, I do not have subscription access to any of the pharmaceutical compendia that CMS authorizes and utilizes for Medicaid/Medicare. I was curious if your group could tell me what compendia they utilize and provide a copy of the compendia recommendations for the specific pharmaceuticals used in pubertal suspension and cross-sex hormone treatment hormones commonly used in treatment for gender dysphoria.

Follow up response:

The Social Security Act section 1861(t)(2)(B)(ii)(I) recognizes the following compendia: American Medical Association Drug Evaluations, United States Pharmacopoeia-Drug Information or its successor publication [amended in Section 6001 (f)(1) of the Deficit Reduction Act of 2005] and American Hospital Formulary Service-Drug Information, Micromedex/DrugDex®.

Lupron Depot, Synarel, and Supprelin LA are drugs approved by the U.S. Food and Drug Administration (FDA) for puberty suppression. The compendia does not address off-label use of treatment for gender dysphoria.

Testosterone cypionate, conjugated estrogens, and ethinyl estradiol are FDA approved for hormone replacement. The compendia addresses off-label use for cross-sex hormone therapy for individuals diagnosed with gender dysphoria.

Some of the drugs mentioned above require prior authorization.

From: Elliott, Arlene

Sent: Friday, December 2, 2016 5:17 PM

To: Harris, Shevaun < <u>Shevaun.Harris@ahca.myflorida.com</u>>; Sokoloski, Kristin

<Kristin.Sokoloski@ahca.myflorida.com>

Subject: FW: NEW DRAFT RESPONSE RE: DUE COB 11/29: Legislative Inquiry: Pharmaceutical

Compendia

From: Elliott, Arlene

Sent: Friday, December 2, 2016 4:20 PM

To: Harris, Shevaun Shevaun.Harris@ahca.myflorida.com

Subject: DRAFT RESPONSE RE: DUE COB 11/29: Legislative Inquiry: Pharmaceutical

Compendia

The Social Security Act section 1861(t)(2)(B)(ii)(I) recognizes the following compendia: American Medical Association Drug Evaluations, United States Pharmacopoeia-Drug Information or its successor publication [amended in Section 6001 (f)(1) of the Deficit Reduction Act of 2005] and American Hospital Formulary Service-Drug Information, Micromedex/DrugDex®.

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Some of the drugs mentioned above require prior authorization.

Arlene Elliott - AGENCY FOR HEALTH CARE ADMINISTRATOR-SES

Bldg. 3, Rm. 2332A - BUREAU OF MEDICAID POLICY 2727 MAHAN DR TALLAHASSEE, FL 32308 412-4152 (Office) Arlene.Elliott@ahca.myflorida.com

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<image004.jpg>

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From: Ryals, Christopher

Sent: Tuesday, November 22, 2016 1:44 PM

To: Harris, Shevaun < Shevaun. Harris@ahca.myflorida.com >; Elliott, Arlene

<Arlene.Elliott@ahca.myflorida.com>

Cc: Ward, Matthew < Matthew. Ward@ahca.myflorida.com >; Reeves, Arabella

<a href="mailto: Arabella.Reeves@ahca.myflorida.com

Subject: DUE COB 11/29: Legislative Inquiry: Pharmaceutical Compendia

Shevaun and Arlene – The Legislative Affairs office received the inquiry below from Tyler Tuszynski with the House Children, Families, & Seniors Subcommittee.

Mr. Tuszynski is requesting information related to the specific pharmaceuticals used in pubertal suspension and cross-sex hormone treatment for gender dysphoria.

Will you please review the request below and provide a response by COB 11/29?

Thanks.

Chris

Request:

Per our telephone call, I do not have subscription access to any of the pharmaceutical compendia that CMS authorizes and utilizes for Medicaid/Medicare. I was curious if your group could tell me what compendia they utilize and provide a copy of the compendia recommendations for the specific pharmaceuticals used in pubertal suspension and cross-sex hormone treatment hormones commonly used in treatment for gender dysphoria.

DRUG UTILIZATION REVIEW BOARD

Agency For Health Care Administration

Tampa Marriott Westshore

Thursday, March 23, 2017

2:08 - 4:18 p.m.

REPORTED BY:

JUANITA ANNETTE BUTLER
INTEGRA REPORTING GROUP, LLC
Stenographic Court Reporter
Notary Public, State of Florida

INTEGRA REPORTING GROUP, LLC Tampa, FL (813) 868-5130

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APPEARANCES:

BOARD MEMBERS:

Moses Allen, Pharm. D. (Vice-Chair) (Acting Chair)
Larry Field, D.O.
Vanessa Goodnow, Pharm D.
Anna Hayden, D.O.
Kevin Olson, Pharm.D.
Alfred Romay, Pharm.D.
Luis Saenz, D.O.
Amy Zitiello, D.O.

AHCA STAFF:

Shevaun Harris, Assistant Deputy Secretary
Medicaid Policy & Quality
Kevin Dewar, Esquire, Assistant General Counsel
Vern Hamilton, AHCA Liaison
Arlene Elliott, R.Ph.,
Medicaid Pharmacy Policy Administrator
Sara Craig, Pharm.D., Senior Pharmacist

MAGELLAN MEDICAID ADMINISTRATION:

Elboni Moore, Pharm.D. Selika Sampson, Pharm.D. Stephanie McGriff, Pharm.D.

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1	PROCEEDINGS
2	THE CHAIRPERSON: The time is now 2:02 and
3 .	we'll be starting our First Quarter AHCA DUR
4	Meeting. For those of you who are AHCA DUR
5	geeks, this is actually the first quarter
6	meeting, even though it's the second meeting of
7	the year, because the fourth quarter meeting
8	was held in January.
9	All right. Before we get started, we're
10	going to have opening remarks from our deputy
11	secretary, Shevaun Harris.
12	MS. HARRIS: Good afternoon, board members
13	and audience members. Thank you for taking
14	time out of your busy schedules to participate
15	in this board meeting to assist the agency.
16	I have just two updates for you. We are
17	in the process of working on the re-procurement
18	of our statewide Medicaid Managed Care program.
19	For those of you who follow what's going on in
20	managed care, I wanted to let you know about
21	that. We plan to issue our solicitation over
22	the summer, so keep an eye out for that.
23	The agency has put out an invitation for
24	any interested parties to let us know of their
25	interest and we received quite a bit of

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1	reedback. And if you're interested in the
2	results of that, it's posted on our website.
3 .	We can get that out to the board members if
4	they're not quite sure where the link is on our
5	website or what page it's posted on on our
6	website.
7	The other thing, I think probably Arlene
8	gave you updates at the last meeting. But if
9	you're not aware, we have solidified our
10	leadership team at the agency. Our secretary,
11	Justin Senior, was appointed by the governor.
12	He moved out of an interim role in January, I
13	believe. And Beth Kidder, my supervisor, was
14	named Medicaid director for the state of
15	Florida. And I was recently promoted to
16	assistant deputy secretary for Medicaid Policy
17	& Quality.
18	So my position as bureau chief over
19	Medicaid Policy is vacant. I'm working to fill
20	that position and hope to still participate in
21	these meetings as frequently as possible, but
22	you probably won't see me as much as you have
23	in the past.
24	We are in the middle of a legislative
25	session. I will note that, too. The agency is

1	tracking quite a bit of activity that's
2	happening. We've had several bills filed that,
3 .	if enacted, would impact our Medicaid Managed
4	Care program. Some activity around pharmacies
5	and how our health plans contract with
6	pharmacies as well. So the agency is just
7	really tracking, at this point, how those bills
8	are working their way through the committee
9	process. And when we meet in June, we will be
10	able to give you an update of any bills that
11	passed that have any major impacts on the
12	Medicaid program, in particular, our prescribed
13	drugs benefit.
14	Any questions for me?
15	Thanks.
16	THE CHAIRPERSON: Outstanding. And
17	congratulations on the promotion. I think at
18	this time, since we know who you are, I'd like
19	to go ahead and have introductions for the
20	remainder of the committee, starting with
21	Stephanie.
22	DR. MCGRIFF: Good afternoon, everyone.
23	I'm Stephanie McGriff. And I'm clinical
24	account manager for Magellan Health Services.
25	DR. SAMPSON: Good evening. I'm Selika

a family practitioner in Ft. Lauderdale,

25

7

- 1 Florida.
- DR. OLSON: Kevin Olson, pharmacist out of
- 3 Tampa, Florida.
- DR. ROMAY: Alfred Romay, director of
- 5 pharmacy, Molina Healthcare of Florida.
- DR. SAENZ: Luis Saenz, medical director
- 7 of Molina.
- 8 DR. ZITIELLO: Amy Zitiello, pediatrician
- 9 and medical director of Avalon Healthcare
- 10 Solutions.
- 11 THE CHAIRPERSON: Great. Okav. We're
- going to go ahead and jump right into the
- 13 agenda. As always, our stenographer does a
- 14 great job of preparing the minutes. At this
- point, I'd like to ask the committee to review,
- 16 and if it meets your approval, I'll need the
- motion to approve.
- DR. HAYDEN: Motion to approve.
- DR. FIELD: Second.
- THE CHAIRPERSON: It's been properly moved
- and seconded. All those in favor, please say
- 22 aye.
- THE COMMITTEE: Aye.
- 24 THE CHAIRPERSON: All right. Moving on.
- 25 Review of the P&T minutes, as we know,

1	this item is for information only, so we don't
2	need an actual vote. So at this time, I just
3 .	wanted to ask if there are any questions or
4	concerns with those minutes.
5	Great. Hearing none. We're going to go
6	ahead and move on to the Quarterly DUR Activity
7	Reports. And at this point, we'll hand it over
8	to Selika and Elboni.
9	DR. SAMPSON: Good afternoon. Without any
10	further delay, we're going to move right into
11	our review for this quarter.
12	Quick overview. Today we are going to
13	follow up on our previous DUR items. In
14	addition, to discuss the first quarter DUR
15	activities and also decide on second quarter,
16	2017, DUR activities.
17	The first topic is Growth Hormone. This
18	was a top therapeutic class review, previously
19	reviewed at the January 2016 DUR meeting. The
20	data at that time was fourth quarter 2015 data.
21	And what we had to do here was follow up on
22	that report due to the auto PA logic being
23	the auto PA logic for preferred growth hormone
24	products diagnosis verification was removed
25	from the fee-for-service side, March 2014, 2016

1	and the post-implementation data was shared at
2	the June 2016 meeting.
3 .	The post-implementation data, once that
4	was removed, you have the clinical PAs that
5	were reviewed for April 1st, 2016 through June
6	30, 2016, and, at that time, it revealed a fill
7	of \$3 million total amount paid over 817 claims
8	for 354 users. So there you can see the
9	decrease.
10	And on the MCO side, due to implementation
11	for the MCOs, when that happened for them,
12	their numbers remained steady. They got more
13	recipients during this time as well.
14	Our next topic, Vesicare, Toviaz, minimum
15	age limit of 18 years old. The purpose of this
16	review was to address the misuse of long-acting
17	agents in the pediatric population. The added
18	details are as follows: Vesicare and Toviaz
19	are not indicated in children. Recipients must
20	be at least 18 years or older for either of
21	those two products, and claims for Vesicare and
22	Toviaz are directed to the preferred
23	alternatives for children.
24	The fee-for-service and MCO utilization
25	has significantly decreased 64 percent and 84

1	percent, respectively, 78 percent decrease
2	collectively.
3	The prior authorization intervention for
4	pediatric recipients under the age of 18 years
5	is working. There were 54 claims at roughly
6	\$15,000 and also 58 claims for \$16,000 on the
7	MCO side.
8	Now, we'll take a look at the breakout for
9	Toviaz. The pre-edit for children under 18
10	years of age for fee-for-service, it was a
11	small population, but, again, the reason why
12	the edit was done was because it's not
13	indicated for children under 18.
14	And so, you can see there, again, that the
15	intervention is working. Utilization has
16	decreased overall. Relatively 60 percent for
17	the fee-for-service and 76 percent for the MCO.
18	And when we take a look at Vesicare, that
19	agent, again, you have a smaller population.
20	Fee-for-service, overall utilization decreased
21	relatively about 66 percent and MCO relatively
22	about 83 percent.
23	Now, during the January 2017 P&T meeting,
24	the PT committee recommended for the DUR board
25	to review vasopressin receptor antagonists. At

1	that time, they asked for DUR to review it due
2	to current utilization. And so, we took a
3 .	deeper look into this particular class.
4	Vasopressin receptor antagonists are used
5	to treat hypovolemic and euvolemic
6	hyponatremia. So overall, it helps recipients
7	with diseased states, such as hyponatremia as
8	well as hypovolemia.
9	The population reviewed was a small
10	population on the fee-for-service side. There
11	was only one prior authorization done during
12	the review period, January 2016 through June
13	of I'm sorry, that should have been
14	December. It was a whole year. There was only
15	one PA on the fee-for-service side. And on the
16	MCO side, for that entire, the claims total
17	\$239,861.
18	Currently, Florida Medicaid does have
19	criteria for the oral product that is
20	available.
21	Vaprisol is the other agent in this class
22	that is available and it does not currently
23	have criteria. The P&T committee, at that
24	time, wanted the DUR board to review the class
25	in its totality. So currently you have one

1	agent which is available and there is clinical
2	criteria available. And then you have another
3 .	agent in which we do not have any criteria at
4	this time.
5	Our next topic that we're following up on,
6	the opiate dependents treatments, agonists and
7	antagonists. During the P&T committee for
8	January 2017, the committee desired for the DUR
9	board to determine how fee-for-service and MCO
10	recipients were utilizing the medication
11	Subutex, buprenorphine, the single agent
12	medication. Did the recipients have a
13	pregnancy diagnosis in addition to their need
14	for the medication? The indication for
15	buprenorphine with naloxone, the combination
16	product, SUBOXONE, versus the single agent
17	product, Subutex, preferred for maintenance
18	therapy in medication assistance treatment
19	patients.
20	The World Health Organization recommends
21	buprenorphine mono therapy without naloxone for
22	women who must receive an opioid agonist during
23	pregnancy or while nursing.
24	So this came back to the DUR board due to
25	the high utilization of the single agents

1	medication and they wanted to know, Well, do
2	these recipients have a diagnosis of pregnancy,
3 .	which would mean they should more likely get
4	this particular medication versus the
5	combination product? The utilization revealed
6	only 14 percent of the fee-for-service claims
7	have a diagnosis for pregnancy or nursing. And
8	only 23 percent of the recipients reviewed
9	of the MCO recipients have a diagnosis for
10	pregnancy or nursing.
11	Now, we might add that each claim does not
12	come with a diagnosis attached to it. So we
13	have to do a two-year look-back from the study
14	period. Both fee-for-service and MCO data was
15	reviewed for October 1st through December 31st
16	of 2016 within those respective populations.
17	THE CHAIRPERSON: I have a question.
18	So this is good information. Obviously,
19	looking at this from a resolution standpoint,
20	would it be possible to take a look at a gender
21	edit for this? I think I would be curious to
22	know if some of the non-pregnant members that
23	received the Subutex, if they were men. If
24	that were women at least the scenario that I
25	picture in my mind is, a member comes on

board -- let's just say it's January and the 1 2 member is pregnant January. I think if I recall, it's a six-month approval that you 3 generally give this agent. 4 5 DR. SAMPSON: Roughly. It varied. THE CHAIRPERSON: So the PA comes in for 6 7 review again at Month 6. Then you approve it 8 for another six months and they could, in 9 theory, fall into this non-pregnancy category, 10 which -- I mean, it is what it is. If they're a woman. But if they're a man, they shouldn't 11 12 be on it at all. I mean, I can't think of a 13 reason why a male would need to be on the 14 Subutex. 15 DR. SAMPSON: Right. Other than them 16 stating they have some type of reaction --17 THE CHAIRPERSON: To Latoxin, right. 18 DR. SAMPSON: Right. And so, when we --19 DR. HAYDEN: Selika? 20 DR. SAMPSON: Yes. 21 DR. HAYDEN: Isn't that another indication for induction, so that could --22 23 DR. SAMPSON: Right. That could be it 24 too. Correct. They have both of those there. 25 And what I was going to say is Florida Medicaid

1	fee-for-service side, they do look at all
2	aspects of that for the indication. And if it
3 .	is a female, then she must also have any proof
4	there, if she falls out of the other category,
5	that she is either pregnant or nursing.
6	THE CHAIRPERSON: So just to make sure
7	that I'm clear: On the actual PA, we're fine
8	with this one, or are we taking
9	recommendations?
10	DR. SAMPSON: At this point, when you look
11	at the data, the fee-for-service side actually
12	had lower utilization in that population.
13	Whereby, the Subutex category, if the recipient
14	was pregnant and/or nursing, the utilization
15	there for total paid was only 765 for
16	fee-for-service recipients. And that category
17	had relatively the recipient numbers were
18	low there. Whereby, when you look at it from
19	the MCO side, their total utilization there was
20	54,000. And they had more recipients, whereby
21	it was mixed, male and female.
22	So the recommendation was to go back and
23	look at the prior authorization process because
24	both medications do require a prior
25	authorization. And there's lower utilization

Τ	on the ree-for-service side. So it would be
2	back in the hands of the MCOs.
3 .	The next topic was the Narcan naloxone
4	product. Again, another P&T activity. During
5	the January 2017 meeting, the P&T committee
6	asked for the DUR board to establish quantity
7	limits and criteria for Narcan nasal spray.
8	The indication for Narcan nasal spray. It is
9	an emergency treatment of known or suspected
10	opiate overdose as manifested by, of course,
11	respiratory and/or central nervous system
12	depression. The current quantity limit set is
13	one pack, two nasal sprays every 365 days.
14	That was established as the quantity limit.
15	Subsequent treatment would require a prior
16	authorization at this time.
17	We did take a look, in terms of
18	utilization, during a year period and there was
19	little to no utilization on both
20	fee-for-service and MCO sides. So, as it
21	stands, the quantity limit that's currently set
22	is one pack, two nasal sprays, every 365 for
23	Florida Medicaid recipients.
24	Our last follow-up prior to going into
25	quarterly activity information is the gender

1	dysphoria. This was a third quarter add-on
2	agenda item that the state presented.
3 .	And, at this time, I will turn it over to
4	Ms. Elliott.
5	MS. ELLIOTT: So in the last meeting, we
6	distributed the criteria and we were going to
7	bring it back to this meeting to see if the DUF
8	members had any recommendations. Remember that
9	is a special service criteria. It's not a
10	regular criteria. This is separate than the
11	other criteria that have FDA limitations. So
12	this was, like we call it, a special service.
13	So I'm going to open it for discussion, if
14	I may.
15	DR. HAYDEN: I have a question on the
16	logistics behind it.
17	So it's not a covered Florida Medicaid
18	item. It goes under special services. Where
19	does it come out of the, I guess, budgetary
20	it's a separate item. And is it in our purview
21	for Florida Medicaid to look at is it in our
22	scope to look at this information because it's
23	not a Florida Medicaid item?
24	MS. HARRIS: So there are federal
25	regulations that require the agency and all

State Medicaid programs to cover services that 1 2 are medically necessary for recipients under the age of 21. I generically call them 3 4 "children" even though the 18-to-20 population 5 are adults. 6 This is through the early and periodic 7 screening diagnosis and treatment regulations that the federal government has established. 8 9 We call it EPSDT. You might have heard us use 10 that terminology before. 11 DR. HAYDEN: Right. 12 MS. HARRIS: Even if something is not 13 covered under Florida Medicaid, we have to have 14 a process in place to review and determine if 15 the request is medically necessary if it's not 16 listed on our fee schedule or on our PDL. For most of our drugs, if it's not on our PDL -- or 17 for almost all drugs, if it's not on the PDL, 18 19 we have prior auth criterion in place. And we look at whether or not the FDA has authorized 20 21 it or it's authorized through one of the 22 compendia. 23 When we brought this to the DUR board, it 24 was because these drugs were being used 25 off-label. We had requests for an off-label

1	use of the drug, not supported by the FDA, not
2	authorized through the compendia.
3 .	So we needed to make sure the agency, in
4	its plans, had criteria that they could use
5	when such requests come in to ensure we were
6	reviewing it under the EPSDT guidelines.
7	So it's not about what budget line it
8	falls into or not. It's really about making
9	sure we have solid criteria, so that we can
10	remain in compliance with the federal regs that
11	state that states need to have processes in
12	place for these outlier types of requests and
13	it doesn't happen that often with drugs.
14	Actually, in my years with Medicaid, this is
15	the first time.
16	DR. HAYDEN: What are the medications? I
17	guess I'm not quite familiar with the I
18	mean, I've heard of it. I've seen the name
19	across from years of working, but, I
20	guess and I understand we look at it, but is
21	it in the logistically, is it in our scope?
22	MS. HARRIS: Yes, it is.
23	DR. ZITIELLO: We would just hope that
24	health plans and other people making the
25	decisions will have some sort of consistency in

1	their decision making. Because, truly, under
2	the age of 21, you should not render a decision
3	for not being a benefit. It really needs to be
4	a medical necessity decision. So it's just
5	it's the consistency factor, I think, you're
6	looking for.
7	MS. HARRIS: You said it well. Thank you.
8	THE CHAIRPERSON: There wasn't any
9	criteria previously, that this is being
10	introduced to take care of scenarios where
11	essentially for the transgender situation and
12	maybe they may need hormone therapy.
13	And, essentially, you're looking for the
14	committee to take a vote, really, on this
15	initial criteria to address these issues.
16	DR. SAMPSON: Yes. So we brought it two
17	quarters ago. If I'm not mistaken, the
18	committee voted on the criteria that was
19	established by the agency, but the committee
20	had a request to have the agency bring the
21	criteria back for re-review. I don't believe
22	we've had any requests to actually use it, but
23	still we're honoring that request.
24	DR. HAYDEN: So on the criteria itself, I
25	looked at the information that was before us,

1	special services criteria. The only question I
2	had was this language about a mental health
3	provider. And I wasn't quite sure what that
4	meant. If it was a licensed clinical social
5	worker or a psychologist?
6	Because actually the prescription will be
7	coming from the endocrinologist from what I
8	understand, not the mental health provider.
9	Psychologists don't prescribe. Social workers
10	doesn't prescribe.
11	MS. HARRIS: Yes, because a part of the
12	prior auth process, the plan for the agency
13	would look to see that the individual or child
14	has an established relationship with a mental
15	health counselor, licensed clinician. It can
16	be a LCSW or a licensed psychologist. Because,
17	particularly with this diagnosis and condition,
18	there are a number of comorbid mental health
19	issues present, and we want to make sure that
20	those are being treated.
21	DR. HAYDEN: I got that, yeah. But the
22	guest of the prior auth is special services.
23	It doesn't clearly delineate who is it
24	doesn't say the endocrinologist is prescribing,
25	I guess.

1	MS. HARRIS: So are you requesting that we
2	add who is the prescriber?
3 .	DR. HAYDEN: Just a clarification. I
4	understand there's a clinical team, that the
5	patient is in care, and I understand that. But
6	putting a mental health just putting those
7	words in there gives them you know. Are we
8	giving them prescribing authority here?
9	I mean, it's kind of confusing when I read
10	the document. That's what I'm saying.
11	MS. HARRIS: Okay.
12	DR. HAYDEN: So it's just a further
13	clarification. Because it's the
14	endocrinologist who is ultimately responsible
15	for the with the team approach, of course.
16	Those are the comments. Thank you.
17	MS. HARRIS: Thank you, Dr. Hayden.
18	DR. SAENZ: But you still need that
19	psychologist or mental health standard because
20	part of the guidelines that were established
21	for gender dysphoria by this association, which
22	is, like, WPATH, they state that before the
23	trans because some of these kids may later
24	want to become full you know, do the gender
25	reassignment, so they still need to have this

before they get to that point. So it should be 1 2 the same hormones. There's some counseling 3 that needs to be involved. So I think --That is fine. It's just that 4 DR. HAYDEN. I was a little bit confused. I wasn't sure if 5 6 the psychiatrist was writing the prescription 7 or was the endo, when I read the document and I 8 just wanted further clarity on that. That was 9 it. 10 DR. ZITIELLO: Could we say something like 11 "the appropriate prescribing provider as part 12 of the disciplinary team treating the patient," 13 and that would cover any appropriate provider? MS. HARRIS: Yes. 14 15 DR. HAYDEN: Do we make a motion for approval then with the edits? I make a motion 16 17 to approve the language with the language that Amy -- Dr. Zitiello --18 19 THE CHAIRPERSON: Okay. Great. We have a 20 motion on the floor from Dr. Hayden. Can I get 21 a second? 22 DR. ROMAY: Second. 23 THE CHAIRPERSON: A motion has been made 24 and properly seconded. All those in favor say 25 aye.

1	THE COMMITTEE: Aye.
2	THE CHAIRPERSON: Motion passes.
3 .	DR. MOORE: I'd like to go back to the
4	vasopressin receptor antagonist, if we can.
5	There was some actionable items that the P&T
6	actually requested. And so I think we kind of
7	missed that as we were going through the
8	review. So I'll have Selika flip back to
9	SAMSCA.
10	There are two products in this class that
11	the P&T committee reviewed back in January, and
12	they asked for the DUR board to create some
13	criteria around these products. And when we
14	did further review, we realized that we had
15	criteria for the oral product, but not the IV
16	Vaprisol.
17	So it would mostly kind of be a class
18	criteria at this point because there's more
19	than one agent, and that's the IV product, but
20	it's supposed to be given in the hospital.
21	It's for a hospitalized patient.
22	So I think that if you-all want to move
23	that over to, like, medical services, so it can
24	be managed on that side of the business, I
25	think that's the most logical approach. But I

needed to be sure that you-all were aware of 1 2 that and so you-all can vote for that to occur. 3 DR. ROMAY: I think the current criteria for the SAMSCA, we would just want to maybe go 4 back and look at it, see if it needs revisions. 5 6 DR. MOORE: Yes. 7 DR. ROMAY: I mean, not that I'm looking 8 to add more criteria points to it, but it's a two-question criteria, so I think we might have 9 10 to look back to see if there's other 11 indications or anything --12 DR. MOORE: Absolutely. We can do that 13 now, or do you want to take that back and then review it and then let us know at the next 14 15 meeting or -- it's up to you-all. What do you 16 want to do? Your pleasure. 17 DR. FIELD: Is it also open for any 18 physician around or specifically for a 19 nephrologist? DR. MOORE: It's open for any at this 20 21 time. The SAMSCA? 22 DR. FIELD: Yeah. 23 DR. MOORE: Any. 24 DR. SAMPSON: This is the current criteria

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for the SAMSCA oral tablet, to the left, your

25

1	left. The recipient must be 18 years of age or
2	older. They must have a confirmed diagnosis of
3	hyponatremia, the serum sodium level should be
4	below 125 milliequivalents per liter, or the
5	serum sodium level must be greater than or
6	equal to 125 with symptoms and resisted
7	correction with fluid restriction noted in the
8	clinical notes. That is the current criteria.
9	DR. FIELD: Do we have data on what
10	physicians, meaning class of physicians who
11	is actually writing that? Is it nephrologists
12	already, or is it
13	DR. SAMPSON: We do have that data. I can
14	provide that for you. At this moment, I
15	wouldn't want to readily say who they are, but
16	we do have that data, yes.
17	DR. FIELD: I'd like to see it.
18	DR. GOODNOW: Those lab values are just
19	single numbers? Do they require two
20	consecutive I think when we were talking
21	about more detailed, what we might want to
22	elaborate on is and we can definitely share
23	some criteria from different facilities, but
24	they may require, maybe, like, two consecutive
25	or that number being the last number that the

Τ	patient had, as opposed to ever having a number
2	at that level.
3 .	So I do think some enhancement would be
4	very effective.
5	DR. ROMAY: I agree with Dr. Goodnow. And
6	that's what I was referring to. Like, for the
7	second bullet point I mean, what's
8	"resistive correction"? How much time frame
9	does the member have to have that low sodium
10	before it's considered, you know, chronic,
11	where intervention is needed versus just other
12	things to correct it?
13	DR. GOODNOW: I think that this might be a
14	greater example of where the two teams can work
15	together because if the patient is initiated or
16	the inpatient side to make that process for the
17	patient a little bit more smooth. So there
18	might be a way for the medical side and the
19	pharmacy side to work together so that the
20	patient doesn't go without during that
21	transition period, that it's a little smoother
22	for all parties involved.
23	DR. FIELD: Do you also have the average
24	time period the patients are given the
25	medication? Are they on it for a week? Are

they on it for 30 days? Are they on it for six 1 2 months? 3 DR. SAMPSON: It's a short prior 4 authorization approval for the course of 5 therapy written. So it's not an extended 6 period. 7 DR. ROMAY: Yeah, the current criteria, 8 it's 30 --9 DR. SAMPSON: Up to --10 DR. ROMAY: Date of service, per 11 prescription, up to 30 days. But there are 12 people who are on it longer. 13 DR. SAMPSON: And they have to do another 14 prior authorization to reevaluate. 15 DR. GOODNOW: And I think there's also 16 patients that sort of hang out with a lab --17 like, they're just chronically at certain levels and it's not affecting them. I think 18 19 that the specification is a good request because you don't want to hit one lab value and 20 21 then do the prior auth based on one level. 22 THE CHAIRPERSON: So I think I'm going to 23 try and summarize here. I think there's still 24 two items we have to address. 25 I think the first was Dr. Moore is asking,

essentially, for a vote on the Vaprisol, if we 1 2 want to keep it under the pharmacy benefit or move it under the medical benefit due to the 3 4 use in the hospital. So I'll ask the committee to take action 5 6 on that item, if someone wants to make a 7 motion. DR. OLSON: Motion to move it to the 8 9 medical side. 10 DR. ZITIELLO: Second. 11 THE CHAIRPERSON: So the motion has been properly moved and second to move Vaprisol from 12 13 the pharmacy benefit over to the medical benefit. All those in favor of that motion 14 15 please say aye. 16 THE COMMITTEE: Aye. 17 THE CHAIRPERSON: The motion has properly 18 passed. 19 I think the next item here was 20 essentially, at least from my interpretation, 21 is to take the SAMSCA criteria back for review. 22 There, obviously, were a number of suggestions, 23 to take a look at the provider type, the time 24 frame on the sodium. So maybe this is just me 25 being ignorant to the fact, but what I

1	understood the next step in the process would
2	be is for the committee to take those
3 .	recommendations back and present it at the next
4	committee meeting.
5	DR. MOORE: So we'll certainly look up the
6	provider types for the PAs that we've received
7	from the fee-for-service side because that's
8	all that we have exposure to. And then, the
9	date for the lab value is certainly a valid
10	concern. And if you-all want to clearly state
11	what you would like the criteria to be and take
12	a vote upon it, we'll take it back to the
13	agency for final approval and then institute
14	it.
15	DR. ROMAY: I think that's what we want.
16	We want to be able to have input into what the
17	criteria would look like, and then we can bring
18	it back to the agency for approval.
19	THE CHAIRPERSON: So essentially what
20	we're saying is, we're going to take the SAMSCA
21	criteria back for review, and we'll bring our
22	suggestions back next quarter?
23	DR. ROMAY: Correct.
24	THE CHAIRPERSON: Okay.
25	DR. MOORE: Okay.

1	THE CHAIRPERSON: So we don't need to vote
2	on that?
3	DR. MOORE: At this time, no. So thank
4	you for that on Vaprisol.
5	MS. ELLIOTT: I want to clarify something.
6	We will address the criteria on our side, bring
7	it back next time and you vote on it?
8	DR. ROMAY: Well, we are, but we probably
9	want to
10	MS. ELLIOTT: Table the whole thing?
11	DR. ROMAY: Yeah. We'll bring our
12	recommendations the next time, then we can vote
13	on it.
14	DR. GOODNOW: Is it more efficient if
15	we can we provide, like, recommendations in
16	advance of the meeting or, like, we can maybe
17	work on a draft during the time period until
18	the next meeting and then vote it final at the
19	meeting?
20	DR. MOORE: Yes. It can be filtered
21	through Vern.
22	MS. ELLIOTT: What we'll do is we will
23	email you the criteria that we have right now
24	so you can see exactly what we have. It's
25	easier to do it that way.

1	THE CHAIRPERSON: Just one point of
2	clarity for Dr. Phil's request. He actually
3	was requesting the provider type first.
4	DR. MOORE: Yes. We'll certainly bring
5	that back for the next meeting. Absolutely.
6	DR. FIELD: Well, before we give you
7	recommendations because that, perhaps, would
8	filter into a recommendation.
9	DR. MOORE: Okay. So we'll submit it and
10	Vern will pass it along to you. Is that good?
11	THE CHAIRPERSON: Okay. So I think that
12	closes the discussion on those agents. I think
13	we can move to quarterly activities.
14	DR. MOORE: Yes. I have something to say
15	before we move right into the quarterly
16	activity.
17	In the past, we had looked for some
18	congruency between the DUR and the P&T
19	committees. Probably like a few years ago, we
20	started looking at how we can best utilize the
21	two committees together. I think that we've
22	come leaps and bounds from where we were.
23	you-all are talking to each other very well
24	now. But in the past, there was zero
25	communication between the two committees.

Τ	where we started was the Par classes. So
2	in the past, many drugs were open. It was
3 ·	almost like open access for most of the
4	classes. And so, we said, Well, maybe we can
5	start streamlining these classes with the
6	recommendation from the DUR committee to the
7	P&T committee to kind of tighten some of these
8	classes up.
9	Each class is reviewed every year. So
10	year after year, we're looking at the same
11	classes over and over. And we've gotten to a
12	point where our sister team that runs the P&T
13	committee, they've done a really good job along
14	with the agency in tightening down the
15	availability of so mean products being
16	available on a PDL that we've come to a point
17	where it's probably time to just move on from
18	that approach. That was a starting point to
19	begin conversations between the two committees.
20	While we're happy to continue to look at
21	specific classes that you-all would like to
22	look at, we're happy to do that. But, in the
23	past, we would bring the top five classes that
24	we noticed that maybe there was some area where
25	we could tighten up the criteria or maybe the

preferred drug list. 1 2 But like I said, the drug list is pretty well maintained at this point. And we'd be 3 4 happy to entertain specific classes if you would like to look at them. 5 6 So what we're going to move into is 7 something that we did used to do in the past, 8 reporting the top 10 therapeutic classes from 9 the MCO space and fee-for-service space --10 because those are the classes where we spend 11 most of our money -- and take a look to see if 12 there are any edits or suggestions that you-all 13 would like to do within those specific classes. So that's what Selika has next on the 14 15 docket for you to look at and I just wanted to 16 explain why those P&T classes were listed in 17 your report, but they're not in this 18 presentation. 19 So any questions on that? 20 All right. Thank you. 21 DR. SAMPSON: Fee-for-service top 22 therapeutic classes by total paid. 23 reporting period was for January 1, 2017 24 through March 1, 2017. So here you'll find the 25 top 10.

- You have your agents to treat hemophilia. 1 2 They came in about 16 million. Antiretrovirals, 6 million. Anticonvulsants, 3 4 5.9 million. Antineoplastic, 3.9 million. 5 Human Growth Hormone, 3.3 million. Insulin 6 agents, 3 million. Antipsychotic agents, 7 3 million. Rheumatoid agents, 2.5. Cystic 8 Fibrosis, 2.4 million. And Pulmozyme agents, 1.9 million. 9 10 So this is where they fall at this time. 11 THE CHAIRPERSON: Does the antiretrovirals, does that include the Hep C 12 13 and HIV -- AIDS together? DR. SAMPSON: That number does not. 14 15 THE CHAIRPERSON: So would it just be 16 Hep C for that -- that's represented in that antiretroviral class? 17 DR. SAMPSON: One moment. 18
- 19 Yes. The hepatitis -- I'm sorry, I
- apologize. It does include the hepatitis 20
- 21 agents, the Hep C agents.
- 22 DR. GOODNOW: It might be nice to have the
- 23 number of patients and the number of scripts
- 24 filled so that can give us an idea of how long
- 25 a patient is staying in that category because I

- 1 think that might answer some questions.
- DR. SAMPSON: Okay. Thank you. And I can
- 3 pull that data for you.
- 4 DR. GOODNOW: For this side?
- 5 DR. SAMPSON: Right. Because the other
- side is just the same, whereby when we pulled
- 7 the data, we pulled the therapeutic class in
- 8 addition to the total amount paid.
- 9 So, yes, I will pull that up for you in a
- 10 minute.
- 11 THE CHAIRPERSON: Just one more question,
- 12 I guess, just for clarity.
- DR. SAMPSON: Sure.
- 14 THE CHAIRPERSON: So on this slide it has
- antiretrovirals, which I quess I have to assume
- that would be HIV. But then, on the fourth
- 17 column, it has HCV antiretrovirals, which --
- DR. SAMPSON: That one is broken up for
- 19 the MCOs.
- THE CHAIRPERSON: Gotcha.
- DR. SAMPSON: Two separate ones.
- THE CHAIRPERSON: Okay.
- DR. SAMPSON: That one is spelled out.
- And we were discussing that sidebar. Yes,
- it's two separate numbers.

1	DR. GOODNOW: And the Anticonvulsants
2	Miscellaneous, is that just called
3 .	"anticonvulsants" or is it a specific are
4	other anticonvulsants not included?
5	DR. SAMPSON: That number includes all.
6	Hold on one second and this, it is grouped
7	with all of them. And what was your specific
8	question that you want to know so I can pull it
9	for you?
10	DR. GOODNOW: I was just making sure that
11	the category was all anticonvulsants and not
12	just miscellaneous anticonvulsants.
13	DR. SAMPSON: No, all.
14	DR. GOODNOW: All? Okay.
15	DR. SAMPSON: And wrapping up the
16	interventions that are coming out this quarter
17	by the end of first quarter going into second
18	quarter and the third quarter, previous topics
19	that have been discussed with the DUR board:
20	Overlapping use of benzodiazepines and opiates.
21	Soft messaging to the pharmacies at the point
22	of sale. That was previously voted on by the
23	DUR board. This intervention would require the
24	pharmacist to enter a code as of August 31,
25	2016. Of course, you know, the FDA issued a

1	black box warning on opiate products and
2	benzodiazepine products discouraging use
3 .	together.
4	The September 2016 DUR board review, the
5	first quarter '16 data: At that time, 23,000
6	fee-for-service and MCO recipients had at least
7	one overlapping claim for both products. And
8	the end resolve was the soft messaging. So
9	that particular intervention will deploy third
10	quarter 2017; it's projected to go into
11	production.
12	The second intervention is the Zolpidem
13	intervention. It was discussed at the June
14	2016 and September 2016 DUR activity. Based on
15	FDA Safety Communication published in 2013, the
16	labeled dosing for Zolpidem products now states
17	that the recommended initial dose of
18	immediate-release Zolpidem product is
19	5 milligrams for women, while the recommended
20	initial dose for extended release is 6.25
21	milligrams for women.
22	At the September meeting, the DUR board
23	voted to implement a step therapy edit. In
24	this particular step therapy edit, it will
25	actually go across the board. There was much

1	discussion about that for male and female
2	recipients, whereby, before they can get higher
3	dosing, they must step through the lower
4	therapy or at least a 24-day supply must be
5	utilized before the recipient can have the
6	higher agent. And that edit is set to deploy
7	third quarter '17.
8	The next edit intervention that's coming
9	up is the maximum daily dose of antidepressants
10	for recipients greater than or equal to six
11	years of age. The DUR board approved
12	recommended maximum daily doses of
13	antidepressants in recipients age 6 or older.
14	That edit is set to deploy by second quarter
15	'17.
16	The tumor necrosis factor edit was
17	discussed at the September DUR meeting. This
18	particular edit, it will prevent the use of
19	more than one TNF inhibitor and/or the use of
20	any other biologic agent that is not classified
21	as a TNF inhibitor. It is set to deploy third
22	quarter '17.
23	Last but certainly not least, the IR
24	Before ER opiate step therapy edit. There's
25	been much discussion on this particular topic

Τ	since the September DUR meeting. The IR Before
2	ER intervention will deploy late March. That's
3 .	the end of first quarter '17.
4	The IR Before ER edit has been merged into
5	one intervention that also encompasses
6	abuse-deterrent criteria, the
7	narcotic automated prior authorization. The
8	edit addresses the CDC's recommendation for
9	recipients to receive an immediate-release
10	product before an extended-release product.
11	The abuse and this is all inside of your
12	written packet. If you refer to pages 18
13	through 19, and it will take you through the
14	steps for that automation.
15	While you're looking through that or
16	thinking about that IR Before ER edit, in
17	addition to that, we included the FDA-approved
18	abuse-deterrent products and some of their
19	release dates. Some of them are out there
20	expected to be out there, but currently there
21	aren't any NDCs for them, so the products are
22	not available, but they're expected to be
23	available in the near future.
24	We also included the abuse-deterrent
25	formulations that are non-FDA approved just for

1	a point of information. They have claims for
2	having abuse deterrents, but they do not meet
3 .	the FDA standard for having all of the desired
4	properties needed.
5	DR. MOORE: I wanted to know if you-all
6	had a chance to look at the abuse-deterrent
7	edit? The narcotic edit is what we're
8	affectionately calling it. But if you have any
9	questions about it, I'm happy to answer any
10	questions that you may have. We can step
11	through it if you would like to, specifically,
12	because I know the plans will need to
13	understand the edit. So it's completely up to
14	you how you want to proceed.
15	DR. ROMAY: Did we ever revisit, instead
16	of doing an automated PA setup, doing more of a
17	criteria?
18	DR. MOORE: For the abuse deterrent?
19	DR. ROMAY: Yeah, instead of doing an
20	automated. I know a lot of the MCO plans don't
21	have those capabilities of adding multiple
22	steps to have a PA logic work. So did we ever
23	look and see if, maybe, we can just convert it
24	into a criteria to make it easier to navigate
25	through it?

DR. MOORE: Right. I think the agency is 1 2 okay with a manual-based PA, if you do not have the capability to automate. 3 4 DR. ROMAY: Yeah, that's one of our 5 challenges that we run into when we're 6 programming these things with our PBMs. It's a 7 lot of factors and there's system limitations. 8 So I don't know if the group feels the 9 same, but I think it would work better if 10 there's a document. 11 DR. MOORE: The criteria or the steps to the automation will be provided in your weekly 12 13 file. And so if your PBM is unable to automate 14 it, they can just follow the steps of the 15 automation as a paper-based or manual-based PA. 16 DR. ROMAY: Okay. 17 DR. MOORE: If they want to use our criteria. 18 19 DR. ROMAY: So are you saying --20 DR. MOORE: They don't have to use this --21 DR. ROMAY: Well, are you saying that the 22 agency is willing to just move towards, like, a 23 just regular criteria base versus this? It's 24 just a suggestion. 25 MS. ELLIOTT: Well, the initiative was to

do an auto PA to facilitate -- I mean, it 1 2 prevents doctors having to send manual PAs every time. So we're fine if your plan can do 3 4 the auto PA. You just use the same exact --5 DR. ROMAY: Okay. So we can create our 6 own criteria based on this and --7 MS. ELLIOTT: Right. 8 DR. ROMAY: Okay. 9 MS. ELLIOTT: As long as it follows 10 ours --11 DR. ROMAY: Fine. Yeah. 12 MS. ELLIOTT: -- and it's not more --13 DR. ROMAY: Absolutely. Yeah. 14 Definitely. 15 THE CHAIRPERSON: Could I make a comment? 16 I remember this topic from the last 17 meeting and, I guess, I have two concerns. 18 Let's just say, for example, Dr. Field writes a 19 prescription for morphine, right? He comes in. And even if he wants the morphine, it's going 20 21 to reject him. He has to go to mData, right? That's pretty much -- right? And I get the 22 23 rebates and everything. 24 But let's say, for example, he can't use the mData because, I don't know, he gets highs 25

or whatever. So now, I guess, based on the 1 2 wording of the criteria, and since there's no other abuse-deterrent products, really, I 3 4 quess, from my perspective, his only recourse 5 is to go back to a non-abuse-deterrent agent, 6 right? I mean, if he -- I guess, based on the way the criteria is right now, if Dr. Field writes 8 9 for another agent, he's going to be redirected 10 to a beta, which he failed. So I don't know if 11 there is another avenue to get to another 12 abuse-deterrent agent. 13 I don't want my personal feelings about 14 abuse-deterrent products to dictate what the 15 group does. I personally don't agree with 16 them. But, you know, since it's on the PDL, I get it; we have to do it. But I just think the 17 18 way that the criteria is set up right now, it 19 makes it very difficult for a provider who actually wants their patient to be on an 20 21 abuse-deterrent agent. They essentially just 22 have one choice. 23 DR. MOORE: And we did talk about this at 24 the last meeting. I think it was No. 5 on our 25 quarterly activities to do and it did not make

1	the cut for this meeting.
2	But Selika and I actually talked about
3	this extensively this week. I think your
4	concern was, well, what else are these patients
5	taking? Because you have a valid concern that
6	if you cannot take Embeda, then what? We were
7	going to pull the claims for patients who may
8	have had Embeda in their past and may not be on
9	it today, just to see what they are taking.
10	And that was No. 1 for our quarterly topics for
11	next quarter. So you did make the cut for this
12	coming quarter.
13	THE CHAIRPERSON: Moving on up.
14	DR. MOORE: Yes. And, absolutely, we'll
15	address the criteria concerns at that time,
16	what's next. And I think that's probably where
17	we were headed with that conversation at the
18	last meeting, so yes.
19	THE CHAIRPERSON: Thank you, Dr. Moore.
20	DR. SAMPSON: And this graph chart should
21	look very familiar as we continue our
22	discussion about morphine milligram
23	equivalents, meaning continued since September
24	and January and now. This chart was shared
0.5	

previously, whereby it is second quarter '16

25

1	data for Florida Medicaid recipients and
2	approved fee-for-service and MCO recipients.
3 .	The data at that point revealed 10,383
4	fee-for-service and MCO recipients combined
5	that were receiving a cumulative 90 morphine
6	milligram equivalents per day or greater. This
7	data did exclude recipients that had a
8	diagnosis of cancer or sickle cell or were in
9	hospice care. At that time, the DUR board
10	voted to establish a maximum daily dose based
11	on the CDC guidelines but, at the same time,
12	they wanted to get a deeper dive into that
13	10,383 number and that's what we did.
14	So this is how the information comes back
15	for those recipients in both categories. When
16	you look at the cumulative number, the
17	biostatistician was able to pull the data and
18	give to us where the recipients were.
19	So starting from the top, you see you have
20	a few recipients in that number that were
21	receiving a greater than or equal to 500 MMEs
22	within the review period and so on and so
23	forth. And then the majority of the population
24	was falling somewhere at that 150 number. So
25	greater than or equal to 150 but less than 200

1	MMEs per day. You were looking at about 1,600
2	recipients on both sides.
3 .	The most common diagnoses associated with
4	this number again, we cannot match claims to
5	diagnoses, but we can go back and look at a
6	two-year review period and use our knowledge
7	there to see what the ailment may have
8	been. The top five diagnoses during that
9	period all were related to pain in some way,
10	some fashion. Joint, limb pain, abdominal
11	pain, chest pain, back pain, other long-term
12	pain was associated with all of those claims
13	that you see there over a two-year period.
14	So, where does that leave us? What we
15	know for sure, we know that higher dosages
16	yield higher risk. So patients who receive
17	higher dosages of opiates have a higher risk of
18	overdose and death. We also know that dosages
19	above 50 MME per day increase the risk for
20	overdose by at least two times. This is data
21	that we know for sure.
22	So where do we go from here? The
23	September 2016 DUR board voted to establish
24	that maximum daily dose guideline based on the
25	CDC's recommendation. An intervention edit

released over time to reach the 90 MMEs per day 1 2 is what we see currently trending across the country. So no one is being cut off or 3 4 anything of that nature. But it's making the 5 providers aware of what the daily amount will 6 be and then slowly releasing those edits over 7 time. 8 MR. OLSON: Do you have number of claims for MME less than 90? 9 10 DR. SAMPSON: Yes, because those were the 11 numbers that we previously discussed. I'm 12 happy to pull that up for you. If we go back 13 to -- this slide? This is answering your 14 question? 15 MR. OLSON: Yeah, okay. 16 DR. SAMPSON: Okay. So what we have here, 17 right, that number for the 50 MMEs -- greater 18 than 50, that was a total on both sides, 19 72,000. And then if you look at the greater 20 than or equal to 50, but less than 90, 17,000. 21 DR. GOODNOW: And these are not unique 22 recipients? So they are not doubled up if they 23 were fee-for-service and --24 DR. SAMPSON: Okay, the statistician did address that. No, she can't confirm that 25

because sometime the patients do move. 1 2 Good question. DR. FIELD: Do we have an idea whether 3 4 those were coming out of certified pain clinics 5 or whether they were done by, again -- since 6 that dosage is quite high and normally you 7 would expect somebody who specializes in pain 8 to be writing that kind of stuff? DR. SAMPSON: Right. We would have to go 9 10 back in and look specifically at those numbers. 11 But for the majority of the part, the 12 physicians were all categories, all types. But 13 if you want to look at the ones that are 14 greater than or equal to 90 in terms of the 15 providers? DR. FIELD: Yeah, the 10,000 that may 16 be --17 18 DR. GOODNOW: And then given the top 10 19 providers of that 10,000, just to see if there's a trend for higher utilization, if 20 21 there's a higher frequency provider in that 22 higher -- the only thing is they're oncology 23 now --24 DR. FIELD: Oncology was included, 25 correct? Cancer was excluded?

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1	DR. MOORE: Yes.
2	DR. FIELD: So essentially we're talking
3 .	about chronic nonmalignant pain?
4	DR. MOORE: Yes.
5	DR. FIELD: So we already know what
6	physicians in the state have to be matched up
7	and declare that you're going to prescribe like
8	that. I don't know how many of us have that
9	next to our license. But in that dosage, you
10	would expect somebody to have a specialty. If
11	it wasn't coming out of somebody with a
12	specialty, that would be kind of surprising.
13	DR. SAMPSON: Yes, it would.
14	It was a cumulative edit, so we did it
15	over time whereby each claim, we would go in
16	and then add what would be their day because
17	they were able to fill on the 1st, and then
18	they were able to fill again on the 28th, and
19	then they were able to fill again, maybe on the
20	20th. So we kept track of that and that's how
21	the cumulative count went.
22	DR. MOORE: From a data perspective, we do
23	not get a provider's specialty on the claim, so
24	it's essentially impossible for us to determine
25	the specialty of the physician.

1	Now, for the SAMSCA because that's
2	similar, what you want you want us to do is
3 .	to look up to see if it's a nephrologist.
4	Because it's a paper-based PA, chances are I
5	will be able to tell if this a primary or some
6	type of specialty clinic, so that's why I know
7	we can probably do that. But from products
8	that do not require a PA or PDO and claims just
9	pay, we won't be able to determine provider
10	type because we don't get a provider's
11	specialty.
12	DR. FIELD: I think we had this
13	conversation before, but it goes back to an
14	NPI, and the NPI has a toxomity related to it.
15	There are ways, but it doesn't mean that we
16	have the automated system to do it.
17	DR. MOORE: Well, we don't we don't
18	gather that information from our vendor. I'm
19	sorry.
20	THE CHAIRPERSON: So I just want to do a
21	quick temperature check. The time is 3:05. It
22	looks like we have two topics left, HIV and
23	Transderm Scop. So I want to ask if anyone
24	needed a quick break here, bladder relief, or
25	do you want to push through?

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1	THE COMMITTEE: Push through.
2	THE CHAIRPERSON: I agree.
3 .	DR. SAMPSON: HIV polypharmacy.
4	DR. MOORE: I want to restate the
5	actionable items so that we're clear on what
6	the request is because the homework from the
7	last meeting was to bring back a stratification
8	of the doses that were above 90 so that
9	Magellan has a corporate solution that does
10	evaluate any claims that had an MME of 90 and
11	above. And we talked about perhaps setting
12	that threshold a little higher, and so that's
13	why we brought back the stratification. But I
14	believe there's additional items that have come
15	forth now.
16	DR. SAMPSON: The physician was one that
17	we were unable to do.
18	DR. MOORE: And is that the only thing?
19	DR. ROMAY: So as I understand the
20	threshold on the MME, is the approach going to
21	be that we're going to do, like, a banner
22	message sort of thing to start it out to
23	educate the providers and then we're going
24	implement the hard edit?
25	DR. MOORE: Sure. We can certainly take

that approach -- basic approach and first the 1 2 educational campaign about what we're going to do and then move into -- honestly, because the 3 4 coding takes a little while to get into place. 5 So yes, I believe that's it. 6 DR. ROMAY: So I guess we'll bring this 7 back -- we'll table this back for the next 8 go-round. 9 DR. MOORE: Yes. 10 DR. SAMPSON: The P&T committee requested 11 for the DUR board to look into HIV polypharmacy from a stance of, they wanted to evaluate 12 13 recipients who are receiving multiple 14 single-agent antiretroviral therapy medication 15 versus some of the newer combination products 16 where applicable. 17 So you have two additional -- here, we 18 just created a cheat sheet that's already 19 available -- readily available on the aidsinfo.org website. And so, here, at your 20 21 desk, you have the FDA-approved HIV 22 medications. And you have the class. 23 Everything from the NRTs, NNRTs, PIs, so on and 24 so forth. And then, on the back of the document 25

1	there, you also have the combination products
2	that are available, their generic name, the
3 .	brand name and what the combination is
4	comprised of.
5	In this particular look, as we already
6	know, the gold standard for most patients, they
7	may have two or more HIV medicines from one or
8	more drug classes.
9	So what was done? The pharmacy claims
10	were reviewed from October 1st to December
11	31st, 2016. Who was included? Recipients who
12	received five or more HIV agents as single
13	agents and/or via a combination therapy.
14	We'll go deeper into how that breaks out,
15	how the data was pulled. What we have? We had
16	recipients on the fee-for-service side, as well
17	as the MCO side. Some of recipients received
18	all single agents, so that means they didn't
19	have any combination therapy, whatsoever. And
20	you see the low numbers there for
21	fee-for-service and MCO during that time
22	period.
23	Then you have a population that may have
24	had a two-agent combination, either with a
25	two-agent combination medication and then so on

1	and so forth, whereby if the recipient had four
2	agents, they could have had four by two
3	combination, or a three combination plus one.
4	That's how the statistician was able to pull
5	the data back based on the drug class. And so
6	it will make more sense when you take a look at
7	the sample.
8	To your left you have all single-agent
9	regimens. That was for the time period
10	reviewed: October, November, December. And
11	then, the way the data came back for October,
12	November, December, you have a recipient there
13	that had the four or more agents, but that four
14	or more was comprised of therapy whereby it was
15	a two-combination drug and then two additional
16	or where you have one that is a four
17	combination drug and then one additional.
18	So overall, when we took even a deeper
19	dive into it, it could have been the course of
20	therapy the start of therapy for these
21	particular recipients, so we did not put up any
22	latent red flags that there was an issue or
23	problem.
24	Transderm Scop. This came up as a
25	quarterly activity that the DUR board wanted to

1	look into. The first quarter data for 2017 was
2	reviewed. The data review was October 1st
3	through December 31st. There was a diagnosis
4	check for the past two years for the
5	FDA-approved indication for the Transderm Scop
6	patches.
7	As you know, it is indicated for nausea
8	and vomiting associated with motion sickness
9	and postoperative nausea and vomiting. Each
10	patch delivers 1 milligram of scopolamine over
11	a three-day period. Only one patch should be
12	worn at any particular time. One package
13	equals four patches. Florida Medicaid will
14	reimburse for 10 patches every rolling 327
15	days.
16	Based on the claims, we took a look at the
17	diagnosis for a two-year period. And what we
18	discovered was that there were at least 80
19	percent of the fee-for-service recipients and
20	27 percent of the MCO recipients, they did not
21	have a valid diagnosis for Transderm Scop
22	during that period. Again, we cannot match
23	claims to diagnoses, but we can look back at a
24	two-year period and figure, did they have the
25	diagnosis during that said time.

1	DR. ZITIELLO: Was there a look at age
2	there since it's not approved for under 18?
3	DR. SAMPSON: For under 18? Yes. We do
4	have the ages. It wasn't pulled within this
5	particular data, but we do have their age
6	available.
7	DR. ZITIELLO: I think the concern was
8	some use in nursing homes, some use like that.
9	It's not my area, but is that correct?
10	MS. ELLIOTT: We brought up the drooling
11	condition for nursing homes.
12	DR. MOORE: Right.
13	DR. SAMPSON: But when you take a look at
14	did they have the FDA-approved diagnoses, no,
15	the majority of the recipients did not. So the
16	decision would be for you to discuss
17	considering how you would like to proceed with
18	the medication as currently preferred
19	medication, but should a diagnosis check be
20	added to the processing of the claim at the
21	point of sale.
22	MR. OLSON: Do you have the information
23	for what the diagnoses were? Because that
24	would help determine
25	DR. SAMPSON: Oh, well, again, we can't

match the diagnoses to the claim. We can take 1 2 a look at all that they had and it was a gamut of everything that the recipients may have had. 3 4 But to try to narrow it down in terms of they 5 definitely had said diagnoses, off-label use --6 DR. MOORE: So what we did was, the 7 utilization came back. And then we also had the biostatistician pull any type of diagnosis 8 9 that they had on file at the time of the date 10 of service. 11 So there isn't a one-to-one comparison. We have to use deductive reasoning. So if 12 13 there was a diagnosis of nausea and vomiting 14 at the time of date of service, we said, Okay, 15 check, you met the criteria because we don't 16 require a diagnosis at this time. 17 So maybe that's the next step, is attach 18 the FDA-approved diagnoses to this product so 19 patients that are getting the product on that date of service actually have a diagnosis -- an 20 21 approved diagnosis on file. 22 DR. ROMAY: I think we cite a diagnosis as 23 other agents that the member would probably 24 benefit from using prior to Transderm Scop. I 25 mean, they're having nausea and vomiting, any

of the antiemetics that are currently on 1 2 market -- you know, decadrone, things like that, or promethazine, things like that -- I 3 think we need to kind of look at those to see 4 5 if it's really, truly the only agent that's 6 going to be suitable to control those symptoms. 7 So maybe a PA with criteria outlining some diagnoses that are preapproved, maybe an age 8 9 and maybe something along the lines of 10 preferred agents that should be used prior 11 to -- depending on the diagnosis. 12 DR. MOORE: So then the next step would 13 be -- this would be a recommendation to P&T. 14 Because it is a preferred product, so it has to 15 go through that process first. But it's good. Like I said, we've come leaps and bounds. 16 17 We're making recommendations to the P&T committee, saying, we reviewed this class. 18 19 It's a class coming up, I think, relatively 20 soon, and the recommendation is to move it to a 21 non-preferred status with this criteria. 22 that's the process. 23 If that's the route we want to go, we can 24 certainly discuss that right now. I have to 25 check the cycle. I think it might be up for

review in June, so we would need to discuss it. 1 2 DR. GOODNOW: The other potential is if they're also on another concomitant antiemetic. 3 4 Sometimes they use, like, a multimodal 5 approach. So that might meet criteria if 6 they're already on an antiemetic and they need 7 a stronger agent. I don't see it a lot, but theoretically perhaps some of the claim is just 8 9 the multimodal approach to get them on multiple 10 products. 11 DR. ROMAY: I think the majority of the 12 use that is currently seen with that product is 13 for vertigo. People taking a cruise or taking 14 a long trip and doesn't want to be taking oral 15 tablets. It's just a convenience factor a lot of times, so that's where I usually see it 16 17 most. I mean, there may be some scenarios 18 where either medically fragile kids who are 19 either on benz or something that their secretions aren't controlled and they need to 20 21 suppress it with more aggressive therapy. 22 DR. MOORE: So do you-all want to decide 23 on the level of intervention you want to do? 24 Do you want to do it as a diagnosis, attach a 25 diagnosis -- because it is referred right

now -- so attach a diagnosis, or do you want to 1 2 take a more stringent approach and say, Hey, we want make a recommendation to a non-preferred 3 4 status and then establish some type of 5 criteria? 6 DR. SAENZ: What is the utilization? 7 There's a cost. How much is it really, like, 8 driving the cost? 9 DR. ROMAY: We had that last time. 10 DR. SAENZ: We had that last time? 11 DR. ROMAY: Yeah. 12 DR. SAENZ: I forgot how much it was then. 13 I guess it must have been a lot of --14 DR. ROMAY: Yeah, there was a lot of funds 15 associated with that drug. I remember. 16 DR. MOORE: Right. It's in the report, the report that you got. 17 DR. SAENZ: Okay. It looks like it was a 18 19 lot of utilization. Otherwise, we wouldn't 20 be --21 DR. MOORE: Right. Yeah. It was a P&T 22 class that we brought forth at the last 23 meeting. 24 DR. SAENZ: I agree with his comments. 25 DR. ROMAY: So I motion to move that

1	forward to the P&T for non-PDL with criteria.
2	DR. HAYDEN: There was a lot of patients
3 .	on this, but was the fiscal impact great to the
4	Florida Medicaid program as well, or is it just
5	the number of patients on it?
6	DR. MOORE: I'm going to see if I can
7	resurrect that file that we talked about at the
8	last meeting so we can give you a point of
9	reference.
10	THE CHAIRPERSON: So at this point, we
11	have a motion on the floor. We are going to
12	table the motion until we get the information
13	from Dr. Moore, and then, perhaps, a second of
14	that motion, we'll deal with it and close out
15	that issue.
16	DR. ZITIELLO: Can we also look at dual
17	therapy with the antiemetics to Dr. Goodnow's
18	point? Because I would hate to hold up therapy
19	for somebody who is getting multimodal
20	approach.
21	THE CHAIRPERSON: So I think just from
22	Robert's Rules of Order, can I ask you to
23	rescind your motion since we have some
24	unreadiness here? Can you remove your motion
25	from the floor because we have some

1	unreadiness?
2	DR. ROMAY: Sure. I remove my motion.
3 .	THE CHAIRPERSON: So you are looking up
4	information for Dr. Goodnow.
5	DR. MOORE: Yeah, I just sent it to
6	Salika.
7	DR. ROMAY: Wouldn't there be a DUR reject
8	that's triggered if those two antiemetics are
9	going to be delivered at the same time?
10	DR. MOORE: It would trigger. However, it
11	will pay if it's the same physician and same
12	pharmacy. So if there's a different physician
13	or a different pharmacy, it will deny. But the
14	pharmacy can override it with those service
15	intervention codes, prescriber consulted MO,
16	whatever those codes are.
17	DR. ROMAY: Well, I think we captured that
18	intention if we do what we were going to do
19	initially.
20	DR. MOORE. It would only stop if the
21	doctor or pharmacy are different. Otherwise,
22	the claim would continue to process.
23	DR. ROMAY: I just don't see that scenario
24	coming up very often. It's very, very, very
25	infrequently where the member requires two

antiemetics to control their condition. I 1 2 mean, I just don't see that. At least in my clinical practice, I haven't encountered that. 3 DR. MOORE: Okay. So "N" means 4 fee-for-service. "Y" means encounter, so 5 6 plans. The data was from September 1st of '16 7 through November 30th of '16. 8 DR. SAMPSON: Fee-for-service and MCO. 9 DR. MOORE: Yeah. The other carrier 10 amount, that's how much the plan paid. 11 DR. ROMAY: September? November? 12 DR. MOORE: September. So all of 13 September, all of October and all of November. Accounting for that, was the motion for 14 15 moving Transderm Scop to the non-preferred 16 status along with criteria creation, was that 17 passed? THE CHAIRPERSON: No. We rescinded the 18 19 motion. I think we had some unreadiness. We had some questions on the floor. We have the 20 21 data here. I think we need to make an informed 22 decision. 23 Do you want to restate your motion? 24 DR. ROMAY: I would restate it, yes. 25 move forward to suggestion of moving it to

- 1 non-PDL with a criteria creation to supplement
- 2 the edit.
- 3 THE CHAIRPERSON: All right. We have a
- 4 motion on the floor.
- 5 DR. FIELD: Second.
- 6 THE CHAIRPERSON: Second by Dr. Field.
- 7 Ready for the question. All those in favor say
- 8 aye.
- 9 THE COMMITTEE: Aye.
- 10 THE CHAIRPERSON: Motion passes.
- DR. MOORE: Thank you.
- 12 Would you like to discuss the criteria?
- Some items that you'd like to see in the
- 14 criteria?
- DR. ZITIELLO: Diagnosis.
- DR. MOORE: First and foremost.
- 17 All right. So I heard diagnosis. I think
- 18 I heard age somewhere.
- DR. ZITIELLO: Yes, age.
- DR. ROMAY: Formulate alternatives.
- DR. MOORE: Okay.
- DR. ROMAY: I think we can use the same
- concept as we did with the previous agent that
- 24 we were reviewing that we were going to --
- THE CHAIRPERSON: SAMSCA.

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1	DR. MOORE: SAMSCA?
2	DR. ROMAY: The SAMSCA.
3 .	DR. MOORE: Okay.
4	DR. ROMAY: So we can kind of look I
5	guess we can all get together and submit our
6	recommendations.
7	DR. MOORE: Sure. Okay.
8	We'll review those at the next meeting.
9	And I can certainly make the recommendation to
10	our sister team that runs the P&T committee to
11	move Transderm Scop to the non-preferred
12	status. I can go ahead and make that
13	recommendation.
14	Thank you.
15	THE CHAIRPERSON: Okay. I think that
16	concludes our Quarterly DUR Activity Reports.
17	If I'm not mistaken, we're going have an
18	audible here to the agenda. We have open
19	discussion next. But it's my understanding
20	that we have some individuals in our audience
21	that would like to some public comments.
22	I think we're going to just go ahead move
23	right through it.
24	MS. ELLIOTT: Oh, I thought it was the
25	report that we were going to okay.

1	MS. HARRIS: Just roll on.
2	THE CHAIRPERSON: The big boss has spoken.
3 .	We open the floor for public comment. Does
4	anyone want to step forward here for any items
5	of discussion?
6	I think in the Moses imaginary rule book
7	here, after 30 seconds, we close the floor.
8	MS. FUHR: Hello, everyone. We were given
9	the opportunity to come here and speak. My
10	name is Debbie Fuhr. I'm with Biogen. I'm the
11	account manager that covers Florida.
12	I'd like to just give a very high overview
13	on the new product that we just launched for
14	spinal muscular atrophy. It's called SPINRAZA
15	or nusinersen. I'd like to get into just a
16	little bit of the dosing, the lab tests that
17	are required, the distribution model, and then
18	I'd like to bring up Biogen's rare disease
19	reimbursement manager to come up and discuss a
20	little bit about coding, site of care issues
21	and that type of thing. We were told that we
22	could have five minute, so we're going to fly
23	through.
24	SPINRAZA (nusinersen) is a survival motor
25	neuron 2, which is an SMN2. It's directed

1	antisense oligonucleotide and the first and
2	only FDA-approved therapy indicated for the
3 .	treatment of SMA in pediatric and adult
4	patients.
5	The efficacy and safety of SPINRAZA was
6	demonstrated in a double-blind double-sham,
7	which went as a placebo. When it's an
8	intrathecal injection, they would, for the
9	sham-controlled, actually puncture the skin, so
10	it's the placebo equivalent for an intrathecal
11	injection, in controlled clinical trials for
12	patients with infantile onset of SMA. And it
13	was also supported by open-label clinical
14	trials in presymptomatic and symptomatic
15	patients.
16	Of the 82 patients that were eligible for
17	this interim analysis, there was statistical
18	significant differences in the percentages of
19	patients that were able to achieve motor
20	milestones and response where patients would
21	normally not. So that includes kick, head
22	control, rolling, sitting up, standing,
23	walking; 40 percent for the SPINRAZA-treated
24	patient versus zero in the sham-controlled.
25	And then, in addition, a greater percent

1	of the patients that were treated with SPINRAZA
2	actually survived where untreated patients
3 ·	would not be expected to.
4	In the open-label uncontrolled trials, let
5	me tell you that the FDA stopped our trials.
6	They deemed that it would unethical to keep the
7	patients that were on placebo because of the
8	results that they showed. So then we have
9	ongoing clinical trials go on.
10	Patients who were likely to develop SMA
11	Type 1, 2 or 3, achieved milestones, such as
12	the ability to walk or stand unassisted when
13	they would otherwise not be expected to do so.
14	Again, maintain motor milestones at the ages
15	when they would not be expected to do so and
16	survive to ages where they would not be
17	expected to do so.
18	I'll quickly go through the dosing again.
19	SPINRAZA is administered intrathecally by or
20	under the direction of a healthcare
21	professional experienced in performing lumbar
22	punctures.
23	It comes in a 12 milligram vial and it is
24	not weight based. So a newborn infant would
25	get the same dose as child that would be 15.

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The dosing includes four loading doses: Day 1 2 zero, 14 days after that, so Day 14, Day 28. The final loading dose would be around Day 58. 3 And then, thereafter, as a maintenance dose, it 4 5 is once every four months. 6 The testing that needs to be done at 7 baseline and prior to each dose would be a 8 platelet count, a prothrombin time and 9 quantitative spot urine protein test. 10 The distribution model, as with rare 11 diseases, it's very common to have a limited distribution model. Accredo is the resource 12 13 therapy, along with CuraScript, so that's the 14 SP. And the reason they do that is to keep the 15 handling, the storage, the distribution, and 16 the transportation all very contained so it can be tracked. 17 At this time, I'd like to bring up Brenda 18 19 for the other two minutes and let her tell you a little bit about the reimbursement and 20 21 coding. 22 MS. WEAVER: Hi. My name is Brenda 23 Weaver. I'm a rare disease reimbursement 24 manager. 25 My qualifications include -- I'm a

1	clinical nurse. Practiced in ped ICU. I
2	worked for Blue Cross Blue Shield in medical
3 .	policy in Minnesota for eight years. And then
4	I'm also a certified holder for physicians as
5	well as for outpatient settings.
6	So some of the things that we are hearing
7	from sites, at least on SPINRAZA, are they're
8	very, very concerned. In the rare disease
9	space, the products are very expensive. This
10	is no exception to that rule. And these
11	patients, they tend to congregate in MDA
12	centers. So there's only so many MDA centers
13	around the country. And so these institutions
14	have actually quite large populations.
15	So when you have a drug in this expensive
16	of a bracket, they simply can't afford to buy
17	and bill the product. They just don't have the
18	budget in their pharmacy whether it's well,
19	these are mostly hospitals. A physician clinic
20	certainly can't afford to buy and bill the
21	product. So this is becoming kind of an issue
22	with payors, especially in the Medicaid space,
23	because Medicaid typically uses buy and bill as
24	a methodology.
25	So I want to just see if we can open a

1	dialogue about whether or not this product
2	could be allowed under the specialty pharmacy
3	benefit as well or the pharmacy benefit versus
4	medical. Accredo can dispense under the
5	medical, but what we're finding out is a
6	barrier is they need to have a letter of
7	agreement in place with the payor. And
8	typically inside the payor, those letters of
9	agreement are single case agreements or
10	contracting. That's going to go to a separate
11	area in the payor, at least it did for us, a
12	silo department.
13	They are non-clinical in nature and so
14	they really don't understand the urgency behind
15	getting these contracts done quickly. And they
16	typically don't communicate with the medical
17	side either. So that's kind of an issue that
18	we're having.
19	I also can help you, if you need we can
20	talk about this offline at some point. But we
21	wrote our own edits. I wrote edits for our
22	claim system at Blue Cross. And I've had some
23	Medicaid plans that have said to me, we're a
24	little bit concerned about using the SPB
25	benefit or the pharmacy benefit because we

1	don't want to get the pharmacy claim
2	adjudicated and then also have a medical claim
3 .	externally billed to us, which that could
4	happen in a mistake.
5	And so, we problem-solved and we talked
6	about some ways to do reverse claim steps in
7	the medical system in the medical payment
8	system so that you can catch those claims. And
9	I can take that offline, if you have questions
10	like that.
11	Any questions that I can address?
12	MS. ELLIOTT: I just have a comment. This
13	is a public information. I don't know if the
14	members know how much the drug cost or are they
15	interested?
16	DR. ZITIELLO: I'm interested.
17	MS. WEAVER: The price of SPINRAZA at the
18	WAC price is \$125,000 per vial. In the first
19	year, treatment for a treatment-naive patient,
20	that is going to be six doses in that first 12
21	months, \$750,000 as a first-year treatment.
22	Thereafter, SPINRAZA is dosed at every four
23	months, three times a year, so that's \$375,000.
24	Biogen participates in one discount
25	program that would be the Medicaid rebate

program. So that's another thing to consider 1 2 if you think about moving this over to your pharmacy benefit manager. If you produce this 3 4 as a pharmacy benefit, Medicaid is going to get 5 that rebate. It's very easy to adjudicate and 6 control rebates on the pharmacy side versus on 7 the medical side when have you the institution 8 buying and billing. 9 I'm not saying that the best thing would 10 necessarily be to block this drug to just a pharmacy benefit because, of course, when we 11 12 did our research on this population, what we 13 found, when the population is identified, they 14 typically have a commercial insurer. Mom and 15 dad might both be working. 16 But then, when this diagnosis hits, 17 usually at least one parent ends up having to 18 stop working to take care of the needs of the 19 child. So what happens, in about six months time, these patients go onto a Medicaid --20 21 either Medicaid as a primary payor or Medicaid 22 as a secondary payor. 23 If you would block this only to a pharmacy 24 benefit, then what could happen then is, if you 25 have an instance where you have a commercial

payor as primary, Medicaid is the secondary, we 1 2 would still want a buy-and-bill channel or at least a medical benefit channel. Because 3 4 Accredo could provide the drug under the medical benefit as well. And then Medicaid 5 6 would just have to pick up as a secondary 7 payor, if that makes sense. 8 THE CHAIRPERSON: I have two questions. 9 Thanks for great information. 10 Could you restate what the incidence is of 11 this order? Forgive me if you stated that 12 before. 13 MS. WEAVER: I did not. The incidence is 14 approximately 3- to 400 life births per year in 15 the United States. That doesn't mean that we -- I don't know exactly what the true 16 17 population is, living population today. 18 There's estimates between 8 and 10,000, I 19 think, as far as live patients with SMA either Types 1, 2, 3 or 4. 20 21 DR. ZITIELLO: And there's very vast 22 differences between the types in spinal 23 muscular atrophy. The one that I was brought 24 up in pediatrics understanding was type 1, 25 where I think dispensing would have some

1	efficacy.
2	A little more concerned about the types 2
3 .	and 3 and this being implemented so soon after
4	it's approved. There's also and I know this
5	very well
6	THE CHAIRPERSON: Would there be any
7	dosing variations?
8	DR. ZITIELLO: Well, the studies that I
9	have read, the dosing was very different for
10	the types 2 and 3. There wasn't a real control
11	on that. So that's why I'm concerned.
12	MS. FUHR: It's the same dosing.
13	And for the later onset for the SMA types
14	2 or 3, any functioning that they currently
15	have, you would want to preserve. So if the
16	older child has the ability to move the
17	electric wheelchair, obviously, you would want
18	to save that for mobility.
19	And I do have some literature I can leave.
20	We just didn't know what the setup was here and
21	what we could do. So I have some information
22	for you.
23	MS. WEAVER: Type 3 is very variable as
24	far as how it presents later in life. It can

be very mild weakness also. When we're talking

25

1	wheelchairs, those would be more severe cases.
2	The American College of Obstetrics & Gynecology
3 .	just this month determined that all women who
4	are pregnant and are wanting preconceptual care
5	get SMA carrier so there's probably going to be
6	recommendation of more of this disease coming
7	out. So that's another way I see utilization
8	will increase.
9	DR. ZITIELLO: Have you guys had an
10	opportunity to comb through your claims data,
11	by any chance, just to identify what you think
12	your patient population is for your plan?
13	MS. WEAVER: We're the process of doing
14	that.
15	DR. ZITIELLO: Okay. Sidebar. If you'd
16	like, I can help identify and narrow down those
17	diagnosis codes.
18	MS. WEAVER: We'll take that under
19	advisement.
20	DR. HAYDEN: I just have a question.
21	Logistically, if it goes to a pharmacy benefit
22	and it's intrathecal infusion, do the parents
23	pick it up at the pharmacy or what is the
24	process?
25	MS. WEAVER: Good question. That's an

1	excellent question.
2	This product requires cold chain for chain
3 .	of custody. So in the case of specialty
4	pharmacy procurement, Accredo Specialty
5	Pharmacy would ship from their pharmacy to the
6	hospital pharmacy. This drug can't go in the
7	hands of a family.
8	DR. HAYDEN: Or the infusion center.
9	MS. WEAVER: Right. It eventually gets to
10	the infusion center. But typically how it
11	works, it just goes into the inpatient
12	pharmacy. The inpatient pharmacy does all
13	their required storage and inventory and all
14	that.
15	And then, at the time of the injection,
16	then they hand it over, like, hand-walk it over
17	to the suite where the injection is being done.
18	And to the physician over here, to the
19	point of the variability, there's also a great
20	degree of variability just from an injection
21	standpoint. You have some patients that are
22	extremely stable. They still have good
23	respiratory support. They're okay to be put in
24	the position for a lumbar puncture.
25	Then you have, on the end of the scale,

somebody that might already have scoliosis, 1 2 growing rods, things like that, and they might actually need interventional radiology. 3 4 I've had a very few patients injected in 5 the clinic setting because they were stable and 6 safe. But the large majority of these are 7 requiring actual hospital outpatient services for the injection. 8 9 And that's sort of what's coming back from 10 some of the payors, with the hospital outpatient dates of service they've told me --11 12 at least their CFOs have told me that their 13 payment methodologies for buy and bill tend to be on a bundled rate, which is problematic if 14 15 we don't have a carve-out or some way to carve 16 out the price for the product if they have to 17 buy and bill. So there's two reasons, really, why 18 19 they're really not able to buy and bill. Reimbursement, that's one of them. But then 20 21 also just the strain to the budget, the impact 22 to their overall pharmacy budget. 23 THE CHAIRPERSON: Very good. Thank you. 24 MS. HARRIS: I just wanted to make sure 25 the board members are aware that we are

1	bringing forward the clinical criteria that
2	would be utilized by the agency. And the
3	health plan, if they so choose, they cannot be
4	more restrictive than the criteria that the
5	agency adopted. And so, if you had any
6	additional questions for the speaker, as you
7	contemplate the criteria that you have before
8	you, I just wanted to make sure you are aware
9	of that. The drugs that we're speaking of are
10	not on our PDL and will be subject to prior
11	auth.
12	THE CHAIRPERSON: Any additional public
13	comments?
14	MS. HANSON: Hi. Jill Hanson. I just
15	wanted to add a couple of comments.
16	First, just the importance of
17	MS. ELLIOTT: Is it for the same drug?
18	MS. HANSON: My first comment is.
19	MS. ELLIOTT: Oh, okay.
20	MS. HANSON: I just wanted to first
21	comment on SPINRAZA and just add one point for
22	our health plan. We are in close communication
23	for the LOAs SCA process for clinical and
24	non-clinical. So I just wanted to mention that
25	as far as covering it under medical. Some

1	plans are in very close communication with that
2	process.
3 .	There's definitely a need for consistent
4	criteria for not just this drug but other
5	high-cost drugs that's on list, one, and the
6	speed of getting those criteria out is
7	important to us. So thank you for looking at
8	this. We definitely appreciate the I guess,
9	expediting it potentially.
10	My last comment, I just wanted to go back
11	to the opiate dependence discussion and the
12	buprenorphine. Since plans cannot be more
13	restrictive than the criteria, I had hoped that
14	the committee would look at the reapproval
15	criteria for straight buprenorphine and revisit
16	that because of the concern for overuse and
17	misuse.
18	So that would be my suggestion, is to
19	revisit that reapproval criteria.
20	Thank you.
21	MS. ELLIOTT: Before the next speaker
22	comes up, I just want to make a comment.
23	I know you-all received the draft criteria
24	for the two products that we're talking about.
25	I just wanted to let you know that your chair,

Dr. Martarana, he had submitted some edits or 1 2 recommendations for SPINRAZA. And I just wanted to let you know that I'll pass it 3 4 around. Because it was so late, I didn't have 5 time to send it. 6 Thank you. 7 MR. FERNANDEZ: I want to thank the committee for giving me a few minutes to speak 8 9 about another drug. I didn't know that 10 SPINRAZA was on the agenda and I would ask to 11 say a few words about it. 12 My name is Ray Fernandez. I'm a pediatric 13 neurologist in Tampa. I've been in private practice since forever -- since 1976, 40, 41 14 15 years. As mentioned, in private practice. I'm 16 not an expert. 17 MS. HARRIS: Excuse me. Can I interrupt you really quickly? So for those in the 18 19 audience, before you videotape or record this session, you must ask the permission of members 20 21 of the audience. We already have a court 22 reporter. And once that transcription is 23 finalized, it will become a public record and 24 you can request that from the agency. But if 25 you are going to videotape, you need to request

1	permission from everyone in the audience.
2	THE CHAIRPERSON: And can I add one
3 .	additional comment?
4	For most of the legacy DUR attendees, it's
5	pretty atypical to have this many public
6	comments as opposed to our sister committee.
7	The P&T committee generally grants a two-minute
8	time approval. So I do not want this to come
9	across as a surprise to anyone, but I am
10	keeping time here just for organizational
11	purposes up here.
12	So if I cut you off, the intent is not to
13	be rude but just to keep time.
14	MR. FERNANDEZ: How much time?
15	THE CHAIRPERSON: Four minutes and 40
16	seconds left.
17	MR. FERNANDEZ: I just want you to know,
18	I've been in private practice in Tampa since
19	1976. I had the good fortune of having the
20	Muscular Dystrophy Association contact me 35
21	years ago. They asked me to establish a clinic
22	in Tampa for children with muscle disease. I
23	said, sure. It was easy then because we did
24	not know a whole lot about it.
25	What has happened over the past 35 years

T	is I have gained a whole lot of experience. I
2	don't consider myself to be an expert, but
3 .	experience is a very good teacher.
4	I've seen diseases over time from spinal
5	muscular atrophy and Duchenne muscular
6	dystrophy. Genetic advances began sometime in
7	the '80s and they have skyrocketed since then.
8	By mid 1980s to late 1980s, we were able to
9	establish a diagnosis very specifically by DNA
10	or gene analysis.
11	And then to subcategorize diseases, again,
12	based on genetic analysis very specifically.
13	Spinal muscular atrophy, people have
14	mentioned types 1 through type 4. The
15	incidence of a disease, the frequency of a
16	disease, is very tricky. When Biogen, I
17	believe, began clinical trials for type 1 SMA,
18	we had two babies born with it within a month:
19	one in Tampa, one in St. Petersburg. Both were
20	referred into the drug trials. I wasn't privy
21	to what was happening so I do not know the
22	outcome of these two early treated babies.
23	But I can tell you the treatment of the
24	babies with type 1 with SPINRAZA, also called
25	nusinersen, has made a huge difference. I

1	mean, these babies died by age two years.
2	It was a diagnosis that you could spot
3	when you walked in the room. It was a baby
4	that was hardly moving, struggling to breathe,
5	at the age of a month or earlier. It
6	progressed rapidly. Death within about two
7	years. But I think treatment with SPINRAZA has
8	made a huge difference.
9	The type 2 form is milder, but it's not
10	really mild if you see it. The type 3 form was
11	commented on. I have two children with type 2
12	spinal muscular atrophy. One just stopped
13	walking at the age of 10 years. We're
14	struggling now with whether we should fuse her
15	spine now because she needs it. Her scoliosis
16	is progressing rapidly. Or whether we should
17	start treating her with nusinersen by spinal
18	tap. Intrathecal is given by spinal tap. I
19	have agreed to be the spinal tapper.
20	We have one child approved and we hope to
21	be starting soon at St. Joseph's Hospital, the
22	Day Hospital, the outpatient center.
23	The treatment of the type 1 babies has
24	made a big difference. They're achieving
25	milestones that they never would have achieved

untreated. There's no doubt it. 1 2 They're living beyond the age of two years. They're crawling, pulling up, standing 3 4 with assistance, taking steps with assistance. 5 That never happened. 6 So I would compel and urge you to consider 7 this drug very closely. It's expensive, yes, 8 but it makes -- it seems to make a big 9 difference in the outcome, both in terms of 10 quality of life and life span. 11 Do I go on to the next or does anybody 12 have any questions? 13 THE CHAIRPERSON: You have one more minute, 60 seconds. 14 15 MR. FERNANDEZ: All right. 16 Well, as a treating doctor, I write 17 prescriptions. And with these drugs, often there's denial and I follow it with a letter of 18 19 appeal. Another denial. Another letter of appeal. And slowly, but surely, we are getting 20 21 patients approved. 22 Again, the first one, the first approval 23 for SPINRAZA, I was informed of while I was in 24 Washington this past weekend at a muscle disease meeting. And this is a topic of 25

1	our discussion in Washington. It came up, the
2	logistics and the difficulties involved with
3	how to administer the drug, et cetera, and the
4	cost of the drug. That's not part of my job
5	description, but I recognize it is expensive
6	and it creates a problem.
7	So, hopefully, we'll be able to move on
8	with this because there are a number of
9	patients these diseases I don't know what
10	the numbers mean to you, 1 in 5,000 or 1 in
11	10,000, but we see them and they're not that
12	THE CHAIRPERSON: Sir.
13	MR. FERNANDEZ: they're not uncommon.
14	THE CHAIRPERSON: Thank you very much.
15	MR. FERNANDEZ: Should I continue?
16	THE CHAIRPERSON: Does anyone have any
17	questions.
18	DR. ZITIELLO: Any experience with SMA3 in
19	treatment?
20	MR. FERNANDEZ: None have been treated
21	that I know of. I'm not sure what's happening
22	with the drug trials.
23	I have two patients with type 3 SMA that
24	we're planning to treat. The indication for
25	treatment is all four forms.

1	I understand from my adult colleagues
2	that they call me when an adult calls them
3 ·	and asks them if the adult should be treated.
4	I don't think we know. I'm not sure what the
5	experiences are. I think most of the
6	experience in clinical trials has been with the
7	type 1 form.
8	But I think it is our intent to treat all
9	patients with spinal muscular atrophy, no
10	matter the type. And there will be exceptions.
11	I think that we try to be reasonable about
12	this. There's some patients in whom there will
13	not be reasonable expectation of improvement.
14	I don't think that any of us would push for
15	treatment in that particular circumstance.
16	These would be very far advanced people, very
17	weak, virtually unable to do anything
18	independently.
19	THE CHAIRPERSON: Very good. Thank you.
20	MR. FERNANDEZ: I was asked to say a few
21	words about another drug. Do I get another
22	five minutes for a second drug?
23	THE CHAIRPERSON: Unfortunately, no.
24	PUBLIC SPEAKER: So my name is Pratik
25	Parikh. I'm the senior medical science liaison

Τ	with Sarepta Therapeutics. Duchenne muscular
2	dystrophy is a progressive neuromuscular
3 .	disease and Sarepta got accelerated at the
4	approval on September 19, 2016 for Exondys 51.
5	I will actually, if it's okay with the
6	committee, yield my time back to Dr. Fernandez,
7	my five minutes, so he can speak on Duchenne.
8	And if you have any questions, please feel free
9	to ask me afterwards or during your discussion.
10	If that's okay?
11	THE CHAIRPERSON: That is fine. We're at
12	four minutes before yield.
13	MR. FERNANDEZ: All right. It's the same
14	drug. I want to talk a little bit about
15	another disease to talk about is Duchenne
16	muscular dystrophy. Relatively common. I
17	think I see new patients with Duchenne muscular
18	dystrophy every year.
19	We just moved our clinic to Shriners
20	Hospital. We have a multidisciplinary clinic
21	where I am the director, and I have been for
22	about 35 years. We have cardiologists,
23	pulmonologists, physical therapists, everybody
24	that we need to take care of these kids.
25	Duchenne muscular dsytrophy was brought

Τ	to attention every year by Jerry Lewis. It's
2	probably, along with spinal muscular atrophy,
3 ·	it's about the most severe muscle disease
4	you'll see.
5	The Duchenne form is the severe form.
6	It's an x-linked disease carried by mothers,
7	passed on to their boys.
8	There's a milder form called Becker that
9	differs genetically in terms of mutation and
10	the type of mutation. What we can do now with
11	eteplirsen, which is Exondys 51, is more or
12	less genetically, anyway, convert the severe
13	Duchenne form to the milder Becker form.
14	And if there are questions about it, I
15	will be glad to try to answer them. But,
16	basically, that's what we do in terms of
17	alteration of the mutation within the gene.
18	This drug is administered intravenously,
19	so that's, somewhat, less complicated. It's
20	administered weekly. The indications for
21	treatment are very specific. Treatment will
22	only be prescribed for boys that have a
23	specific mutation that is amenable to exon 51
24	skipping. And that is accomplished by
25	eteplirsen or Exondys 51.

1	That encompasses about 10 to 13 percent of
2	boys with Duchenne 10 to 13 percent of the
3 .	total of all boys with Duchenne muscular
4	dystrophy. Only that relatively small fraction
5	will be eligible for treatment.
6	The same problem arises as it does with
7	spinal muscular atrophy. We have degeneration
8	of older people that have never been treated.
9	We feel if they qualify for treatment, based on
10	their mutation type, that they should be
11	treated. And these are older these are
12	teenagers and young adults and, yes, some of
13	them have severe weakness. Most of them are
14	wheelchair-confined. They have not been able
15	to walk since the age of about 10 or 12 years.
16	We do not feel that should exclude them from
17	treatment. And, again, we will be reasonable.
18	We do have some treatment criteria or treatment
19	indications that I'll send to the committee in
20	written form.
21	And we also have come up with some
22	exclusion criteria, so that not everyone who
23	has a mutation that is amenable to exon 51
24	skipping will be recommended for treatment,
25	depending on the degree of function of their

1	upper extremities mainly and depending on their
2	ventilatory capacity. And those criteria have
3 .	been drawn up. I have them. I'll get them to
4	you in writing at the appropriate time.
5	We're starting to treat some boys with
6	Duchenne muscular dystrophy. Two young adults
7	have been approved for treatment.
8	We were planning to give the first few
9	doses in the outpatient setting of the
10	hospital. That became complicated. I made
11	some phone calls around the country. Talked to
12	real experts and they said, Why don't you just
13	start treatment at home? That's being done.
14	I met the first boy we treated in Tampa.
15	I made a home visit. The IV nurse was there.
16	And the boy received his first dose without any
17	untoward effect. In fact, it's really quite
18	safe.
19	We know that boys that are treated are
20	able to produce a protein that is called
21	dystrophin, which they otherwise cannot make
22	because of their Duchenne mutation. With
23	treatment, these boys are able to make
24	some dystrophin and it's incorporated within
25	their muscle fibers.

1	THE CHAIRPERSON: Thank you for
2	information. Unfortunately, your time is up.
3 .	I think I can pretty much speak on behalf
4	of the board. I do not want to speak on behalf
5	of the agency. But what I will say is this:
6	Thank you for bringing that. I think it was
7	very informative. I think the agency has shown
8	their attentiveness to this matter by already
9	beginning construction of PA criteria.
10	Certainly, the plans will lean on it heavily.
11	I'm sure we'll have more development on this
12	issue to come.
13	MR. FERNANDEZ: If there are questions, I
14	can be available at any time by telephone or
15	whatever else it takes to move this along.
16	THE CHAIRPERSON: Perfect. Thank you.
17	MS. DUSSAULT: Hi. Good afternoon. My
18	name Ginger Dussault. I'm a mother of a boy
19	with Duchenne muscular dystrophy. I'd also
20	like to speak to Exondys.
21	Duchenne is a rare progressive where boys
22	lose their muscle function due to a missing
23	protein call dystrophin. He is 21 years old.
24	My son Dalton is patient of Sunshine
25	Healthcare. He was diagnosed at the age of 17

1	months, meaning that he was born with a
2	mutation on the dystrophin gene that keeps his
3 .	body from producing the dystrophin and his
4	muscles functioning properly. Dalton is here
5	with his dog, Chulip (ph.), that helps him in
6	his day-to-day life.
7	As you know, the FDA recently approved
8	this drug, Exondys, and it treats Dalton's
9	specific mutation; 48 through 50 are his
10	missing exons. It skips 51 and puts together
11	47 and 52, and lets him express and make
12	dystrophin.
13	Dalton is very lucky to have this specific
14	treatable mutation. Like Dr. Fernandez just
15	mentioned, only 13 percent of the entire
16	Duchenne population is amenable to the skipping
17	of exon 51 and eligible for this treatment.
18	Based off of my son's genetic report and
19	Dr. Fernandez' years of experience in treating
20	patients, such as my son, he has recommended my
21	son for treatment. You've heard his testimony.
22	Since the FDA approval was granted four
23	months ago, we've seen three separate denials
24	in tireless efforts by myself, my doctor and
25	this clinic. Sunshine Healthcare just finally

1	approved Dalton, his prior authorization, for
2	last Thursday. Even though they only gave us a
3 .	a three-month supply of that drug to start,
4	Dalton will receive his first infusion next
5	week. This is huge for our family.
6	I understand the purpose of today's
7	meeting is to review the evidence surrounding
8	Exondys 51 and to begin drafting a policy for
9	the use and reimbursement of Exondys in
10	Duchenne patients amenable.
11	Thank you for taking the time to hear from
12	families and patients and for taking our
13	perspectives into consideration. Given that
14	Duchenne is such a rare and complex disease and
15	that there has never been before an
16	FDA-approved treatment for this disease, I urge
17	you to also listen to the small number of
18	medical experts who have dedicated their lives
19	to treating children and young men with
20	Duchenne. Dr. Fernandez is one. Dr. Byrne of
21	the University of Florida Medical Center,
22	Dr. Giordano, at Numerous Hospital, Dr. Finkel,
23	and Dr. King, who is at Gainesville Medical
24	Center are some of the Duchenne experts located
25	in Florida who have provided written testimony

and are willing to provide guidance and 1 recommendations to Florida's policy for 2 Exondvs 51. 3 4 While I encourage you to take time to hear 5 from all of these experts and make thoughtful 6 policy decisions based off their guidance, 7 please do not take too much more time. 8 Duchenne community and the state of Florida 9 cannot afford to wait any longer to access this 10 drug. 11 During this period of information and 12 evidence gathering, I also urge you to review a 13 recent Medicaid policy that was established in California in collaboration with their Duchenne 14 15 expert for Exondys-51-amenable residents who 16 are on California state's Medicaid. Medi-Cal created this policy after robust engagement and 17 18 communication with experts and patients and 19 provided Medi-Cal with a better understanding of the natural history and -- anyway, the 20 21 natural history of how it happens in Duchenne, 22 the mechanism of action in exon 51 and how this 23 therapy could affect patients in all stages of 24 the disease progression. 25 Another example is that the Pennsylvania

1

Medicaid agency engaged the clinical experts to 2 draft their state policy as well. Washington state and Louisiana have also done the same. 3 4 Typically, plans which have consulted with 5 experts have resulted in policies reflective of 6 FDA-approved and approving drugs for patients 7 that will likely show a benefit. 8 I also want to remind you that your 9 decisions today will affect whether or not 10 Dalton is reauthorized by Sunshine Health Care 11 to continue with treatment beyond the current 12 three-month approval that we've been granted. 13 Dr. Fernandez, Dalton and I are all well 14 aware that your decision here, today, on policy 15 will have a direct impact on whether or not he 16 gets to continue the drug past three 17 months. The longer Dalton and other young men 18 with Duchenne wait for Exondys 51, the more 19 muscle function they lose. Their losses are irreversible. Once lost, the patients never 20 21 gain skills that they once had, like, walking. 22 Dalton lost his ability at age 10. He's now 23 21. 24 I'm sorry, I have to cut THE CHAIRPERSON: 25 you off. Thank you so much for your time.

1	PUBLIC SPEAKER: I won't take up a lot of
2	your time. I'm piggy-backing upon
3	Dr. Fernandez and Ginger with Dalton.
4	My name is Joe Wilshire. I'm active duty
5	military. I'm a single father. My son was
6	diagnosed with Duchenne muscular dystrophy at
7	the age of 7. He is currently on Exondys 51,
8	eteplirsen. He's been in the trial for
9	today was his 107th dose.
10	My son is 13 now. He's still able to get
11	up from his chair and walk to the bathroom on
12	his own. That's not typical. You can ask the
13	lady right here how important that is. Just
14	little things. He's able to open a bottle of
15	water on his own, which is not typical.
16	These boys need this drug to maintain what
17	they have. And in some instances, he may gain
18	things. My son has fallen and hurt himself
19	really bad and has recovered. That's not
20	typical for Duchenne.
21	He's never going to run a marathon. He's
22	never going to do any of those things. He's
23	not going to be your typical kid, playing
24	football or anything like that. But he can
25	take care of himself at his house now.

Τ	The drug is expensive. I don't know the
2	dollar amounts. That's all you-all's type
3 .	thing. I'm more of a witness on what the drug
4	does. I have nothing scripted for you. I can
5	just go by my experience. I can talk to you
6	guys after if that's what is needed as well.
7	It affects everybody differently. All
8	drugs aspirins work for some people and
9	don't work for others and what not, so there's
10	going to be the variety of difference in it.
11	But, I think, regardless of whether they're in
12	a chair already permanently or not, it
13	shouldn't exclude these boys from a chance.
14	My son's pulmonary functions have
15	improved. Not typical. Cardiology functions,
16	his heart, maintained. Not typical, not for
17	his age.
18	So I don't waste any more of your time,
19	please, really, really consider what these
20	people are talking about. These are boys who
21	deserve a chance and a dollar amount shouldn't
22	affect that chance. If you guys have children,
23	your children have a chance.
24	So that's what I've got to say.
25	THE CHAIRPERSON: Thank you. Thank you

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1	for your comments and your time.
2	Any additional public comments?
3	Hearing none. We're going to transition
4	back to Open Discussion topics for next
5	quarter.
6	I'm sorry. Arlene?
7	MS. ELLIOTT: Yes. I just want, for the
8	record, for everybody to know that the draft
9	criteria that the members have received was a
10	compilation of other state's Medicaid
11	commercial plans. We received the one from
12	California Medicaid yesterday, so the committee
13	members haven't seen it yet.
14	So I don't know how you want to proceed,
15	do an interim meeting or via email. But I have
16	also Dr. Martarana's recommendations with your
17	letter there.
18	THE CHAIRPERSON: I would make a motion to
19	have an interim meeting.
20	DR. ZITIELLO: Second.
21	THE CHAIRPERSON: Okay. We'll move to our
22	Open Discussion topics now.
23	Any topics?
24	MS. HARRIS: Mr. Vice Chair, you have to
25	have a vote on your motion.

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1	MS. HARRIS: I'm sorry. You're right.
2	I will rescind my motion. I don't think I
3 .	can yeah, I'm going to rescind my motion.
4	Basically someone else has to make it.
5	DR. ZITIELLO: I move to have an interim
6	discussion on these policies.
7	DR. ROMAY: Second.
8	THE CHAIRPERSON: All right. The motion
9	has been moved and properly second. All those
10	in favor, please say aye.
11	THE COMMITTEE: Aye.
12	THE CHAIRPERSON: Now, we are at the Open
13	Discussion.
14	DR. HAYDEN: So at the last P&T, I saw
15	that one of the GLP-1 agents was removed from
16	the Preferred Drug List. The Bydureon, I
17	believe. It said, long acting.
18	MS. ELLIOTT: I'm sorry, I was
19	DR. HAYDEN: At the last P&T, the
20	formulary update revealed a Bydureon GLP-1
21	agent was removed from the Preferred Drug List.
22	MS. ELLIOTT: Was it both formulations? I
23	can't remember.
24	DR. HAYDEN: And so we have no GLP-1
25	agents available currently on the Preferred

1	Drug List. So I have to do prior
2	authorizations for all my patients. It's time
3 .	consuming, but I'm doing them.
4	MS. ELLIOTT: Was it the pen versus the
5	vial by any chance? Let me look it up.
6	DR. HAYDEN: Yeah, because right now, I
7	think it was the pen. I think that was what
8	was available before. And then it went to
9	non-preferred. And so now, I'm completing
10	prior auths.
11	DR. ROMAY: I believe the vial is
12	preferred and the pen is non-preferred. It's
13	the vials. It the formulation.
14	MS. ELLIOTT: Yeah, the P&T it was a
15	financial decision by P&T.
16	DR. HAYDEN: So the vials are on there.
17	So if she has the connect, she can inject.
18	The patients have to mix it themselves
19	now? Because I didn't see that on the
20	formulary. I just saw
21	DR. ROMAY: Yeah, the 2 milligram vial is
22	the one that's on the formulary. It's the
23	vial, which is the same thing. It's just a
24	different formulation. It's just the
25	formulation.

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1	DR. GOODNOW: We already mentioned it but
2	I think the classes are very helpful, very
3 .	interesting to take a look at. And I think
4	looking at the number of patients and the
5	number of scripts in addition will help us
6	make some recommendations for that class.
7	THE CHAIRPERSON: I actually I'm sorry.
8	Did you have any recommendations, Luis?
9	DR. SAENZ: No.
10	THE CHAIRPERSON: Alfred?
11	DR. ROMAY: I'd like to bring
12	back Hepatitis C in terms of retreatment. And
13	also, the current change in the criteria is to
14	the black box warning on the reactivation of
15	Hep B. I think the criteria and I think I
16	reached out initially to make some
17	recommendations on adding things to that
18	criteria, but I think we need to bring that
19	criteria back to the board and relook at it to
20	see because there's a lot of things that
21	need clarification in terms of products
22	and certain retreatment and certain other
23	scenarios that are not really evident on the
24	criteria or spelled out.
25	THE CHAIRPERSON: Dr. Havden?

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1	DR. HAYDEN: I'm looking at the formulary
2	guide.
3 .	THE CHAIRPERSON: Elboni, are we at our
4	quota for
5	DR. MOORE: I am the quota keeper.
6	So I've been taking my notes. I have the
7	Embeda utilization. What are patients taking
8	now? How do they get to the other agents? And
9	criteria development for that. That's
10	something that Magellen would handle as a
11	quarterly topic.
12	And there's follow-up on the SAMSCA
13	utilization to see what types of providers have
14	been requesting these products.
15	There's homework for the committee to
16	reviews vasopressin receptor antagonist
17	criteria, specifically, Vaprisol and also
18	Transderm Scop criteria.
19	And then, another follow-up item for
20	Magellan regarding the top 10 classes are to
21	bring in the recipients, the claims, the dollar
22	amount, possibly the PDL status, which I think
23	that would be helpful for you guys to see that
24	for some of those products.
25	And also, Dr. Romay's Hep C development,

1	specifically around retreatment. He wants to
2	look back at the criteria to see if there's a
3 .	need to enhance the criteria. So that is not
4	necessarily a quarterly topic. That's just
5	follow-up. So you still have two more.
6	THE CHAIRPERSON: I just want to introduce
7	one other thing. I think this was tabled from
8	the last meeting, particularly since you
9	weren't able to list the top 10 therapeutic
10	classes.
11	I'm looking at antipsychotics and the
12	fee-for-service as the top it's the second
13	most expensive nonclass I suspect a large
14	percentage of that are LAIs, so Abilify and
15	Respidol and all of those are generic now.
16	I guess the question that I would like to
17	propose to the state is, you know we're
18	spending money on LAIs. I can tell you, in our
19	plan, even though it requires a prior
20	authorization, our approval rates are close to
21	96 97 percent.
22	But I guess what I'm looking to know is,
23	since we're paying for these agents, they are
24	approximately \$15- to \$1800 per injection. Are
25	the patients being compliant? How many of

1	those patients or still compliant on a dose
2	post six months or something?
3 .	Because if we're essentially making the
4	investment to make sure that they're compliant
5	for that first 30 days, but they're not coming
6	back in, it kind of defeats the purpose and
7	perhaps plans may want to take a different
8	approach, put them in case management, et
9	cetera, et cetera.
10	DR. MOORE: Okay.
11	DR. ROMAY: Two more. I know we have room
12	for two more.
13	THE CHAIRPERSON: We just have room for
14	one more.
15	DR. ROMAY: Well, I can mention it and we
16	can always, I guess, talk about it.
17	One item is, I know I previous a
18	couple, couple, couple meetings before we
19	had discussed, before Humera went preferred and
20	Embril went non-preferred, we had talked about
21	having I don't know if this I know we
22	created auto PA criteria but I think we had
23	once talked about creating specifically a
24	criteria for rheumatoid arthritis diagnoses.
25	And I think, right now, it's just the PA the

auto PA is just strictly if you have these 1 2 diagnoses, it pays. But I think we had talked about the need for making sure that those 3 4 members are adhering to just the gold 5 standards, which are the DMARDS, you know, 6 things like that. 7 I don't know if that was something that we 8 just phased out because we moved to a different 9 approach. 10 DR. MOORE. It boiled down to the specific 11 contracting language and I can't get into that. 12 DR. ROMAY: Okay. 13 DR. MOORE: That was negotiated upon, so 14 we had to move away from that approach and go 15 with the method that we went with. 16 DR. ROMAY: Okay. 17 And then my second one was surrounding the 18 bupropion products. So on the criteria, I 19 think -- I don't know if I remember seeing this on here, but I think it was just updated where 20 21 they added some film was where the preferred 22 product was redirected to. 23 So I was wondering what led to that? 24 was just, you know, the pricing, or is it just a brand preferred. Because the bupropion 25

- 1 tablets are available in a generic form.
- MS. ELLIOTT: Right. It was a financial
- decision.
- 4 DR. ROMAY: Okay. I just wanted to check.
- 5 That's what I thought it was, but I wanted to
- 6 verify that it was okay on that.
- 7 MS. ELLIOTT: But it's preferred with a
- 8 clinical PA, just for the record.
- 9 DR. ROMAY: Right. Right. Right.
- Right. Because I know before, that wasn't on
- 11 there. So I know it was just recently done.
- 12 Okay. Thank you.
- 13 THE CHAIRPERSON: Okay. I think that
- 14 pretty much wraps up the open discussion.
- 15 Before we adjourn here, a couple of thank yous.
- 16 No. 1, thank you to the attendees for
- 17 coming. Obviously, you could be somewhere
- 18 else.
- I want to thank those who came up for the
- 20 public comments. I think those were very
- 21 educational and certainly powerful.
- I would like to thank AHCA, obviously, for
- assembling these meetings.
- And thank the committee. As you know, our
- 25 chair is unable to make it today, so we thank

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1	you for having confidence in me to
2	honerate (sic) this meeting.
3 .	With that being said, I need a motion to
4	adjourn.
5	DR. HAYDEN: Motion to adjourn.
6	DR. ZITIELLO: Second.
7	THE CHAIRPERSON: Was that a third by
8	Alfred?
9	Meeting adjourned. Thank you.
10	(Thereupon, the proceedings were
11	adjourned at 4:18 p.m.)
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1	CERTIFICATE OF REPORTER
2	STATE OF FLORIDA
3 .	COUNTY OF HILLSBOROUGH
4	
5	I, JUANITA BUTLER, Court Reporter, certify that
6	I was authorized to and did stenographically report
7	the foregoing proceeding; and that the transcript is
8	a true record of said proceeding.
9	
10	I FURTHER CERTIFY that I am not a relative,
11	employee, attorney, or counsel of any of the
12	parties, nor am I a relative or employee of the
13	parties' attorneys or counsel connected with the
14	action, nor am I financially interested in the
15	action.
16	
17	Dated this 17th day of March, 2017.
18	
19	
20	
21	
22	JUANITA ANNETTE BUTLER
23	Stenographic Court Reporter INTEGRA REPORTING GROUP, LLC.
24	Notary Public, State of Florida Commission No. FF 944824
25	Expires: December 21, 2019

JUSTIN M. SENIOR SECRETARY



Date:

July 19, 2017

To:

Beth Kidder, Deputy Secretary for Medicaid

From:

Bureau of Medicaid Policy

Subject:

Gender Confirmation Surgery

PURPOSE

In order for the use of gender confirmation surgery to be covered under the Florida Medicaid program, it must meet medical necessity criteria as defined in Rule 59G-1.010, Florida Administrative Code. (F.A.C.), and be funded through the General Appropriations Act of Chapter 216, Florida Statutes (F.S.).

Pursuant to the criteria set forth in 59G-1.010, F.A.C., the use of gender confirmation surgery must be consistent with generally accepted professional medical standards (GAPMS) as determined by the Medicaid program, and not experimental or investigational.

In accordance with the determination process established in rule 59G-1.035, F.A.C., the Deputy Secretary for Medicaid will make the final determination as to whether gender confirmation surgery is consistent with generally accepted professional medical standards and not experimental or investigational.

If it is determined that gender confirmation surgery is consistent with generally accepted professional medical standards, this report will be supplemented with an addendum which analyzes additional factors to determine whether this health service should be covered under the Florida Medicaid program.

REPORT WITH RECOMMENDATION

This report with recommendation is presented as the summary assessment considering the factors identified in 59G-1.035, F.A.C. based on the collection of information from credible sources of reliable evidence-based information. The intent is to provide a brief analysis with justification in support of the final recommendation.

The analysis described in this report includes:

- A high-level review of relevant disease processes
- An overview of the health service information
- Clearance from the government regulatory body (e.g. U.S. Food and Drug Administration)

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- A review of the literature considered by the relevant medical community or practitioner specialty associations from credible scientific evidence-based literature published in peer reviewed journals and consensus of coverage policy from commercial and other state Medicaid insurers
- Evidence based clinical practice guidelines

HEALTH SERVICE SUMMARY

Gender identity, the sense of being male or female (Dheine, Lichtenstein, Boman, Johansson, Långström, & Landén, 2011), is experienced by everyone. Gender identity develops in early childhood and is thought to be firmly established by the age of four in most people (American Academy of Pediatrics, 1999, as cited in World Professional Association for Transgender Health [WPATH], 2016). The American Psychological Association (2015) further elaborates, stating that although gender identity is established in young toddlerhood, an individual's awareness that their gender identity is not fully aligned with their assigned sex can occur during childhood, adolescence, or adulthood. Gender dysphoria is the discomfort or distress a person feels due to the discrepancy between their experienced gender and their sex assigned at birth. Individuals with gender dysphoria have a strong, persistent desire to live and be accepted as a member of the opposite sex (Bizic, Kojovic, Duisin, Stanojevic, Vujovic, Milosevic, et al., 2014). These individuals often feel they are members of the opposite sex "trapped" in the wrong body (Jarolím, 2000). "Transgender" is a broad term used to describe people whose gender identity or gender expression differs from their assigned sex at birth (The American College of Obstetricians and Gynecologists, 2011). Currently, the United States is home to approximately 1.4 million transgender adults (0.6% of the population) and 150,000 transgender adolescents age 13-17 years (Baker, 2017). The prevalence of male-to-female (MtF) transgender persons is greater than that of female-to-male (FtM) individuals (Barrett, 2014; Bizec et al., 2014; Jarolím, 2000; Selvaggi, Dhejne, Landen, & Elander, 2012). It is important to note that not all transgender individuals experience gender dysphoria or seek treatment.

Transsexualism, first described as a "syndrome" in 1953, was classified as a disorder of sexual identification (Jarolím, 2000). Currently, the International Classification of Diseases, 10th Edition (ICD-10) classifies transsexualism as a disorder of personality and behavior (Barrett, 2014), and a formal diagnosis is made when gender dysphoria reaches a significant level of distress (Selvaggi et al., 2012). In the Diagnostic and Statistical Manual of Mental Disorders (DSM), previous editions used the term "gender identity disorder." In 2013, the latest edition (DSM-5) updated the terminology to "gender dysphoria" to reflect the consensus that gender nonconformity is not a psychiatric disorder, as previously categorized, while also recognizing that access to medical treatment requires a diagnosis (Costa & Colizzi, 2016; Hayes, 2014). Additionally, gender dysphoria has its own chapter in the DSM-5 and is no longer listed under Sexual Dysfunctions and Paraphilic Disorders (American Psychiatric Association, 2013), Multiple professional and government entities, including the WPATH (2016), the European Parliament (Jokić-Begić, Korajlija, & Jurin, 2014), the American Psychological Association (2015), and the World Health Organization (2017), believe gender dysphoria should not be viewed as a psychiatric disorder. Rather, they view gender identity as a continuum and gender nonconformity as a gender variation (Jokić-Begić et al., 2014) that should not be considered negative or pathological (Hess, Rossi Neto, Panic, Rübben, & Senf, 2014).

Minority stress theory is a prominent theoretical framework for health risks of sexual minorities and proposes that stressors encountered in hostile and homophobic or transphobic environments can explain health disparities. The stressors are not experienced by other populations, are chronic, and are socially based (American Public Health Association, 2016).

Transgender people are frequently victims of discrimination, including mistreatment by health care professionals, rejection, and harassment in places of public accommodation. Discrimination can occur when accessing housing, health care, employment, education, public assistance, and other social services. These negative experiences worsen health disparities, such as depression, anxiety, exposure to violence, and HIV infection, which are already disproportionately high in this population. For example, a transgender individual facing homelessness or employment discrimination may engage in survival sex (exchanging sex for food, clothing, shelter, or other basic needs), increasing their risk for exposure to violence and HIV infection. Transgender individuals who are also low income, of color, or members of other marginalized communities face even higher rates of discrimination and disparities (Baker, 2017; American Psychological Association, 2015; American College of Obstetricians and Gynecologists, 2011; World Health Organization, 2017). The transgender population also experiences an extremely high prevalence of suicidal ideation and suicide attempts. Across the United States, Europe, and Canada, studies have shown prevalence rates of suicide attempts among transgender individuals to range from 22-43% over a lifetime and 9-10% in the previous year. In comparison, just 0.6% of the general Canadian population reported a previous year attempt (Bauer, Scheim, Pyne, Travers, & Hammond, 2015).

Treatment

Treatment, according to the WPATH (2016), can include legal name and sex or gender change on identity documents, medically necessary hormone treatment, counseling, psychotherapy, and other medical procedures required to effectively address an individual's gender dysphoria. The WPATH emphasize that not every patient will have a medical need for identical procedures and clinically appropriate treatments must be determined on an individualized and contextual basis in consultation with the patient's medical providers.) For adolescents, treatment may also include pubertal delay (de Vries, McGuire, Steensman, Wagenaar, Doreleijers, & Cohen-Kettenis, 2014). This report will focus on individuals age 18 and older. It is important to note that not all transgender individuals pursue medical or surgical treatment (American Academy of Family Physicians, 2016; American Academy of Pediatrics, 2013), as not everyone with gender nonconforming behavior experiences distress or suffering (Selvaggi et al., 2012). Some people are able to realize their gender identity without surgery, but for others, gender confirmation surgery is an essential, medically necessary step to treat their gender dysphoria (Hess et al., 2014). In 2015, the prevalence of gender confirmation surgery was reported to be 1 in 100,000 (or approximately 3,000-9,000) in the United States (Padula, Heru, & Campbell, 2015), though the transgender population is estimated at 1.4 million adults (Baker, 2017). Genital surgery for FtM patients is performed in only about a third of transgender males (Barrett, 2014). For those who do seek treatment, access to affordable, culturally competent, and reliable health care has been shown to reduce negative health outcomes, such as psychological distress, substance use, HIV vulnerability, suicidal ideation, suicide attempt, suicide, and homicide (American Public Health Association, 2016).

Hormone Therapy

Cross-sex hormones for male-to-female (MtF) individuals include estrogen alone or in combination with spironolactone. Female-to-male (FtM) individuals are prescribed testosterone. The Endocrine Society published guidelines for initiating and monitoring transgender hormone therapy in 2009. Risks associated with hormone therapy include cancer, hypertension, thrombosis, weight changes, hyperkalemia, and polycythemia. The risks are the same for transgender individuals and for biological males and females receiving hormone therapy for other purposes. However, the risks of cross-sex hormone therapy stem from and are worsened by inadvertent or intentional use of excessive doses of sex hormones or inadequate doses to

maintain normal physiology (Endocrine Society, 2009; Rotondi, Bauer, Scanion, Kaay, R. Travers, & A. Travers, 2013; Meriggiola, Jannini, Lenzi, Maggi, & Manieri, 2010). According to Fernandez and Tannock (2016), research on these risks has been inconsistent, as some studies show no metabolic changes and other studies show significant metabolic changes. The authors examined transgender individuals receiving cross-sex hormone therapy at an endocrinology clinic and concluded this therapy is safe. They also agreed with established guidelines recommending that this population be monitored for changes in lipid parameters, body mass index, and hemogram parameters. The Endocrine Society recommends regular clinical and laboratory monitoring every three months during the first year and then once or twice yearly thereafter.

Non-medical, Non-surgical, and Non-genital Surgical Treatment Options

Non-medical and non-surgical treatments include, but are not limited to, legal name and sex or gender change on identity documents (WPATH, 2016), mental health services (Baker, 2017), vocal training, body hair removal (Dhejne et al., 2011), and lifestyle coaching. There are non-genital surgical procedures, such as facial feminization surgeries, voice surgeries, (Selvaggi et al., 2012), body contouring, gluteal or pectoral implants, and other cosmetic procedures, to assist individuals with their transition.

Gender Confirmation Surgery

Gender confirmation surgery (also referred to as sex reassignment surgery in the literature) consists of removing and/or altering the primary and secondary sex characteristics to make them congruent with a person's gender identity. The following surgical procedures are utilized for FtM transitions (Monstrey, Ceulemans, & Hoebeke, 2011; Hayes, 2014):

- Mastectomy
- Hysterectomy
- Salpingo-oophorectomy or ovariectomy
- Vaginectomy
- Urethroplasty
- Metoidioplasty or phalloplasty
- Scrotoplasty
- Insertion of testicular and/or erection prostheses

The following surgical procedures are utilized for MtF transitions (Selvaggi et al., 2012; Hayes, 2014):

- Penectomy
- Orchiectomy
- Vaginoplasty
- Clitoroplasty
- Labiaplasty
- Breast augmentation

Government Regulatory Body Approval

The United States Food and Drug Administration (FDA) does not regulate surgical procedures. However, prosthetic devices/implants commonly utilized in gender confirmation surgeries, such as testicular, penile/erectile, and breast prostheses, require premarket approval prior to being placed in commercial distribution per Title 21 of the Code of Federal Regulations. The FDA also regulates new (initiated after May 28,1976) surgical instruments, such as laparoscopic and endoscopic instruments and accessories. New surgical instruments must go through premarket

notification procedures prior to commercial distribution, supplying information pertaining to safety and effectiveness through a 510(k) summary (FDA, 2016).

LITERATURE REVIEW

This analysis summarizes information obtained from scientific literature published in credible peer-reviewed journals related to gender confirmation surgery. This section also briefly cites the positions from the relevant medical societies.

Psychological Outcomes

Much research has evaluated psychological outcomes and quality of life following genderconfirmation surgery: Duišin, Batinić, Barišić, Djordjevic, Vujović, and Bizic (2014) stated gender confirmation surgery has proven to be an effective intervention for people with gender dysphoria, as confirmed by multiple follow-up studies reporting high levels of postsurgical satisfaction and improvements in quality of life and general functioning. After analyzing surgical outcomes and reviewing available literature, Rossi Neto, Hintz, Krege, Rübben, and vom Dorp (2012) concluded surgical outcomes have a positive impact on patient quality of life due to improved social relationships and psychological/psychiatric functioning, and that gender confirmation surgery is the best treatment option for gender dysphoria. Costa and Colizzi (2016) report the literature has shown gender confirmation procedures appear to be beneficial in reducing mental distress. The Endocrine Society (2009) indicates the mental health of individuals undergoing these surgeries seems to be improved by participating in a treatment program that includes hormones and surgery. Meriggiola et al. (2010) state medical and surgical sex reassignments represent effective treatment. Early and prompt treatment of gender dysphoria seems to be associated with better outcomes (Barrett, 2014; de Vries et al., 2014). Lowenberg, Lax, Rossi Neto, and Krege (2010), as reported in Hess et al. (2014) found that even though just 69% of patients were satisfied with their overall life situation following gender confirmation surgery, 96% would opt for surgery again. Rotondi et al. (2013) state medical and social transitioning is important and necessary in order to maximize health, personal safety, psychological well-being, and self-fulfillment, as non-treatment of transgender patients is associated with worsening psychological outcomes. Barriers to transition-related health care can result in the use of nonprescribed hormones and "do-it-yourself" surgeries, such as removal of testes or breasts.

quality of life. Birkett, Newcomb, and Mustanski (2015) conducted a longitudinal study among LGBTQ youth to characterize trajectories of psychological distress and victimization. Results were consistent with minority stress theory, which suggests that increased victimization and other stigma-related stressors might influence chronic stress and coping. Social support was significantly associated with lower levels of psychological distress, but prior social support did not have a significant impact on later levels of psychological distress, indicating supportive relationships might not be enough to buffer psychological distress if experiences of victimization continue. De Vries et al. (2014) reported on young adult psychological outcomes after puberty suppression and gender confirmation surgery performed between 2008-2012. The authors found that not only was gender dysphoria resolved, but well-being was comparable to peers in many respects. After gender confirmation surgery, psychological functioning improved steadily over time, with rates of clinical problems comparable to that seen in the general population. Quality of life, satisfaction with life, and subjective happiness were comparable to same-aged peers. All of the young adults in their study were generally satisfied with their physical appearance and none regretted treatment. Puberty suppression had caused their bodies to not

further develop contrary to their experienced gender. The authors believe a treatment protocol

Research shows that gender confirmation surgeries reduce psychological distress and improve

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including puberty suppression leads to improved psychological functioning on transgender adolescents.

Jokić-Begić et al. (2014) assessed the psychosocial adjustment of six transgender individuals (3 FtM and 3 MtF). All participants expressed very high satisfaction with their decision to undergo surgery. Almost all participants reported satisfaction with sexual functioning following surgery. Assessments of mood variations fell within normal range. Participants reported increased selfesteem due to having a physical body that matched their gender identities. The authors concluded that their results are consistent with other reports confirming the generally stable and favorable function of transgender individuals following gender confirmation surgery. They reference a meta-analysis by Murad et al. (2010) that indicated transition led to a significant increase in quality of life for 80% of transgender people and a decrease in psychological disturbances in cases where such disturbances were present prior to transition. In contrast, Dhejne et al. (2011) found that individuals who underwent gender confirmation surgery between 1973-2003 had a higher risk of psychiatric inpatient care (for conditions other than gender identity disorder) than controls matched on birth year and birth sex. However, they did not compare rates between transgender females and biological females or transgender males and biological males. Additionally, there have been advances in psychological & medical health care among this population since that time.

Several studies have shown decreased risk for suicidal ideation, suicide attempt, and suicide after gender confirmation surgery. Bauer et al. (2015) stated recent longitudinal studies have demonstrated reductions in psychological distress following medical transition, though suicide attempts and deaths among individuals who received hormonal treatment and/or gender confirmation surgery remained elevated compared to the general population. They posit the reason for this is that the transgender population almost universally experiences some degree of social exclusion and transphobia, and certain social exclusions and victimization are key factors in suicide disparities across marginalized populations. They identified intervenable factors and categorized them into three major constructs: social inclusion, transphobia, and sex/gender transition. They found that suicidal ideation was significantly reduced for those in the process of medically transitioning versus those who were planning but had not vet begun to transition; however, individuals with suicidal thoughts were at greater risk of attempting suicide during transition in comparison to those who were planning. There was no increased risk of suicide among individuals who completed a medical transition; completing a medical transition had beneficial individual and population effects. The authors extrapolated the data and found that facilitating completion of a medical transition would equate to a 44% reduction in suicidal ideation and a 69% reduction in suicide attempts, preventing an estimated 240 attempts per 1,000 transgender individuals. These results suggest the need for supports for those who may feel suicidal while in the process of transition, and call into question the safety of clinical and procedural practices that delay transition treatments until depressive symptoms or suicidality are well-controlled or otherwise result in long delays in the medical transition process.

Dhejhe et al. (2011) found that death from suicide was much higher in sex-reassigned individuals compared to matched controls. Specifically, MtF individuals displayed a significantly increased risk of suicide compared to male controls but not female controls. These results suggest that MtFs are at higher risk for suicide attempt after surgery, but the rate is comparable to biological females; FtMs maintained a biological female pattern of suicide attempt after surgery kaplan, Nehme, Aunon, de Vries, and Wagner (2016) found that history of attempted suicide was significantly associated with lower general social support, lower social integration, lower support from peers, greater openness about transgender identity in public, and any use of hormones (past or present). Although depression was not significantly related to suicide

attempts, 55% who attempted suicide reported depressive symptoms compared to only 33% who reported depressive symptoms and no history of attempts.

Hess et al. (2014) assessed satisfaction following MtF gender confirmation surgery among 254 patients from 2004-2010. Results indicated 61.2% of patients were "satisfied" and an additional 26.2% were "very satisfied" with their outward appearance as women. Regarding the gender confirmation surgery process, 45.5% were "very satisfied," 30% were "satisfied," 22.7% were "mostly satisfied," and only 1.8% were "dissatisfied." Overall, approximately 75% of patients reported being "satisfied" or "very satisfied" with the aesthetic outcome, and an additional 22.3% were "mostly satisfied." Seventy-two percent of patients were "satisfied" or "very satisfied" with the functional outcome of surgery, and an additional 19.4% of patients were "mostly satisfied." Most participants (68.4%) felt their lives had "definitely" become easier since surgery, 14.7% found life to be "somewhat easier," 9.5% found life to be "somewhat harder," and 7.4% felt their lives were "harder." Expectations of life as female were "completely fulfilled" for 50% of respondents, "mostly fulfilled" for 40.2%, "mostly not fulfilled" for 5.9%, and "not fulfilled at all" for 3.9%. There was a correlation between how respondents saw themselves and whether they felt life had become easier or their expectations of life as female had been fulfilled. Those who saw themselves completely as women had higher scores for current life satisfaction than those who only saw themselves as more female than male. The authors found their results comparable to other studies assessing outcomes among similarly sized populations. Subjective satisfaction rates in the other studies ranged from 80-94%.

Surgical Outcomes

Multiple studies have been conducted on physical health outcomes following gender confirmation surgery. Results indicate outcomes are mostly successful in helping patients reach their treatment goals and in alleviating gender dysphoria. The overwhelming majority of research supports gender confirmation surgery as a safe and effective treatment. Bogliolo, Cassani, Babilonti, Gardella, Zanellini, Dominoni, et al. (2014) stated cross-sex surgery should be offered to all transgender individuals who do not desire fertility because surgery can result in improved quality of life in multiple areas (socioprofessional, relationship, psychological), improved social and sexual functioning, and reduced risks of hormone-dependent cancers related to long-term hormone exposure. They found that transgender patients undergoing hysterectomies experienced low rates of complications, none of which were because the patients were transgender. Selvaggi et al. (2012) stated follow-up studies have shown surgery has positive effects on postoperative outcomes, such as subjective well-being, cosmetics, and sexual functioning. They stress the importance of an in-depth consultation between surgeons and patients to discuss extensively the different techniques available and the advantages and disadvantages of each, the limitations of a procedure to achieve "ideal" results, and the inherent risks and complications of the various techniques. Surgeons must be sure that patients have realistic expectations of the outcomes, and that the achievable result would alleviate the patient's gender dysphoria.

Across studies, rates of serious complications are generally low and most are typical of any surgical procedure (such as wound healing difficulties and bleeding). Some complications are specific to individual procedures), others can be attributed to patient noncompliance (such as vaginal prolapse due to not using vaginal dilators as instructed after surgery) and smoking (Monstrey et al., 2011). Complications associated with either MtF or FtM gender confirmation surgery include:

Well leg compartment syndrome (Masumori & Tsukamoto, 2013)

Hematoma

Gender Confirmation Surgery | 8

- Necrosis
- Abscess formation
- Urinary fistulae and/or stenosis (Monstrey et al., 2011)
- Poor erogenous sensation
- Postoperative bleeding (Bogliolo et al., 2014)
- Inadequate final or cosmetic outcome
- Infection (Garaffa, Sansalone, & Ralph, 2013)
- Herniation
- Thrombo-embolic complications
- Intestinal fistulae
- Incontinence of urine and stool (Jarolím, 2000)

Complications specifically associated with MtF gender confirmation surgeries include:

- Neovaginal prolapse (Bucci, Mazzon, Liguori, Napoli, Pavan, Bormioli, et al., 2014)
- Absence of natural lubrication (Bizic et al., 2014)
- Peritoneal perforation and rectal laceration (De Stefani, Trombetta, Raber, Savoca, Moro, & Belgrano, 2004)

Complications specifically associated with FtM gender confirmation surgeries include:

- Donor site morbidity and significant scarring (Garaffa, Ralph, & Christopher, 2010)
- Poor graft take (Garaffa et al., 2013)

Although no particular surgical procedures have been identified as the "gold standard," consensus in the literature is that the radial artery-based forearm free flap (RAFFF) is the preferred method for penile reconstruction and results in the best cosmetic and functional outcomes. As many as 99% of patients are able to void while standing and 97% are fully satisfied with cosmesis and size (Garaffa et al., 2010; Garaffa et al., 2013; Monstrey et al., 2011). Penile inversion vaginoplasty (with or without scrotal flaps) in combination with glansderived sensate clitoroplasty is the preferred method in MtF gender confirmation surgery, as it allows for adequate sensation, good depth, good erotic sensitivity of the neoclitoris, and aesthetically acceptable labia minora and majora. Intestinal pedicled transplants are considered the best choice for those who have previously undergone total penectomy and orchiectomy, those with previously failed skin vaginoplasty, or for patients with Mayer-Rokitansky syndrome (Rossi Neto et al., 2012; Bizic et al., 2014).

Rossi Neto et al. (2012) reported on 13-year surgical outcomes among 332 MtF individuals who underwent surgery from 1995-2008. Due to technique modifications introduced in 2008, individuals who had operations after that time were not included in the study so as to not bias results. All recipients underwent the same vaginoplasty procedure. They categorized surgical complications into five main groups: genital region, urinary tract, gastrointestinal events, wound healing disorders, and unspecific events. The main complication was progressive obstructive voiding disorder due to meatal stenosis, occurring in 40% of patients. Minor wound healing disorders occurred in 33% of patients. Other complications included stricture of vaginal introitus (15%), vaginal stenosis (12%), loss of vaginal depth (8%), and rectal injury (3%). Loss of depth complaints were frequently related to patients' low compliance with post-surgical vaginal dilation. Additional surgeries were needed to correct some complications, whereas other complications were transient and required no treatment. Despite complications, functionality remained intact. The authors stated their findings on complication rates did not indicate permanent, limiting adverse events that could decisively influence functionality after gender confirmation surgery.

Bucci et al. (2014) evaluated neovaginal prolapse among MtF individuals by studying two different surgical techniques. With the first technique, which used two sutures, 1.53% of patients experienced total prolapse and 10.76% experienced partial prolapse. With the second technique, which used four sutures, no instances of total prolapse occurred and only 4.14% of patients experienced partial prolapse. Most patients reported the prolapse occurred following prolonged sexual intercourse in "uncomfortable places" without the use of any lubricant. The authors concluded that the use of four stitches results in a lower risk of prolapse. Specifically, two sutures in one area reduces the risk of total prolapse and two additional sutures in another substantially reduces the risk of partial prolapse. They also strongly recommend the regular use of vaginal stents after surgery to maintain adequate depth and diameter, ensure the skin cylinder adheres to the cavity, facilitate recovery, reduce the risk of stenosis, and reduce the risk of infection by assuring adequate drainage of fluids collected inside the neovagina:

De Stefani et al. (2004) recommended using microlaparoscopy in MtF surgery to reduce the risk of rectal injury. With microlaparoscopy, the dissection of the rectovesical space to create the neovaginal cavity can be directly guided, reducing risk of injury to the surrounding structures. It also allows complementary maneuvers, such as suturing the apex of the neovagina to the bottom of the perineal cavity. It is simple to perform and only adds about 15 minutes to the total operation time.

Garaffa et al. (2010) studied the radial artery-based forearm free flap (RAFFF) in FtM transitions among 27 patients who had previously undergone pre-fashioned pedicled pubic phalloplasty. The revisions were carried out in two stages. At the time of follow-up, 19 patients had completed both stages. Among all patients at the time of follow-up, 93% had a neourethra that reached the tip of the phallus and were fully satisfied with cosmetic and functional results. All 19 patients who completed both stages were able to void from the tip of the phallus while standing with no irritative or obstructive urinary symptoms and with minimal residual bladder urine (as assessed by ultrasonography). Complications occurring after stage one included complete necrosis of the RAFFF urethroplasty (2 patients), abscess formation in the phallus (1 patient), urethral stricture (1 patient), and incomplete graft take (3 patients). Complications occurring after stage two were hematoma (1 patient), abscess (1 patient), and urinary fistula (both patients). Aside from the two patients who experienced necrosis, only three developed complications requiring further revision surgery.

Cost Effectiveness

Padula et al. (2015) analyzed the cost-effectiveness of health insurance coverage for medically necessary and preventive services compared to no coverage in the U.S. adult transgender population using data collected from a review of over 30 randomized controlled trials, observational data, and case series. Effectiveness was measured as quality-adjusted life years (QALYs) in both groups. Those without benefits had less favorable outcomes, including depression, HIV, and death. For those with provider coverage, there was an annual cost of \$2175 associated with medically necessary services and preventive care. Provider coverage was cost-effective relative to no health benefits at 5 and 10 years from a willingness-to-pay threshold of \$100,000/QALY. The 5-year incremental cost-effectiveness was greater than that at 10 years, as upfront costs of transitional therapy were not yet offset by costly long-term outcomes associated with lack of coverage (HIV, drug abuse). The 5-year budget impact analysis indicated a cost of \$0.016 per member per month. The incremental cost effectiveness ratio of provider coverage for medically necessary services and preventive care at 10 years was estimated at \$9,3000/QALY, suggesting that coverage would be relatively efficient on a perpatient basis. Probabilistic sensitivity analysis showed that coverage was cost-effective compared to no coverage in 8,477 out of 10,000 simulations. The authors point out that the

issue of coverage for transgender care can be compared to patients with rare diseases, such as cystic fibrosis, who have access to necessary health technology due to the Orphan Drug Act of 1983. The cost of medication to treat cystic fibrosis is neither affordable nor efficient, but treatment is available because of the Act and absorption of cost across the U.S. population, with a budget impact of approximately \$0.05 per member per month. The authors also point out that other costly surgeries, procedures, and health technologies (such as spinal fusion for chronic back pain, in vitro fertilization, and drugs for erectile dysfunction) that consensus dictates are not medically necessary are still covered by payers. They concluded that provider coverage of gender confirmation surgery is affordable, efficient, and equitable.

Baker (2017) provided a summary of the history of coverage for transgender care. Until recently, most payers categorically excluded coverage of any service or procedure related to gender transition. A shift occurred in 2012 when the California Department of Insurance promulgated a regulation prohibiting categorical exclusions of coverage for health care services related to gender transition if the services were covered for other conditions. Services typically a part of gender transition, such as hormone therapy, breast reconstruction, hysterectomy, vaginoplasty, or phalloplasty, are regularly covered for indications such as endocrine disorders. cancer treatment or prevention, intersex conditions, and treatment after traumatic injury. Changes in federal, regulations (as discussed below) have led to increased coverage for transgender care. Challenges to those regulations have left state and federal courts trying to figure out the degree to which federal sex-nondiscrimination laws expressly protect transgender people. Nonetheless, private-sector employers are increasingly providing coverage for transgender issues. No Fortune 500 company offered employee coverage for gender transition in 2002, but 50% did by the end of 2016. Many public employers, including public universities. counties, states, and the Federal Employees Health Benefits Program, now cover transitionrelated care. Since 2012, 18 states and the District of Columbia have interpreted their own laws as prohibiting private plans from discriminating against transgender people, and 12 states and the District of Columbia have updated their Medicaid rules to affirmatively cover transitionrelated care. Baker asserts that to date, these reforms have imposed minimal or no new costs. Massachusetts conducted a cost-utility analysis on the expansion of transgender-inclusive coverage and determined that covering transition-related services is cost-effective, especially given the high financial and human costs associated with untreated gender dysphoria. California conducted an economic-impact analysis of their regulation removing transgender exclusions and found an "immaterial" effect on premium costs. They concluded, "The benefits of eliminating discrimination far exceed the insignificant costs," the benefits being improved health outcomes (reduced suicide risk, lower rates of substance use, increased adherence to HIV treatment).

The present form of gender confirmation surgery has been practiced for over 50 years and is the internationally recognized treatment to relieve gender dysphoria in transgender individuals. However, research on outcomes is limited or flawed for a variety of reasons. Methodologically, Short duration. Generalizability of results is limited because different studies utilize different surgical techniques and different assessments to measure outcomes. Several authors conclude that although there have been significant advances in this field and current surgical techniques are effective with minimal complications, there remains a need to improve upon surgical techniques to further reduce risk of complications. randomized controlled trials are not feasible given the nature of this issue. The population is confirmation surgery is safe, effective in treating gender dysphoria, improves health outcomes,

Ocspite Huse Unitations

is cost-effective, and is the only treatment option for individuals whose gender dysphoria is not relieved by hormone therapy or other treatments.

Evidence-Based Clinical Practice Guidelines

The World Professional Association for Transgender Health (WPATH) was founded in 1979 and is an international, interdisciplinary, professional association devoted to the understanding and treatment of individuals with gender dysphoria. Members come from medical, mental health, social science, and legal backgrounds. They have developed the WPATH Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People (SOC), first issued in 1979 and periodically revised to reflect advances in evidence-based clinical practice and scientific research. The standards were last updated in 2012 (Version 7). The SOC articulate the "professional consensus about the psychiatric, psychological, medical and surgical management of GD" [gender dysphoria], The SOC reflect the WPATH's conclusion that treatment is medically necessary. The board of directors' opinion, based on clinical and peer reviewed evidence, is that gender affirming/confirming treatments and surgical procedures, properly indicated and performed according to the SOC, have proven beneficial and effective in the treatment of individuals with transsexualism or gender dysphoria. Furthermore, they state gender confirmation surgery plays an undisputed role in contributing toward favorable outcomes. Multiple professional societies have issued statements in support of the SOC, such as the American Medical Association, the Endocrine Society, the American Psychiatric Association, the American Psychological Association, the American Academy of Family Physicians, the National Commission of Correctional Health Care, the American Public Health Association, the National Association of Social Workers, the American College of Obstetrics and Gynecology, the American Society of Plastic Surgeons, and the World Health Organization (WPATH, 2016).

The Endocrine Society's Clinical Practice Guideline, published in 2009, frequently references the WPATH SOC and peer-reviewed research. The guideline recommends hormonal therapy and surgery for sex reassignment for transsexual adults as a treatment for transsexualism or gender identity disorder [known as gender dysphoria in the DSM-5]. Surgery is recommended only after both the physician responsible for endocrine transition therapy and the mental health professional find surgery advisable, and the individual has completed at least one of year of consistent and compliant hormone treatment. It is further recommended that the physician responsible for endocrine treatment medically clear the individual for sex reassignment surgery and collaborate with the surgeon regarding hormone use during and after surgery. The Endocrine Society recommends deferring surgery until an individual is at least 18 years old.

In 2005, the American Psychological Association (APA) Council of Representatives authorized the creation of the Task Force on Gender Identity and Gender Variance. In 2009, the APA Council of Representatives adopted the Resolution on Transgender, Gender Identity, & Gender Expression Non-Discrimination, which, among other endeavors, supports the provision of adequate and necessary mental and medical health care; recognizes the efficacy, benefit, and medical necessity of gender transition; and supports access to appropriate treatment in institutional settings. The APA published the Guidelines for Psychological Practice with Transgender and Gender Nonconforming People (TGNC) in 2015 to assist psychologists in the provision of culturally competent, developmentally appropriate, and trans-affirmative psychological practice with TGNC people. The APA indicate the Guidelines are intended to complement other treatment guidelines, such as those set forth by the WPATH SOC and the Endocrine Society.

The American Psychiatric Association's Position Statement on Access to Care for Transgender and Gender Variant Individuals, published in 2012, indicates the American Psychiatric Association:

- 1. Recognizes that appropriately evaluated transgender and gender variant individuals can benefit greatly from medical and surgical gender transition treatments.
- 2. Advocates for removal of barriers to care and supports both public and private health insurance coverage for gender transition treatment.
- 3. Opposes categorical exclusions of coverage for such medically necessary treatment when prescribed by a physician.

The American Psychiatric Association also issued a Position Statement on Discrimination Against Transgender and Gender Variant Individuals in 2012, which states the American Psychiatric Association:

- 1. Supports laws that protect the civil rights of transgender and gender variant individuals.
- Urges the repeal of laws and policies that discriminate against transgender and gender variant individuals.
- Opposes all public and private discrimination against transgender and gender variant individuals in such areas as health care, employment, housing, public accommodations, education, and licensing.
- 4. Declares that no burden of proof of such judgment, capacity, or reliability shall be placed upon these individuals greater than that imposed on any other persons.

The American College of Obstetrics and Gynecology (ACOG) issued a committee opinion regarding health care for transgender individuals in December 2011. The ACOG opposes discrimination on the basis of gender identity and urges public and private health insurance plans to cover the treatment of gender identity disorder. They discuss hormone therapy, surgery, and necessary screenings for FtM and MtF transgender individuals in order to facilitate quality health care by assisting with transition, if desired, and providing long-term preventive health care.

The American Medical Association (AMA) has published several statements regarding transgender care. The AMA opposes the use of "reparative" or "conversion" therapy for sexual orientation and gender identity and supports public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician (2016). The AMA also affirms "there is no medically valid reason to exclude transgender individuals from service in the U.S. military and affirms transgender service members be provided care as determined by patient and physician according to the same medical standards that apply to non-transgender personnel" (2015).

The American Society of Plastic Surgeons published their Guiding Principles regarding gender confirmation surgery in 2017 to provide a template for use in establishing standardized methods for surgical training in transgender care. The article was unanimously approved by the WPATH Board of Directors as the framework for surgical training for gender confirmation procedures. The article indicates no single discipline can satisfy all treatment needs for transgender persons and recommends a multidisciplinary approach including mental health professionals, primary care providers, endocrinologists, plastic surgeons, urologists, gynecologists, colorectal (or general) surgeons, otolaryngology/head and neck (voice) surgeons, and midlevel practitioners. Additional practitioners, including speech and physical therapists, social workers, and case managers are also desirable.

More to say

The World Health Organization (2017) states transgender people share many of the same health needs as the general population, but they may also have other specialist health care needs, such as gender-affirming hormone therapy and surgery. The WHO also discusses barriers to treatment and outlines best practices in the public provision of gender-affirming health care.

The American Academy of Family Physicians (2016) published recommended curriculum guidelines for family medicine residents regarding lesbian, gay, bisexual, and transgender (LGBT) health. The guidelines recommend: basic understanding of surgical options for transitioning, including common post-operative complications and follow-up issues; familiarity with various treatment recommendations (e.g., the Endocrine Society Clinical Practice Guidelines, the WPATH SOC); referring appropriately to support services for patients needing additional care for gender transition, mental health, sexual health, social services, or other services related to LGBT identity; and managing the transition-related health care of transgender patients of all ages through either hormone administration (and/or puberty-blocking medications) or appropriate referral, as well as referral to any necessary mental health services and/or gender affirmation surgeries and related follow-up care.

The American Public Health Association (2016) encourages public health and health care practices that are inclusive of transgender and gender nonconforming people.

The National Association of Social Workers (2008) "supports the rights of all individuals to receive health insurance and other health coverage without discrimination on the basis of gender identity, and specifically without exclusion of services related to transgender or transsexual transition...which may include hormone replacement therapy, surgical interventions, prosthetic devices, and other medical procedures" (Lambda Legal, 2016).

The National Commission on Correctional Health Care published a position statement regarding transgender, transsexual, and gender nonconforming health care in correctional settings in 2009, which was updated in April 2015. The statement indicates correctional health staff should manage transgender patients in a manner that respects their biomedical and psychological needs. There are 25 principles, including the following:

- Management of medical or surgical transgender care should follow accepted standards developed by professionals with expertise in transgender health (such as WPATH SOC), and treatment decisions should be made on a case-by-case basis
- There should be no blanket administrative or other policies that restrict specific medical treatments; policies that make treatments available only to those who received them prior to incarceration or that limit transition and/or maintenance are inappropriate, out of step with medical standards, and should be avoided
- Accepted treatments for gender dysphoria should be made available to people with gender dysphoria; providing mental health care, while necessary, is not sufficient
- Psychotherapy such as "reparative" or "conversion" therapy or attempts to alter gender identity should never be employed
- Sex reassignment surgery should be considered on a case-by-case basis and provided when determined to be medically necessary for a patient
- Treatment for genital self-harm or for complications arising from self-treatment should be provided when medically necessary

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COVERAGE POLICY

Federal Regulations

Section 1557 is the nondiscrimination provision of the Affordable Care Act, enacted in 2010. The law prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities. Section 1557 builds on long-standing federal civil rights laws; in particular, sex discrimination protections are based on Title IX of the Education Amendments of 1972 and apply to all health system entities that receive federal funds, including Medicare, Medicaid, of health insurance marketplaces. The HHS Office for Civil Rights has enforced provisions of Section 1557 since its enactment. On May 13, 2016, HHS issued a regulation interpreting this provision as encompassing discrimination based on gender identity. Although federal regulation does not require health plans to cover any specific service, plans are prohibited from excluding a service related to gender transition for transgender individuals when the same service is covered for others. However, on December 31, 2016, the U.S. District court for the Northern District of Texas issued an opinion in Franciscan Alliance, Inc., et al. v. Burwell, enjoining the Section 1557 regulation's prohibitions against discrimination on the basis of gender identity and termination of pregnancy on a nationwide basis. Accordingly, HHS' Office for Civil Rights may not enforce these two provision of the regulation while the injunction is in place (U.S. Department of Health and Human Services, n.d.; Baker, 2017).

Medicare

The Centers for Medicare and Medicaid Services (CMS) published an initial national coverage determination (NCD) on August 1, 1989, denying coverage for all transsexual surgery. On May 30, 2014, the HHS Departmental Appeals Board (DAB) determined the NCD was not valid. CMS no longer has a NCD on gender confirmation surgery. Currently, coverage for gender confirmation surgery is determined by Medicare Administrative Contractors (MACs) on a caseby-case basis (CMS, 2016). A search of the CMS website on July 19, 2017 did not reveal any LCDs for "gender confirmation surgery," "gender reassignment surgery," "sex reassignment surgery," or "transsexual surgery."

Florida Medicaid

Florida Medicaid does not expressly cover or deny coverage of gender confirmation surgery but does reimburse for procedures typically performed during gender confirmation surgeries, such as tissue transfer or rearrangement, autologous fat transfer, blepharoplasty, lipectomy, mastectomy, mastopexy, mammoplasty, nipple/areola reconstruction, genioplasty, facial reconstruction, rhinoplasty, urethroplasty, penectomy, orchiectomy, scrotoplasty, prostatectomy, metoidioplasty, phalloplasty, vulvectomy, clitoroplasty, vaginectomy, colpectomy, vaginoplasty, hysterectomy, and salpingo-oophorectomy. Some procedures require prior authorization.

State Medicaid Programs

State Medicaid Programs

Fourteen states explicitly deny coverage of gender confirmation surgery! Twenty-three states (including Florida) do not explicitly deny or proclaim coverage for gender confirmation surgery. as their policies do not reference gender dysphoria, transsexualism, or associated treatments. Illinois' administrative code indicates medical or surgical transsexual treatment, for dates of service prior to April 1, 2015 are not covered; however, a formal policy specifying coverage could not be found.

California, Colorado, Connecticut, the District of Columbia, Massachusetts, Minnesota, New York, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington have specific policies regarding gender confirmation surgery. Overall, the states have similar prerequisite criteria for surgery, which are largely consistent with the WPATH standards of care, though Vermont has more stringent criteria. In general, the following criteria are required, with minor variations from state to state:

- Must be at least 18 years of age and have the capacity to provide fully informed consent (Vermont requires individuals to be at least 21)
- Must have completed 12 months of continuous cross-sex hormone treatment unless hormone therapy is contraindicated (Vermont requires 24 months)
- Must provide two signed letters of referral from licensed providers who have independently assessed the individual and are recommending surgery
 - Some states indicate both letters must be from licensed mental health providers and some states indicate the letters can be from a licensed mental health provider, a licensed medical provider, or a combination of both
 - > Referral letters must indicate a diagnosis of gender dysphoria and medical necessity
- Must live full-time in a gender role congruent with gender identity for 12 consecutive months
- Significant medical or mental health concerns, if present, must be optimally managed and reasonably well-controlled

All states cover the basic genital reconstruction procedures, mastectomy, and hysterectomy. All states also cover augmentation mammoplasty, though most require that the individual have insufficient breast growth after at least two years of hormone therapy before covering the procedure. Five states (Connecticut, District of Columbia, New York, Pennsylvania, and Washington) also cover other transition procedures that are typically considered cosmetic, such as facial feminization procedures, electrolysis, or voice surgery and/or speech therapy.

Connecticut allows mastectomy and creation of a male chest in adolescent FtM transgender reassignment, preferably after ample time of living in the desired gender role and after one year of testosterone treatment.

Commercial Insurers

The following is a sampling of some of the commercial insurance providers who cover gender confirmation surgery for the treatment of gender dysphoria:

- Capital Health Plan
- Florida Blue
- BlueCross/BlueShield of California
- BlueCross/BlueShield of Texas
- BlueCross/BlueShield of Arizona
- BlueCross/BlueShield of Tennessee
- BlueCross/BlueShield of South Carolina
- Aetna
- Humana
- Cigna
- United HealthCare
- Tufts Health Plan
- Regence

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

This report recommends gender confirmation surgery as a health service that is consistent with generally accepted professional medical standards. Gender confirmation surgery is demonstrated to be an effective treatment option for gender dysphoria. Numerous well-respected professional medical societies endorse gender confirmation surgery as a safe and effective treatment. Research in this field, though difficult to conduct given the constraints in studying this population, also supports gender confirmation surgery as a safe and effective treatment for gender dysphoria. Additionally, research has shown that lack of care for this population results in greater health disparities, including poorer long-term outcomes for medical and mental health, increased risk of HIV infection, and increased rates of suicidal ideation, suicide attempt, homelessness, incarceration, and engagement in survival sex. These significant health disparities result in increased societal and medical costs. Furthermore, analyses regarding cost-effectiveness demonstrate that gender confirmation surgery is a cost-effective treatment option that improves quality of life and reduces health disparities.

Rationale		
Concur	Do not Concur	
Comments:		
	W	
		3
Deputy Secretary for	Medicaid (or designee)	

From:

Sent: Friday, December 31, 0001 7:00 PM EST

To: Peoples, Leeanne
Subject: RE: Gender Reassignment
Attachments: image001.png, image002.jpg

Dear Ms. Peoples,

Eligible Medicaid providers may receive reimbursement for the services described in Florida Statutes Chapter 409 Part III if services are rendered in accordance with state and federal law to eligible Medicaid recipients. The most current and appropriate coding must be reported to the highest level of specificity. All of the criteria of medical necessity, as defined in Rule 59G-1.010, Florida Administrative Code, must be supported in order for a Medicaid coverage determination to be made.

Florida Medicaid must determine if a diagnostic test, therapeutic procedure, or medical device or technology is experimental or investigational, as one of the components of the medical necessity criteria. The guidelines that Florida Medicaid will use when determining the circumstances under which a health service is consistent with generally accepted professional medical standards (GAPMS) and not experimental or investigational are described in 59G-1.035 F.A.C., "Determining Generally Accepted Professional Medical Standards." This rule also includes the types of information to be considered in the decision making process and names the person(s) qualified to make the final determination. If you're interested in learning more about our GAPMS process, please visit the Agency's website.

Florida Medicaid does not expressly cover or deny coverage for gender confirmation surgery but does reimburse for procedures typically performed during gender confirmation surgeries such as tissue transfer or rearrangement and autologous fat transfer. Reimbursement for services is in accordance with the <u>Service-Specific Coverage Policy</u>, the American Medical Association Current Procedural Terminology, and the applicable <u>Florida Medicaid fee schedule(s)</u>. Some procedures require prior authorization. The <u>Service-Specific Coverage Policies</u> provide Florida Medicaid's minimum coverage and service requirements for Florida Medicaid services.

Providers, including those that contract with health plans, must comply with the service coverage requirements outlined in the policy, unless otherwise specified in the Agency for Health Care Administration's (AHCA) contract with the health plans. The provision of services to recipients in a Florida Medicaid health plan must not be subject to more stringent service coverage limits than specified in Florida Medicaid policies. Florida Medicaid health plans may negotiate mutually agreed upon rates with their network providers, as well as authorization, documentation, and reimbursement standards. The plans may place appropriate limits on a service on the basis of medical necessity in accordance with 42 CFR 438.210(a)(4)(ii), provided the services furnished can be reasonably expected to achieve their purpose. The Agency's contract with the plans prohibits them from discriminating on the basis of religion, gender identity, sex, sexual

orientation, race, color, age or national origin, health status, pre-existing condition or need for health care services and the plans are prohibited from using any policy or practice that has the effect of such discrimination.

I hope this information will be helpful to you. If you would like more information or have any further questions, please contact the recipient and provider contact center: 1-877-254-1055.

Sincerely,



Claire Davis - REGISTERED NURSE CONSULTANT

- MEDICAID POLICY 2727 Mahan Drive Tallahassee, FL 32308 850-412-4266 (Office) Claire.Davis@ahca.myflorida.com



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From: Peoples, Leeanne

Sent: Tuesday, June 12, 2018 1:31 PM

To: MEDICAIDPOLICY < MEDICAIDPOLICY@ahca.myflorida.com>

Subject: FW: Gender Reassignment

Good afternoon,

AMG has a provider and adult member inquiring about gender reassignment surgery. Could you please advise on whether gender reassignment is covered or not under Medicaid? They do not have a request with clinical information yet that they could share, but will be happy to do so once the prior authorization request with clinical information is received. Please advise.

Thank you.

Leeanne

From: Davis, Ashley H. < Ashley Davis@amerigroup.com

Sent: Tuesday, June 12, 2018 12:54 PM

To: Peoples, Leeanne < Leeanne. Peoples@ahca.myflorida.com >

Cc: dl-flregulatory (Florida Regulatory) <dl-flregulatory floridaregulatory@anthem.com>

Subject: Gender Reassignment

Hi Leeanne,

We have a provider and adult member inquiring about gender reassignment surgery. Could you please inquire with Policy for guidance on whether gender reassignment is covered or not under Medicaid. We do not believe it is, but would like to know how the Agency would like us to approach this service. We do not have a request with clinical information yet that we could share, but will be happy to do so once the prior authorization request with clinical information is received.

Thanks. Ashley

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From: Bouquio, Rebecca

Sent: Tuesday, June 12, 2018 4:02 PM EDT

To: Anthony-Davis, Claire

Subject: Helpful info

Hi Claire,

Here is a snippet from the report I completed last year. After our discussion, I forgot to mention you may want to check any pertinent policies to make sure they have not been updated since July 2017, which is when I completed my report. There may be changes I'm not aware of.

Florida Medicaid

Florida Medicaid does not expressly cover or deny coverage for gender confirmation surgery but does reimburse for procedures typically performed during gender confirmation surgeries, such as tissue transfer or rearrangement, autologous fat transfer, blepharoplasty, lipectomy, mastectomy, mastopexy, mammoplasty, nipple/areola reconstruction, genioplasty, facial reconstruction, rhinoplasty, urethroplasty, penectomy, orchiectomy, scrotoplasty, prostatectomy, metoidioplasty, phalloplasty, vulvectomy, clitoroplasty, vaginectomy, colpectomy, vaginoplasty, hysterectomy, and salpingo-oophorectomy. Some procedures require prior authorization.

Please let me know if you need more information on this topic.

Thanks, Rebecca

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	Medical and Behavioral Health Coverage Policy						
	Claire Anthony-Davis						
	Registered Nurse Consultant						
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From: Vracar, Christina

Sent: Friday, July 20, 2018 4:40 PM EDT

To: Boatwright, Lakeysha

CC: Anthony-Davis, Claire; Richardson, Katuria; Phinazee, Lisa (Kim); Uddin, Abm; Peoples, Leeanne

Subject: 313644 RE: CorrFlow/Medicaid Policy inbox assignments

Hi Lakeysha,

Please close this assignment. The contract manager and I called the plan to discuss Medicaid coverage on Wednesday, July 18, 2018 at 2:55pm. The inquirer was satisfied with the response.

Thank you,

Christina M. Vracar, DA, MPH, CPC-A

Agency for Health Care Administrator

Medical and Behavioral Health Section

Medicaid Policy

Agency for Health Care Administration

2727 Mahan Drive, MS #20

Tallahassee, Florida 32308

E: < mailto: Christina. Vracar@ahca.myflorida.com > Christina. Vracar@ahca.myflorida.com

O: (850) 412-4212

F: (850) 414-1721

<file:///C:/Windows/ahcalogo614.PNG>

<file:///C:/Windows/ReportFraud.jpg>

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From: Boatwright, Lakeysha

Sent: Tuesday, July 10, 2018 10:29 AM

To: Anthony-Davis, Claire <Claire.Davis@ahca.myflorida.com <mailto:Claire.Davis@ahca.myflorida.com>>

Subject: CorrFlow/Medicaid Policy inbox assignments
Good morning,
Can you please provide me with an update on the following assignment(s):
6/12/18
Policy Inbox
313644
Gender Reassignment
Leanne Peoples
Claire Anthony-Davis
6/22/18
28
P
6.15.18 w/Erica
Thank you,
< <u>file:///C:/Windows/ahcalogo614.PNG</u> >
Lakeysha Boatwright, M.B.A., F.C.C.M.
Program Administrator
Florida Certified Contract Manager
BUREAU OF MEDICAID POLICY 2727 MAHAN DR TALLAHASSEE, FL 32308 850-412-4210 (Office)
850-228-9895 (Cell)

Lakeysha.Boatwright@ahca.myflorida.com <mailto:Lakeysha.Boatwright@ahca.myflorida.com>

http://ahca.myflorida.com/Executive/Inspector_General/complaints.shtml

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From: Kumar, Theresa

Sent: Tuesday, October 27, 2020 8:16 AM EDT

To: \"\"Bottcher\"\",\"\" Jesse; Jesse.Bottcher@ahca.myflorida.com

Subject: Gender Reassignment Surgery Codes to be PA'd

Attachments: CG-SURG-27 Gender Reassignment Surgery.pdf, GENDER REASSIGNMENT SURGERY MODEL NCD.pdf,

Gender Dysphoria Treatment - Commercial Medical Policy.pdf

Hi Jesse,

Do you want to discuss incorporating more codes to be PA'd for gender reassignment surgery? Thanks,

Terrie

https://www.unicare.com/dam/medpolicies/unicare/active/guidelines/gl_pw_a051166.html

https://www.cms.gov/medicare/coverage/determinationProcess/downloads/Kalra_comment 01022016.pdf

https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/gender-dysphoria-treatment.pdf

For example, for male-to-female surgery the following may be coded:

- Orchiectomy (54520, 54690)
- Penectomy (54125)
- Vaginoplasty (57335)
- Colovaginoplasty (57291-57292.
- Clitoroplasty (56805)
- Labiaplast(58999)
- Breast augmentation (19324-19325)
- Tracea shave/reduction thyroid chondroplasty (31899)

Theresa Kumar - REGISTERED NURSING CONSULTANT



Bldg 3 Rm 2364 - BUREAU OF MEDICAID POLICY 2727 MAHAN DR., TALLAHASSEE, FL. 32308 +1 850-412-4232 (Office) - (850) 922-7303 (Fax) Theresa.Kumar@ahca.myflorida.com



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From: Pickle, Devona

Sent: Wednesday, January 5, 2022 1:03 PM EST

To: \"\"Sokoloski\"\",\"\" Kristin; Kristin.Sokoloski@ahca.myflorida.com

Subject:

Matt recalls that Rebecca did a GAPMS on that issue. He recalled that she found it is an evidence-based treatment for gender dysphoria, but Medicaid does not cover it. I found an ARTS assignment that Erica personally handled, and it was only covered under EPSDT.

D.D. Pickle, Program Director Canadian Prescription Drug Importation Program Agency for Health Care Administration Office - **850-412-4646** Medicaid Helpline - **1-877-254-1055** Document ID: 0.7.322.10995

Case 4:22-cv-00325-RH-MAF Document 181-37 Filed 04/27/23 Page 1 of 2

From: Peoples, Leeanne

Subject: RE: Attention: A New Collateral Received for Filing: SFL-PM-0019-21 Simply CHA PM Annual Review

To: ""Gomez"","" Daralice; dgomez1@simplyhealthcareplans.com

Cc: dl-FL Regulatory Collaterals

Sent: March 24, 2022 11:00 AM (UTC-04:00)

Attached: Agency Acknowledged 032422 nb SFL-PM-0019-21 Simply CHA PM Annual Review STATE V3.docx

Good morning,

I acknowledge the attached provider material.

Thank you, Leeanne

From: Gomez, Daralice <dgomez1@simplyhealthcareplans.com>

Sent: Wednesday, March 23, 2022 9:49 AM

To: Peoples, Leeanne < Leeanne. Peoples@ahca.myflorida.com>

Cc: dl-FL Regulatory Collaterals <dl-FLRegulatoryCollaterals@anthem.com>

Subject: RE: Attention: A New Collateral Received for Filing: SFL-PM-0019-21 Simply CHA PM Annual Review

Hi Leeanne,

Please find the revised version attached.

Sincerely,

Simply Healthcare Plans, Inc.

-

Daralice Gomez, FL Medicaid Compliance Consultant 9250 W. Flagler St. Suite 600, Miami, FL 33174

O: (561) 669-3216

Dgomez1@simplyhealthcareplans.com

From: Peoples, Leeanne < Leeanne. Peoples@ahca.myflorida.com >

Sent: Monday, February 14, 2022 9:02 AM

To: Gomez, Daralice < dgomez1@simplyhealthcareplans.com>

Cc: dl-FL Regulatory Collaterals < dl-FLRegulatoryCollaterals@anthem.com>

Subject: {EXTERNAL} RE: Attention: A New Collateral Received for Filing: SFL-PM-0019-21 Simply CHA PM Annual

Review

This email originated outside the company. Do not click links or attachments unless you recognize the sender.

Good morning,

Please see the attached document with Agency comments.

Thank you, Leeanne

From: Gomez, Daralice < dgomez1@simplyhealthcareplans.com>

Sent: Tuesday, January 18, 2022 5:25 PM

To: Peoples, Leeanne < Leeanne.Peoples@ahca.myflorida.com >

Cc: dl-FL Regulatory Collaterals < dl-FLRegulatoryCollaterals@anthem.com>

Subject: FW: Attention: A New Collateral Received for Filing: SFL-PM-0019-21 Simply CHA PM Annual Review

Hi Leeanne,

Please find the attached updated Provider Manual for your review. The TC and previous acknowledgement have been attached.

Material Name	SFL-PM-0019-21 Simply CHA PM Annual Review	
Job Number ID	SFL-PM-0019-21	
Description and	This is the annual update for the Simply CHA Provider Manual. This is a revision	
Objective	of document SFL-PM-0017-21	

Sincerely,

Simply Healthcare Plans, Inc.

_ D

Daralice Gomez, FL Medicaid Compliance Consultant 9250 W. Flagler St. Suite 600, Miami, FL 33174

O: (561) 669-3216

Dgomez1@simplyhealthcareplans.com

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Simply

How to apply for participation

If you're interested in applying for participation with Simply Healthcare Plans, Inc. (Simply) and Clear Health Alliance (CHA), please visit http://www.simplyhealthcareplans.com/provider or www.clearhealthalliance.com/provider, or call our Provider Services team at 844-405-4296.

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1 INTRODUCTION

Welcome

Simply Healthcare Plans, Inc. and Clear Health Alliance (Simply) would like to welcome you to the Florida Statewide Medicaid Managed Care and Florida Healthy Kids provider network family. We are pleased you joined our network, which represents some of the finest providers in the country.

We bring the best expertise available nationally to operate local, community-based health care plans with experienced local staff to complement our operations. We are committed to helping you provide quality care and services to our members.

We believe hospitals, physicians and other providers play a pivotal role in managed care, and we can only succeed by working collaboratively with you and other caregivers. Earning your loyalty and respect is essential to maintaining a stable, high-quality provider network. All network providers are contracted with Simply through a *Participating Provider Agreement*.

Note: This manual provides standards for services to Simply and Clear Health Alliance members enrolled in the Medicaid Managed Care, Medicaid Specialty Plan and Florida Healthy Kids programs. If a section of the manual applies only to a specific program, that program will be indicated. If there is no such indication, the information is applicable to all programs.

This provider manual does not apply to members of the Medicare Advantage or the SMMC Long-Term Care (LTC) program. For more information about providing services to Medicare Advantage members, call **844-405-4297**. For more information about providing services to LTC members, call **877-440-3738**.

The LTC provider manual is posted online at www.simplyhealthcareplans.com/provider.

Updates and Changes

The most updated version of this provider manual is available online at www.simplyhealthcareplans.com/provider or www.clearhealthalliance.com/provider. To request a printed copy of this manual at no cost, call Provider Services at 844-405-4296, and we'll be happy to send you a copy.

The provider manual, as part of your *Participating Provider Agreement* and related addendums, may be updated at any time and is subject to change. In the event of an inconsistency between information contained in the manual and the agreement between you or your facility and Simply, the agreement shall govern.

In the event of a material change to the provider manual, we will make all reasonable efforts to notify you in advance of the change through web-posted newsletters, fax communications and other mailings. In such cases, the most recently published information should supersede all previous information and be considered the current directive.

This manual is not intended to be a complete statement of all policies and procedures. We may publish other policies and procedures not included in this manual on our website or in specially targeted communications including but not limited to bulletins and newsletters.

2 OVERVIEW

Who Is Simply?

As a leader in managed health care services for the public sector, we provide health care coverage exclusively to low-income families, children and pregnant women. We participate in the Florida Healthy Kids, Statewide Medicaid Managed Care (SMMC) Long-Term Care, SMMC Managed Medical Assistance programs, and Clear Health Alliance. Clear Health Alliance is a Medicaid specialty plan for people living with HIV/AIDS. References to Simply in this manual include Clear Health Alliance unless otherwise indicated.

Mission

Together, we are transforming health care with trusted and caring solutions.

Strategy

Our strategy is to:

- Improve access to preventive primary care services by ensuring the selection of a primary care physician who will serve as provider, care manager and coordinator for all basic medical services.
- Improve the health status and outcomes of members.
- Educate members about their benefits, responsibilities and the appropriate use of health care services.
- Encourage stable, long-term relationships between providers and members.
- Discourage medically inappropriate use of specialists and emergency rooms.
- Commit to community-based enterprises and community outreach.
- Facilitate the integration of physical and behavioral health care.
- Foster quality improvement mechanisms that actively involve providers in re-engineering health care delivery.
- Encourage a customer service orientation with regular measurement of member and provider satisfaction.

Summary

The Florida legislature created a new program called Statewide Medicaid Managed Care (SMMC). As a result, the Agency for Health Care Administration (AHCA) has changed how some individuals receive health care from the Florida Medicaid program. Two components make up the SMMC program:

- The Florida Managed Medical Assistance (MMA) and specialty program
- The Florida Long-Term Care (LTC) Managed Care program

The goals of the MMA program are to provide:

- Coordinated health care across different health care settings.
- A choice of the best-managed care plans to meet recipients' needs.
- The ability for health care plans to offer different, or more, services.
- The opportunity for recipients to become more involved in their health care.

The goals of the LTC program are to:

- Provide coordinated LTC services to members across different residential living settings.
- Enable members to remain in their homes through the provision of home-based services or in alternative placement, such as assisted living facilities.

For more information on the LTC program, please refer to our LTC provider manual at www.simplyhealthcareplans.com/provider.

The MMA program was implemented in all Florida regions on August 1, 2014. These changes are not due to national health care reform or the Affordable Care Act. Medicaid recipients who qualify and are enrolled in the MMA program will receive all health care services other than long-term care through a managed care plan.

In 1990, the state of Florida created the Florida Healthy Kids Corporation, a nonprofit organization, to administer the Florida Healthy Kids program. Through this program, parents can get affordable health care coverage for eligible children ages 5 through 18.

3 QUICK REFERENCE INFORMATION

Call Provider Services for precertification/notification, network information, member eligibility, claims information, inquiries, and recommendations you may have about improving our processes and/or managed care program.

Simply Phone Numbers

Department/Function	Phone Number
Provider Services	1-844-405-4296 (phone)
	1-800-964-3627 (fax)
TTY number	711
Automated Provider Inquiry Line for Member Eligibility	1-844-405-4296
Electronic Data Interchange (EDI)	1-800-282-4548
Member Services (including the 24/7 NurseLine)	Medicaid: 1-844-406-2396 (TTY 711)
	FHK: 1-844-405-4298 (TTY 711)
	Clear Health Alliance: 1-844-406-2398 (TTY 711)
Pharmacy Services	1-844-405-4296
Medical Injectable Medication Prior Authorization Fax	1-844-509-9862 (fax)

Other Telephone Numbers

Organization / Dragram	Dhana Numbar
Organization/Program	Phone Number
Clear Health Alliance Case Management	1-855-459-1566
iCare (vision)	1-855-373-7627
Beacon Health (behavioral health services)	1-844-280-9633 for Clear Health Alliance
	1-844-375-7215 for MMA
20/20 Hearing Care Network, Inc.	1-844-575-4327
Vaccines for Children (for MMA only)	1-877-888-7468
Immunization Registry (SHOTS)	1-877-888-SHOT (1-877-888-7468)
Healthy Start Program	1-850-245-4465 (toll free)
	1-386-758-1135 (or the local health department)
Women, Infants, and Children and Nutritional	1-800-342-3556
Service	
Florida Quitline (smoking cessation)	1-877-U-CAN-NOW (1-877-822-6669)
AIM (radiology authorization)	1-800-252-2021
IngenioRx (pharmacy benefit manager)	1-833-235-2030
IngenioRx Specialty Pharmacy	1-833-255-0646
LabCorp	1-800-877-5227
Elder Abuse Hotline	1-800-96-ABUSE (1-800-962-2873)
ModivCare	1-866-779-5235
MCT (transportation for Regions 10 and 11)	1-844-628-0388
(CHA: 1-877-671-6671,
American Therapy Administrators	1-888-550-8800
Health Network One (effective until 04/30/2022)	1-800-595-9631 (Dermatology)
Dermatology Network Solutions (effective	1-844-222-3535
05/01/2022)	1-044-755-3333
Podiatry Network Solutions (effective 05/01/2022)	1-844-222-3939

American Specialty Health Group Inc. (chiropractic/acupuncture)

1-800-972-4226 for MMA and LTC

Simply Provider Websites

Visit our websites at www.simplyhealthcareplans.com/provider or www.clearhealthalliance.com/provider for the full complement of online provider resources. They feature online provider inquiry tools for real-time information about member eligibility, prior authorization requirements, claims status, claims resubmission and claims disputes. You can also submit demographic changes and provider rosters.

In addition, the websites have other resources and materials to help you work with us, including provider forms, the MMA and FHK *Preferred Drug Lists*, a list of drugs requiring prior authorization, provider manuals, referral directories, a provider newsletter, electronic remittance advice and electronic funds transfer information, updates, and clinical practice guidelines.

Provider Experience Program

To thank you for the quality of care you give our members, we work to continuously increase service quality for you. Our Provider Experience program, focused on claims payment and issue resolution, does just that! **Call 1-844-405-4296 with claims payment questions or issues.** The Provider Experience program support model connects you with a dedicated resource team to ensure:

- Availability of helpful, knowledgeable representatives to assist you.
- Increased first-contact and issue-resolution rates.
- Significantly improved turnaround time of inquiry resolution.
- Increased outreach communications to keep you informed of your inquiry status.

Our representatives are available Monday to Friday, 8 a.m. to 7 p.m. ET (excluding state holidays). Additional staff is available after-hours for authorization inquiries and requests.

Ongoing Provider Communications

To ensure you are up-to-date with information required to work effectively with us and our members, we provide frequent communications in the form of faxes, provider manual updates, newsletters and information posted to the website.

The additional information below will help you in your day-to-day interactions with Simply.

Department/Function	Additional Details	
Member Eligibility	Contact the Provider Inquiry Line at 1-844-405-4296 or visit our	
	provider websites.	
Member	Medicaid recipients can enroll in Simply online at	
Enrollment/Disenrollment	ment www.flmedicaidmanagedcare.com or by calling 1-877-711-3662	
	(TTY 1-866-467-4970). Florida Healthy Kids members should contact	
	the Florida Healthy Kids Corporation at 1-800-821-5437 .	
Notification/Precertification Precertification requests may be submitted:		
	Online: Availity.com (Select Patient Registration >	
	Authorizations & Referrals)	
	By phone: 1-844-405-4296	
	By fax: 1-800-964-3627	

Department/Function	Additional Details
	The following data is required for complete notification/
	precertification:
	Member ID
	Legible name of referring provider
	 Legible name of individual referred to provider
	National provider identifier and/or tax ID number
	Number of visits/services
	Date(s) of service
	Diagnosis
	CPT/HCPCS codes
	0. 1,110. 00 00000
	In addition, clinical information is required for precertification.
	Authorization forms are available on our provider websites.
Claims Information	Submit paper claims to:
	Simply Healthcare Plans, Inc.
	Florida Claims
	P.O. Box 61010
	Virginia Beach, VA 23466-1010
	Availity Electronic claims payer IDs:
	Simply = SMPLY
	 Clear Health Alliance = CLEAR
	For EDI assistance, providers may call Availity Client Services at
	800-282-4548.
	Timely filing is within six months of the date of service or discharge
	from an inpatient facility or the date the nonparticipating provider
	was furnished with the correct name and address of the plan when
	applicable.
	For other commercial, non-Medicare-insurer crossover claims,
	timely filing is 90 days after the final determination of final payer,
	and is three years for Medicare crossover claims.
	Simply provides an online resource designed to significantly reduce
	the time your office spends on eligibility verification, claims status
	and authorization status, which is available through our provider
	websites.
	If you're unable to access the internet, you may receive claims,
	eligibility and authorization status over the phone by calling our
	toll-free, automated Provider Services line at 844-405-4296 .
Medical Authorizations Appeal	Providers may submit a medical authorizations-related appeal
Information	within 45 calendar days from the date of an adverse
	determination. Within three business days of receipt of a
	complaint, Simply will notify the provider (in writing) the complaint
	has been received and the expected date of resolution. They will:
	Document why a complaint is unresolved after 30 days of receipt
	and provide written notice of the status to the provider every 30
	days thereafter.
	Resolve all complaints within 90 days of receipt.
	Provide written notice of the disposition and basis of the resolution
	to the provider within three business days of resolution.

Department/Function	Additional Details
Payment Dispute	 The preferred method for providers to submit appeal requests is via the web at https://www.availity.com. To find more details on Availity and submitting electronic appeals, visit our Availity Portal Pocket Guide: https://provider.simplyhealthcareplans.com/docs/inline/FLFL_CH A_SMH_PE_AvailityPortalPocketGuide.pdf?v=202002032126 Providers may also mail appeal requests to: Simply Healthcare Plans, Inc. Medical Appeals P.O. Box 62429 Virginia Beach, VA 23466-2429 Providers have 90 calendar days from the date of the final determination of the primary payer to file a written complaint for claims issues. Within three business days of receipt of a claim complaint, Simply will notify the provider (verbally or in writing) the complaint has been received and the expected date of resolution. Within thirty (30) days of receipt of a claim dispute, Simply will provide written notice of the status of the dispute to the Agency and provider. In accordance with Section 641.3155 F.S., Simply will resolve all claims complaints within 30 days of receipts and provide written notice of the disposition and basis of the resolution to the provider within three business days of resolution. Our Provider Experience program also helps you with claims payment and issue resolution. Just call 844-405-4296 and select the Claims prompt. File a payment dispute to: Simply Healthcare Plans, Inc. Payment Disputes P.O. Box 61599
Grievances	Virginia Beach, VA 23466-1599 Provider grievances that are not related to claims payment should be
	submitted in writing to: Simply Healthcare Plans, Inc. Grievance and Appeals Team 4200 W. Cypress St., Suite 900 Tampa, FL 33607 Providers have 45 calendar days from the day of occurrence to file a written grievance. Resolve all grievances within 90 days of receipt. Provide written notice of the disposition and basis of the resolution to the provider within three business days of resolution.
Case Managers	Case managers are available from Monday to Friday, 8 a.m. to 5 p.m. ET.

Department/Function	Additional Details
	 For urgent issues, assistance is available after normal business hours, on weekends and on holidays through the Provider Services line at 844-405-4296. For Clear Health Alliance case managers, call 855-459-1566.
Pharmacy Prior Authorization (PA)	 For links to the <i>Preferred Drug Lists</i> (<i>PDLs</i>), pharmacy PA criteria, and pharmacy PA forms, go to the <i>Pharmacy</i> section on our provider websites. You can initiate PA requests by: Calling the Simply Provider Services line at 1-844-405-4296 Faxing completed pharmacy PA forms to Simply at 1-877-577-9045 for retail pharmacy requests or 1-844-509-9862 for medical injectable requests. Submitting electronic PA requests through https:covermymeds.com.
IngenioRx Specialty Pharmacy	 To submit prescriptions to IngenioRx Specialty Pharmacy Call IngenioRx Specialty pharmacy at 1-833-255-0646 Fax IngenioRx Specialty pharmacy at 1-833-263-2871, please include a copy of the member's Medicaid ID card

4 PRIMARY CARE PHYSICIANS

Primary Care Physicians

The PCP serves as the entry point into the health care system for the member. The PCP must be a physician or network provider/subcontractor who provides or arranges for the complete care of his or her patients, including but not limited to providing primary care, coordinating and monitoring referrals to specialist care, authorizing hospital services, case management, and maintaining continuity of care. The PCP's responsibilities include, at a minimum:

- Managing the medical and health care needs of members to ensure all medically necessary services are made available in a timely manner.
- Monitoring and following up on care provided by other medical service providers for diagnosis and treatment, including services available under Medicaid Fee-for-Service.
- Providing the coordination necessary for the referral of patients to specialists and for the referral of patients for services that may be available through Fee-for-Service Medicaid.
- Processing patient referrals within three business days of an office visit to ensure timely care;
- Advising members to schedule appointments for services requiring referrals at least one week after the PCP visit to allow for processing.
- Maintaining a medical record of all services rendered by the PCP and other referral providers.
- Seeing newly enrolled pregnant members within 30 days of enrollment.

The PCP may practice in a solo or group setting or may practice in a clinic (for example, a Federally Qualified Health Center [FQHC] or Rural Health Center [RHC] or outpatient clinic).

Simply encourages enrollees to select a PCP who provides preventive and primary medical care as well as authorization and coordination of all medically necessary specialty services. Members are encouraged to make

an appointment with their PCP within 90 calendar days of their effective date of enrollment. For more information on appointment availability standards, see the **Access and Availability** section. FQHCs, RHCs and County Health Departments may function as a PCP.

Providers must arrange for coverage of services to assigned members:

- 24 hours a day, 7 days a week, in person or by an on-call physician.
- By answering emergency telephone calls from members within 30 minutes.
- By providing a minimum of 20 office hours per week of personal availability as a PCP.

Provider Specialties

Physicians with the following specialties can apply for enrollment with Simply as a PCP:

- Family practitioners
- General practitioners
- General pediatricians
- General internists
- Advanced registered nurses
- Nurse practitioners

- Practitioners certified as specialists in family practice/pediatrics
- FQHCs and RHCs
- Obstetricians/gynecologists (OB/GYNs) (for women when they are pregnant)
- Infectious Disease providers (CHA only)

The provider must be enrolled in the Medicaid program at the service location where he or she wishes to practice as a PCP before contracting with Simply. PCPs must also be registered in the Vaccines for Children (VFC) program and obtain all vaccines for our eligible members through the VFC program. Please note, Title XXI MediKids members are not eligible for vaccines through the VFC program.

A provider must be a board-certified pediatrician, family practitioner or physician extender working under the direct supervision of a board-certified practitioner if he or she wishes to practice as a Florida Healthy Kids PCP (unless granted an exemption by the Florida Healthy Kids Corporation board of directors).

Our primary care network may also include PCPs who:

- 1. Have recently completed a residency program in pediatrics or family practice approved by the National Board for Certification of Training Administrators of Graduate Medical Education programs and
- 2. Are eligible for but have not yet achieved board certification. If a PCP does not achieve board certification within the first three years of initial credentialing, we will remove that provider from our network and reassign members to a board-certified PCP.

All PCPs in our network must provide all covered immunizations to Simply members and be enrolled in the Florida State Health Online Tracking System (SHOTS), the statewide immunization registry.

Primary Care Physician Onsite Availability

Simply is dedicated to ensuring access to care for our members, and this depends on the accessibility of network providers. Simply network providers are required to abide by the following standards:

- PCPs must offer telephone access to member 24 hours a day, 7 days a week.
- A 24-hour telephone service may be utilized. The service may be answered by a designee, such as an on-call
 physician or nurse practitioner with physician backup, an answering service, or a pager system; however,
 this must be a confidential line for member information and/or questions. An answering machine is not
 acceptable. If an answering service or pager system is used, the call must be returned within 30 minutes.
- The PCP or another physician/advanced registered nurse practitioner must be available to provide medically necessary services.
- Covering physicians are required to follow the referral/precertification guidelines.

• It is **not** acceptable to automatically direct the member to the emergency room when the PCP is not available.

We encourage our PCPs to offer after-hours office care in the evenings and on weekends.

For more information on access and availability standards, see the Access and Availability section.

Provider Termination/Disenrollment Process

Providers may cease participation with Simply for either involuntary or voluntary reasons. Involuntary termination occurs when a provider becomes unavailable due to immediate, unforeseen reasons. Examples of this include illness and/or death. A notice to affected members will be issued immediately upon the health plan becoming aware of the situation.

Providers must give timely notice of voluntary contract termination per the required timeframes in their Simply contracts but not to exceed 90 calendar days. Should a provider cease participation for a voluntary reason such as retirement, a written notice to the affected members will be issued no less than 90 calendar days prior to the effective date of the termination and no more than 10 calendar days after receipt or issuance of the termination notice.

If a member is in a preauthorized, ongoing course of treatment with the provider who suddenly ceases participation as a result of death, illness or Medicaid exclusion, we'll notify the member in writing within 10 calendar days from the date we become aware of the provider's network status.

Member Enrollment

Members who meet the state's eligibility requirements for participation in managed care are eligible to join Simply. Members are enrolled without regard to their health status. Members are enrolled for a period of 12 months, contingent upon continued eligibility.

The member may request disenrollment without cause at any time during the 120 days following the date of the member's initial enrollment with Simply or with agency approval. Unless the member loses eligibility or submits an oral or a written disenrollment request to change managed care plans for cause, the member remains enrolled in a health plan for the remainder of the 12-month period.

Simply will ensure all written and oral disenrollment requests are promptly referred to Florida Statewide Medicaid Managed Care (SMMC). When we receive a written request, we'll send a letter notification to the member within three business days that advises to call SMMC enrollment and disenrollment services at 1-877-771-3662 (TTY 1-866-467-4970).

For member enrollment for Florida Healthy Kids, call 1-800-821-KIDS (5437).

Involuntary Disenrollment

Simply may request involuntary disenrollment of a member under the following conditions:

- Member's Medicaid ID card is fraudulently used.
- Falsification of prescriptions by a member.
- Member takes part in disruptive and abusive behavior not related to a member's behavioral health condition.

Action related to a request for involuntary disenrollment conditions must be clearly documented in the member's records and submitted to the local Simply Provider Operations department. The Agency for Health

Care Administration (AHCA) will be responsible for reviewing, approving and processing all requests for disenrollments.

The documentation must include attempts to bring the member into compliance. A member's disruptive and/or abusive behavior resulting in their failure to be in compliance with their treatment plan must be documented prior to submitting a request for involuntary disenrollment to AHCA. The member must have received at least one verbal and one written warning regarding the implications of his or her actions including involuntary disenrollment.

For any action to be taken, it is mandatory that copies of all supporting documentation from the member's file are submitted with the request.

In addition to the reasons cited in *Rule 59G-8.60 (o),F.A.C.,* if the member is an American Indian or Alaskan Native as defined in *42 CFR 438.14(a),* that constitutes a cause for disensolment.

Simply must be notified before transferring a member out of a physician's practice.

Newborn Enrollment

All providers are responsible for reporting member pregnancies to us to initiate the unborn child's Medicaid eligibility process and ensure appropriate case management.

Simply is responsible for all Medicaid-eligible newborns of enrolled members. This includes payment of medically necessary services and well-child care for the newborn from the date of his or her birth regardless of the mother's continued enrollment in the plan (unless the newborn is disenrolled).

For all pregnant members we're aware of, we'll submit a request to Department of Children and Families (DCF) for the assignment of an inactive Medicaid ID for the unborn child. When the baby is born, we'll submit a request to DCF to activate the Medicaid ID to ensure plan enrollment and claims payment. For babies born without a Medicaid ID, we'll submit a request to DCF for a presumptive eligible newborn Medicaid determination to obtain a Medicaid ID for the baby.

Members Eligibility Listing

The PCP can review his or her panel of assigned members online through *Provider Online Reporting* located on Availity's Payer Spaces (www.availity.com). To receive a listing of assigned panel members by mail on the first day of each month, the PCP must request the list from his or her Provider Relations representative. The list will consist of Simply members who have chosen the PCP's office to provide services. If a member calls to change his or her PCP, the change will be effective the next business day. The PCP should verify that each Simply member receiving treatment in his or her office is on the membership listing. If a PCP does not receive the listing in a timely manner, he or she should contact a Provider Relations representative. For questions regarding a member's eligibility, providers can access our provider websites or call the automated Provider Inquiry Line at **1-844-405-4296**.

Member ID Cards

The ID card identifies the member as a participant in the Simply program. Providers should verify member eligibility and plan enrollment prior to rendering services via the state's Florida Medicaid Management Information System (FMMIS) and/or the Simply provider portal.

The ID card will include the following:

- The member's ID number
- The member's name (first and last names and middle initial)

- The member's enrollment effective date
- Toll-free phone numbers for information and/or authorizations
- Toll-free 24/7 NurseLine information (accessible 24 hours a day, 7 days a week)
- Descriptions of procedures to be followed to obtain emergency or specialty services
- The PCP's name, address and telephone number
- Pharmacy claims processing information
- A phone number for nonparticipating providers to access billing information

Americans with Disabilities Act Requirements

Simply policies and procedures are designed to promote compliance with the Americans with Disabilities Act of 1990. Providers are required to take actions to remove an existing barrier and/or to accommodate the needs of members who are qualified individuals with a disability. This action plan includes:

- Street-level access.
- An elevator or accessible ramp into facilities.
- Access to a lavatory that accommodates a wheelchair.
- Access to an examination room that accommodates a wheelchair.
- Handicapped parking space(s) that are clearly marked, unless there is street-side parking.
- Provisions to communicate in the language or fashion primarily used by his or her members.

Medically Necessary Services

Medically necessary health services mean health services that are:

- Necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain.
- Individualized, specific and consistent with symptoms or confirm diagnosis of the illness or injury under treatment and not in excess of the patient's needs.
- Consistent with the generally accepted professional medical standards as determined by the Medicaid program and not experimental or investigational.
- Reflective of the level of service where care can be provided safely and for which no equally effective and more conservative or less costly treatment is available statewide.
- Furnished in a manner not primarily intended for the convenience of the enrollee, the enrollee's caretaker or the provider.

For services furnished in a hospital on an inpatient basis, medical necessity means appropriate medical care cannot be effectively given more economically on an outpatient basis or in an inpatient facility of a different type.

The fact that a provider has prescribed, recommended or approved medical, allied, or long-term care goods or services does not, in itself, make such care, goods or services medically necessary, a medical necessity or a covered service/benefit.

Continuity of Care: New Members

Simply provides continuation of services until the member's PCP, or behavioral health provider as applicable, reviews the member's treatment plan.

We'll honor any written documentation of prior authorization of ongoing covered services for a period of up to 60 days after the effective date of enrollment or until the member's PCP (or behavioral health provider, as applicable) reviews the member's treatment plan, whichever comes first. For all members, written documentation of prior authorization of ongoing medical and behavioral health services includes the following, provided the services were prearranged prior to enrollment with Simply:

- Prior existing orders
- Provider appointments (i.e., transportation, dental appointments, surgeries, etc.)
- Prescriptions (including prescriptions at nonparticipating pharmacies)
- Prior authorizations
- Treatment plan/plan of care

We won't delay service authorization if written documentation is not available in a timely manner; however, we're not required to approve claims for which we haven't received written documentation.

The following services may extend beyond the 60-day continuity of care period, and we'll continue the entire course of treatment with the member's current provider as described below:

- Prenatal and postpartum care We'll continue to pay for services provided by a pregnant member's current provider for the entire course of a pregnancy including the completion of a woman's postpartum care up to six weeks after birth regardless of whether the provider is in the Simply network.
- Transplant services We'll continue to pay for services provided by the current provider for one year post-transplant regardless of whether the provider is in the Simply network.
- Oncology (radiation and/or chemotherapy services) We'll continue to pay for services provided by the
 current provider for the duration of the current round of treatment regardless of whether the provider is in
 the Simply network.
- Hepatitis C treatment drugs We'll continue to pay for the full course of therapy.

No service will be denied for absence of authorization in circumstances where care was in place prior to the transition date.

The continuity of care provisions stated above apply to both participating and nonparticipating Simply providers.

Continuity of Care: Provider Termination

Simply allows members to continue receiving medically necessary services from a non-for-cause terminated provider and will process claims for services rendered to such members, until the member selects another provider, for a minimum of 60 days after termination of the provider contract. For continuity of care services under these circumstances, Simply will continue to abide by the same contract terms in place prior to contract termination.

For members moving enrollment from one Florida Healthy Kids subsidized plan to another Florida Healthy Kids subsidized plan (without a break in coverage), there is a 60-day continuity of care period.

5 SIMPLY HEALTH CARE BENEFITS AND COPAYMENTS

Simply Covered Services

Any modification to covered services will be distributed via a provider update by mail, fax, provider newsletter, provider manual addendum and/or contractual amendment. Covered services include those listed below and may vary by product.

Statewide Medicaid Managed Care services

Service	Coverage/Limitations	PA
Addictions Receiving Facility Services Services used to help people who are struggling with drug or alcohol addiction	As medically necessary and recommended by us.	Required
Allergy Services Services to treat conditions such as sneezing or rashes that are not caused by an illness	We cover blood or skin allergy testing and up to 156 doses per year of allergy shots.	Not required
Ambulance Transportation Services Ambulance services are for when members need emergency care while being transported to the hospital or special support when being transported between facilities	Covered as medically necessary.	Required for nonemergent transportation services
Ambulatory Detoxification Services Services provided to people who are withdrawing from drugs or alcohol	As medically necessary and recommended by us.	Required
Ambulatory Surgical Center Services Surgery and other procedures that are performed in a facility that is not the hospital (outpatient)	Covered as medically necessary.	May be required
Anesthesia Services Services to keep you from feeling pain during surgery or other medical procedures	Covered as medically necessary.	Not required
Assistive Care Services Services provided to adults (ages 18 and older) help with activities of daily living and taking medication	We cover 365/366 days of services per year.	Required
Behavioral Health Assessment Services Services used to detect or diagnose mental illnesses and behavioral health disorders	 We cover: One initial assessment per year. One reassessment per year. Up to 150 minutes of brief behavioral health status assessments (no more than 30 minutes in a single day). 	Not required
Behavioral Health Overlay Services Behavioral health services provided to children (ages 0 to 18) enrolled in a DCF program	We cover 365/366 days of services per year, including therapy, support services and aftercare planning	Required

Service	Coverage/Limitations	PA
Cardiovascular Services Services that treat the heart and circulatory (blood vessels) system Child Health Services Targeted Case Management Services provided to children (ages 0 to 3) to help them get health care and other services	We cover the following as prescribed by your doctor: Cardiac testing Cardiac surgical procedures Cardiac devices Child must be enrolled in the DOH Early Steps program.	May be required for cardiac testing and surgical procedures Required
Chiropractic Services Diagnosis and manipulative treatment of misalignments of the joints, especially the spinal column, which may cause other disorders by affecting the nerves, muscles and organs	 We cover: One new patient visit. 24 established patient visits per year. Maximum of one visit per day. X-rays. Ultrasound or electrical stimulation. 	Not required
Clinic Services Health care services provided in a county health department, federally qualified health center or a rural health clinic		Not required
Clinical Trials Biomedical or behavioral research studies on human participants designed to answer specific questions about biomedical or behavioral interventions including new treatments and known interventions that warrant further study and comparison.	Florida Medicaid reimburses for services as a result of a recipient participating in a clinical trial in accordance with the service-specific coverage policy when the services: • Are covered under the Florida Medicaid program • Would otherwise be provided to a recipient who is not participating in a clinical trial • Are related to complications or side effects arising during the clinical trial • Are not expected or unique to the experimental or investigational treatment • Are not covered by the clinical trial sponsor	Required
Community-Based Wrap-Around Services Services provided by a mental health team to children who are at risk of going into a mental health treatment facility	As medically necessary and recommended by us.	Required
Crisis Stabilization Unit Services Emergency mental health services that are performed in a facility that is not a regular hospital	As medically necessary and recommended by us.	Not required

Service	Coverage/Limitations	PA
Dialysis Services Medical care, tests and other treatments for the kidneys. This service also includes dialysis supplies, and other supplies that help treat the kidneys.	As prescribed by a treating doctor, we cover: Hemodialysis treatments Peritoneal dialysis treatments	Required
Drop-In Center Services Services provided in a center that helps homeless people get treatment or housing	As medically necessary and recommended by us.	Required
Durable Medical Equipment and Medical Supplies Services Medical equipment is used to manage and treat a condition, illness or injury. Durable medical equipment is used over and over again and includes things like wheelchairs, braces, crutches, and other items. Medical supplies are items meant for one-time use and then thrown away.	Some service and age limits apply. Call 1-844-406-2396 (TTY 711) for more information.	Required
Early Intervention Services Services to children ages 0 to 3 who have developmental delays and other conditions	 We cover: One initial evaluation per lifetime, completed by a team. Up to three screenings per year. Up to three follow-up evaluations per year. Up to two training or support sessions per week. 	Not required
Emergency Transportation Services Transportation provided by ambulances or air ambulances (helicopter or airplane) to get you to a hospital because of an emergency	Covered as medically necessary.	Required for air ambulances
Evaluation and Management Services Services for doctor's visits to stay healthy and prevent or treat illness	 We cover: One adult health screening (check-up) per year. Well-child visits, based on age and developmental needs. One visit per month for people living in nursing facilities. Up to two office visits per month for adults to treat illnesses or conditions. 	Not required
Family Therapy Services Services for families to have therapy sessions with a mental health professional	We cover up to 26 hours per year of family or individual therapy services, one hour per day.	Not required
Family Training and Counseling for Child Development	As medically necessary and recommended by us.	Required

Service	Coverage/Limitations	PA
Services to support a family during their child's mental health treatment		
Gastrointestinal Services Services to treat conditions, illnesses or diseases of the stomach or digestion system	Covered as medically necessary.	May be required for diagnostic tests and procedures
Genitourinary Services Services to treat conditions, illnesses, or diseases of the genitals or urinary system	Covered as medically necessary.	May be required for diagnostic tests and procedures
Group Therapy Services Services for a group of people to have therapy sessions with a mental health professional	We cover up to 39 hours per year.	Not required
Hearing Services Hearing tests, treatments and supplies that help diagnose or treat problems with hearing. This includes hearing aids and repairs.	 We cover hearing tests and the following as prescribed by a doctor: Cochlear implants. One new hearing aid per ear, once every three years repairs. Up to three pairs of ear molds per year. One fitting and dispensing service per ear every three years. One hearing test every three years to determine the need for hearing aid and the most appropriate hearing aid. Up to two newborn hearing screenings for recipients under 12 months of age; a second screening may be performed only if the recipient does not pass the first hearing screening in one or both ears. 	Required for cochlear implants and bone anchored hearing aids
Home Health Services Nursing services and medical assistance provided in your home to help you manage or recover from a medical condition, illness or injury	We cover: Up to four visits per day for pregnant recipients and recipients ages 0 to 20. Up to three visits per day for all other recipients.	Required

Service	Coverage/Limitations	PA
Hospice Services Medical care, treatment and emotional support services for people with terminal illnesses or who are at the end of their lives to help keep them comfortable and pain free. Support services are also available for family members or caregivers.	Covered as medically necessary.	Not required
Individual Therapy Services Services for people to have one-to-one therapy sessions with a mental health professional	We cover up to 26 hours per year of family or individual therapy services, one hour per day.	Not required
Infant Mental Health Pre and Post Testing Services Testing services by a mental health professional with special training in infants and young children	As medically necessary and recommended by us.	Required
Inpatient Hospital Services Medical care members get while in the hospital. This can include any tests, medicines, therapies and treatments, visits from doctors and equipment used to treat members	We cover the following inpatient hospital services based on age and situation: Up to 365/366 days for recipients ages 0 to 20. Up to 45 days for all other recipients (extra days are covered for emergencies).	Required for elective inpatient admissions
Integumentary Services Services to diagnose or treat skin conditions, illnesses or diseases	Covered as medically necessary.	Requires PCP referral
Laboratory Services Services that test blood, urine, saliva or other items from the body for conditions, illnesses or diseases	Covered as medically necessary.	Required for genetic testing
Medical Foster Care Services Services that help children with health problems who live in foster care homes	Must be in the custody of the Department of Children and Families.	Required
Medication Assisted Treatment Services Services used to help people who are struggling with drug addiction	Covered as medically necessary.52 visits per year.	Not required
Medication Management Services Services to help people understand and make the best choices for taking medication	Covered as medically necessary.52 visits per year.	Not required
Mental Health Partial Hospitalization Program Services Treatment provided for more than three hours per day, several days per week, for people who are recovering from mental illness	As medically necessary and recommended by us.	Required

Service	Coverage/Limitations	PA
Mental Health Targeted Case Management Services to help get medical and behavioral health care for people with mental illnesses	Covered as medically necessary.	Required
Mobile Crisis Assessment and Intervention Services A team of health care professionals who provide emergency mental health services, usually in people's homes	As medically necessary and recommended by us.	Required
Neurology Services Services to diagnose or treat conditions, illnesses or diseases of the brain, spinal cord or nervous system	Covered as medically necessary.	May be required for diagnostic tests and procedures
Nonemergency Transportation Services Transportation to and from all medical appointments. This could be on the bus, a van that can transport disabled people, a taxi, or other kinds of vehicles Nursing Facility Services Medical care or nursing care that members	Through ModivCare – (Regions 1-9) and MCT (Regions 10, 11) we cover the following services for recipients who have no other means of transportation: • Out-of-state travel. • Transfers between hospitals or facilities. • Escorts when medically necessary. We cover 365/366 days of services in nursing facilities as medically necessary.	PA is required for out-of-state travel and transfers between hospitals or facilities. PA is required for one way trips greater than 100 miles. Required
get while living full-time in a nursing facility. This can be a short-term rehabilitation stay or long-term.	That sing facilities as incurcally necessary.	
Occupational Therapy Services Occupational therapy includes treatments that help members do things in their daily life, like writing, feeding themselves, and using items around the house.	For children ages 0 to 20 and for adults under the \$1,500 outpatient services cap, we cover: One initial evaluation per year. Up to 210 minutes of treatment per week. One initial wheelchair evaluation per five years. Up to two casting and strapping applications per day. One therapy re-evaluation every five months. For people of all ages, we cover: Follow-up wheelchair evaluations, one at delivery and one six months later.	Required
Oral Surgery Services Services that provide teeth extractions (removals) and to treat other conditions, illnesses or diseases of the mouth and oral cavity	Covered as medically necessary.	Required

Service	Coverage/Limitations	PA
Orthopedic Services Services to diagnose or treat conditions, illnesses or diseases of the bones or joints	Covered as medically necessary.	May be required for diagnostic tests and procedures
Outpatient Hospital Services Medical care members get while in the hospital but not staying overnight. This can include any tests, medicines, therapies and treatments, visits from doctors and equipment used to treat members	 Emergency services are covered as medically necessary. Nonemergency services cannot cost more than \$1,500 per year for recipients ages 21 and over. 	Required for nonemergent services
Pain Management Services Treatments for long-lasting pain that does not get better after other services have been provided	 Covered as medically necessary. Some service limits may apply. Up to 12 facet joint injections in a six-month period Up to four percutaneous radiofrequency neurolysis in a four-month period 	Required
Physical Therapy Services Physical therapy includes exercises , stretching and other treatments to help your body get stronger and feel better after an injury, illness or because of a medical condition	For children ages 0 to 20 and for adults under the \$1,500 outpatient services cap, we cover: One initial evaluation per year. One therapy re-evaluation every five months. Up to two casting and strapping applications per day. Up to 210 minutes of treatment per week. One initial wheelchair evaluation per five years. For people of all ages, we cover: Follow-up wheelchair evaluations, one at delivery and one six months later.	Required
Podiatry Services Medical care and other treatments for the feet	 We cover: Up to 24 office visits per year. Foot and nail care. X-rays and other imaging for the foot, ankle and lower leg. Surgery on the foot, ankle or lower leg. 	Not required

Service	Coverage/Limitations	PA
Prescribed Drug Services This service is for drugs that are prescribed by a doctor or other health care provider	 We cover: Up to a 31-day supply of drugs, per prescription. Refills, as prescribed. Up to two 72-hour emergency supplies per prescription within 30 consecutive days. 	Authorization required for some drugs
Private Duty Nursing Services Nursing services provided in the home to people ages 0 to 20 who need constant care	We cover up to 24 hours per day.	Required
Psychological Testing Services Tests used to detect or diagnose problems with memory, IQ or other areas	We cover 10 hours of psychological testing per year.	Required
Psychosocial Rehabilitation Services Services to assist people re-enter everyday life. They include help with basic activities such as cooking, managing money and performing household chores.	We cover up to 480 hours per year.	Required
Radiology and Nuclear Medicine Services Services that include imaging such as X-rays, MRIs or CAT scans. They also include portable X-rays.	 Covered as medically necessary. Up to two biophysical profiles per pregnancy. One fetal echocardiography per pregnancy; up to two follow-up tests for high-risk pregnancy. One mammography screening per year. Up to three obstetrical ultrasounds per pregnancy. 	May be required
Regional Perinatal Intensive Care Center Services Services provided to pregnant women and newborns in hospitals that have special care centers to handle serious conditions	Covered as medically necessary.	Not required
Reproductive Services Services for women who are pregnant or want to become pregnant. They also include family planning services that provide birth control drugs and supplies to help plan family size.	We cover family planning services. Members can get these services and supplies from any Medicaid provider; they do not have to be a part of our plan. PA is not required; these services are free. These services are voluntary and confidential, even for members under 18 years old.	Not required
Respiratory Services Services that treat conditions, illnesses or diseases of the lungs or respiratory system	 We cover: Respiratory testing. Respiratory surgical procedures. Respiratory device management. 	May be required for diagnostic tests and procedures

Service	Coverage/Limitations	PA
Respiratory Therapy Services Services for recipients ages 0 to 20 to help members breathe better while being treated for a respiratory condition, illness or disease	 We cover: One initial evaluation per year. One therapy re-evaluation per six months. Up to 210 minutes of therapy treatments per week (maximum of 60 minutes per day). 	Not required
Self-Help/Peer Services Services to help people who are in recovery from an addiction or mental illness	As medically necessary and recommended by us.	Required
Specialized Therapeutic Services Services provided to children ages 0 to 20 with mental illnesses or substance use disorders	We cover: Assessments. Foster care services. Group home services.	Required
Speech-Language Pathology Services Services that include tests and treatments to help members talk or swallow better	 For children ages 0 to 20, we cover: Communication devices and services. Up to 210 minutes of treatment per week. One initial evaluation per year. One re-evaluation every five months. For adults, we cover: One communication evaluation per five years. 	Required
Statewide Inpatient Psychiatric Program Services Services for children with severe mental illnesses that need treatment in the hospital	Covered as medically necessary for children ages 0 to 20.	Required
Substance Abuse Intensive Outpatient Program Services Treatment provided for more than three hours per day, several days per week, for people who are recovering from substance use disorders.	As medically necessary and recommended by us.	Required
Substance Abuse Short-term Residential Treatment Services Treatment for people who are recovering from substance use disorders.	As medically necessary and recommended by us.	Required
Therapeutic Behavioral On-Site Services Services provided by a team to prevent children ages 0 to 20 with mental illnesses or behavioral health issues from being placed in a hospital or other facility.	We cover up to nine hours per month.	Required

Service	Coverage/Limitations	PA
Transplant Services Services that include all surgery and pre- and post-surgical care.	Covered as medically necessary.	Required
Visual Aid Services Visual aids are items such as glasses, contact lenses and prosthetic (fake) eyes.	 When prescribed by a doctor, we cover: Two pairs of eyeglasses for children ages 0 to 20. Contact lenses. Prosthetic eyes. 	May be required for prosthetic devices
Visual Care Services Services that test and treat conditions, illnesses and diseases of the eyes	Covered as medically necessary.	May be required for procedures and some tests

Florida Healthy Kids Services

Benefit	Limitations	Copays
Inpatient Services All covered services provided for the medical care and treatment of a member admitted as an inpatient to a hospital licensed under part I of Chapter 395 Covered services include: physician's services; room and board; general nursing care; patient meals; use of operating room and related facilities; use of intensive care unit and services; radiological, laboratory and other diagnostic tests; drugs; medications; biologicals; anesthesia and oxygen services; special duty nursing; radiation and chemotherapy; respiratory therapy; administration of whole blood plasma; physical, speech and occupational therapy; medically necessary services of other health professionals	 Simply must authorize all admissions. The length of the patient stay is determined based on the medical condition of the member in relation to the necessary and appropriate level of care. Room and board may be limited to semi-private accommodations unless a private room is considered medically necessary or semi-private accommodations are not available. Private duty nursing is limited to circumstances where such care is medically necessary. Admissions for rehabilitation and physical therapy are limited to 15 days per contract year. Inpatient services do not include experimental or investigational procedures defined as a drug, biological product, device, medical treatment or procedure that meets any one of the following criteria as determined by Simply: Reliable evidence shows the drug, biological product, device, medical treatment or procedure when applied to the circumstances of a particular patient is the subject of ongoing phase I, II or III clinical trials. Reliable evidence shows the drug, biological product, device, medical treatment or procedure when applied to the circumstances of a particular patient is under study with a written protocol to determine maximum tolerated dose, toxicity, safety, efficacy or efficacy in comparison to conventional alternatives. Reliable evidence shows the drug, biological product, device, medical treatment, or procedure is being delivered or should be delivered subject to the approval and 	None

Includes visits to an emergency room or other licensed facility within the U.S. and its territories if needed immediately due to an injury or illness and delay means risk of permanent damage to the member's health Covered services also means inpatient and outpatient services furnished by a qualified provider, per §1932(b)(2) and 42 CFR 438.114(a), and are needed to evaluate or stabilize an emergency medical condition. 641 • Sub the oth	supervision of an Institutional Review Board (IRB) as required and defined by federal regulations, particularly those of the U.S. Food and Drug Administration or the Department of Health and Human Services. Inply must also comply with the provisions of § 1.513, Florida Statutes. Diject to the provisions of federal and state law, member has the right to use any hospital or liver setting for emergency care. Inply is responsible for any post-stabilization vices obtained within or outside of the network it are preapproved by Simply, or where such proval has been sought by the facility or provider its Simply has failed to respond within one hour of the request for further post-stabilization services it are administered to maintain, improve or colve the member's stabilized position. Inply limits noncovered charges to members for its-stabilization care services to an amount not later than what the facility or provider would large the member if the member had obtained the vices through Simply. In did not preapprove post-stabilization care, our lancial responsibility ends when one of the owing occur: An in-network provider with privileges at the treating facility assumes responsibility for the member's care. An in-network provider assumes responsibility for the member's care through transfer.	\$10 per visit; waived if admitted or authorized by PCP

Benefit	Limitations	Copays
Maternity Services and Newborn Care Includes maternity and newborn care, prenatal and postnatal care, initial inpatient care of adolescent participants including nursery charges and initial pediatric or neonatal examination	 The infant is covered for up to three days following birth or until the infant is transferred to another medical facility, whichever occurs first. Coverage may be limited to the fee for vaginal deliveries. 	None
Organ Transplantation Services Includes pretransplant, transplant and postdischarge services and treatment of complications after transplantation	 Coverage is available for transplants and medically related services if deemed necessary and appropriate by the Organ Transplant Advisory Council or the Bone Marrow Transplant Advisory Council as may be applicable. 	None
Outpatient Services Preventive, diagnostic, therapeutic, palliative care, and other services provided to a member in the outpatient portion of a health facility licensed under Chapter 395 Includes well-child care, including those services recommended in the Guidelines for Health Supervision of Children and Youth as developed by Academy of Pediatrics; immunizations and injections as recommended by the Advisory Committee on Immunization Practices; health education counseling and clinical services; family planning services; vision screening; hearing screening; clinical radiological, laboratory and other outpatient diagnostic tests; ambulatory surgical procedures; splints and casts; consultation with and treatment by referral physicians; radiation and chemotherapy; chiropractic services; and podiatric services	 Services must be provided directly by Simply or through pre-approved referrals. The PCP must provide the routine hearing screening and immunizations. Family planning is limited to one annual visit and one supply visit each 90 days. Chiropractic services are provided in the same manner as in the Florida Medicaid program. Podiatric services are limited to one visit per day, totaling two visits per month for specific foot disorders. Dental services must be provided by an oral surgeon for medically necessary reconstructive dental surgery due to injury. Treatment for temporomandibular joint (TMJ) disease is specifically excluded. Abortions may only be provided in the following situations: The pregnancy is the result of an act of rape or incest. A physician finds the abortion is necessary to save the life of the mother. Outpatient services do not include experimental or investigational procedures defined as a drug, biological product, device, medical treatment or procedure that meets any one of the following criteria as determined by Simply: Reliable evidence shows the drug, biological product, device, medical treatment or procedure when applied to the circumstances of a particular member is the subject of ongoing phase I, II or III clinical trials. Reliable evidence shows the drug, biological product, device, medical treatment or 	\$5 per office visit; no copay for well-child care, preventive care, or routine vision and hearing screenings

Benefit	Limitations	Copays
Mental Health Services Includes inpatient and outpatient care for psychological or psychiatric evaluation, diagnosis and treatment by a licensed mental health professional	procedure when applied to the circumstances of a particular member is under study with a written protocol to determine maximum tolerated dose, toxicity, safety, efficacy or efficacy in comparison to conventional alternatives. Reliable evidence shows the drug, biological product, device, medical treatment, or procedure is being delivered or should be delivered subject to the approval and supervision of an Institutional Review Board (IRB) as required and defined by federal regulations, particularly those of the U.S. Food and Drug Administration or the Department of Health and Human Services. All services must be provided directly by Simply or upon approved referral. Covered services include inpatient and outpatient services for mental and nervous disorders as defined in the most recent edition of the <i>Diagnostic and Statistical Manual of Mental Disorders</i> published by the American Psychiatric Association. Such benefits include psychological or psychiatric evaluation, diagnosis and treatment by a licensed mental health professional meeting the requirements of Section 3-2-2(C) of the state contract. Any benefit limitations, including duration of services, number of visits, or number of days for hospitalization or residential services, will not be any less favorable than those for physical illnesses generally.	Inpatient: none Outpatient: none
Substance Use Services Includes coverage for inpatient and outpatient care for drug and alcohol abuse, including counseling and placement assistance Outpatient services include evaluation, diagnosis and treatment by a licensed practitioner.	 All services must be provided directly by Simply or upon approved referral. Covered services include inpatient, outpatient and residential services for substance disorders. Such benefits include evaluation, diagnosis and treatment by a licensed professional meeting the requirements of Section 3-2-2(C) of the state contract. Any benefit limitations, including duration of services, number of visits, or number of days for hospitalization or residential services, will not be any less favorable than those for physical illnesses generally. 	Inpatient: none Outpatient: none

Benefit	Limitations	Copays
Therapy Services Includes physical, occupational, respiratory and speech therapies for short-term rehabilitation where significant improvement in the member's condition will result	 All treatments must be performed directly or as authorized by Simply. Therapy services are limited to up to 24 treatment sessions within a 60-day period per episode or injury, with the 60-day period beginning with the first treatment. 	\$5 per visit
Home Health Services Includes prescribed home visits by both registered and licensed practical nurses to provide skilled nursing services on a part-time intermittent basis Hospice Services Includes reasonable and necessary services for palliation or	 Coverage is limited to skilled nursing services only. Meals, housekeeping and personal comfort items are excluded. Services must be provided directly by Simply. Private duty nursing is limited to circumstances where such care is medically appropriate. Services required for conditions totally unrelated to the terminal condition are covered to the extent that such services are otherwise covered under this contract. 	\$5 per visit \$5 per visit
management of a member's terminal illness		
Nursing Facility Services Covered services include regular nursing services, rehabilitation services, drugs and biologicals, medical supplies, and the use of appliances and equipment furnished by the facility	 All admissions must be authorized by Simply and provided by a Simply-affiliated facility. Participant must require and receive skilled services on a daily basis as ordered by an in-network physician. The length of the member's stay is determined by the medical condition of the member in relation to the necessary and appropriate level of care, but it cannot be more than 100 days per contract year. Room and board is limited to semi-private accommodations unless a private room is considered medically necessary or semi-private accommodations are not available. Specialized treatment centers and independent kidney disease treatment centers are excluded. Private duty nurses, television and custodial care are excluded. Admissions for rehabilitation and physical therapy are limited to 15 days per contract year. 	None
Durable Medical Equipment and Prosthetic Devices Equipment and devices medically indicated to assist in the treatment of a medical condition and specifically prescribed as medically necessary by the member's in-network physician	 Equipment and devices must be provided by an authorized Simply supplier. Covered prosthetic devices include artificial eyes, limbs, braces and other artificial aids. Low vision and telescopic lenses are not included. Hearing aids are covered only when medically indicated to assist in the treatment of a medical condition. 	None
Refractions Examination by a Simply optometrist to determine the need for and to prescribe	The member must have failed vision screening by their PCP.	\$5 per visit; \$10 for corrective lenses

Benefit	Limitations	Copays
corrective lenses as medically indicated Pharmacy	 Corrective lenses and frames are limited to one pair every two years unless head size or prescription changes. Coverage is limited to frames with plastic or SYL nontinted lenses. This benefit includes all prescribed drugs covered 	FHK
Prescribed drugs for the treatment of illness or injury	 This benefit includes all prescribed drugs covered under the Florida Medicaid program; some may require prior authorization. Please refer to the Pharmacy section of the Provider website for the Preferred Drug Lists for FHK and Medicaid. Simply is responsible for the coverage of any drugs prescribed by the member's dental provider under FHK. Brand name products are covered if a generic substitution is not available or where the prescribing physician indicates a brand name is medically necessary. All medications must be dispensed through Simply or a Simply-designated pharmacy. All prescriptions must be written by the member's PCP, Simply-approved specialist or consultant physician, or the member's dental provider. 	Members: \$5 per prescription for up to a 31-day supply Medicaid Members: No copays for medications
Transportation Services Emergency transportation as determined to be medically necessary in response to an emergency situation	Transportation services must be in response to an emergency situation.	\$10 per service

Enhanced Benefits

Simply has decided to offer a group of enhanced benefits. The expanded services identified below are additional benefits not included in the Florida MMA/Florida Healthy Kids (FHK) core benefits.

Simply waives all copays for Statewide Medicaid Managed Care Managed Medical Assistance members; providers are prohibited from charging Medicaid member copays for covered services.

Copays are not waived for Florida Healthy Kids members; providers are responsible for collecting copays from Florida Healthy Kids members, and the amount paid by Simply will be the contracted amount less any applicable copays.

Members identified as Native Americans or Alaskan Natives are prohibited from paying any cost-sharing amounts, including copays.

Statewide Medicaid Managed Care Managed Medical Assistance Enhanced Benefits

Service	Coverage/Limitations	Prior Authorization
Acupuncture 30 minutes of acupuncture services	30 minutes of treatment once weekly for up to three months; members 21 years of age and older	Required
Behavioral Health Day Services/Day Treatment Behavioral health day treatment or day care services	Additional 10 units per year of day treatment; one day per week, up to 52 per year of day care services; members 21 years of age and older	Not required
Behavioral Health Medical Services (Drug Screening) Behavioral health medical services (alcohol and other drug screening specimen collection)	Additional eight behavioral health-related medical services per year; members 21 years of age and older	Required
Behavioral Health Medical Services (Medication Management) Medication management for behavioral health or substance abuse	Additional eight behavioral health-related medical services per year; members 21 years of age and older	Required
Behavioral Health Medical Services (Verbal Interaction) Behavioral health medical services (verbal interaction), mental health or substance abuse	Additional eight behavioral health-related medical services per year; members 21 years of age and older	Required
Behavioral Health Screening Services Behavioral health screening services	One additional per year; members 21 years of age and older	Not required
Cellular Phone Service Members can sign up for the Lifeline program and receive a free smart phone, free monthly minutes, a minimum of 500 MB of data and text messaging. Members receive free minutes for calls to a toll-free customer service phone number.	One Lifeline Smart phone benefit per member	Not required
Chiropractic Diagnosis and manipulative treatment of misalignments of the joints, especially the spinal column, which may cause other disorders by affecting the nerves, muscles, and organs	Eligible members will receive 35 additional visits per year; members 21 years of age and older	Not required
Computerized Cognitive Behavioral Analysis Health and behavior assessment (i.e., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires)	Unlimited through Simply's online well-being tool; members 21 years of age and older	Not required

Service	Coverage/Limitations	Prior Authorization
Prenatal and postpartum home visits to provide physical, emotional and informational support; provides ongoing birthing support throughout labor and delivery process	Unlimited home visits per pregnancy	Not required
Electric Stimulators (pain management) Transcutaneous electrical nerve stimulation (TENS) device for pain management	Members 21 years and older	Required
Flu/Pandemic Prevention Kit (Clear Health Alliance) • 3-ply face masks – 10 piece • Oral digital thermometer • Hand sanitizer	Eligible for the first 1,000 Clear Health Alliance members who have received their flu vaccine (Must be requested by Case Manager)	Not required
Hearing Services Hearing assessment, hearing aid assessment and hearing aids for in or behind the ear	 One evaluation per two years One assessment per two years One hearing aid, per ear, per two years Members 21 years of age and older 	Required
Home Delivered Meals — Post-Facility Discharge (Hospital or Nursing Facility) Home delivered meals including preparation (per meal)	Two meals per day for seven days; must be after three-day or more surgical hospital stay; members 18 years of age and older	Required
Home delivered meals - Disaster Preparedness/Relief 5 Shelf stable meals delivered at home in an affected area with governor declared state of emergency.	First 500 members requesting per line of business (Simply MMA and CHA); members 18 years of age and older	Not required
Home Health Nursing/Aide Services Nursing services and medical assistance provided in members' homes to help them manage or recover from a medical condition, illness or injury	One additional unit of service per day; members 21 years of age and older	Required
Housing Assistance Supported housing, per month	\$500 per lifetime for homeless individuals	Required
Substance Abuse Intensive Outpatient Treatment Alcohol and/or drug services; intensive outpatient	Three hours per day, three days per week, nine hours per week, maximum eight weeks; pregnant women 21 to 54 years of age	Required
Massage Therapy Therapeutic procedures involving massage, mobilization, manipulation or manual traction for pain relief	Eight units (two hours) per year for eligible members, 21 years of age and older, with acute musculoskeletal pain	Required

Service	Coverage/Limitations	Prior Authorization
Meals — Nonemergency Transportation Day-Trips Nonemergency transportation and meals for members and required escort to medically necessary doctor visits greater than 100 miles each way	\$200 per day; members 21 years of age and older	Required
Newborn Circumcision Circumcision	One per lifetime within first 28 days of birth	Not required
Nutritional Counseling Nutritional counseling, dietician visit	Six visits per year for eligible members	Not required
Occupational Therapy Evaluation moderate complexity Re-evaluation Treatment visit	One evaluation and re-evaluation per year; up to seven therapy treatment units per week; members 21 years of age and older	Required
Outpatient Hospital Services Medical care members get while they are in the hospital but not staying overnight. This can include any tests, medicines, therapies and treatments, visits from doctors and equipment that is used to treat members.	\$200 additional per year, excluding lab services; members 21 years of age and older	* Refer to online quick tool for exact requirements by CPT code.
Over-the-Counter Benefit Cough, cold and allergy medications, vitamins and supplements, ophthalmic/otic preparations, pain relievers, gastrointestinal products, first aid care, hygiene products insect repellent (DEET and non-DEET), oral hygiene products, skin care	Limited to \$25 per household per month on an approved list of products	Not required
 Physical Therapy Evaluation moderate complexity Re-evaluation Treatment visit 	One evaluation and re-evaluation per year; up to seven therapy treatment units per week; members 21 years of age and older	Required
Prenatal Services — Prenatal/Perinatal Visits • Breast pump rental for breast feeding • Antepartum management: 14 visits for low-risk pregnancies and 18 visits for high-risk pregnancies • Postpartum care: Three visits within 90 days following delivery	Breast pump: one per two years; rental only	Required
Primary Care Visit Services for Adults Services for doctor's visits to stay healthy and prevent or treat illness	Unlimited visits for members 21 years of age and older	Not required
Respiratory Supplies Supplies needed for use of approved positive airway pressure device	Members 21 years and older	Not required

Service	Coverage/Limitations	Prior Authorization
 Respiratory Therapy Initial evaluation and re-evaluation Respiratory therapy visit 	One per year for members 21 years of age and older	Not required
Speech Therapy/Speech Language Pathology Evaluation/re-evaluation Evaluation of swallowing function Speech therapy visit Augmentative and alternative communication (AAC) initial evaluation/re-evaluation AAC fitting, adjustment and training visit	One evaluation/re-evaluation per year; up to seven therapy treatment units per week; one AAC evaluation/re-evaluation per year; up to 30 minutes AAC fitting adjustment and training sessions per year; members 21 years of age and older	Required
Therapy — Art Activity therapy, such as music, dance, art or play therapies not for recreation, related to the care and treatment of patient's disabling mental health problems, per session	Unlimited visits for members receiving behavioral health services	Required
Vaccine — Pneumonia (Pneumococcal) Pneumococcal conjugate vaccine 13 valent intramuscular Pneumococcal polysaccharide vaccine 23 valent adult or immunosuppressed dosage subcutaneous or intramuscular	Adults 21 to 64 years of age when medically necessary; adults 65 years or older	Not required
 Vaccine — Influenza Influenza virus vaccine split virus preservative free intramuscular, 90656 Influenza virus vaccine, 90664, 90666, 90667, 90668 Administration of vaccine, G0008 	Members 21 years of age or older; unlimited per pregnancy	Not required
 Vaccine — Shingles (Varicella-Zoster) Zoster shingles vaccine live Subcutaneous/medicine-immunization administration 	One vaccine per member per lifetime, for members 60 years of age and older	Not required for Simply MMA members. PA required for CHA members.
Vaccine — TDaP Tetanus diphtheria toxoids acellular pertussis vaccine (TDaP) intramuscular	One vaccine per pregnancy; members 21 years of age and older	Not required
Vision Services Eye exam exclusively to screen visual acuity without need of reported vision problem, illness, disease or injury; contact lenses; frames	One exam per year; one frame per year; six months of contact lenses with prescription; members 21 years of age and older	Not required
Waived Copayments The plan waives copays on the following services: birthing center; chiropractic; community behavioral health; FQHC; inpatient and outpatient hospital;	Members 21 years of age and older	Not required

Service	Coverage/Limitations	Prior Authorization
independent labs; nonemergency transportation; ARNP; optometrist; physician assistant; physician; podiatrist; portable X-ray; RHC; registered nurse first assistant		

Specialty Enhanced Services

Service	Coverage/Limitations	Prior Authorization
Acupuncture 30 minutes of acupuncture services	30 minutes of treatment once weekly for up to three months; members 21 years of age and older	Required
Behavioral Health Day Services/Day Treatment Behavioral health day treatment or day care services	Additional 10 units per year of day treatment; one day per week, up to 52 per year of day care services; members 21 years of age and older	Not required
Behavioral Health Medical Services (Drug Screening) Behavioral health medical services (alcohol and other drug screening specimen collection)	Additional eight behavioral health-related medical services per year; members 21 years of age and older	Required
Behavioral Health Medical Services (Medication Management) Medication management for behavioral health or substance abuse	Additional eight behavioral health-related medical services per year; members 21 years of age and older	Required
Behavioral Health Medical Services (Verbal Interaction) Behavioral health medical services (verbal interaction), mental health or substance abuse	Additional eight behavioral health-related medical services per year; members 21 years of age and older	Required
Behavioral Health Screening Services Behavioral health screening services	One additional per year; members 21 years of age and older	Not required
Cellular Phone Service Members can sign up for the Lifeline program and receive a free smart phone, free monthly minutes, a minimum of 500 MB of data and text messaging. Members receive free minutes for calls to and from a selected toll-free customer service phone number.	One Lifeline Smart phone benefit per member, 18 years of age and older	Not required
Chiropractic Diagnosis and manipulative treatment of misalignments of the joints, especially the spinal column, which may cause other disorders by affecting the nerves, muscles, and organs	Eligible members will receive 35 additional visits per year; members 21 years of age and older	Not required

Service	Coverage/Limitations	Prior Authorization
Computerized Cognitive Behavioral Analysis Health and behavior assessment (for example, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires)	Unlimited through Simply's online well-being tool; members 21 years of age and older	Not required
Prenatal and postpartum home visits to provide physical, emotional and informational support; provides ongoing birthing support throughout labor and delivery process	Unlimited home visits per pregnancy	Not required
(pain management) Transcutaneous electrical nerve stimulation (TENS) device for pain management	Members 21 years and older	Required
Hearing Services Hearing assessment, hearing aid assessment and hearing aids for in or behind the ear	 One evaluation per two years One assessment per two years One hearing aid per ear per two years Members 21 years of age and older 	Required
Home Delivered Meals — Post-Facility Discharge (Hospital or Nursing Facility) Home delivered meals, including preparation (per meal)	Two meals per day for seven days; must be after three-day or more surgical hospital stay; members 18 years of age and older	Required
Home Health Nursing/Aide Services Nursing services and medical assistance provided in members' homes to help them manage or recover from a medical condition, illness or injury	One additional unit of service per day; members 21 years of age and older	Required
Housing Assistance Supported housing	\$500 per lifetime for homeless individuals; members 21 years of age and older	Required
Massage Therapy Therapeutic procedures involving massage, mobilization, manipulation or manual traction for pain relief	Eight units (two hours) per year for eligible members, 21 years of age and older, with acute musculoskeletal pain	Required
Meals — Nonemergency Transportation Day-Trips Nonemergency transportation and meals for members and required escort to medically necessary doctor visits greater than 100 miles each way	\$200 per day; members 21 years of age and older	Required

Service	Coverage/Limitations	Prior Authorization
Newborn Circumcision Circumcision	One per lifetime within first 28 days of birth	Not required
Nutritional Counseling Nutritional counseling, dietician visit	Six visits per year for eligible members	Not required
Occupational Therapy	One evaluation and re-evaluation per year; up to seven therapy treatment units per week; members 21 years of age and older	Required
Outpatient Hospital Services Medical care members get while they are in the hospital but not staying overnight. This can include any tests, medicines, therapies and treatments, visits from doctors and equipment that is used to treat members.	\$200 additional per year, excluding lab services; members 21 years of age and older	* Refer to online quick tools for exact requirements by CPT code.
Over-the-Counter Benefit Cough, cold and allergy medications, vitamins and supplements, ophthalmic/otic preparations, pain relievers, gastrointestinal products, first aid care, hygiene products insect repellent (DEET and non-DEET), oral hygiene products, skin care	Limited to \$25 per household per month	Not required
 Physical Therapy Evaluation moderate complexity Re-evaluation Treatment visit 	One evaluation and re-evaluation per year; up to seven therapy treatment units per week; members 21 years of age and older	Required
Prenatal Services — Prenatal/Perinatal Visits • Breast pump rental for breast feeding • Antepartum management: 14 visits for low-risk pregnancies and 18 visits for high-risk pregnancies • Postpartum care: three visits within 90 days following delivery	Breast pump: one per two years; rental only	Required
Primary Care Visit Services for Adults Services for doctor's visits to stay healthy and prevent or treat illness	Unlimited visits for members 21 years of age and older	Not required
Respiratory Supplies Supplies needed for use of approved positive airway pressure device	Members 21 years and older	Not required
Respiratory Therapy Initial evaluation and re-evaluationRespiratory therapy visit	One per year for members 21 years of age and older	Not required

Service	Coverage/Limitations	Prior Authorization
 Speech Therapy/Speech Language Pathology Evaluation/re-evaluation Evaluation of swallowing function Speech therapy visit AAC initial evaluation/re-evaluation AAC fitting, adjustment and training visit 	One evaluation/re-evaluation per year; up to seven therapy treatment units per week; one AAC evaluation/re-evaluation per year; up to 30 minutes AAC fitting adjustment and training sessions per year; members 21 years of age and older	Required
Substance Abuse — Intensive Outpatient Treatment Alcohol and/or drug services; intensive outpatient	Three hours per day, three days per week, nine hours per week, maximum eight weeks; members 21 to 54 years of age	Required
Therapy — Art Activity therapy, such as music, dance, art or play therapies not for recreation, related to the care and treatment of patient's disabling mental health problems, per session	Unlimited visits for members receiving behavioral health services	Required
Vaccine — Pneumonia (Pneumococcal) Pneumococcal conjugate vaccine 13 valent intramuscular Pneumococcal polysaccharide vaccine 23 valent adult or immunosuppressed dosage subcutaneous or intramuscular	Adults 21 to 64 years of age when medically necessary; adults 65 years or older	Not required
Vaccine — Hepatitis B Hepatitis B vaccine, adult dosage	All adults who have not been previously vaccinated are eligible to receive the vaccine.	Not required
Vaccine — Human Papilloma Virus HPV vaccine	All adults ages 21 to 26 who have not previously received the vaccine are eligible	Not required
 Vaccine — Influenza Influenza virus vaccine split virus preservative free intramuscular, 90656 Influenza virus vaccine, 90664, 90666, 90667, 90668 Administration of vaccine, G0008 	Members 21 years of age or older; unlimited per pregnancy	Not required
Vaccine — Meningococcal Meningococcal conjugate vaccine serogroups A, C, Y, W-135 tetravalent intramuscular	All adults with HIV who have not been previously vaccinated are eligible to receive two primary doses at least two months apart and be revaccinated every five years	Not required
Vaccine — TDaP Tetanus diphtheria toxoids acellular pertussis vaccine (TDaP) intramuscular	All pregnant members are eligible to receive two primary doses at least two months apart and revaccination every five years; members 21 years of age and older	Not required

Service	Coverage/Limitations	Prior Authorization
Vision Services Eye exam exclusively to screen visual acuity without need of reported vision problem, illness, disease or injury; contact lenses; frames	One exam per year; one frame per year; six months of contact lenses with prescription; members 21 years of age and older	Not required
Waived Copays The plan waives copays on the following services: birthing center; chiropractic; community behavioral health; FQHC; inpatient and outpatient hospital; independent labs; nonemergency transportation; ARNP; optometrist; physician assistant; physician; podiatrist; portable X-ray; RHC; registered nurse first assistant	Members 21 years of age and older	Not required

Florida Healthy Kids Expanded Benefits

- \$10 a month to buy certain personal care items and over-the-counter (OTC) medicines
- \$100 for hypoallergenic bedding (if medically needed)
- Six months of free fitness and healthy behavior coaching for members 7 to 13 years of age
- A free mouth guard for children who play contact sports
- Our 24-hour Nurse HelpLine to answer medical questions anytime at 1-866-864-2544 (TTY 711)

Taking Care of Baby and Me® Program

Taking Care of Baby and Me® is a proactive case management program for all expectant mothers and their newborns that uses extensive methods to identify pregnant women as early in their pregnancy as possible through review of state enrollment files, claims data, hospital census reports, Availity and notification of pregnancy forms as well as provider and self-referrals. Once pregnant members are identified, we act quickly to assess obstetrical risk and ensure the appropriate levels of care and case management services are provided.

Experienced case managers work with members and providers to establish a care plan for our highest risk pregnant members. Case managers collaborate with community agencies to ensure mothers have access to necessary services, including transportation, WIC, home-visitor programs, breastfeeding support and counseling. When it comes to our pregnant members, we are committed to keeping both mom and baby healthy. That's why we encourage all of our moms-to-be to take part in our Taking Care of Baby and Me program – a comprehensive case management and care coordination program offering:

- Individualized, one-on-one case management support for women at the highest risk.
- Care coordination for moms who may need a little extra support.
- Educational materials and information on community resources.
- Incentives to keep up with prenatal and postpartum checkups and well-child visits after the baby is born.

As part of the Taking Care of Baby and Me® program, members are also offered the **My Advocate®** program. This program provides pregnant women proactive, culturally appropriate outreach and education through interactive voice response (IVR). Eligible members receive regular phone calls with tailored content from a voice personality (Mary Beth), or they may choose to access the program via a smartphone application or website.

This program does not replace the high-touch case management approach for high-risk pregnant women; however, it does serve as a supplementary tool to extend our health education reach. The goal of the expanded outreach is to identify pregnant women who have become high-risk, to facilitate connections between them and our case managers, and improve member and baby outcomes. For more information on My Advocate, visit www.myadvocatehelps.com.

Simply encourages notification of pregnancy after the first prenatal visit and notification of delivery following birth. You may choose to complete the notification of pregnancy and delivery in the online Interactive Care Reviewer or fax the forms to Simply at **1-800-964-3627**.

We also encourage providers to complete the Maternity form in Availity.

- Perform an Eligibility and Benefits (E&B) request on the desired member.
- Choose one of the following benefit service types: maternity, obstetrical, gynecological, or obstetrical/gynecological.
- Before the benefit results screen, you will be asked if the member is pregnant. Choose "Yes", if applicable. If you indicate "Yes" you may provide the estimated due date, if it is known, or leave it blank if the due date is unknown.
- After submitting your answer, the E&B will display. If the member was identified as pregnant, a Maternity form will be generated. You may access the form by navigating to the "Applications" tab and selecting the "Maternity" link.

Taking Care of Baby and Me provides care management to:

- Improve the member's level of knowledge about her pregnancy.
- Create systems that support the delivery of quality care.
- Measure and maintain or improve member outcomes related to the care delivered.
- Facilitate care with providers to promote collaboration, coordination and continuity of care.

NICU Case Management

For parents with infants admitted to the neonatal intensive care unit (NICU), we offer the NICU Case Management program. The NICU Case Management program is committed to ensuring that all NICU members have a well-defined plan for quality care and a safe and successful transition from hospital to home. Experienced and dedicated NICU case managers provide parents/caregivers with individualized, one-on-one case management support specifically designed to help with the day-to-day stress of having a baby in the NICU.

Once a NICU member is identified, the NICU case manager proactively collaborates with the parent/caregiver, provider and/or hospital to ensure all outpatient needs are met. NICU case managers work closely with the parent/caregiver to establish an individualized plan of care for the member and to provide education and resources that outline successful strategies they may use when collaborating with their baby's NICU care team during and after their NICU stay. NICU case managers also provide parent/caregivers with appropriate community agency resources to ensure access to necessary outpatient services.

The stress of having an infant in the NICU may result in Post-Traumatic Stress Disorder (PTSD) symptoms for parents and loved ones. To reduce the impact of PTSD among our members, we assist by:

- Guiding parent(s) into hospital-based support programs, if available
- Screening parent(s) for PTSD approximately one month after their baby's date of birth
- Referring parent(s) to behavioral health program resources, if indicated
- Reconnecting with a one-month follow-up call to assess if the parent(s) received benefit from initial contact and PTSD awareness

If you are caring for a NICU member or are working with a parent/caregiver that would benefit from NICU Case Management services, please call Provider Services at **844-405-4296**. Parents/caregivers can also call our 24/7 NurseLine at **844-406-2396** (TTY **711**), available 24 hours a day, 7 days a week.

Quality Enhancement Program

Simply offers quality-enhanced programs for the benefit of members and providers. These include:

- 1. Children's programs We provide regular general wellness programs for ages birth to 5 years, or we make a good faith effort to involve members in existing community children's programs.
 - a. We rely on providers seeing children to provide prevention and early intervention services for at-risk members. We approve claims for services recommended by the early intervention programs when they are covered services and medically necessary.
 - b. We offer annual training to providers (through monthly provider agendas, the Simply website, etc.) that promote proper nutrition, breastfeeding, immunizations, wellness, prevention and early intervention services.
- 2. Domestic violence programs We require PCPs to screen members for signs of domestic violence and require PCPs to offer referral services to applicable domestic violence prevention community agencies.
- 3. Pregnancy prevention We conduct pregnancy prevention programs or make a good faith effort to involve members in existing community pregnancy prevention programs. These programs will be targeted toward teen enrollees but be open to all ages.
- 4. Prenatal/postpartum pregnancy programs We provide regular home visits by a home health nurse or aide and offer counseling and educational materials to pregnant and postpartum members who are not in compliance with the health plan's prenatal and postpartum programs. We will coordinate our efforts with the local Healthy Start care coordinator to prevent duplication of services. We require that all providers supply voluntary family planning, including a discussion of all methods of contraception, as appropriate. We require that all providers give all women of childbearing age HIV counseling and offer them HIV testing.
- 5. Smoking cessation We provide smoking cessation counseling to members. We provide participating PCPs with a quick reference card to help identify tobacco users and support delivery of effective smoking cessation interventions. Please see the "Smoking Cessation Program" section below.
- 6. Substance abuse programs We offer annual substance abuse screening training to our providers. In addition, several screening tools and other resources are available on our provider website to help providers identify substance abuse and make appropriate referrals.
 - a. At a minimum, all PCPs are required to screen members for signs of substance abuse as part of prevention evaluation at the following times:
 - i) During initial contact with a new member
 - ii) During routine physical examinations
 - iii) During initial prenatal contact
 - iv) When the member displays serious overutilization of medical, surgical, trauma or emergency services
 - v) When documentation of emergency room visits suggests the need
 - b. Providers identifying patients with substance abuse needs should refer patients to community substance abuse programs.

Encounter submission is critical to ensuring the quality of services by validating the work providers perform. To obtain credit for services rendered, all providers must submit encounters when including providers contracted under a capitated arrangement.

Well-Child Visits/Early and Periodic Screening, Diagnosis and Treatment (EPSDT) for Statewide Medicaid Managed Care Managed Medical Assistance and MediKids Members

Simply members are encouraged to contact their physician within the first 90 days of enrollment to schedule a well-child visit and within 24 hours for newborns. Simply members are eligible to receive these services from birth to age 20. For EPSDT members, if a service is medically necessary, it must be covered, regardless of whether the service is on the fee schedule or not. This applies to all EPSDT members under 21 years of age.

Note: EPSDT requirements are applicable to Medicaid and MediKids.

The program provides the following:

- Comprehensive health and development history
- Physical and mental development assessment
- Comprehensive unclothed physical examination
- Age-appropriate immunizations
- Appropriate laboratory tests
- Health education

Newborn well-child services should be performed for newborns in the hospital and then at the following ages:

- 3 to 5 days old
- 6 months

• 1 month

• 9 months

2 months

• 12 months

• 4 months

In the child's second year of life, he or she should see a PCP at 15 months, 18 months, 24 months and 30 months of age. During the span of a child's third year of life until age 20, the child should be seen by his or her PCP at least on an annual basis. Simply educates our members about these guidelines and monitors encounter data for compliance.

Simply recommends that participating providers who treat children under the age of 21 utilize the American Academy of Pediatrics Bright Futures well-child forms to ensure all aspects of an EPSDT visit are captured. The forms are at https://brightfutures.aap.org (Tools and Resources).

Simply requires providers to:

- Participate in the EPSDT program if they treat children under the age of 21.
- Provide all needed initial, periodic and interperiodic EPSDT health assessments, diagnosis and treatment to
 all eligible members in accordance with the Florida Agency for Health Care Administration's approved
 Medicaid administrative regulation Sect. III C.9.b and the periodicity schedule provided by the American
 Academy of Pediatrics (AAP).
- Refer members to an out-of-network provider for treatment if the service is not available within our network
- Provide vaccines and immunizations in accordance with the Advisory Committee on Immunization Practices (ACIP) guidelines.
- Provide vaccinations in conjunction with EPSDT/well-child visits; providers are required to use vaccines
 available without charge under the Vaccine for Children (VFC) program for Medicaid children 18 years of
 age and younger (excludes MediKids).
- Address unresolved problems, referrals and results from diagnostic tests, including results from previous EPSDT visits.

- Request a prior authorization for a medically necessary EPSDT special service in the event other health care, diagnostic, preventive or rehabilitative services or treatment, or other measures described in 42 U.S.C. 1396d(a) are not otherwise covered under the Florida Medicaid program.
- Monitor, track and follow up with members:
 - Who have not had a health assessment screening.
 - Who miss appointments, to assist them in obtaining an appointment.
- Ensure members receive the proper referrals to treat any conditions or problems identified during the health assessment, including tracking, monitoring and following up with members to ensure they receive the necessary medical services.
- Assist members with transition to other appropriate care for children who age-out of EPSDT services.

Simply recommends that participating providers who administer immunizations to children under the age of 18 utilize the Centers for Disease Control (CDC) Immunization Schedule for Persons Aged 0 through 18. This schedule is located at www.cdc.gov/vaccines/schedules/index.html.

Well-Child Visits Reminder Program

Based on Simply claims data, we send a list of members who may not have received wellness services according to schedule to the members' PCPs each quarter. Additionally, we mail information to these members encouraging them to contact their PCPs' offices to set up appointments for needed services. Please note:

- The specific service(s) needed for each member is listed in the report; reports are based only on services received during the time the member is enrolled with Simply.
- Services must be rendered on or after the due date in accordance with federal EPSDT and state Department of Health guidelines. In accordance with these guidelines, services received prior to the specified schedule date do not fulfill EPSDT requirements.
- This list is generated based on Simply claims data received prior to the date printed on the list; in some instances, the appropriate services may have been provided after the report run date.
- To ensure accuracy in tracking preventive services, please submit a completed claim form for those dates of service to the Simply Claims department at:

Simply Healthcare Plans, Inc.

Florida Claims

P.O. Box 61010

Virginia Beach, VA 23466-1010

Blood Lead Testing Requirements

During every well-child visit for children between the ages of 6 months and 6 years, the PCP should screen each child for lead poisoning. Simply requires all PCPs to test for high blood lead levels assuring compliance with CMS requirements. These requirements state that all Medicaid enrollees must have a blood lead test performed at 12 months and 24 months of age to determine lead exposure and toxicity. In addition, children over the age of 24 months, up to 72 months, should receive a blood lead test if there is no past record of a test.

We encourage providers to contact Medtox to receive supplies to test children's blood lead levels in their offices. With a simple finger prick and a drop of blood on the filter paper from Medtox, the member will not have to go to another provider/lab to have the services done. Once you return the sample by mail, Medtox will send you the results and bill Simply for the test.

For those children who have a blood level greater than or equal to 10, continued testing is required until the blood level is below 10.

Vaccines for Children for Medicaid Recipients

The VFC program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of an inability to pay. VFC was created by the Omnibus Budget Reconciliation Act of 1993 as an entitlement program to be a required part of each state's Medicaid plan. The program was officially implemented in October 1994.

Funding for the VFC program is approved by the Office of Management and Budget and allocated through CMS to the Centers for Disease Control and Prevention (CDC). CDC buys vaccines at a discount and distributes them to grantees (that is, state health departments and certain local and territorial public health agencies) that then distribute them at no charge to those private physicians' offices and public health clinics registered as VFC providers.

Simply requires our providers to participate in the VFC program and have sufficient vaccine supplies. For additional information on the VFC program, visit https://www.cdc.gov/vaccines/programs/vfc/index.html.

Family Planning Services

Members have direct access to both network and non-network providers for all family planning services, including exams, assessments and traditional contraceptive devices. Services are not covered for members under the age of 18 unless they are married, a parent, pregnant or will suffer health hazards if services are not provided. FHK coverage of family planning is limited to one annual visit and one visit for a supplier every 90 days. Oral and injectable contraceptives and condoms are always covered for MMA members 12 and older and FHK members 10 and older.

Healthy Rewards - Healthy Behaviors Rewards Program

We offer programs to members who want to stop smoking, lose weight or address any drug abuse problems, and we reward members who join and meet certain goals. We also offer Well Child Visit programs, and Asthma Management. Our Healthy Rewards Programs include:

- Smoking cessation program.
- Weight management program.
- Alcohol and substance abuse program.
- Maternal child program.
- Well Child Visits
- Asthma Management

Setting Healthy Goals

The Simply Healthy Rewards program exists to help our members. Together, we make a plan and set goals to beat tough health issues. For example, for alcohol and substance abuse and smoking cessation, we offer help and support through coaching and participation in community groups. For weight management and nutrition, we offer help and support from a nurse in making healthy exercise and food choices.

Resources and Tools

The Florida Quitline is a toll-free, telephone-based tobacco use cessation service. Any person living in Florida who wants to try to quit smoking can use the Quitline. The following services are available through the Quitline:

- Counseling sessions
- Self-help materials
- Counseling and materials in English and Spanish
- Translation service for other languages
- Pharmacotherapy assistance

TDD service for the deaf or hard of hearing

Online Resources

Website	Resource Information
https://smokefree.gov	A cravings journal, information on medicines to help members quit, <i>Pathways to Freedom for African Americans</i> and <i>Guia para Dejar de Fumar</i> (Spanish resource)
 www.ffsonline.org 	American Lung Association's Freedom from Smoking Program
 https://quitnet.com 	Additional resources, including support to quit, Information about
 http://quitsmokingsupport.com 	why to quit and how to get help
 https://www.cancer.gov/cancertop ics/factsheet/tobacco/cessation 	

Online Continuing Education for Physicians

Providers can receive continuing education training online through these resources:

- MAHP Oral Health and Tobacco Cessation Educational Program for Primary Care Providers
- Treating Tobacco Use and Dependence through the Wisconsin Medical School
- www.medscape.com
- Tobacco Cessation Podcasts for Physicians

Printed Resources for Members

We offer the following printed resources you can share with members:

- You Can Quit Smoking
- Tobacco Use Breaking the Habit
- Tobacco Use Reasons to Quit

Printed Resources for Providers

Quick Reference Guide: Treating Tobacco Use and Dependence

All member materials are available on the member website, and provider materials are on the provider website.

Audiology Services

Simply provides audiology services in line with those offered by Florida Medicaid plus additional expanded benefits for Medicaid members. :

Outpatient Laboratory and Radiology Services

All outpatient laboratory tests should be performed at a network facility outpatient lab or at one of the Simply preferred network labs (LabCorp) unless the test is a Clinical Laboratory Improvement Amendments (CLIA)-approved office test. Visit the CMS website at https://www.cms.hhs.gov for a complete list of approved accreditation organizations under CLIA. AIM Specialty Health® (AIM) provides diagnostic radiology management services and will provide precertifications for CAT scans, MRA, MRI, nuclear cardiology and PET scans. Contact AIM at 800-252-2021 or www.aimspecialtyhealth.com for more information.

Pharmacy Services

The Simply pharmacy benefit provides coverage for medically necessary medications from licensed prescribers for the purpose of saving lives in emergency situations or during short-term illness, sustaining life in chronic or long-term illness, or limiting the need for hospitalization. Members have access to national pharmacy chains and many independent retail pharmacies.

Covered Drugs

The Simply Pharmacy program uses a *Preferred Drug List (PDL)*. This is a list of the preferred drugs within the most commonly prescribed therapeutic categories. To prescribe medications that do not appear on the *PDL*, you may initiate an electronic prior authorization request through https://www.covermymeds.com. Prescribers may also call Pharmacy Services at 877-577-9044 or fax a completed *Pharmacy Prior Authorization Form* to 877-577-9045 for retail pharmacy requests and 844-509-9862 for medical injectable requests. Please refer to the *Pharmacy Prior Authorization Form*, MMA and Florida Healthy Kids *PDLs*, and prior authorization criteria links on our provider website.

Drugs Requiring Prior Authorization

Providers are strongly encouraged to write prescriptions for preferred products as listed on the appropriate *PDL* for that member (either MMA or FHK). If a member cannot use a preferred product because of a medical condition, providers are required to contact Simply Pharmacy Services to obtain prior authorization. To request prior authorization, call the Pharmacy department at **877-577-9044** or fax a completed *Pharmacy Prior Authorization Form* (available on the provider website) to **877-577-9045** for retail pharmacy requests and **844-509-9862** for medical injectable requests. You may also initiate electronic prior authorization requests through https://www.covermymeds.com. Providers must be prepared to provide relevant clinical information regarding the member's need for a nonpreferred product or a medication requiring prior authorization. Decisions are based on medical necessity and are determined according to certain established medical criteria.

Over-The-Counter Drugs

Simply provides coverage of several OTC drugs when accompanied by a prescription. The following are examples of covered OTC medication classes. Providers should consult the MMA and FHK *PDL*s for specifics on covered products and limits (members may be able to access OTC products under the Value Added OTC Benefit):

- Analgesics/antipyretics
- Antacids
- Antifungals, topical
- Antifungals, vaginal
- Antihistamines
- Antihistamine-decongestant combinations
- Emergency contraceptives

- Cough and cold preparations
- Iron replacement supplements
- Laxatives
- Pediculicides
- Respiratory agents (including spacer devices)
- Select vitamins and multi-vitamins

Excluded Drugs

The following drugs are examples of medications that are excluded from the pharmacy benefit:

- Weight control
- Anti-wrinkle agents (for example, Renova)
- Drugs used for cosmetic reasons (hair growth or hair removal)
- Drugs used for experimental or investigational indication
- Erectile dysfunction drugs to treat impotence
- Drugs that duplicate therapy

Informed Consent for Psychotherapeutic Medications for Children (Statewide Medicaid Managed Care Managed Medical Assistance Members)

Pursuant to *F.S.A.* 409.912(13), the Agency for Health Care Administration (AHCA) may not pay for a psychotropic medication prescribed for a child under the age of 13 years in the Medicaid program without the express and informed consent of the child's parent or legal guardian. The physician must document the consent in the child's medical record and provide the pharmacy with a signed attestation of this documentation with the prescription.

The psychotherapeutic drugs include (but are not limited to) antipsychotics, antidepressants, anti-anxiety medications and mood stabilizers. Certain anti-convulsants and ADHD medications (that is, stimulants and nonstimulants) are not included at this time (subject to change). A signed *Informed Consent Form* must be presented to the pharmacy with each new prescription for an affected drug for a member under 13 years of age. Consent forms are available at http://ahca.myflorida.com/medicaid/prescribed_drug/med_resource.shtml.

Carved Out Medications

Hemophilia drugs are an excluded service from the health plan's Medicaid benefit package. They are covered through the fee-for-service Statewide Medicaid Comprehensive Hemophilia Disease Management Program.

The Agency for Health Care Administration (Agency) entered into a contract with CVS Caremark (Vendor) to fulfill the responsibilities of the Statewide Medicaid Comprehensive Hemophilia Management Program. The Vendor's contract combines the provision of pharmaceutical products, pharmaceutical management, and disease management (e.g., treatment and prevention of bleeding episodes, medical consultation, home infusion education, training, twenty-four hours per day, seven days a week access to a registered nurse and a licensed pharmacist) for the Florida Medicaid recipients diagnosed with hemophilia or Von Willebrand disease.

Should you have any questions about the Hemophilia Disease Management Program, please feel free to contact:

- The Agency's Provider and Recipient Assistance Bureau Monday – Friday, 8:00 a.m. EST - 5:00 p.m. EST 1-877-254-1055 (TDD 1-866-467-4970) or online at: https://www.flmedicaidmanagedcare.com/home/contact
- CVS Caremark
 Monday Friday, 8:00 a.m. EST 5:00 p.m. EST
 1-888-826-5621 Option 4

There are no carved out medications for FHK members

Copies of the consent form must be maintained in the member's medical records.

Behavioral Health Services

Overview

Pursuant to the Simply contract with AHCA and the state MMA plan, Simply will provide coverage, via its subcontractor Beacon Health Strategies, for a full range of behavioral health care services (that is, treatment for psychiatric and emotional disorders), including community mental health services and mental health targeted case management services to all members in contracted counties. Simply will provide coverage of mental health and alcohol and drug treatment for Florida Healthy Kids members residing in the counties in which Simply participates as part of the member's behavioral health benefit.

Primary and Specialty Services

PCPs are encouraged to screen members for behavioral health and alcohol and drug abuse conditions as part of the initial assessment, or whenever there is a suspicion a member may have a behavioral health condition.

Age-appropriate validated behavioral health screening and assessment tools for children and adolescents:

- ADHD: NICHQ Vanderbilt Assessment Scale
- ADHD: ADHD Rating Scale-Home Version
- Anxiety: Generalized Anxiety Disorder-7 (GAD-7)
- Autism: Modified Checklist for Autism in Toddlers Revised (M-CHAT-R)

- Autism: First Signs Screening Tools
- Depression: Adolescent Patient Health Questionnaire-9 (PHQ9)
- Substance Use Disorder: The CRAFFT Screening Interview
- Substance Use Disorder: AUDIT-PC Screening Tool
- Substance Use Disorder: CAGE Questionnaire Alcohol Screening tool

Additional behavioral health and substance use disorder assessment tools can be found on our website: https://provider.simplyhealthcareplans.com/florida-provider/behavioral-health

A PCP can offer covered behavioral health and/or alcohol and drug abuse services when:

- Services are within the scope of the PCP's license.
- The member's current condition is not so severe, confounding or complex as to warrant a referral to a mental health and alcohol and drug abuse provider.
- The member is willing to be treated by the PCP.
- Services are within the scope of the benefit plan.

PCPs are encouraged to educate members with behavioral health and/or alcohol and drug abuse conditions about the nature of the condition and its treatment. As appropriate, PCPs are also encouraged to educate members about the relationship between physical and behavioral health and alcohol and drug abuse conditions. Referral for Mental Health and Alcohol and Drug Abuse Conditions

Members may self-refer, or providers may direct members to the Simply network of behavioral health care providers.

Experienced behavioral health care clinicians are available 24 hours a day, 7 days a week by calling the Provider Inquiry Line (1-844-405-4296) to assist with identifying the closest and most appropriate behavioral health service.

Behavioral Health Claims

Submit paper behavioral health claims to: Beacon Health Options Claims Department P.O. Box 1850 Hicksville, NY 11802-1850

Electronic behavioral health claims may be submitted through the Simply contracted clearinghouses. To initiate the electronic claims submission process or obtain additional information, please contact the Simply Electronic Data Interchange (EDI) Hotline at **1-800-590-5745**.

Behavioral Health Emergency Services

Behavioral health emergency services are those services that are required to meet the needs of an individual who is experiencing an acute crisis resulting from a mental illness, which is at a level of severity that would meet the requirements for involuntary examination pursuant to *Section 394.463*, *F.S.*, and who, in the absence of a suitable alternative or psychiatric medication, would require hospitalization. Examples of behavioral health and alcohol and drug abuse emergency medical conditions are when:

- The member is suicidal.
- The member is homicidal.
- The member is violent with objects.
- The member has suffered a precipitous decline in functional impairment and is unable to take care of his or her activities of daily living.

The member is alcohol- or drug-dependent and there are signs of severe withdrawal.

In the event of a behavioral health and/or alcohol and drug abuse emergency, the safety of the member and others is paramount. The member should be instructed to seek immediate attention at an emergency room or behavioral health and alcohol and drug abuse crisis service facility. An emergency dispatch service or 911 should be contacted if the member is a danger to his or her self or others and is unable to go to an emergency setting.

Behavioral Health Medically Necessary Services

Simply defines medically necessary behavioral health services as those that are:

- Reasonably expected to prevent the onset of an illness, condition or disability; reduce or ameliorate the
 physical, behavioral or developmental effects of an illness, condition, injury or disability; and assist the
 member to achieve or maintain maximum functional capacity in performing daily activities, taking into
 account both the functional capacity of the member and those functional capacities appropriate for
 members of the same age.
- Reasonably expected to provide an accessible and cost-effective course of treatment or site of service that
 is equally effective in comparison to other available, appropriate and substantial alternatives and is no
 more intrusive or restrictive than necessary.
- Sufficient in amount, duration and scope to reasonably achieve their purpose as defined in federal law.
- Of a quality that meet standards of medical practice and/or health care generally accepted at the time services are rendered.

Behavioral Health Coordination of Care

Simply, through its contracted providers and case management services, will be responsible for the coordination and active provision of continuity of care for all members. Appropriate and timely sharing of information is essential when the member is receiving psychotropic medications or has a new or ongoing medical condition. Additionally, if applicable, Simply will coordinate medical and behavioral health services.

The exchange of medical information facilitates behavioral and medical health care collaboration. For example, if the PCP obtains the member's consent via the *Authorization for Release of Information* form, the form is completed and sent to the behavioral health care provider. The behavioral health care provider may use the release as necessary for the administration and provision of care.

Simply behavioral health providers are mandated to utilize the Functional Assessment Rating Scale (FARS) and Children's Functional Assessment Rating Scale (CFARS), which are the outcome measures used by the state of Florida for Medicaid providers. CFARSs are administered for patients ages 6 to 17 and FARSs are administered for patients ages 18 and older. FARS/CFARS assessments are required to be completed at admission, every six months after admission (as long as the member remains a patient) and at discharge.

A FARS/CFARS should not be completed for members who: 1) only receive a one-time assessment service and are immediately discharged or 2) are served in medication-only settings. Additionally, FARS is not required when a member is admitted and discharged from a crisis stabilization unit. Changes to any other level of service will require administration of the FARS.

Free Training and Certification Websites

Note that only staff with certification should be providing assessment services. Free trainings are available online:

- CFARS: https://samhweb.myflfamilies.com/FARS/cfars/cfars_home.aspx
- FARS: https://samhweb.myflfamilies.com/FARS/fars/fars_home.aspx

The behavioral health care provider is required to note contacts and collaboration efforts in the member's chart as well as determine whether referral assistance is needed for the member for noncovered services.

When the member has seen a behavioral health care provider, that provider is required to send a copy of a completed *Coordination of Care and Treatment Summary Form* to both Simply and the member's PCP. This form is available on our provider website.

If a PCP refers a member to a contracted behavioral health care provider, the PCP will fax a copy of a completed *Coordination of Care and Treatment Summary Form* to the designated behavioral health care fax (**1-800-370-1116**) and to the behavioral health care provider.

The behavioral health care provider will send initial and quarterly (or more frequently if clinically indicated) summary reports of the member's behavioral health status to the member's PCP. The PCP will be contacted if there is a change in the behavioral health treatment plan. The PCP will contact the behavioral health care provider and document the information on the *Coordination of Care and Treatment Summary Form* if the member's medical condition could reasonably be expected to affect the member's mental health treatment planning or outcome.

Self-Referral Services

The following services do not need a referral from a PCP:

- Emergent care (regardless of network status with Simply)
- Family planning (regardless of network status with Simply)
- Behavioral health assessments (nonparticipating providers must seek prior approval from Simply)
- OB care (nonparticipating providers must seek prior approval from Simply)
- Well-woman/GYN care (nonparticipating providers must seek prior approval from Simply)
- EPSDT/well-child services (nonparticipating providers must seek prior approval from Simply)
- Tuberculosis, STD, HIV/AIDS testing and counseling services (regardless of network status with Simply)

Member Rights and Responsibilities

Florida law requires that providers or health care facilities recognize the rights of members while they are receiving medical care and that members respect the health care provider's or health care facility's right to expect certain behavior on the part of members. Members may request a copy of the full text of this law from their health care provider or health care facility. The following is a summary of the member's rights and responsibilities (see *Section 381.026, Florida Statutes*).

Patients' Rights

Patients have a right to:

- Be treated with respect and with due consideration for dignity and privacy.
- A prompt and reasonable response to questions and requests.
- Know who is providing medical services and who is responsible for their care.
- A right to receive information about the organization, its services, its practitioners and providers and member rights and responsibilities
- A right to make recommendations regarding the organization's member right and responsibilities policy
- Know what member support services are available, including whether an interpreter is available if they don't speak English.
- Know what rules and regulations apply to their conduct.
- Receive information on available treatment options and alternatives, presented in a manner appropriate to their conditions and ability to understand, regardless of cost or benefit coverage.

- Be given the opportunity to be involved in decisions involving their health care, except when such participation is contraindicated (not recommended) for medical reasons.
- Refuse treatment.
- Be given health care services in line with federal and state regulations.
- Be given, upon request, full information and necessary advice of available financial help for their care.
- Receive, upon request, before treatment, a reasonable estimate of charges for medical care.
- Receive a copy of a reasonably clear and easy-to-understand itemized bill and, upon request, have the charges explained.
- Impartial access to medical treatment or accommodations, no matter of race, national origin, religion, physical handicap or source of payment.
- Treatment for any emergency medical condition that will get worse from not getting the proper treatment.
- Know if medical treatment is for experimental research and give consent or refusal to be involved in that research.
- File grievances and appeals regarding any violation of their rights, as stated in Florida law, through the grievance procedure to the health plan, health care provider or health care facility that served them and to the appropriate state licensing agency.
- Be free from any form of restraint (control) or seclusion used as coercion (force), discipline, convenience or retaliation (revenge).
- Ask for and get a copy of their medical records and ask that those records be updated or corrected.
- A right to a candid discussion of appropriate or medically necessary treatment options for
- their conditions, regardless of cost or benefit coverage

Patients' Responsibilities

Patients have the responsibility to:

- Provide their health care provider, to the best of their knowledge, correct and complete information about present complaints, past illnesses, hospitalizations, medications (including over-the-counter products), dietary supplements, any allergies or sensitivities, and other matters relating to their health.
- Report unexpected changes in their conditions to their health care providers.
- Report to their health care providers whether they understand a planned action and what is expected of them
- Participate in developing the mutually agreed upon treatment plan recommended by their health care provider and follow the plan and instructions.
- Keep appointments and, when not able to for any reason, tell the health care provider or health care facility.
- Understand their actions if they refuse treatment or don't follow the health care provider's instructions.
- Inform their providers about any living wills, medical powers of attorney or other directives that could change their care.
- Make sure the needs of their health care are met as quickly as possible.
- Follow health care facility rules and regulations about member care and conduct.
- Behave in a way that is respectful of all health care providers and staff as well as of other members.

First Line of Defense Against Fraud

General Obligation to Prevent, Detect and Deter Fraud, Waste and Abuse

As a recipient of funds from federally and state-sponsored health care programs, we each have a duty to help prevent, detect and deter fraud, waste and abuse. Simply's commitment to detecting, mitigating and preventing fraud, waste and abuse is outlined in our Corporate Compliance Program. Electronic copies of this policy and the Simply Code of Business Conduct and Ethics are available at www.simplyhealthcareplans.com/provider and www.simplyhealthcareplans.com/provider and www.simplyhealthcareplans.com/provider and

As part of the requirements of the federal Deficit Reduction Act, each Simply provider is required to adopt Simply policies on detecting, preventing and mitigating fraud, waste and abuse in all the federally and state-funded health care programs in which Simply participates.

As a Simply provider and a participant in government-sponsored health care, you and your staff are obligated to report suspected fraud, waste and abuse. You can report anonymously if you suspected fraud by calling the Special Investigations Unit (SIU) hotline at **1-866-847-8247**. Any incident of fraud, waste or abuse may be reported to us anonymously; however, our ability to investigate an anonymously reported matter may be handicapped without enough information. Hence, we encourage you to give as much information as possible. We appreciate your time in referring suspected fraud, but be advised that we do not routinely update individuals who make referrals as it may potentially compromise an investigation.

When reporting concerns involving a PROVIDER (a doctor, dentist, counselor, medical supply company, etc.) include:

- Name, address and phone number of provider
- Name and address of the facility (hospital, nursing home, home health agency, etc.)
- Medicaid number of the provider and facility, if you have it
- Type of provider (doctor, dentist, therapist, pharmacist, etc.)
- Names and phone numbers of other witnesses who can help in the investigation
- Dates of events
- Summary of what happened

When reporting concerns involving a MEMBER include:

- The member's name
- The member's date of birth, Social Security Number or case number if you have it
- The city where the member resides
- Specific details describing the fraud, waste or abuse

Learn more at www.fighthealthcarefraud.com.

As an alternative, you can also report suspected fraud or abuse in Florida Medicaid directly to the Agency for Health Care Administration by calling their Consumer Complaint Hotline toll-free at **1-888-419-3456** or complete a *Medicaid Fraud and Abuse Complaint Form*, which is available online at

https://apps.ahca.myflorida.com/mpi-complaintform. If you report suspected fraud and your report results in a fine, penalty or forfeiture of property from a doctor or other health care provider, you may be eligible for a reward through the Inspector General's Fraud Rewards Program. You can call the Inspector General's office at 1-866-866-7226 (toll-free). The reward may be up to 25% of the amount recovered or a maximum of \$500,000 per case (Florida Statutes Chapter 409.9203). You can talk to the Attorney General's office about keeping your identity confidential and protected.

To meet the requirements under the Deficit Reduction Act, you must adopt the Simply fraud, waste and abuse policies and distribute them to any of your staff or contractors. If you have questions or would like to have more details concerning the Simply fraud, waste and abuse detection, prevention and mitigation program, please contact **1-844-405-4296**.

Importance of Detecting, Deterring and Preventing Fraud, Waste and Abuse

Health care fraud costs taxpayers increasingly more money every year. There are state and federal laws designed to crack down on these crimes and impose strict penalties. Fraud, waste and abuse in the health care

industry may be perpetuated by every party involved in the health care process. There are several stages to inhibiting fraudulent acts, including detection, prevention, investigation and reporting.

We are committed to protecting the integrity of our health care program and the effectiveness of our operations by preventing, detecting and investigating fraud, waste and abuse. Combating fraud, waste and abuse begins with knowledge and awareness.

- Fraud Any type of intentional deception or misrepresentation made with the knowledge that the deception could result in some unauthorized benefit to the person committing it -- or any other person. The attempt itself is fraud, regardless of whether or not it is successful
- Waste includes overusing services, or other practices that, directly or indirectly, result in unnecessary costs. Waste is generally not considered to be driven by intentional actions, but rather occurs when resources are misused.
- Abuse when health care providers or suppliers do not follow good medical practices resulting in unnecessary or excessive costs, incorrect payment, misuse of codes, or services that are not medically necessary.

In this section, we educate providers on how to help prevent member and provider fraud by identifying the different types so you can be the first line of defense.

Many types of fraud, waste and abuse have been identified, including the following:

Examples of Provider Fraud, Waste and Abuse (FWA):

- Altering medical records to misrepresent actual services provided
- Billing for services not provided
- Billing for medically unnecessary tests or procedures
- Billing professional services performed by untrained or unqualified personnel
- Misrepresentation of diagnosis or services
- Soliciting, offering or receiving kickbacks or bribes
- Unbundling when multiple procedure codes are billed individually for a group of procedures which should be covered by a single comprehensive procedure code
- Upcoding when a provider bills a health insurance payer using a procedure code for a more expensive service than was actually performed

Providers can help prevent fraud, waste and abuse by ensuring the services rendered are medically necessary, accurately documented in the medical records and billed according to American Medical Association guidelines.

Examples of Member Fraud, Waste and Abuse

- Forging, altering or selling prescriptions
- Letting someone else use the member's ID (Identification) card
- Obtaining controlled substances from multiple providers
- Relocating to out-of-service Plan area
- Using someone else's ID card
- Subrogation and/or third party liability fraud
- Transportation fraud

To help prevent fraud, waste and abuse, providers can educate members about the types of fraud and the penalties levied. Also, spending time with patients and reviewing their records for prescription administration will help minimize drug fraud and abuse.

One of the most important steps to help prevent member fraud is reviewing the Simply member ID card; it's the first line of defense against fraud. Simply may not accept responsibility for the costs incurred by providers rendering services to a patient who is not a member even if that patient presents a Simply member ID. Providers should take measures to ensure the cardholder is the person named on the card. Additionally, encourage members to protect their cards as they would a credit card or cash, carry their Simply member ID at all times, and report any lost or stolen cards to Simply as soon as possible.

We believe awareness and action are vital to keeping the state and federal programs safe and effective. Understanding the various opportunities for fraud, waste or abuse and working with members to protect their Simply ID cards can help prevent fraud, waste and abuse. We encourage our members and providers to report any suspected instance of fraud, waste or abuse by calling Member Services at 1-844-406-2396 (Medicaid); 1-844-405-4298 (FHK) or Provider Services at 1-844-405-4296. No individual who reports violations or suspected fraud, waste or abuse will be retaliated against, and Simply will make every effort to maintain anonymity and confidentiality.

HIPAA

The Health Insurance Portability and Accountability Act (HIPAA, also known as the Kennedy-Kassebaum bill) was signed into law in August 1996. The legislation improves the portability and continuity of health benefits, ensures greater accountability in the area of health care fraud, and simplifies the administration of health insurance.

Simply strives to ensure that both Simply and contracted providers conduct business in a manner that safeguards patient/member information in accordance with the privacy regulations enacted pursuant to HIPAA. Contracted providers must have the following procedures implemented to demonstrate compliance with the HIPAA privacy regulations.

- We recognize our responsibility under the HIPAA privacy regulations to only request the minimum necessary member information from providers to accomplish the intended purpose. Conversely, network providers should only request the minimum necessary member information required to accomplish the intended purpose when contacting Simply.
 - Please note, privacy regulations allow the transfer or sharing of member information, which may be requested by Simply to conduct business and make decisions about care (such as a member's medical record), to make an authorization determination, or resolve a payment appeal. Such requests are considered part of the HIPAA definition of treatment, payment or health care operations.
- Fax machines used to transmit and receive medically sensitive information should be maintained in an
 environment with restricted access to individuals who need member information to perform their jobs.
 When faxing information to Simply, verify the receiving fax number is correct, notify the appropriate staff
 at Simply and verify the fax was appropriately received.
- Email (unless encrypted) should not be used to transfer files containing member information to Simply (for example, Excel spreadsheets with claim information). Such information should be mailed or faxed.
- Use professional judgment when mailing medically sensitive information such as medical records. The
 information should be in a sealed envelope marked confidential and addressed to a specific individual, post
 office box or department at Simply.
- The Simply voicemail system is secure and password-protected. When leaving messages for Simply associates, only leave the minimum amount of member information required to accomplish the intended purpose.
- When contacting Simply, please be prepared to verify the provider's name, address and tax identification number, national provider identifier or Simply provider ID.

6 MEMBER MANAGEMENT SUPPORT

Welcome Call

As part of our member management strategy, Simply offers a welcome call to new members. During the welcome call, new members are educated regarding the health plan and available services. Additionally, Member Services representatives offer to assist the member with any current needs such as scheduling an initial checkup.

Appointment Scheduling

Through our participating providers, we ensure members have access to primary care services for routine, urgent and emergency services and to specialty care services for chronic and complex care. Providers will respond to a Simply member's needs and requests in a timely manner, per the guidelines outlined in the **Access and Availability** section.

24/7 NurseLine

The Simply 24/7 NurseLine is designed to support providers by offering information and education to members after hours about medical conditions, health care and prevention. Members can call **1-844-406-2396** — This number is also listed on the member's ID card. We provide triage services and help direct members to appropriate levels of care. This ensures members have an additional avenue of access to health care information when needed. Features of the 24/7 NurseLine include:

- Availability 24 hours a day, 7 days a week.
- Information based on nationally recognized and accepted guidelines.
- Free translation services for 150 different languages and for members that are deaf or hard of hearing.
- Education for members regarding appropriate alternatives for handling nonemergent medical conditions.
- Faxing of the member's assessment report to the provider's office within 24 hours of receipt of a call.

24/7 Pharmacy Member Services

The IngenioRx Pharmacy Member services hotline is available for members 24/7 to provide assistance related to the pharmacy benefit. Simply Medicaid members can call < 1-833-214-3607>, Clear Health Alliance Medicaid members can call <1-833-235-2028> and FHK members can call <1-833-267-3110> for assistance.

Interpreter Services

Interpreter services are available if needed (including language translation services and Braille). Simply provides interpreter services, free of charge, for enrollees whose primary language is not English. Interpretation services are provided by Voiance*, which offers over 100 different languages and corresponding interpreters. Additionally, language translation services are available for enrollees who are hearing-impaired. Effective physician-patient communication is critical in improving comprehension, utilization, clinical outcomes, patient satisfaction and quality of care. It is important that patients and their providers are aware of available interpreter services and know how to access them.

How providers can access these services:

- Identify members with limited English proficiency.
- Ask these members if they prefer to communicate in a language other than English.
 - o If yes, provide them with information regarding the available interpreter services. You or the member can call Member Services at **1-844-406-2396** and ask for assistance.

Health Promotion

Simply strives to improve healthy behaviors, reduce illness and improve the quality of life for our members through comprehensive programs. Educational materials are developed or purchased and then disseminated to our members, and health education classes are available through in-network community organizations and providers.

Ongoing projects that offer our members education and information regarding their health include:

- A newsletter to members at least once a year.
- Creation and distribution of a Simply health education tool newsletter used to inform members of health promotion issues and topics.
- Health Tips on Hold educational telephone messages that play while the member is on hold.
- A monthly member calendar of health education programs.
- Development of health education curricula and procurement of other health education tools (for example, breast self-exam cards).
- Relationship development with community-based organizations to enhance opportunities for members.
- Available community resources via the Simply website at www.simplyhealthcareplans.com.

Case Management

Case management is designed to proactively respond to a member's needs when conditions or diagnoses require care and treatment for long periods of time. When a member is identified (usually through initial health risk assessment process, a predictive model, precertification, admission review, and/or provider or member request), the Simply case manager helps to identify the appropriate case management program and any medically appropriate alternative methods or settings in which care may be delivered.

A provider, on behalf of the member, may refer them to case management. The clinician will work with the member, provider and/or the hospital to identify the necessary:

- Intensity level of case management services needed.
- Appropriate alternate settings where care may be delivered.
- Health care services required.
- Equipment and/or supplies required.
- Community-based services available.
- Communication required (that is, between the member and PCP as well as other providers).

During an admission, the Simply case manager will assist the member, utilization review team, and PCP and/or hospital in developing the discharge plan of care, ensuring that the member's medical needs are met, and linking the member with community resources and Simply programs for outpatient case and/or disease management.

Please note, a Simply case manager cannot perform services that are limited to providers, such as overriding a prior authorization requirement for prescription medications.

HIV/AIDS Specialty Care

Clear Health Alliance provides members with comprehensive case and disease management. Our program includes care coordination across the continuum of care as well as secondary and tertiary prevention interventions. These services are based on a comprehensive, multidisciplinary and system-wide approach that encompasses evidence-based guidelines, practitioner practice and member empowerment strategies to improve members' health outcomes.

CHA's case management and care coordination staff work with the member's provider, often an HIV specialist (see **Credentialing**), to ensure adherence with HIV antiretroviral therapy and medical care visits. This includes coordination of care for:

- Appointments with primary and specialist providers.
- Transportation.
- Other assistance as needed to facilitate care for members including surrogate decision makers if the
 enrollee is not capable of making his or her own decisions but does not have a legal representative or
 authorized representative available.

Case managers address the acuity level and service the unique needs of each member. They score the results of *Health Risk Assessments* and assign a member risk category. This category is based on specific disease stratification algorithms and may be assigned to include low, moderate or high score. Results guide the development of the individualized care plan, and the corresponding interventions designed to improve compliance and health outcomes and prevent acute events. Care plans are:

- Created in collaboration with the member/caregiver, legal guardian or other legally authorized individual.
- Based on member stratification.
- Designed to address interventions that:
 - o Improve member ability to adhere to the physician/provider treatment plan.
 - o Improve self-management.
 - Decrease health risks.

We share the care plan with the primary and/or specialist provider(s) for review and feedback. We document, note and/or adjust the care plan as applicable based on any feedback obtained. And when a member receives services from a community agency (i.e., Ryan White) with member approval, we share the established care plan as appropriate with the case managers in these agencies to ensure all issues are addressed and there is no duplication of services.

Clear Health Alliance allows HIV specialists, including infectious disease providers, to be PCPs, which is unique to our plan and increases access to care. These providers, marked with a red ribbon in our provider directory, receive additional training in longitudinal management of HIV/AIDS and frequent comorbidities and bring experience, expertise and cultural sensitivity to our members. These providers are acutely aware of the incidence and implications of physical and behavioral health comorbidities, and they've developed robust integrated processes to deliver whole-person care.

Clear Health Alliance works closely with our primary care partners to build capacity for integrated care and expand member access to routine screening and follow-up for behavioral health conditions. Nationwide, more than half of patients seek treatment for behavioral health conditions from their PCPs, with non-psychiatrists writing more than three-fourths of antidepressant prescriptions. The presence of several mental health and substance use diagnoses are known to be common among people living with HIV/AIDS. Clear Health Alliance requires PCPs to routinely screen members for a range of behavioral health and substance use conditions as part of routine, preventive care. We provide our PCPs with the tools and expertise needed to complete the screenings, and we reimburse PCPs for routine screenings. Screening requirements are included in our provider contracts and in this provider manual.

We make many valid and reliable screening tools for behavioral health conditions easily accessible on our provider website (www.clearhealthalliance.com/provider) and train PCPs on the appropriate use of them. Examples of these tools include:

- Depression screening: Patient Health Questionnaire-9 (PHQ-9)
- ADHD screening: Conners rating forms, Vanderbilt scale, Barkley scale

- Psychosocial problems screening: The Pediatric Symptom Checklist
- Mood Disorder Questionnaire
- Anxiety screening: Generalized Anxiety Disorder-7
- SUD screening: CAGE-AID
- Mini-Cognitive Assessment Instrument
- Comprehensive training on SBIRT
- The "5 A's" model for treating tobacco use and dependence

Disease Management / Population Health Services

Disease management services are based on a system of coordinated care management interventions and communications designed to assist physicians and others in managing members with chronic conditions. The programs include a holistic, focusing on the needs of the member through telephonic and community-based resources. Motivational interviewing techniques used in conjunction with member self-empowerment. The ability to manage more than one disease to meet the changing health care needs of our member population.

Our disease management programs include:

- Behavioral health
 - Bipolar Disorder
 - Major Depressive Disorder Adult
 - Major Depressive Disorder Child/Adolescent
 - Schizophrenia
 - o Substance Use Disorder
- Cardiac
 - Coronary Artery Disease
 - o Congestive Heart Failure
- Alzheimer's/Dementia

- Oncology (active and post-treatment)¹
- End of life (palliative program)¹
- Diabetes
- HIV/AIDS
- Hypertension
- Pulmonary
 - Asthma
 - Chronic Obstructive Pulmonary Disease

In addition to our condition-specific programs listed above, our member-centric, holistic approach also allows us to assist members with weight management and smoking cessation education.

Program Features

- Proactive population identification processes
- Program content is based on -evidence-based clinical practice guidelines
- Collaborative practice models to include physician and support in treatment planning
- Continuous self-management education
- Ongoing communication with primary and ancillary providers regarding patient status
- Nine of our Disease Management programs are National Committee for Quality Assurance accredited and incorporate outreach, education, care coordination and follow-up to improve treatment compliance and enhance self-care.

Simply DM programs are based on nationally approved clinical practice guidelines, located on our provider website. A copy of the guidelines can be printed from the website.

Who is Eligible?

Members diagnosed with one or more of the above listed conditions are eligible for DM services.

As valued provider, we welcome your referrals of patients who can benefit from additional education and disease management support. Our case managers will work collaboratively with you to obtain your input in the development of care plans. Members identified for participation in any of the programs are assessed and risk-stratified based on the severity of their disease. They are provided with continuous education on self-management concepts, which include primary prevention, coaching healthy behaviors and compliance/monitoring as well as case/care management for high-risk members. Program evaluation, outcome measurement and process improvement are built into all the programs, and we provide telephonic and/or written updates regarding patient status and progress.

DM Provider Rights and Responsibilities

The provider has the right to:

- Obtain information about Simply, staff qualifications and any contractual relations.
- Decline to participate in or work with the Simply programs and services for his or her patients, depending on contractual requirements.
- Be informed of how Simply coordinates our interventions with treatment plans for individual patients.
- Know how to contact the person case manager responsible for managing and communicating with the provider's patients.
- Be supported by the organization to make decisions interactively with patients regarding their health care.
- Receive courteous and respectful treatment from Simply staff.
- Communicate complaints regarding the DM program as outlined in the Simply provider complaint and grievance procedure.

Hours of Operation

Simply DM case managers are registered nurses and are available Monday to Friday, 8:30 a.m. to 5:30 p.m. ET. Confidential voicemail is available 24 hours a day.

Contact Information

Call **1-888-830-4300** to reach a case manager, or refer to our provider website for additional information about DM. Members can obtain information about our DM program by visiting http://www.simplyhealthcareplans.com/Medicaid and www.clearhealthalliance.com/member or calling **1-888-830-4300**.

Health Management: Healthy Families Program

Program offering families assistance with leading a healthy lifestyle and improving childhood obesity in our members. The Healthy Families program helps members by providing education, community resources, and individualized plans of care over a 6 month period. Program offered to members ages 7 to 17.

Enrollee Advisory Committee

The enrollee advisory committee, sometimes called the member advisory committee, provides advice to Simply regarding member health education and outreach program development. The committee strives to ensure materials and programs meet cultural competency requirements and are both understandable to the member and address the member's health education needs. The committee seeks members' input into the quality improvement projects, in order to improve quality, as needed.

The committee's responsibilities are to:

- Provide input into the annual review of policies and procedures, the QM program results and outcomes, and future program goals and interventions.
- Identify health education needs of the membership based on review of demographic and epidemiologic data.

- Assist the health plan in decision-making in the areas of member grievances, marketing, member services, case management, outreach, health needs, performance improvement projects and cultural competency.
- Identify cultural values and beliefs that must be considered in developing a culturally competent health education program.
- Assist in the review, development, implementation and evaluation of the member health education tools for the outreach program.
- Review the health education plan and make recommendations on health education strategies.

Women, Infants and Children Program

The Women, Infants and Children (WIC) program impacts the health of mothers and children in the medically needy population. Optimal nutritional status during pregnancy and early childhood provides the best chance for the future of Floridians. Medicaid recipients eligible for WIC benefits include the following classifications:

- Pregnant women
- Women who are breastfeeding infant(s) up to one year postpartum
- Women who are not breastfeeding up to six months postpartum
- Infants under the age of 1
- Children under the age of 5

Network providers are expected to coordinate with the WIC program. Coordination includes referral to the local WIC office for all infants and children up to age 5 and pregnant, breastfeeding and postpartum women.

WIC Referrals

Simply providers are required to refer all infants and children up to age 5 and pregnant, breastfeeding and postpartum women to the local WIC office. Providers are required to send WIC:

- A completed Florida WIC program medical referral form with the current height or length and weight (taken within 60 calendar days of the WIC appointment).
- Hemoglobin or hematocrit.
- Any identified medical and/or nutritional problems.

For each subsequent WIC certification, providers are required to coordinate with the local WIC office to provide the above referral data from the most recent EPSDT visit. Each time providers complete the WIC referral form, they are required to give a copy to the patient and keep a copy in the patient's medical record. Providers should keep a copy of these documents in the medical record to provide evidence the required process has taken place.

Members may apply for WIC services at their local WIC agency service. Please call Provider Services at **1-844-405-4296** for the agency nearest to the member. For more information, please visit http://doh.state.fl.us/family/wic.

Pregnancy-Related Requirements

Prenatal Risk Screening

Providers seeing Simply members for pregnancy-related diagnoses must:

- See the pregnant member within 30 days of enrollment.
- Complete Florida's Healthy Start prenatal risk screening instrument for each pregnant member as part of her first prenatal visit as required by Section 383.14, F.S., Section 381.004, F.S., and 64C-7.009, F.A.C.*
 - Use the Department of Health prenatal risk form (*DH Form 3134*), which can be obtained from the local County Health Department (CHD).
 - o Retain a copy of all documentation of Healthy Start screenings, assessments, findings and referrals in the enrollees' medical records.

- o Submit the completed *DH Form 3134* to the CHD in the county in which the prenatal screen was completed within ten business days of completion of the screening.
- Collaborate with the Healthy Start care coordinator within the member's county of residence to assure risk-appropriate care is delivered.
- * Pregnant members or infants who do not score high enough to be eligible for Healthy Start care coordination may be referred for services, regardless of their score on the Healthy Start risk screen, in the following ways:
- If the referral is to be made at the same time the Healthy Start risk screen is administered, the provider may indicate on the risk screening form that the member or infant is invited to participate based on factors other than score.
- If the determination is made subsequent to risk screening, the provider may refer the enrollee or infant directly to the Healthy Start care coordinator based on assessment of actual or potential factors associated with high risk, such as HIV, hepatitis B, substance abuse or domestic violence.

Infant Risk Screening

Providers must complete Florida's Healthy Start infant (postnatal) risk screening instrument (*DH Form 3135*) with the certificate of live birth and transmit the documents to the CHD in the county in which the infant was born within five business days of the birth. Providers must retain a copy of the completed *DH Form 3135* in the patient's medical record and provide a copy to the patient.

HIV Testing

Providers are required to give all women of childbearing age HIV counseling and offer them HIV testing (see *Chapter 381, F.S.*).

- Providers, in accordance with Florida law, must offer all pregnant women counseling and HIV testing at the initial prenatal care visit and again at 28 to 32 weeks of pregnancy.
- Providers must attempt to obtain a signed objection if a pregnant woman declines an HIV test (see Section 384.31, F.S. and 64D-3.019, F.A.C.)
- For those women who are infected with HIV, providers must offer and provide counseling about the latest antiretroviral regimen recommended by the U.S. Department of Health & Human Services (per the Public Health Service Task Force Report titled *Recommendations for the Use of Antiretroviral Drugs in Pregnant HIV-1 Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States*). To receive a copy of the guidelines, contact the Department of Health, Bureau of HIV/AIDS, at 1-850-245-4334 or visit https://aidsinfo.nih.gov/guidelines.

Hepatitis B Screenings

Providers are required to:

- Screen all pregnant members receiving prenatal care for the Hepatitis B surface antigen (HBsAg) during the first prenatal visit.
- Perform a second HBsAg test between 28 and 32 weeks of pregnancy for all pregnant members who tested
 negative at the first prenatal visit and are considered high-risk for Hepatitis B infection; this test shall be
 performed at the same time the other routine prenatal screenings are ordered.
- Report all HBsAg-positive women to the local CHD and refer to Healthy Start Program regardless of their Healthy Start screening score.

Hepatitis B and Hepatitis B Immune Globulin Vaccines

• Infants born to HBsAg-positive members must receive Hepatitis B immune globulin and the Hepatitis B vaccine once they are physiologically stable, preferably within 12 hours of birth, and complete the Hepatitis B Maxine vaccine series according to the recommended vaccine schedule established by the Recommended Childhood Immunization Schedule for the United States.

- Providers must test infants born to HBsAg-positive members for HBsAg and Hepatitis B surface antibodies (anti-HBs) six months after the completion of the vaccine series to monitor the success or failure of the therapy.
- Providers must report to the local CHD a positive HBsAg result in any child 24 months or younger within 24 hours of receipt of the positive test results.
- Providers must refer infants born to members who are HBsAg-positive to Healthy Start regardless of their Healthy Start screening scores.

Testing Positive for Hepatitis B

Providers are required to:

- Report to the perinatal Hepatitis B prevention coordinator at the local CHD all prenatal or postpartum patients who test HBsAg-positive.
- Report said patients' infants and contacts to the perinatal Hepatitis B prevention coordinator at the local CHD
- Report the following information: name, date of birth, race, ethnicity, address, infants, contacts, laboratory
 test performed, date the sample was collected, the due date or EDC, whether or not the enrollee received
 prenatal care, and immunization dates for infants and contacts.
- Use the perinatal Hepatitis B case and contact report (DH Form 1876) for reporting purposes.

Providers are required to provide the most appropriate and highest level of quality care for pregnant members, including but not limited to the following:

- Prenatal care
 - Complete a pregnancy test and a nursing assessment with referrals to a physician, physician assistant or advanced registered nurse practitioner for comprehensive evaluation.
 - o Complete case management through the gestational period according to the needs of the member.
 - Ensure any necessary referrals and follow-up.
 - Schedule return prenatal visits at least every four weeks until week 32, every two weeks until week
 36 and every week after until delivery unless the member's condition requires more frequent visits.
 - Contact those members who fail to keep their prenatal appointments as soon as possible and arrange for their continued prenatal care.
 - Assist members in making delivery arrangements if necessary.
 - Screen all pregnant members for tobacco use and make smoking cessation counseling and appropriate treatment available as needed.
- Nutritional assessment/counseling Providers are required to:
 - Supply nutritional assessment and counseling to all pregnant members.
 - o Ensure the provision of safe and adequate nutrition for infants by promoting breastfeeding and the use of breast-milk substitutes.
 - Offer a mid-level nutrition assessment.
 - o Provide individualized diet counseling and a nutrition care plan by a public health nutritionist, a nurse or a physician following the nutrition assessment.
 - Keep documentation of the nutrition care plan in the medical record by the person providing counseling.
- Obstetrical delivery Simply has developed and uses generally accepted and approved protocols for both low-risk and high-risk deliveries, which reflect the highest standards of the medical profession, including Healthy Start and prenatal screening, and requires all providers use these protocols:
 - Providers must document preterm delivery risk assessments in the enrollee's medical record by the 28th week.

- o If the provider determines the member's pregnancy is high-risk, the provider's obstetrical care during labor and delivery must include preparation by all attendants for symptomatic evaluation and as the member progresses through the final stages of labor and immediate postpartum care.
- Newborn care Providers are required to supply the highest level of care for the newborn beginning immediately after birth. Such level of care shall include but not be limited to the following:
 - o Instilling prophylactic eye medications into each eye of the newborn
 - When the mother is Rh-negative, securing a cord blood sample for type Rh determination and direct Coombs testing
 - Weighing and measuring the newborn
 - Examining the newborn for abnormalities and/or complications
 - Administering 0.5 mg of vitamin K
 - o Calculating an Apgar score
 - Assessing any other necessary and immediate need for referral in consultation with a specialty physician, such as the Healthy Start (postnatal) infant screen
 - Administering any necessary newborn and infant hearing screenings (must be conducted by a licensed audiologist pursuant to *Chapter 468, F.S.*; a physician licensed under *Chapters 458* or *459, F.S.*; or an individual who has completed documented training specifically for newborn hearing screenings and who is directly or indirectly supervised by a licensed physician or a licensed audiologist)
- Postpartum care The provider is required to:
 - \circ Administer a postpartum examination for the member between 7 84 (1 12 weeks) days post-delivery.
 - Supply voluntary family planning, including a discussion of all methods of contraception as appropriate.
 - Ensure eligible newborns are enrolled with Simply and that continuing care of the newborn is provided through the EPSDT program component.

Healthy Start Program

Healthy Start is a national program that provides comprehensive developmental services for pregnant women, infants and preschool children up to age 3. We collaborate with community Healthy Start programs to provide timely and age-appropriate health screening and referrals for routine health services.

- Simply provides each member with a community-based PCP.
- Simply encourages Healthy Start staff to refer members to see their PCP for screenings and health services.
- Simply supports timely and complete immunization of all children.
- Simply supports routine dental, vision and hearing exams for members.
- Simply encourages physical exams in accordance with the EPSDT periodicity schedule.
- Simply supports personal hygiene as part of the child's daily routine through age-appropriate educational programs.
- The Simply Member Services staff, nurse case managers and Health Promotion staff coordinate the delivery of services for children and work with their caretakers to eliminate barriers to timely health care.

Local Health Department

Simply works collaboratively with local health departments. Members have access to any county health department without authorization for the following services:

- Diagnosis and treatment of sexually transmitted diseases and other communicable diseases, such as tuberculosis and HIV.
- Immunizations.
- Family planning services and related pharmaceuticals.

- School health services listed above and services rendered on an urgent basis by such providers.
- Adult Screening Services
- Well-Child visits
- Medical Primary Care Services
- Registered Nurse Services

7 PROVIDER RESPONSIBILITIES

Medical Home

The PCP is the foundation of the medical home, responsible for providing, managing and coordinating all aspects of the member's medical care and providing all care that is within the scope of his or her practice. The PCP is responsible for coordinating member care with specialists and conferring and collaborating with the specialists, using a collaborative concept known as a medical home.

Simply promotes the medical home concept to all of its members. The PCP is the member and family's initial contact point when accessing health care. The PCP relationship with the member and family, together with the health care providers within the medical home and the extended network of consultants and specialists with whom the medical home works, have an ongoing and collaborative contractual relationship. The providers in the medical home are knowledgeable about the member and family's special and health-related social and educational needs and are connected to necessary resources in the community that will assist the family in meeting those needs. When a member is referred for a consultation or specialty/hospital services or for health and health-related services by the PCP through the medical home, the medical home provider maintains the primary relationship with the member and family. He or she keeps abreast of the current status of the member and family through a planned feedback mechanism with the PCP, who receives them into the medical home for continuing primary medical care and preventive health services.

Providers' Bill of Rights

Each health care provider who contracts with the Florida Agency for Health Care Administration (AHCA) and/or Florida Healthy Kids or subcontracts with Simply to furnish services to members will be assured of the following rights:

- To advise or advocate (within the lawful scope of practice) on behalf of a member who is his or her patient for the following:
 - The member's health status, medical care or treatment options, including any alternative treatment that may be self-administered
 - Any information the member needs to decide among all relevant treatment options
 - o The risks, benefits and consequences of treatment or nontreatment
 - The member's right to participate in decisions regarding his or her health care, including the right to refuse treatment and to express preferences about future treatment decisions
- To receive information on the grievance, appeal and fair hearing procedures
- To have access to the Simply policies and procedures covering the authorization of services
- To be notified of any decision by Simply to deny a service authorization request or to authorize a service in an amount, duration or scope that is less than requested
- To challenge, on behalf of Medicaid members, the denial of coverage of or payment for medical assistance
- To be free from provider selection policies and procedures that discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment
- To be free from discrimination for participation, reimbursement or indemnification when acting within the scope of his or her license or certification under applicable state law, solely on the basis of that license or certification

Responsibilities of the PCP

The PCP is a network physician who has responsibility for the complete care of his or her members, whether providing it himself or herself or by referral to the appropriate provider of care within the network. FQHCs health and RHCs may be included as PCPs. Some of the PCP's responsibilities are listed below:

All Florida Healthy Kids PCPs must be board-certified pediatricians or family practice physicians.

- All PCPs must provide coverage 24 hours a day, 7 days a week, and regular hours of operation must be clearly defined and communicated to members.
- All PCPs must provide services ethically and legally in a culturally competent manner and meet the unique needs of members with special health care requirements.
- The PCP is the coordinator of all care. Therefore, the PCP agrees to ensure continuity of care to Simply members and arrange for the provision of services when the PCP's office is not open. Documentation of emergency room visits, hospital discharge summaries or operative reports are to be obtained by the PCP and maintained in the medical record.
- The PCP agrees to practice in his or her profession ethically and legally, provide all services in a culturally
 competent manner, accommodate those with disabilities, and not discriminate against anyone based on his
 or her health status.
- The PCP must conduct a health assessment of all new enrollees within 90 days of the effective date of enrollment.
- When clinically indicated, the PCP agrees to contact Simply members regarding appropriate follow-up of identified problems and abnormal laboratory, radiological or other diagnostic findings.
- The PCP must establish office procedures to facilitate the follow-up of member referrals and consultations.
 The PCP is responsible for obtaining and maintaining in the medical record the results or findings of
 consultant referrals. If findings were communicated through telephonic consultation, a summary of the
 findings and name of the specialist must be documented.
- The PCP must participate in any system established by Simply to facilitate the sharing of medical records (subject to applicable confidentiality requirements in accordance with 42 CFR, Part 431, Subpart F, including a minor's consultation, examination and drugs for STDs in accordance with Section 384.30 (2), F.S.).
- The PCP agrees, when the need arises, to contact Simply regarding interpretive services via AT&T or other service for members who may require language assistance.
- If a new PCP is added to a group, Simply must approve and credential the provider before the provider may treat members. Notification of changes in the provider staff is the responsibility of the provider's office and must be communicated to Simply in writing.
- The PCP agrees to participate and cooperate with Simply in quality management, utilization review, continuing education and other similar programs established by Simply.
- The PCP agrees to participate in and cooperate with the Simply grievance and appeal procedures when Simply notifies the PCP of any member complaints or grievances.
- Balance billing for a covered service is not permitted. A Florida Healthy Kids member can only be billed for applicable copays if the copay was not collected at the time the service was rendered.
- If a PCP agreement with Simply is terminated, the PCP must continue care in progress during and after the termination period for up to six months until a provision is made by Simply for the reassignment of members. Pregnant members can continue receiving services through postpartum care. Payment for covered services under this continuity of care period will be made in accordance with the rates effective in the provider's participating agreement at the time of termination.
- The PCP may opt to go bare and not carry malpractice liability insurance but must follow the requirements under *F.S.* 458.320.
- The PCP must comply with all applicable federal and state laws regarding the confidentiality of member records
- The PCP must certify to Simply, upon credentialing and recredentialing, that their active patient load does not exceed 3,000 (including all commercial, Medicare, Florida Healthy Kids, other SMMC plan and children's medical services patients). Patients are defined as active when the PCP sees them at least two times a year.
- The PCP agrees to develop and have an exposure control plan in compliance with Occupational Safety and Health Administration (OSHA) standards regarding blood-borne pathogens.

- The PCP agrees to establish appropriate policies and procedures to fulfill obligations under the Americans with Disabilities Act (ADA).
- The PCP agrees to support and cooperate with the Simply Quality Management Program to provide quality care in a responsible and cost-effective manner.
- The PCP agrees to provide HIV counseling and offer HIV testing to all members of childbearing age.
- The PCP agrees to refer pregnant women or infants to Healthy Start and WIC programs within 30 days of enrollment.
- The PCP agrees to provide counseling and education in support of Medicaid quality and benefit
 enhancement (QBE) services, which include children's programs, domestic violence, pregnancy prevention
 (including abstinence), prenatal/postpartum care, smoking cessation and substance use programs. The PCP
 agrees to include information on the programs and community resources encouraged by Simply.
- The PCP agrees to provide counseling and offer the recommended antiretroviral regimen to all pregnant women who are HIV-positive and to refer them and their infants to Healthy Start programs regardless of their screening scores.
- The PCP agrees to offer screening for Hepatitis B surface antigen to all women receiving prenatal care. If they test positive, the PCP agrees to refer them to Healthy Start regardless of their screening score and to provide Hepatitis B Immune Globulin and the Hepatitis B vaccine series to children born to such mothers.
- The PCP agrees to inform Simply if he or she objects to the provision of any counseling, treatments or referral services on religious grounds.
- The PCP agrees to treat all members with respect and dignity, provide them with appropriate privacy, and treat members' disclosures and records confidentially, giving members the opportunity to approve or refuse their release in accordance with HIPAA and applicable state laws.
- The PCP agrees to provide members with complete information concerning their diagnosis, evaluation, treatment and prognosis and give members the opportunity to participate in decisions involving their health care, regardless of whether members have completed an advance directive, except when contraindicated for medical reasons.
- The PCP agrees to an adequate and timely communication among providers and the transfer of information when members are transferred to other health care providers. The PCP agrees to obtain a signed and dated release allowing for the release of information to Simply and other providers involved in the member's care
- The PCP agrees to physically screen members taken into the protective custody, emergency shelter or
 foster care programs by the Department of Children and Families (DCF) within 72 hours or immediately if
 required.
- The PCP must ensure food snacks or services provided to members meet their clinical needs and are prepared, stored, secured and disposed of in compliance with local health department requirements.
- The PCP agrees that provisions will be made to minimize sources and transmission of infection in the office.
- The PCP agrees to maintain communication with the appropriate agencies such as local police, social services agencies and poison control centers to provide quality member care.
- The PCP agrees that any notation in a member's clinical record indicating diagnostic or therapeutic intervention as part of clinical research will be clearly contrasted with entries regarding the provision of nonresearch-related care.
- The PCP agrees to use certified EHR technology in a meaningful manner, as described in the Florida Medicaid EHR Incentive Program.
- The PCP is enrolled in the Florida state Health Online Tracking System (SHOTS) statewide registry. Providers should bill Medicaid Fee-for-Service directly for immunizations provided to Title XXI MediKids participants.
- The PCP agrees to provide immunization information to the DCF upon receipt of members' written permission and DCF's request for members requesting temporary cash assistance from the DCF.

- The PCP agrees to attempt to obtain medical records on any member(s) receiving services from a nonnetwork provider with the proper release specific to any diagnosis signed by the member. These services include but are not limited to family planning, preventive services and sexually transmitted diseases.
- The PCP agrees to maintain vaccines safely and in accordance with specific guidelines, to provide member immunizations according to professional standards, and to maintain up-to-date member immunization records. PCP providers who render immunization to children are required to administer Vaccines in accordance with the Recommended Childhood and Adolescent Immunization Schedule for the United States.
 - Providers who render vaccines to Simply and Title XXI (MediKids and FHK) children are required to enroll with Florida's statewide online immunization registry, the Florida State Health Online Tracking System (SHOTS), and continue to keep the Simply member's immunization record updated in the SHOTS database.
 - Providers must also registered with the Vaccines for Children Program to obtain vaccines free of charge for Simply members, excluding MediKids members (Medicaid program codes: MK A, MK B, MK C)
 - The Vaccines for Children (VFC) Program does not provide vaccines for the Title XXI (MediKids and FHK) members. Providers must utilize their purchased vaccines stock for this population.
 - All claims for immunizations rendered to MediKids, FHK and Medicaid members must be submitted to Simply for payment.
 - For all Medicaid members, excluding MediKids population, Simply will render payment for the administration of the vaccines only; as vaccines are expected to be obtained free of charge from the VFC Program.

For the Title XXI (MediKids and FHK) members, Simply reimburses at a proprietary fee schedule based on the CDC and Private Sector Pricing for FHK and Medikids vaccine reimbursement. Simply will review for pricing changes and will update its vaccine fee schedule twice a year. Payment for updated pricing changes will be applied prospectively. Simply pays a separate \$10.00 fee for the administration of vaccines. In order to be appropriately reimbursed, providers should bill for vaccine administration in addition to the vaccine product on the same claim.

Immunization Schedules and Requirements:

http://www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/schedules-and-requirements/index.html

CDC Vaccine Price List:

https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html

- The PCP agrees to reach out to members to schedule an appointment for post-discharge or after they are notified the member went to the emergency room.
- The PCP agrees to assist with Clear Health Alliance eligibility verification through provision of HIV status verification when available.
- The PCP agrees to make provisions to communicate in the language or fashion primarily used by his or her assigned members.

Simply allows immunizations to be administered at locations other than a PCP's office so long the treating provider submits the information to SHOTS or notifies the Enrollee's PCP of the immunization administration. However, Simply PCPs are prohibited from refusing to proactively offer or administer immunizations at their offices.

Role of the PCP

- Each Medicaid and Florida Healthy Kids member will select or be assigned a PCP at the time of enrollment. Medicaid membership is limited to 1,500 members per full-time PCP and may be increased by 750 members for each advanced registered nurse practitioner (ARNP) or physician assistant (PA) affiliated with the physician. The maximum is a 3,000 active patient load for all populations (including but not limited to Medicaid FFS, children's medical services, other SMMC plans and Kidcare/Florida Healthy Kids).
- The PCP coordinates the member's health care needs through a comprehensive network of specialty, ancillary and hospital providers.
- For new members, the provider will contact each new member within 60 days of enrollment to perform an initial health risk assessment.
 - The provider must notify Simply if he or she is unable to contact the member within the 90-day enrollment period. Simply will send a release form to Medicaid members for the purpose of Simply and state agency review. Once a release has been signed, the PCP will request records from previous care providers. The PCP will use the previous medical records and the health risk assessments to identify members who have not received age-appropriate preventive health screenings (Child Health Check-Ups) for children from birth through 20 years of age according to the standards established by the American Academy of Pediatrics and endorsed by AHCA. Health screenings for adults will meet Simply standards, including those standards established by the Centers for Disease Control and Prevention and the U.S. Preventive Services Task Force. When external regulating agencies impose more stringent health screening standards, the PCP is required to comply with those standards.
- The PCP is responsible 24/7 for providing or arranging all covered services, including prescribing, directing
 and obtaining appropriate authorizations of all care for members who have been assigned to the PCP.
 After-hours coverage consists of an answering service, call forwarding, provider call coverage or other
 customary means approved by Simply. The chosen method must connect the caller to someone who can
 render a clinical decision or reach the PCP for a clinical decision.
- To the extent necessary, the PCP is responsible for coordinating coverage for members with an alternate Simply network physician. All financial arrangements must be made between the PCP and covering physician. The PCP is also responsible for notifying Simply in writing two weeks prior to his or her absence of the duration of the absence and the physician who will be providing the coverage. The covering physician must be a Simply network physician.
- All PCPs must be credentialed by Simply or one of the Simply delegated credentialing entities. All personnel
 assisting in the provision of health care services to members are to be appropriately trained, qualified and
 supervised in the care provided.
- PCPs must notify their Provider Relations representative when a new provider joins the practice.
- Anytime a new provider joins a practice and members are directed to the provider that individual must be credentialed with the plan and cannot see members until the credentialing process is completed.
 Nonemergent services must not be provided by a noncredentialed physician, and such services will not be covered by Simply. The PCP is responsible for the direct training and supervision of medical assistants.
 Duties of the medical assistant will be strictly limited to those identified in F.S. Section 458.3485.
- All PCP facilities must have handicap accessibility, adequate space, supplies, good sanitation and fire safety procedures in operation.
- The PCP will only collect copays from Florida Healthy Kids members when applicable and permitted under state and federal law. The PCP must not charge any member for missed appointments.
- PAs and ARNPs may not be assigned as the PCP for Simply members.

Physician Extenders

Physician extenders (for example, ARNPs, PAs) must be credentialed prior to seeing Simply members. They must clearly and appropriately identify themselves as an ARNP or PA to the member. Office staff must appropriately refer to and identify physician extenders as ARNPs or PAs.

Background Checks

All Simply providers must have a Level 2 criminal history background screening completed prior to joining the Simply network. This includes the provider's subcontractors or any employees or volunteers of their subcontractors who meet the definition of "direct service provider" to verify that these individuals do not have disqualifying offenses as provided for in *F.S. Section 430.0402* as created and *F.S. Section 435.04*. Any subcontractor, employee or volunteer of a subcontractor meeting the definition of a "direct service provider" who has a disqualifying offense is prohibited from providing services to the elderly as set forth in *F.S. Section 430.0402*.

Abuse, Neglect and Exploitation

All Simply providers are required to report elder abuse, neglect and exploitation of vulnerable adults to the statewide Elder Abuse Hotline at **1-800-96ABUSE** (**1-800-962-2873**).

- Simply direct-service providers are also required to complete abuse, neglect and exploitation training including training on how to identify victims of human trafficking.
- Per s.408.812, F.S., Simply providers are required to report suspected unlicensed assisted licensed facilities and adult family care homes to AHCA and Simply.

Abuse means any willful act or threatened act by a caregiver that causes or is likely to cause significant impairment to an enrollee's physical, mental or emotional health. Abuse includes acts and omissions.

Exploitation of a vulnerable adult means a person who:

- Stands in a position of trust and confidence with a vulnerable adult and knowingly, by deception or intimidation, obtains or uses or endeavors to obtain or use, a vulnerable adult's funds, assets or property for the benefit of someone other than the vulnerable adult.
- Knows (or should know) the vulnerable adult lacks the capacity to consent and obtains or uses, or
 endeavors to obtain or use, the vulnerable adult's funds, assets or property with the intent to temporarily
 or permanently deprive the vulnerable adult of the use, benefit or possession of the funds, assets or
 property for the benefit of someone other than the vulnerable adult.

Neglect of an adult means the failure or omission on the part of the caregiver to provide the care, supervision and services necessary to maintain the physical and behavioral health of the vulnerable adult, including but not limited to food, clothing, medicine, shelter, supervision and medical services that a prudent person would consider essential for the well-being of the vulnerable adult. The term neglect also means the failure of a caregiver to make a reasonable effort to protect a vulnerable adult from abuse, neglect or exploitation by others. Neglect is repeated conduct or a single incident of carelessness that produces or could reasonably be expected to result in serious physical or psychological injury or a substantial risk of death.

Identifying Victims of Human Trafficking

The following is a list of potential red flags and indicators of human trafficking. If you see any of these red flags, contact the National Human Trafficking Hotline at **1-888-373-7888** to report the situation or for specialized, victim services referrals.

The presence of these red flags is an indication that further assessment may be necessary to identify a potential human-trafficking situation. This list is not exhaustive and represents only a selection of possible indicators. Also, the red flags in this list may not be present in all trafficking cases and are not cumulative. Indicators reference conditions a potential victim might exhibit.

Common work and living conditions:

- Is not free to leave or come and go as they wish
- Is in the commercial sex industry and has a pimp/manager
- Is unpaid, paid very little or paid only through tips
- Works excessively long and/or unusual hours
- Is not allowed breaks or suffers under unusual restrictions at work
- Owes a large debt and is unable to pay it off
- Was recruited through false promises concerning the nature and conditions of their work
- High security measures exist in the work and/or living locations (i.e., opaque windows, boarded-up windows, bars on windows, barbed wire, security cameras, etc.)

Poor mental health or abnormal behavior:

- Is fearful, anxious, depressed, submissive, tense, nervous or paranoid
- Exhibits unusually fearful or anxious behavior after bringing up law enforcement
- Avoids eye contact

Poor physical health:

- Lacks medical care and/or is denied medical services by employer
- Appears malnourished or shows signs of repeated exposure to harmful chemicals
- Shows signs of physical and/or sexual abuse, physical restraint, confinement or torture

Lack of control:

- Has few or no personal possessions
- Is not in control of their own money, has no financial records or bank account
- Is not in control of their own identification documents (ID or passport)
- Is not allowed or able to speak for themselves (a third party may insist on being present and/or translating)

Other:

- Claims of just visiting and inability to clarify where they're staying/address
- Lack of knowledge of whereabouts and/or of what city they're in
- Loss of sense of time
- Has numerous inconsistencies in their story

Note: According to federal law, any minor under the age of 18 engaging in commercial sex is a victim of sex trafficking, regardless of the presence of force, fraud or coercion.

Access and Availability

All providers are expected to meet the federal and state accessibility standards and those defined in the Americans with Disabilities Act of 1990. Health care services provided through Simply must be accessible to all members.

Simply is dedicated to arranging access to care for our members. The ability of Simply to provide quality access depends on the accessibility of network providers. Providers are required to adhere to the following access standards:

Service	Access Requirement
Emergent or emergency visits	Immediately upon presentation
Urgent care for BH	Florida Healthy Kids
	Within 24 hours
Urgent, non-emergency visits,	MMA/Specialty
medical health and Behavioral	Within 48 hours of request for services that do not require prior
Health (FHK)	authorization
	Within 96 hours of request for services that require prior authorization
	Florida Healthy Kids
	Within 24 hours
Non-urgent medical	MMA/Specialty
	Within 30 days of request for a primary care appointment
	Within 60 days of request for a pediatric specialist appointment after
	the appropriate referral is received by the specialist
	Florida Healthy Kids
	7 days for routine care
	4 weeks for routine physical exams
Nonurgent, behavioral health	MMA/Specialty
, , , , , , , , , , , , , , , , , , , ,	7 days post discharge from an inpatient behavioral health admission
	for follow-up behavioral health treatment
	14 days for initial outpatient behavioral health treatment
	Florida Healthy Kids
	7 days for routine care
	4 weeks for routine physical exams

Providers must also ensure member access to a follow-up appointment within seven days of discharge.

Providers may not use discriminatory practices, such as preference to other insured or private-pay patients, separate waiting rooms, or appointment days.

Simply will routinely (no less than quarterly) monitor adherence to the access care standards, including monitoring PCPs, specialists and behavioral health providers. We will report results for Medicaid PCPs to AHCA.

To ensure continuous 24-hour coverage, PCPs must maintain one of the following arrangements for their members to contact the PCP after normal business hours:

- Have the office telephone answered after hours by an answering service that can contact the PCP or another designated network medical practitioner; all calls answered by an answering service must be returned within 30 minutes.
- Have the office telephone answered after normal business hours by a recording in the language of each of
 the major population groups served by the PCP, directing the member to call another number to reach the
 PCP or another provider designated by the PCP; someone must be available to answer the designated
 provider's telephone; another recording is not acceptable.

• Have the office telephone transferred after office hours to another location where someone will answer the telephone and be able to contact the PCP or a designated Simply network medical practitioner who can return the call within 30 minutes.

The following telephone answering procedures are **not** acceptable:

- Only answering the office telephone during office hours
- Only answering the office telephone after hours by a recording that tells members to leave a message
- Answering the office telephone after hours by a recording that directs members to go to an emergency room for any services needed
- Answering the office telephone with an answering machine that does not explain what to do in an emergency (for example, dial 911, etc.)
- Returning after-hours calls outside of 30 minutes

Member Missed Appointments

Simply members may sometimes cancel or not appear for necessary appointments and fail to reschedule the appointment. This can be detrimental to their health. Simply requires providers to attempt to contact members who have not shown up for or canceled an appointment without rescheduling the appointment. The contact must be by telephone and should be designed to educate the member about the importance of keeping appointments and to encourage the member to reschedule the appointment.

Simply members who frequently cancel or fail to show up for an appointment without rescheduling the appointment may need additional education in appropriate methods of accessing care. Simply staff will contact the member and provide more extensive education and/or case management as appropriate. Our goal is for members to recognize the importance of maintaining preventive health visits and to adhere to a plan of care recommended by their PCP. Please note that the provider agrees not to charge a member for missed appointments.

Noncompliant Simply Members

Simply recognizes that providers may need help in managing noncompliant members. If you have an issue with a member regarding behavior, treatment cooperation and/or completion of treatment, and/or making or appearing for appointments, please call Provider Services at **844-405-4296**. Members should be referred to Simply for case management services.

PCP Transfers

To maintain continuity of care, Simply encourages members to remain with their PCP. However, members may request to change their PCP for any reason by contacting Member Services at **844-406-2396**. The member's name will be provided to the PCP on the membership roster.

Members can call to request a PCP change any day of the month. PCP change requests will be processed generally on the same day or by the next business day. Members will receive a new ID card within 10 days.

Covering Physicians

During a provider's absence or unavailability, the provider needs to arrange for coverage for his or her members. The provider will either: 1) make arrangements with one or more network providers to provide care for his or her members or 2) make arrangements with another similarly licensed and qualified provider who has appropriate medical staff privileges at the same network hospital or medical group, as applicable, to provide care to the members in question. Covering providers must have an active limited or fully enrolled Medicaid ID number.

In addition, the covering provider will agree to the terms and conditions of the network provider agreement, including without limitation, any applicable limitations on compensation, billing and participation. Providers will be solely responsible for a non-network provider's adherence to such provisions. Providers will be solely responsible for any fees or monies due and owed to any non-network provider providing substitute coverage to a member on the provider's behalf.

Specialist as a PCP

Under certain circumstances, when a member requires the regular care of the specialist, a specialist may be approved by Simply to serve as a member's PCP. The criteria for a specialist to serve as a member's PCP include the member having a chronic, life-threatening illness or condition of such complexity whereby:

- The need for multiple hospitalizations exists.
- The majority of care needs to be given by a specialist.
- The administrative requirements arranging for care exceed the capacity of the nonspecialist PCP. This
 would include members with complex neurological disabilities, chronic pulmonary disorders, HIV/AIDS,
 complex hematology/oncology conditions, cystic fibrosis, etc.

The specialist must meet the requirements for PCP participation, including contractual obligations and credentialing; provide access to care 24 hours a day, 7 days a week; and coordinate the member's health care, including preventive care. When such a need is identified, the member or specialist must contact the Simply Member Services department and complete a *Specialist as PCP Request Form*. A Simply case manager will review the request and submit it to the Simply medical director. Simply will notify the member and the provider of its determination in writing within 30 days of receiving the request. Should Simply deny the request, Simply will provide written notification to the member and provider outlining the reason(s) for the denial of the request within one day of the decision. Specialists serving as PCPs will continue to be paid fee-for-service while serving as the member's PCP. The designation cannot be retroactive.

Note: Clear Health Alliance allows Infectious Disease providers to serve as a PCPs for Clear Health Alliance members.

Specialty Referrals

To reduce the administrative burden on the provider's office staff, Simply has established procedures that are designed to permit a member with a condition that requires ongoing care from a specialist physician or other health care provider to request an extended authorization.

The provider can request an extended authorization by contacting the member's PCP. The provider must supply the necessary clinical information that will be reviewed by the PCP to complete the authorization review.

On a case-by-case basis, an extended authorization will be approved. In the event of termination of a contract with the treating provider, the continuity-of-care provisions in the provider's contract with Simply will apply. The provider may renew the authorization by submitting a new request to the PCP. Additionally, Simply requires the specialist physician or other health care provider to provide regular updates to the member's PCP (unless acting also as the designated PCP for the member). Should the need arise for a secondary referral, the specialist physician or other health care provider must contact Simply for a coverage determination.

If the specialist or other health care provider needed to provide ongoing care for a specific condition is not available in the Simply network, the referring physician will request authorization from Simply for services outside the network. Access will be approved to a qualified non-network health care provider within a reasonable distance and travel time at no additional cost if medical necessity is met.

If a provider's application for an extended authorization is denied, the member (or the provider on behalf of the member) may appeal the decision through the Simply medical appeal process.

Providers may contact case management to facilitate referrals to services outside our network or services provided through interagency agreements. The case manager will assist as needed to meet the member's additional supportive care needs such as food, bank, legal or housing assistance; support groups/psychosocial counseling; clinical trials; and outpatient substance abuse-related programs geared towards the issues and concerns of our members.

Second Opinions

A member, parent, and/or legally appointed representative or the member's PCP may request a second opinion in any situation where there is a question concerning a diagnosis or the options for surgery or other treatment of a health condition. The second opinion will be provided at no cost to the member.

The second opinion must be obtained from a network provider (see the provider referral directory) or with precertification from a non-network provider if there is not a network provider with the expertise required for the condition. Once approved, the PCP will notify the member of the date and time of the appointment and forward copies of all relevant records to the consulting provider. The PCP will notify the member of the outcome of the second opinion.

Simply may also request a second opinion at our own discretion. This may occur under the following circumstances:

- Whenever there is a concern about care expressed by the member or the provider
- Whenever potential risks or outcomes of recommended or requested care are discovered by the plan during its regular course of business
- Before initiating a denial of coverage of service
- When denied coverage is appealed
- When an experimental or investigational service is requested

When we request a second opinion, we'll make the necessary arrangements for the appointment, payment and reporting. Simply will inform the member and the PCP of the results of the second opinion and the consulting provider's conclusion and recommendation(s) regarding further action.

Specialty Care Providers

To participate in our programs, providers must be enrolled in Florida Medicaid and have an active limited or fully enrolled Medicaid ID number. Providers must also be a licensed provider by the state before signing a contract with Simply.

Simply contracts with a network of provider specialty types to meet the medical specialty needs of members and provide all medically necessary covered services. The specialty care provider is a network physician who has the responsibility for providing specialized care for members, usually upon appropriate referral from a PCP within the network (see Role and Responsibility of the Specialty Care Provider). In addition to sharing many of the same responsibilities as the PCP (see Responsibilities of the PCP), the specialty care provider provides services that includes but is not limited to the following:

- Allergy and immunology services
- Burn services
- Community behavioral health (for example, mental health and substance abuse) services
- Cardiology services

- Clinical nurse specialists, psychologists and clinical social workers (that is, behavioral health)
- Critical care medical services
- Dermatology services
- Endocrinology services
- Gastroenterology services
- General surgery
- Hematology/oncology services
- Neonatal services
- Nephrology services
- Neurology services
- Neurosurgery services
- Ophthalmology services
- Orthopedic surgery services
- Otolaryngology services
- Perinatal services
- Pediatric services
- Psychiatry (adult) assessment services
- Psychiatry (child and adolescent) assessment services
- Trauma services
- Urology services

Role and Responsibility of the Specialty Care Provider

Members may self-refer to a participating specialist provider, including mental health and substance abuse providers. Obligations of the specialist include but are not limited to the following:

- Complying with all applicable statutory and regulatory requirements of the Medicaid program
- Accepting all Simply members who self-refer or are directed to the specialist provider for care
- Submitting required claims information
- Arranging for coverage with network providers while off-duty or on vacation
- Verifying member eligibility and precertification of services (if required) at each visit
- Providing consultation summaries or appropriate periodic progress notes to the member's PCP on a timely basis, following a referral or routinely scheduled consultative visit
- Notifying the member's PCP when scheduling a hospital admission or scheduling any procedure
- Coordinating care, as appropriate, with other providers involved in providing care for members, especially
 in cases where there are medical and behavioral health comorbidities or co-occurring mental health and
 substance abuse disorders
- Making provisions to communicate in the language or fashion primarily used by his or her members

The specialist will:

- Manage the medical and health care needs of members, including monitoring and following up on care
 provided by other providers, including those engaged on a Fee-For-Service (FFS) basis; provide coordination
 necessary for referrals to other specialists and FFS providers (both in- and out-of-network); and maintain a
 medical record of all services rendered by the specialist and other providers.
- Provide 24/7 coverage and maintain regular hours of operation that are clearly defined and communicated to members.

- Provide services ethically and legally in a culturally competent manner and meet the unique needs of members with special health care requirements.
- Participate in the systems established by Simply that facilitate the sharing of records, subject to applicable confidentiality and HIPAA requirements.
- Participate and cooperate with Simply in any reasonable internal or external quality assurance, utilization review, continuing education, or other similar programs established by Simply.
- Make reasonable efforts to communicate, coordinate and collaborate with other specialty care providers, including behavioral health providers, involved in delivering care and services to members.
- Participate in and cooperate with the Simply complaint and grievance processes and procedures; Simply will notify the specialist of any member grievance brought against the specialist.
- Not balance bill members.
- Continue care in progress during and after termination of his or her contract for up to 60 days until a continuity of care plan is in place to transition the member to another provider or through postpartum care for pregnant members in accordance with applicable state laws and regulations.
- Comply with all applicable federal and state laws regarding the confidentiality of patient records.
- Develop and have an exposure control plan regarding blood-borne pathogens in compliance with OSHA standards.
- Make best efforts to fulfill the obligations under the ADA applicable to his or her practice location.
- Support, cooperate and comply with the Simply Quality Management Program initiatives and any related policies and procedures designed to provide quality care in a cost-effective and reasonable manner.
- Inform Simply if a member objects for religious reasons to the provision of any counseling, treatment or referral services.
- Treat all members with respect and dignity; provide members with appropriate privacy and treat member disclosures and records confidentially, giving the members the opportunity to approve or refuse their release as allowed under applicable laws and regulations.
- Provide members complete information concerning their diagnosis, evaluation, treatment and prognosis and give members the opportunity to participate in decisions involving their health care, except when contraindicated for medical reasons.
- Advise members about their health status, medical care or treatment options, regardless of whether benefits for such care are provided under the program, and advise members on treatments that may be self-administered.
- When clinically indicated, contact members as quickly as possible for follow-up regarding significant problems and/or abnormal laboratory or radiological findings.
- Have a policy or procedure to ensure proper identification, handling, transport, treatment and disposal of hazardous and contaminated materials and wastes to minimize sources and transmission of infection.
- Agree to maintain communication with the appropriate agencies such as local police, social services agencies and poison control centers to provide quality patient care.
- Agree that any notation in a patient's clinical record indicating diagnostic or therapeutic intervention that is part of a clinical research study is clearly distinguished from entries pertaining to nonresearch-related care.

Specialty Care Providers Access and Availability

Simply will maintain a specialty network to ensure access and availability to specialists for all members. A provider is considered a specialist if he or she has a provider agreement with Simply to provide specialty services to members. For more information on our access and availability guidelines, refer to the **Access and Availability** section.

Open-Access Specialist Providers

Members may self-refer to the network providers listed below without a PCP referral. Providers should establish processes for the identification of the member's PCP and forward information concerning the member's evaluation and treatment to the PCP after obtaining consent from the member as appropriate under legal requirements.

- Chiropractors
- Podiatrists
- Dermatologists
- OB/GYN

Culturally and Linguistically Appropriate Services

Patient panels are increasingly diverse and needs are becoming more complex. It is important for providers to have the knowledge, resources, and tools to offer culturally competent and linguistically appropriate care. Simply wants to help, as we all work together to achieve health equity.

The U.S. Department of Health and Human Services (HHS) defines cultural competence as the ability to honor and respect the beliefs, languages, interpersonal styles, and behaviors of individuals and families receiving services, as well as staff members who are providing such services. It is a dynamic, ongoing developmental process requiring long-term commitment. The Agency for Healthcare Research and Quality (AHRQ) Patient Safety Network explains that healthcare is defined through a cultural lens for both patients and providers. A person's cultural affiliations can influence:

- Where and how care is accessed, how symptoms are described,
- Expectations of care and treatment options,
- Adherence to care recommendations.

Providers also bring their own cultural orientations, including the culture of medicine.

Offering culturally and linguistically appropriate care incorporates a variety of skills and knowledge, including, but not limited to, the ability to:

- Recognize the cultural factors (norms, values, communication patterns and world views) that shape personal and professional behavior.
- Develop understanding of others' needs, values and preferred means of having those needs met
- Formulate culturally competent treatment plans.
- Understand how and when to use language support services, including formally trained interpreters and auxiliary aids and services, to support effective communication.
- Avoid use of family members, especially minors, to act as interpreters for limited English proficient patients.
- Understand and adhere to regulations to support the needs of diverse patients, such as the Americans with Disabilities Act (ADA).
- Use culturally appropriate community resources as needed to support patient needs and care.

Simply ensures providers have access to resources to help support delivery of culturally and linguistically appropriate services. Simply encourages providers to access and utilize the following resources.

MyDiversePatients.com: The My Diverse Patient website offers resources, information, and techniques, to help provide the individualized care every patient deserves regardless of their diverse backgrounds. The site also

includes learning experiences on topics related to cultural competency and disparities that offer free Continuing Medical Education (CME) credit. Current CME offerings include:

- Caring for Children with ADHD: Promotes understanding of and adherence to diagnosis and treatment guidelines; use of AAP's Resource Toolkit for Clinicians; awareness of and strategies for addressing disparities.
- Creating an LGBT-Friendly Practice: Helps providers understand the fears and anxieties LGBT patients often feel about seeking medical care, learn key health concerns of LGBT patients, & develop strategies for providing effective health care to LGBT patients.
- **Improving the Patient Experience:** Helps providers identify opportunities and strategies to improve patient experience during a health care encounter.
- Medication Adherence: Helps providers identify contributing factors to medication adherence disparities for diverse populations & learn techniques to improve patient-centered communication to support needs of diverse patients.
- **Moving Toward Equity in Asthma Care:** Helps providers understand issues often faced by diverse patients with asthma & develop strategies for communicating to enhance patient understanding.
- Reducing Health Care Stereotype Threat (HCST): Helps providers understand HCST and the implications for diverse patients as well as the benefits of reducing HCST to both providers' patients and practices, and how to do so.
- Cultural Competency Training (Cultural Competency and Patient Engagement): A training resource to
 increase cultural and disability competency to help effectively support the health and health care needs
 of your diverse patients.
- Caring for Diverse Populations Toolkit: A comprehensive resource to help providers and office staff increase effective communication by enhancing knowledge of the values, beliefs, and needs of diverse patients.

Simply appreciates the shared commitment to ensuring Members receive culturally and linguistically appropriate services to support effective care and improved health outcomes.

Marketing

When it comes to marketing, you need to be aware of and comply with the following:

- Providers are permitted to make available and/or distribute Simply-approved marketing materials as long
 as the provider and/or the facility distributes or makes available marketing materials for all managed care
 plans with which the provider participates.
- Providers are permitted to display posters or other materials in common areas such as the provider's waiting room. Marketing may not be conducted in areas where patients primarily intend to receive health care services or are waiting to receive health care services.
- Long-term care facilities are permitted to provide materials in admission packets announcing all managed care plan contractual relationships.

We will provide education, outreach and monitoring to ensure you are aware of and comply with the following:

- To the extent a provider can assist a recipient in an objective assessment of his or her needs and potential options to meet those needs, the provider may do so. Providers may engage in discussions with recipients should a recipient seek advice. However, providers must remain neutral when assisting with enrollment decisions.
- Providers may not:
 - Offer marketing/appointment forms.

- Make phone calls or direct, urge or attempt to persuade recipients to enroll in a managed care plan based on financial or any other interests of the provider.
- o Mail marketing materials on behalf of a managed care plan.
- o Offer anything of value to induce recipients/enrollees to select them as their provider.
- o Offer inducements to persuade recipients to enroll in the managed care plan.
- Conduct health screening as a marketing activity.
- o Accept compensation directly or indirectly from the managed care plan for marketing activities.
- o Distribute marketing materials within an exam room setting.
- Furnish the managed care plan with lists of their Medicaid patients or the membership of any managed care plan.

Providers may:

- o Provide the names of the managed care plans with which they participate.
- o Make available and/or distribute managed care plan marketing materials.
- o Refer their patients to other sources of information, such as the managed care plan, the enrollment broker or the local Medicaid area office.
- o Share information with patients from the Agency's website or the CMS website.
- O Distribute printed information provided by the managed care plan to their patients comparing the benefits of all of the different managed care plans with which the providers contract.

• Provider affiliation information

- o Providers may announce new or continuing affiliations with the managed care plan through general advertising (for example, radio, television, websites).
- o Providers may make new affiliation announcements within the first 30 calendar days of the new provider agreement.
- o Providers may make one announcement to patients of a new affiliation that names only the managed care plan when such announcement is conveyed through direct mail, email or phone.
- Additional direct mail and/or email communications from providers to their patients regarding affiliations must include a list of all managed care plans with which the provider contracts.
- Any affiliation communication materials that include managed care plan-specific information (for example, benefits, formularies) must be prior approved by the Agency.

Member Records

Providers are required to maintain medical records for each patient in accordance with the medical record requirements below and with 42 CFR 431 and 42 CFR 456. A permanent medical record will be maintained at the primary care site for every member and be available to the PCP and other physicians. Medical records shall include the quality, quantity, appropriateness and timeliness of services performed.

Providers are required to have a designated person in charge of medical records. This person's responsibilities include but are not limited to:

- The confidentiality, security and physical safety of records.
- The timely retrieval of individual records upon request.
- The unique identification of each patient's record.
- The supervision of the collection, processing, maintenance, storage and appropriate access to the usage of records.
- The maintenance of a predetermined, organized and secured record format.

Medical Record Standards

Except when otherwise required by law, the content and format of clinical records, including the sequence of information, are uniform. Records are organized in a consistent manner that facilitates continuity of care.

All patient medical records are to reflect all aspects of patient care, including ancillary services. Providers must follow the medical record standards set forth below for each member's medical records as appropriate:

- Include the enrollee's identifying information, including name, enrollee identification number, date of birth, gender, and legal guardianship or responsible party if applicable
- Include information relating to the enrollee's use of tobacco, alcohol, and drugs/substances
- Maintain each record legibly and in detail
- Include a summary of significant surgical procedures, past and current diagnoses or problems, allergies, untoward reactions to drugs and current medications and any other health conditions
- Include all services provided (this includes but is not limited to family planning services, preventive services and services for the treatment of sexually transmitted diseases)
- Record the presence or absence of allergies and untoward reactions to drugs, current medications and/or
 materials in a prominent and consistent location in all clinical records; this information should be verified at
 each patient encounter and updated whenever new allergies or sensitivities are identified
- Ensure all entries are dated and signed by the appropriate party
- Indicate in all entries the chief complaint or purpose of the visit, the objective, diagnoses, and medical findings or impression of the provider
- Indicate in all entries the studies ordered (for example, laboratory, X-ray, electrocardiogram) and referral reports
- Indicate in all entries the therapies administered and prescribed
- Record all medications prescribed and documentation or medication reconciliation, including any changes in prescription and nonprescription medication with name and dosage when available
- Include in all entries the name and profession of the provider rendering services (for example, MD, DO), including the provider's signature or initials
- Include in all entries the disposition, recommendations, instructions to member, evidence of follow-up and outcome of services
- Documentation of the express written and informed consent of the enrollee's authorized representative
 prescriptions for psychotropic medication (i.e., antipsychotics, antidepressants, antianxiety medications,
 and mood stabilizers) prescribed for an enrollee under the age of thirteen (13) years
- Documentation of the child's consent and proof that a signed attestation has been provided to the pharmacy
- Ensure all records contain an immunization history and documentation of body mass index
- Ensure all records contain information relating to the member's use of tobacco products and alcohol and/or substance abuse
- Ensure all records contain summaries of all emergency services and care and hospital discharges with appropriate and medically indicated follow-up
- Document referral services in all members' medical records
- Include all services provided such has family planning services, preventive services and services for the treatment of sexually transmitted diseases
- Ensure all records reflect the primary language spoken by the member and any translation needs of the member
- Ensure all records identify members needing communication assistance in the delivery of health care services
- Ensure all records contain documentation of the member being provided with written information concerning his or her rights regarding advance directives (that is, written instructions for living will or power of attorney) and whether or not he or she has executed an advance directive.
 - Note: Neither the health plan nor any of its providers can require, as a condition of treatment, the member to execute or waive an advance directive. The health plan must maintain written policies and procedures for advance directives.
- Maintain copies of any advance directives executed by the member

- Enter in the patient's clinical record and appropriately sign or initial significant medical advice given to a patient by telephone or online, including medical advice provided after hours
- Clearly contrast any notation in a patient's clinical record indicating diagnostic or therapeutic intervention as part of clinical research with entries regarding the provision of non-research-related care
- Review and incorporate into the record in a timely manner all reports, histories, physicals, progress notes
 and other patient information such as laboratory reports, X-ray readings, operative reports and
 consultations
- Document a summary of past and current diagnoses or problems, including past procedures if a patient has had multiple visits/admissions or the clinical record is complex and lengthy
- Include a notation concerning cigarettes if present for patients ages 12 and older (abbreviations and symbols may be appropriate)
- Provide health education to the member
- Screen patients for substance abuse and document in the medical record as part of a prevention evaluation during the following times:
 - o Initial contact with a new member
 - o Routine physical examinations
 - o Initial prenatal contact
 - When the member evidences serious overutilization of medical surgical, trauma or emergency services
 - o When documentation of emergency room visits suggests the need

The following requirements must also be met regarding the patient's medical records:

- Consultations, referrals and specialist reports Notes from any referrals and consultations must be in the
 record. Consultation, lab and X-ray reports filed in the chart must have the ordering physician's initials or
 other documentation signifying review. Consultation and any abnormal lab and imaging study results must
 have an explicit notation in the record of follow-up plans, including timely notification with patient or
 responsible party (adult).
- 2. **Emergencies** All emergency care provided directly by the contracted provider or through an emergency room and the hospital discharge summaries for all hospital admissions while the patient is part of the PCP's panel must be noted.
- 3. **Hospital discharge summaries** Discharge summaries must be included as part of the medical record for all hospital admissions that occur while the patient is enrolled and for prior admissions as appropriate. Prior admissions pertaining to admissions that may have occurred prior to the patient being enrolled may be pertinent to the patient's current medical condition.
- 4. **Security** Providers must maintain a written policy and are required to ensure medical records are safeguarded against loss, tampering, alteration, destruction, or unauthorized or inadvertent use.
- 5. **Storage** Providers must maintain a system for the proper collection, processing, maintenance, storage, retrieval and distribution of patient's records. Also, the records must be easily accessible to personnel in the provider's office and readily available to authorized personnel any time the organization is open to patients.
- 6. **Release of information** Written procedures are required for releasing information and obtaining consent for treatment.
- 7. **Documentation** Documentation is required setting forth the results of medical, preventive and behavioral health screenings as well as all treatment provided and the outcome of such treatment, including significant medical advice given to a patient by telephone.
- 8. **Multidisciplinary teams** Documentation is required of the team members involved in the multidisciplinary team of a patient needing specialty care.
- 9. **Integration of clinical care** Documentation of the integration of clinical care in both the physical and behavioral health records is required. Such documentation must include:
 - Screening for behavioral health conditions, including those which may be affecting physical health care and vice versa, and referral to behavioral health providers when problems are indicated.

- o Screening and referral by behavioral health providers to PCPs when appropriate.
- Receipt of behavioral health referrals from physical medicine providers and the disposition/outcome of those referrals.
- At least quarterly, or more often if clinically indicated, a summary of the status/progress from the behavioral health provider to the PCP.
- o A written release of information that will permit specific information-sharing between providers.
- Documentation that behavioral health professionals are included in primary and specialty care service teams when a patient with disabilities or chronic or complex physical or developmental conditions has a co-occurring behavioral disorder.
- 10. **Domestic violence** Documentation of screening and referral to the applicable community agencies is required.
- 11. **Consent for psychotherapeutic medications** Pursuant to *F.S. 409.912(13)*, providers must document informed consent from the parent or legal guardian of members younger than age 13 who are prescribed psychotherapeutic medications and must provide the pharmacy with a signed attestation of this documentation. Pharmacies are required to obtain and keep these consents on file prior to filing a psychotherapeutic medication.
- 12. **Behavioral health services provided through telemedicine** Documentation of behavioral health services provided through telemedicine is required. Such documentation must include:
 - o A brief explanation of the use of telemedicine in each progress note.
 - o Documentation of telemedicine equipment used for the particular covered services provided.
 - A signed statement from the enrollee or the enrollee's representative indicating the choice to receive services through telemedicine. This statement may be for a set period of treatment or for a one-time visit, as applicable to the service(s) provided.
 - o For telepsychiatry the results of the assessment, findings and practitioner(s) plan for next steps.

Simply will periodically review medical records to ensure compliance with these standards. Simply will institute actions, including corrective actions for improvement, when standards are not met.

Patient Visit Data

At a minimum, documentation of individual encounters must provide adequate evidence of the following:

- 1. Date of service; name, signature and profession (for example, MD, OD, RN) of the person(s) providing the service; type of service provided; department of facility (if applicable); chief complaint; changes in medications with name and dosage; disposition; recommendations or instructions provided; and documentation of missed or cancelled appointments
- 2. A history and physical exam that includes appropriate subjective and objective information obtained for the presenting complaints
- 3. For patients receiving behavioral health treatment:
 - o Documentation that includes at-risk factors such as danger to self and/or others, ability to care for self, affect, perceptual disorders, cognitive functioning, and significant social health concerns.
 - A documented assessment that is done with each visit relating to client status/symptoms and that
 may indicate initial symptoms of the behavioral health condition as decreased, increased or
 unchanged during the treatment period, along with the type and units of service provided.
 - A treatment plan that includes the member and/or parent or guardian's preferences for treatment, identifies reasonable and appropriate objectives, provides the necessary services to meet the objectives, and includes a retrospective review to confirm that care provided and its outcomes were consistent with the approved treatment and member's needs.
 - o Documented therapies and other prescribed regimens; and show evidence of family involvement as applicable and include evidence that the family was included in therapy sessions when appropriate.
- 4. An admission or initial assessment that includes current support systems or lack of support systems

- 5. A plan of treatment that includes activities/therapies to be carried out and goals to be met
- 6. Diagnostic tests
- 7. For follow-up care encounter forms or notes with a notation indicating follow-up care, a call or a visit that must note in weeks, months or PRN (as needed) the specific time to return with unresolved problems from any previous visits being addressed in subsequent visits
- 8. Referrals and results, including all other aspects of patient care, such as ancillary services

Simply will systematically review medical records to ensure compliance with these standards. We will share the results of our audits and institute actions for improvement when standards are not met.

We maintain an appropriate record-keeping system for services to members. This system will collect all pertinent information relating to the medical management of each member and make that information readily available to appropriate health professionals and appropriate state agencies. All records will be retained in accordance with the record retention requirements of 45 CFR 438.3110, which states that records must be retained for ten years from the date of termination of Simply's SMMC contract with AHCA and retained further if records are under review or audit until the audit or review is complete. Prior approval from Simply is required for the disposition of records if subcontract is continuous, per 438.4.u.

Misrouted Protected Health Information

Providers and facilities are required to review all member information received from Simply to ensure no misrouted protected health information (PHI) is included. Misrouted PHI includes information about members that a provider or facility is not treating. PHI can be inadvertently misrouted to providers and facilities by mail, fax, email or electronic remittance advice. Providers and facilities are required to immediately notify Simply upon receipt of the information, not forward or copy the documents, and destroy the misrouted PHI or safeguard the PHI for as long as it is retained. In no event are providers or facilities permitted to misuse or redisclose misrouted PHI. If providers or facilities cannot destroy or safeguard misrouted PHI, they should call Provider Services at **1-844-405-4296** for help.

Advance Directives

Simply respects the right of the member to control decisions relating to his or her own medical care, including the decision to have provided, withheld or withdrawn the medical or surgical means or procedures calculated to prolong his or her life. This right is subject to certain interests of society, such as the protection of human life and the preservation of ethical standards in the medical profession.

Simply adheres to the Patient Self-Determination Act and maintains written policies and procedures regarding advance directives. Advance directives are documents signed by a competent person giving direction to health care providers about treatment choices in certain circumstances. There are two types of advance directives. A durable power of attorney for health care (that is, durable power) allows the member to name a patient advocate to act on behalf of the member. A living will allows the member to state his or her wishes in writing but does not name a patient advocate.

Member Services and Outreach associates encourage members to request an advance directive form and education from their PCP at their first appointment.

Members over age 18 and emancipated minors are able to make an advance directive. His or her response is to be documented in the medical record. Simply will not discriminate or retaliate based on whether a member has or has not executed an advance directive.

While each member has the right without condition to formulate an advance directive within certain limited circumstances, a facility or an individual physician may conscientiously object to an advance directive. Member Services and Outreach associates will assist members regarding questions about advance directives; however, no Simply associate may serve as witness to an advance directive or as a member's designated agent or representative.

Simply notes the presence of advance directives in the medical records when conducting medical chart audits.

Telemedicine

Florida defines telemedicine as the practice of health care delivery by a practitioner who is located at a site other than the site where a recipient is located for the purposes of evaluation, diagnosis, or treatment (59G-1.057, F.A.C.).

If we approve you to provide services through telemedicine as exhibited in your *Participating Provider*Agreement or Amendment, you must implement telemedicine fraud and abuse protocols that address:

- Authentication and authorization of users.
- Authentication of the origin of the information.
- The prevention of unauthorized access to the system or information.
- System security, including the integrity of information that is collected, program integrity and system integrity.
- Maintenance of documentation about system and information usage.

When providing services through telemedicine:

• The telecommunication equipment and telemedicine operations must meet the technical safeguards required by 45 CFR 164.312, and Rule 59G-1.057 F.A.C. where applicable.

We educate the patient, obtain consent, document the choice for telemedicine in the patient's medical record, and include detailed notes from each visit.

You must comply with HIPAA and other state and federal laws pertaining to patient privacy.

8 MEDICAL MANAGEMENT

Medical Review Criteria

Simply has its own nationally recognized medical policy process. Simply medical policies, which are publicly accessible on the subsidiary websites, are the primary benefit plan policies for determining whether services are considered to be 1) investigational/experimental, 2) medically necessary, and 3) cosmetic or reconstructive.

A list of the specific *Clinical Utilization Management Guidelines* used is posted and maintained on the Simply provider website and can be obtained in hard copy by written request. Providers can also contact Provider Services at **1-844-405-4296** for more information. These policies will support precertification requirements, clinical-appropriateness claims edits and retrospective review.

Federal and state law as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first when determining eligibility for coverage. As such, in all cases, state Medicaid contracts or CMS requirements will supersede Simply medical policy criteria. Medical technology is constantly evolving, and we reserve the right to review and periodically update medical policy and clinical utilization management criteria.

Simply uses MCG care guidelines for inpatient concurrent reviews except for those hospitals where the contract states differently. Unless superseded by state Medicaid or CMS requirements, all nonbehavioral health, behavioral health outpatient precertification requests, and behavioral health concurrent reviews will be determined using Simply *Medical Policies* and *Clinical Utilization Management Guidelines*.

We work with network providers to develop clinical guidelines of care for our membership. The medical advisory committee assists us in formalizing and monitoring guidelines.

If we utilize noncommercial criteria, the following standards apply to the development of the criteria:

- Criteria are developed with involvement from appropriate providers with current knowledge relevant to the content of treatment guidelines under development.
- Criteria are based on review of market practice and national standards/best practices.
- Criteria are evaluated at least annually by appropriate, actively practicing physicians and other providers
 with current knowledge relevant to the criteria of treatment guidelines under review and updated, as
 necessary. The criteria must reflect the names and qualifications of those involved in the development, the
 process used in the development, and when and how often the criteria will be evaluated and updated.

Precertification/Notification Process

Simply may require members to seek a referral from their PCP prior to accessing nonemergency specialty physical health services.

Precertification is defined as the **prospective** process whereby licensed clinical associates apply designated criteria against the intensity of services to be rendered and a member's severity of illness, medical history and previous treatment to determine the medical necessity and appropriateness of a given coverage request. **Prospective** means the coverage request occurred prior to the service being provided.

Notification is defined as faxed, telephonic or electronic communication received from a provider informing Simply of the intent to render covered medical services to a member. There is no review against medical necessity criteria; however, member eligibility and provider status (network and non-network) are verified.

Notification should be provided prior to rendering services. For services that are emergent or urgent, notification should be given within 24 hours or the next business day.

Utilization Management Decision Making

Simply, as a corporation and as individuals involved in utilization management (UM) decisions, is governed by the following statements:

- UM decision-making is based only on appropriateness of care and service and existence of coverage.
- Simply does not specifically reward practitioners or other individuals for issuing denial of coverage or care.
 Decisions about hiring, promoting or terminating practitioners or other staff are not based on the likelihood or perceived likelihood that they support, or tend to support, denials of benefits.
- Financial incentives for UM decision-makers do not encourage decisions that result in underutilization or create barriers to care and service.

Access to UM Staff

- UM staff is available at least eight hours a day during normal business hours for inbound collect or toll-free calls at **1-844-405-4296**. Staff are available Monday to Friday, 8 a.m. to 7 p.m. ET (excluding state holidays) to assist with inquiries and problems related to the provision of services and claims. The helpline is additionally staffed after-hours to respond to authorization requests.
- Staff can receive inbound communication regarding UM issues after normal business hours at
 1-844-405-4296. Our after-hours answering service will ensure providers can leave a message for our managers, nurses or the medical director as appropriate.
- Staff identify themselves by first name/first initial of last name, title and organization name when initiating or returning calls regarding UM Issues.
- TDD/TTY services are available by dialing 711.
- Language assistance, such as interpreter services, is available by calling Provider Services at 1-844-405-4296.

Preventive Care Guidelines

Simply uses nationally recognized preventive care, evidence-based clinical practice information, guidelines and protocols. This information is on the provider website to ensure fair, consistent and quality health care services and treatments are provided to members. Our clinical practice and preventive care guidelines: https://provider.simplyhealthcareplans.com/docs/FLFL_SMH_ClinicalPracticeGuidelines_June2019.pdf

The following are links to the HIV/AIDS-specific guidelines:

Adult HIV	http://www.aidsinfo.nih.gov/Guidelines	U.S. Dept. of Health and Human
Primary Care Guidelines for the Management of Persons Infected with HIV	https://academic.oup.com/cid/advance- article/doi/10.1093/cid/ciaa1391/5956736	Services, Clin. Guidelines Guidelines updated: August 16, 2021
		2020 Update by the HIV Medicine Association of the Infectious Diseases Society of America
Guidelines for Prevention and	https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent- opportunistic-infection/whats-new-guidelines	National Institutes of Health, AIDS

Treatment of	Information
Opportunistic	updated Nov 18,
Infections in HIV-	2021
Infected Adults	
and Adolescents	

Treatment adherence services are available through Simply. Case managers communicate the information to members, and information is made available to all PCPs.

Clinical Practice Guidelines

Clinical practice guidelines are resources to assist with the management of chronic medical conditions for the care of our membership. The medical advisory committee (MAC) oversees and directs Simply in adopting and monitoring guidelines. We must review and revise the guidelines at least every two years or whenever the guidelines change.

The clinical criteria are guidelines developed by industry specialty associations and organizations, including but not limited to:

- American Academy of Child and Adolescent Psychiatry
- American Academy of Family Physicians
- American Academy of Pediatrics
- American Cancer Society
- American College of Obstetricians and Gynecologists (ACOG)
- American College of Physicians
- American Diabetes Association
- American Lung Association
- American Medical Association
- Centers for Disease Control and Prevention
- Department of Health and Human Services Commission
- National Institutes of Health
- U.S. Preventive Services Task Force

Visit our provider website at https://medicalpolicy.simplyhealthcareplans.com to review and download a copy of the clinical practice guidelines. You may also call Provider Services at 1-844-405-4296 to request a hard copy, and we will gladly mail it to you.

Clinical Criteria

The criteria provide a system for screening proposed medical care based on member specific best medical care practices and rule-based systems to match appropriate services to member needs based upon clinical appropriateness. Criteria include:

- Acute care (adult and pediatric)
- Rehabilitation
- Subacute care
- Home care
- Surgery and procedures
- Imaging studies and X-rays

Simply utilization reviewers use these criteria as part of the precertification of scheduled admission, concurrent review and discharge planning process to determine clinical appropriateness and medical necessity for coverage of continued hospitalization. These criteria are reviewed at least annually.

Simply is available 24/7 to accept precertification requests. When a request is received from the physician via telephone, online submission or fax for medical services, the care specialist will verify eligibility and benefits. This information will be forwarded to the precertification nurse. The precertification nurse will review the coverage request and the supporting medical documentation to determine the medical appropriateness of diagnostic and therapeutic procedures. When appropriate, the precertification nurse will assist the physician in identifying alternatives for health care delivery as supported by the medical director.

When the clinical information received is in accordance with the definition of medical necessity and in conjunction with our *Clinical UM Guidelines* criteria, a Simply reference number will be issued to the referring physician. All utilization guidelines must be supported by an individualized determination of medical necessity based on the member's needs and medical history. Decisions on urgent requests (that is, expedited service authorizations) will be made within two calendar days.

If medical necessity criteria for the admission are not met on the initial review, the medical director will contact the requesting physician upon request to discuss the case.

If the precertification documentation is incomplete or inadequate, the precertification nurse will not approve coverage of the request but will notify the referring provider to submit the additional necessary documentation. Two requests for additional information will be made over a 48-hour period. If information is not received within the specified time period, the request will be denied. If the medical director denies coverage of the request, the appropriate denial letter (including the member's appeal rights) will be mailed to the requesting provider, the member's PCP and the member.

If the medical director denies the request for coverage, the appropriate notice of proposed action will be mailed to the requesting provider, the member's PCP, the facility and the member.

Our Interactive Care Reviewer (ICR), which is accessed online through the Availity Portal at https://www.availity.com, is the preferred method for submitting preauthorization requests; it offers a streamlined and efficient experience for providers requesting inpatient and outpatient medical or behavioral health services for our members. Additionally, providers can use this tool to make inquiries and check on the status of previously submitted requests, regardless of how they were sent (phone, fax, ICR or other online tool). Capabilities and benefits of the ICR include:

- Initiating preauthorization requests online eliminating the need to fax. The ICR allows detailed text, photo images and attachments to be submitted along with your request.
- Making inquiries on previously submitted requests via phone, fax, ICR or other online tool.
- Having instant accessibility from almost anywhere, including after business hours.
- Utilizing a dashboard that provides a complete view of all utilization management requests with real-time status updates, including email notifications if requested using a valid email address.
- Viewing real-time results for common procedures with immediate decisions.
- Requesting and checking the status of clinical appeals for denied authorizations.
- Viewing letters affiliated with the case.
- Submit an appeal for a UM denial

You can access the ICR under **Authorizations and Referrals** on the Availity Portal. For an optimal experience with the ICR, use a browser that supports 128-bit encryption. This includes Internet Explorer, Chrome, Firefox and Safari

The ICR is not currently available for:

- Transplant services.
- Services administered by vendors, such as AIM Specialty Health and Health Network One (HN1). For these requests, follow the same preauthorization process you use today.

We'll update our website as additional functionality is added throughout the year.

Hospital and Elective Admission Management

Simply requires precertification of all inpatient elective admissions. The referring primary care provider (PCP) or specialist physician is responsible for precertification. The referring physician identifies the need to schedule a hospital admission and must submit the request to the Simply Medical Management department.

Requests for precertification with all supporting documentation should be submitted immediately upon identifying the inpatient request or at least 72 hours prior to the scheduled admission. This will allow Simply to verify benefits and process the precertification request. For services that require precertification, Simply makes case-by-case determinations that consider the individual's health care needs and medical history in conjunction with medical necessity criteria.

The hospital can confirm that an authorization is on file by calling the Simply automated Provider Inquiry Line at **1-844-405-4296** or accessing our secure website. If coverage of an admission has not been approved, the facility should call Simply at **1-844-405-4296**. Simply will contact the referring physician directly to resolve the issue.

Emergent Admission Notification Requirements

Simply prefers immediate notification by network hospitals of emergent admissions. Network hospitals must notify Simply of emergent admissions within one business day. Simply Medical Management staff will verify eligibility and determine benefit coverage. No prior authorization is required for emergency admissions.

Simply is available 24/7 to accept emergent admission notification at 1-844-405-4296.

Coverage of emergent admissions is authorized based on review by a concurrent review nurse. When the clinical information received meets the criteria, a Simply reference number will be issued to the hospital. Two requests for clinical information will be made over a 48-hour period if clinical information was not provided with notification. If information is not received within 72 hours of the initial request, the request will be denied. If the notification documentation provided is incomplete or inadequate, Simply will not approve coverage of the request and will notify the hospital to submit the additional necessary documentation. If the medical director denies coverage of the request, the appropriate denial letter will be mailed to the hospital, member's PCP and the member.

Nonemergent Outpatient and Ancillary Services: Precertification and Notification Requirements

Simply requires precertification for coverage of selected nonemergent outpatient and ancillary services. To ensure timeliness of the authorization, the expectation is for the facility and/or provider to provide the following:

- Member name, DOB and ID
- Name, phone and fax number, TIN (or NPI and address) of the physician performing the elective service
- Name of the facility and telephone number where the service is to be performed

- Date of service
- Member ICD-10 diagnosis
- Name of elective procedure to be performed with CPT code
- Medical information to support requested services (medical information includes current signs/symptoms, past and current treatment plans, response to treatment plans, and medications)

For more information on prior authorization and notification requirements, refer to the **Simply Health Care Benefits and Copays** and our provider website.

Inpatient Reviews

Inpatient Admission Review

We'll review all inpatient hospital admissions, including urgent and emergent admissions, within 24 hours of admission notification. The Simply utilization review clinician determines the member's medical status through communication with the hospital's utilization review department. Appropriateness of stay is documented and concurrent review is initiated. Cases may be referred to the medical director, who renders a decision on the coverage of hospitalization. Diagnoses meeting specific criteria are referred to the medical director for possible coordination by the Care Management program.

Inpatient Concurrent Review

Each network hospital will have an assigned Utilization Management (UM) nurse. Each UM nurse will conduct a utilization review of the hospital medical record using EMR, phone or onsite at the facility if indicated, to determine the authorization of coverage for a continued stay.

When a Simply UM nurse reviews the medical record, he or she works closely with the hospital case management team and contacts the member or member representative as needed to discuss any discharge planning needs and verify that the member or family is aware of the PCP's name, address and telephone number. The UM nurse will conduct continued stay reviews and review discharge plan needs.

When the clinical information received meets medical necessity criteria, approved continued stay days will be communicated to the hospital. The request for the clinical information needed will be communicated to the designated department within the hospital. Simply asks that the hospital reviewer provide only the necessary information being requested.

Upon discharge Simply UM clinician will help coordinate discharge planning needs with the hospital utilization review staff and attending physician. The attending physician is expected to coordinate with the member's PCP regarding follow-up care after discharge. The PCP is responsible for contacting the member to schedule all necessary follow-up care. In the case of a behavioral health discharge, the attending physician is responsible for ensuring the member has secured an appointment for a follow-up visit with a behavioral health provider to occur within seven calendar days of discharge.

Simply will authorize covered length of stay one day at a time based on the clinical information that supports the continued stay. Exceptions to the one-day length of stay authorization are made for confinements when the severity of the illness and subsequent course of treatment is likely to be several days or is predetermined by state law. Examples of confinement and/or treatment include the following: ICU, CCU, behavioral health rehabilitation, and C-section or vaginal deliveries. Exceptions are made by the medical director.

If the medical director denies coverage for an inpatient stay request based on appropriate criteria and after offering a peer-to-peer discussion, the appropriate notice of action will be mailed to the hospital, the member's PCP and the member.

Discharge Planning

Discharge planning is designed to assist the provider in the coordination of the member's discharge when acute care (that is, hospitalization) is no longer necessary.

When long-term care is necessary, Simply works with the provider to plan the member's discharge to an appropriate setting for extended services. These services can often be delivered in a nonhospital facility, such as:

- A hospice facility
- A convalescent facility
- A home health care program (for example, home IV antibiotics)

When the provider identifies medically necessary and appropriate services for the member, we will assist the provider and the discharge planner in providing a timely and effective transfer to the next appropriate level of care.

Discharge plan authorizations follow Simply *Clinical UM Guidelines*. Authorizations include, but are not limited to, home health, durable medical equipment, pharmacy, follow-up visits to practitioners or outpatient procedures.

Confidentiality of Information

Utilization Management (UM), case management, disease management, discharge planning, quality management and claims payment activities are designed to ensure patient-specific information, particularly protected health information obtained during review, is kept confidential in accordance with applicable laws, including the HIPAA. Information is used for the purposes defined above. Information is shared only with entities who have the authority to receive such information and only with those individuals who need access to such information in order to conduct UM and related processes.

Emergency Services

Simply provides a 24/7 NurseLine with clinical staff to provide triage advice and referral and, if necessary, to make arrangements for treatment of the member. The staff has access to qualified behavioral health professionals to assess behavioral health emergencies.

Simply does not discourage members from using the 911 emergency system or deny access to emergency services. Emergency services are provided to members without requiring precertification. Any hospital or provider calling for an authorization for emergency services will be granted one immediately upon request. Emergency services coverage includes services that are needed to evaluate or stabilize an emergency medical condition. Criteria used to define an emergency medical condition are consistent with the prudent layperson standard and comply with federal and state requirements:

An emergency medical condition is defined as a physical or behavioral condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson who possesses an average knowledge of health and medicine could reasonably expect the absence of immediate medical attention to result in the following: 1) place the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, 2) serious impairment to bodily functions, or 3) serious dysfunction of any bodily organ or part.

Emergency response is coordinated with community services, including the police, fire and EMS departments, juvenile probation, the judicial system, child protective services, chemical dependency, and local mental health authorities, if applicable.

When a member seeks emergency services at a hospital, the determination as to whether the need for those services exists will be made for purposes of treatment by a physician licensed to practice medicine or, to the extent permitted by applicable law, by other appropriately licensed personnel under the supervision of, or in collaboration with, a physician licensed to practice medicine. The physician or other appropriate personnel will indicate in the member's chart the results of the emergency medical screening examination. Simply will compensate the provider for the screening, evaluations and examination that are reasonable and calculated to assist the health care provider in determining whether or not the patient's condition is an emergency medical condition.

If there is concern surrounding the transfer of a patient (that is, whether the patient is stable enough for discharge or transfer or whether the medical benefits of an unstable transfer outweigh the risks), the judgment of the attending physician(s) actually caring for the member at the treating facility prevails and is binding on Simply. If the emergency department is unable to stabilize and release the member, Simply will assist in coordination of the inpatient admission, regardless of whether the hospital is network or non-network. All transfers from non-network to network facilities are to be conducted only after the member is medically stable and the facility is capable of rendering the required level of care.

If the member is admitted, the Simply concurrent review nurse will implement the concurrent review process to ensure coordination of care.

Urgent Care

Simply requires its members to contact their PCP in situations where urgent, unscheduled care is necessary. Precertification with Simply is not required for a member to access a participating urgent care center.

9 QUALITY MANAGEMENT

Quality Management Program

Overview

Simply maintains a comprehensive Quality Management (QM) program to objectively monitor and systematically evaluate access to care and the quality and appropriateness of care and services rendered, to promote quality of care and patient outcomes (see 42 CFR 438.340 and 438.330). The scope and content of the program reflects the demographic and epidemiological needs of the population served. Studies are planned across the continuum of care and service with ongoing proactive evaluation and refinement of the program.

Members and providers have opportunities to make recommendations for areas of improvement. The QM program goals and outcomes are available, upon request, to providers and members. The easiest way for providers to access this information is by going to the provider website, and members can go to the member website.

The initial program development was based on a review of the needs of the population served. Systematic re-evaluation of the needs of the plan's specific population occurs on an annual basis. This includes not only age and gender distribution, but also a review of utilization data — inpatient; emergent/urgent care; and office visits by type, cost and volume. This information is used to define areas that are high-volume or problem-prone.

There is a comprehensive committee structure in place with oversight from the Simply governing body. Not only are the traditional medical advisory committee (MAC) Peer Review Committee (PRC) and Credentialing committee in place, but a community/enrollee advisory committee are also integral components of the quality management committee (QMC) structure.

Quality of Care

All physicians, advanced registered nurse practitioners and physician assistants are evaluated for compliance with pre-established standards as described in the Simply credentialing program.

Review standards are based on medical community standards, external regulatory and accrediting agencies requirements, and contractual compliance.

Reviews are accomplished by Florida licensed nurses and associate professionals who strive to develop relationships with providers and hospitals that will positively impact the quality of care and services provided to our members.

Results are submitted to the Simply QM department and incorporated into a profile.

The Simply quality program includes review of quality-of-care issues identified for all care settings. QM staff use peer review, performance improvement projects (PIP), medical/case record audits, performance measures, surveys, member complaints, and other information to evaluate the quality of service and care provided to our members. In addition, Simply reviews and analyzes adverse or critical incidents to identify and work to eliminate potential and actual quality of care and/or health and safety issues.

Use of Performance Data

Practitioners and providers must allow Simply to use performance data in cooperation with our quality improvement program and activities.

Quality Management Committee

The purpose of the QMC is to maintain quality as a cornerstone of Simply culture and to be an instrument of change through demonstrable improvement in care and service. The QMC's responsibilities are to:

- Establish strategic direction and monitor and support implementation of the QM program.
- Establish processes and structure that ensure accreditation compliance.
- Review and accept corporate and local QM policies and procedures as appropriate.
- Analyze, review and make recommendations regarding the planning, implementation, measurement and outcomes of clinical/service quality improvement studies.
- Address and resolve any problems/issues identified but not included in a process improvement program.
- Coordinate communication of QM activities throughout the health plans.
- Review and analyze HEDIS® and CAHPS® data and action plans for improvement.
- Review, monitor and evaluate program compliance against Simply, state, federal and accreditation standards.
- Review and approve the annual QM *Program Description* and work plan.
- Provide oversight and review of delegated services.
- Provide oversight and review of operational indicators.
- Assure interdepartmental collaboration, coordination and communication of quality improvement activities.
- Measure compliance to medical and behavioral health practice guidelines.
- Monitor continuity of care between medical and behavioral health services.
- Monitor accessibility and availability with cultural assessment.
- Make information publicly available to members and practitioners about our actions to improve patient safety.
- Make information available about our quality improvement program to members and practitioners; members and providers can request the program by calling Customer Service.
- Assure practitioner involvement through direct input from our MAC or other mechanisms that allow practitioner involvement.
- Provide communication to and from the BOD regarding strategic direction for the QM plan.

Medical Advisory Committee

The MAC has multiple purposes. It:

- Assesses levels and quality of care provided to members and recommends, evaluates and monitors standards of care.
- Monitors practice patterns to identify appropriateness of care and for improvement/risk prevention activities.
- Identifies opportunities to improve services and clinical performance by establishing, reviewing and updating clinical practice guidelines based on review of demographics and epidemiologic information to target high-volume, high-risk and problem-prone conditions.
- Oversees the peer review process, which provides a systematic approach for the monitoring of quality and the appropriateness of care.
- Conducts a systematic process for network maintenance through the credentialing/recredentialing process.
- Advises health plan administration in any aspect of health plan policy or operation affecting network providers or members.
- Approves and provides oversight of the peer review process, the QM program and the utilization review program.
- Oversees and makes recommendations regarding health promotion activities.

HEDIS is a registered trademark of the National Committee for Quality Assurance (NCQA). CAHPS is a registered trademark of the Agency for Healthcare Research and Quality.

The MAC's responsibilities are to:

- Utilize an ongoing peer review system to assess levels of care and quality of care provided.
- Monitor practice patterns to identify risk prevention activities and the appropriateness of care.
- Review, provide input and approve evidence-based clinical protocols and guidelines to facilitate the
 delivery of quality care and appropriate resource utilization.
- Review clinical study designs and results.
- Develop and approve action plans and recommendations regarding clinical quality improvement studies.
- Consider and act in regard to physician sanctions.
- Review, provide input for, and approve policies and procedures for credentialing/recredentialing, QM, utilization management and disease/case management.
- Review and provide feedback regarding new technologies.
- Oversee the compliance of delegated services.
- Review and provide input to credentialing and recredentialing policies and procedures; clinically oriented
 quality management policies and procedures; utilization management policies and procedures; and
 disease/case management policies and procedures.
- Review and provide feedback regarding new technologies.
- Oversee compliance of delegated services.

Peer Review Committee (PRC)

Purpose

As a subcommittee of the QMC, the goal of the Peer Review Committee is to continually improve the quality of care and service provided to members and to ensure that care is consistent with appropriate medical practice standards.

Responsibilities

- The Peer Review is responsible for evaluating the appropriateness of care rendered by the plan's contracted providers;
- Reviewing provider's practice methods and patterns.
- Evaluating provider performance, trends in quality of care and service issues.
- Developing and analyzing plan wide audits.
- It may also serve as the plan's provider advisory council providing input and recommendations to the plan
 concerning, but not limited to, the clinical guidelines adopted, QM Trilogy documents, Credentialing report,
 PIPS, process improvements, quality indicators, performance measures, HEDIS, and Provider Satisfaction
 Survey tools and results

Provider Orientation and Education

Medical Reviewer nurses are available to provide a thorough orientation of Simply review standards. Educational sessions can be scheduled at a provider's convenience. The QM staff is also available to furnish providers with a thorough explanation of review findings during an exit conference on the day of the medical record review. If a provider's schedule does not allow for sufficient time on the day of the review, we can schedule a follow-up appointment. Experience has taught that provider participation in orientation and education sessions helps improve standards' compliance, and therefore decreases the frequency for required reviews.

Medical Record Documentation Review Standards

This applies to the Medicaid programs for Simply Healthcare Plans, Inc. (Simply) and Clear Health Alliance (CHA) as well as the Florida Healthy Kids (FHK) program for Simply.

Administrative Component (A)		
Element	Standard	
Record is organized, legible and easily	Records are fastened with contents organized in a logical,	
accessible to the healthcare practitioners	consistent manner to facilitate information retrieval. There is individual	
and personnel	record for each member. The record must be legible.	
Member ID on file	A copy of membership card on file or in the medical record and	
	written office policy to verify member eligibility before rendering	
	service.	
Personal Identifying data. Legal	Required information: Name, DOB, sex, address, and telephone	
Guardian.	number. For pediatric members (under 21 years old) names of parents	
	or legal guardian are required.	
Primary language and translation	All records must reflect the member's primary spoken language and	
	translation needs, to include services for the deaf/hearing impaired, as	
	well as evidence of access to a translator. If English is the primary	
	language, this must be documented.	
Advance Directives advisement	All records member's 18 years and older must contain Document	
	that the member was provided written information concerning	
	Advance Directive.	
Copy of Advance Directives	If the patient chose to make an Advance Directive, there should be	
	a copy of it in the MR.	
Patient ID on each page	Patient name, first & last, and/or identification number are on ALL	
. 5	pages, reports, documents in the record. Pages that are used on both	
	sides require identification on each side.	
	·	
Entries dated and signed	All entries are signed and dated with month, day and year. All	
	entries contain author identification and professional status (MD, DO,	
	ARNP, PA) when applicable.	

Administ	trative Component (A) - cont'd.
Element	Standard
All entries shall include the disposition, recommendations, instructions to the enrollee, evidence of whether there was follow-up and outcome of services;	As described
Copies of consent or attestation or Court Order to prescribed psychotherapeutic medications to children under 13 years old	As described
Test Accomplished and filed	Process are in place to obtain and follow up on diagnostic studies i.e., log book, computer log, copies of all diagnostic studies are on file.
F/U on missed/cancelled app	Documentation of follow-up for missed and cancelled app. Is required.
Signed HIPAA information form	Signed HIPAA Privacy Statement Form and place in the Medical Record.
Telephone or e-mail communication	Significant medical advice or prescriptions given to a patient by phone or internet should be entered in the medical record and signed or initialed, including medical advice provided after hours or telephone triage.
Translation or other communication needs	If translation is needed must be documented and included services for the deaf/hearing impaired.
Legal Guardian (if applicable)	As described
No white out or alterations	The Medical Record must not contain any alterations or the use of white out for legal purposes, if an error is done a single line is drawn through the error with "error" written above with initials and date.
Record provided timely for review	All Medical Records will be provided in a timely manner the date of the review if you have not inconvenient.
Retention of active records/retirement of inactive records	As described.
If telemedicine, documentation that the member had a choice of whether to access services through a face-to-face or telemedicine encounter.	If applicable.
Medicaid services	Evidence that the member had a choice of whether to receive Medicaid covered service or an in lieu of service.

Adult Preventive Components (B)	
Element	Standard
Complete Medical History for New Members/Complete PE for New Members	All new member s should have a complete Medical History that includes: CC/HIP/PMH/PSxHx/PSocial Hx/Tobacco Hx ETOH/Drugs/ Allergies/ROS and must be updated when necessary. All new members should have a complete Physical Exam: Vital Signs/General/HEENT/Chest/Lungs/Heart/Abdomen Extremities/Skin/GU/Nodes/Neurology.
High Risk Behaviors and Anticipatory Guidance.	Screening to identify high risk individuals and documented in the chart. Teaching specific topics. Obtain consent for tests for the clinical findings or referred to appropriate treatment; Tobacco/Cigarette use/ETOH/Substance abuse/HIV/STD/ Hepatitis Risk/Safe Sex Practices/Nutrition/Injury, Safety prevention/Violence/Abuse/Social/Emotional Health/ Depression/Activity/Exercise.
Measurement/Vital Signs	Document Vital signs: BP/HR/RR/Wt. /Ht. on each visit. Adult Body Mass Index
Screening	All screening preventive tests must be documented in the MR. Cholesterol: Starting at 20 years, obtained once every 5 years. EKG: Test to be done for patient at high risk. Diabetes Screening: Starting at age 45 every 3 years. AAA Screening: One time screening by U/S for men 65-75 smokers. TB: Skin testing for asymptomatic high risk patients. Osteoporosis Screening/Testing: Age 65 and older, routine screening every 2 years or patient at high risk. Menopause Screening: Screening at physician discretion. Vision Screening: Annually. Hearing Screening: Starting at 20 years, obtained once every 10 yr. Dental Health Screening: Annually. Chlamydia: All sexually active females <26 years, as well as other at risk. Breast Exam/Mammography: Annually for ages 40 and older. PAP Smear: Annually. Colorectal CA Screening: At 50 both men and women start Colorectal CA screening Colonoscopy/ Sigmoidoscopy every 5 years or at physician discretion. The choice of specific screening strategy should be based on patient preferences (FOBT), medical contraindications, patient adherence, and available resources for testing (FOBT) and follow-up. Prostate Exam/PSA: Annually beginning at age 50. Skin Cancer: Regular Checkup. HIV Testing: HIV counseling and offer of HIV Testing for Females of Childbearing age and Males. Copy of completed screening Instruments in the enrollee record and proof that a copy has been provided to the enrollee.

Diabetes Component (C) Element Standard	
Nutritional Status, Wt. Hx.	Eating pattern, Nutritional status, Check Wt. Hx on each visit.
DKA frequency, Hypoglycemia	Document Diabetes complications, DKA, Low BS.
BP at every routine visit	BP at each visit lower 130/80.
Dilated eye exam	Dilated retinal exam annually.
Thyroid palpation annually	Thyroid palpation or T3-T4-TSH annually
Skin examinations.	At every routine visit.
Neurology/foot examination	At every routine visit/ annually for neuropathy.
Hb A1C Test	Hb A1C Test every 3 months for abnormal results (>7), every 6 months for normal result (<7).
Liver function test	Liver function test annually.
Micro albuminuria	Micro albuminuria test annually.
Serum creatinine/GFR	A baseline serum creatinine level is indicated for all Diabetes patients.
LDL Control	Fasting lipid profiles are indicated annually. Goals: <100 mg/dL.
Influenza Vaccine	Influenza Vaccine every year.
Pneumococcal Vaccination	The Pneumococcal Vaccine is indicated for all patients with Diabetes. Revaccination every 5 years.
Obesity Management for BMI >24	Medical Nutrition Therapy (MNT) involving a nutritional assessment to evaluate the patient's food intake, metabolic status, lifestyle, readiness to make changes, and goal setting dietary instruction and evaluation.
Education on Nutrition	Document patient Education on Nutrition, Plan should be individualized and take into account cultural, life style and financial considerations. Refer to a Diabetic educator if necessary.
Education on Physical Activity	Encourage Physical Activity. Referrals if needed. Documented.
Weight	Encourage for Weight control. Referrals if needed to a Nutritionist as needed.
Advise all patients not to Smoke	Document and advise all patients not to smoke.
Advise all patients on alcohol consumption	Document and advise all patients on alcohol consumption.
Referrals	Document any Referrals if needed.
Comorbidities:	Provider addresses impact of comorbidities and treatments.

General Medical Component (D)	
Element	Standard
ASSESSMENT:	
Medical History & Physical Exam	A complete medical, psychosocial, and medical-surgical history must be documented in the MR, including a Review of systems. A complete Physical Exam (General, Heart, Lungs, Abdomen, Extremities, HEENT, Neck and GU). Include g all VS. Updated as needed.
Chief Complain/Subjective	Describe the symptom, problem, condition or other factor that is the reason for a medical encounter.
Past Medical History	Should contain the total sum of a patient's health status prior to the presenting problem and must include: Past illnesses, Hospitalizations, Injuries, Surgeries, Blood Transfusions.
Past Surgical History.	See General Medical Component #1.
Past Social History	These must include: occupational and recreational aspects of the patient's personal life i.e. Alcohol, Tobacco, Illicit drugs.
Family History	A family history consists of information about disorders from which the direct blood relatives of the patient suffered, i.e. DM/Cardiovascular disease/Cancer/Autoimmune Disorders.
Blood Transfusion History	See General Medical Component #1.
Health Risk Assessment, if applicable	A Health Risk Assessment is to be completed on all Medicare members and all high-risk members
Allergies/untoward reactions	Allergies or absence of allergies and untoward reactions to drugs and materials recorded in a prominent and consistent location, verified at each patient encounters and updated to reflect new allergies and sensitivities.
Diagnosis or medical impressions	At the end of each Office Visit you must document a Diagnosis or a Clinical impression that is congruent with H&P and the symptoms/presenting complaint.
Medication list	A medication profile documenting all past, present medications including those for chronic conditions, over-the-counter products and dietary supplements. Medications must document dosage, route frequency, and start and stop dates. Documentation of acute medications cannot be documented solely on the progress notes.
Evidence that the needs of the caregiver have been assessed and addressed (if applicable).	As described

General Medical Component (D) – cont'd.		
Element Standard		
TREATMENT PLAN:		
Treatment Plan is consistent with diagnosis	The rationale for which a plan is formulated, the diagnostic impression, is required. Appropriateness based on the findings in the History and Physical. Please refer to General Medical Component #9.	
The working Dx. are consistent with findings	Addresses each chief complaint (subjective/objective) and clinical finding with a working Diagnosis.	
Plan of Care/Studies ordered	Every Office Visit must document: Plan of Care/Studies ordered (if applicable) for the clinical findings and/or diagnosis stated.	
Documentation of patient participation in	Evidence of discussion of treatment with the patient and	
treatment and follow up with recommendations	his/her active participation or lack of it thereof.	
Absence of clinically unnecessary diagnostic/therapeutic procedures	As described.	
Opioid Medications	Opioid Medication prescribed for the treatment of Acute Pain listed in Schedule II-limited to 3 day supply. (pain related to cancer, terminal illness, palliative care and serious traumatic injury are excluded from theses prescribing limits)	
Acute Pain Exemption	Pain listed in Schedule II –limited to 7 day supply. (pain related to cancer, terminal illness, palliative care and serious traumatic injury are excluded from these prescribing limits)	
Prescription for Controlled Substance	Controlled substances in Schedule III, IV, V for treatment of acute pain is limited to 14 day supply. Pain related to cancer, terminal illness, palliative care and serious traumatic injury are excluded from these prescribing limits.	
PATIENT VISIT/PROGRESS NOTES DOCUMENTA	ATION:	
Date and Department, if department applicable	The complete date and time when services were rendered. If a department is applicable, include the department's name.	
Chief Complaint/Purpose of Visit	As described.	
Clinical Objective Findings/VS/BMI	Each Office Visit must contain a Complete Objective Finding including Vital Signs and Body Mass Index documented in the MR. If BMI is over 29.9 an appropriate diagnosis of Obesity and subsequent treatment documented.	
Current review of medications/Reconciliation	Current review of medications (prescription & non-prescription including over-the-counter and dietary supplements). Medications must document dosage, route frequency, and start and stop dates.	
Diagnosis or medical impression	See General Medical Component #9.	
Studies ordered	Studies ordered such as laboratory tests, X-rays studies, etc. reviewed and incorporated in the record in a timely manner.	
General Medical Component (D) – cont'd.		

Element	Standard
Care rendered and therapies	Addresses therapies administered and prescribed according to
administered/prescribed	clinical findings.
Disposition, recommendations and	Documentation of case disposition, recommendations and
instructions given to patient	instructions to the patient must be documented in all progress notes.
Authentication and verification of contents by health care professional	All documentation is to be authenticated and verified by a healthcare professional.
•	·
Documentation regarding missed/cancelled apt.	Documentation of patient cancelations, if applicable.
Signature of healthcare professional.	All progress notes must be signed and dated the day that services were rendered. Signatures should legible with the name and credentials of the health care professional who rendered the services.
Unresolved problems from previous visits are addressed in subsequent visits.	Documentation of follow up care is present: Unresolved Problems from previous visits are addressed in subsequent visits. Follow up of high risk issues identified in the history, physical, or at subsequent visits.
Documentation of all services provided if any.	Document in the MR any services provided to the patient i.e., Family Planning, STD Treatment.
Any notation in the clinical record indicating	Documentation of services provided as part of clinical
diagnostic or therapeutic intervention as part of clinical research is clearly contrasted with entries	research is clearly identified and contrasted with entries related to non-research care.
regarding the provision of non-research related	non-research care.
care.	
Discussions with the patient concerning the	All discussions with the patient concerning the necessity,
necessity, appropriateness and risks of proposed	appropriateness and risks of proposed care, surgery or procedure, as well as discussions of treatment alternatives and A.D. must be
care, surgery or procedure, as well as discussions of treatment alternatives and advanced	clearly documented, if applicable.
directives, if applicable.	oreany accumentes, it appreasies
Documentation supporting that health and	All discussions regarding health education and wellness,
wellness promotion services have occurred within the context of a clinical visit or not.	whether they occurred within the context of a visit or a discussion with office staff.
Evidence of chronic illness management or acute care documentation	All Progress Notes regarding chronic illness treatment
COORDINATION OF CARE/FOLLOW UP AND OU	TREACH:
Are consultants used appropriately?	Document in the Medical Record Referrals to Consultants The MR reflects an appropriate utilization of Consultants.
Consultations promptly reviewed and followed.	All consultations reports, labs, imaging reports must be filed, reviewed, dated and signed by a PCP.
Obtained Medical Records and Office Visits from PCP/specialties, if applicable.	Evidence of documentation from other providers present on the medical record, if applicable.
General Medical Component (D) – cont'd.	
Element Standard	

Provided MR to health care professionals, if	Provider met record requests, as required.
applicable.	
Follow-up after an ER visit or hospitalization.	If a member was seen in ER or was Inpatient Status a f/u must be done in the PCP's office and also a copy of the Hospital and D/C Summaries must be place in the Medical Record and dated.
Appropriate and timely referrals	Referrals made within a reasonable time frame depending on condition.
For records with multiple visits/admissions or complex and lengthy history diagnostic summaries are utilized in accordance with P&P.	All Medical Records with the annexed description must contain diagnostic summaries, updated, as needed.
Documentation of referral	Documentation of referral services in the enrollee Record, including reports resulting from the referral
All clinical information is available to authorized personnel any time the provider is open to patients.	Evidence that all clinical information is available to authorized personnel any time the office is open to patients.
Community resources are utilized, if applicable.	Any documentation of referrals to social services agencies, support groups, etc.
Provider has read/consulted last office encounters or visits to other providers	Evidence that last office visit or visits to other providers have been read and reviewed.
Incorporation of records from previous transitions of care and summaries when a member is being transferred to a new provider or consultant. Evidence of attempts to collect records from previous providers or consultants.	Evidence of copies of previous records or attempts to providers, obtain them.
Supporting documentation:	
Problem List maintained	An Active problem list is included and updated as needed
Record contains Immunization History.	An immunization record for children is up to date, or an appropriate history has been made in the record for adults. For children, there is a completed immunization history in the chart. See schedule for vaccinations.
Reports, histories and physicals/progress notes reviewed	Lab reports, x-ray readings, op reports, and consultations) were reviewed, followed up significant problems and incorporated in the record in a timely manner.
Documentation of Emergency care	Documentation of emergency care encounters in the Enrollee record with appropriate medially indicated Follow-up.
Significant patient advice given by telephone, online, provided after-hours is entered in the clinical records and appropriately signed or initialed	Progress note with this information included, if applicable.
Element	edical Component (D) – cont'd. Standard
Release of information contained in MR	If applicable
	

Treatment records from another current or	If applicable
transferring provider is present.	
Evaluation or member participation with	Progress note indicating members participation with
Provider recommendations.	providers' recommendation.
Evidence of preventive care ID documented in the record.	
Evidence of End-of-Life care if applicable.	Progress Notes indication that end-of life care has been addressed, if applicable.
	nity Medical Component (E)
Element Initial Prenatal care Visit	Standard Document when the first PN visit was rendered; 1 st trim.
ilitiai Fieliatai Cale Visit	42 days of Plan enrollment/3 wks. after dx/1 wk. of a pregnancy Dx. Referrals for comprehensive evaluation and Florida's Healthy Start prenatal risk screening. 1st trimester visit within 3 wks. of a pregnancy diagnosis via + Human Chorionic G Gonadotropin (HCG) 2nd trimester visit within 2 wks. of a pregnancy diagnosis via + HCG 3rd trimester visit within 1 wk. of a pregnancy diagnosis via +
	HCG Evidence of contact if the enrollee fails to keep appointment and arrange for continued prenatal care as soon as possible. Evidence of care coordination/case management depending on the needs of the enrollee
Pregnancy Hx and risks.	Pregnancy history and/or risks must include: G/P/Rh status/ Type of delivery/ Gestational age at delivery/Anesthesia/ Length of labor/Birth outcome/risks/Maternal complications/Sex/weight of child. Risk and management counseling concerning Diabetes- Type I/Type II/ Gestational
Medical-Surgical and Psychosocial Hx.	These must include: Serious accidents/Operations/Infections/Illness/Substance abuse/Mental health/Screening for depression/Gyn. Conditions/Infertility/Stress/Living situation/Socioeconomic evaluation.
Prenatal Care	A review of familial history of birth defect, deformities mental retardation, or inherited disease (e.g., muscular dystrophy, hemophilia, cystic fibrosis). Maternal >35 years/paternal >50 years at time of delivery. Ethnicity.
Preterm Delivery Risk Assessment	Documentation of preterm delivery risk assessment in the enrollee record by week twenty-eight (28)
Evidence of any necessary referrals	Referrals and follow up, if applicable
Evidence of delivery arrangements	Assistance to enrollee in making delivery arrangements

Maternity Medical Component (E) – cont'd.		
Element Nutritional screening and counseling	Standard The Nutritional screening and counseling must include:	
Nutritional screening and counseling.	The Nutritional screening and counseling must include: Dietary intake/Hydration/Prenatal vitamins/Wt. loss/Wt. gain/ Elimination/Food/Shelter resources. Evidence of provider promoted safe/adequate infant nutrition by promoting breast- feeding and use of breast milk substitutes. Provider offered midlevel assessment. Member provided individualized diet counseling and care plan by a public health nutritionist, a nurse or physician following the nutrition assessment. Documentation of nutrition care plan by the person providing the counseling. WIC referral for Nutritional counseling and enrollment in the Food and Nutrition Program for Women, Infants, and Children (WIC attached Referral Form) WIC Referral (Children up to 5 y/o, Preg BF, Postop) with the current height and weight taken within 60 days of the WIC appointment and including Hb and Hct and nutritional problems. Copy to the enrollee. Evidence for subsequent WIC certifications the Managed Care Plan shall ensure that provider coordinated with the local WIC office to provide the above referral data from the most recent CHCUP and copy to the enrollee. A copy of completed screening instrument is in the enrollee	
Risk Behaviors/exposures.	record and proof that a copy has been provided to the enrollee. These must include an appropriate notation concerning: Tobacco/ETOH/Chemical Dependency/HIV/STD/Hepatitis HPV risks/Domestic violence/Safe sex practices/Sexual abuse/Safety risks, environmental/occupational/HIV Test recommendation & counseling 28 wks./32 wks. Signed objection if member declined HIV test. Infected member counseled and offered latest recommended ART regime, appropriate education and treatment referral/ If member HBsAg-positive report to the local CDC, regardless of HS score/Evidence that the provider performed a second HBsAg test between 28 and 32 weeks of pregnancy for enrollees who tested negative eat the first pre-natal visit but who are considered to be high-risk for Hepatitis B infection. Domestic Violence/Sexual abuse. Safe Sex Safety risks/environmental/occupational. HIV Test (initial visit/28 and 32 weeks. Signed objection if HIV test declined. If member infected she was counseled and offered latest recommended ART regimen. Offered appropriate education and referrals, including smoking cessation. Evidence of documentation of emergency care	
Physical Exam.	encounters with appropriate medically indicated follow-up. A Physical Exam must include: a comprehensive review of systems/a focused Gyn. Safe sex practices. And OB examination/ presenting complaints, if any/EDD confirmation/18-20 week EDD update.	

Maternity Medical Component (E) – cont'd.	
Element	Standard
Ongoing Prenatal Care Visits	General Visit Frequency: Every 4 weeks until 28/32 weeks* gestation/every 2 weeks until 36 weeks gestation/every week thereafter until delivery. Evidence of preterm risk assessment by week 28/evidence to f/u to members who fail appointment. Evidence of offering assistance in making delivery arrangements.
OB screening/each Prenatal visit.	Each ongoing prenatal visit must include weeks' gestation Fundal height/Presentation/Fetal Heart Rate/Fetal movement. Preterm labor signs and symptoms/Cervical exam/Weight/BP/Urine albumin, glucose/Problems/comments.
Immunization.	An appropriate immunization history has been made with notation that immunizations are up-to-date/scheduled for catch up. Documentation of communicable diseases.
Treatment plans.	Treatment plans are clearly documented in the record and reflect: High risk patient/Specialty physician care/Dental care/Diagnostic Testing and counseling/Pregnancy Education and counseling.
Prenatal risk screen Form.	Evidence of a DH Form 3134 completed and a copy given to the patient with referral services offered. Evidence that the provider submitted the prenatal risk assessment to the CHD in the county where the prenatal screen was completed within 10 business days of completion. Referral for services regardless of score.
Prenatal Zika Virus Screen	All pregnant women with a history of travel to an area with ongoing Zika virus transmission should be tested for infection. -If positive or inconclusive then consider serial fetal ultrasounds, and consider amniocentesis. -If negative, one fetal ultrasound should be performed to detect microcephaly of intracranial calcifications. -If microcephaly or intracranial calcifications are present, then retest pregnant women and consider amniocentesis. -If negative for microcephaly or intracranial calcifications, then continue with routine prenatal care.
Post- Natal Screening Form	Evidence of transmission Healthy Start (Postnatal) Risk Screening Instrument Certificate of Live Birth to the County CHD within 5 business days of the birth. If the referral is made at the same time the Healthy Start risk screen is administered, the provider may indicate on the risk screening form that the enrolle or infant is invited to participate based on factors other than score. If the determination is made subsequent to risk screening, the provider may refer the enrollee or infant directly to the Healthy Start care coordinator based on assessment of actual or potential factors associated with high risk, such as HIV, Hepatitis B, substance abuse or domestic violence.

Maternity Medical Component (E) – cont'd.	
Element	Standard
Delivery care	If the provider determines that the enrollee's pregnancy is high risk, documentation will evidence that the provider's obstetrical care during labor and delivery included preparation by all attendants for symptomatic evaluation and that the enrollee progress through the final stages of labor and immediate postpartum care.
Post-Partum	The post-partum visit must include: Date of delivery/Infant's birth weight Gestational age at birth, evidence of inspecting the newborn for abnormalities and/or complication. Type of birth: vaginal, C/S/Postpartum 21-56 days after delivery date, PE: BP, weight, pelvic exam, Abdomen, Breast exam, Education on postpartum changes/Personal health habits/Family planning to all women and their partners/Newborn care (eye medication, APGAR, admin 5 mg of vitamin K), Weight and measuring, inspection for abnormalities or complications/Evidence of continuing care of the newborn is provided through the CHCUP program component and documented in the child's medical records./ if the mother is RH negative there is evidence of securing a cord blood sample for type Rh determination and direct Coomb test, /Sexual activity/Nutrition/Signs of Depression Referral for community resources for mother and child made as appropriate. If member tested + for HBsAG, evidence of referral to the Perinatal Hepatitis B Prevention Coordinator at the local CHD. Evidence the infants born to HBsAg-positive enrollees receive Hepatitis B Immune Globulin (HBIG) and the Hepatitis B vaccine once they are physiologically stable, preferably within twelve (12) hours of birth, and shall complete the Hepatitis B vaccine series according to the vaccine schedule established by the Recommended Childhood Immunization Schedule for the United States. Evidence that infants born to HBsAg-positive enrollees for HBsAg and Hepatitis B surface antibodies (anti-HBs) are tested six (6) months after the completion of the vaccine series to monitor the success or failure of the therapy. Evidence that the informant born to the enrollee who tested positive for HBsAG was referred to the Healthy Start regardless of screening score. Evidence of provider report to the local CHD of any positive HBsAg result in any child age 24 months or less within 24 hours of receipt of the positive test result.

AIDS/HIV Preventive Component (F)	
Element Initial History (HPI)	MR with date of first positive HIV test, last negative HIV test documented, care received, current CD4 count, and chart with lowest/highest CD4 count, chart with first and current viral load count, documentation if patient is participating in research studies.
HIV - Related Illnesses	Documentation of any opportunistic infections/cancer, documentation of TB test with results or IGRA, medications taken for anti-TB and HIV, documentation of missed doses and any side effects of medication, viral load or CD4 count while taking medications.
Past Medical History	Documentation of past medical history
GYN and Women's Health	Last pap smear test and result, LMP, breast examination/ mammograms, UTI or yeast infection documented
Obstetric	History of G/P/A/LB, HIV test done during pregnancy, children with positive HIV
Anorectal History	Anal Pap test and results, history of anal warts
Urologic History	UTI, prostate enlargement or infection, PSA test and results
STD History	Documented history of STD's
Dental Oral Care	Oral health examination, dentures
Eye Care	Vision examination, dilated retinal examination
Medication List maintained	List of current medications and side effects reviewed
Allergies documented	Documentation of all allergies
Immunizations	Pneumovax, Tdap, Flu, H1N1, Hepatitis A, Hepatitis B, Chicken Pox, MMR.
Health-Related Behaviors	Tobacco use, ETOH use, Drug or Substance Abuse, exercise, Diet (raw milk, raw eggs, raw meat, raw fish, caffeine).
Gender Identity	Male/Female/Sex change
Sexual Practices	Protection used during intercourse, sex with men/women/both, type of sex used such as anal/vaginal/oral sex
HIV prevention	Protection used to prevent transmission, whether partner also has HIV
Family History	Family history documented
Social History	Social History documented
Mental health History	History of mental health documented

AIDS/HIV Preventive Component (F) – cont'd.	
Element	Standard
ROS/Physical Exam	Presence of s/s: tired, fever, night sweats, anorexia, etc. Evidence of PE done: VS/BMI/nourishment/well or ill.
Assessment	Evidence of a complete assessment done
Plan	Care plan completed and revised frequently according to condition changes
HIV Education	Information on testing, Rx., treatment adherence and prevention of HIV transmission to fetus or sexual partners
Pediatric and Ad Element	dolescent Preventive Component (G) Standard
A Complete History & Physical Examination.	A complete Medical History and Physical Exam must be done to all new patient (CC/HPI/All/PMH/PSHX/PSURGICAL HXFAMILY HX/ROS/VITAL SIGNS/PE: General/HEENT/Neck/Chest/Lungs/ Heart/Abdomen/Extremities/Nodes/Skin/Neurological evaluation/Gait/Hip abduction/Genitalia/Psychosocial Hx/Prenatal care/delivery/birth Hx. The CHCUP schedule is: Birth or neonatal examination. Within 3-5 days of birth and within 48-72 hours after discharge from a hospital, to include evaluation for feeding and jaundice. For newborns discharged in less than 48 hours after delivery, the infant must be examined within 48 hours of discharge. By 1 m/2m/4m/6m/9m/12m/15m/18m/24m/30m/Once per year for 3 through 20 years old.
High Risk Behaviors and Anticipatory Guidance.	Encourage patient on Nutritional status/Dental care-3 yrs. old and or referral/Injury prevention/safety/Report any violence or abuse. Social/Emotional Health/Depression/Advise on ETOH, cigarette, E-cigarettes, drug abuse beginning at age 11/encourage exercise/Illness. Prevention/Sleep Positioning/HIV/STD/Hepatitis Risk query teaching instructions with the parent or guardian/18 months and 24 months Screening for Autism. Assessment of Parent/Guardian for Alcohol, Tobacco and Drug use/abuse.
Immunizations.	An appropriate immunization history has been made with notation that immunizations are up to date/scheduled for catch up. Evidence of provider participation in FL SHOTS.
Measurements.	Document Height/Wt./BMI /HC/BP for each routine visits. BMI annually starting at age 2 yrs., BP annually starting at age 3 yrs.
Sensory Screening.	Vision Screening starting at age years then at 4, 5, 6, 8, 10, 12, 15, and 18 years of age. Hearing screening starting at age 4 years then at 5, 6, 8, and 10 years of age.

Pediatric and Adolescent Preventive Component (G) – cont'd.	
Element	Standard
General Screening.	Lead Testing at 12 months and 24 months of age. Children between the ages of 36 and 72 mo. who have not been previously screened for lead poisoning. H&H at 12 mo. of age. Urinalysis: starting at 9 months of age and patient's at high risk. Hereditary and Metabolic Screening processed through the State Public Health Laboratory: Screening for PKU, Thyroid, Hemoglobinopathies, Galactosemia. If a child is found to have lead blood levels equal to or greater than 10 micrograms per deciliter, providers should use their medical discretion, with reference to the current Center for Disease Control and Prevention (CDC) guidelines covering patient management and treatment, including follow-up tests and initiating investigations as to the source of lead where indicated.
Procedures: At Risk.	TB Testing for all pediatric patients and at risk. Dyslipidemia screening: To be done at ages 2-4-6-8-10 and each year from 11-17 and or patients at risk. HIV/STD/Hepatitis/Pelvic Exam/PAP Smear/Sickle Cell Test: For all patients at risk/Family History.
Child Abuse.	Screening for child abuse is conducted/suspected and reported to appropriate regulatory agencies and documented.
Treatment Plan for Opioid Medications.	Opioid Medication prescribed for the treatment of Acute Pain listed in Schedule II-limited to 3 day supply (pain related to cancer, terminal illness, palliative care and serious traumatic injury are excluded from theses prescribing limits) Acute Pain Exemption: Pain listed in Schedule II –limited to 7 day supply. (pain related to cancer, terminal illness, palliative care and serious traumatic injury are excluded from these prescribing limits). Prescription for Controlled Substance: Controlled substances in Schedule III, IV, V for treatment of acute pain is limited to 14 day supply. (pain related to cancer, terminal illness, palliative care and serious traumatic injury are excluded from theses prescribing limits)
Safety Element	Preventive Component (H) Standard
Evidence of Staff training	Staff training on infection control and universal precautions. Evidence of boxes to dispose of hazardous materials and contaminated materials and waste.
Emergency disaster plan	Evidence of Emergency/Disaster Preparedness Plan addressing internal/external emergencies for administrative offices and ensures member safety and evacuation plan.
After-hours access	Evidence of accessibility to after-hours services by asking the appropriate office staff to show next available appointment.

Safety Preventive Component (H) Element Standard	
Safety Program	Management of identified hazards, potential threats, near misses, violence in the workplace, extreme threats like bomb threats, firearms, terrorism and other safety concerns. Awareness of, and a process for, the reporting of known adverse incidents to appropriate state and federal agencies when required by law to do so. Processes to reduce and avoid medication errors, including expiration date monitoring on medications, reagents and solutions. Evidence that the Thermometer log in the refrigerator is being read. Evidence that opened medication in the refrigerator is Not over 28 days. Prevention of falls or physical injuries involving patients, staff and all others.
Fire prevention	Evidence of staff education and fire drills (fire drills once a year). Local/Federal fire prevention regulations for all sites, if applicable. Compliance with applicable State/Local Building codes and regulations. Contain fire-fighting equipment to control a limited fire, including appropriately maintained and placed fire extinguishers of the proper type. Have prominently displayed illuminated signs with emergency power capability at all exits from each floor or hall. Have emergency lighting, as appropriate to the facility, to provide adequate evacuation of members and staff, in case of an emergency. Have stairwells protected by fire doors, if applicable.
Member Privacy/Accessibility	Provide examination rooms, dressing rooms, and reception areas that are constructed and maintained in a manner that ensures member privacy during interviews, examinations, treatment and consultation.
Have provisions to reasonably accommodate disabled individuals.	Self-Explanatory
Evidence that Members' Rights poster is prominently displayed.	Self-Explanatory
Posted information regarding lack of malpractice insurance coverage, if applicable. Information is ported in a prominent location.	Self-Explanatory

Adult Family Care Home (AFCH)	
Element	Standard
RESIDENT RECORDS	
Bill of Rights/Proc. Lodging complaints with Complaints with Residents	Documented Bill of Rights /List Lodging Residents
Discussion of House Rules	Documentation that show that House Rules were discussed
Resident record on the premises by provider	Documentation of the resident record on the premises kept by the provider
Resident Health Assessment (Form 1110)	Documented proof of a completed Resident Health Assessment (Form 1110) on file.
Residency Agreement	Residency agreement on file completed before or at admission
Residency Agreement	Residency agreement must have all required information filled out
Resident Advised Grievance and fair hearing process	Documentation of a Resident Advised Grievance and hearing process, if applicable.
Demographic information in each resident	Documentation of Demographic info on each resident on file
Complete accounting of resident funds for safekeeping	File indicating that a complete account of resident funds is being kept
Resident's medication	Documented record of each resident's Medication
Annual Health Risk Assessment or when significant changes occur	Documented Annual Health Assessment on file or when significant changes happen
Health Risk Assessment (HRA) conducted and signed by an authorized individual	HRA must be conducted and signed by a physician or other licensed practitioner of the healing arts defined as a Physician Assistant, Advanced Registered Nurse Practitioner or Registered Nurse acting within the scope of their practice under state law; documented and signed
Service plan developed after the initial HRA	Documentation of a Service Plan developed within 15 days after the initial HRA, based on HRA information and containing all required information; signatures of a resident/legal guardian/designated administrator must be present.
Medication orders	Documentation that medication orders are reviewed and current
Nursing Progress Notes	Documentation provided where it shows nursing progress notes are being kept when nursing services are provided
Special Diet for the member	Copy in the member's file of any special diet order prescribed by resident's health care provider.
Coordination of care	Documentation of the coordination of care by providers/licensed practitioner/nurse for the member
Any major incidents or significant health changes	Documentation of any major incidents or significant health changes and action taken in response to such incidents or changes

Adult Family Care Home (AFCH) – cont'd.	
Element	Standard
Monthly weight record	Documentation that monthly weights are being done for the member and in file; includes resident's name, admission weight, weighing and recording of each resident on a monthly basis
Resident discharge notices sent by provider	Resident records shall contain a copy of any notice of discharge sent to the resident or the resident's representative
Closed resident records kept 5 yrs.	Closed resident records shall be kept for a period of five years after the resident leaves the AFCH. Ask the AFCH provider whether or not resident records are being retained by the home after a resident is discharged
Personal Needs Allowance (PNA) for the resident	Evidence, if applicable, that the resident has been provided with a PNA in an amount equal to that set by rule 65A-2.036, F.A.C.
FACILITY RECORDS/SAFETY	
Facility Records	Documentation of Facility Records shall be on file on the premises and up-to-date
Resident Service Log (AHCA-Med Serv. Form 037-Appendix D, July 2009)	Evidence of a complete Resident Service Log (AHCA-Med Serv. Form 037-Appendix D, July 2009) on file; make sure log is filled out properly (Resident name, Medicaid #, Facility name, month/year, etc.)
Certification of Medical Necessity for Evidence of a Certification of Medical necessity for Medical Medicaid ACS-AHCA-Med Ser., Form 035	ACS-AHCA-Med Ser., Form 035; this form needs to certify that the recipient is in need of an integrated set of assistive care services on a 24-hour basis, which includes at least two of four service components on a daily basis; make sure that it is filled out completely.
Admission/Discharge log	Evidence of an admission/discharge log on file for residents on the premises.
AFCH License	Evidence of an AFCH license available upon request to public.
Current county health department inspection.	Evidence of a current county health department inspection on file.
Current fire safety inspection	Evidence of a current fire safety inspection for the AFCH must be kept on file and ready for agency inspection.
Radon Testing (If applicable)	Documentation of radon testing shall be kept on the premises by the provider and ready for agency inspection for AFCHs located in counties requiring radon testing.
Emergency Plan	Evidence of an emergency plan kept by provider on the premises and in file; the AFCH shall have a written plan which specifies emergency and evacuation procedures for fires and such natural disasters as hurricanes, floods and tornadoes. There should also be an indication that the plan's emergency and evacuation procedures have been reviewed with the residents, the relief person, all staff and all household members.

Adult Family Care Home (AFCH) – cont'd.	
Element	Standard
Survey, complaint investigation reports and notices of sanctions and moratoriums issued to the AFCH	Evidence that the AFCH providers are keeping on the premises all completed survey and complaint investigation reports, and notices of sanctions and moratoriums issued to the AFCH by the agency within the last 3 years.
Emergency telephone numbers Emergency telephone numbers	Verify that the emergency telephone numbers are located by a designated telephone and includes emergency # 911, police #, fire dept. #, ambulance #, Florida Poison Info Ctr. #, Abuse Hotline#, AHCA's Field Office, etc.
Information regarding a resident's location to essential medical services providers in disaster/emergency situations	Evidence that in the event of a disaster/ emergency, the AFCH provider can make available all necessary information regarding a resident's location to essential medical service providers, both during and after the disaster/emergency.
Proof of fire safety inspection every 365 days	See Element and Standard #29
Written emergency evacuation procedures/rev	See Element and Standard #31
Emergency and first aid supplies	Check to see that the provider at all times maintains first aid and emergency supplies including a 3-day supply of non-perishable food based on the number of residents and household members currently residing in the home, and 2 gallons of drinking water per current resident and household member.
Telephone available/accessible for residents' use	Evidence that the ACFH, at a minimum, maintains a telephone in the home which is available and accessible for the resident's use at all times and placed in an area that allows facilitated private communication.
Non-ambulatory/impaired residents on ground floor	Verify that residents who are non- ambulatory or who require assistance with, or supervision of, ambulation are housed on the ground floor.
Grab bars for physically handicapped; hot water supervision	Verify that the bathrooms used by physically handicapped residents have grab bars for toilets, bathtubs and showers; verify that hot water temperature is supervised for persons unable to self-regulate water temperature.
Safety cover on hot tub/spa	Evidence that if the home has a hot tub or spa that it has a safety cover when not in use.
Supervision/aware resident whereabouts/ ensures safe/reminding of appointments and unattended no more than 2 hours	Evidence that the AFCH provider is providing general supervision 24 hours per day, where the provider is aware of the resident's whereabouts and well-being while the resident is in care of the AFCH. The resident may be with no supervision in an AFCH for up to 2 hours in a 24 hour period, as long as approved by the provider.

Adult Family Care Home (AFCH) – cont'd.	
Element	Standard
Report significant physical/mental changes, weight loss	Evidence that the AFCH provider is being responsible in observing, recording and reporting any significant changes in the resident's normal appearance, behavior or state of health; significant changes include a sudden or major shift in behavior or mood; a deterioration in health status, such as unplanned weight change, stroke, heart condition, or stage 2 pressure sore. Evidence of timeliness of LTC CM communication of all admissions, discharges and ER visits within 48-hours.
Medication Standards	Determine that correct assistance/supervision is being made when meds are given; that self-administration of meds is being encouraged verbally by trained staff; trained staff may also make available such items as water, juice, cups and spoons; trained staff must observe the resident take the medication; proof that for the facilities that provide medication administration that there is a staff member that has a license to administer meds in accordance with a health provider's order or prescription label to meet requirements; Documented proof that a list of all current prescribed meds is in file; Documented proof that a nurse is managing a pill organizer and/or list of centrally stored meds in container.
Element	Adult Living Facility Standard
RESIDENTS' RIGHTS	
Residents' rights posted.	Residents' rights must be visibly posted.
Residents informed of their rights.	Resident must be informed about their rights, documented in MR.
Safe and Homelike environment.	Review if environment is homelike and safe for the resident.
Use of needed adaptive equipment.	If resident has and uses the adaptive equipment needed for his/her condition and safety.
Resident participating in activities.	Review if resident is participating in activities.
Resident participation in selecting activities.	If resident was given opportunity to select activities.
Member's opinion about his/her room & general Environment.	Self explanatory.
Transportation arranged for medical appointments	Review in Medical records notation about transportation for medical appointments.
Encourage resident to participate on their	Notes about staff encouraging residents to participate in their
care.	care.
Resident funds for safekeeping	Staff keeps money or possessions for residents and give it back when resident needs/wants them.
Resident having his/her medicines all the time	Resident never run out of medications.

Adult Living Facility – cont'd.	
Element	Standard
Resident receiving assistance with other services	Residents receiving assistance with other services as needed, must be documented at MR.
Quality of food service	Resident opinion about food service in the Facility.
Staff attention to residents	How does staff communicates with residents and responds to their concerns.
RECORD REVIEW	
Height and weight	Documented correct height and weight on MR.
Diagnosis	Documented correct diagnosis and is in member's chart.
Allergies	Documented all of the member's allergies.
ADLs assessment and score	Documented full ADL (Activities of Daily Living) assessments and scores.
Evidence of special precautions taken	Documented all special precautions taken at this facility. (i.e. fall precautions, skin breakdown precautions, universal precautions, UTI precautions, precautions for PU).
Evidence of cognitive and behavioral assessment	Documented proof of assessment(s) done on member to determine his/her cognitive and behavioral levels.
If evidence of Pressure Ulcer stage II present in Member	Documented notes where it shows proof of wound care, any observations made by the RN and any notations if the wound is improving within 30 days.
Any significant changes in member's health	Documented any significant changes in member's health on MR.
Evidence of appropriate people notified of member's changes in his/her condition	Documented evidence that indicates that if there are any changes in the member's condition the significant people are notified (Family, guardian, CM, PCP, Psych/SW.
Medications	Indication that the medications ordered for the member are documented in the member's file
Annual MD evaluation of medical restraints	Documentation of annual MD evaluation for restraints.
Renewal of Restraints' Orders	Documented proof that Orders for Restraints have been renewed (if applicable).
Form 1823 completion	Demonstrate that Form 1823 (Resident Health Assessment for Assisted Living Facilities) is Filled out completely.
Photo ID of resident at elopement risk (if applicable)	Proof of a photo ID for resident if he/she is at risk of elopement.
Hospice services care plan on file (if applicable)	Proof of care plan for hospice services on file (if applicable).
ALF House Rules and Bill of Rights	Proof of copy of ALF House Rules and Bill of Rights.

Adult	Living Facility – cont'd.
Element	Standard
Contract signed by the guardian/surrogate (if applicable)	Proof of a contract signed by a guardian/ surrogate for the member. Evidence of timeliness of LTC CM communication of all admissions, discharges and ER visits within 48-hours.
LTC CM communication	Evidence of timeliness of LTC CM communication of all admissions, discharges and ER visits within 48 hours.
Safety Component	Determine if the environment for the ALF is clean and comfortable, home-like; are there NO safety hazards observed; look at adaptive equipment to make sure that it is clean and well maintained; look at the resident's appearance to make sure that it is well overall. Documentation or observation of restraints use. Make sure all medications are stored and secured properly; analyze if the staff is able to perform their duties; no evidence of allegations or suspect of abuse/neglect or exploitation.
Medication Standards	Determine that correct assistance/supervision is being made when medications are given; that self-administration of meds is being encouraged verbally by trained staff; trained staff may also make available such items as water, juice, cups and spoons; trained staff must observe the resident take the medication; proof that for facilities that provide medication administration that there is a staff member that has a license to administer meds in accordance with a health care provider's order or prescription label to meet requirements; Documented proof that a list of all current prescribed meds is in file; Documented proof that a nurse is managing a pill organizer and/or list of centrally stored meds in original container.
Sk Element	illed Nursing Facility Standard
RECORD REVIEW	
Member Name	Each page in the record contains member name of member ID number.
Each page in the record contains member name of member ID number.	Each page in the record contains member name of member ID number. Personal data includes address, employer, telephone numbers, Emergency contact, marital status, etc.
All entries signed/dated	Including dictation are signed or initiated by the licensed Professional. NA notes are to be cosigned by the supervising Professional. All verbal orders are cosigned by the physician. All entries are dated.
The record is legible	All parts of the enrollee record are legible.
Advanced directives	There is documentation of Advanced Directives being discussed and copy of the document if executed. DNR documentation if applicable.

Element	Skilled Nursing Facility Standard
Medication list	Medication list is up-to-date. There is a medication list with
ivieuication list	dosage and frequency of medication. Effectiveness of PRN medications is documented.
Administered medications	Evidence that all administered medications are recorded wh Given. Entries have complete signatures.
Medication Review	Evidence of medication review as required by member condition. At a minimum medications are reviewed annually.
Allergies	Allergies and adverse reactions are prominently displayed o the member's chart.
Past nursing history	Past nursing history including serious injuries, operations are illnesses, and secondary conditions and any other disorders that impact on the members care.
Past medical history	Past medical history including the physician's history, member's physical exam, and the current need for care.
Tobacco use	Tobacco use/non-use including tobacco, chew, pipe.
Alcohol/drugs use	Alcohol/ Illicit drugs/Legally prescribed drugs assessment
Diagnosis	Diagnosis is clearly related to services being rendered and t symptoms described.
Nutritional assessment	Documentation of a nutritional assessment. Documentation nutritional needs and responses at least quarterly.
Functional assessment	Documentation of functional assessment. Documentation includes skilled observations/assessment.
Pain assessment	Documentation on pain assessment.
Interdisciplinary team	There is documentation of an interdisciplinary team approat to care.
Physician's orders	Physician orders must be in writing and present in the reco
Member seen by physician	Evidence that the member has been seen by a physician or another licensed professional acting within their scope of pract at least 1X/30 days for the first 90 days and at least 1X/60 days thereafter.
LTC CM Communication	Evidence of Timelines of LTC CM communication of all admissions, discharges and ER visits within 48-hours
Plan of care	Plan of care completed 7 days after the assessment, within days of admission and every 12 months thereafter. Plan of Care reviewed every 3 months of promptly after a significant change Plan of care must include functional limitations and be written collaboration with the member, family or responsible party at t member's option.
	Skilled Nursing Facility
Element	Standard

Discharge planning	There is documentation of discharge planning and a discharge summary signed by physician within 30 days of discharge.
Social services	Evidence that social services are provided by a staff member with the appropriate training and experience and who is responsible for making integration arrangements so the member can return back into the community, transfer to a home, or transfer to another facility where appropriate level of care is available.
Relevant information	There is documentation of relevant information to the PCP/ordering physician on a regular basis, and at discharge. There is evidence of continuity and coordination of care between all members of the treatment team.
Designated FT employee	There is designated FT employee responsible and accountable for the facility's medical records. If this employee is not a qualified Medical Record Practitioner, then the facility shall have the services of a qualified Medical Record Practitioner on a consultan basis.
MEMBERS' RIGHTS	
Statement posted	Statement of Member Rights posted
Resident bills of rights copy	Evidence that members have been given a copy of the resident's bill of rights and that these have been discussed with the member.
Right to private communication	Rights statement include the right to have private communication with any person of his or her choice.
Right to present grievances	The right to present grievances on behalf of himself, herself, or others to the facility's staff or administrator, to government officials, or to any person without fear of reprisal, and to join with other patients or individuals to work for improvements in patient care.
Right to be fully informed	The right to be fully informed in writing, prior to at the time of admission and during his or her attendance, of fees and services not covered.
Right to be adequately informed	The right to be adequately informed of his or her medical condition and proposed treatment unless otherwise indicated in the written medical plan of treatment by the physician, and to participate in the planning of all medical treatment, including the right to refuse medication and treatment, unless otherwise indicated in the written medical plan of treatment by the physician, and to know the consequences of such actions.
Right of adequate care	The right to receive adequate and appropriate health care consistent with established and recognized practice standards within the community and with rules as promulgated by the AHCA.
	killed Nursing Facility – cont'd.
Element	Standard Sta

Right to privacy	The right to have privacy in treatment and in caring for personal needs, confidentiality in the treatment of personal and medical records.
Right to be treated courteously	The right to be treated courteously, fairly, and with the fullest measure of dignity and to receive a written statement of the services provided by the facility.
Right to freedom of choice	The right to freedom of choice in selecting a nursing home.
Staff training	Evidence that staff has been trained regarding residents' rights.
<u>SAFETY</u>	
Isolation	Members with communicable diseases are adequately and appropriately isolated.
Incidents report	Evidence of a system to report accidents, adverse, critical or unusual incidents to the Plan and to AHCA.
Staff Education	Staff Education plan contains prevention and control of infection, fire prevention, life safety and disaster preparedness, accident prevention and safety awareness program.
Environment	Environment is safe, clean, comfortable and home-like and it allows the member to sue personal belongings to the extent possible.
Disaster preparedness	Evidence of written Disaster Preparedness plan to be followed in the event of an internal or externally caused disaster.
Evidence of procedures	Evidence of procedures that assure the accurate acquiring, receiving, dispensing and administering of all drugs and biologicals to meet the needs of the members
Drugs and biologicals	Drugs and biologicals used in the facility shall be labeled in accordance with currently accepted professional principles, Chapter 499, F.S., and Chapter 64B16, F.A.C. Drugs and non-prescription medications requiring refrigeration shall be stored in a refrigerator. When stored in a general-use refrigerator, they shall be stored in a separate, covered, waterproof, and labeled receptacle.
Controlled substances	All controlled substances shall be disposed of in accordance with state and federal laws. All non-controlled substances may be destroyed in accordance with the facility's policies and procedures. Records of the disposition of all substances shall be maintained in sufficient detail to enable an accurate reconciliation.

Skille Element	ed Nursing Facility – cont'd. Standard
Additional standards for SNF that admit of	children 0-20
Evidence of assessment	Evidence of an assessment upon admission by licensed physical, occupational, and speech therapists who are experienced in working with children.
Determination of level of care	There is determination of LOC made a physician (intermediate/skilled/fragile nursing care).
Evidence of written order	Evidence of a written order by the child's attending physician in consolation with parents/legal guardians.
Medicaid certification	For Medicaid certified nursing facilities, the recommendations for placement of a Medicaid applicant or recipient in the nursing facility shall be made by the Multiple Handicap Assessment Team. Consideration must be given to relevant medical, emotional, psychosocial, and environmental factors.
Physician's orders	Documentation of Physician's orders, diagnosis, medical history, physical examination and rehabilitative or restorative needs.
Preliminary evaluation	A preliminary nursing evaluation with physician orders for immediate care, completed on admission.
Standardized assessment	A comprehensive, accurate, reproducible, and standardized assessment of each child's functional capability which is completed within 14 days of the child's admission to the facility and every twelve months thereafter. Assessment reviewed no less than once every 120 days or promptly after a significant change.
Plan of care	The plan of care should contain measurable objectives and timetables to meet the child's medical, nursing, mental and psychosocial needs identified in the comprehensive assessment. The Plan of care is completed within 7 days after the assessment and reviewed every 60 days.
Education	For children 3-15 there is evidence of home-bound education or attempts made by the facility to engage the County School Board. Children 16 - 20 years are enrolled in an education program according to their ability to participate.
Evaluation and documentation	Evidence that evaluation and documentation on the status of the child's condition is done at least monthly.
Verbal orders	Verbal orders are signed within 72 hours after the order was given.
Activities	There are indoor and outdoor activities designed to Encourage exploration and maximize the child's capabilities and that accommodate mobile and non-mobile children. Outdoor activities are held in secure with areas of sun and shade, free of safety hazards; and equipped with age appropriate recreational equipment for developmental level of children and has storage space for same.

	Skilled Nursing Facility – cont'd.
Element	Standard Sta
Emergency Medication Kit	The facility shall maintain an Emergency Medication Kit of pediatric medications, as well as adult dosages for those children who require adult doses.
Transportation	The facility must provide access to emergency and other forms of transportation for children.
Life support certification	At least one licensed health care staff person with current Life Support certification for children shall be on the unit at all times where children are residing.
Pediatric equipment	Pediatric equipment and supplies shall be available as follows Suction machines, oxygen, thermometers, sphygmomanometers, apnea monitor and pulse oximeter.
Additional standards geriatric out	patient nurse clinic
Maintain clinical record	The clinic shall maintain a clinical record for every patient receiving health services that contain the following: Identificatio data including name, address, telephone number, date of birth, sex, social security number, clinic case number if used, next of kir or guardian and telephone number, name and telephone numbe of patient's attending physician.
Health care plan	Health Care Plan including diagnose, type, and frequency of services and when receiving medications and medical treatments the medical treatment plan and dated signature of the health professional licensed in this state to prescribe such medications and treatments.
Clinical notes	Clinical notes, signed and dated by staff providing service.
Progress notes	Progress notes with changes in the patient's condition.
Services rendered	Documentation of services rendered with progress reports/Observations.
Instructions	Instructions provided to the patient and family.
Consultations	Evidence of consultation reports
Case conferences	Documentation of case discussion
Report to physicians	Documentation of reports provided
Termination summary	Termination summary including the reasons on for the termination, dates of first and last visit, total number of visits by discipline, evaluation of achievements of previously established goals and condition of the member at discharge.
Confidentiality	All clinical records shall be maintained confidential according to the law.
Prescriptions	All prescriptions for medications shall be noted on the patier record, and include the date, drug, dosage, frequency, method o site of administration, and the authorized health care professional's signature.

Skilled Nursing Facility – cont'd.	
Element	Standard
Verbal orders	All verbal orders for medication or medication changes shall be taken by the clinic registered nurse or physician's assistant. Such must be in writing and signed by the authorized health care professional within eight (8) days and added to the member's records.
Administered medications	The clinic registered nurse or physician's assistant shall record and sign for each medication administrated, by drug, dosage, method, time and site on patient's record.
Emergency plan/Kit	An emergency plan for reversal of drug reaction to include the facility's PRN standing orders for medications available in the emergency medication kit. If there is not a separate emergency medication kit in the clinic, the facility's emergency medication kit shall be immediately accessible for use in the outpatient clinic.
Prescribed medications	Prescribed medications for individual outpatients may be retained in clinic. These medications shall be stored separately from those of the nursing home in-patients for preventive measures and treatment of minor illnesses. Multi-dose containers shall be limited to medications or biologicals commonly prescribed for preventive measures and treatment of minor illnesses.
	Long-term care
Element	Standard
Demographic Data	Complete Administrative Component.
Contact Information	Emergency Contact Information Legal data; guardianship papers, court orders, release forms.
Permission/Consent	All permission, consent forms, assessments evaluations, medical and medication information.
Eligibility	Copies of eligibility documents, including level of care determination by CARES and LOC determinations.
Healthcare Practitioner	Name and contact information of PCP.
Current Medical Condition	Enrollee's current medical/functional/behavioral health status including strengths and needs.
Enrollee's support system	Identification of family/informal support system or community resources and their availability to assist the enrollee, including barriers to assistance; -Documentation of interaction and contacts (including telephone contacts) with enrollee, family of enrollees, service providers or others related to services -Documentation of issues relevant to the enrollee remaining in the community with supports and services consistent with his or her capacities and abilities. This includes monitoring achievement of goals and objectives as set forth in the plan of care.

Loi	ng-term care – cont'd.
Element	Standard
Enrollee's Participation	Enrollee's ability to participate in the review and/or who case manager discusses service needs and goals with if the enrollee was unable to participateEnvironmental and/or other special needs, if applicable.
Assessments	Needs assessments, including all physician referrals.
Plan of Care	Plan of care documented on medical record.
ALF residents	For enrollees residing in ALFs and AFCHs or receiving ADHC services, evidence of documentation of enrollee's response to HCB Settings Requirements queries and enrollee limitations.
Residential agreement	Agreement between facilities and the enrollee.
Authorizations	Record of Services authorization.
Assessments	CARES assessment documents.
Enrollee's Program information	Documentation that the enrollee has received and signed, if applicable, all required plan and program information (including copies of the enrollee handbook, provider directory, etc.) -Documentation of the discussion with the enrollee on the procedures for filing complaints and grievances; -Documentation of the choice of a participant-directed care option; -Documentation of the choice of PDO, initially, annually and upon reassessmentDocumentation of the signed participant agreement.
Notices to Enrollee	Notices of Action sent to the enrollee regarding denial or changes to services (discontinuance, termination, reduction or suspension) if applicable - Enrollee-Specific correspondence
Submission to DCF	Proof of submission to DCF of the completed CF-ES 2506A form.
Physicians orders/evaluations	Physicians' orders for LTC services and equipmentProvider evaluations, assessments, and/or Progress Notes (Home Health, Physical Therapy, Behavioral Health, etc.)

Long-term care – cont'd.	
Element	Standard
Case Management	Case Management Files - Case management enrollee file information is maintained by the Plan in compliance with state regulations for record retention. Per 42 CFR 441.303(c) (3), written and electronically retrievable documentation of all evaluations and re-evaluations shall be maintained as required in 45 CFR 92.42. The Plan specifies in policy where records of evaluation and re-evaluations of level of care are maintained and exchanged with the CARES unit. -Case notes including documentation of the type of contact made with the enrollee and/or all other persons who may be involved with the enrollee's care (e.g., providers) -Copy of the contingency plan and other documentation that indicates the enrollee/authorized representative has been advised regarding how to report unplanned gaps in authorized service delivery; copy of the disaster/emergency pan for the enrollee's household that considers the special needs of the enrollee. -Documentation of choice between institutional, home and community based services (HCBS). -Evidence of Care for Older Adults (COA) documentation -Documentation of choice between institutional and home and community based services. -Evidence of Timelines of LTC CM communication of all admissions, discharges and ER visits within 48-hours.

Behavioral Health		
Element Standard		
Demographic Data	Complete Administrative Component.	
Contact information	Emergency Contact Information; Guardian Contact, if applicable.	
Consent	Consent for Behavioral Health treatment that is signed by the recipient or the recipient's legal guardian. An explanation must be provided for signatures omitted in situations of exception.	
Evaluation/Assessment	Evidence of evaluation or assessment that is signed by the recipient or legal guardian, if applicable. Evaluation contains; Components of a brief behavioral health status exam; Evaluation is conducted by a physician, psychiatrist, a licensed practitioner of the healing arts (LPHA), or master's level certified addictions professional (CAP) for diagnostic and treatment planning purposes. -For new admissions, the evaluation or assessment by an LPHA for treatment planning purposes must have been completed within the past six months; -Copies of relevant assessments, reports, and tests; -Service notes (progress toward treatment plans and goals) -Documentation of service eligibility, if applicable. -Current treatment plans (within the last six months) -Current treatment Plan reviews and addenda. -Copies of all certification forms (e.g., comprehensive behavioral health assessment). -The practitioner's orders and results of diagnostic and laboratory tests. -Documentation of medication assessment, prescriptions and medication management -Copy of the Preadmission Screening and Resident Review (PASRR) Level I and II present on the record, if applicable.	
Service Documentation	Recipient's Name; Date the service was rendered; Start and	
Talomadicino	end times; Identification of the setting in which the service was rendered; Identification of the specific problem, behavior, or skill deficit for which the service is being provided; Identification of the service rendered. Updates regarding the recipient's progress toward meeting treatment related goals and objectives addressed during the provision of a service. -Dated signature of the individual who rendered the service -Printed or stamped name identifying the signature of the individual who rendered the service and the credentials (e.g., licensed clinical social worker) or functional title (e.g., treating practitioner)	
Telemedicine	If telemedicine, services must be delivered from a facility enrolled in Medicaid as a community behavioral health services provider.	

Behavioral Health – cont'd.		
Element Standard		
Presenting Problems	Presenting problems, along with relevant psychological and social conditions affecting the enrollee's medical and psychiatric status, are documented in the treatment record; relevant medical conditions are listed, prominently identified, and revised as appropriate in the treatment record. -Special status situation, such as suicidal ideation, or elopement potential, are prominently noted, documented and revised in the treatment record in compliance with Amerigroup Florida written protocols.	
Allergies	Allergies, adverse reactions or no known allergies are clearly documented in the treatment record.	
Medical History	A medical and psychiatric history is documented in the treatment record, including previous treatment dates, provider identification, therapeutic interventions and responses, sources of clinical data, relevant family information, results of laboratory tests, and consultation reports. This should include history of trauma, assessment of suicide risk and risk for aggressive behavior and history of psychiatric hospitalization and ED visits for psychiatric issues.	
Enrollees 12 and older	Documentation in the treatment record includes past and present use of cigarettes and alcohol as well as illicit, prescribed, and over-the-counter drugs. N/A if the enrollee is under the age of twelve. -A mental status evaluation that includes the enrollee's affect, speech, mood, thought content, judgment, insight, attention, concentration, memory and impulse control is documented in the treatment record. -A DSM-V/ICD10 diagnosis, consistent with the presenting problems, history, mental status examination, and/or other assessment data is documented in the treatment record -Treatment plans are consistent with diagnoses and have both objective measurable goals and estimated time frames for goal attainment or problem resolution. -The focus of treatment interventions is consistent with the treatment plan goals and objectives.	
Records	Each treatment record indicates what medications have been prescribed, the dosages of each, and the dates of initial prescription or refills. For non-prescribing practitioners, each treatment record indicates what medications have been prescribed and the name of the prescriber. N/A is scored if medications are not prescribed.	
Informed Consent	Informed consent for medication and the enrollee's level of understanding is documented. N/A if medication is not prescribed or the practitioner being reviewed is not a prescriber (e.g., MSW, PhD)	

Behavioral Health – cont'd.		
Element	Standard	
Medications	When medication is prescribed, there is evidence of consistency among the signs and symptoms, diagnosis, and medication prescribed. N/A is scored if medication is not prescribed or the practitioner being reviewed is not a prescriber (e.g. MSW, PhD)	
Progress Notes	Progress notes describe enrollee strengths and limitations in achieving treatment plan goals and objectives.	
Homicidal/Suicidal	Enrollees who become homicidal, suicidal, or unable to conduct activities of daily living are promptly referred to the appropriate level of care. N/A is scored if the enrollee is not homicidal, suicidal, or unable to conduct activities of daily living.	
Treatments	The treatment record documents preventive services, as appropriate (e.g. relapse prevention, stress management, wellness programs, lifestyle changes, and referrals to community resources). -The treatment record documents dates of follow-up appointments or, as appropriate, a discharge plan. -There is evidence that the clinical assessment is culturally relevant (i.e. addresses issues relevant to the enrollee's race, religion, ethnicity, age, gender, sexual orientation, level of education, socio-economic level, etc.) -The treatment record has evidence of continuity and coordination of care between behavioral healthcare institutions, ancillary providers and or consultants; There is evidence in the record of coordination of care with the PCP or declination of this coordination by the enrollee.; -The treatment record reflects evidence of coordination of care with other outpatient behavioral health practitioners -The record reflects evidence of coordination with the EAP/employer if a referral was made; The record reflects linking to community services or other support services.	
Abuse and domestic violence Reports and Evidence	Evidence that suspected or reported vulnerable adult/child abuse is reported to the appropriate authorities.; Evidence that the Plan was notified within 24-hours of awareness of incident; Evidence the provider screened enrollees for signs of domestic violence and provided referral services to applicable domestic-violence prevention community agencies.	

Behavioral Health – cont'd.		
Element	Standard	
Child and adolescents		
Records Only	For children and adolescents, prenatal and perinatal events, along with a complete developmental history including physical, psychological, social, intellectual, and academic are documented in the treatment record. N/A if the enrollee is over the age of 18. -The record reflects the active involvement of the family/primary caretakers in the assessment and treatment of the enrollee, unless contraindicated. -The record indicates the parent(s) or caretaker(s) have given signed consent for the various treatments provided. - The record shows evidence of an assessment of school functioning. -The record shows evidence of coordination with the youth's school to achieve school related treatment goals. -Documentation of the express written and informed consent of the enrollee's authorized representative for prescriptions for psychotropic medication (i.e., antipsychotics, antidepressants, antianxiety medications, and mood stabilizers) prescribed for an enrollee under the age of thirteen (13) years.	
Treatment Record-Based Adherence Indicators	Score these items if the diagnosis for any case reviewed is in the 295, 296.2, 296.0x, 296.40, 296.4x, 296.5x, 296.6x, 296.7, 296.89 or 314 series. Data related to these adherence indicators is used only in the aggregate – it does not enter into the total score/evaluation of the records of this individual practitioner but the results are shared with the practitioner.	
Major Depression – 296.2 or 296.3 Series	Evidence of a comprehensive assessment that takes into account both the degree of functional impairment and /or disability associated with the depression and the duration of episode, history of depression and comorbid mental health or physical disorders, any past history of mood elevation, any past experience of, and response to treatments, the quality of interpersonal relationships, living conditions and social isolation, culture, social determinants and support system. OB/GYN and maternity history, if applicable. Evidence of substance use/abuse screening. Mood symptoms and suicidality are assessed at every visit; Comorbid problems are assessed upon initial evaluation and at least annually; When medication is prescribed, there is evidence of consistency among the signs and symptoms, diagnosis, and medication prescribed. N/A if medication is not prescribed or the practitioner being reviewed is not a prescriber (e.g. MSW, PhD)	

Behavioral Health – cont'd.		
Element	Standard	
Schizophrenia – 295 Series	There is evidence of an assessment of positive signs of psychosis, e.g., delusions and/or hallucinations. -Co-morbid problems are assessed upon initial evaluation and at least annually -When medication is prescribed, there is evidence of consistency among the signs and symptoms, diagnosis, and medication prescribed. N/A if medication is not prescribed or the practitioner being reviewed is not a prescriber (e.g., MSW, PhD) -When anti-psychotic medications are prescribed, there is evidence of observation for side effects including EPS such as dystonic reactions, akathisia, ("can't sit still"), or akinesia. {Note: this applies to all discipline levels; N/A may not be checked)	
ADHD- 314.00; 314.01; 314.9	-The record reflects the active involvement of the family/primary caregivers in the assessment and treatment of the enrollee unless contraindicated. N/A is scored if contraindicatedCo-morbid problems are assessed upon initial evaluation and at least semi-annuallyThe record reflects education about ADHD and parent training in behavioral managementWhen medication is prescribed, there is evidence of consistency among the signs and symptoms, diagnosis, and medication prescribed. N/A is scored if medication is not prescribed or the practitioner being reviewed is not a prescriber (e.g., MSW, PhD) -When medication is prescribed, there is evidence of an evaluation of the enrollee's response to medication and adjustments as needed.	
Bipolar Disorder - 296.0x, 296.40, 296.4x, 296.5x, 296.6x, 296.7, 296.89 Series	Mood symptoms and suicidality are assessed at every visit; -Co-morbid problems are assessed upon initial evaluation and at least annuallyWhen medications are prescribed that require serum level monitoring and/or laboratory tests to screen for medication side effects, those tests are conducted as recommended by the drug manufacturer. N/A is scored for non-prescribing practitioners (e.g. MSW, PhD).	
Diabetes Screening/Monitoring and Cardiovascular Disease for Patients with Schizophrenia or Bipolar Disorder	-There is evidence of diabetes screening for people with schizophrenia or bipolar disorder who are using antipsychotic -There is evidence of care coordination with PCP/Specialist treating the diabetes to ascertain appropriate monitoring -There is evidence of care coordination with PCP/Specialist treating cardiovascular disease for patients with schizophrenia or bipolar disorder.	

B	Behavioral Health – cont'd.		
Element	nt Standard		
Co-Occurring Psychiatric and Substance Related List One — Psych Diagnoses Major Depression — 296.XX Bipolar Disorder — 296.XX Schizophrenia — 295.XX Depressive Disorder NOZ — 311			
	- Treatment plan includes both SA and psychiatric issues and		
Opioid-Related Disorders – 304.00, 305.50, 292.89x, 292.81x	- Treatment plan includes both SA and psychiatric issues and interventions Withdrawal evaluation completed within 24 hours to determine the level of detoxification services needed (level I D through level IV D, refer to ASAM PPC-2 -The evaluation includes the documentation of consideration of appropriate pharmacotherapy for substance abuse disorder. Rationale is provided for each component of the treatment plan including additional medications -Co-occurring) disorders should be assessed to identify both medical and psychiatric symptoms, which may be masked by substance abuse. If a co-occurring disorder is present, there must be evidence of coordination of care with the medical provider. -Evaluation of behaviors correlated with continues use and abuse of illicit drugs -Family/support system involvement in treatment, when appropriate.		
So	cial Determinants of Health		
Element Economic stability	Evidence of screening for financial problems, housing, living situation, utility needs and employment. Food insecurity/ Transportation Needs.		
Education	Level of education, language and literacy.		
Social and community context	Civic participation, discrimination and incarceration.		
Health and health care	Medical problems/illnesses/Hospitalizations/Surgeries/ Infectious Diseases/Gynecological Conditions/Infertility/ Mental Health disorders/Screening for Depression/ Stress/Substance Abuse/Violence/Domestic Violence/ Serious accidents/ Disabilities/Access to primary care and health literacy. Physical activity		
Neighborhood and built environment	Family and community support, environmental conditions, crime and violence.		

COVID-19		
Element	Standard	
Population	Age 65 years or older	
Past medical history	Immunocompromised /Special Healthcare Needs/Disabilities	
Signs and Symptoms	Cough, fever, shortness of breath, mild/severe	
Exposure	Recent travel, hospitalization, facility/other exposure from family member/caregiver	
Testing	Type of test used (Viral/Antibody test), Result/Referral, Repeated test.	
Quarantine & Isolation	Advised to home quarantine	
Positive Covid-19	Confirmed positive result	
Hospitalization & treatment	Documentation of hospital admission, ER visit, treatment and a copy of the Hospital and D/C records must be place in the Medical Records	
	Cognitive Assessment	
Element	Standard	
Cognitive Assessment	Evidence that cognitive assessment tools have been used to identify cognitive impairments and determine whether a full dementia evaluation is needed to assess for a possible dementia syndrome.	

References:

Condition/disease	Guideline title	Recognized source(s)	URL
ADULT HEALTH			
Alzheimer's Disease/Dementia	Practice Guideline for the Treatment of Patients with Alzheimer's Disease and Other Dementias (Guideline Watch October 2014)	American Psychiatric Association (APA)	https://psychiatryonline.org/pb/assets/raw/sit ewide/practice_guidelines/guidelines/alzheime rwatch.pdf
Anxiety	Anxiety Disorders (Last Revised July 2018)	National Institute of Mental Health (NIMH)	http://www.nimh.nih.gov/health/publications/ anxiety-disorders/treatment-of-anxiety- disorders.shtml
Asthma	Guidelines for the Diagnosis and Management of Asthma (EPR-3) (August 2007)	National Heart, Lung and Blood Institute (NHLBI)	https://www.nhlbi.nih.gov/health- topics/guidelines-for-diagnosis-management- of-asthma
Asthma	Asthma Clinical Practice Guidelines (2019)	Global Initiative for Asthma (GINA)	https://ginasthma.org/
Behavioral Health Screening, Assessment and Treatment	The American Psychiatric Association Practice Guidelines for the Psychiatric Evaluation of Adults 3rd edition (August 2015)	American Psychiatric Association (APA)	https://psychiatryonline.org/doi/full/10.1176/appi.books.9780890426760.pe02
Bipolar Disorder* *addresses diagnosis and treatment of bipolar disorder in special populations such as children and adolescents	CANMAT and International Society for Bipolar Disorders (ISBD) 2018 guidelines for the management of patients with bipolar disorder	Canadian Network for Mood and Anxiety Treatments (CANMAT)	https://www.canmat.org/2019/03/27/2018-bipolar-guidelines
Coronary Artery	AHA / ACCF Secondary Prevention and Risk Reduction Therapy for Patients With Coronary and Other Atherosclerotic Vascular Disease (November 2011 Update)	American Heart Association/ American College of Cardiology Foundation (AHA/ACCF)	https://www.ahajournals.org/doi/pdf/10.1161 /CIR.0b013e318235eb4d
Disease (CAD)	Treatment of Hypertension in Patients With Coronary Artery Disease (March 2015)	American Heart Association, American College of Cardiology, and American Society of Hypertension	https://www.ahajournals.org/doi/pdf/10.1161 /CIR.000000000000000000000000000000000000

Condition/disease	Guideline title	Recognized source(s)	URL
ADULT HEALTH - Cont'd			
Disease (CAD) (cont'd)	Effectiveness-Based Guidelines for the Prevention of Cardiovascular Disease in Women- 2011 Update (February 2011)	American Heart Association (AHA)	https://www.ahajournals.org/doi/pdf/10.1161 /CIR.0b013e31820faaf8
	ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease (2019)	American College of Cardiology/American Heart Association (ACC/AHA)	http://www.onlinejacc.org/content/accj/74/10 /e177.full.pdf?_ga=2.181326051.571613739.1 574282939-178208357.1556140440
Celiac Disease	ACG Clinical Guidelines: Diagnosis and Management of Celiac Disease (April 2013)	American College of Gastroenterology	http://gi.org/wp-content/uploads/2013/05/ACG_Guideline_CeliacDisease_May_2013.pdf
Fou Out (NK clini all s dise	The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI)™ evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD) and related complications	National Kidney Foundation	https://www.kidney.org/professionals/guidelines/guidelines_commentaries
	Chronic Kidney Disease: Detection and Evaluation (2017)	American Academy of Family Physicians (AAFP)	https://www.aafp.org/afp/2017/1215/p776.ht ml
Chronic Kidney	National Chronic Kidney Disease Fact Sheet (2017)	Centers for Disease Control and Prevention (CDC)	https://www.cdc.gov/diabetes/pubs/pdf/kidne y_factsheet.pdf
Disease (CKD)	KDIGO (Kidney Disease Improving Global Outcomes) 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (January 2013)	International Society of Nephrology	http://www.kdigo.org/clinical_practice_guidelines/pdf/CKD/KDIGO_2012_CKD_GL.pdf
	KDIGO (Kidney Disease Improving Global Outcomes) 2017 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (July 2017)	International Society of Nephrology	https://kdigo.org/wp- content/uploads/2017/02/2017-KDIGO-CKD- MBD-GL-Update.pdf
Chronic Obstructive Pulmonary Disease (COPD)	Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2019)	Global Initiative for Chronic Obstructive Lung Disease (GOLD)	http://goldcopd.org/gold-reports/

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Condition/disease	Guideline title	Recognized source(s)	URL
ADULT HEALTH - Cont'd			
	Depression in Adults: Screening (January 2016)	U.S. Preventive Services Task Force (USPSTF)	https://www.uspreventiveservicestaskforce.or g/Page/Document/UpdateSummaryFinal/depr ession-in-adults-screening1
	CANMAT Clinicians Guidelines 2016 Depression Guidelines	Canadian Network for Mood and Anxiety Treatments (CANMAT)	https://www.canmat.org/resources/
Depression	Nonpharmacologic Versus Pharmacologic Treatment of Adult Patients With Major Depressive Disorder: A Clinical Practice Guideline From the American College of Physicians (2016)	American College of Physicians (ACP)	https://annals.org/aim/fullarticle/2490527/no npharmacologic-versus-pharmacologic- treatment-adult-patients-major-depressive- disorder- clinical?_ga=2.240375883.977749235.1576523 219-1562492790.1557437793
	Depression in adults: recognition and management Clinical Guideline CG90 (Updated April 2018).	National Collaborating Centre for Mental Health <i>commissioned by</i> <i>the</i> National Institute for Health & Clinical Excellence	https://www.nice.org.uk/guidance/cg90/resources/depression-in-adults-recognition-and-management-pdf-975742638037
Diabetes	Standards of Medical Care in Diabetes (January 2019)	American Diabetes Association (ADA)	http://care.diabetesjournals.org/content/42/S upplement_1
Gender-Dysphoria/	Endocrine Treatment of Gender-Dysphoric/Gender- Incongruent Persons: An Endocrine Society* Clinical Practice Guideline (September 2017)	The Endocrine Society	https://academic.oup.com/jcem/article/102/1 1/3869/4157558
Incongruence	Correction to Clinical Practice Guideline (February 2018)		https://academic.oup.com/jcem/article/103/2/699/4675081
	Correction to Clinical Practice Guideline (July 2018)		https://academic.oup.com/jcem/article/103/7/ 2758/5036711
	Falls Prevention in Community- Dwelling Older Adults: Interventions	U.S. Preventive Services Task Force (USPSTF)	https://www.uspreventiveservicestaskforce.or g/Page/Document/RecommendationStatemen tFinal/falls-prevention-in-older-adults- interventions1
Fall Risk	Evidence –Based Falls Prevention Programs: Resources for Professionals and Advocates	National Council on Aging	https://www.ncoa.org/center-for-healthy-aging/falls-resource-center/falls-prevention-tools-and-resources/resources-for-professionals/

Condition/disease	Guideline title	Recognized source(s)	URL
ADULT HEALTH - Cont'd			
Heart Failure (HF)	2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines (October 2013)	American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines/ Heart Failure Society of America (ACCF/ AHA/HFSA)	http://www.onlinejacc.org/content/62/16/e14 7?ijkey=079f90818917662ed8e6c54bd132bb1 0bede26a1&keytype2=tf_ipsecsha
	ACCF/AHA/HFSA Guideline for the Management of Heart Failure (Focused Update 2017)		http://www.onlinejacc.org/content/70/6/776? _ga=2.23313085.667318568.1514996759- 679389624.1511900706
Hyperlipidemia	2018 AHA/ACC/AACVPR/AAPA/ABC/ ACPM/ADA/AGS/APhA/ASPC,N LA/PCNA Guideline on the Management of Blood Cholesterol (October 2018)	American College of Cardiology/American Heart Association/ American Association of Cardiovascular and Pulmonary Rehabilitation/American Academy of Physician Assistants/Association of Back Cardiologists/American College of Preventive Medicine/American Diabetes Association/American Geriatrics Society/American Pharmacists Association/American Society of Preventive Cardiology/National Lipid Association/Preventive Cardiovascular Nurses Association (ACC/AHA/AACVPR/AAPA/ABC/AC PM/ADA/AGS/APhA/ASPC/NLA/PC NA)	https://www.acc.org/~/media/Non- Clinical/Files-PDFs-Excel-MS-Word- etc/Guidelines/2018/Guidelines-Made-Simple- Tool-2018-Cholesterol.pdf
Hypertension	ACC/AHA/AAPA/ABC/ACPM/A GS/APhA/ASH/ASPC/NMA/PCN A Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults (November 2017) Correction to Guideline (May 2018)	American College of Cardiology (ACC)/ American Heart Association (AHA)/ American Academy of Physician Assistants (AAPA)/ Association of Black Cardiologists (ABC)/ American College of Preventive Medicine (ACPM)/ American Geriatrics Society (AGS)/ American Pharmacists Association (APhA)/ American Society of Hypertension (ASH)/ American Society for Preventive Cardiology (ASPC)/ National Medical Association (NMA)/ Preventive Cardiovascular Nurses Association (PCNA)	http://www.onlinejacc.org/content/early/2017 /11/04/j.jacc.2017.11.006?sso=1&sso_redirect _count=1&access_token= http://www.onlinejacc.org/content/71/19/227 5

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ADULT HEALTH - Cont'd			
Low back Pain	Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians (2017)	American College of Physicians (ACP)	https://annals.org/aim/fullarticle/2603228/no ninvasive-treatments-acute-subacute-chronic-low-back-pain-clinical-practice?_ga=2.247433220.1028399561.15754 92235-1562492790.1557437793
	Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults(September 2018)	U.S. Preventive Services Task Force (USPSTF)	https://www.uspreventiveservicestaskforce.or g/Page/Document/UpdateSummaryFinal/obesi ty-in-adults-interventions1
Obesity	AHA /ACC /TOS Guideline for the Management of Overweight and Obesity in Adults (November 2013)	American College of Cardiology (ACC)/ American Heart Association (AHA) Task Force on Practice Guidelines and The Obesity Society (TOS)	http://circ.ahajournals.org/content/early/2013 /11/11/01.cir.0000437739.71477.ee
Oppositional Defiant Disorder (ODD)	Common Questions About Oppositional Defiant Disorder (April 2016)	American Academy of Family Physicians (AAFP)	https://www.aafp.org/afp/2016/0401/p586.pd f
	Clinical Practice Guideline for the Treatment of Posttraumatic Stress Disorder (PTSD) in Adults (February 2017)	American Psychiatric Association (APA)	https://www.apa.org/ptsd-guideline/ptsd.pdf
Posttraumatic Stress Disorder	VA/DOD Clinical Practice Guideline for the Management of Posttraumatic Stress Disorder and Acute Stress Disorder (V3.2017)	Department of Veterans Affairs Department of Defense: The Management of Posttraumatic Stress Disorder Work Group	https://www.healthquality.va.gov/guidelines/ MH/ptsd
	PTSD Screening Instruments	Department of Veterans Affairs: PTSD: National Center for PTSD	https://www.ptsd.va.gov/professional/assess ment/screens/index.asp
	American College of Rheumatology: Referral Guidelines (August 2015)	American College of Rheumatology (ACR)	https://www.rheumatology.org/Portals/0/Files /Referral%20Guidelines.pdf
Rheumatoid Arthritis	2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis (October 2015)		https://www.rheumatology.org/Portals/0/Files /ACR%202015%20RA%20Guideline.pdf

Condition/disease	Guideline title	Recognized source(s)	URL
ADULT HEALTH - Cont'd			
Schizophrenia	Treatment Guidelines: Schizophrenia	Page maintained by the College of Psychiatric & Neurologic Pharmacists (CPNP). Sources include, but not limited to: • Agency for Health Research and Quality (AHRQ) • American Academy of Child & Adolescent Psychiatry • American Psychiatric Association (APA) • Canadian Psychiatric Association National Institute for Health and Clinical Excellence (NICE) Guidelines	https://cpnp.org/guideline/external/schizophrenia
Sickle Cell Anemia	Evidence-Based Management of Sickle Cell Disease: Expert Panel Report (September 2014)	National Heart, Lung, Blood Institute (NHLBI)	https://www.nhlbi.nih.gov/health- topics/evidence-based-management-sickle- cell-disease
Suicide Risk	SAFE-T: Suicide Assessment Five Step Evaluation and Triage Assessment and Management of Patients at Risk for Suicide	Suicide Prevention Resource Center (SPRC) Veterans Administration/ Department of Defense (VA/DoD)	https://www.integration.samhsa.gov/images/res/SAFE_T.pdf https://www.healthquality.va.gov/guidelines/mh/srb/index.asp
	(2019) Surgical technical evidence review for gynecologic surgery conducted for the Agency for Healthcare Research and Quality Safety Program for Improving Surgical Care and Recovery (December 2018)	Agency for Healthcare Research and Quality (AHRQ)	https://www.ajog.org/article/S0002- 9378(18)30583-0/pdf
Surgery	Surgical Technical Evidence Review for Colorectal Surgery Conducted for the AHRQ Safety Program for Improving Surgical Care and Recovery (October 2017)	AHRQ	https://www.ncbi.nlm.nih.gov/pubmed/28797 562
	Surgical Technical Evidence Review for Elective Total Joint Replacement Conducted for the AHRQ Safety Program for Improving Surgical Care and Recovery (February 2018)	AHRQ	https://journals.sagepub.com/doi/pdf/10.1177 /2151458518754451

Condition/disease	Guideline title	Recognized source(s)	URL
ADULT HEALTH - Cont'd			
Trauma Care	A Treatment Improvement Protocol: Trauma-Informed Care in Behavioral Health Services (2014)(2014) Trauma-Informed Care in Behavioral Health Services:	Substance Abuse and Mental Health Services Administration (SAMHSA)	https://store.samhsa.gov/system/files/sma14- 4816_litreview.pdf https://store.samhsa.gov/series/tip-series- treatment-improvement-protocols-tips
	Treatment Improvement Protocol (TIP) Series		
INFECTIOUS DISEASE – R	Return to Table of content		
Chlamydia/ Human Papillomavirus (HPV)	Sexually Transmitted Diseases Treatment Guidelines	Center for Disease Control and Prevention (CDC)	https://www.cdc.gov/std/tg2015/tg-2015- print.pdf
Hepatitis B	AASLD Guidelines for Treatment of Chronic Hepatitis B (August 2015)	American Association for the Study of Liver Diseases (AASLD)	http://www.aasld.org/sites/default/files/guidel ine_documents/hep28156.pdf
	Update on Prevention, Diagnosis, and Treatment of Chronic Hepatitis B: AASLD 2018 Hepatitis B Guidance (Jan 2018)		https://www.aasld.org/sites/default/files/2019 -06/HBVGuidance_Terrault_et_al-2018- Hepatology.pdf
Hepatitis C	HCV Guidance: Recommendations for Testing, Managing and Treating Hepatitis C	Infectious Diseases Society of America (IDSA)/ American Association for the Study of Liver Disease (AASLD)	http://www.hcvguidelines.org/
	Guidelines for the Screening, Care and Treatment of Persons with Chronic Hepatitis C Infection (April 2016)	World Health Organization (WHO)	http://apps.who.int/iris/bitstream/handle/106 65/205035/9789241549615_eng.pdf;jsessionid =569946A6B8399B8CED0D09D7F7A9BD3C?seq uence=1
HIV/AIDS	Primary Care Guidelines for the Management of Persons Infected With HIV: 2013 Update by the HIV Medicine Association of the Infectious Diseases Society of America (November 2013)	HIV Medicine Association of the Infectious Diseases Society of America (IDSA	https://www.idsociety.org/practice-guideline/primary-care-management-of-patients-infected-with-hiv/
	Recommendations for HIV Prevention with Adults and Adolescents with HIV in the United States (December 2014)	Centers of Disease Control and Prevention (CDC)	https://stacks.cdc.gov/view/cdc/44064
	2017 HIVMA of IDSA Clinical Practice Guideline for the Management of Chronic Pain in Patients Living With HIV (September 2017)	Infectious Diseases Society of America	https://www.idsociety.org/globalassets/idsa/practice-guidelines/2017-hivma-of-idsa-clinical-practice-guideline-for-the-management-of-chronic-pain-in-patients-living-with-hiv.pdf
	HIV and Adolescents: Guidance for HIV testing and counselling and care for adolescents living with HIV (2013)	World Health Organization (WHO)	http://apps.who.int/iris/bitstream/handle/106 65/94334/9789241506168_eng.pdf?sequence =1

Condition/disease	Guideline title	Recognized source(s)	URL
		olar Disorder for resources for bipolar o	disorder in the pediatric and adolescent
Attention Deficit Hyperactivity Disorder (ADHD)	Table of Content. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents (October 2019)	American Academy of Pediatrics (AAP)	https://pediatrics.aappublications.org/content /144/4/e20192528
Autism	Practice parameter: Screening and diagnosis of autism (Reaffirmed August 2014) Identification Evaluation and Management of Children With Autism Spectrum Disorder (January 2020)	American Academy of Neurology (AAN) and the Child Neurology Society (CNS) American Academy of Pediatrics (AAP)	https://n.neurology.org/content/neurology/55 /4/468.full.pdf https://pediatrics.aappublications.org/content /pediatrics/early/2019/12/15/peds.2019- 3447.full.pdf
Celiac Disease	Guideline for the Diagnosis and Treatment of Celiac Disease in Children: Recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (January 2005)	North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN)	http://www.naspghan.org/files/documents/pd fs/position- papers/celiac_guideline_2004_jpgn.pdf
Depression	Depression in Children and Adolescents: Screening (February 2016) Depression in children and young people: identification and management (updated September 2017)	U.S. Preventive Services Task Force (USPSTF) National Institute for Health and Care Excellence (NICE)	https://www.uspreventiveservicestaskforce.or g/Page/Document/UpdateSummaryFinal/depr ession-in-children-and-adolescents-screening1 https://www.nice.org.uk/guidance/cg28/resou rces/depression-in-children-and-young-people- identification-and-management-pdf- 975332810437
Hypertension in Children and Adolescents	Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents (September 2017)	American Academy of Pediatrics (AAP)	http://pediatrics.aappublications.org/content/pediatrics/140/3/e20171904.full.pdf
Obesity	Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report (December 2007)	American Academy of Pediatrics (AAP)	http://pediatrics.aappublications.org/content/ 120/Supplement_4/S164.full.pdf
	Clinical Report: The Role of the Pediatrician in Primary Prevention of Obesity (July 2015)	American Academy of Pediatrics (AAP)	http://pediatrics.aappublications.org/content/early/2015/06/23/peds.2015-1558

Condition/disease	Guideline title	Recognized source(s)	URL
		olar Disorder for resources for bipolar o	disorder in the pediatric and adolescent
Oppositional Defiant Disorder (ODD)	Table of Content. – Cont'd. Fifty years of preventing and treating childhood behavior disorders: a systematic review to inform policy and practice (April 2017)	National Institute of Health (NIH) PubMed	https://www.ncbi.nlm.nih.gov/pmc/articles/P MC5950520/
SUBSTANCE USE – Retur	n to Table of Content. – Cont'd.		
	Medication-Assisted Treatment of Adolescents With Opioid Use Disorders (September 2016)	American Academy of Pediatrics (AAP)	http://pediatrics.aappublications.org/content/early/2016/08/18/peds.2016-1893
Substance use	Unhealthy Alcohol Use in Adolescents and Adults: Screening and Behavioral Counseling Interventions (November 2018)	U.S. Preventive Services Task Force (USPSTF)	https://www.uspreventiveservicestaskforce.or g/Page/Document/UpdateSummaryFinal/unhe althy-alcohol-use-in-adolescents-and-adults- screening-and-behavioral-counseling- interventions
	CDC Guideline for Prescribing Opioids for Chronic Pain — United States (March 2016)	Centers for Disease Control and Prevention (CDC)	http://www.cdc.gov/mmwr/volumes/65/rr/rr6 501e1.htm
	Medication-Assisted Treatment (MAT) (Last Updated February 2018)	Substance Abuse Mental Health Services Administration (SAMHSA)	http://dpt.samhsa.gov/
	Smoking & Tobacco Use	Center for Disease Control and Prevention (CDC)	https://www.cdc.gov/tobacco/index.htm
	Identifying and Treating Patients Who Use Tobacco (July 2017)	U.S. Department of Health and Human Services	https://millionhearts.hhs.gov/files/Tobacco- Cessation-Action-Guide.pdf
	ACC Expert Consensus Decision Pathway on Tobacco Cessation Treatment (2018)	American College of Cardiology (ACC)	http://www.onlinejacc.org/content/accj/early/2018/11/29/j.jacc.2018.10.027.full.pdf?_ga=2.215406675.571613739.1574282939-178208357.1556140440
Electronic Cigarettes	Electronic Cigarettes	Centers for Disease Control and Prevention (CDC)	https://www.cdc.gov/tobacco/basic_informati on/e-cigarettes/index.htm
All states offer free smoking cessation telephone quit line services. Dialing 1-800-QUIT NOW will connect the caller to their state quit line.			
WOMEN'S HEALTH – Re Routine Antepartum Care	American Academy of Pediatrics, Guidelines for Perinatal Care, Eighth Edition (September 2017)	American Academy of Pediatrics (AAP) & American Congress of Obstetrics and Gynecology (ACOG)	https://shop.aap.org/guidelines-for-perinatal- care-8th-edition-ebook/ Members only
Preventive Care	Women's Preventive Services Guidelines. (Last Reviewed 2017)	Health Resources and Services Administration (HRSA)	https://www.hrsa.gov/womens-guidelines- 2016/index.html

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WOMEN'S HEALTH – Ref	turn to Table of Contents – Cont'd.		
Cancer Screening	Women's Health Care Physicians: Cervical Cancer FAQs (December 2015)	American Congress of Obstetrics and Gynecology (ACOG)	https://www.acog.org/Patients/FAQs/Cervical- Cancer
	Cervical Cancer: Screening (August 2018)	U.S. Preventive Services Task Force (USPSTF)	https://www.uspreventiveservicestaskforce.or g/Page/Document/UpdateSummaryFinal/cervi cal-cancer-screening
	Management of Diabetes in Pregnancy (January 2019)	American Diabetes Association (ADA)	http://care.diabetesjournals.org/content/42/S upplement_1/S165
	Gestational Diabetes Mellitus, Screening (January 2014)	United States Preventive Services Task Force (USPSTF)	https://www.uspreventiveservicestaskforce.or g/Page/Document/UpdateSummaryFinal/gesta tional-diabetes-mellitus- screening?ds=1&s=gestational diabetes
Diabetes and Pregnancy	Gestational Diabetes	American Congress of Obstetrics and Gynecology (ACOG)	http://www.acog.org/Search?Keyword=gestati onal+diabetes
	Postpartum Screening for Abnormal Glucose Tolerance in Women Who Had Gestational Diabetes Mellitus	American Congress of Obstetrics and Gynecology (ACOG)	http://www.acog.org/Search?Keyword=Postpa rtum+Screening+for+Abnormal+Glucose+Toler ance+in+Women+Who+Had+Gestational+Diab etes+Mellitus&Topics=43d4646b-dc34-4c12- abeb-bb516387312f Members only
Obstetrical Care	Guidelines for Antenatal Care	American Congress of Obstetrics and Gynecology (ACOG)	https://www.acog.org/Search?Keyword=anten atal&Topics=906bff1e-0656-4579-a7df- 4a22f9bce483
	WHO recommendations for Prevention and treatment of pre-eclampsia and eclampsia (2011)	World Health Organization (WHO)	http://whqlibdoc.who.int/publications/2011/9 789241548335_eng.pdf
	Committee Opinion 455. Magnesium Sulfate Before Anticipated Preterm Birth for Neuroprotection (Reaffirmed 2018)	American Congress of Obstetrics and Gynecology (ACOG)/ Society for Maternal Fetal Health (SMFH)	https://www.acog.org/Clinical-Guidance-and- Publications/Committee-Opinions/Committee- on-Obstetric-Practice/Magnesium-Sulfate- Before-Anticipated-Preterm-Birth-for- Neuroprotection
	Pre-Gestational Diabetes Mellitus Number 201 (December 2018)	American Congress of Obstetrics and Gynecology (ACOG)	https://www.acog.org/Search?Keyword=prege stational+diabetes Members only
	Management of Preterm Labor Number 171 (Reaffirmed 2018)	American Congress of Obstetrics and Gynecology (ACOG)	http://www.acog.org/Search?Keyword=manag ement+of+preterm+labor Members only
	Gestational Hypertension and Preeclampsia (Jun 2020)	American Congress of Obstetrics and Gynecology (ACOG)	https://www.acog.org/clinical/clinical- guidance/practice- bulletin/articles/2020/06/gestational- hypertension-and-preeclampsia

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WOMEN'S HEALTH – Return to Table of Contents – Cont'd.				
	Alcohol Abuse and Other Substance Use Disorders: Ethical Issues in Obstetric and Gynecologic Practice. Number 633	American Congress of Obstetricians and Gynecologists (ACOG)	https://www.acog.org/clinical/clinical- guidance/committee- opinion/articles/2015/06/alcohol-abuse-and- other-substance-use-disorders-ethical-issues- in-obstetric-and-gynecologic-practice	
Obstetrical Care Cont'd.	Guidelines for the identification and management of substance use and substance use disorders in pregnancy (2014)	World Health Organization (WHO)	http://apps.who.int/iris/bitstream/10665/1071 30/1/9789241548731_eng.pdf?ua=1	
	Smoking Cessation During Pregnancy ACOG. Number 721 (October 2017)	American Congress of Obstetrics and Gynecology (ACOG)	https://www.acog.org/Clinical-Guidance-and- Publications/Committee-Opinions/ Committee- on-Obstetric-Practice/ Smoking-Cessation- During-Pregnancy	
Smoking Cessation during Pregnancy	Need Help Putting Out That Cigarette?	American Congress of Obstetrics and Gynecology (ACOG)	http://www.tobacco-cessation.org/ PDFs/NeedHelpBooklet.pdf	
	Smoking Cessation During Pregnancy	Obstetrics & Gynecology Journal	https://journals.lww.com/greenjournal/Fulltex t/2017/10000/Committee_Opinion_No721_ _Smoking_Cessation.58.aspx	

Infection Prevention

For our providers to ensure members are treated in a safe and sanitary environment, you must implement nationally recognized infection control guidelines, such as those through the CDC. The infection prevention program's purpose is to identify and prevent infections and maintain a sanitary practice environment.

Your office staff must be educated on:

- A process for identifying and preventing infections through activities such as proper hand hygiene and safe injection practices.
- A process for the management of identified hazards, potential threats, near misses, and other safety concerns; this includes monitoring of products including medications, reagents and solutions that carry an expiration date.
- Being aware of and a process for the reporting of known adverse incidents to the appropriate state and federal agencies when required by law to do so.
- A process to reduce and avoid medication errors.
- Prevention of falls or physical injuries involving patients, staff and all others.

You must have a written emergency and disaster preparedness plan to address internal and external emergencies to ensure member safety, including an evacuation plan.

You must provide for accessible and available health services, ensuring information about services when provider practices are not open.

Simply and our providers must comply with applicable state and local building codes and regulations; applicable state and local fire prevention regulations, such as the NFPA 1010 Life Safety Code, 2000 edition, published by the National Fire Protection Association, Inc.; and applicable federal regulations.

Provider practice sites must:

- Contain fire-fighting equipment to control a limited fire, including appropriately maintained and placed fire extinguishers of the proper type for each potential type of fire.
- Have prominently displayed illuminated signs with emergency power capability at all exits, including exits from each floor or hall.
- Have emergency lighting, as appropriate to the facility, to provide adequate illumination for evacuation of member and staff, in case of an emergency.
- Have stairwells protected by fire doors when applicable.
- Provide examination rooms, dressing rooms and reception areas that are constructed and maintained in a manner ensuring member privacy during interviews, examinations, treatment and consultation.
- Operate in a safe and secure manner.
- Have provisions to reasonably accommodate disabled individuals.
- Have provisions to safeguard member privacy, accessibility and member rights.
- Ensure they have the necessary personnel, equipment, supplies and procedures to deliver safe care and handle medical and other emergencies that may arise.
- Hold periodic drills and have periodic instruction of all staff in the proper use of safety, emergency and fireextinguishing equipment.
- Ensure that staff has been trained on infection control, OSHA and Universal Precautions.
- Establish a safety program and an emergency disaster plan.

These items will be reviewed during site review for each cycle of credentialing and recredentialing. All items will be scored using the practitioner site office tool.

Risk Management

Risk management is defined as the identification, investigation, analysis and evaluation of risks and the selection of the most advantageous method of correcting, reducing or eliminating identifiable risks.

Our risk management program is intended to protect and conserve the human and financial assets, public image and reputation of the provider of care and/or the organization from the consequences of risks associated with members, visitors and employees at the lowest reasonable cost:

- To minimize the incidents of legal claims against the provider of care and/or organization.
- To enhance the quality of care provided to members.
- To control the cost of losses.
- To maintain patient satisfaction with the provider of care and the organization.

The scope of the risk management program is organization-wide. Each member of the medical care team has an equally important role to play in minimizing the occurrence of incidents. All providers of care, agents and employees of Simply have the affirmative duty to report adverse or untoward incidents (potential or actual) on an incident report form and to send that report to specific personnel for necessary follow-up.

The activities of the risk manager will contribute to the quality of care and a safer environment for members, employees, visitors and property, as well as to reduce the cost of risk to the provider of care and the organization.

These activities are categorized as those directed toward loss prevention (pre-loss) and those for loss reduction (post-loss).

The primary goal of pre-loss activity is to correct, reduce, modify or eliminate all identifiable risk situations, which could result in claims and litigation for injury or loss. This can be accomplished through:

- Providing ongoing education and training programs in risk management and risk prevention.
- Participating in safety, utilization review, quality assessment and improvement activities.
- Interfacing with the medical staff to ensure communication and cooperation in risk management.
- Exchanging information with professional organizations, peers and other resources to improve and update the program.
- Analyzing member grievances that relate to member care and the quality of medical services for trends and patterns.

The primary goal of post-loss activity is the selection of the most advantageous methods of correcting identifiable risks and claim control. This can be accomplished through an effective and efficient incident reporting system.

Internal Incident Reporting System

All Simply employees are educated on the Internal Incident Reporting System, which establishes the policy and procedure for reporting adverse incidents and includes: the definition of adverse incidents, access to the incident reporting form, appropriate routing and the required time frame for reporting incidents to the risk manager. Provider input and participation in the QM process further emphasizes the identification of potential risks in the clinical aspects of member care.

Definitions

Adverse incident — occurs during the delivery of managed care plan covered services that:

- Are associated in whole or in part with medical intervention rather than the condition for which such intervention occurred.
- Are not consistent with or expected to be a consequence of such service provision.
- Occur as a result of service provision to which the patient has not given his informed consent.
- Occur as a result of any other action or lack thereof on the part of the facility, staff or the provider.
- Causes injury to a member.

Injury — any of the following outcomes when caused by an adverse incident:

- Death
- Fetal death
- Brain damage
- Spinal damage
- Permanent disfigurement
- Fracture or dislocation of bones or joints
- Any condition requiring definitive or specialized medical attention that is not consistent
 with the routine management of the patient's case or patient's preexisting physical condition
- Any condition requiring surgical intervention to correct or control
- Any condition resulting in transfer of the patient, within or outside the facility, to a unit providing a more acute level of care

Critical incident — events that negatively affect the health, safety or welfare of a member, including the following:

- Abuse/neglect/exploitation
- Altercations requiring medical intervention
- Elopement
- Escape

- Homicide
- Major illness
- Medication errors
- Sexual battery
- Suicide
- Suicide attempt
- Unexpected death

Reporting Responsibilities

- All participating and direct service providers are required to report adverse incidents to the managed care
 plans within 48 hours of the incident. The managed care plan must ensure all participating and direct
 service providers are required to report adverse incidents to the Agency immediately but not more than 24
 hours of the incident. Reporting will include information such as the enrollee's identity, description of the
 incident and outcomes, including the current status of the enrollee.
- Simply will immediately report to the (DCF) any suspected cases of abuse, neglect or exploitation of enrollees, in accordance with s.39.201 and Chapter 415, F.S. The DCF Adult Protective Services Program has the responsibility for investigating allegations of abuse, neglect and exploitation of elders and individuals with disabilities. The Abuse Hotline number is **1-800-96-ABUSE** (**1-800-96-22873**).
- Additionally, Simply reports any adverse and critical incidents to AHCA monthly.

Procedural Responsibilities

- The provider staff member involved in observing or first discovering the unusual incident or a Simply staff
 member who becomes aware of an incident is responsible for initiating the incident report. Reports will be
 fully completed on the incident report form and will provide a clear, concise, objective description of the
 incident. The director of the department involved in observing the risk situation will assist in the
 completion of the form, if necessary.
- All incident reports resulting in serious or potentially serious member harm will be forwarded to the risk manager or risk manager designee immediately.
- Incident reports are logged and date-stamped.
- The National Customer Care department associate is responsible for initiating incident reports for member grievances that relate to an adverse or untoward incident.
- Simply employees refer quality of care and quality of service issues to our QM department. The QM department may solicit information from other departments and/or providers during clinical reviews.
- The QM committee will review all pertinent safety-related reports.
- The QM committee, MAC and/or peer review committee will review pertinent member-related reports.
- Documentation related to the suspected abuse, neglect or exploitation, including the reporting of such, must be kept in a file, separate from the enrollee's case file, that is designated as confidential. Such file will be made available to the Agency upon request.
- A member incident report will be kept in a risk management computerized file, and the report will not be
 photocopied or carbon copied. Employees, providers and agents are prohibited from placing copies of an
 incident report in the medical record. Employees, providers and agents are prohibited from making a
 notation in the medical record referencing the filing of an incident report.
- The risk manager will communicate with department directors and managers to provide follow-up as appropriate. If corrective action is needed on the part of a Simply employee, the Human Resources department will execute it.
- The risk manager will follow up on all incidents pertinent to quality to determine causes and possible preventive interventions.
- The risk manager will keep statistical data of incidents for analysis purposes.

- The risk manager will keep incident reports in computerized files for no less than 10 years and longer for audits or litigation as specified elsewhere in the MMA contract.
 - Florida Healthy Kids records will be retained for a period of at least ten years following the term of Simply's Florida Healthy Kids contract with Florida Healthy Kids Corporation, except if an audit is in progress or audit findings are yet unresolved, in which case records will be kept until all tasks are completed.

Incident Report Review and Analysis

- The risk manager will review all incident reports and analyze them for trends and patterns. This includes the frequency, cause and severity of incidents by location, practitioner and type of incident.
- The risk manager will have free access to all health maintenance organization or provider medical records.
- The incident reports will be utilized to develop categories of incidents that identify problems.
- Once problems become evident, the risk manager will make recommendations for corrective actions, such as procedure revisions.

An incident report is an official record of the incident and is privileged and confidential in all regards. No copies will be made of any incident report for any reason, other than those situations authorized by applicable law.

Credentialing

Simply credentialing policies and procedures incorporate the current National Committee for Quality Assurance (NCQA) *Standards and Guidelines for the Accreditation of Managed Care Organizations* as well as the Florida Department of Health (FDOH) requirements for the credentialing and recredentialing of licensed independent providers and organizational providers with whom we contract.

Simply will accept the provider's copy of the Council for Affordable Quality Healthcare (CAQH) applications in lieu of a Simply application form.

Each provider agrees to submit for verification all requested information necessary to credential or recredential physicians providing services in accordance with the standards established by Simply. Each provider will cooperate with Simply as necessary to conduct credentialing and recredentialing pursuant to our policies, procedures and rules.

Credentialing Requirements

Each provider, applicable ancillary/facility and hospital will remain in full compliance with the Simply credentialing criteria as set forth in our credentialing policies and procedures and all applicable laws and regulations. Each provider, applicable ancillary/facility and hospital will complete the Simply application form upon request. Each provider will comply with other such credentialing criteria as may be established by Simply.

We're authorized to take whatever steps necessary to ensure each provider is recognized by the state Medicaid program, including its choice counseling/enrollment broker contractor(s) as a participating provider of Simply, and the provider's submission of encounter data is accepted by the Florida Medicaid Management Information Systems and/or the state's encounter data warehouse. Each provider must supply us with his or her active, enrolled or limited-enrolled Medicaid ID number.

Simply requires each provider to have a National Provider Identifier (NPI) in accordance with s. 1173(b) of the Social Security Act, as enacted by s. 4707(a) of the Balanced Budget Act of 1997.

Credentialing Procedures

Health care practitioners:

Initial applicants must meet the following criteria in order to be considered for participation:

- A. Must not be currently federally sanctioned, debarred or excluded from participation in any of the following programs: Medicare, Medicaid or FEHBP;
- B. Possess a current, valid, unencumbered, unrestricted, and non-probationary license in the state(s) where he or she provides services to Members; and
- C. Possess a current, valid, and unrestricted Drug Enforcement Agency ("DEA") and/or Controlled Dangerous Substances ("CDS") registration for prescribing controlled substances, if applicable to his/her specialty in which he or she will treat Members; the DEA/CDS registration must be valid in the state(s) in which the practitioner will be treating Members. Practitioners who see Members in more than one (1) state must have a DEA/CDS registration for each state.

<u>Initial</u> applications should meet the following criteria in order to be considered for participation, with exceptions reviewed and approved by the CC:

- A. For MDs, DOs, DPMs, and DMDs/DDSs practicing oral and maxillofacial surgery, the applicant must have current, in force board certification (as defined by the American Board of Medical Specialties ("ABMS"), American Osteopathic Association ("AOA"), Royal College of Physicians and Surgeons of Canada ("RCPSC"), College of Family Physicians of Canada ("CFPC"), American Board of Foot and Ankle Surgery ("ABFAS"), American Board of Podiatric Medicine ("ABPM"), or American Board of Oral and Maxillofacial Surgery ("ABOMS") in the clinical discipline for which they are applying.
- B. If not certified, MDs and DOs will be granted five (5) years or a period of time consistent with ABMS or AOA board eligibility time limits, whatever is greater, after completion of their residency or fellowship training program to meet the board certification requirement.
- C. If not certified, DPMs will be granted five (5) years after the completion of their residency to meet this requirement for the ABPM. Non-certified DPMs will be granted seven (7) years after completion of their residency to meet this requirement for ABFAS.
- D. Individuals no longer eligible for board certification are not eligible for continued exception to this requirement.
 - 1. As alternatives, MDs and DOs meeting any one (1) of the following criteria will be viewed as meeting the education, training and certification requirement:
 - a. Previous board certification (as defined by one (1) of the following: ABMS, AOA, RCPSC, CFPC, ABFAS, ABPM, or ABOMS) in the clinical specialty or subspecialty for which they are applying which has now expired and a minimum of ten (10) consecutive years of clinical practice;
 - b. Training which met the requirements in place at the time it was completed in a specialty field prior to the availability of board certifications in that clinical specialty or subspecialty; or
 - c. Specialized practice expertise as evidenced by publication in nationally accepted peer review literature and/or recognized as a leader in the science of their specialty and a

faculty appointment of assistant professor or higher at an academic medical center and teaching facility in Simply network and the applicant's professional activities are spent at that institution at least fifty percent (50%) of the time.

- 2. Practitioners meeting one (1) of these three (3) alternative criteria (a, b, c) will be viewed as meeting all Simply education, training and certification criteria and will not be required to undergo additional review or individual presentation to the CC. These alternatives are subject to Simply review and approval. Reports submitted by delegates to Simply must contain sufficient documentation to support the above alternatives, as determined by Simply.
- E. For MDs and DOs, the applicant must have unrestricted hospital privileges at a The Joint Commission ("TJC"), National Integrated Accreditation for Healthcare Organizations ("NIAHO"), Center for Improvement in Healthcare Quality ("CIHQ"), a Healthcare Facilities Accreditation Program ("HFAP") accredited hospital, or a Network hospital previously approved by the committee. Some clinical disciplines may function exclusively in the outpatient setting, and the CC may at its discretion deem hospital privileges not relevant to these specialties. Also, the organization of an increasing number of physician practice settings in selected fields is such that individual physicians may practice solely in either an outpatient or an inpatient setting. The CC will evaluate applications from practitioners in such practices without regard to hospital privileges. The expectation of these physicians would be that there is an appropriate referral arrangement with a Network practitioner to provide inpatient care.
- F. For Genetic Counselors, the applicant must be licensed by the state to practice independently. If the state where the applicant practices does not license Genetic Counselors, the applicant must be certified by the American Board of Genetic Counseling or the American Board of Genetics and Genomics.

II. Criteria for Selecting Practitioners

- A. New Applicants (Credentialing)
 - 1. Submission of a complete application and required attachments that must not contain intentional misrepresentations or omissions;
 - 2. Application attestation signed date within one hundred eighty (180) calendar days of the date of submission to the CC for a vote;
 - 3. Primary source verifications within acceptable timeframes of the date of submission to the CC for a vote, as deemed by appropriate accrediting agencies;
 - 4. No evidence of potential material omission(s) on application;
 - 5. Current, valid, unrestricted license to practice in each state in which the practitioner would provide care to Members;
 - 6. No current license action;
 - 7. No history of licensing board action in any state;
 - 8. No current federal sanction and no history of federal sanctions (per System for Award Management ("SAM"), OIG and OPM report nor on NPDB report);
 - 9. Possess a current, valid, and unrestricted DEA/CDS registration for prescribing controlled substances, if applicable to his/her specialty in which he or she will treat Members. The DEA/CDS registration must be valid in the state(s) in which the practitioner will be treating Members. Practitioners who treat Members in more than one (1) state must have a valid DEA/CDS registration for each applicable state.

Initial applicants who have no DEA/CDS registration will be viewed as not meeting criteria and the credentialing process will not proceed. However, if the applicant can provide evidence that he or she has applied for a DEA/CDS registration, the credentialing process may proceed if all of the following are met:

- a. It can be verified that this application is pending.
- b. The applicant has made an arrangement for an alternative practitioner to prescribe controlled substances until the additional DEA/CDS registration is obtained. If the alternate provider is a practice rather than an individual, the file may include the practice name. The Company is not required to arrange an alternative prescriber;
- c. The applicant agrees to notify Simply upon receipt of the required DEA/CDS registration.
- d. Simply will verify the appropriate DEA/CDS registration via standard sources.
 - i. The applicant agrees that failure to provide the appropriate DEA/CDS registration within a ninety (90) calendar day timeframe will result in termination from the Network.
 - ii. <u>Initial</u> applicants who possess a DEA certificate in a state other than the state in which they will be seeing Simply's members will be notified of the need to obtain the additional DEA, unless the practitioner is delivering services in a telemedicine environment only and does not require a DEA or CDS registration in the additional location(s) where such telemedicine services may be rendered under federal or state law. If the applicant has applied for an additional DEA registration the credentialing process may proceed if <u>all</u> the following criteria are met:
 - (a) It can be verified that the applicant's application is pending; and
 - (b) The applicant has made an arrangement for an alternative provider to prescribe controlled substances until the additional DEA registration is obtained; and
 - (c) The applicant agrees to notify Simply upon receipt of the required DEA registration; and
 - (d) Simply will verify the appropriate DEA/CDS registration via standard sources; and
 - (e) The applicant agrees that failure to provide the appropriate DEA registration within a ninety (90) day timeframe will result in termination from the network.
 - iii. Practitioners who voluntarily choose to not have a DEA/CDS registration if that practitioner certifies the following:
 - (a) controlled substances are not prescribed within his/her scope of practice; or in their professional judgement, the patients receiving their care do not require controlled substances and
 - (b) he or she must provide documentation that an arrangement exists for an alternative provider to prescribe controlled substances should it be clinically appropriate. If the alternate provider is a practice rather than an individual, the file may include the practice name. The Company is not required to arrange an alternative prescriber; and
 - (c) DEA/CDS registration is or was not suspended, revoked, surrendered or encumbered for reasons other than those aforementioned.
- 10. No current hospital membership or privilege restrictions and no history of hospital membership or privileges restrictions;
- 11. No history of or current use of illegal drugs or history of or current alcoholism;
- 12. No impairment or other condition which would negatively impact the ability to perform the essential functions in their professional field.
- 13. No gap in work history greater than six (6) months in the past five (5) years with the exception of those gaps related to parental leave or immigration where twelve (12) month gaps will be

- acceptable and viewed as "Level I". Other gaps in work history of six (6) months to five (5) years will be reviewed by the chair/vice-chair of the geographic CC and may be presented to the geographic CC if the gap raises concerns of future substandard Professional Conduct and Competence. In the absence of this concern the chair/vice-chair of the CC may approve work history gaps up to five (5) years;
- 14. No convictions, or pleadings of guilty or no contest to, or open indictments of, a felony or any offense involving moral turpitude or fraud. In addition, no other criminal or civil litigation history that together with any other relevant facts, raises a reasonable suspicion of future substandard professional conduct and/or competence. A minimum of the past ten (10) years of malpractice case history is reviewed.
- 15. Meets Credentialing Standards for education/training for the specialty(ies) in which practitioner wants to be listed in Simply's Network directory as designated on the application. This includes board certification requirements or alternative criteria for MDs and DOs and board certification criteria for DPMs, and oral and maxillofacial surgeons;
- 16. No involuntary terminations from an HMO or PPO;
- 17. No "yes" answers to attestation/disclosure questions on the application form with the exception of the following:
 - a. Investment or business interest in ancillary services, equipment or supplies;
 - b. Voluntary resignation from a hospital or organization related to practice relocation or facility utilization;
 - c. Voluntary surrender of state license related to relocation or nonuse of said license;
 - d. An NPDB report of a malpractice settlement or any report of a malpractice settlement that does not meet the threshold criteria;
 - e. Non-renewal of malpractice coverage or change in malpractice carrier related to changes in the carrier's business practices (no longer offering coverage in a state or no longer in business);
 - f. Previous failure of a certification exam by a practitioner who is currently board certified or who remains in the five (5) year post residency training window;
 - g. Actions taken by a hospital against a practitioner's privileges related solely to the failure to complete medical records in a timely fashion;
 - h. History of a licensing board, hospital or other professional entity investigation that was closed without any action or sanction.
- 18. National Provider Identifier (NPI) Simply requires each provider to have a National Provider Identifier (NPI) in accordance with s. 1173(b) of the Social Security Act, as enacted by s. 4707(a) of the Balanced Budget Act of 1997.
- 19. Verification of Medicaid Eligibility Simply will ensure that providers are eligible for participation in the Medicaid program, consistent with provider disclosure, screening, and enrollment requirements.
- 20. Active Patient Load Attestation Attestation that the total active patient load (all populations, including but not limited to Medicaid FFS, Children's Medical Services, SMMC plans, Medicare, KidCare, and commercial coverage) is no more than 3,000 patients per physician. An active patient is one that is seen by the provider a minimum of two times per year.
- 21. **Office location review** At the time of initial credentialing, for PCPs and high-volume specialists, a Simply provider representative will complete a site visit for each office location of all providers to determine whether the provider's office can accommodate the members and meets all requirements.

Note: the CC will individually review any practitioner that does not meet one (1) or more of the criteria required for initial applicants.

- B. Additional Participation Criteria and Exceptions for Behavioral Health practitioners (Non Physician) Credentialing.
 - 1. Licensed Clinical Social Workers ("LCSW") or other master level social work license type:
 - Master or doctoral degree in social work with emphasis in clinical social work from a program accredited by the Council on Social Work Education ("CSWE") or the Canadian Association on Social Work Education ("CASWE");
 - b. Program must have been accredited within three (3) years of the time the practitioner graduated:
 - c. Full accreditation is required, candidacy programs will not be considered; and
 - d. If master's level degree does not meet criteria and practitioner obtained PhD degree as a clinical psychologist, but is not licensed as such, the practitioner can be reviewed. To meet the criteria, the doctoral program must be accredited by the American Psychological Association ("APA") or be regionally accredited by the Council for Higher Education Accreditation ("CHEA"). In addition, a doctor of social work from an institution with at least regional accreditation from the CHEA will be viewed as acceptable.
 - Licensed professional counselor ("LPC") and marriage and family therapist ("MFT") or other master level license type:
 - Master's or doctoral degree in counseling, marital and family therapy, psychology, counseling psychology, counseling with an emphasis in marriage, family and child counseling or an allied mental field. Master or doctoral degrees in education are acceptable with one (1) of the fields of study above;
 - b. Master or doctoral degrees in divinity do not meet criteria as a related field of study;
 - c. Graduate school must be accredited by one (1) of the Regional Institutional Accrediting Bodies and may be verified from the Accredited Institutions of Post-Secondary Education, APA, Council for Accreditation of Counseling and Related Educational Programs ("CACREP"), or Commission on Accreditation for Marriage and Family Therapy Education ("COAMFTE") listings. The institution must have been accredited within three (3) years of the time the practitioner graduated;
 - d. Practitioners with PhD training as a clinical psychologist can be reviewed. To meet criteria this doctoral program must either be accredited by the APA or be regionally accredited by the CHEA. A Practitioner with a doctoral degree in one (1) of the fields of study noted will be viewed as acceptable if the institution granting the degree has regional accreditation from the CHEA and;
 - e. Licensure to practice independently.
 - 3. Clinical nurse specialist/psychiatric and mental health nurse practitioner:
 - a. Master's degree in nursing with specialization in adult or child/adolescent psychiatric and mental health nursing. Graduate school must be accredited from an institution accredited by one (1) of the Regional Institutional Accrediting Bodies within three (3) years of the time of the practitioner's graduation:
 - Registered Nurse license and any additional licensure as an Advanced Practice Nurse/Certified Nurse Specialist/Adult Psychiatric Nursing or other license or certification as dictated by the appropriate State(s) Board of Registered Nursing, if applicable;
 - c. Certification by the American Nurses Association ("ANA") in psychiatric nursing. This may be any of the following types: Clinical Nurse Specialist in Child or Adult Psychiatric Nursing, Psychiatric and Mental Health Nurse Practitioner, or Family Psychiatric and Mental Health Nurse Practitioner; and

d. Valid, current, unrestricted DEA/CDS registration, where applicable with appropriate supervision/consultation by a Network practitioner as applicable by the state licensing board. For those who possess a DEA registration, the appropriate CDS registration is required. The DEA/CDS registration must be valid in the state(s) in which the practitioner will be treating Members.

4. Clinical Psychologists:

- a. Valid state clinical psychologist license;
- Doctoral degree in clinical or counseling, psychology or other applicable field of study from an institution accredited by the APA within three (3) years of the time of the practitioner's graduation;
- c. Education/Training considered as eligible for an exception is a practitioner whose doctoral degree is not from an APA accredited institution, but who is listed in the National Register of Health Service Providers in Psychology or is a diplomat of the American Board of Professional Psychology; and
- d. Master's level therapists in good standing in the Network, who upgrade their license to clinical psychologist as a result of further training, will be allowed to continue in the Network and will not be subject to the above education criteria.

5. Clinical Neuropsychologist:

- Must meet all the criteria for a clinical psychologist listed in B.4 above and be Board certified by either the American Board of Professional Neuropsychology ("ABPN") or American Board of Clinical Neuropsychology ("ABCN");
- A practitioner credentialed by the National Register of Health Service Providers ("National Register") in psychology with an area of expertise in neuropsychology may be considered; and
- Clinical neuropsychologists who are not board certified, nor listed in the National Register, will require CC review. These practitioners must have appropriate training and/or experience in neuropsychology as evidenced by one (1) or more of the following:
 - Transcript of applicable pre-doctoral training;
 - Documentation of applicable formal one (1) year post-doctoral training (participation in CEU training alone would not be considered adequate);
 - iii Letters from supervisors in clinical neuropsychology (including number of hours per week); or
 - iv Minimum of five (5) years' experience practicing neuropsychology at least ten (10) hours per week.

6. Licensed Psychoanalysts:

- a. Applies only to practitioners in states that license psychoanalysts.
- b. Practitioners will be credentialed as a licensed psychoanalyst if they are not otherwise credentialed as a practitioner type detailed in Credentialing Policy (e.g. psychiatrist, clinical psychologist, licensed clinical social worker).
- c. Practitioner must possess a valid psychoanalysis state license.
 - i. Practitioner shall possess a master's or higher degree from a program accredited by one (1) of the Regional Institutional Accrediting Bodies and may be verified from the Accredited Institutions of Post-Secondary Education, APA, CACREP, or the COAMFTE listings. The institution must have been accredited within three (3) years of the time the practitioner graduates.
 - ii. Completion of a program in psychoanalysis that is registered by the licensing state as licensure qualifying; or accredited by the American Board for Accreditation in Psychoanalysis (ABAP) or another acceptable

accrediting agency; or determined by the licensing state to be the substantial equivalent of such a registered or accredited program.

- (a) A program located outside the United States and its territories may be used to satisfy the psychoanalytic study requirement if the licensing state determines the following: it prepares individuals for the professional practice of psychoanalysis; and is recognized by the appropriate civil authorities of that jurisdiction; and can be appropriately verified; and is determined by the licensing state to be the substantial equivalent of an acceptable registered licensure qualifying or accredited program.
- (b) Meet minimum supervised experience requirement for licensure as a psychoanalyst as determined by the licensing state.
- (c) Meet examination requirements for licensure as determined by the licensing state.
- C. Additional Participation Criteria and Exceptions for Certified Nurse Midwives (Non Physician) Credentialing.
 - 1. Process, Requirements and Verifications Certified Nurse Midwives:
 - a. The Certified Nurse Midwife (CNM) applicant will submit the appropriate application and supporting documents as required of any other practitioner with the exception of differing information regarding education, training and board certification.
 - b. The required educational/training will be at a minimum that required for licensure as a registered nurse with subsequent additional training for licensure as a Certified Nurse Midwife by the appropriate licensing body. Verification of this education and training will occur either via primary source verification of the license, provided that state licensing agency performs verification of the education, or from the certification board if that board provides documentation that it performs primary verification of the professional education and training. If the state licensing agency or the certification board does not verify education, the education will be primary source verified in accordance with policy.
 - c. The license status must be that of CNM as verified via primary source from the appropriate state licensing agency. Additionally, this license must be active, unencumbered, unrestricted and not subject to probation, terms or conditions. Any applicant whose licensure status does not meet these criteria, or who have in force adverse actions regarding Medicare or Medicaid will be notified of this and the applicant will be administratively denied.
 - d. If the CNM has prescriptive authority, which allows the prescription of scheduled drugs, their DEA and/or state certificate of prescriptive authority information will be requested and primary source verified via normal Simply procedures. If there are current adverse actions against the DEA, the applicant will be notified and the applicant will be administratively denied.
 - e. All CNM applicants will be certified by either:
 - i. The National Certification Corporation for Ob/Gyn and neonatal nursing; or
 - ii. The American Midwifery Certification Board, previously known as the American College of Nurse Midwifes.

This certification must be active and primary source verified. If the state licensing board primary source verifies one (1) of these certifications as a requirement for licensure, additional verification by Simply is not required. If the applicant is not certified or if their

- certification has expired, the application will be submitted for individual review by the geographic CC.
- f. If the CNM has hospital privileges, they must have unrestricted hospital privileges at a CIHQ, TJC, NIAHO, or HFAP accredited hospital, or a network hospital previously approved by the committee or in the absence of such privileges, must not raise a reasonable suspicion of future substandard professional conduct or competence. Information regarding history of any actions taken against any hospital privileges held by the CNM will be obtained. Any history of any adverse action taken by any hospital will trigger a Level II review. In the event the CNM provides only outpatient care, an acceptable admitting arrangement via the collaborative practice agreement must be in place with a participating OB/Gyn.
- g. The CNM applicant will undergo the standard credentialing process outlined in Simply's Credentialing Policies. CNMs are subject to all the requirements of the Credentialing Policies including (but not limited to): the requirement for CC review for Level II applicants, re-credentialing every three (3) years, and continuous sanction and performance monitoring upon participation in the network.
- h. Upon completion of the credentialing process, the CNM may be listed in Simply's provider directories. As with all providers, this listing will accurately reflect their specific licensure designation and these providers will be subject to the audit process.
- i. CNMs will be clearly identified:
 - i. On the credentialing file;
 - ii. At presentation to the CC; and
 - iii. Upon notification to network services and to the provider database.

D. Currently Participating Applicants (Re-credentialing)

- 1. Submission of complete re-credentialing application and required attachments that must not contain intentional misrepresentations;
- 2. Re-credentialing application signed date within one hundred eighty (180) calendar days of the date of submission to the CC for a vote;
- 3. Must not be currently federally sanctioned, debarred or excluded from participation in any of the following programs; Medicare, Medicaid or FEHBP. If, once a practitioner participates in Simply's programs or provider Network(s), federal sanction, debarment or exclusion from the Medicare, Medicaid or FEHBP programs occurs, at the time of identification, the practitioner will become immediately ineligible for participation in the applicable government programs or provider Network(s) as well as Simply's other credentialed provider Network(s).
- 4. Current, valid, unrestricted, unencumbered, unprobated license to practice in each state in which the practitioner provides care to Members:
- 5. No new history of licensing board reprimand since prior credentialing review;
- 6. *No current federal sanction and no new (since prior credentialing review) history of federal sanctions (per SAM, OIG and OPM Reports or on NPDB report);
- 7. Current DEA/CDS registration and/or state controlled substance certification without new (since prior credentialing review) history of or current restrictions;
- 8. No current hospital membership or privilege restrictions and no new (since prior credentialing review) history of hospital membership or privilege restrictions; or for practitioners in a specialty defined as requiring hospital privileges who practice solely in the outpatient setting there exists a defined referral relationship with a Network practitioner of similar specialty at a Network HDO who provides inpatient care to Members needing hospitalization:
- 9. No new (since previous credentialing review) history of or current use of illegal drugs or alcoholism:

- 10. No impairment or other condition which would negatively impact the ability to perform the essential functions in their professional field;
- No new (since previous credentialing review) history of criminal/felony convictions, including a plea of no contest;
- 12. Malpractice case history reviewed since the last CC review. If no new cases are identified since last review, malpractice history will be reviewed as meeting criteria. If new malpractice history is present, then a minimum of last five (5) years of malpractice history is evaluated and criteria consistent with initial credentialing is used.
- 13. No new (since previous credentialing review) involuntary terminations from an HMO or PPO:
- 14. No new (since previous credentialing review) "yes" answers on attestation/disclosure questions with exceptions of the following:
 - a. Voluntary resignation from a hospital or organization related to practice relocation or facility utilization;
 - Voluntary surrender of state license related to relocation or nonuse of said license;
 - c. An NPDB report of a malpractice settlement or any report of a malpractice settlement that does not meet the threshold criteria:
 - d. Nonrenewal of malpractice coverage or change in malpractice carrier related to changes in the carrier's business practices (no longer offering coverage in a state or no longer in business);
 - e. Previous failure of a certification exam by a practitioner who is currently board certified or who remains in the five (5) year post residency training window;
 - f. Actions taken by a hospital against a practitioner's privileges related solely to the failure to complete medical records in a timely fashion;
 - g. History of a licensing board, hospital or other professional entity investigation that was closed without any action or sanction.
- 15. No quality improvement data or other performance data including complaints above the set threshold.
- 16. Re-credentialed at least every three (3) years to assess the practitioner's continued compliance with Simply standards.

*It is expected that these findings will be discovered for currently credentialed network practitioners and HDOs through ongoing sanction monitoring. Network practitioners and HDOs with such findings will be individually reviewed and considered by the CC at the time the findings are identified.

Note: the CC will individually review any credentialed Network practitioners and HDOs that do not meet one (1) or more of the criteria for re-credentialing.

III. HDO Eligibility Criteria

All HDOs must be accredited by an appropriate, recognized accrediting body or in the absence of such accreditation, Simply may evaluate the most recent site survey by Medicare, the appropriate state oversight agency, or site survey performed by a designated independent external entity within the past thirty-six (36) months. If a HDO has satellite facilities that follow the same policy and procedures, Simply may limit site visits to the main facility. Non-accredited HDOs are subject to individual review by the CC and will be considered for Member access need only when the CC review indicates compliance with Simply standards and there are no deficiencies noted on the Medicare or state oversight review which would adversely affect quality or care or patient safety. HDOs are re-credentialed at least every three (3) years to assess the HDO's continued compliance with Simply standards.

A. General Criteria for HDOs:

- 1. Valid, current and unrestricted license to operate in the state(s) in which it will provide services to Members. The license must be in good standing with no sanctions.
- 2. Valid and current Medicare certification.
- 3. Must not be currently federally sanctioned, debarred or excluded from participation in any of the following programs; Medicare, Medicaid or the FEHBP. Note: If, once an HDO participates in Simply's programs or provider Network(s), exclusion from Medicare, Medicaid or FEHBP occurs, at the time of identification, the HDO will become immediately ineligible for participation in the applicable government programs or provider Network(s) as well as Simply's other credentialed provider Network(s).
- 4. Liability insurance acceptable to Simply.
- If not appropriately accredited, HDO must submit a copy of its CMS, state site or a designated independent external entity survey for review by the CC to determine if Simply's quality and certification criteria standards have been met.

Additional Considerations

We encourage those providers who wish to be participating providers for Clear Health Alliance, and who are not credentialed by the American Academy of HIV Medicine (AAHIVM) or recognized by the Florida/Caribbean AIDS Education and Treatment Centers (AETC), to do so and refer them accordingly.

While all providers are required to undergo credentialing, we give particular focus to providers serving in the primary care role for our members with HIV/AIDS. We include an *Education/Training Attestation* for participation as an HIV/AIDS PCP in the credentialing packet, which includes the qualifications described below.

Participation as an HIV/AIDS-designated PCP requires that the provider attest that they meet the criteria to care for our members in one of the following ways:

- Be credentialed as an AAHIVM HIV specialist by the American Academy of HIV Medicine (www.aahivm.org)
- Be board-certified in the field of infectious disease and, if not certified in the past year through the
 American Board of Medical Specialties, has clinically managed a minimum of 25 patients in the preceding 12
 months as well as successfully completed a minimum of 10 hours of continuing medical education (CME)
 with at least five hours related to antiretroviral therapy in the past year
- Be recognized by the Florida/Caribbean AIDS Education and Training Center as having sufficient clinical experience and additional ongoing training in HIV/AIDS to be considered a specialist.

Delegated Credentialing

We will ensure the quality of our credentialing program through direct verification and through delegation of credentialing functions to qualified provider organizations. Where a provider group is believed to have a strong credentialing program, we may evaluate a delegation of credentialing and recredentialing. The provider group must have a minimum of 100 in scope practitioners.

The Enterprise Delegation Oversight & Management department will review the prospective delegate's written credentialing policies and a randomized sample of practitioner files to ensure compliance with contractual, state and federal, as well as NCQA standards. Steps, if any, are identified where the group's credentialing policy does not meet the Simply standards. We will perform or arrange for the group to perform the Simply credentialing steps not addressed by the group.

We will perform a pre-delegation audit of the group's credentialing program.

- A compliant score is between 95 percent and 100%. If the potential delegate has a compliant status and approved by the regional Credentialing Committee, they will be added to the annual audit schedule no more than 12 months from the pre-delegation date.
- A partial compliance score is between 80% and 94%. If the potential delegate has a partial compliance score and approved by the regional Credentialing Committee, any identified deficiencies will be tracked to closure via a corrective action plan (CAP). If the delegate contract is not executed within six months of the pre-delegation audit, the delegate must submit a new pre-delegation audit request.
- If the delegate scores below 80% and denied by the regional Credentialing Committee, the audit is considered a fail. The delegate can submit for reconsideration after a waiting period of six months from the pre-delegation audit date. When a final delegation decision has been made, notice of the audit findings and, if applicable, corrective action plan (CAP) request will be provided to the prospective delegate.

The group is expected to submit an acceptable corrective action plan within 30 days of receipt of the audit results and monitored monthly. The CAP must be acceptable to Simply and completed within the mutually agreed upon time frame but not to exceed 90 days of the submission.

If there are serious deficiencies, we will recommend the regional Credentialing Committee deny the delegation. Simply is responsible for oversight of any delegated credentialing arrangement and schedules appropriate reviews. The reviews are held annually at a minimum.

Peer Review

The peer review process provides a systematic approach for monitoring the quality and appropriateness of care. Peer review responsibilities are to:

- Participate in the implementation of the established peer review system, which reviews a provider's
 practice methods and patterns, morbidity and mortality rates, and all grievances filed relating to medical
 treatment.
- Evaluate the appropriateness of the care rendered and implement corrective action if needed.
- Review and make recommendations regarding individual provider peer-review cases.
- Work in accordance with the executive medical director.

Should investigation of a member grievance or complaint result in concern about a physician's compliance with community standards of care or service, all elements of peer review will be followed.

Dissatisfaction severity codes and levels of severity are applied to quality issues. The medical director assigns a level of severity to the grievance. Peer review includes investigation of physician actions by or at the discretion of the medical director. The medical director takes action based on the quality issue and the level of severity, invites the cooperation of the physician, and consults and informs the Peer Review Committee (PRC). The medical director informs the physician of the committee's decision, recommendations, follow-up actions and/or disciplinary actions to be taken. Outcomes are reported to the appropriate internal and external entities, which include the QM committee.

Simply has a peer review committee, which has the following responsibilities:

- Evaluating the appropriateness of care rendered by our contracted providers
- Reviewing provider's practice methods and patterns
- Evaluating provider performance, trends in quality of care and service issues
- Developing and analyzing plan wide audits.

If the medical advisory committee cannot convene, the peer review committee may also serve as the Simply's provider advisory council, providing input and recommendations to the plan about clinical guidelines, QM trilogy

documents, credentialing reports, PIPS, process improvements, quality indicators, performance measures, HEDIS, and provider satisfaction survey tools and results.

The peer review policy is available upon request.

Quality Measurement Standards for Providers and Requirements for Exchange of Data

Simply and Clear Health Alliance contract with an NCQA-certified software vendor, which produces eligible populations, analyzes compliance/noncompliance and reports rates, including but not limited to for the following measures:

Measure Indicator	Measure Description	
	AWC was combined with "Well-Child Visits in the Third, Fourth, Fifth and	
	Sixth Years of Life into WCV added at the end	
AAP	Adults' Access to Preventive/Ambulatory Health Services	
AMM	Antidepressant Medication Management	
BCS	Breast Cancer Screening	
CCS	Cervical Cancer Screening	
CIS	Childhood Immunization Status - Combo 3	
CDC	Comprehensive Diabetes Care	
	Hemoglobin A1c (HbA1c) Testing	
	HbA1c poor control	
	HbA1c control (<8%)	
	Eye exam (retinal) performed	
CBP	Controlling High Blood Pressure	
KED	Kidney Health Evaluation for Patients with Diabetes	
SSD	Diabetes Screening for People with Schizophrenia or Bipolar Disorder who are	
	using Antipsychotic Medications	
ADD	Follow-up Care of Children Prescribed ADHD Medication	
IMA	Immunizations for Adolescents	
CHL	Chlamydia Screening in Women	
PPC	Prenatal and Postpartum Care	
AMR	Asthma Medication Ratio	
W30	Well-Child Visits in the First 30 Months of Life	
W15	Well-Child Visits in the First 15 Months of Life	
IET	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment	
AMB	Ambulatory Care	
LSC	Lead Screening in Children	
MPM	Annual Monitoring for Patients on Persistent Medications	
FPC	Frequency of Ongoing Prenatal Care	
SAA	Adherence to Antipsychotic Medications for Individuals With Schizophrenia	
APM	Metabolic Monitoring for Children and Adolescents on Antipsychotics	
APC	Use of Multiple Concurrent Antipsychotics in Children and Adolescents	
APP	Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics	
FUM	Follow-Up After Emergency Department Visit for Mental Illness	

Measure Indicator	Measure Description
PCR	Plan All-Cause-Readmissions
UOD	Use of Opioids at High Dosage
FUA	Follow up after emergency department visit for alcohol and other drug abuse or
	dependence
HEDIS- and Agency-	Defined
FHM	Follow-up after Hospitalization for Mental-Illness
Agency-Defined	
RER	Mental Health Readmission Rate
TRT	Transportation Timeliness
TRA	Transportation Availability
HAART	Highly Active Anti-Retroviral Treatment
HIVV	HIV-Related Outpatient Medical Visits
Child Core Set	
WCC	Weight Assessment and Counseling for Nutrition and Physical Activity for
	Children/Adolescents: Body Mass Index Assessment for Children/Adolescents
WCV	Child and Adolescent Well-Care Visits
ССР-СН	Contraceptive Care – Postpartum Women Ages 15-20
CCW-CH	Contraceptive Care – All Women Ages 15-20
PC-01	Elective Delivery
Adult Core Set	
VLS	HIV Viral Load Suppression
MSC	Medical Assistance with Smoking and Tobacco Use Cessation
CCP-AD	Contraceptive Care – Postpartum Women Ages 21-44
CCW-AD	Contraceptive Care – All Women Ages 21-44
COB-AD	Concurrent Use of Opioids and Benzodiazepines
CDF-AD	Screening for Depression and Follow-up Plan: Age 18 and Older
OHD-AD	Use of Opioids at High Dosage in Persons without Cancer

10 MEMBER APPEAL AND GRIEVANCE PROCEDURES

Overview

Simply has a formal appeal and grievance process to handle disputes pertaining to administrative issues and nonpayment-related matters. For payment disputes, see the **Provider Payment Disputes** section.

The appeal process is the procedure for addressing member appeals, which are requests for review of an adverse benefit determination. Adverse benefit determinations are defined as the following:

- The denial or limited authorization of a requested service, including the type or level of service pursuant to 42 CFR 438 400(b)
- The reduction, suspension or termination of a previously authorized service
- The denial, in whole or part, of a payment for a service
- The failure to provide services in a timely manner as defined by the state
- The failure of the plan to act within the time frames provided in Sec. 438.408(b)

Members have the right to tell Simply if they are not happy with their care or the coverage of their health care needs by calling Member Services Monday to Friday, 8 a.m. to 7 p.m. ET. These are called grievances and appeals:

- A **grievance** is when a member is unhappy about something besides his or her health benefits. A grievance could be about a doctor's behavior or about information the member should have received but did not.
- An **appeal** is a formal request from a member to seek a review of an adverse benefit determination made by Simply.

Complaints and Grievances

Simply has a process to solve complaints and grievances. If a member has a concern that is easy to solve and can be resolved within 24 hours, Member Services can help. If the concern cannot be handled within 24 hours and needs to be looked at by our grievance coordinator, the concern is noted and turned over to the grievance coordinator.

A complaint or grievance must be given orally or in writing any time after the event happened.

To file a complaint or grievance, the member can call Member Services at **1-844-406-2396** (TTY **711**) or write us a letter regarding the concern and mail it to:

Simply Healthcare Plans, Inc. Grievance Coordinator 4200 W. Cypress St., Suite 900 Tampa, FL 33607-4173

Members can have someone else help them with the grievance process. This person can be:

- A family member.
- A friend.
- A doctor.
- A lawyer.

The member must give written permission in order for someone else to file a grievance or an appeal on his or her behalf.

If a member needs help filing the complaint, Simply can help. He or she can call Member Services at **1-844-406-2396** (TTY **711**).

If the member or member's representative would like to speak with the grievance coordinator to give more information, they should tell Member Services when the complaint is filed or put it in a letter.

Once Simply gets the grievance (oral or written), we send the member a letter within three business days, telling them the date we received the grievance.

What happens next?

- 1. The grievance coordinator reviews the concern.
- 2. If more information is needed or you have asked to talk to the coordinator, the coordinator will call the member or the designated representative.
- 3. If you have more information to give us, you can bring it to us in person or mail it to: Simply Healthcare Plans, Inc.

Grievance Coordinator

4200 W. Cypress St., Suite 900

Tampa, FL 33607-4173

- 4. Medical concerns are looked at by medical staff.
- 5. Simply will tell the member the decision of the grievance within 90 calendar days from the date we received the grievance.

Medical Appeals

There may be times when Simply says it will not pay, in whole or in part, for care that a member's doctor recommended. If we do this, a member or someone on behalf of a member (with the member's written consent) can appeal the decision. A medical appeal is when Simply is asked to look again at the care being asked for that we said we will not pay for. Members must file for an appeal within 60 days from the date on the letter that says Simply has denied, limited, reduced, suspended or terminated services. Simply will not hold it against the member or the doctor for filling an appeal.

The member can have someone else help them with the appeal process. This person can be a family member, friend, doctor or lawyer. Write this person's name on the appeal form and fill out a request to designate a personal representative form.

Members can ask us to send you more information to help them understand why we would not pay for the service you requested.

I want to ask for an appeal. How do I do it?

An appeal may be filed verbally or in writing within 60 calendar days of when the member gets the notice of adverse benefit determination.

There are four ways to file an appeal:

- 1. Write us and ask to appeal.
- 2. Call Member Services at 1-844-406-2396 (TTY 711).
- 3. Send a fax to 1-866-216-3482.
- 4. Email us at flmedicaidgrievances@simplyhealthcareplans.com.

What else do I need to know?

If the member wants someone else to help with the appeal process, let us know, and we will send the member a form for that.

When Simply receives an appeal, we will send the member a letter within five business days notifying them of the receipt of the appeal request.

Members may ask for a free copy of the guidelines, records or other information used to make the denial and/or appeal decision.

We will notify the member of the decision within 30 calendar days of getting the appeal request. If we reduce coverage for a service a member is receiving and the member wants to continue to get the service during the appeal, the member can call Simply to ask for continuation of benefits. The member must call within 10 days of the date of the initial denial letter that tells him or her Simply will not pay for the service.

If you or the member has more information to give us, you can bring it in person or mail it to the address below. Also, the member can look at medical records and information on this decision before and during the appeal process.

The time frame for an appeal may be extended up to 14 calendar days if:

- The member asks for an extension.
- Simply finds additional information is needed, and the delay is in the member's interest.

If the time frame of the appeal is extended other than at the member's request, Simply will call the member on the same day and notify the member in writing within two calendar days of when the ruling is made. If a member has a special need, Simply will give additional help to file the appeal.

Please call Simply Member Services at **844-406-2396** (TTY **711**) or CHA Member Services at **844-406-2398**, Monday to Friday, 8 a.m. to 7 p.m. ET.

Where do I mail my letter?

Mail all medical information and medical necessity appeals to: Simply Healthcare Plans, Inc. Medical Appeals P.O. Box 62429 Virginia Beach, VA 23466-2429

What can I do if Simply still will not pay?

The member, or representative on the member's behalf with the member's written consent, has a right to ask for a state fair hearing. Members must complete the appeal process before requesting a Medicaid fair hearing. If the member would like to request a fair hearing, he or she must do so no later than 120 calendar days from the date of the notice of plan appeal resolution letter.

The Medicaid Hearing Unit is not part of Simply. They look at appeals of Medicaid members who live in Florida. If you contact the Medicaid Hearing Unit, we will give them information about your case, including the information you have given us.

Members have the right to ask to receive benefits while the hearing is pending. To do so, they can call Member Services toll free at **1-844-406-2396** (TTY **711**).

Note: Members cannot ask for a Medicaid fair hearing if they have MediKids or FHK. These members should request a review from the state.

How do I contact the state for a state fair hearing?

You can contact the Medicaid Hearing Unit at:
Agency for Health Care Administration
Medicaid Hearing Unit
P.O. Box 60127
Ft. Myers, FL 33906
1-877-254-1055 (toll-free)
1-239-338-2642 (fax)
MedicaidHearingUnit@ahca.myflorida.com

What can I do if I think I need an urgent or expedited appeal?

Members can ask for an urgent or expedited appeal if they or their physician think the time frame for a standard appeal process could seriously jeopardize the member's life or health or ability to attain, maintain or regain maximum function.

Members can also ask for an expedited appeal by calling Member Services toll free at **1-844-406-2396** (TTY **711**), Monday to Friday, 8 a.m. to 7 p.m. ET.

We must respond to the expedited request within 48 hours after we receive the appeal request, whether the appeal was made verbally or in writing.

If the request for an expedited appeal is denied, the appeal will be transferred to the time frame for standard resolution, and the member will be notified orally by close of business on the same day and a written notice will be sent within two calendar days.

If you have any questions or need help, please call Member Services toll free at **1-844-406-2396** (TTY **711**), Monday to Friday, 8 a.m. to 7 p.m. ET.

11 CLAIM SUBMISSION AND ADJUDICATION PROCEDURES

Electronic Submission

Simply encourages the submission of claims electronically through Electronic Data Interchange (EDI). Providers must submit claims within 180 days from the date of discharge for inpatient services or from the date of service for outpatient services. Electronic claims submission is available through:

- Availity (formerly THIN) claim payer ID:
 - Simply = SMPLY
 - Clear Health Alliance = CLEAR

Methods to exchange EDI transmissions with the Availity EDI Gateway:

- 1. Already exchanging EDI files? You can use your existing clearinghouse or billing company for your Simply transmissions. (*Please work with them to ensure connectivity to the Availity EDI Gateway*)
- 2. Become a direct trading partner with the Availity EDI Gateway
- 3. Use direct single claim entry through the Availity Portal

Providers, Billing services and Clearinghouses who are *not* currently exchanging EDI transactions can register for the Simply Plan with Availity.

Already registered with Availity?

Use your existing login and choose: My Providers > Enrollments Center.

Additionally, the following will guide you through the transition:

- Use the EDI Connectivity Services Startup Guide for detailed instructions.
- Use Availity's EDI Companion Guide

Your organization can exchange the following transactions through the Availity EDI Gateway:

- 275 Electronic Medical Attachments
- 278 Authorizations/Referrals
- 837- Institutional Claims
- 837- Professional Claims
- 835- Electronic Remittance Advice
- 276/277- Claim Status- Batch
- 270/271- Eligibility Request- Batch

The advantages of electronic claims submission are as follows:

- Facilitates timely claims adjudication
- Acknowledges receipt and rejection notification of claims electronically
- Improves claims tracking
- Improves claims status reporting
- Reduces adjudication turnaround
- Eliminates paper
- Improves cost-effectiveness
- Allows for automatic adjudication of claims

The guide for EDI claims submission is located on our provider website. The EDI claim submission guide includes additional information related to the EDI claim process. To initiate the electronic claims submission process or obtain additional information, please contact the Simply EDI Hotline at **1-800-590-5745**.

Paper Claims Submission

Providers also have the option of submitting paper claims. Simply uses optical character reading (OCR) technology as part of its front-end claims processing procedures. The benefits include the following:

- Faster turnaround times and adjudication
- Claims status availability within five days of receipt
- Immediate image retrieval by Simply staff for claims information allowing more timely and accurate response to provider inquiries

To use OCR technology, claims must be submitted on original red claim forms (not black-and-white or photocopied forms) and laser printed or typed (not handwritten) in a large, dark font. Providers must submit a properly completed *CMS-1450* or *CMS-1500* (08-05) within 180 days from the date of discharge for inpatient services or from the date of service for outpatient services, except in cases of coordination of benefits/subrogation or in cases where a member has retroactive eligibility. For cases of coordination of benefits/subrogation, the time frames for filing a claim will begin on the date the third party documents resolution of the claim.

Paper claims must be submitted within 180 days of the date of service and submitted to the following address:

Simply Healthcare Plans, Inc. Florida Claims P.O. Box 61010 Virginia Beach, VA 23466-1010

Encounter Data

Simply maintains a system to collect member encounter data. Due to reporting needs and requirements, network providers who are reimbursed by capitation must send encounter data to Simply for each member encounter. Encounter data can be submitted through EDI submission methods or on a *CMS-1500 (08-05)* claim form unless other arrangements are approved by Simply. Data will be submitted in a timely manner, but no later than 180 days from the date of service.

Encounter data should be submitted to the following address:

Simply Healthcare Plans, Inc. P.O. Box 61010 Virginia Beach, VA 23466-1010

Through claims and encounter data submissions, HEDIS information is collected. This includes but is not limited to:

- Preventive services (for example, childhood immunization, mammography, Pap smears).
- Prenatal care (for example, LBW, general first trimester care).
- Acute and chronic illness (for example, ambulatory follow-up and hospitalization for major disorders).

Compliance is monitored by the Simply utilization and quality improvement staff, coordinated with the medical director and reported to the quality management committee on a quarterly basis. The primary care provider (PCP) is monitored for compliance with reporting of utilization. Lack of compliance will result in training and follow-up audits and could result in termination from the network.

Claims Adjudication

Simply is dedicated to providing timely adjudication of provider claims for services rendered to members. All network and non-network provider claims that are submitted for adjudication are processed according to generally accepted claims coding and payment guidelines. These guidelines comply with industry standards as defined by the CPT-4 and ICD manuals. Institutional claims should be submitted using EDI submission methods or a *UB-04 CMS-1450* or successor forms; provider services should be submitted using the *CMS-1500*.

Providers must use HIPAA-compliant billing codes when billing Simply. This applies to both electronic and paper claims. When billing codes are updated, the provider is required to use appropriate replacement codes for submitted claims. Simply will not pay any claims submitted using noncompliant billing codes. Simply reserves the right to use code-editing software to determine which services are considered part of, incidental to or inclusive of the primary procedure.

For claims payment to be considered, providers must adhere to the following time limits:

- Submit claims within 180 days from the date the service is rendered; for inpatient claims filed by a hospital, submit claims within 180 days from the date of discharge unless contract timeframes state otherwise.
- In the case of other insurance (crossover claim submission), the claim must be received within 90 days of receiving a response from the primary payer's determination or three years for Medicare crossover claims.
- Claims for members whose eligibility has not been added to the state's eligibility system must be received within 180 days from the date the eligibility is added and Simply is notified of the eligibility/enrollment. Claims submitted after the 180-day filing deadline will be denied.

After filing a claim with Simply, review the *Explanation of Payment (EOP)*. If the claim does not appear on an *EOP* within 30 business days as adjudicated or you have no other written indication that the claim has been received, check the status of your claim at https://www.availity.com or through the Provider Inquiry Line at 1-844-405-4296. If the claim is not on file with Simply, resubmit your claim within 180 days from the date of service. If filing electronically, check the confirmation reports for acceptance of the claim you receive from your EDI or practice management vendor.

International Classification of Diseases, 10th Revision (ICD-10) Description

As of October 1, 2015, ICD-10 became the code set for medical diagnoses and inpatient hospital procedures in compliance with HIPAA requirements and in accordance with the rule issued by the U.S. Department of Health and Human Services (HHS).

ICD-10 is a diagnostic and procedure coding system endorsed by the World Health Organization (WHO) in 1990. It replaces the International Classification of Diseases, 9th Revision (ICD-9), which was developed in the 1970s. Internationally, the codes are used to study health conditions and assess health management and clinical processes. In the United States, the codes are the foundation for documenting the diagnosis and associated services provided across health care settings.

Although we often use the term ICD-10 alone, there are actually two parts to ICD-10:

- Clinical modification (CM): ICD-10-CM is used for diagnosis coding.
- Procedure coding system (PCS): ICD-10-PCS is used for inpatient hospital procedure coding; this is a variation from the WHO baseline and unique to the United States.

ICD-10-CM replaces the code sets ICD-9-CM, volumes one and two for diagnosis coding, and ICD-10-PCS replaces ICD-9-CM, volume three for inpatient hospital procedure coding.

Clean Claims Payment

A clean claim is a request for payment for a service rendered by a provider that:

- Is submitted by the provider in a timely manner
- Is accurate
- Is submitted on a HIPAA-compliant standard claim form, including a CMS-1500 or CMS-1450, or successor forms thereto, or the electronic equivalent of such claim form
- Requires no further information, adjustment or alteration by the provider or by a third party in order to be processed and paid by Simply

Clean claims are adjudicated within 20 days (for electronic) or 40 days (for paper) of receipt. If Simply does not adjudicate the clean claim within the time frames specified above, we will pay all applicable interest as required by law.

We produce and mail an EOP Monday through Saturday, which delineates the status of each claim that has been adjudicated during the previous week. Upon receipt of the requested information from the provider, we must complete processing of the clean claim within 30 business days.

Paper claims that are determined to be unclean will be returned to the billing provider along with a letter stating the reason for the rejection. Electronic claims that are determined to be unclean will be returned to the Simply contracted clearinghouse that submitted the claim.

In accordance with state requirements, we will pay at least 90% of all clean claims from practitioners either in individual or group practice or who practice in shared health facilities within 30 days of the date of receipt. We will pay at least 99% of all clean claims from practitioners either in individual or group practice or who practice in shared health facilities within 90 days of the date of receipt. The date of receipt is the date Simply receives the claim as indicated by its date stamp on the claim. The date of payment is the date of the check or other form of payment.

Claims Status

You can visit the provider website or call the automated Provider Inquiry Line at **1-844-405-4296** to check claims status.

High-dollar claims may be placed in a prepayment pending status to enable third-party vendor (Equian) claims review. An itemized bill may be requested for claims review, only if otherwise indicated in your contract.

Provider Reimbursement

Increased Medicaid Payments for Primary Care Physicians and Eligible Providers

In compliance with the Patient Protection and Affordable Care Act (PPACA), as amended by Section 1202 of the Health Care and Education Reconciliation Act, Simply reimburses eligible Medicaid primary care providers (PCPs) at parity with Medicare rates for qualified services in calendar years 2013 and 2014.

If you meet the requirements for the PPACA enhanced physician reimbursement and haven't yet submitted a completed attestation, you should do so as soon as possible to qualify for enhanced payments. Visit the provider website for links to information and instructions.

Simply Process for Supporting Enhanced Payments to Eligible Providers

As set forth in "Section 1202" of the PPACA:

- Conditioned upon the state of Florida requiring and providing funding to Simply, Simply will provide
 increased reimbursement to Medicare levels or some other federal or state-mandated level for specified
 CPT-4 codes for primary care services furnished with dates of service in 2013 and 2014 by providers who
 have attested to their eligibility to receive such increased reimbursement as set forth in "Section 1202" of
 the PPACA.
- Such CPT-4 codes will be paid in accordance with the requirements of PPACA, and the state and will not be subject to any further enhancements from Simply or any other source.

Provider Responsibilities with Regard to Payments

If you completed the attestation process as required by the state, the following procedures and guidelines apply to you regarding payments received from Simply:

- If you are a group provider, entity or any person other than the eligible provider who performed the service, you acknowledge and agree you will direct any and all increased reimbursements to such eligible providers or otherwise ensure such eligible providers receive direct and full benefit of the increased reimbursement in accordance with the final rule implementing PPACA.
- You also acknowledge and agree you will provide Simply with evidence of your compliance with this requirement upon request.

Electronic Remittance Advice (835)

The 835 eliminates the need for paper remittance reconciliation.

Use Availity to register and manage ERA account changes with these three easy steps:

- 1. Log in to Availity https://apps.availity.com/availity/web/public.elegant.login
- 2. Select My Providers
- 3. Click on Enrollment Center and select Transaction Enrollment

Note: If you use a clearinghouse or vendor, please work with them on ERA registration and receiving your ERA's.

Electronic Funds Transfer (EFT)

Electronic claims payment through electronic funds transfer (EFT) is a secure and fastest way to receive payment reducing administrative processes. EFT deposit is assigned a trace number that is matched to the 835 Electronic Remittance Advice (ERA) for simple payment reconciliation.

Visit https://provider.simplyhealthcareplans.com/florida-provider/electronic-data-interchange for EFT registration instructions.

Maternity Coverage, Billing, Reimbursement Policies

Effective **January 1, 2022**, Simply Healthcare Plans will no longer reimburse postpartum visit Current Procedural Terminology (CPT) Code, 59430, Postpartum care only, if billed in conjunction with a global or bundled billed CPT code.

• If CPT code "59430" is billed after a delivery claim using "59400, 59510, 59610, 59618, 59410, 59515, 59614", then "59430" should be denied.

Also, effective **January 1, 2022**, Simply Healthcare Plans will begin down coding all bundled payments to delivery service only CPT codes if the postpartum CPT Category II Code (Table 1.2) is not submitted within timely filling (180 days) to verify postpartum visit completion.

• If cat II code "0503F" for postpartum visit is not submitted within 270 days (90 days postpartum window and 180 days timely filling) after the DOS on bundled delivery claims CPT codes "59410, 59515, 59614" then they should be down coded to the corresponding delivery service only code.

- **59410** to **59409** *Vaginal delivery only (with or without episiotomy and/or forceps)*
- **59510 to 59514** *Cesarean delivery only*
- **59614 to 59612** Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps)

PCP Reimbursement

Simply reimburses PCPs according to their contractual arrangement.

Specialist Reimbursement

Reimbursement to network specialty care providers and network providers not serving as PCPs is based on their contractual arrangement with Simply.

Specialty care providers will obtain PCP and Simply approval prior to rendering or arranging any treatment that is beyond the specific treatment authorized by the PCP's referral or beyond the scope of self-referral permitted under this program.

Specialty care provider services will be covered only when there is documentation of appropriate notification or precertification and receipt of the required claims and encounter information to Simply.

Overpayment Process

Refund notifications may be identified by two entities: 1) Simply and its contracted vendors or 2) the providers.

Once an overpayment has been identified by Simply, Simply will notify the provider of the overpayment. The overpayment notification will include instructions on how to refund the overpayment. Providers have up to 60 days to dispute an overpayment. If a refund check is not received, the identified overpayment will offset against future claims payments. Notification of overpayment will be submitted to facility claims within 30 months and to physician claims within 12 months.

The provider may also identify an overpayment and proactively submit a refund check to reconcile the overpayment amount. If a provider identifies an overpayment and submits a refund, a completed *Refund Notification Form* specifying the reason for the return must be included. This form is located on the provider website. The submission of the *Refund Notification Form* will allow us to process and reconcile the overpayment in a timely manner. For questions regarding the refund notification procedure, please call Provider Services at **1-844-405-4296** and select the appropriate prompt.

In instances where we are required to adjust previously paid claims to adhere to a new published rate, we will initiate a reconciliation of the affected claims. As such, we will determine the cumulative adjusted reimbursement amount based on the new rates. In the event the outcome of this reconciliation results in a net amount owed to us, Simply will notify the provider of the overpayment, then commence recovery of such

^{*} Exception: when submitting bundle bill cpt code, 59622, provider's may also bill up to three postpartum visits (CPT code 59430) within 90 days following delivery, as delivery services only CPT code, 59620 -cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery, is not on the 2021 AHCA practitioner fee schedule (Florida Agency For Health Care Administration, 2021).

amounts through an offset against future claims payments. Such recoveries are not considered part of the overpayment recovery process described above or in the provider agreement.

Changes addressing the topic of overpayments have taken place with the passage of the Patient Protection and Affordable Care Act (PPACA), commonly known as the Healthcare Reform Act.

The provision directly links the retention of overpayments to false claim liability. The language of 42 U.S.C.A. § 1320a-7k makes explicit that overpayments must now be reported and returned to states or respective MCOs within 60 days of identification of the overpayment or by the date any corresponding cost report is due, whichever is later. After 60 days, the overpayment is considered a false claim, which triggers penalties under the False Claims Act, including treble damages. In order to avoid such liability, health care providers and other entities receiving reimbursement under Medicare or Medicaid should implement policies and procedures on reporting and returning overpayments that are consistent with the requirements in the PPACA.

The provision entitled "Reporting and Returning Overpayments – Deadline for Reporting and Returning Overpayments," codified at 42 U.S.C.A. § 1320a-7k, clarifies the uncertainty left by the 2009 Fraud Enforcement and Recovery Act. This provision of the HealthCare Reform Act applies to providers of services, suppliers, Medicaid managed care organizations, Medicare Advantage organizations and Medicare Prescription Drug Program sponsors. It does not apply to beneficiaries.

Reimbursement Policies

Reimbursement policies serve as a guide to assist you in accurate claim submissions and to outline the basis for reimbursement if the service is covered by a member's Simply benefit plan. These policies can be accessed on the provider site <u>.</u> Services must meet authorization and medical necessity guidelines appropriate to the procedure and diagnosis as well as to the member's state of residence. Covered services do not guarantee reimbursement unless specific criteria are met.

You must follow proper billing and submission guidelines, including using industry standard, compliant codes on all claim submissions. Services should be billed with Current Procedure Terminology (CPT) codes, Healthcare Common Procedure Coding System (HCPCS) codes and/or revenue codes which indicate the services and/or procedures performed. The billed code(s) are required to be fully supported in the medical record and/or office notes. Unless otherwise noted within the policy, our policies apply to participating providers and facilities; a non-contracting provider who accepts Medicare assignment will be reimbursed for services according to the original Medicare reimbursement rates.

If appropriate coding/billing guidelines or current reimbursement policies are not followed, Simply may:

- Reject or deny the claim
- Recover and/or recoup claim payment
- Adjust the reimbursement to reflect the appropriate services and/or procedures performed

The reimbursement policies are developed based on nationally accepted industry standards and coding principles. These policies may be superseded by mandates in provider, state, federal, or CMS contracts and/or requirements.

All documentation is subject to nationally and generally accepted general industry standards including, but not limited to the American Medical Association (AMA) Current Procedural Terminology (CPT) Code Set, the Healthcare Common Procedure Coding System (HCPCS), and the American Hospital Association (AHA) Coding Clinic Guidelines.

In addition to nationally and generally accepted industry standards, the primary authority for all coverage provisions for Medicare is the Social Security Act, the Code of Federal Regulations (CFR) and the Center for Medicare and Medicaid Services (CMS). Medicaid may be subject to requirements of your State agency responsible for operating the Medicaid program and/or health care laws in your state. In lieu of State-specific rules, Medicaid will defer to Medicare guidelines and other applicable provisions in the Provider Manual.

Reimbursement Hierarchy

Claims submitted for payments must meet all aspects of criteria for reimbursement. The reimbursement hierarchy is the order of payment conditions that must be met for a claim to be reimbursed. Conditions of payment could include benefits coverage, medical necessity/clinical criteria, authorization requirements and/or stipulations within a reimbursement policy. Neither payment rates nor methodology are considered to be conditions of payments.

Review Schedules and Updates to Reimbursement Policies

Reimbursement policies undergo reviews for updates to state contracts, federal or CMS requirements. Additionally, updates may be made at any time if we are notified of a mandated change or due to a business decision. We reserve the right to review and revise our policies when necessary. When there is an update, we will publish the most current policies to our provider website.

Medical Coding

The Medical Coding department ensures that correct coding guidelines have been applied consistently through Simply. Those guidelines include, but are not limited to:

- Correct modifier use
- Effective date of transaction code sets (CPT, HCPCS, ICD diagnosis/procedures, revenue codes, etc.)
- Code editing rules are appropriately applied and within regulatory requirements
- Analysis of codes, code definition and appropriate use

Reimbursement by Code Definition

Simply allows reimbursement for covered services based on their procedure code definitions or descriptor, as opposed to their appearance under particular CPT categories or sections, or descriptors unless otherwise noted by state or provider contracts or state, federal or CMS contracts and/or requirements. There are eight CPT sections:

- 1. Evaluation and management
- 2. Anesthesia
- 3. Surgery
- 4. Radiology (nuclear medicine and diagnostic imaging)
- 5. Pathology and laboratory
- 6. Medicine
- 7. Category II codes: supplemental tracking codes that can be used for performance measurement
- 8. Category III codes: temporary codes for emerging technology, services or procedures

Claim Payment Disputes

Provider Claim Payment Dispute Process

If you disagree with the outcome of a claim, you may begin the Simply provider payment dispute process. The simplest way to define a claim payment dispute is when the claim is finalized, but you disagree with the outcome.

Please be aware there are three common, claim-related issues that are not considered claim payment disputes. To avoid confusion with claim payment disputes, we've defined them briefly here:

- Claim inquiry: a question about a claim but not a request to change a claim payment
- Claims correspondence: when Simply requests further information to finalize a claim; typically includes medical records, itemized bills or information about other insurance a member may have
- Medical necessity appeals: a pre-service appeal for a denied service; for these, a claim has not yet been submitted

For more information on each of these, please refer to the appropriate section in this provider manual.

The Simply provider payment dispute process consists of two internal steps and/or a third external step alternative. You will **not** be penalized for filing a claim payment dispute, and no action is required by the member.

- 1. **Claim payment reconsideration:** This is the first step in the Simply provider payment dispute process. The reconsideration represents your initial request for an investigation into the outcome of the claim. Most issues are resolved at the claim payment reconsideration step.
- 2. **Claim payment appeal:** This is the second step in the Simply provider payment dispute process. If you disagree with the outcome of the reconsideration, you may request an additional review as a claim payment appeal.
- 3. **Regulatory complaint:** Providers have the option to utilize the state arbitration process and do not need to exhaust the aforementioned plan processes prior to requesting an external review..

A claim payment dispute may be submitted for multiple reason(s), including:

- Contractual payment issues.
- Disagreements over reduced or zero-paid claims.
- Post-service authorization issues.
- Other health insurance denial issues.
- Claim code editing issues.
- Duplicate claim issues.
- Retro-eligibility issues.
- Experimental/investigational procedure issues.
- Claim data issues.
- Timely filing issues.*

Claim Payment Reconsideration

The first step in the Simply claim payment dispute process is called the reconsideration. It is your initial request to investigate the outcome of a finalized claim. Please note, we cannot process a reconsideration without a finalized claim on file.

We accept reconsideration requests in writing, verbally and through our secure provider website within 90 days from the date on the *EOP* (see below for further details on how to submit). Reconsiderations filed more than 90 days from the *EOP* will be considered untimely and denied unless good cause can be established.

^{*} We will consider reimbursement of a claim that has been denied due to failure to meet timely filing if you can:
1) provide documentation the claim was submitted within the timely filing requirements or 2) demonstrate good cause exists.

When submitting reconsiderations, please include as much information as you can to help us understand why you think the claim was not paid as you would expect. If a reconsideration requires clinical expertise, the appropriate clinical Simply professionals will review it.

Simply will make every effort to resolve the claims payment reconsideration within 30 calendar days of receipt. If additional information is required to make a determination, the determination date may be extended by 30 additional calendar days. We will mail you a written extension letter before the expiration of the initial 30 calendar days.

We will send you our decision in a determination letter, which will include:

- A statement of the provider's reconsideration request.
- A statement of what action Simply intends to take or has taken.
- The reason for the action.
- Support for the action, including applicable statutes, regulations, policies, claims, codes or provider manual references.
- An explanation of the provider's right to request a claim payment appeal within 30 calendar days of the date of the reconsideration determination letter.
- An address to submit the claim payment appeal.

If the decision results in a claim adjustment, the payment and EOP will be sent separately.

Claim Payment Appeal

If you are dissatisfied with the outcome of a reconsideration determination you may submit a claim payment appeal. Please note, we cannot process a claim payment appeal without a reconsideration on file.

We accept claim payment appeals through our provider website or in writing within 30 calendar days of the date on the reconsideration determination letter.

Claim payment appeals received more than 30 calendar days after the claims reconsideration determination letter will be considered untimely and upheld unless good cause can be established.

When submitting a claim payment appeal, please include as much information as you can to help us understand why you think the reconsideration determination was in error. If a claim payment appeal requires clinical expertise, it will be reviewed by appropriate clinical Simply professionals.

Simply will make every effort to resolve the claim payment appeal within 30 calendar days of receipt. If additional information is required to make a determination, the determination date may be extended by 30 additional calendar days. We will mail you a written extension letter before the expiration of the initial 30 calendar days.

We will send you our decision in a determination letter, which will include:

- A statement of the provider's claim payment appeal request.
- A statement of what action Simply intends to take or has taken.
- The reason for the action.
- Support for the action, including applicable statutes, regulations, policies, claims, codes or provider manual references.

If the decision results in a claim adjustment, the payment and EOP will be sent separately.

How to Submit a Claim Payment Dispute

We have several options to file a claim payment dispute:

- Preferred Method: Online (for reconsiderations and claim payment appeals): Use the secure Provider
 Availity Payment Appeal Tool at https://www.availity.com. Through Availity, you can upload supporting
 documentation and will receive immediate acknowledgement of your submission.
- Verbally (for reconsiderations only): Call Provider Services at 1-844-405-4296.
- Written (for claim payment appeals only): Mail all required documentation (see below for more details), including the Claim Payment Appeal Form or the Reconsideration Form, to:

Payment Dispute Unit Simply Healthcare Plans, Inc. P.O. Box 61599 Virginia Beach, VA 23466-1599

Submit written claim payment appeals on the form *Claim Payment Appeal Form*, located in *Appendix A* of this manual.

If a provider is dissatisfied with the claim payment appeal resolution, the provider may appeal the Simply decision to Maximus (the vendor for AHCA for provider disputes).

Application forms and instructions on how to file claims are available from Maximus directly. For information updates, call Maximus at **1-866-763-6395** and ask for the Florida Appeals Process department

Required Documentation for Claims Payment Disputes

Simply requires the following information when submitting a claim payment dispute (reconsideration or claim payment appeal):

- Your name, address, phone number, email, and either your NPI or TIN
- The member's name and his or her Simply or Medicaid ID number
- A listing of disputed claims, which should include the Simply claim number and the date(s) of service(s)
- All supporting statements and documentation

Claim Inquiries

A question about a claim or claim payment is called an inquiry. Inquiries do not result in changes to claim payments, but the outcome of the claim inquiry may result in the initiation of the claim payment dispute. In other words, once you get the answer to your claim inquiry, you may opt to begin the claim payment dispute process.

Our Provider Experience program helps you with claim inquiries. Just call 1-844-405-4296 and select the *Claims* prompt within our voice portal. We connect you with a dedicated resource team, called the Provider Service Unit (PSU), to ensure:

- Availability of helpful, knowledgeable representatives to assist you.
- Increased first-contact, issue resolution rates.
- Significantly improved turnaround time of inquiry resolution.
- Increased outreach communication to keep you informed of your inquiry status.

The PSU is available to assist you in determining the appropriate process to follow for resolving your claim issue.

Claim Correspondence

Claim correspondence is different from a payment dispute. Correspondence is when Simply requires more information to finalize a claim. Typically, Simply makes the request for this information through the *EOP*. The claim or part of the claim may, in fact, be denied, but it is only because more information is required to process the claim. Once the information is received, Simply will use it to finalize the claim.

The following table provides examples of the most common correspondence issues along with guidance on the most efficient ways to resolve them.

Type of Issue	What Do I Need to Do?
EDI Rejected Claim(s)	
	Contact Availity Client Services at 1-800-Availity (1-800-282-
	4548). Availity Client Services is available Monday - Friday 8 a.m.
	- 8 p.m. ET.
EOP Requests for Supporting	Submit a Claim Correspondence Form, a copy of your EOP and
Documentation (Sterilization/	the supporting documentation to:
Hysterectomy/Abortion Consent	Claims Correspondence
Forms, Itemized Bills and Invoices)	P.O. Box 61599
	Virginia Beach, VA 23466-1599
EOP Requests for Medical Records	Submit a Claim Correspondence Form, a copy of your EOP and
	the medical records to:
	Claims Correspondence
	P.O. Box 61599
	Virginia Beach, VA 23466-1599
Need to Submit a Corrected Claim	Submit a Claim Correspondence Form and your corrected claim
due to Errors or Changes on	to:
Original Submission	Claims Correspondence
	P.O. Box 61599
	Virginia Beach, VA 23466-1599
	Clearly identify the claim as corrected. We cannot accept claims
	with handwritten alterations to billing information. We will
	return claims that have been altered with an explanation of the
	reason for the return. Provided the claim was originally received
	timely, a corrected claim must be received within 365 days of
	the date of service. In cases where there was an adjustment to a
	primary insurance payment and it is necessary to submit a
	corrected claim to Simply to adjust the other health insurance
	(OHI) payment information, the timely filing period starts with
	the date of the most recent OHI EOB.
Submission of Coordination of	Submit a Claim Correspondence Form, a copy of your EOP and
Benefits (COB)/Third-Party Liability	the COB/TPL information to:
(TPL) Information	Claims Correspondence
	P.O. Box 61599
	Virginia Beach, VA 23466-1599
Emergency Room Payment Review	Submit a Claim Correspondence Form, a copy of your EOP and
	the medical records to:
	Claims Correspondence
	P.O. Box 61599

Type of Issue	What Do I Need to Do?
	Virginia Beach, VA 23466-1599

Medical Necessity Appeals

Medical necessity appeals refer to a situation in which an authorization for a service was denied prior to the service. Medical necessity appeals/prior authorization appeals are different than claim payment disputes and should be submitted in accordance with the medical necessity appeal process.

Coordination of Benefits

State-specific guidelines will be followed when coordination of benefits (COB) procedures are necessary. Simply agrees to use covered medical and hospital services whenever available or other public or private sources of payment for services rendered to members in the Simply plan.

Simply and our providers agree the Medicaid program will be the payer of last resort when third-party resources are available to cover the costs of medical services provided to Medicaid members. When Simply is aware of these resources prior to paying for a medical service, we will avoid payment by either rejecting a provider's claim and redirecting the provider to bill the appropriate insurance carrier or, if Simply does not become aware of the resource until sometime after payment for the service was rendered, by pursuing postpayment recovery of the expenditure. Providers must **not** seek recovery in excess of the Medicaid payable amount.

Simply will avoid payment of trauma-related claims where third-party resources are identified prior to payment. Otherwise, we will follow a pay-and-pursue policy on prospective and potential subrogation cases. Paid claims are reviewed and researched postpayment to determine likely cases with multiple letters and phone calls being made to document the appropriate details. The filing of liens and settlement negotiations are handled internally and externally via our subrogation vendor, ACS Recovery Services.

We will require members to cooperate in the identification of any and all other potential sources of payment for services.

Any questions or inquiries regarding paid, denied or pended claims should be directed to Provider Services at **1-844-405-4296**.

Billing Members

Overview

Before rendering services, providers should always inform members that the cost of services not covered by Simply will be charged to the member.

A provider who chooses to provide services **not covered** by Simply:

- Understands Simply only reimburses for medically necessary services, including hospital admissions and other services.
- Obtains the member's signature on the client acknowledgment statement, which specifies the member will be held responsible for payment of services.
- Understands he or she may not bill or take recourse against a member for denied or reduced claims for services that are within the amount, duration and scope of benefits of the Medicaid program.

Simply members must not be balance-billed for the amount above that which is paid by Simply for covered services.

In addition, providers may **not** bill a member if any of the following occurs:

- Failure to submit a claim timely, including claims not received by Simply
- Failure to submit a claim to Simply for initial processing within the six-month filing deadline
- Failure to submit a corrected claim within the 180-day filing resubmission period
- Failure to appeal a claim within the 90 day administrative appeal period
- Failure to appeal a utilization review determination within 30 days of notification of coverage denial
- Submission of an unsigned or otherwise incomplete claim
- Errors made in claims preparation, claims submission or the appeal process

Client Acknowledgment Statement

A provider may bill a Simply member for a service that has been denied as not medically necessary or not a covered benefit **only if** both of the following conditions are met:

- The member requests the specific service or item
- The provider obtains and keeps a written acknowledgement statement signed by the member and the provider stating:

"I understand that, in the opinion of (provider's name), the services or items that I have requested to be
provided to me on (dates of service) may not be covered under Simply as being reasonable and medically
necessary for my care or may not be a covered benefit. I understand that Simply has established the medical
necessity standards for the services or items that I request and receive. I also understand that I am
responsible for payment of the services or items I request and receive if these services or items are
determined to be inconsistent with the Simply medically necessary standards for my care or are not a
covered benefit."
Signature:
Data
Date:

Accessing Claim Status, Member Eligibility and Authorization Determinations

Simply recognizes that for you to provide the best service to our members, we must share with you accurate, up-to-date information. To access claim status, member eligibility and authorization determination (24 hours a day, 365 days a year):

- Access https://www.availity.com, your exclusive, secure multi-payer portal to access real-time claim status, eligibility verification and precertification status. You can also submit a claim or precertification or obtain a member panel listing. Detailed instructions for use of the provider online reporting tool are located on the provider website.
- Call the toll-free, automated Provider Inquiry Line at **1-844-405-4296** for real-time member status, claim status and precertification status. This option also offers the ability to be transferred to the appropriate department for other needs, such as seeking advice in case/care management.

APPENDIX A: FORMS

The following forms are available on the provider website. You may download them for your use as needed.

Referral and Claim Submission Forms

- Authorization Request Form
- Maternity Notification Form
- Child Health Check-Up 221 Form and Claim Instructions This form and instructions are available at www.fdhc.state.fl.us/medicaid or by calling 1-800-289-7799
- Specialist as a PCP Request Form
- CMS-1500 (08-05) Claim Form
- UB-04-Claim Form

Precertification Forms

- Precertification Information Required for Hysterectomy
- Precertification Information Required for Gastroplasty
- Precertification Information Required for Tonsillectomy, Adenoidectomy, Adenotonsillectomy

Provider Grievances and Appeals Forms

- Provider Payment Dispute and Correspondence Submission
- Provider Medical Necessity Appeal Form
- Grievance Form

Medical Record Documentation Forms

- Adult Health Form
- Oral Lead Risk Form English
- Oral Lead Risk Form Spanish
- Incident Report Form
- Inpatient Medical Review Form
- Advance Directive English
- Advance Directive Spanish
- Durable Power of Attorney English/Spanish
- Living Will English/Spanish
- Site Review Form

Other Forms

- Florida Assisted Living Facility Form
- Authorization Request Form
- Pharmacy Prior Authorization Form
- Medical Injectable Prior Authorization Form
- Incident Report Form
- Sterilization Consent Form
- Hysterectomy Acknowledgement Form
- Abortion Certificate Form
- Provider Payment Dispute Form

Pharmacy Synagis Order Form

• Synagis Enrollment Form

Behavioral Health Forms

- Alzheimer's Mini-Cog Screening
- ASSIST SUD Screening
- AUDIT Alcohol Use Questionnaire
- CRAFFT Adolescent SUD Screening
- Functional Activities Questionnaire
- Michigan Alcohol Screening Test (MAST)
- Mood Disorder Questionnaire Bipolar Disorder Screening
- Pediatric Symptom Checklist
- PHQ-9 Depression Screening
- Vanderbilt Assessment Scales ADHD Screening
- Tip Sheet: PCP Toolkit & Telehealth Resource

Hysterectomy and Sterilization Forms

- Acknowledgement of Receipt of Hysterectomy Information
- Consent to Sterilization Form

Cost Containment Form

• Refund Notification Form



Simply Healthcare Plans, Inc. Medicaid Managed Care

Claim Payment Appeal — Submission Form

This form should be completed by providers for payment appeals only.

DOB:			
1ember ID:			
IPI:			
State:	ZIP:		
participating provider			
	ibility, you must include a		
	rm.		
☐ Law firm ☐ Othe	r:		
Phone:			
T a	T =		
State:	ZIP:		
	and all all all all and the states		
you can use one form	n and attach a listing of the claims		
illed amount:			
aciionzacion number			
Payment appeal A payment appeal is defined as a request from a health care provider to change a decision made by Simply			
Healthcare Plans, Inc. (Simply) related to claim payment for services already provided. A provider payment			
appeal is not a member appeal (or a provider appeal on behalf of a member) of a denial or limited			
authorization as communicated to a member in a notice of action.			
☐ First-level appeal ☐ Second-level appeal			
III p l l	State: articipating provider potential financial lia Waiver of Liability For Law firm Other Phone: State: You can use one form lled amount: art date of service: athorization numbers on care provider to chart for services alread in behalf of a member of the care provider of a member of the care provider of a member of the care provider to chart for services alread in behalf of a member of the care provider to chart for services alread in behalf of a member of the care provider to chart for services alread in behalf of a member of the care provider to chart for services alread in behalf of a member of the care provider to chart for services alread in behalf of a member of the care provider to chart for services alread in behalf of a member of the care provider to chart for services alread in the care provider to chart for services a		

To ensure timely and accurate processing of your request, please complete the following **Payment dispute** section by checking the applicable determination provided on the Simply determination letter or *Explanation of Payment*.



Simply Healthcare Plans, Inc. Medicaid Managed Care

Payment dispute			
☐ Untimely filing	☐ Claim code editing denial	☐ Denied as duplicate	
☐ No authorization	☐ Retrospective authorization issue	☐ Denial related to provider data issue	
☐ Denied for other health insurance (OHI), but member doesn't have OHI	☐ Disagree that you were paid according to your contract	☐ Member retro-eligibility issue	
☐ Experimental/investigational procedure denial	□ Data elements on the claim on file do not match the claim originally submitted	☐ ER level of payment review	
□ Other:			

Mail this form, a listing of claims (if applicable) and supporting documentation to:

Simply Healthcare Plans, Inc. Attn: Payment Appeals P.O. Box 61599 Virginia Beach, VA 23466-1599 Copyright January 2022[Date] Simply Healthcare Plans, Inc. and Clear Health Alliance

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Simply

How to apply for participation

If you're interested in applying for participation with Simply, <u>Healthcare Plans</u>, <u>Inc. (Simply) and Clear Health Alliance (CHA)</u>, please visit http://www.simplyhealthcareplans.com/provider or www.clearhealthalliance.com/provider, or call our Provider Services team at 844–405–4296.

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INTRODUCTION

Welcome

Simply Healthcare Plans, Inc. and Clear Health Alliance (Simply) would like to welcome you to the Florida Statewide Medicaid Managed Care and Florida Healthy Kids provider network family. We are pleased you joined our network, which represents some of the finest providers in the country.

We bring the best expertise available nationally to operate local, community-based health care plans with experienced local staff to complement our operations. We are committed to helping you provide quality care and services to our members.

We believe hospitals, physicians and other providers play a pivotal role in managed care, and we can only succeed by working collaboratively with you and other caregivers. Earning your loyalty and respect is essential to maintaining a stable, high-quality provider network. All network providers are contracted with Simply through a Participating Provider Agreement.

Note: This manual provides standards for services to Simply and Clear Health Alliance members enrolled in the Medicaid Managed Care, Medicaid Specialty Plan and Florida Healthy Kids programs. If a section of the manual applies only to a specific program, that program will be indicated. If there is no such indication, the information is applicable to all programs.

This provider manual does not apply to members of the Medicare Advantage or the SMMC Long-Term Care (LTC) program. For more information about providing services to Medicare Advantage members, call <u>866-805-4589</u>.

844-405-4297. For more information about providing services to LTC members, call 877-440-3738.

The LTC provider manual is posted online at www.simplyhealthcareplans.com/provider.

Updates and Changes

The most updated version of this provider manual is available online at www.simplyhealthcareplans.com/provider or www.clearhealthalliance.com/provider. To request a printed copy of this manual at no cost, call Provider Services at 844-405-4296, and we'll be happy to send you a copy.

The provider manual, as part of your *Participating Provider Agreement* and related addendums, may be updated at any time and is subject to change. In the event of an inconsistency between information contained in the manual and the agreement between you or your facility and Simply, the agreement shall govern.

In the event of a material change to the provider manual, we will make all reasonable efforts to notify you in advance of the change through web-posted newsletters, fax communications and other mailings. In such cases, the most recently published information should supersede all previous information and be considered the current directive.

This manual is not intended to be a complete statement of all policies and procedures. We may publish other policies and procedures not included in this manual on our website or in specially targeted communications including but not limited to bulletins and newsletters.

2 OVERVIEW

Who Is Simply?

As a leader in managed health care services for the public sector, we provide health care coverage exclusively to low-income families, children and pregnant women. We participate in the Florida Healthy Kids, Statewide Medicaid Managed Care (SMMC) Long-Term Care, SMMC Managed Medical Assistance programs, and Clear Health Alliance. Clear Health Alliance is a Medicaid specialty plan for people living with HIV/AIDS. References to Simply in this manual include Clear Health Alliance unless otherwise indicated.

Mission

Together, we are transforming health care with trusted and caring solutions.

Strategy

Our strategy is to:

- Improve access to preventive primary care services by ensuring the selection of a primary care physician who will serve as provider, care manager and coordinator for all basic medical services.
- Improve the health status and outcomes of members.
- Educate members about their benefits, responsibilities and the appropriate use of health care services.
- Encourage stable, long-term relationships between providers and members.
- Discourage medically inappropriate use of specialists and emergency rooms.
- Commit to community-based enterprises and community outreach.
- Facilitate the integration of physical and behavioral health care.
- Foster quality improvement mechanisms that actively involve providers in re-engineering health care delivery.
- Encourage a customer service orientation with regular measurement of member and provider satisfaction.

Summary

The Florida legislature created a new program called Statewide Medicaid Managed Care (SMMC). As a result, the Agency for Health Care Administration (AHCA) has changed how some individuals receive health care from the Florida Medicaid program. Two components make up the SMMC program:

- The Florida Managed Medical Assistance (MMA) and specialty program
- The Florida Long-Term Care (LTC) Managed Care program

The goals of the MMA program are to provide:

- Coordinated health care across different health care settings.
- A choice of the best-managed care plans to meet recipients' needs.
- The ability for health care plans to offer different, or more, services.
- The opportunity for recipients to become more involved in their health care.

The goals of the LTC program are to:

- Provide coordinated LTC services to members across different residential living settings.
- Enable members to remain in their homes through the provision of home-based services or in alternative placement, such as assisted living facilities.

For more information on the LTC program, please refer to our LTC provider manual at www.simplyhealthcareplans.com/provider.

The MMA program was implemented in all Florida regions on August 1, 2014. These changes are not due to national health care reform or the Affordable Care Act. Medicaid recipients who qualify and are enrolled in the MMA program will receive all health care services other than long-term care through a managed care plan.

In 1990, the state of Florida created the Florida Healthy Kids Corporation, a nonprofit organization, to administer the Florida Healthy Kids program. Through this program, parents can get affordable health care coverage for eligible children ages 5 through 18.

3 QUICK REFERENCE INFORMATION

Call Provider Services for precertification/notification, network information, member eligibility, claims information, inquiries, and recommendations you may have about improving our processes and/or managed care program.

Simply Phone Numbers

Department/Function	Phone Number
Provider Services	<u>1</u> -844-405-4296 (phone)
	<u>1-</u> 800- <u>-</u> 964- <u>-</u> 3627 (fax)
TTY number	711
Automated Provider Inquiry Line for Member Eligibility	<u>1-</u> 844-405-4296
Electronic Data Interchange (EDI)	<u>1-</u> 800-282-4548
Member Services (including the 24/7 NurseLine)	Medicaid: <u>1-</u> 844- <u>-</u> 406- <u>-</u> 2396 (TTY 711)
	FHK: <u>1-</u> 844-405-4298 (TTY 711)
	Clear Health Alliance: <u>1-</u> 844-406-2398 (TTY 711)
Pharmacy Services	<u>1-</u> 844-405-4296
Medical Injectable Medication Prior Authorization Fax	<u>1-</u> 844-509-9862 (fax)

Other Telephone Numbers

Organization/Program	Phone Number
Clear Health Alliance Case Management	<u>1-855-459-1566</u>
iCare (vision)	<u>1-</u> 855-373-7627
Beacon Health (behavioral health services)	1-844-280-9633 for Clear Health Alliance
	<u>1</u> -844-375-7215 for MMA
20/20 Hearing Care Network, Inc.	<u>1</u> -844-575-4327
Vaccines for Children (for MMA only)	800-483-2543 1-877-888-7468
Immunization Registry (SHOTS)	<u>1</u> -877-888-SHOT (<u>1</u> -877-888-7468)
It's Great to Wait Pregnancy Prevention Program	866-232-3309
Healthy Start Program	800 541 BABY1-850-245-4465 (toll free)
	1-386-758-1135 (or the local health department)
Women, Infants, and Children and Nutritional	1-800-342-3556
Service	-
Florida Quitline (smoking cessation)	<u>1-</u> 877-U-CAN-NOW (<u>1-</u> 877-822-6669)
AIM (radiology authorization)	1-800-252-2021
IngenioRx (pharmacy benefit manager)	1-833-235-2030
IngenioRx Specialty Pharmacy	1-833-255-0646
LabCorp	1-800-877-5227
Elder Abuse Hotline	1-800-96-ABUSE (1-800-962-2873)
LogistiCare ModivCare (transportation — for Regions	1-866- 372-9794 779-5235
1-9)	-
MCT (transportation) for Regions 10 & and 11)	1-844-628-0388 ₇
· · · / <u>-</u> · ·	CHA-: 1-877-671-6671,
	LTC 844-671-6662
American Therapy Administrators	1-888-550-8800 (Therapy)
Health Network One	1-800-595-9631 (Dermatology)
American Specialty Health Group Inc.	1-800-972-4226 for MMA and LTC
(chiropractic/acupuncture)	
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Simply Provider Websites

Visit our websites at www.simplyhealthcareplans.com/provider or www.clearhealthalliance.com/provider for the full complement of online provider resources. They feature online provider inquiry tools for real-time information about member eligibility, prior authorization requirements, claims status, claims resubmission and claims disputes. You can also submit demographic changes and provider rosters.

In addition, the websites have other resources and materials to help you work with us, including provider forms, the MMA and FHK *Preferred Drug Lists*, a list of drugs requiring prior authorization, provider manuals, referral directories, a provider newsletter, electronic remittance advice and electronic funds transfer information, updates, and clinical practice guidelines.

Provider Experience Program

To thank you for the quality of care you give our members, we work to continuously increase service quality for you. Our Provider Experience program, focused on claims payment and issue resolution, does just that!

Call 1-844-405-4296 with claims payment questions or issues. The Provider Experience program support model connects you with a dedicated resource team to ensure:

- Availability of helpful, knowledgeable representatives to assist you.
- Increased first-contact and issue-resolution rates.
- Significantly improved turnaround time of inquiry resolution.
- Increased outreach communications to keep you informed of your inquiry status.

Our representatives are available Monday to Friday, 8 a.m. to 7 p.m. ET (excluding state holidays). Additional staff is available after-hours for authorization inquiries and requests.

Ongoing Provider Communications

To ensure you are up-to-date with information required to work effectively with us and our members, we provide frequent communications in the form of faxes, provider manual updates, newsletters and information posted to the website.

The additional information below will help you in your day-to-day interactions with Simply.

Department/Function	Additional Details	
Member Eligibility	Contact the Provider Inquiry Line at <u>1</u> -844-405-4296 or visit our provider websites.	
Member Enrollment/Disenrollment	Medicaid recipients can enroll in Simply online at www.flmedicaidmanagedcare.com or by calling <u>1</u> _877-711-3662 (TTY <u>1</u> _866-467-4970). Florida Healthy Kids members should contact	
	the Florida Healthy Kids Corporation at <u>1-</u> 800-821-5437.	
Notification/Precertification	Precertification requests may be submitted: Online: Availity.com (Select Patient Registration > Authorizations & Referrals) By phone: 1_844-405-4296 By fax: 1_800_964_3627	
	The following data is required for complete notification/ precertification:	

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Department/Function	Additional Details
	Member ID
	Legible name of referring provider
	Legible name of individual referred to provider
	National provider identifier and/or tax ID number
	Number of visits/services
	Date(s) of service
	• Diagnosis
	CPT/HCPCS codes
	• Criffic C3 codes
	In addition, clinical information is required for precertification.
	Authorization forms are available on our provider websites.
Claims Information	Submit paper claims to:
<u> </u>	Simply Healthcare Plans, Inc.
	Florida Claims
	P.O. Box 61010
	Virginia Beach, VA 23466-1010
	Availity Electronic claims payer IDs:
	⊕—
	○ Simply = SMPLY
	Clear Health Alliance = CLEAR
	For EDI assistance, providers may call Availity Client Services at
	800-282-4548.
	Timely filing is within six months of the date of service or discharge
	from an inpatient facility or the date the nonparticipating provider
	was furnished with the correct name and address of the plan when
	applicable.
	For other commercial, non-Medicare-insurer crossover claims,
	timely filing is 90 days after the final determination of final payer,
	and is three years for Medicare crossover claims.
	Simply provides an online resource designed to significantly reduce
	the time your office spends on eligibility verification, claims status
	and authorization status, which is available through our provider
	websites.
	If you're unable to access the internet, you may receive claims,
	eligibility and authorization status over the phone by calling our
	toll-free, automated Provider Services line at 844-405-4296.
Medical Authorizations Appeal	Providers may submit a medical authorizations-related appeal
Information	within 45 calendar days from the date of an adverse
	determination. Within three business days of receipt of a
	complaint, Simply will notify the provider (in writing) the complaint
	has been received and the expected date of resolution. They will:
	Document why a complaint is unresolved after 4530 days of
	receipt and provide written notice of the status to the provider
	every <u>1530</u> days thereafter.
	Resolve all complaints within 90 days of receipt.
	Provide written notice of the disposition and basis of the resolution
	to the provider within three business days of resolution.

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Department/Function	Additional Details	
Payment Dispute	The preferred method for providers to submit appeal requests is via the web at https://www.availity.com. To find more details on Availity and submitting electronic appeals, visit our Availity Portal Pocket Guide: https://provider.simplyhealthcareplans.com/docs/inline/FLFL_CH A_SMH_PE_AvailityPortalPocketGuide.pdf?v=202002032126 Providers may also mail appeal requests to: Simply Healthcare Plans, Inc. Medical Appeals P.O. Box 62429 Virginia Beach, VA 23466-2429 Providers have 90 calendar days from the date of the final	
	determination of the primary payer to file a written complaint for claims issues. Within three business days of receipt of a claim complaint, Simply will notify the provider (verbally or in writing) the complaint has been received and the expected date of resolution. Within fifteen (15thirty (30) days of receipt of a claim dispute, Simply will provide written notice of the status of the dispute to the Agency and provider. In accordance with Section 641.3155 F.S., Simply will resolve all claims complaints within 6030 days of receipts and provide written notice of the disposition and basis of the resolution to the provider within three business days of resolution. Our Provider Experience program also helps you with claims payment and issue resolution. Just call 844-405-4296 and select the Claims prompt. File a payment dispute to: Simply Healthcare Plans, Inc. Payment Disputes P.O. Box 61599 Visigin Baseb, VA 23466 1500	
Grievances	Virginia Beach, VA 23466-1599 Provider grievances that are not related to claims payment should be	
	submitted in writing to: Simply Healthcare Plans, Inc. Grievance and Appeals Team 4200 W. Cypress St., Suite 900 Tampa, FL 33607 Providers have 45 calendar days from the day of occurrence to file a written grievance. Resolve all grievances within 90 days of receipt. Provide written notice of the disposition and basis of the resolution to the provider within three business days of recolution.	
Case Managers	Case managers are available from Monday to Friday, 8 a.m. to	
	5 p.m. ET.	

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Department/Function	Additional Details		
	 For urgent issues, assistance is available after normal business hours, on weekends and on holidays through the Provider Services line at 844-405-4296. For Clear Health Alliance case managers, call 855-459-1566. 		
Pharmacy Prior Authorization (PA)	For links to the <i>Preferred Drug Lists</i> (<i>PDLs</i>), pharmacy PA criteria, and pharmacy PA forms, go to the <i>Pharmacy</i> section on our provider websites.		
	You can initiate PA requests by: Calling the Simply Provider Services line at 1-844-405-4296 Faxing completed pharmacy PA forms to Simply at 1-877-577-9045 for retail pharmacy requests or 1-844-509-9862 for medical injectable requests. Submitting electronic PA requests through https:covermymeds.com.		
IngenioRx Specialty Pharmacy	 To submit prescriptions to IngenioRx Specialty Pharmacy Call IngenioRx Specialty pharmacy at 1-833-255-0646 Fax IngenioRx Specialty pharmacy at 1-833-263-2871, please include a copy of the member's Medicaid ID card 		

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4 PRIMARY CARE PHYSICIANS

Primary Care Physicians

The PCP serves as the entry point into the health care system for the member. The PCP must be a physician or network provider/subcontractor who provides or arranges for the complete care of his or her patients, including but not limited to providing primary care, coordinating and monitoring referrals to specialist care, authorizing hospital services, case management, and maintaining continuity of care. The PCP's responsibilities include, at a minimum:

- Managing the medical and health care needs of members to ensure all medically necessary services are made available in a timely manner.
- Monitoring and following up on care provided by other medical service providers for diagnosis and treatment, including services available under Medicaid Fee-for-Service.
- Providing the coordination necessary for the referral of patients to specialists and for the referral of patients for services that may be available through Fee-for-Service Medicaid.
- Processing patient referrals within three business days of an office visit to ensure timely care;
- Advising members to schedule appointments for services requiring referrals at least one week after the PCP visit to allow for processing.
- Maintaining a medical record of all services rendered by the PCP and other referral providers.
- Seeing newly enrolled pregnant members within 30 days of enrollment.

The PCP may practice in a solo or group setting or may practice in a clinic (for example, a Federally Qualified Health Center [FQHC] or Rural Health Center [RHC] or outpatient clinic).

Simply encourages enrollees to select a PCP who provides preventive and primary medical care as well as authorization and coordination of all medically necessary specialty services. Members are encouraged to make

an appointment with their PCP within 90 calendar days of their effective date of enrollment. For more information on appointment availability standards, see the Access and Availability section. FQHCs, RHCs and County Health Departments may function as a PCP.

Providers must arrange for coverage of services to assigned members:

- 24 hours a day, 7 days a week, in person or by an on-call physician.
- By answering emergency telephone calls from members within 30 minutes.
- By providing a minimum of 20 office hours per week of personal availability as a PCP.

Provider Specialties

Physicians with the following specialties can apply for enrollment with Simply as a PCP:

- Family practitioners
- General practitioners
- General pediatricians
- · General internists
- Advanced registered nurses
- Nurse practitioners

- Practitioners certified as specialists in family practice/pediatrics
- FQHCs and RHCs
- Obstetricians/gynecologists (OB/GYNs) (for women when they are pregnant)
- Infectious Disease providers (CHA only)

The provider must be enrolled in the Medicaid program at the service location where he or she wishes to practice as a PCP before contracting with Simply. PCPs must also be registered in the Vaccines for Children (VFC) program and obtain all vaccines for our eligible members through the VFC program. Please note, Title XXI MediKids members are not eligible for vaccines through the VFC program.

A provider must be a board-certified pediatrician, family practitioner or physician extender working under the direct supervision of a board-certified practitioner if he or she wishes to practice as a Florida Healthy Kids PCP (unless granted an exemption by the Florida Healthy Kids Corporation board of directors).

Our primary care network may also include PCPs who:

- 1. Have recently completed a residency program in pediatrics or family practice approved by the National Board for Certification of Training Administrators of Graduate Medical Education programs and
- Are eligible for but have not yet achieved board certification. If a PCP does not achieve board certification within the first three years of initial credentialing, we will remove that provider from our network and reassign members to a board-certified PCP.

All PCPs in our network must provide all covered immunizations to Simply members and be enrolled in the Florida State Health Online Tracking System (SHOTS), the statewide immunization registry.

Primary Care Physician Onsite Availability

Simply is dedicated to ensuring access to care for our members, and this depends on the accessibility of network providers. Simply network providers are required to abide by the following standards:

- PCPs must offer telephone access to member 24 hours a day, 7 days a week.
- A 24-hour telephone service may be utilized. The service may be answered by a designee, such as an on-call
 physician or nurse practitioner with physician backup, an answering service, or a pager system; however,
 this must be a confidential line for member information and/or questions. An answering machine is not
 acceptable. If an answering service or pager system is used, the call must be returned within 30 minutes.
- The PCP or another physician/advanced registered nurse practitioner must be available to provide medically necessary services.
- $\bullet \quad \hbox{Covering physicians are required to follow the referral/precertification guidelines}.$

It is not acceptable to automatically direct the member to the emergency room when the PCP is not
available.

We encourage our PCPs to offer after-hours office care in the evenings and on weekends.

For more information on access and availability standards, see the Access and Availability section.

Provider Termination/Disenrollment Process

Providers may cease participation with Simply for either involuntary or voluntary reasons. Involuntary termination occurs when a provider becomes unavailable due to immediate, unforeseen reasons. Examples of this include illness and/or death. A notice to affected members will be issued immediately upon the health plan becoming aware of the situation.

Providers must give timely notice of voluntary contract termination per the required timeframes in their Simply contracts but not to exceed 90 calendar days. Should a provider cease participation for a voluntary reason such as retirement, a written notice to the affected members will be issued no less than 90 calendar days prior to the effective date of the termination and no more than 10 calendar days after receipt or issuance of the termination notice.

If a member is in a preauthorized, ongoing course of treatment with the provider who suddenly ceases participation as a result of death, illness or Medicaid exclusion, we'll notify the member in writing within 10 calendar days from the date we become aware of the provider's network status.

Member Enrollment

Members who meet the state's eligibility requirements for participation in managed care are eligible to join Simply. Members are enrolled without regard to their health status. Members are enrolled for a period of 12 months, contingent upon continued eligibility.

The member may request disenrollment without cause at any time during the 120 days following the date of the member's initial enrollment with Simply or with agency approval. Unless the member loses eligibility or submits an oral or a written disenrollment request to change managed care plans for cause, the member remains enrolled in a health plan for the remainder of the 12-month period.

Simply will ensure all written and oral disenrollment requests are promptly referred to Florida Statewide Medicaid Managed Care (SMMC). When we receive a written request, we'll send a letter notification to the member within three business days that advises to call SMMC enrollment and disenrollment services at 1-877-771-3662 (TTY 1-866-467-4970).

For member enrollment for Florida Healthy Kids, call <u>1-</u>800-821-KIDS (5437).

Involuntary Disenrollment

Simply may request involuntary disenrollment of a member under the following conditions:

- Member's Medicaid ID card is fraudulently used.
- Falsification of prescriptions by a member.
- Member takes part in disruptive and abusive behavior not related to a member's behavioral health condition.

Action related to a request for involuntary disenrollment conditions must be clearly documented in the member's records and submitted to the local Simply Provider Operations department. The Agency for Health

Care Administration (AHCA) will be responsible for reviewing, approving and processing all requests for disensollments.

The documentation must include attempts to bring the member into compliance. A member's disruptive and/or abusive behavior resulting in their failure to be in compliance with their treatment plan must be documented prior to submitting a request for involuntary disenrollment to AHCA. The member must have received at least one verbal and one written warning regarding the implications of his or her actions including involuntary disenrollment.

For any action to be taken, it is mandatory that copies of all supporting documentation from the member's file are submitted with the request.

In addition to the reasons cited in *Rule 59G-8.60 (o),F.A.C.,* if the member is an American Indian or Alaskan Native as defined in 42 CFR 438.14(a), that constitutes a cause for disenrollment.

Simply must be notified before transferring a member out of a physician's practice.

Newborn Enrollment

All providers are responsible for reporting member pregnancies to us to initiate the unborn child's Medicaid eligibility process and ensure appropriate case management.

Simply is responsible for all Medicaid-eligible newborns of enrolled members. This includes payment of medically necessary services and well-child care for the newborn from the date of his or her birth regardless of the mother's continued enrollment in the plan (unless the newborn is disenrolled).

For all pregnant members we're aware of, we'll submit a request to Department of Children and Families (DCF) for the assignment of an inactive Medicaid ID for the unborn child. When the baby is born, we'll submit a request to DCF to activate the Medicaid ID to ensure plan enrollment and claims payment. For babies born without a Medicaid ID, we'll submit a request to DCF for a presumptive eligible newborn Medicaid determination to obtain a Medicaid ID for the baby.

Members Eligibility Listing

The PCP can review his or her panel of assigned members online through *Provider Online Reporting* located on Availity's Payer Spaces (www.availity.com). To receive a listing of assigned panel members by mail on the first day of each month, the PCP must request the list from his or her Provider Relations representative. The list will consist of Simply members who have chosen the PCP's office to provide services. If a member calls to change his or her PCP, the change will be effective the next business day. The PCP should verify that each Simply member receiving treatment in his or her office is on the membership listing. If a PCP does not receive the listing in a timely manner, he or she should contact a Provider Relations representative. For questions regarding a member's eligibility, providers can access our provider websites or call the automated Provider Inquiry Line at 1-844-405-4296.

Member ID Cards

The ID card identifies the member as a participant in the Simply program. Providers should verify member eligibility and plan enrollment prior to rendering services via the state's Florida Medicaid Management Information System (FMMIS) and/or the Simply provider portal.

The ID card will include the following:

- The member's ID number
- The member's name (first and last names and middle initial)

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- The member's enrollment effective date
- Toll-free phone numbers for information and/or authorizations
- Toll-free 24/7 NurseLine information (accessible 24 hours a day, 7 days a week)
- Descriptions of procedures to be followed to obtain emergency or specialty services
- The PCP's name, address and telephone number
- Pharmacy claims processing information
- A phone number for nonparticipating providers to access billing information

Americans with Disabilities Act Requirements

Simply policies and procedures are designed to promote compliance with the Americans with Disabilities Act of 1990. Providers are required to take actions to remove an existing barrier and/or to accommodate the needs of members who are qualified individuals with a disability. This action plan includes:

- Street-level access.
- An elevator or accessible ramp into facilities.
- Access to a lavatory that accommodates a wheelchair.
- Access to an examination room that accommodates a wheelchair.
- Handicapped parking space(s) that are clearly marked, unless there is street-side parking.
- Provisions to communicate in the language or fashion primarily used by his or her members.

Medically Necessary Services

Medically necessary health services mean health services that are:

- Necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain.
- Individualized, specific and consistent with symptoms or confirm diagnosis of the illness or injury under treatment and not in excess of the patient's needs.
- Consistent with the generally accepted professional medical standards as determined by the Medicaid program and not experimental or investigational.
- Reflective of the level of service where care can be provided safely and for which no equally effective
 and more conservative or less costly treatment is available statewide.
- Furnished in a manner not primarily intended for the convenience of the enrollee, the enrollee's caretaker
 or the provider.

For services furnished in a hospital on an inpatient basis, medical necessity means appropriate medical care cannot be effectively given more economically on an outpatient basis or in an inpatient facility of a different type

The fact that a provider has prescribed, recommended or approved medical, allied, or long-term care goods or services does not, in itself, make such care, goods or services medically necessary, a medical necessity or a covered service/benefit.

Continuity of Care: New Members

Simply provides continuation of services until the member's PCP, or behavioral health provider as applicable, reviews the member's treatment plan.

We'll honor any written documentation of prior authorization of ongoing covered services for a period of up to 60 days after the effective date of enrollment or until the member's PCP (or behavioral health provider, as applicable) reviews the member's treatment plan, whichever comes first. For all members, written documentation of prior authorization of ongoing medical and behavioral health services includes the following, provided the services were prearranged prior to enrollment with Simply:

- Prior existing orders
- Provider appointments (i.e., transportation, dental appointments, surgeries, etc.)
- Prescriptions (including prescriptions at nonparticipating pharmacies)
- Prior authorizations
- Treatment plan/plan of care

We won't delay service authorization if written documentation is not available in a timely manner; however, we're not required to approve claims for which we haven't received written documentation.

The following services may extend beyond the 60-day continuity of care period, and we'll continue the entire course of treatment with the member's current provider as described below:

- Prenatal and postpartum care We'll continue to pay for services provided by a pregnant member's
 current provider for the entire course of a pregnancy including the completion of a woman's postpartum
 care up to six weeks after birth regardless of whether the provider is in the Simply network.
- Transplant services We'll continue to pay for services provided by the current provider for one year
 post-transplant regardless of whether the provider is in the Simply network.
- Oncology (radiation and/or chemotherapy services) We'll continue to pay for services provided by the
 current provider for the duration of the current round of treatment regardless of whether the provider is in
 the Simply network.
- Hepatitis C treatment drugs We'll continue to pay for the full course of therapy.

No service will be denied for absence of authorization in circumstances where care was in place prior to the transition date.

The continuity of care provisions stated above apply to both participating and nonparticipating Simply providers.

Continuity of Care: Provider Termination

Simply allows members to continue receiving medically necessary services from a non-for-cause terminated provider and will process claims for services rendered to such members, until the member selects another provider, for a minimum of 60 days after termination of the provider contract. For continuity of care services under these circumstances, Simply will continue to abide by the same contract terms in place prior to contract termination.

For members moving enrollment from one Florida Healthy Kids subsidized plan to another Florida Healthy Kids subsidized plan (without a break in coverage), there is a 60-day continuity of care period.

5 SIMPLY HEALTH CARE BENEFITS AND COPAYMENTS

Simply Covered Services

Any modification to covered services will be distributed via a provider update by mail, fax, provider newsletter, provider manual addendum and/or contractual amendment. Covered services include those listed below and may vary by product.

Statewide Medicaid Managed Care services

Service	Coverage/Limitations	PA
Addictions Receiving Facility Services Services used to help people who are struggling with drug or alcohol addiction	As medically necessary and recommended by us.	Required
Allergy Services Services to treat conditions such as sneezing or rashes that are not caused by an illness	We cover blood or skin allergy testing and up to 156 doses per year of allergy shots.	Not required
Ambulance Transportation Services Ambulance services are for when members need emergency care while being transported to the hospital or special support when being transported between facilities	Covered as medically necessary.	Required for nonemergent transportation services
Ambulatory Detoxification Services Services provided to people who are withdrawing from drugs or alcohol	As medically necessary and recommended by us.	Required
Ambulatory Surgical Center Services Surgery and other procedures that are performed in a facility that is not the hospital (outpatient)	Covered as medically necessary.	May be required
Anesthesia Services Services to keep you from feeling pain during surgery or other medical procedures	Covered as medically necessary.	Not required
Assistive Care Services Services provided to adults (ages 18 and older) help with activities of daily living and taking medication	We cover 365/366 days of services per year.	Required
Behavioral Health Assessment Services Services used to detect or diagnose mental illnesses and behavioral health disorders	We cover: One initial assessment per year. One reassessment per year. Up to 150 minutes of brief behavioral health status assessments (no more than 30 minutes in a single day).	Not required
Behavioral Health Overlay Services Behavioral health services provided to children (ages 0 to 18) enrolled in a DCF program	We cover 365/366 days of services per year, including therapy, support services and aftercare planning	Required

Service	Coverage/Limitations	PA
Cardiovascular Services Services that treat the heart and circulatory (blood vessels) system Child Health Services Targeted Case Management	We cover the following as prescribed by your doctor: Cardiac testing Cardiac surgical procedures Cardiac devices Child must be enrolled in the DOH Early Steps program.	May be required for cardiac testing and surgical procedures
Services provided to children (ages 0 to 3) to help them get health care and other services		
Chiropractic Services Diagnosis and manipulative treatment of misalignments of the joints, especially the spinal column, which may cause other disorders by affecting the nerves, muscles and organs	We cover: One new patient visit. 24 established patient visits per year. Maximum of one visit per day. X-rays. Ultrasound or electrical stimulation.	Not required
Clinic Services Health care services provided in a county health department, federally qualified health center or a rural health clinic		Not required
Clinical Trials Biomedical or behavioral research studies on human participants designed to answer specific questions about biomedical or behavioral interventions including new treatments and known interventions that warrant further study and comparison.	Florida Medicaid reimburses for services as a result of a recipient participating in a clinical trial in accordance with the service-specific coverage policy when the services: • Are covered under the Florida Medicaid program • Would otherwise be provided to a recipient who is not participating in a clinical trial • Are related to complications or side effects arising during the clinical trial • Are not expected or unique to the experimental or investigational treatment • Are not covered by the clinical trial sponsor	Required
Community-Based Wrap-Around Services Services provided by a mental health team to children who are at risk of going into a mental health treatment facility	As medically necessary and recommended by us.	Required
Crisis Stabilization Unit Services Emergency mental health services that are performed in a facility that is not a regular hospital	As medically necessary and recommended by us.	Not required

Service	Coverage/Limitations	PA
Dialysis Services Medical care, tests and other treatments for the kidneys. This service also includes dialysis supplies, and other supplies that help treat the kidneys.	As prescribed by a treating doctor, we cover: • Hemodialysis treatments • Peritoneal dialysis treatments	Required
Drop-In Center Services Services provided in a center that helps homeless people get treatment or housing	As medically necessary and recommended by us.	Required
Durable Medical Equipment and Medical Supplies Services Medical equipment is used to manage and treat a condition, illness or injury. Durable medical equipment is used over and over again and includes things like wheelchairs, braces, crutches, and other items. Medical supplies are items meant for one-time use and then thrown away.	Some service and age limits apply. Call <u>1-844-406-2396 (TTY 711)</u> for more information.	Required
Early Intervention Services Services to children ages 0 to 3 who have developmental delays and other conditions	We cover: One initial evaluation per lifetime, completed by a team. Up to three screenings per year. Up to three follow-up evaluations per year. Up to two training or support sessions per week.	Not required
Emergency Transportation Services Transportation provided by ambulances or air ambulances (helicopter or airplane) to get you to a hospital because of an emergency	Covered as medically necessary.	Required for air ambulances
Evaluation and Management Services Services for doctor's visits to stay healthy and prevent or treat illness	We cover: One adult health screening (check-up) per year. Well-child visits, based on age and developmental needs. One visit per month for people living in nursing facilities. Up to two office visits per month for adults to treat illnesses or conditions.	Not required
Family Therapy Services Services for families to have therapy sessions with a mental health professional	We cover up to 26 hours per year of family or individual therapy services, one hour per day.	Not required
Family Training and Counseling for Child Development	As medically necessary and recommended by us.	Required

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Service	Coverage/Limitations	PA
Services to support a family during their child's mental health treatment		
Gastrointestinal Services Services to treat conditions, illnesses or diseases of the stomach or digestion system	Covered as medically necessary.	May be required for diagnostic tests and procedures
Genitourinary Services Services to treat conditions, illnesses, or diseases of the genitals or urinary system	Covered as medically necessary.	May be required for diagnostic tests and procedures
Group Therapy Services Services for a group of people to have therapy sessions with a mental health professional	We cover up to 39 hours per year.	Not required
Hearing Services Hearing tests, treatments and supplies that help diagnose or treat problems with hearing. This includes hearing aids and repairs.	We cover hearing tests and the following as prescribed by a doctor: Cochlear implants. One new hearing aid per ear, once every three years repairs. Up to three pairs of ear molds per year. One fitting and dispensing service per ear every three years. One hearing test every three years to determine the need for hearing aid and the most appropriate hearing aid. Up to two newborn hearing screenings for recipients under 12 months of age; a second screening may be performed only if the recipient does not pass the first hearing screening in one or both ears.	Required for cochlear implants and bone anchored hearing aids
Home Health Services Nursing services and medical assistance provided in your home to help you manage or recover from a medical condition, illness or injury	We cover: Up to four visits per day for pregnant recipients and recipients ages 0 to 20. Up to three visits per day for all other recipients.	Required

Service	Coverage/Limitations	PA
Hospice Services Medical care, treatment and emotional support services for people with terminal illnesses or who are at the end of their lives to help keep them comfortable and pain free. Support services are also available for family members or caregivers.	Covered as medically necessary.	Not required
Individual Therapy Services Services for people to have one-to-one therapy sessions with a mental health professional	We cover up to 26 hours per year of family or individual therapy services, one hour per day.	Not required
Infant Mental Health Pre and Post Testing Services Testing services by a mental health professional with special training in infants and young children	As medically necessary and recommended by us.	Required
Inpatient Hospital Services Medical care members get while in the hospital. This can include any tests, medicines, therapies and treatments, visits from doctors and equipment used to treat members	We cover the following inpatient hospital services based on age and situation: Up to 365/366 days for recipients ages 0 to 20. Up to 45 days for all other recipients (extra days are covered for emergencies).	Required for elective inpatient admissions
Integumentary Services Services to diagnose or treat skin conditions, illnesses or diseases	Covered as medically necessary.	Requires PCP referral
Laboratory Services Services that test blood, urine, saliva or other items from the body for conditions, illnesses or diseases	Covered as medically necessary.	Required for genetic testing
Medical Foster Care Services Services that help children with health problems who live in foster care homes	Must be in the custody of the Department of Children and Families.	Required
Medication Assisted Treatment Services Services used to help people who are struggling with drug addiction	Covered as medically necessary.52 visits per year.	Not required
Medication Management Services Services to help people understand and make the best choices for taking medication	Covered as medically necessary.52 visits per year.	Not required
Mental Health Partial Hospitalization Program Services Treatment provided for more than three hours per day, several days per week, for people who are recovering from mental illness	As medically necessary and recommended by us.	Required

Service	Coverage/Limitations	PA
Mental Health Targeted Case Management Services to help get medical and behavioral health care for people with mental illnesses	Covered as medically necessary.	Required
Mobile Crisis Assessment and Intervention Services A team of health care professionals who provide emergency mental health services, usually in people's homes	As medically necessary and recommended by us.	Required
Neurology Services Services to diagnose or treat conditions, illnesses or diseases of the brain, spinal cord or nervous system	Covered as medically necessary.	May be required for diagnostic tests and procedures
Nonemergency Transportation Services Transportation to and from all medical appointments. This could be on the bus, a van that can transport disabled people, a taxi, or other kinds of vehicles Nursing Facility Services Medical care or nursing care that members get while living full-time in a nursing facility. This can be a short-term rehabilitation stay	Through LogistiCareModivCare – Regions 1-9) and MCT (Regions 10, 11) we cover the following services for recipients who have no other means of transportation: Out-of-state travel. Transfers between hospitals or facilities. Escorts when medically necessary. We cover 365/366 days of services in nursing facilities as medically necessary.	PA is required for out-of-state travel and transfers between hospitals or facilities. PA is required for one way trips greater than 100 miles. Required
or long-term. Occupational Therapy Services Occupational therapy includes treatments that help members do things in their daily life, like writing, feeding themselves, and using items around the house.	For children ages 0 to 20 and for adults under the \$1,500 outpatient services cap, we cover: One initial evaluation per year. Up to 210 minutes of treatment per week. One initial wheelchair evaluation per five years. Up to two casting and strapping applications per day. One therapy re-evaluation every five months. For people of all ages, we cover: Follow-up wheelchair evaluations, one at delivery and one six months later.	Required
Oral Surgery Services Services that provide teeth extractions (removals) and to treat other conditions,	Covered as medically necessary.	Required

Service	Coverage/Limitations	PA
illnesses or diseases of the mouth and oral cavity		
Orthopedic Services Services to diagnose or treat conditions, illnesses or diseases of the bones or joints	Covered as medically necessary.	May be required for diagnostic tests and procedures
Outpatient Hospital Services Medical care members get while in the hospital but not staying overnight. This can include any tests, medicines, therapies and treatments, visits from doctors and equipment used to treat members	 Emergency services are covered as medically necessary. Nonemergency services cannot cost more than \$1,500 per year for recipients ages 21 and over. 	Required for nonemergent services
Pain Management Services Treatments for long-lasting pain that does not get better after other services have been provided	 Covered as medically necessary. Some service limits may apply. Up to 12 facet joint injections in a six-month period Up to four percutaneous radiofrequency neurolysis in a four-month period 	Required
Physical Therapy Services Physical therapy includes exercises, stretching and other treatments to help your body get stronger and feel better after an injury, illness or because of a medical condition	For children ages 0 to 20 and for adults under the \$1,500 outpatient services cap, we cover: One initial evaluation per year. One therapy re-evaluation every five months. Up to two casting and strapping applications per day. Up to 210 minutes of treatment per week. One initial wheelchair evaluation per five years. For people of all ages, we cover: Follow-up wheelchair evaluations, one at delivery and one six months later.	Required
Podiatry Services Medical care and other treatments for the feet	We cover: Up to 24 office visits per year. Foot and nail care. X-rays and other imaging for the foot, ankle and lower leg. Surgery on the foot, ankle or lower leg.	Not required

Service	Coverage/Limitations	PA
Prescribed Drug Services This service is for drugs that are prescribed by a doctor or other health care provider	We cover: Up to a 31-day supply of drugs, per prescription. Refills, as prescribed. Up to two 72-hour emergency supplies per prescription within 30 consecutive days.	Authorization required for some drugs
Private Duty Nursing Services Nursing services provided in the home to people ages 0 to 20 who need constant care	We cover up to 24 hours per day.	Required
Psychological Testing Services Tests used to detect or diagnose problems with memory, IQ or other areas	We cover 10 hours of psychological testing per year.	Required
Psychosocial Rehabilitation Services Services to assist people re-enter everyday life. They include help with basic activities such as cooking, managing money and performing household chores.	We cover up to 480 hours per year.	Required
Radiology and Nuclear Medicine Services Services that include imaging such as X-rays, MRIs or CAT scans. They also include portable X-rays.	 Covered as medically necessary. Up to two biophysical profiles per pregnancy. One fetal echocardiography per pregnancy; up to two follow-up tests for high-risk pregnancy. One mammography screening per year. Up to three obstetrical ultrasounds per pregnancy. 	May be required
Regional Perinatal Intensive Care Center Services Services provided to pregnant women and newborns in hospitals that have special care centers to handle serious conditions	Covered as medically necessary.	Not required
Reproductive Services Services for women who are pregnant or want to become pregnant. They also include family planning services that provide birth control drugs and supplies to help plan family size.	We cover family planning services. Members can get these services and supplies from any Medicaid provider; they do not have to be a part of our plan. PA is not required; these services are free. These services are voluntary and confidential, even for members under 18 years old.	Not required
Respiratory Services Services that treat conditions, illnesses or diseases of the lungs or respiratory system	We cover: Respiratory testing. Respiratory surgical procedures. Respiratory device management.	May be required for diagnostic tests and procedures

Service	Coverage/Limitations	PA
Respiratory Therapy Services Services for recipients ages 0 to 20 to help members breathe better while being treated for a respiratory condition, illness or disease	We cover: One initial evaluation per year. One therapy re-evaluation per six months. Up to 210 minutes of therapy treatments per week (maximum of 60 minutes per day).	Not required
Self-Help/Peer Services Services to help people who are in recovery from an addiction or mental illness	As medically necessary and recommended by us.	Required
Specialized Therapeutic Services Services provided to children ages 0 to 20 with mental illnesses or substance use disorders	We cover: Assessments. Foster care services. Group home services.	Required
Speech-Language Pathology Services Services that include tests and treatments to help members talk or swallow better	For children ages 0 to 20, we cover: Communication devices and services. Up to 210 minutes of treatment per week. One initial evaluation per year. One re-evaluation every five months. For adults, we cover: One communication evaluation per five years.	Required
Statewide Inpatient Psychiatric Program Services Services for children with severe mental illnesses that need treatment in the hospital	Covered as medically necessary for children ages 0 to 20.	Required
Substance Abuse Intensive Outpatient Program Services Treatment provided for more than three hours per day, several days per week, for people who are recovering from substance use disorders.	As medically necessary and recommended by us.	Required
Substance Abuse Short-term Residential Treatment Services Treatment for people who are recovering from substance use disorders.	As medically necessary and recommended by us.	Required
Therapeutic Behavioral On-Site Services Services provided by a team to prevent children ages 0 to 20 with mental illnesses or behavioral health issues from being placed in a hospital or other facility.	We cover up to nine hours per month.	Required

Service	Coverage/Limitations	PA
Transplant Services Services that include all surgery and pre- and post-surgical care.	Covered as medically necessary.	Required
Visual Aid Services Visual aids are items such as glasses, contact lenses and prosthetic (fake) eyes.	 When prescribed by a doctor, we cover: Two pairs of eyeglasses for children ages 0 to 20. Contact lenses. Prosthetic eyes. 	May be required for prosthetic devices
Visual Care Services Services that test and treat conditions, illnesses and diseases of the eyes	Covered as medically necessary.	May be required for procedures and some tests

Florida Healthy Kids Services

Benefit	Limitations	Copays
Inpatient Services All covered services provided for the medical care and treatment of a member admitted as an inpatient to a hospital licensed under part I of Chapter 395 Covered services include: physician's services; room and board; general nursing care; patient meals; use of operating room and related facilities; use of intensive care unit and services; radiological, laboratory and other diagnostic tests; drugs; medications; biologicals; anesthesia and oxygen services; special duty nursing; radiation and chemotherapy; respiratory therapy; administration of whole blood plasma; physical, speech and occupational therapy; medically necessary services of other health professionals	 Simply must authorize all admissions. The length of the patient stay is determined based on the medical condition of the member in relation to the necessary and appropriate level of care. Room and board may be limited to semi-private accommodations unless a private room is considered medically necessary or semi-private accommodations are not available. Private duty nursing is limited to circumstances where such care is medically necessary. Admissions for rehabilitation and physical therapy are limited to 15 days per contract year. Inpatient services do not include experimental or investigational procedures defined as a drug, biological product, device, medical treatment or procedure that meets any one of the following criteria as determined by Simply: Reliable evidence shows the drug, biological product, device, medical treatment or procedure when applied to the circumstances of a particular patient is the subject of ongoing phase I, II or III clinical trials. Reliable evidence shows the drug, biological product, device, medical treatment or procedure when applied to the circumstances of a particular patient is under study with a written protocol to determine maximum tolerated dose, toxicity, safety, efficacy or efficacy in comparison to conventional alternatives. Reliable evidence shows the drug, biological product, device, medical treatment, or procedure is being delivered or should be delivered subject to the approval and 	None

Benefit	Limitations	Copays
Emergency Services Includes visits to an emergency room or other licensed facility within the U.S. and its territories if needed immediately due to an injury or illness and delay means risk of permanent damage to the member's health Covered services also means inpatient and outpatient services furnished by a qualified provider, per §1932(b)(2) and 42 CFR 438.114(a), and are needed to evaluate or stabilize an emergency medical condition.	supervision of an Institutional Review Board (IRB) as required and defined by federal regulations, particularly those of the U.S. Food and Drug Administration or the Department of Health and Human Services. Simply must also comply with the provisions of § 641.513, Florida Statutes. Subject to the provisions of federal and state law, the member has the right to use any hospital or other setting for emergency care. Simply is responsible for any post-stabilization services obtained within or outside of the network that are preapproved by Simply, or where such approval has been sought by the facility or provider and Simply has failed to respond within one hour of such request for further post-stabilization services that are administered to maintain, improve or resolve the member's stabilized position. Simply limits noncovered charges to members for post-stabilization care services to an amount not greater than what the facility or provider would charge the member if the member had obtained the services through Simply. If we did not preapprove post-stabilization care, our financial responsibility ends when one of the following occur:	\$10 per visit; waived if admitted or authorized by PCP
	• •	
	 An in-network provider with privileges at the 	
	treating facility assumes responsibility for the member's care.	
	An in-network provider assumes	
	responsibility for the member's care through transfer.	
	 The member is discharged. 	

Benefit	Limitations	Copays
Maternity Services and Newborn Care Includes maternity and newborn care, prenatal and postnatal care, initial inpatient care of adolescent participants including nursery charges and initial pediatric or neonatal examination	 The infant is covered for up to three days following birth or until the infant is transferred to another medical facility, whichever occurs first. Coverage may be limited to the fee for vaginal deliveries. 	None
Organ Transplantation Services Includes pretransplant, transplant and post dischargepostdischarge services and treatment of complications after transplantation Outpatient Services	Coverage is available for transplants and medically related services if deemed necessary and appropriate by the Organ Transplant Advisory Council or the Bone Marrow Transplant Advisory Council as may be applicable.	None \$5 per office
Outpatient Services Preventive, diagnostic, therapeutic, palliative care, and other services provided to a member in the outpatient portion of a health facility licensed under Chapter 395 Includes well-child care, including those services recommended in the Guidelines for Health Supervision of Children and Youth as developed by Academy of Pediatrics; immunizations and injections as recommended by the Advisory Committee on Immunization Practices; health education counseling and clinical services; family planning services; vision screening; hearing screening; clinical radiological, laboratory and other outpatient diagnostic tests; ambulatory surgical procedures; splints and casts; consultation with and treatment by referral physicians; radiation and chemotherapy; chiropractic services; and podiatric services	 Services must be provided directly by Simply or through pre-approved referrals. The PCP must provide the routine hearing screening and immunizations. Family planning is limited to one annual visit and one supply visit each 90 days. Chiropractic services are provided in the same manner as in the Florida Medicaid program. Podiatric services are limited to one visit per day, totaling two visits per month for specific foot disorders. Dental services must be provided by an oral surgeon for medically necessary reconstructive dental surgery due to injury. Treatment for temporomandibular joint (TMJ) disease is specifically excluded. Abortions may only be provided in the following situations: The pregnancy is the result of an act of rape or incest. A physician finds the abortion is necessary to save the life of the mother. Outpatient services do not include experimental or investigational procedures defined as a drug, biological product, device, medical treatment or procedure that meets any one of the following criteria as determined by Simply: Reliable evidence shows the drug, biological product, device, medical treatment or procedure when applied to the circumstances of a particular member is the subject of ongoing phase I, II or III clinical trials. 	\$5 per office visit; no copay for well-child care, preventive care, or routine vision and hearing screenings

Benefit	Limitations	Copays
Mental Health Services	Reliable evidence shows the drug, biological product, device, medical treatment or procedure when applied to the circumstances of a particular member is under study with a written protocol to determine maximum tolerated dose, toxicity, safety, efficacy or efficacy in comparison to conventional alternatives. Reliable evidence shows the drug, biological product, device, medical treatment, or procedure is being delivered or should be delivered subject to the approval and supervision of an Institutional Review Board (IRB) as required and defined by federal regulations, particularly those of the U.S. Food and Drug Administration or the Department of Health and Human Services.	Innatient
Includes inpatient and outpatient care for psychological or psychiatric evaluation, diagnosis and treatment by a licensed mental health professional	 All services must be provided directly by Simply or upon approved referral. Covered services include inpatient and outpatient services for mental and nervous disorders as defined in the most recent edition of the <i>Diagnostic and Statistical Manual of Mental Disorders</i> published by the American Psychiatric Association. Such benefits include psychological or psychiatric evaluation, diagnosis and treatment by a licensed mental health professional meeting the requirements of Section 3-2-2(C) of the state contract. Any benefit limitations, including duration of services, number of visits, or number of days for hospitalization or residential services, will not be any less favorable than those for physical illnesses generally. 	Inpatient: none Outpatient: none
Substance Use Services Includes coverage for inpatient and outpatient care for drug and alcohol abuse, including counseling and placement assistance Outpatient services include evaluation, diagnosis and treatment by a licensed practitioner.	 All services must be provided directly by Simply or upon approved referral. Covered services include inpatient, outpatient and residential services for substance disorders. Such benefits include evaluation, diagnosis and treatment by a licensed professional meeting the requirements of Section 3-2-2(C) of the state contract. Any benefit limitations, including duration of services, number of visits, or number of days for hospitalization or residential services, will not be any less favorable than those for physical illnesses generally. 	Inpatient: none Outpatient: none

Benefit	Limitations	Copays
Therapy Services Includes physical, occupational, respiratory and speech therapies for short-term rehabilitation where significant improvement in the member's condition will result	 All treatments must be performed directly or as authorized by Simply. Therapy services are limited to up to 24 treatment sessions within a 60-day period per episode or injury, with the 60-day period beginning with the first treatment. 	\$5 per visit
Home Health Services Includes prescribed home visits by both registered and licensed practical nurses to provide skilled nursing services on a part-time intermittent basis Hospice Services Includes reasonable and necessary services for palliation or management of a member's	Coverage is limited to skilled nursing services only. Meals, housekeeping and personal comfort items are excluded. Services must be provided directly by Simply. Private duty nursing is limited to circumstances where such care is medically appropriate. Services required for conditions totally unrelated to the terminal condition are covered to the extent that such services are otherwise covered under this contract.	\$5 per visit \$5 per visit
terminal illness Nursing Facility Services Covered services include regular nursing services, rehabilitation services, drugs and biologicals, medical supplies, and the use of appliances and equipment furnished by the facility	 All admissions must be authorized by Simply and provided by a Simply-affiliated facility. Participant must require and receive skilled services on a daily basis as ordered by an in-network physician. The length of the member's stay is determined by the medical condition of the member in relation to the necessary and appropriate level of care, but it cannot be more than 100 days per contract year. Room and board is limited to semi-private accommodations unless a private room is considered medically necessary or semi-private accommodations are not available. Specialized treatment centers and independent kidney disease treatment centers are excluded. Private duty nurses, television and custodial care are excluded. Admissions for rehabilitation and physical therapy are limited to 15 days per contract year. 	None
Durable Medical Equipment and Prosthetic Devices Equipment and devices medically indicated to assist in the treatment of a medical condition and specifically prescribed as medically necessary by the member's in-network physician Refractions	 Equipment and devices must be provided by an authorized Simply supplier. Covered prosthetic devices include artificial eyes, limbs, braces and other artificial aids. Low vision and telescopic lenses are not included. Hearing aids are covered only when medically indicated to assist in the treatment of a medical condition. The member must have failed vision screening by 	None \$5 per visit;
Examination by a Simply optometrist to determine the need for and to prescribe	their PCP.	\$10 for corrective lenses

Benefit	Limitations	Copays
corrective lenses as medically indicated	Corrective lenses and frames are limited to one pair every two years unless head size or prescription changes. Coverage is limited to frames with plastic or SYL nontinted lenses.	
Pharmacy Prescribed drugs for the treatment of illness or injury	 This benefit includes all prescribed drugs covered under the Florida Medicaid program; some may require prior authorization. Please refer to the Pharmacy section of the Provider website for the Preferred Drug Lists for FHK and Medicaid. Simply is responsible for the coverage of any drugs prescribed by the member's dental provider under FHK. Brand name products are covered if a generic substitution is not available or where the prescribing physician indicates a brand name is medically necessary. All medications must be dispensed through Simply or a Simply-designated pharmacy. All prescriptions must be written by the member's PCP, Simply-approved specialist or consultant physician, or the member's dental provider. 	FHK Members: \$5 per prescription for up to a 31-day supply Medicaid Members: No copays for medications
Transportation Services Emergency transportation as determined to be medically necessary in response to an emergency situation	 Transportation services must be in response to an emergency situation. 	\$10 per service

Enhanced Benefits

Simply has decided to offer a group of enhanced benefits. The expanded services identified below are additional benefits not included in the Florida MMA/Florida Healthy Kids (FHK) core benefits.

Simply waives all copays for Statewide Medicaid Managed Care Managed Medical Assistance members; providers are prohibited from charging Medicaid member copays for covered services.

Copays are not waived for Florida Healthy Kids members; providers are responsible for collecting copays from Florida Healthy Kids members, and the amount paid by Simply will be the contracted amount less any applicable copays.

Members identified as Native Americans or Alaskan Natives are prohibited from paying any cost-sharing amounts, including copays.

Statewide Medicaid Managed Care Managed Medical Assistance Enhanced Benefits

Service	Coverage/Limitations	Prior Authorization
Acupuncture 30 minutes of acupuncture services	30 minutes of treatment once weekly for up to three months; members 21 years of age and older	Required
Behavioral Health Day Services/Day Treatment Behavioral health day treatment or day care services	Additional 10 units per year of day treatment; one day per week, up to 52 per year of day care services; members 21 years of age and older	Not required
Behavioral Health Medical Services (Drug Screening) Behavioral health medical services (alcohol and other drug screening specimen collection)	Additional eight behavioral health-related medical services per year; members 21 years of age and older	Required
Behavioral Health Medical Services (Medication Management) Medication management for behavioral health or substance abuse	Additional eight behavioral health-related medical services per year; members 21 years of age and older	Required
Behavioral Health Medical Services (Verbal Interaction) Behavioral health medical services (verbal interaction), mental health or substance abuse	Additional eight behavioral health-related medical services per year; members 21 years of age and older	Required
Behavioral Health Screening Services Behavioral health screening services	One additional per year; members 21 years of age and older	Not required
Cellular Phone Service Members can sign up for the Lifeline program and receive a free smart phone, free monthly minutes, a minimum of 500 MB of data and text messaging. Members receive free minutes for calls to and from a selecteda toll-free customer service phone number.	One Lifeline Smart phone benefit per member, 18 years of age and older	Not required
Chiropractic Diagnosis and manipulative treatment of misalignments of the joints, especially the spinal column, which may cause other disorders by affecting the nerves, muscles, and organs	Eligible members will receive 35 additional visits per year; members 21 years of age and older	Not required
Computerized Cognitive Behavioral Analysis Health and behavior assessment (i.e., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires)	Unlimited through Simply's online well-being tool; members 21 years of age and older	Not required

Service	Coverage/Limitations	Prior Authorization
CVS Discount Program	None	Not required
20% off approved products in select CVS		
stores		
Doula services		Not required
Prenatal and postpartum home visits to	Unlimited home visits per pregnancy	
provide physical, emotional and	Unlimited home visits per pregnancy	
informational support; provides ongoing		
birthing support throughout labor and		
delivery process Prenatal and postpartum home visits to		
provide physical, emotional and		
informational support; provides ongoing		
birthing support throughout labor and		
delivery process		
Electric Stimulators	Members 21 years and older	Required
(pain management)	Wiembers 21 years and older	Required
Transcutaneous electrical nerve stimulation		
(TENS) device for pain management		
Flu/Pandemic Prevention Kit (Clear Health	Eligible for the first 1,000 Clear Health	Not required
Alliance)	Alliance members who have received	
• 3-ply face masks – 10 piece	their flu vaccine (Must be requested by	
Oral digital thermometer	Case Manager)	
Hand sanitizer		
Hearing Services	One evaluation per two years	Required
Hearing assessment, hearing aid assessment	One assessment per two years	
and hearing aids for in or behind the ear	One hearing aid, per ear, per two	
	years	
	Members 21 years of age and older	
Home Delivered Meals — Post-Facility	Two meals per day for seven days; must	Required
Discharge (Hospital or Nursing Facility)	be after three-day or more surgical	
Home delivered meals including preparation	hospital stay; members 18 years of age	
(per meal)	and older	
Home delivered meals - Disaster	First 500 members requesting per line of	Not required
Preparedness/Relief	business (Simply MMA and CHA);	
5 Shelf stable meals delivered at home in an	members 18 years of age and older	
affected area with governor declared state		
of emergency.		
Home Health Nursing/Aide Services	One additional unit of service per day;	Required
Nursing services and medical assistance	members 21 years of age and older	
provided in members' homes to help them		
manage or recover from a medical		
condition, illness or injury		
Housing Assistance	\$500 per lifetime for homeless	Required
Supported housing, per month	individuals ; members 21 years of age	
	and older	

Service	Coverage/Limitations	Prior Authorization
Substance Abuse Intensive Outpatient Treatment Alcohol and/or drug services; intensive outpatient	Three hours per day, three days per week, nine hours per week, maximum eight weeks; pregnant women 21 to 54 years of age	Required
Massage Therapy Therapeutic procedures involving massage, mobilization, manipulation or manual traction for pain relief	Eight units (two hours) per year for eligible members, 21 years of age and older, with acute musculoskeletal pain	Required
Meals — Nonemergency Transportation Day-Trips Nonemergency transportation and meals for members and required escort to medically necessary doctor visits greater than 100 miles each way	\$200 per day; members 21 years of age and older	Required
Newborn Circumcision Circumcision	One per lifetime within first 28 days of birth	Not required
Nutritional Counseling Nutritional counseling, dietician visit	Six visits per year for eligible members	Not required
Occupational Therapy	One evaluation and re-evaluation per year; up to seven therapy treatment units per week; members 21 years of age and older	Required
Outpatient Hospital Services Medical care members get while they are in the hospital but not staying overnight. This can include any tests, medicines, therapies and treatments, visits from doctors and equipment that is used to treat members.	\$200 additional per year, excluding lab services; members 21 years of age and older	* Refer to online quick tool for exact requirements by CPT code.
Over-the-Counter Benefit Cough, cold and allergy medications, vitamins and supplements, ophthalmic/otic preparations, pain relievers, gastrointestinal products, first aid care, hygiene products insect repellent (DEET and non-DEET), oral hygiene products, skin care	Limited to \$25 per household per month on an approved list of products	Not required
Physical Therapy • Evaluation moderate complexity • Re-evaluation • Treatment visit	One evaluation and re-evaluation per year; up to seven therapy treatment units per week; members 21 years of age and older	Required
Prenatal Services — Prenatal/Perinatal Visits Breast pump rental for breast feeding Antepartum management: 14 visits for low-risk pregnancies and 18 visits for high-risk pregnancies	Breast pump: one per two years; rental only	Required

Service	Coverage/Limitations	Prior Authorization
Postpartum care: Three visits within 90 days following delivery		
Primary Care Visit Services for Adults Services for doctor's visits to stay healthy and prevent or treat illness	Unlimited visits for members 21 years of age and older	Not required
Respiratory Supplies Supplies needed for use of approved positive airway pressure device	Members 21 years and older	Not required
Respiratory Therapy Initial evaluation and re-evaluation Respiratory therapy visit	One per year for members 21 years of age and older	Not required
Speech Therapy/Speech Language Pathology Evaluation/re-evaluation Evaluation of swallowing function Speech therapy visit Augmentative and alternative communication (AAC) initial evaluation/re-evaluation AAC fitting, adjustment and training visit	One evaluation/re-evaluation per year; up to seven therapy treatment units per week; one AAC evaluation/re-evaluation per year; up to 30 minutes AAC fitting adjustment and training sessions per year; members 21 years of age and older	Required
Therapy — Art Activity therapy, such as music, dance, art or play therapies not for recreation, related to the care and treatment of patient's disabling mental health problems, per session	Unlimited visits for members receiving behavioral health services	Required
Vaccine — Pneumonia (Pneumococcal) Pneumococcal conjugate vaccine 13 valent intramuscular Pneumococcal polysaccharide vaccine 23 valent adult or immunosuppressed dosage subcutaneous or intramuscular	Adults 21 to 64 years of age when medically necessary; adults 65 years or older	Not required
Vaccine — Influenza Influenza virus vaccine split virus preservative free intramuscular, 90656 Influenza virus vaccine, 90664, 90666, 90667, 90668 Administration of vaccine, G0008	Members 21 years of age or older; unlimited per pregnancy	Not required
Vaccine — Shingles (Varicella-Zoster) Zoster shingles vaccine live Subcutaneous/medicine-immunization administration	One vaccine per member per lifetime, for members 60 years of age and older	Not required for Simply MMA members. PA required for CHA members.

Service	Coverage/Limitations	Prior Authorization
Vaccine — TDaP Tetanus diphtheria toxoids acellular pertussis vaccine (TDaP) intramuscular	One vaccine per pregnancy; members 21 years of age and older	Not required
Vision Services Eye exam exclusively to screen visual acuity without need of reported vision problem, illness, disease or injury; contact lenses; frames	One exam per year; one frame per year; six months of contact lenses with prescription; members 21 years of age and older	Not required
Waived Copayments The plan waives copays on the following services: birthing center; chiropractic; community behavioral health; FQHC; inpatient and outpatient hospital; independent labs; nonemergency transportation; ARNP; optometrist; physician assistant; physician; podiatrist; portable X-ray; RHC; registered nurse first assistant	Members 21 years of age and older	Not required

Specialty Enhanced Services

Service	Coverage/Limitations	Prior Authorization
Acupuncture 30 minutes of acupuncture services	30 minutes of treatment once weekly for up to three months; members 21 years of age and older	Required
Behavioral Health Day Services/Day Treatment Behavioral health day treatment or day care services	Additional 10 units per year of day treatment; one day per week, up to 52 per year of day care services; members 21 years of age and older	Not required
Behavioral Health Medical Services (Drug Screening) Behavioral health medical services (alcohol and other drug screening specimen collection)	Additional eight behavioral health-related medical services per year; members 21 years of age and older	Required
Behavioral Health Medical Services (Medication Management) Medication management for behavioral health or substance abuse	Additional eight behavioral health-related medical services per year; members 21 years of age and older	Required
Behavioral Health Medical Services (Verbal Interaction) Behavioral health medical services (verbal interaction), mental health or substance abuse	Additional eight behavioral health-related medical services per year; members 21 years of age and older	Required
Behavioral Health Screening Services Behavioral health screening services	One additional per year; members 21 years of age and older	Not required

Service	Coverage/Limitations	Prior Authorization
Cellular Phone Service Members can sign up for the Lifeline program and receive a free smart phone, free monthly minutes, a minimum of 500 MB of data and text messaging. Members receive free minutes for calls to and from a selected toll-free customer service phone number.	One Lifeline Smart phone benefit per member, 18 years of age and older	Not required
Chiropractic Diagnosis and manipulative treatment of misalignments of the joints, especially the spinal column, which may cause other disorders by affecting the nerves, muscles, and organs	Eligible members will receive 35 additional visits per year; members 21 years of age and older	Not required
Computerized Cognitive Behavioral Analysis Health and behavior assessment (for example, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires)	Unlimited through Simply's online well-being tool; members 21 years of age and older	Not required
Prenatal and postpartum home visits to provide physical, emotional and informational support; provides ongoing birthing support throughout labor and delivery process	Unlimited home visits per pregnancy	Not required
Electric Stimulators (pain management) Transcutaneous electrical nerve stimulation (TENS) device for pain management	Members 21 years and older	Required
Hearing Services Hearing assessment, hearing aid assessment and hearing aids for in or behind the ear	 One evaluation per two years One assessment per two years One hearing aid per ear per two years Members 21 years of age and older 	Required
Home Delivered Meals — Post-Facility Discharge (Hospital or Nursing Facility) Home delivered meals, including preparation (per meal)	Two meals per day for seven days; must be after three-day or more surgical hospital stay; members 18 years of age and older	Required
Home Health Nursing/Aide Services Nursing services and medical assistance provided in members' homes to help them manage or recover from a medical condition, illness or injury	One additional unit of service per day; members 21 years of age and older	Required

Service	Coverage/Limitations	Prior Authorization
Housing Assistance Supported housing, per month	\$500 per lifetime for homeless individuals; members 21 years of age and older	Required
Massage Therapy Therapeutic procedures involving massage, mobilization, manipulation or manual traction for pain relief	Eight units (two hours) per year for eligible members, 21 years of age and older, with acute musculoskeletal pain	Required
Meals — Nonemergency Transportation Day-Trips Nonemergency transportation and meals for members and required escort to medically necessary doctor visits greater than 100 miles each way	\$200 per day; members 21 years of age and older	Required
Newborn Circumcision Circumcision	One per lifetime within first 28 days of birth	Not required
Nutritional Counseling Nutritional counseling, dietician visit	Six visits per year for eligible members	Not required
Occupational Therapy	One evaluation and re-evaluation per year; up to seven therapy treatment units per week; members 21 years of age and older	Required
Outpatient Hospital Services Medical care members get while they are in the hospital but not staying overnight. This can include any tests, medicines, therapies and treatments, visits from doctors and equipment that is used to treat members.	\$200 additional per year, excluding lab services; members 21 years of age and older	Required* * Refer to online quick tools for exact requirements by CPT code.
Over-the-Counter Benefit Cough, cold and allergy medications, vitamins and supplements, ophthalmic/otic preparations, pain relievers, gastrointestinal products, first aid care, hygiene products insect repellent (DEET and non-DEET), oral hygiene products, skin care	Limited to \$25 per household per month	Not required
Physical Therapy Evaluation moderate complexity Re-evaluation Treatment visit	One evaluation and re-evaluation per year; up to seven therapy treatment units per week; members 21 years of age and older	Required

Service	Coverage/Limitations	Prior Authorization
Prenatal Services — Prenatal/Perinatal Visits Breast pump rental for breast feeding Antepartum management: 14 visits for low-risk pregnancies and 18 visits for high-risk pregnancies Postpartum care: three visits within 90 days following delivery	Breast pump: one per two years; rental only	Required
Primary Care Visit Services for Adults Services for doctor's visits to stay healthy and prevent or treat illness	Unlimited visits for members 21 years of age and older	Not required
Respiratory Supplies Supplies needed for use of approved positive airway pressure device	Members 21 years and older	Not required
Respiratory Therapy Initial evaluation and re-evaluation Respiratory therapy visit	One per year for members 21 years of age and older	Not required
Speech Therapy/Speech Language Pathology Evaluation/re-evaluation Evaluation of swallowing function Speech therapy visit AAC initial evaluation/re-evaluation AAC fitting, adjustment and training visit	One evaluation/re-evaluation per year; up to seven therapy treatment units per week; one AAC evaluation/re-evaluation per year; up to 30 minutes AAC fitting adjustment and training sessions per year; members 21 years of age and older	Required
Substance Abuse — Intensive Outpatient Treatment Alcohol and/or drug services; intensive outpatient	Three hours per day, three days per week, nine hours per week, maximum eight weeks; members 21 to 54 years of age	Required
Therapy — Art Activity therapy, such as music, dance, art or play therapies not for recreation, related to the care and treatment of patient's disabling mental health problems, per session	Unlimited visits for members receiving behavioral health services	Required
Vaccine — Pneumonia (Pneumococcal) Pneumococcal conjugate vaccine 13 valent intramuscular Pneumococcal polysaccharide vaccine 23 valent adult or immunosuppressed dosage subcutaneous or intramuscular	Adults 21 to 64 years of age when medically necessary; adults 65 years or older	Not required
Vaccine — Hepatitis B Hepatitis B vaccine, adult dosage	All adults who have not been previously vaccinated are eligible to receive the vaccine.	Not required

Service	Coverage/Limitations	Prior Authorization
Vaccine — Human Papilloma Virus HPV vaccine	All adults ages 21 to 26 who have not previously received the vaccine are eligible	Not required
Vaccine — Influenza Influenza virus vaccine split virus preservative free intramuscular, 90656 Influenza virus vaccine, 90664, 90666, 90667, 90668 Administration of vaccine, G0008	Members 21 years of age or older; unlimited per pregnancy	Not required
Vaccine — Meningococcal Meningococcal conjugate vaccine serogroups A, C, Y, W-135 tetravalent intramuscular	All adults with HIV who have not been previously vaccinated are eligible to receive two primary doses at least two months apart and be revaccinated every five years	Not required
Vaccine — TDaP Tetanus diphtheria toxoids acellular pertussis vaccine (TDaP) intramuscular	All pregnant members are eligible to receive two primary doses at least two months apart and revaccination every five years; members 21 years of age and older	Not required
Vision Services Eye exam exclusively to screen visual acuity without need of reported vision problem, illness, disease or injury; contact lenses; frames	One exam per year; one frame per year; six months of contact lenses with prescription; members 21 years of age and older	Not required
Waived Copays The plan waives copays on the following services: birthing center; chiropractic; community behavioral health; FQHC; inpatient and outpatient hospital; independent labs; nonemergency transportation; ARNP; optometrist; physician assistant; physician; podiatrist; portable X-ray; RHC; registered nurse first assistant	Members 21 years of age and older	Not required

Florida Healthy Kids Expanded Benefits

- \$10 a month to buy certain personal care items and over-the-counter (OTC) medicines
- \$100 for hypoallergenic bedding (if medically needed)
- Six months of free fitness and healthy behavior coaching for members 7 to 13 years of age
- A free mouth guard for children who play contact sports
- Our 24-hour Nurse HelpLine to answer medical questions anytime at 1-866-864-2544 (TTY 711)

Taking Care of Baby and Me® Program

Taking Care of Baby and Me® is a proactive case management program for all expectant mothers and their newborns that uses extensive methods to identify pregnant women as early in their pregnancy as possible through review of state enrollment files, claims data, hospital census reports, Availity Maternity Module and notification of pregnancy forms as well as provider and self-referrals. Once pregnant members are identified, we

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act quickly to assess obstetrical risk and ensure the appropriate levels of care and case management services are provided.

Experienced case managers work with members and providers to establish a care plan for our highest risk pregnant members. Case managers collaborate with community agencies to ensure mothers have access to necessary services, including transportation, WIC, home-visitor programs, breastfeeding support and counseling. When it comes to our pregnant members, we are committed to keeping both mom and baby healthy. That's why we encourage all of our moms-to-be to take part in our Taking Care of Baby and Me program – a comprehensive case management and care coordination program offering:

- Individualized, one-on-one case management support for women at the highest risk.
- Care coordination for moms who may need a little extra support.
- Educational materials and information on community resources.
- Incentives to keep up with prenatal and postpartum checkups and well-child visits after the baby is born.

As part of the Taking Care of Baby and Me® program, members are also offered the **My Advocate®** program. This program provides pregnant women proactive, culturally appropriate outreach and education through interactive voice response (IVR). Eligible members receive regular phone calls with tailored content from a voice personality (Mary Beth), or they may choose to access the program via a smartphone application or website. This program does not replace the high-touch case management approach for high-risk pregnant women; however, it does serve as a supplementary tool to extend our health education reach. The goal of the expanded outreach is to identify pregnant women who have become high-risk, to facilitate connections between them and our case managers, and improve member and baby outcomes. For more information on My Advocate, visit **www.myadvocatehelps.com**.

Simply <u>encourages</u> notification of pregnancy after the first prenatal visit and notification of delivery following birth. You may choose to complete the notification of pregnancy and delivery in the online Interactive Care Reviewer or fax the forms to Simply at <u>1-800-964-3627</u>.

We also encourage providers to complete the Maternity form in Availity.

- Perform an <u>Eligibility</u> and <u>Benefits (E&B)</u> request on <u>the desired</u> member
- <u>Choose</u> one of the following benefit service types: <u>maternity</u>, <u>obstetrical</u>, <u>gynecological</u>, <u>or obstetrical/gynecological</u>.
- Before the benefit results screen, you will be asked if the member is pregnant. Choose "Yes", if applicable. If you indicate "Yes" you may provide the estimated due date, if it is known, or leave it blank if the due date is unknown.
- After <u>submitting</u> your answer, <u>the E&B will display</u>. If the <u>member was identified as pregnant</u>, a Maternity <u>form</u> will <u>be generated</u>. You <u>may access</u> the <u>form by navigating to the "Applications" tab and selecting the "Maternity" link</u>.

Taking Care of Baby and Me provides care management to:

- Improve the member's level of knowledge about her pregnancy.
- Create systems that support the delivery of quality care.
- Measure and maintain or improve member outcomes related to the care delivered.
- Facilitate care with providers to promote collaboration, coordination and continuity of care.
- Facilitate care with providers to promote collaboration, coordination and continuity of care.

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NICU Case Management

For parents with infants admitted to the neonatal intensive care unit (NICU), we offer the NICU Case Management program. The NICU Case Management program is committed to ensuring that all NICU members have a well-defined plan for quality care and a safe and successful transition from hospital to home. Experienced and dedicated NICU case managers, provide

parents/caregivers with individualized, one-on-one case management support specifically designed to help with

This program focuses on telephonic outreach to parents/caregivers of infants expected to be in the hospital greater than two weeks who were born at 34 or fewer weeks gestation, born weighing 2000 grams or less, born with major congenital anomalies, require ventilator care, or require major surgery. We provide education and with individualized, one-on-one case management support specifically designed to help them cope with the day-to-day stress of having a baby in the NICU, encourage them to stay involved in the care of their babies and help them prepare themselves and their homes for discharge.

Once a NICU member is identified, the NICU case manager proactively collaborates with the parent/caregiver, provider and/or hospital to ensure all outpatient needs are met. NICU case managers work closely with the parent/caregiver to establish an individualized plan of care for the member and to provide education and resources that outline successful strategies they may use when collaborating with their baby's NICU care team during and after their NICU stay. NICU case managers also provide parent/caregivers with appropriate community agency resources to ensure access to necessary outpatient services.

The stress of having <u>an</u> infant in the NICU <u>may</u> result in Post-Traumatic Stress Disorder (PTSD) symptoms <u>for</u> parents and loved ones. <u>To</u> reduce the impact of PTSD among our members, we assist by:

- Guiding parent(s) into hospital-based support programs, if available
- Screening parent(s) for PTSD approximately one month after their baby's date of birth
- Referring parent(s) to behavioral health program resources, if indicated
- Reconnecting with a one-month follow-up call to assess if the parent(s) received benefit from initial
 contact and PTSD awareness

If you <u>are caring for a NICU member</u> or <u>are working with a parent/caregiver that</u> would benefit <u>from NICU Case Management services</u>, please call Provider Services at **844-405-4296**. <u>Parents/caregivers can also call our 24/7 NurseLine at **844-406-2396** (TTY **711**), available 24 hours a day, 7 days a week.</u>

Quality Enhancement Program

Simply offers quality-enhanced programs for the benefit of members and providers. These include:

- Children's programs We provide regular general wellness programs for ages birth to 5 years, or we make a good faith effort to involve members in existing community children's programs.
 - a. We rely on providers seeing children to provide prevention and early intervention services for at-risk members. We approve claims for services recommended by the early intervention programs when they are covered services and medically necessary.
 - b. We offer annual training to providers (through monthly provider agendas, the Simply website, etc.) that promote proper nutrition, breastfeeding, immunizations, wellness, prevention and early intervention services.
- 2. Domestic violence programs We require PCPs to screen members for signs of domestic violence and require PCPs to offer referral services to applicable domestic violence prevention community agencies.

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- 3. Pregnancy prevention We conduct pregnancy prevention programs or make a good faith effort to involve members in existing community pregnancy prevention programs. These programs will be targeted toward teen enrollees but be open to all ages.
- 4. Prenatal/postpartum pregnancy programs We provide regular home visits by a home health nurse or aide and offer counseling and educational materials to pregnant and postpartum members who are not in compliance with the health plan's prenatal and postpartum programs. We will coordinate our efforts with the local Healthy Start care coordinator to prevent duplication of services. We require that all providers supply voluntary family planning, including a discussion of all methods of contraception, as appropriate. We require that all providers give all women of childbearing age HIV counseling and offer them HIV testing.
- Smoking cessation We provide smoking cessation counseling to members. We provide participating PCPs
 with a quick reference card to help identify tobacco users and support delivery of effective smoking
 cessation interventions. Please see the "Smoking Cessation Program" section below.
- Substance abuse programs We offer annual substance abuse screening training to our providers. In
 addition, several screening tools and other resources are available on our provider website to help providers
 identify substance abuse and make appropriate referrals.
 - a. At a minimum, all PCPs are required to screen members for signs of substance abuse as part of prevention evaluation at the following times:
 - i) During initial contact with a new member
 - ii) During routine physical examinations
 - iii) During initial prenatal contact
 - iv) When the member displays serious overutilization of medical, surgical, trauma or emergency services
 - v) When documentation of emergency room visits suggests the need
 - b. Providers identifying patients with substance abuse needs should refer patients to community substance abuse programs.

Encounter submission is critical to ensuring the quality of services by validating the work providers perform. To obtain credit for services rendered, all providers must submit encounters when including providers contracted under a capitated arrangement.

Well-Child Visits/Early and Periodic Screening, Diagnosis and Treatment (EPSDT) for Statewide Medicaid Managed Care Managed Medical Assistance and MediKids Members

Simply members are encouraged to contact their physician within the first 90 days of enrollment to schedule a well-child visit and within 24 hours for newborns. Simply members are eligible to receive these services from birth to age 20. For EPSDT members, if a service is medically necessary, it must be covered, regardless of whether the service is on the fee schedule or not. This applies to all EPSDT members under 21 years of age.

Note: EPSDT requirements are applicable to Medicaid and MediKids.

The program provides the following:

- Comprehensive health and development history
- Physical and mental development assessment
- Comprehensive unclothed physical examination
- Age-appropriate immunizations
- Appropriate laboratory tests
- Health education

Newborn well-child services should be performed for newborns in the hospital and then at the following ages:

- 3 to 5 days old
- 6 months

- 1 month
- 9 months
- 2 months
- 12 months
- 4 months

In the child's second year of life, he or she should see a PCP at 15 months, 18 months, 24 months and 30 months of age. During the span of a child's third year of life until age 20, the child should be seen by his or her PCP at least on an annual basis. Simply educates our members about these guidelines and monitors encounter data for compliance.

Simply recommends that participating providers who treat children under the age of 21 utilize the American Academy of Pediatrics Bright Futures well-child forms to ensure all aspects of an EPSDT visit are captured. The forms are at https://brightfutures.aap.org (Tools and Resources).

Simply requires providers to:

- Participate in the EPSDT program if they treat children under the age of 21.
- Provide all needed initial, periodic and interperiodic EPSDT health assessments, diagnosis and treatment to
 all eligible members in accordance with the Florida Agency for Health Care Administration's approved
 Medicaid administrative regulation Sect. III C.9.b and the periodicity schedule provided by the American
 Academy of Pediatrics (AAP).
- Refer members to an out-of-network provider for treatment if the service is not available within our network.
- Provide vaccines and immunizations in accordance with the Advisory Committee on Immunization Practices (ACIP) guidelines.
- Provide vaccinations in conjunction with EPSDT/well-child visits; providers are required to use vaccines
 available without charge under the Vaccine for Children (VFC) program for Medicaid children 18 years of
 age and younger (excludes MediKids).
- Address unresolved problems, referrals and results from diagnostic tests, including results from previous EPSDT visits.
- Request a prior authorization for a medically necessary EPSDT special service in the event other health
 care, diagnostic, preventive or rehabilitative services or treatment, or other measures described in 42
 U.S.C. 1396d(a) are not otherwise covered under the Florida Medicaid program.
- Monitor, track and follow up with members:
 - o Who have not had a health assessment screening.
 - $\circ\quad$ Who miss appointments, to assist them in obtaining an appointment.
- Ensure members receive the proper referrals to treat any conditions or problems identified during the
 health assessment, including tracking, monitoring and following up with members to ensure they receive
 the necessary medical services.
- Assist members with transition to other appropriate care for children who age-out of EPSDT services.

Simply recommends that participating providers who administer immunizations to children under the age of 18 utilize the Centers for Disease Control (CDC) Immunization Schedule for Persons Aged 0 through 18. This schedule is located at www.cdc.gov/vaccines/schedules/index.html.

Well-Child Visits Reminder Program

Based on Simply claims data, we send a list of members who may not have received wellness services according to schedule to the members' PCPs each quarter. Additionally, we mail information to these members encouraging them to contact their PCPs' offices to set up appointments for needed services. Please note:

• The specific service(s) needed for each member is listed in the report; reports are based only on services received during the time the member is enrolled with Simply.

- Services must be rendered on or after the due date in accordance with federal EPSDT and state Department of Health guidelines. In accordance with these guidelines, services received prior to the specified schedule date do not fulfill EPSDT requirements.
- This list is generated based on Simply claims data received prior to the date printed on the list; in some instances, the appropriate services may have been provided after the report run date.
- To ensure accuracy in tracking preventive services, please submit a completed claim form for those dates of service to the Simply Claims department at: Simply Healthcare Plans, Inc.

Florida Claims

P.O. Box 61010

Virginia Beach, VA 23466-1010

Blood Lead Testing Requirements

During every well-child visit for children between the ages of 6 months and 6 years, the PCP should screen each child for lead poisoning. Simply requires all PCPs to test for high blood lead levels assuring compliance with CMS requirements. These requirements state that all Medicaid enrollees must have a blood lead test performed at 12 months and 24 months of age to determine lead exposure and toxicity. In addition, children over the age of 24 months, up to 72 months, should receive a blood lead test if there is no past record of a test.

We encourage providers to contact Medtox to receive supplies to test children's blood lead levels in their offices. With a simple finger prick and a drop of blood on the filter paper from Medtox, the member will not have to go to another provider/lab to have the services done. Once you return the sample by mail, Medtox will send you the results and bill Simply for the test.

For those children who have a blood level greater than or equal to 10, continued testing is required until the blood level is below 10.

Vaccines for Children for Medicaid Recipients

The VFC program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of an inability to pay. VFC was created by the Omnibus Budget Reconciliation Act of 1993 as an entitlement program to be a required part of each state's Medicaid plan. The program was officially implemented in October 1994.

Funding for the VFC program is approved by the Office of Management and Budget and allocated through CMS to the Centers for Disease Control and Prevention (CDC). CDC buys vaccines at a discount and distributes them to grantees (that is, state health departments and certain local and territorial public health agencies) that then distribute them at no charge to those private physicians' offices and public health clinics registered as VFC providers.

Simply requires our providers to participate in the VFC program and have sufficient vaccine supplies. For additional information on the VFC program, visit https://www.cdc.gov/vaccines/programs/vfc/index.html.

Family Planning Services

Members have direct access to both network and non-network providers for all family planning services, including exams, assessments and traditional contraceptive devices. Services are not covered for members under the age of 18 unless they are married, a parent, pregnant or will suffer health hazards if services are not provided. FHK coverage of family planning is limited to one annual visit and one visit for a supplier every 90

days. Oral and injectable contraceptives and condoms are always covered for MMA members 12 and older and FHK members 10 and older.

Healthy Rewards - Healthy Behaviors Rewards Program

We offer programs to members who want to stop smoking, lose weight or address any drug abuse problems, and we reward members who join and meet certain goals. We also offer Well Child Visit programs, and Asthma Management. Our Healthy Rewards Programs include:

- Smoking cessation program.
- Weight management program.
- Alcohol and substance abuse program.
- Maternal child program.
- Well Child Visits
- Asthma Management

Setting Healthy Goals

The Simply Healthy Rewards program exists to help our members. Together, we make a plan and set goals to beat tough health issues. For example, for alcohol and substance abuse and smoking cessation, we offer help and support through coaching and participation in community groups. For weight management and nutrition, we offer help and support from a nurse in making healthy exercise and food choices.

Resources and Tools

The Florida Quitline is a toll-free, telephone-based tobacco use cessation service. Any person living in Florida who wants to try to quit smoking can use the Quitline. The following services are available through the Quitline:

- Counseling sessions
- Self-help materials
- Counseling and materials in English and Spanish
- Translation service for other languages
- Pharmacotherapy assistance
- TDD service for the deaf or hard of hearing

Online Resources	
Website	Resource Information
https://smokefree.gov	A cravings journal, information on medicines to help members quit, <i>Pathways to Freedom for African Americans</i> and <i>Guia para Dejar de Fumar</i> (Spanish resource)
 www.ffsonline.org 	American Lung Association's Freedom from Smoking Program
https://quitnet.comhttp://quitsmokingsupport.com	Additional resources, including support to quit, Information about why to quit and how to get help
https://www.cancer.gov/cancertop ics/factsheet/tobacco/cessation	, , , , , , , , , , , , , , , , , , , ,

Online Continuing Education for Physicians

Providers can receive continuing education training online through these resources:

- MAHP Oral Health and Tobacco Cessation Educational Program for Primary Care Providers
- Treating Tobacco Use and Dependence through the Wisconsin Medical School
- www.medscape.com
- **Tobacco Cessation Podcasts for Physicians**

Printed Resources for Members

We offer the following printed resources you can share with members:

- You Can Quit Smoking
- Tobacco Use Breaking the Habit
- Tobacco Use Reasons to Quit

Printed Resources for Providers

• Quick Reference Guide: Treating Tobacco Use and Dependence

All member materials are available on the member website, and provider materials are on the provider website.

Audiology Services

 $Simply \ provides \ audiology \ services \ \underline{in \ line \ with \ those \ offered \ by \ Florida \ Medicaid \ plus \ additional}$

expanded benefits for Medicaid members. :

Code/Mod	Description	Unit Length	Frequency
V5090	Dispensing fee, unspecified hearing aid	1 handling	6 every 12 months
	Comprehensive audiometry threshold evaluation and		
92557	speech recognition (92553 and 92556 combined)	1 evaluation	1 every 12 months
92590	Hearing aid examination and selection; monaural	1 evaluation	6 every 12 months
V5011	Fitting/orientation/checking of hearing aid	1 orientation	6 every 12 months
V5275/RT	Ear impression, each — right	1 ear mold	6 every 12 months
V5275/LT	Ear impression, each — left	1 ear mold	6 every 12 months
	Comprehensive audiometry threshold evaluation and		
92557/52	speech recognition (92553 and 92556 combined)	1 re evaluation	6 every 12 months
92592	Hearing aid check; monaural	1 analysis	6 every 12 months
92592/52	Hearing aid recheck; monaural	1 recheck	6 every 12 months
92552	Pure tone audiometry (threshold); air only	1 test	6 every 12 months
92567	Tympanometry (impedance testing)	1 test	6 every 12 months
	Evoked otoacoustic emissions; limited (single stimulus		
92587	level, either transient or distortion products)	1 test	No limit
	Comprehensive or diagnostic evaluation (comparison of		
	transient and/or distortion product otoacoustic		
92588	emissions at multiple levels and frequencies)	1 test	No limit
	Auditory evoked potentials for evoked response		
	audiometry and/or testing of the central nervous system;		
92585	comprehensive	1 test	No limit
	Auditory evoked potentials for evoked response		
	audiometry and/or testing of the central nervous system;		
92585/52	comprehensive	1 test	No limit
9258 4	Electrocochleography	1 test	1 per implant
92626	Evaluation of auditory rehabilitation status; first hour	1 test	10 per year

Outpatient Laboratory and Radiology Services

All outpatient laboratory tests should be performed at a network facility outpatient lab or at one of the Simply preferred network labs (LabCorp) unless the test is a Clinical Laboratory Improvement Amendments (CLIA)-approved office test. Visit the CMS website at https://www.cms.hhs.gov for a complete list of approved

accreditation organizations under CLIA. AIM Specialty Health® (AIM) provides diagnostic radiology management services and will provide pre-certifications for CAT scans, MRA, MRI, nuclear cardiology and PET scans. Contact AIM at **800-252-2021** or www.aimspecialtyhealth.com for more information.

Pharmacy Services

The Simply pharmacy benefit provides coverage for medically necessary medications from licensed prescribers for the purpose of saving lives in emergency situations or during short-term illness, sustaining life in chronic or long-term illness, or limiting the need for hospitalization. Members have access to national pharmacy chains and many independent retail pharmacies.

Covered Drugs

The Simply Pharmacy program uses a *Preferred Drug List (PDL)*. This is a list of the preferred drugs within the most commonly prescribed therapeutic categories. To prescribe medications that do not appear on the *PDL*, you may initiate an electronic prior authorization request through https://www.covermymeds.com. Prescribers may also call Pharmacy Services at 877-577-9044 or fax a completed *Pharmacy Prior Authorization Form* to 877-577-9045 for retail pharmacy requests and 844-509-9862 for medical injectable requests. Please refer to the *Pharmacy Prior Authorization Form*, MMA and Florida Healthy Kids *PDL*s, and prior authorization criteria links on our provider website.

Drugs Requiring Prior Authorization

Providers are strongly encouraged to write prescriptions for preferred products as listed on the appropriate *PDL* for that member (either MMA or FHK). If a member cannot use a preferred product because of a medical condition, providers are required to contact Simply Pharmacy Services to obtain prior authorization. To request prior authorization, call the Pharmacy department at **877-577-9044** or fax a completed *Pharmacy Prior Authorization Form* (available on the provider website) to **877-577-9045** for retail pharmacy requests and **844-509-9862** for medical injectable requests. You may also initiate electronic prior authorization requests through https://www.covermymeds.com. Providers must be prepared to provide relevant clinical information regarding the member's need for a nonpreferred product or a medication requiring prior authorization. Decisions are based on medical necessity and are determined according to certain established medical criteria.

Over-The-Counter Drugs

Simply provides coverage of several OTC drugs when accompanied by a prescription. The following are examples of covered OTC medication classes. Providers should consult the MMA and FHK *PDLs* for specifics on covered products and limits (members may be able to access OTC products under the Value Added OTC Benefit):

- Analgesics/antipyretics
- Antacids
- Antifungals, topical
- Antifungals, vaginal
- Antihistamines
- Antihistamine-decongestant combinations
- Emergency contraceptives

- Cough and cold preparations
- Iron replacement supplements
- Laxatives
- Pediculicides
- Respiratory agents (including spacer devices)
- Select vitamins and multi-vitamins

Excluded Drugs

The following drugs are examples of medications that are excluded from the pharmacy benefit:

- Weight control
- Anti-wrinkle agents (for example, Renova)
- Drugs used for cosmetic reasons (hair growth or hair growth removal)
- Drugs used for experimental or investigational indication

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- · Erectile dysfunction drugs to treat impotence
- Drugs that duplicate therapy

Informed Consent for Psychotherapeutic Medications for Children (Statewide Medicaid Managed Care Managed Medical Assistance Members)

Pursuant to *F.S.A.* 409.912(13), the Agency for Health Care Administration (AHCA) may not pay for a psychotropic medication prescribed for a child under the age of 13 years in the Medicaid program without the express and informed consent of the child's parent or legal guardian. The physician must document the consent in the child's medical record and provide the pharmacy with a signed attestation of this documentation with the prescription.

The psychotherapeutic drugs <u>include (but</u> are <u>not limited to)</u> antipsychotics, antidepressants, antianxiety medications and mood stabilizers. <u>Certain anti</u>-convulsants and ADHD medications (that is, stimulants and nonstimulants) are not included at this time <u>(subject to change)</u>. A signed *Informed Consent Form* must be presented to the pharmacy with each new prescription for an affected drug for a member under 13 years of age. Consent forms are available at

 $http://ahca.my florida.com/medicaid/prescribed_drug/med_resource.shtml.\\$

Carved Out Medications

Hemophilia drugs are an excluded service from the health plan's Medicaid benefit package. They are covered through the fee-for-service Statewide Medicaid Comprehensive Hemophilia Disease Management Program.

The Agency for Health Care Administration (Agency) entered into a contract with CVS Caremark (Vendor) to fulfill the responsibilities of the Statewide Medicaid Comprehensive Hemophilia Management Program. The Vendor's contract combines the provision of pharmaceutical products, pharmaceutical management, and disease management (e.g., treatment and prevention of bleeding episodes, medical consultation, home infusion education, training, twenty-four hours per day, seven days a week access to a registered nurse and a licensed pharmacist) for the Florida Medicaid recipients diagnosed with hemophilia or Von Willebrand disease.

Should you have any questions about the Hemophilia Disease Management Program, please feel free to contact:

 The Agency's Provider and Recipient Assistance Bureau Monday – Friday, 8:00 a.m. EST - 5:00 p.m. EST
 1-877-254-1055 (TDD 1-866-467-4970) or online at:

https://www.flmedicaidmanagedcare.com/home/contact

CVS Caremark
 Monday – Friday, 8:00 a.m. EST - 5:00 p.m. EST
 1-888-826-5621 Option 4

There are no carved out medications for FHK members

Copies of the consent form must be maintained in the member's medical records.

Behavioral Health Services

Overview

Pursuant to the Simply contract with AHCA and the state MMA plan, Simply will provide coverage, via its subcontractor Beacon Health Strategies, for a full range of behavioral health care services (that is, treatment for psychiatric and emotional disorders), including community mental health services and mental health targeted case management services to all members in contracted counties. Simply will provide coverage of mental health

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and alcohol and drug treatment for Florida Healthy Kids members residing in the counties in which Simply participates as part of the member's behavioral health benefit.

Primary and Specialty Services

PCPs are encouraged to screen members for behavioral health and alcohol and drug abuse conditions as part of the initial assessment, or whenever there is a suspicion a member may have a behavioral health condition.

Age-appropriate validated behavioral health screening and assessment tools for children and adolescents:

- ADHD: NICHQ Vanderbilt Assessment Scale
- ADHD: ADHD Rating Scale-Home Version
- Anxiety: Generalized Anxiety Disorder-7 (GAD-7)
- Autism: Modified Checklist for Autism in Toddlers Revised (M-CHAT-R)
- Autism: First Signs Screening Tools
- Depression: Adolescent Patient Health Questionnaire-9 (PHQ9)
- Substance Use Disorder: The CRAFFT Screening Interview
- Substance Use Disorder: AUDIT-PC Screening Tool
- Substance Use Disorder: CAGE Questionnaire Alcohol Screening tool

Additional behavioral health and substance use disorder assessment tools can be found on our website: https://provider.simplyhealthcareplans.com/florida-provider/behavioral-health

A PCP can offer covered behavioral health and/or alcohol and drug abuse services when:

- Services are within the scope of the PCP's license.
- The member's current condition is not so severe, confounding or complex as to warrant a referral to a mental health and alcohol and drug abuse provider.
- The member is willing to be treated by the PCP.
- Services are within the scope of the benefit plan.

PCPs are encouraged to educate members with behavioral health and/or alcohol and drug abuse conditions about the nature of the condition and its treatment. As appropriate, PCPs are also encouraged to educate members about the relationship between physical and behavioral health and alcohol and drug abuse conditions. Referral for Mental Health and Alcohol and Drug Abuse Conditions

Members may self-refer, or providers may direct members to the Simply network of behavioral health care providers.

Experienced behavioral health care clinicians are available 24 hours a day, 7 days a week by calling the Provider Inquiry Line (1-844-405-4296) to assist with identifying the closest and most appropriate behavioral health service.

Behavioral Health Claims

Submit paper behavioral health claims to: Beacon Health Options Claims Department P.O. Box 1850 Hicksville, NY 11802-1850

Electronic behavioral health claims may be submitted through the Simply contracted clearinghouses. To initiate the electronic claims submission process or obtain additional information, please contact the Simply Electronic Data Interchange (EDI) Hotline at 1-800-590-5745.

Behavioral Health Emergency Services

Behavioral health emergency services are those services that are required to meet the needs of an individual who is experiencing an acute crisis resulting from a mental illness, which is at a level of severity that would meet the requirements for involuntary examination pursuant to *Section 394.463, F.S.*, and who, in the absence of a suitable alternative or psychiatric medication, would require hospitalization. Examples of behavioral health and alcohol and drug abuse emergency medical conditions are when:

- The member is suicidal.
- The member is homicidal.
- The member is violent with objects.
- The member has suffered a precipitous decline in functional impairment and is unable to take care of his or her activities of daily living.
- The member is alcohol- or drug-dependent and there are signs of severe withdrawal.

In the event of a behavioral health and/or alcohol and drug abuse emergency, the safety of the member and others is paramount. The member should be instructed to seek immediate attention at an emergency room or behavioral health and alcohol and drug abuse crisis service facility. An emergency dispatch service or 911 should be contacted if the member is a danger to his or her self or others and is unable to go to an emergency setting.

Behavioral Health Medically Necessary Services

Simply defines medically necessary behavioral health services as those that are:

- Reasonably expected to prevent the onset of an illness, condition or disability; reduce or ameliorate the
 physical, behavioral or developmental effects of an illness, condition, injury or disability; and assist the
 member to achieve or maintain maximum functional capacity in performing daily activities, taking into
 account both the functional capacity of the member and those functional capacities appropriate for
 members of the same age.
- Reasonably expected to provide an accessible and cost-effective course of treatment or site of service that
 is equally effective in comparison to other available, appropriate and substantial alternatives and is no
 more intrusive or restrictive than necessary.
- Sufficient in amount, duration and scope to reasonably achieve their purpose as defined in federal law.
- Of a quality that meet standards of medical practice and/or health care generally accepted at the time services are rendered

Behavioral Health Coordination of Care

Simply, through its contracted providers and case management services, will be responsible for the coordination and active provision of continuity of care for all members. Appropriate and timely sharing of information is essential when the member is receiving psychotropic medications or has a new or ongoing medical condition. Additionally, if applicable, Simply will coordinate medical and behavioral health services.

The exchange of medical information facilitates behavioral and medical health care collaboration. For example, if the PCP obtains the member's consent via the *Authorization for Release of Information* form, the form is completed and sent to the behavioral health care provider. The behavioral health care provider may use the release as necessary for the administration and provision of care.

Simply behavioral health providers are mandated to utilize the Functional Assessment Rating Scale (FARS) and Children's Functional Assessment Rating Scale (CFARS), which are the outcome measures used by the state of Florida for Medicaid providers. CFARSs are administered for patients ages 6 to 17 and FARSs are administered for patients ages 18 and older. FARS/CFARS assessments are required to be completed at admission, every six months after admission (as long as the member remains a patient) and at discharge.

A FARS/CFARS should not be completed for members who: 1) only receive a one-time assessment service and are immediately discharged or 2) are served in medication-only settings. Additionally, FARS is not required when a member is admitted and discharged from a crisis stabilization unit. Changes to any other level of service will require administration of the FARS.

Free Training and Certification Websites

Note that only staff with certification should be providing assessment services. Free trainings are available online:

- CFARS: https://samhweb.myflfamilies.com/FARS/cfars/cfars_home.aspx
- FARS: https://samhweb.myflfamilies.com/FARS/fars/fars_home.aspx

The behavioral health care provider is required to note contacts and collaboration efforts in the member's chart as well as determine whether referral assistance is needed for the member for noncovered services.

When the member has seen a behavioral health care provider, that provider is required to send a copy of a completed *Coordination of Care and Treatment Summary Form* to both Simply and the member's PCP. This form is available on our provider website.

If a PCP refers a member to a contracted behavioral health care provider, the PCP will fax a copy of a completed *Coordination of Care and Treatment Summary Form* to the designated behavioral health care fax (1-800-370-1116) and to the behavioral health care provider.

The behavioral health care provider will send initial and quarterly (or more frequently if clinically indicated) summary reports of the member's behavioral health status to the member's PCP. The PCP will be contacted if there is a change in the behavioral health treatment plan. The PCP will contact the behavioral health care provider and document the information on the *Coordination of Care and Treatment Summary Form* if the member's medical condition could reasonably be expected to affect the member's mental health treatment planning or outcome.

Self-Referral Services

The following services do not need a referral from a PCP:

- Emergent care (regardless of network status with Simply)
- Family planning (regardless of network status with Simply)
- Behavioral health assessments (nonparticipating providers must seek prior approval from Simply)
- OB care (nonparticipating providers must seek prior approval from Simply)
- Well-woman/GYN care (nonparticipating providers must seek prior approval from Simply)
- EPSDT/well-child services (nonparticipating providers must seek prior approval from Simply)
- Tuberculosis, STD, HIV/AIDS testing and counseling services (regardless of network status with Simply)

Member Rights and Responsibilities

Florida law requires that providers or health care facilities recognize the rights of members while they are receiving medical care and that members respect the health care provider's or health care facility's right to expect certain behavior on the part of members. Members may request a copy of the full text of this law from their health care provider or health care facility. The following is a summary of the member's rights and responsibilities (see Section 381.026, Florida Statutes).

Patients' Rights

Patients have a right to:

- Be treated with respect and with due consideration for dignity and privacy.
- · A prompt and reasonable response to questions and requests.
- Know who is providing medical services and who is responsible for their care.
- A right to receive information about the organization, its services, its practitioners and providers and member rights and responsibilities
- A right to make recommendations regarding the organization's member right and responsibilities policy
- Know what member support services are available, including whether an interpreter is available if they
 don't speak English.
- Know what rules and regulations apply to their conduct.
- Receive information on available treatment options and alternatives, presented in a manner appropriate to their conditions and ability to understand, regardless of cost or benefit coverage.
- Be given the opportunity to be involved in decisions involving their health care, except when such
 participation is contraindicated (not recommended) for medical reasons.
- · Refuse treatment.
- Be given health care services in line with federal and state regulations.
- Be given, upon request, full information and necessary advice of available financial help for their care.
- Receive, upon request, before treatment, a reasonable estimate of charges for medical care.
- Receive a copy of a reasonably clear and easy-to-understand itemized bill and, upon request, have the charges explained.
- Impartial access to medical treatment or accommodations, no matter of race, national origin, religion, physical handicap or source of payment.
- Treatment for any emergency medical condition that will get worse from not getting the proper treatment.
- Know if medical treatment is for experimental research and give consent or refusal to be involved in that
 research.
- File grievances and appeals regarding any violation of their rights, as stated in Florida law, through the
 grievance procedure to the health plan, health care provider or health care facility that served them and to
 the appropriate state licensing agency.
- Be free from any form of restraint (control) or seclusion used as coercion (force), discipline, convenience or retaliation (revenge).
- Ask for and get a copy of their medical records and ask that those records be updated or corrected.
- A right to a candid discussion of appropriate or medically necessary treatment options for
- their conditions, regardless of cost or benefit coverage

Patients' Responsibilities

Patients have the responsibility to:

- Provide their health care provider, to the best of their knowledge, correct and complete information about
 present complaints, past illnesses, hospitalizations, medications (including over-the-counter products),
 dietary supplements, any allergies or sensitivities, and other matters relating to their health.
- Report unexpected changes in their conditions to their health care providers.
- Report to their health care providers whether they understand a planned action and what is expected of them
- Participate in developing the mutually agreed upon treatment plan recommended by their health care
 provider and follow the plan and instructions.
- Keep appointments and, when not able to for any reason, tell the health care provider or health care facility.
- Understand their actions if they refuse treatment or don't follow the health care provider's instructions.
- Inform their providers about any living wills, medical powers of attorney or other directives that could change their care.
- Make sure the needs of their health care are met as quickly as possible.

- Follow health care facility rules and regulations about member care and conduct.
- Behave in a way that is respectful of all health care providers and staff as well as of other members.

First Line of Defense Against Fraud

General Obligation to Prevent, Detect and Deter Fraud, Waste and Abuse

As a recipient of funds from federally and state-sponsored health care programs, we each have a duty to help prevent, detect and deter fraud, waste and abuse. Simply's commitment to detecting, mitigating and preventing fraud, waste and abuse is outlined in our Corporate Compliance Program. Electronic copies of this policy and the Simply Code of Business Conduct and Ethics are available at www.simplyhealthcareplans.com/provider and www.simplyhealthcareplans.com/provide

As part of the requirements of the federal Deficit Reduction Act, each Simply provider is required to adopt Simply policies on detecting, preventing and mitigating fraud, waste and abuse in all the federally and state-funded health care programs in which Simply participates.

As a Simply provider and a participant in government-sponsored health care, you and your staff are obligated to report suspected fraud, waste and abuse. You can report anonymously if you suspected fraud by calling the Special Investigations Unit (SIU) hotline at 1-866-847-8247. Any incident of fraud, waste or abuse may be reported to us anonymously; however, our ability to investigate an anonymously reported matter may be handicapped without enough information. Hence, we encourage you to give as much information as possible. We appreciate your time in referring suspected fraud, but be advised that we do not routinely update individuals who make referrals as it may potentially compromise an investigation.

When reporting concerns involving a <u>PROVIDER</u> (a doctor, dentist, counselor, medical supply company, etc.) include:

- Name, address and phone number of provider
- Name and address of the facility (hospital, nursing home, home health agency, etc.)
- Medicaid number of the provider and facility, if you have it
- Type of provider (doctor, dentist, therapist, pharmacist, etc.)
- Names and phone numbers of other witnesses who can help in the investigation
- Dates of events
- Summary of what happened

When reporting concerns involving a MEMBER include:

- The member's name
- The member's date of birth, Social Security Number or case number if you have it
- The city where the member resides
- Specific details describing the fraud, waste or abuse

Learn more at www.fighthealthcarefraud.com.

As an alternative, you can also report suspected fraud or abuse in Florida Medicaid directly to the Agency for Health Care Administration by calling their Consumer Complaint Hotline toll-free at <u>1-888-419-3456</u> or complete a *Medicaid Fraud and Abuse Complaint Form*, which is available online at

https://apps.ahca.myflorida.com/mpi-complaintform. If you report suspected fraud and your report results in a fine, penalty or forfeiture of property from a doctor or other health care provider, you may be eligible for a reward through the Inspector General's Fraud Rewards Program. You can call the Inspector General's office at 1-866-866-7226 (toll-free). The reward may be up to 25% of the amount recovered or a maximum of \$500,000 per

case (Florida Statutes Chapter 409.9203). You can talk to the Attorney General's office about keeping your identity confidential and protected.

To meet the requirements under the Deficit Reduction Act, you must adopt the Simply fraud, waste and abuse policies and distribute them to any of your staff or contractors. If you have questions or would like to have more details concerning the Simply fraud, waste and abuse detection, prevention and mitigation program, please contact 1-844-405-4296.

Importance of Detecting, Deterring and Preventing Fraud, Waste and Abuse

Health care fraud costs taxpayers increasingly more money every year. There are state and federal laws designed to crack down on these crimes and impose strict penalties. Fraud, waste and abuse in the health care industry may be perpetuated by every party involved in the health care process. There are several stages to inhibiting fraudulent acts, including detection, prevention, investigation and reporting.

We are committed to protecting the integrity of our health care program and the effectiveness of our operations by preventing, detecting and investigating fraud, waste and abuse. Combating fraud, waste and abuse begins with knowledge and awareness.

- Fraud Any type of intentional deception or misrepresentation made with the knowledge that the
 deception could result in some unauthorized benefit to the person committing it -- or any other person.
 The attempt itself is fraud, regardless of whether or not it is successful
- Waste includes overusing services, or other practices that, directly or indirectly, result in unnecessary
 costs. Waste is generally not considered to be driven by intentional actions, but rather occurs when
 resources are misused.
- Abuse when health care providers or suppliers do not follow good medical practices resulting in
 unnecessary or excessive costs, incorrect payment, misuse of codes, or services that are not medically
 necessary.

In this section, we educate providers on how to help prevent member and provider fraud by identifying the different types so you can be the first line of defense.

Many types of fraud, waste and abuse have been identified, including the following:

Examples of Provider Fraud, Waste and Abuse (FWA):

- Altering medical records to misrepresent actual services provided
- Billing for services not provided
- Billing for medically unnecessary tests or procedures
- Billing professional services performed by untrained or unqualified personnel
- Misrepresentation of diagnosis or services
- Soliciting, offering or receiving kickbacks or bribes
- Unbundling when multiple procedure codes are billed individually for a group of procedures which should be covered by a single comprehensive procedure code
- Upcoding when a provider bills a health insurance payer using a procedure code for a more expensive service than was actually performed

Providers can help prevent fraud, waste and abuse by ensuring the services rendered are medically necessary, accurately documented in the medical records and billed according to American Medical Association guidelines.

Examples of Member Fraud, Waste and Abuse

- · Forging, altering or selling prescriptions
- Letting someone else use the member's ID (Identification) card
- Obtaining controlled substances from multiple providers
- Relocating to out-of-service Plan area
- · Using someone else's ID card
- Subrogation and/or third party liability fraud
- Transportation fraud

To help prevent fraud, waste and abuse, providers can educate members about the types of fraud and the penalties levied. Also, spending time with patients and reviewing their records for prescription administration will help minimize drug fraud and abuse.

One of the most important steps to help prevent member fraud is reviewing the Simply member ID card; it's the first line of defense against fraud. Simply may not accept responsibility for the costs incurred by providers rendering services to a patient who is not a member even if that patient presents a Simply member ID. Providers should take measures to ensure the cardholder is the person named on the card. Additionally, encourage members to protect their cards as they would a credit card or cash, carry their Simply member ID at all times, and report any lost or stolen cards to Simply as soon as possible.

We believe awareness and action are vital to keeping the state and federal programs safe and effective. Understanding the various opportunities for fraud, waste or abuse and working with members to protect their Simply ID cards can help prevent fraud, waste and abuse. We encourage our members and providers to report any suspected instance of fraud, waste or abuse by calling Member Services at 1-844-406-2396 (Medicaid); 1-844-405-4298 (FHK) or Provider Services at 1-844-405-4296. No individual who reports violations or suspected fraud, waste or abuse will be retaliated against, and Simply will make every effort to maintain anonymity and confidentiality.

HIPAA

The Health Insurance Portability and Accountability Act (HIPAA, also known as the Kennedy-Kassebaum bill) was signed into law in August 1996. The legislation improves the portability and continuity of health benefits, ensures greater accountability in the area of health care fraud, and simplifies the administration of health insurance.

Simply strives to ensure that both Simply and contracted providers conduct business in a manner that safeguards patient/member information in accordance with the privacy regulations enacted pursuant to HIPAA. Contracted providers must have the following procedures implemented to demonstrate compliance with the HIPAA privacy regulations.

- We recognize our responsibility under the HIPAA privacy regulations to only request the minimum
 necessary member information from providers to accomplish the intended purpose. Conversely, network
 providers should only request the minimum necessary member information required to accomplish the
 intended purpose when contacting Simply.
 - Please note, privacy regulations allow the transfer or sharing of member information, which may be requested by Simply to conduct business and make decisions about care (such as a member's medical record), to make an authorization determination, or resolve a payment appeal. Such requests are considered part of the HIPAA definition of treatment, payment or health care operations.

- Fax machines used to transmit and receive medically sensitive information should be maintained in an
 environment with restricted access to individuals who need member information to perform their jobs.
 When faxing information to Simply, verify the receiving fax number is correct, notify the appropriate staff
 at Simply and verify the fax was appropriately received.
- Email (unless encrypted) should not be used to transfer files containing member information to Simply (for example, Excel spreadsheets with claim information). Such information should be mailed or faxed.
- Use professional judgment when mailing medically sensitive information such as medical records. The
 information should be in a sealed envelope marked confidential and addressed to a specific individual, post
 office box or department at Simply.
- The Simply voicemail system is secure and password-protected. When leaving messages for Simply
 associates, only leave the minimum amount of member information required to accomplish the intended
 purpose.
- When contacting Simply, please be prepared to verify the provider's name, address and tax identification number, national provider identifier or Simply provider ID.

6 MEMBER MANAGEMENT SUPPORT

Welcome Call

As part of our member management strategy, Simply offers a welcome call to new members. During the welcome call, new members are educated regarding the health plan and available services. Additionally, Member Services representatives offer to assist the member with any current needs such as scheduling an initial checkup.

Appointment Scheduling

Through our participating providers, we ensure members have access to primary care services for routine, urgent and emergency services and to specialty care services for chronic and complex care. Providers will respond to a Simply member's needs and requests in a timely manner, per the guidelines outlined in the Access and Availability section.

24/7 NurseLine

The Simply 24/7 NurseLine is designed to support providers by offering information and education to members after hours about medical conditions, health care and prevention. Members can call 1-844-406-2396 — This number is also listed on the member's ID card. We provide triage services and help direct members to appropriate levels of care. This ensures members have an additional avenue of access to health care information when needed. Features of the 24/7 NurseLine include:

- Availability 24 hours a day, 7 days a week.
- Information based on nationally recognized and accepted guidelines.
- Free translation services for 150 different languages and for members that are deaf or hard of hearing.
- Education for members regarding appropriate alternatives for handling nonemergent medical conditions.
- Faxing of the member's assessment report to the provider's office within 24 hours of receipt of a call.

24/7 Pharmacy Member Services

The IngenioRx Pharmacy Member services hotline is available for members 24/7 to provide assistance related to the pharmacy benefit. Simply Medicaid members can call <1-833-214-3607>, Clear Health Alliance Medicaid members can call <1-833-235-2028> and FHK members can call <1-833-267-3110> for assistance.

Interpreter Services

Interpreter services are available if needed (including language translation services and Braille). Simply provides interpreter services, free of charge, for enrollees whose primary language is not English. Interpretation services are provided by Voiance*, which offers over 100 different languages and corresponding interpreters. Additionally, language translation services are available for enrollees who are hearing-impaired. Effective physician-patient communication is critical in improving comprehension, utilization, clinical outcomes, patient satisfaction and quality of care. It is important that patients and their providers are aware of available interpreter services and know how to access them.

How providers can access these services:

- Identify members with limited English proficiency.
- Ask these members if they prefer to communicate in a language other than English.
 - If yes, provide them with information regarding the available interpreter services. You or the member can call Member Services at <u>1</u>-844-406-2396 and ask for assistance.

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Health Promotion

Simply strives to improve healthy behaviors, reduce illness and improve the quality of life for our members through comprehensive programs. Educational materials are developed or purchased and then disseminated to our members, and health education classes are available through in-network community organizations and providers.

Ongoing projects that offer our members education and information regarding their health include:

- A newsletter to members at least once a year.
- Creation and distribution of a Simply health education tool newsletter used to inform members of health promotion issues and topics.
- Health Tips on Hold educational telephone messages that play while the member is on hold.
- A monthly member calendar of health education programs.
- Development of health education curricula and procurement of other health education tools (for example, breast self-exam cards).
- · Relationship development with community-based organizations to enhance opportunities for members.
- Available community resources via the Simply website at www.simplyhealthcareplans.com.

Case Management

Case management is designed to proactively respond to a member's needs when conditions or diagnoses require care and treatment for long periods of time. When a member is identified (usually through initial health risk assessment process, a predictive model, precertification, admission review, and/or provider or member request), the Simply case manager helps to identify the appropriate case management program and any medically appropriate alternative methods or settings in which care may be delivered.

A provider, on behalf of the member, may refer them to case management. The clinician will work with the member, provider and/or the hospital to identify the necessary:

- Intensity level of case management services needed.
- Appropriate alternate settings where care may be delivered.
- Health care services required.
- Equipment and/or supplies required.
- Community-based services available.
- Communication required (that is, between the member and PCP as well as other providers).

During an admission, the Simply <u>case manager</u> will assist the member, utilization review team, and PCP and/or hospital in developing the discharge plan of care, ensuring that the member's medical needs are met, and linking the member with community resources and Simply programs for outpatient case and/or disease management.

Please note, a Simply case manager cannot perform services that are limited to providers, such as overriding a prior authorization requirement for prescription medications.

HIV/AIDS Specialty Care

Clear Health Alliance provides members with comprehensive case and disease management. Our program includes care coordination across the continuum of care as well as secondary and tertiary prevention interventions. These services are based on a comprehensive, multidisciplinary and system-wide approach that encompasses evidence-based guidelines, practitioner practice and member empowerment strategies to improve members' health outcomes.

CHA's case management and care coordination staff work with the member's provider, often an HIV specialist (see **Credentialing**), to ensure adherence with HIV antiretroviral therapy and medical care visits. This includes coordination of care for:

- Appointments with primary and specialist providers.
- Transportation.
- Other assistance as needed to facilitate care for members including surrogate decision makers if the
 enrollee is not capable of making his or her own decisions but does not have a legal representative or
 authorized representative available.

Case managers address the acuity level and service the unique needs of each member. They score the results of *Health Risk Assessments* and assign a member risk category. This category is based on specific disease stratification algorithms and may be assigned to include low, moderate or high score. Results guide the development of the individualized care plan, and the corresponding interventions designed to improve compliance and health outcomes and prevent acute events. Care plans are:

- Created in collaboration with the member/caregiver, legal guardian or other legally authorized individual.
- · Based on member stratification.
- Designed to address interventions that:
 - o Improve member ability to adhere to the physician/provider treatment plan.
 - o Improve self-management.
 - o Decrease health risks.

We share the care plan with the primary and/or specialist provider(s) for review and feedback. We document, note and/or adjust the care plan as applicable based on any feedback obtained. And when a member receives services from a community agency (i.e., Ryan White) with member approval, we share the established care plan as appropriate with the case managers in these agencies to ensure all issues are addressed and there is no duplication of services.

Clear Health Alliance allows HIV specialists, including infectious disease providers, to be PCPs, which is unique to our plan and increases access to care. These providers, marked with a red ribbon in our provider directory, receive additional training in longitudinal management of HIV/AIDS and frequent comorbidities and bring experience, expertise and cultural sensitivity to our members. These providers are acutely aware of the incidence and implications of physical and behavioral health comorbidities, and they've developed robust integrated processes to deliver whole-person care.

Clear Health Alliance works closely with our primary care partners to build capacity for integrated care and expand member access to routine screening and follow-up for behavioral health conditions. Nationwide, more than half of patients seek treatment for behavioral health conditions from their PCPs, with non-psychiatrists writing more than three-fourths of antidepressant prescriptions. The presence of several mental health and substance use diagnoses are known to be common among people living with HIV/AIDS. Clear Health Alliance requires PCPs to routinely screen members for a range of behavioral health and substance use conditions as part of routine, preventive care. We provide our PCPs with the tools and expertise needed to complete the screenings, and we reimburse PCPs for routine screenings. Screening requirements are included in our provider contracts and in this provider manual.

We make many valid and reliable screening tools for behavioral health conditions easily accessible on our provider website (www.clearhealthalliance.com/provider) and train PCPs on the appropriate use of them. Examples of these tools include:

- Depression screening: Patient Health Questionnaire-9 (PHQ-9)
- ADHD screening: Conners rating forms, Vanderbilt scale, Barkley scale

- Psychosocial problems screening: The Pediatric Symptom Checklist
- Mood Disorder Questionnaire
- Anxiety screening: Generalized Anxiety Disorder-7
- SUD screening: CAGE-AID
- Mini-Cognitive Assessment Instrument
- Comprehensive training on SBIRT
- The "5 A's" model for treating tobacco use and dependence

Disease Management / Population Health Services

Disease management services are based on a system of coordinated care management interventions and communications designed to assist physicians and others in managing members with chronic conditions. The programs include a holistic, focusing on the needs of the member through telephonic and community-based resources. Motivational interviewing techniques used in conjunction with member self-empowerment. The ability to manage more than one disease to meet the changing health care needs of our member population.

Our disease management programs include:

- Behavioral health
 - o Bipolar Disorder
 - o Major Depressive Disorder Adult
 - Major Depressive Disorder –
 - Child/Adolescent
 - Schizophrenia o Substance Use Disorder
- Cardiac
 - o Coronary Artery Disease
 - o Congestive Heart Failure
- Alzheimer's/Dementia

- Oncology (active and post-treatment)1
- End of life (palliative program)1
- Diabetes
- HIV/AIDS
- Hypertension
- Pulmonary
 - o Asthma

 - o Chronic Obstructive Pulmonary Disease

In addition to our condition-specific programs listed above, our member-centric, holistic approach also allows us to assist members with weight management and smoking cessation education.

Program Features

- Proactive population identification processes
- <u>EvidenceProgram content is based on -evidence</u>-based clinical practice guidelines <u>from recognized sources</u>
- Collaborative practice models to include physician and support in treatment planning
- Continuous self-management education
- Ongoing communication with primary and ancillary providers regarding patient status
- Nine of our Disease Management programs are National Committee for Quality Assurance accredited and incorporate outreach, education, care coordination and follow-up to improve treatment compliance and enhance self-care.

Simply DM programs are based on nationally approved clinical practice guidelines, located on our provider website. A copy of the guidelines can be printed from the website.

Who is Eligible?

Members diagnosed with one or more of the above <u>listed</u> conditions are eligible for DM services.

As valued provider, we welcome your referrals of patients who can benefit from additional education and disease management support. Our case managers will work collaboratively with you to obtain your input in the development of care plans. Members identified for participation in any of the programs are assessed and risk-stratified based on the severity of their disease. They are provided with continuous education on self-management concepts, which include primary prevention, coaching healthy behaviors and compliance/monitoring as well as case/care management for high-risk members. Program evaluation, outcome measurement and process improvement are built into all the programs, and we provide telephonic and/or written updates regarding patient status and progress.

DM Provider Rights and Responsibilities

The provider has the right to:

- Obtain information about Simply, staff qualifications and any contractual relations.
- Decline to participate in or work with the Simply programs and services for his or her patients, depending on contractual requirements.
- Be informed of how Simply coordinates our interventions with treatment plans for individual patients.
- Know how to contact the person case manager responsible for managing and communicating with the
 provider's patients.
- Be supported by the organization to make decisions interactively with patients regarding their health care.
- Receive courteous and respectful treatment from Simply staff.
- Communicate complaints regarding the DM program as outlined in the Simply provider complaint and grievance procedure.

Hours of Operation

Simply DM case managers are registered nurses and are available Monday to Friday, 8:30 a.m. to 5:30 p.m. ET. Confidential voicemail is available 24 hours a day.

Contact Information

Call <u>1-888-830-4300</u> to reach a case manager, or refer to our provider website for additional information about DM. Members can obtain information about our DM program by visiting http://www.simplyhealthcareplans.com/Medicaid and www.clearhealthalliance.com/member or calling 1-888-830-4300.

Health Management: Healthy Families Program

Program offering families assistance with leading a healthy lifestyle and improving childhood obesity in our members. The Healthy Families program helps members by providing education, community resources, and individualized plans of care over a 6 month period. Program offered to members ages 7 to 17.

Enrollee Advisory Committee

The enrollee advisory committee, sometimes called the member advisory committee, provides advice to Simply regarding member health education and outreach program development. The committee strives to ensure materials and programs meet cultural competency requirements and are both understandable to the member and address the member's health education needs. The committee seeks members' input into the quality improvement projects, in order to improve quality, as needed.

The committee's responsibilities are to:

- Provide input into the annual review of policies and procedures, the QM program results and outcomes, and future program goals and interventions.
- Identify health education needs of the membership based on review of demographic and epidemiologic data.

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- Assist the health plan in decision-making in the areas of member grievances, marketing, member services, case management, outreach, health needs, performance improvement projects and cultural competency.
- Identify cultural values and beliefs that must be considered in developing a culturally competent health education program.
- Assist in the review, development, implementation and evaluation of the member health education tools for the outreach program.
- Review the health education plan and make recommendations on health education strategies.

Women, Infants and Children Program

The Women, Infants and Children (WIC) program impacts the health of mothers and children in the medically needy population. Optimal nutritional status during pregnancy and early childhood provides the best chance for the future of Floridians. Medicaid recipients eligible for WIC benefits include the following classifications:

- · Pregnant women
- Women who are breastfeeding infant(s) up to one year postpartum
- Women who are not breastfeeding up to six months postpartum
- Infants under the age of 1
- Children under the age of 5

Network providers are expected to coordinate with the WIC program. Coordination includes referral to the local WIC office for all infants and children up to age 5 and pregnant, breastfeeding and postpartum women.

WIC Referrals

Simply providers are required to refer all infants and children up to age 5 and pregnant, breastfeeding and postpartum women to the local WIC office. Providers are required to send WIC:

- A completed Florida WIC program medical referral form with the current height or length and weight (taken within 60 calendar days of the WIC appointment).
- Hemoglobin or hematocrit.
- Any identified medical and/or nutritional problems.

For each subsequent WIC certification, providers are required to coordinate with the local WIC office to provide the above referral data from the most recent EPSDT visit. Each time providers complete the WIC referral form, they are required to give a copy to the patient and keep a copy in the patient's medical record. Providers should keep a copy of these documents in the medical record to provide evidence the required process has taken place.

Members may apply for WIC services at their local WIC agency service. Please call Provider Services at <u>1</u>-844_405-4296 for the agency nearest to the member. For more information, please visit http://doh.state.fl.us/family/wic.

Pregnancy-Related Requirements

Prenatal Risk Screening

Providers seeing Simply members for pregnancy-related diagnoses must:

- See the pregnant member within 30 days of enrollment.
- Complete Florida's Healthy Start prenatal risk screening instrument for each pregnant member as part of her first prenatal visit as required by Section 383.14, F.S., Section 381.004, F.S., and 64C-7.009, F.A.C.*
 - Use the Department of Health prenatal risk form (DH Form 3134), which can be obtained from the local County Health Department (CHD).
 - Retain a copy of all documentation of Healthy Start screenings, assessments, findings and referrals in the enrollees' medical records.

- Submit the completed DH Form 3134 to the CHD in the county in which the prenatal screen was completed within ten business days of completion of the screening.
- Collaborate with the Healthy Start care coordinator within the member's county of residence to assure risk-appropriate care is delivered.
- * Pregnant members or infants who do not score high enough to be eligible for Healthy Start care coordination may be referred for services, regardless of their score on the Healthy Start risk screen, in the following ways:
- If the referral is to be made at the same time the Healthy Start risk screen is administered, the provider
 may indicate on the risk screening form that the member or infant is invited to participate based on factors
 other than score.
- If the determination is made subsequent to risk screening, the provider may refer the enrollee or infant
 directly to the Healthy Start care coordinator based on assessment of actual or potential factors associated
 with high risk, such as HIV, hepatitis B, substance abuse or domestic violence.

Infant Risk Screening

Providers must complete Florida's Healthy Start infant (postnatal) risk screening instrument (*DH Form 3135*) with the certificate of live birth and transmit the documents to the CHD in the county in which the infant was born within five business days of the birth. Providers must retain a copy of the completed *DH Form 3135* in the patient's medical record and provide a copy to the patient.

HIV Testing

Providers are required to give all women of childbearing age HIV counseling and offer them HIV testing (see *Chapter 381, F.S.*).

- Providers, in accordance with Florida law, must offer all pregnant women counseling and HIV testing at the
 initial prenatal care visit and again at 28 to 32 weeks of pregnancy.
- Providers must attempt to obtain a signed objection if a pregnant woman declines an HIV test (see Section 384.31, F.S. and 64D-3.019, F.A.C.)
- For those women who are infected with HIV, providers must offer and provide counseling about the latest
 antiretroviral regimen recommended by the U.S. Department of Health & Human Services (per the Public
 Health Service Task Force Report titled Recommendations for the Use of Antiretroviral Drugs in Pregnant
 HIV-1 Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the
 United States). To receive a copy of the guidelines, contact the Department of Health, Bureau of HIV/AIDS,
 at 1_850-245-4334 or visit https://aidsinfo.nih.gov/guidelines.

Hepatitis B Screenings

Providers are required to:

- Screen all pregnant members receiving prenatal care for the Hepatitis B surface antigen (HBsAg) during the
 first prenatal visit.
- Perform a second HBsAg test between 28 and 32 weeks of pregnancy for all pregnant members who tested
 negative at the first prenatal visit and are considered high-risk for Hepatitis B infection; this test shall be
 performed at the same time the other routine prenatal screenings are ordered.
- Report all HBsAg-positive women to the local CHD and <u>refer</u> to Healthy Start <u>Program</u> regardless of their Healthy Start screening score.

Hepatitis B and Hepatitis B Immune Globulin Vaccines

Infants born to HBsAg-positive members must receive Hepatitis B immune globulin and the Hepatitis B
vaccine once they are physiologically stable, preferably within 12 hours of birth, and complete the Hepatitis
B Maxine vaccine series according to the recommended vaccine schedule established by the
Recommended Childhood Immunization Schedule for the United States.

- Providers must test infants born to HBsAg-positive members for HBsAg and Hepatitis B surface antibodies (anti-HBs) six months after the completion of the vaccine series to monitor the success or failure of the therapy.
- Providers must report to the local CHD a positive HBsAg result in any child 24 months or younger within 24 hours of receipt of the positive test results.
- Providers must refer infants born to members who are HBsAg-positive to Healthy Start regardless of their Healthy Start screening scores.

Testing Positive for Hepatitis B

Providers are required to:

- Report to the perinatal Hepatitis B prevention coordinator at the local CHD all prenatal or postpartum
 patients who test HBsAg-positive.
- Report said patients' infants and contacts to the perinatal Hepatitis B prevention coordinator at the local CHD.
- Report the following information: name, date of birth, race, ethnicity, address, infants, contacts, laboratory
 test performed, date the sample was collected, the due date or EDC, whether or not the enrollee received
 prenatal care, and immunization dates for infants and contacts.
- Use the perinatal Hepatitis B case and contact report (DH Form 1876) for reporting purposes.

Providers are required to provide the most appropriate and highest level of quality care for pregnant members, including but not limited to the following:

- · Prenatal care
 - Complete a pregnancy test and a nursing assessment with referrals to a physician, physician assistant or advanced registered nurse practitioner for comprehensive evaluation.
 - o Complete case management through the gestational period according to the needs of the member.
 - o Ensure any necessary referrals and follow-up.
 - Schedule return prenatal visits at least every four weeks until week 32, every two weeks until week
 36 and every week after until delivery unless the member's condition requires more frequent visits.
 - Contact those members who fail to keep their prenatal appointments as soon as possible and arrange for their continued prenatal care.
 - $\circ \quad \text{Assist members in making delivery arrangements if necessary}.$
 - Screen all pregnant members for tobacco use and make smoking cessation counseling and appropriate treatment available as needed.
- Nutritional assessment/counseling Providers are required to:
 - o Supply nutritional assessment and counseling to all pregnant members.
 - o Ensure the provision of safe and adequate nutrition for infants by promoting breastfeeding and the use of breast-milk substitutes.
 - o Offer a mid-level nutrition assessment.
 - Provide individualized diet counseling and a nutrition care plan by a public health nutritionist, a nurse or a physician following the nutrition assessment.
 - Keep documentation of the nutrition care plan in the medical record by the person providing counseling.
- Obstetrical delivery Simply has developed and uses generally accepted and approved protocols for both low-risk and high-risk deliveries, which reflect the highest standards of the medical profession, including Healthy Start and prenatal screening, and requires all providers use these protocols:
 - Providers must document preterm delivery risk assessments in the enrollee's medical record by the 28th week.

- If the provider determines the member's pregnancy is high-risk, the provider's obstetrical care during labor and delivery must include preparation by all attendants for symptomatic evaluation and as the member progresses through the final stages of labor and immediate postpartum care.
- Newborn care Providers are required to supply the highest level of care for the newborn beginning immediately after birth. Such level of care shall include but not be limited to the following:
 - o Instilling prophylactic eye medications into each eye of the newborn
 - When the mother is Rh-negative, securing a cord blood sample for type Rh determination and direct Coombs testing
 - o Weighing and measuring the newborn
 - o Examining the newborn for abnormalities and/or complications
 - o Administering 0.5 mg of vitamin K
 - o Calculating an Apgar score
 - Assessing any other necessary and immediate need for referral in consultation with a specialty physician, such as the Healthy Start (postnatal) infant screen
 - Administering any necessary newborn and infant hearing screenings (must be conducted by a licensed audiologist pursuant to *Chapter 468, F.S.*; a physician licensed under *Chapters 458* or *459, F.S.*; or an individual who has completed documented training specifically for newborn hearing screenings and who is directly or indirectly supervised by a licensed physician or a licensed audiologist)
- Postpartum care The provider is required to:
 - Administer a postpartum examination for the member between 7 84 (1 12 weeks) days post-delivery.
 - Supply voluntary family planning, including a discussion of all methods of contraception as appropriate.
 - Ensure eligible newborns are enrolled with Simply and that continuing care of the newborn is provided through the EPSDT program component.

Healthy Start Program

Healthy Start is a national program that provides comprehensive developmental services for pregnant women, infants and preschool children up to age 3. We collaborate with community Healthy Start programs to provide timely and age-appropriate health screening and referrals for routine health services.

- Simply provides each member with a community-based PCP.
- Simply encourages Healthy Start staff to refer members to see their PCP for screenings and health services.
- Simply supports timely and complete immunization of all children.
- Simply supports routine dental, vision and hearing exams for members.
- Simply encourages physical exams in accordance with the EPSDT periodicity schedule.
- Simply supports personal hygiene as part of the child's daily routine through age-appropriate educational programs.
- The Simply Member Services staff, nurse case managers and Health Promotion staff coordinate the delivery
 of services for children and work with their caretakers to eliminate barriers to timely health care.

Local Health Department

Simply works collaboratively with local health departments. Members have access to any county health department without authorization for the following services:

- Diagnosis and treatment of sexually transmitted diseases and other communicable diseases, such as tuberculosis and HIV.
- Immunizations.
- Family planning services and related pharmaceuticals.

- School health services listed above and services rendered on an urgent basis by such providers.
- Adult Screening Services
- Well-Child visits
- Medical Primary Care Services
- Registered Nurse Services

PROVIDER RESPONSIBILITIES

Medical Home

The PCP is the foundation of the medical home, responsible for providing, managing and coordinating all aspects of the member's medical care and providing all care that is within the scope of his or her practice. The PCP is responsible for coordinating member care with specialists and conferring and collaborating with the specialists, using a collaborative concept known as a medical home.

Simply promotes the medical home concept to all of its members. The PCP is the member and family's initial contact point when accessing health care. The PCP relationship with the member and family, together with the health care providers within the medical home and the extended network of consultants and specialists with whom the medical home works, have an ongoing and collaborative contractual relationship. The providers in the medical home are knowledgeable about the member and family's special and health-related social and educational needs and are connected to necessary resources in the community that will assist the family in meeting those needs. When a member is referred for a consultation or specialty/hospital services or for health and health-related services by the PCP through the medical home, the medical home provider maintains the primary relationship with the member and family. He or she keeps abreast of the current status of the member and family through a planned feedback mechanism with the PCP, who receives them into the medical home for continuing primary medical care and preventive health services.

Providers' Bill of Rights

Each health care provider who contracts with the Florida Agency for Health Care Administration (AHCA) and/or Florida Healthy Kids or subcontracts with Simply to furnish services to members will be assured of the following rights:

- To advise or advocate (within the lawful scope of practice) on behalf of a member who is his or her patient for the following:
 - The member's health status, medical care or treatment options, including any alternative treatment that may be self-administered
 - o Any information the member needs to decide among all relevant treatment options
 - o The risks, benefits and consequences of treatment or nontreatment
 - The member's right to participate in decisions regarding his or her health care, including the right to refuse treatment and to express preferences about future treatment decisions
- To receive information on the grievance, appeal and fair hearing procedures
- To have access to the Simply policies and procedures covering the authorization of services
- To be notified of any decision by Simply to deny a service authorization request or to authorize a service in an amount, duration or scope that is less than requested
- To challenge, on behalf of Medicaid members, the denial of coverage of or payment for medical assistance
- To be free from provider selection policies and procedures that discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment
- To be free from discrimination for participation, reimbursement or indemnification when acting within the scope of his or her license or certification under applicable state law, solely on the basis of that license or certification

Responsibilities of the PCP

The PCP is a network physician who has responsibility for the complete care of his or her members, whether providing it himself or herself or by referral to the appropriate provider of care within the network. FQHCs health and RHCs may be included as PCPs. Some of the PCP's responsibilities are listed below:

All Florida Healthy Kids PCPs must be board-certified pediatricians or family practice physicians.

- All PCPs must provide coverage 24 hours a day, 7 days a week, and regular hours of operation must be clearly defined and communicated to members.
- All PCPs must provide services ethically and legally in a culturally competent manner and meet the unique needs of members with special health care requirements.
- The PCP is the coordinator of all care. Therefore, the PCP agrees to ensure continuity of care to Simply
 members and arrange for the provision of services when the PCP's office is not open. Documentation of
 emergency room visits, hospital discharge summaries or operative reports are to be obtained by the PCP
 and maintained in the medical record.
- The PCP agrees to practice in his or her profession ethically and legally, provide all services in a culturally
 competent manner, accommodate those with disabilities, and not discriminate against anyone based on his
 or her health status.
- The PCP must conduct a health assessment of all new enrollees within 90 days of the effective date of
 enrollment.
- When clinically indicated, the PCP agrees to contact Simply members regarding appropriate follow-up of identified problems and abnormal laboratory, radiological or other diagnostic findings.
- The PCP must establish office procedures to facilitate the follow-up of member referrals and consultations.
 The PCP is responsible for obtaining and maintaining in the medical record the results or findings of consultant referrals. If findings were communicated through telephonic consultation, a summary of the findings and name of the specialist must be documented.
- The PCP must participate in any system established by Simply to facilitate the sharing of medical records (subject to applicable confidentiality requirements in accordance with 42 CFR, Part 431, Subpart F, including a minor's consultation, examination and drugs for STDs in accordance with Section 384.30 (2), F.S.).
- The PCP agrees, when the need arises, to contact Simply regarding interpretive services via AT&T or other service for members who may require language assistance.
- If a new PCP is added to a group, Simply must approve and credential the provider before the provider may
 treat members. Notification of changes in the provider staff is the responsibility of the provider's office and
 must be communicated to Simply in writing.
- The PCP agrees to participate and cooperate with Simply in quality management, utilization review, continuing education and other similar programs established by Simply.
- The PCP agrees to participate in and cooperate with the Simply grievance and appeal procedures when Simply notifies the PCP of any member complaints or grievances.
- Balance billing for a covered service is not permitted. A Florida Healthy Kids member can only be billed
 for applicable copays if the copay was not collected at the time the service was rendered.
- If a PCP agreement with Simply is terminated, the PCP must continue care in progress during and after the
 termination period for up to six months until a provision is made by Simply for the reassignment of
 members. Pregnant members can continue receiving services through postpartum care. Payment for
 covered services under this continuity of care period will be made in accordance with the rates effective in
 the provider's participating agreement at the time of termination.
- The PCP may opt to go bare and not carry malpractice liability insurance but must follow the requirements under *F.S.* 458.320.
- The PCP must comply with all applicable federal and state laws regarding the confidentiality of member records.
- The PCP must certify to Simply, upon credentialing and recredentialing, that their active patient load does not exceed 3,000 (including all commercial, Medicare, Florida Healthy Kids, other SMMC plan and children's medical services patients). Patients are defined as active when the PCP sees them at least two times a year.
- The PCP agrees to develop and have an exposure control plan in compliance with Occupational Safety and Health Administration (OSHA) standards regarding blood-borne pathogens.

- The PCP agrees to establish appropriate policies and procedures to fulfill obligations under the Americans with Disabilities Act (ADA).
- The PCP agrees to support and cooperate with the Simply Quality Management Program to provide quality care in a responsible and cost-effective manner.
- The PCP agrees to provide HIV counseling and offer HIV testing to all members of childbearing age.
- The PCP agrees to refer pregnant women or infants to Healthy Start and WIC programs within 30 days of enrollment
- The PCP agrees to provide counseling and education in support of Medicaid quality and benefit
 enhancement (QBE) services, which include children's programs, domestic violence, pregnancy prevention
 (including abstinence), prenatal/postpartum care, smoking cessation and substance use programs. The PCP
 agrees to include information on the programs and community resources encouraged by Simply.
- The PCP agrees to provide counseling and offer the recommended antiretroviral regimen to all pregnant women who are HIV-positive and to refer them and their infants to Healthy Start programs regardless of their screening scores.
- The PCP agrees to offer screening for Hepatitis B surface antigen to all women receiving prenatal care. If
 they test positive, the PCP agrees to refer them to Healthy Start regardless of their screening score and to
 provide Hepatitis B Immune Globulin and the Hepatitis B vaccine series to children born to such mothers.
- The PCP agrees to inform Simply if he or she objects to the provision of any counseling, treatments or referral services on religious grounds.
- The PCP agrees to treat all members with respect and dignity, provide them with appropriate privacy, and treat members' disclosures and records confidentially, giving members the opportunity to approve or refuse their release in accordance with HIPAA and applicable state laws.
- The PCP agrees to provide members with complete information concerning their diagnosis, evaluation, treatment and prognosis and give members the opportunity to participate in decisions involving their health care, regardless of whether members have completed an advance directive, except when contraindicated for medical reasons.
- The PCP agrees to an adequate and timely communication among providers and the transfer of information when members are transferred to other health care providers. The PCP agrees to obtain a signed and dated release allowing for the release of information to Simply and other providers involved in the member's
- The PCP agrees to physically screen members taken into the protective custody, emergency shelter or
 foster care programs by the Department of Children and Families (DCF) within 72 hours or immediately if
 required.
- The PCP must ensure food snacks or services provided to members meet their clinical needs and are
 prepared, stored, secured and disposed of in compliance with local health department requirements.
- The PCP agrees that provisions will be made to minimize sources and transmission of infection in the office.
- The PCP agrees to maintain communication with the appropriate agencies such as local police, social services agencies and poison control centers to provide quality member care.
- The PCP agrees that any notation in a member's clinical record indicating diagnostic or therapeutic intervention as part of clinical research will be clearly contrasted with entries regarding the provision of nonresearch-related care.
- The PCP agrees to use certified EHR technology in a meaningful manner, as described in the Florida Medicaid EHR Incentive Program.
- The PCP is enrolled in the Florida state Health Online Tracking System (SHOTS) statewide registry. Providers should bill Medicaid Fee-for-Service directly for immunizations provided to Title XXI MediKids participants.
- The PCP agrees to provide immunization information to the DCF upon receipt of members' written
 permission and DCF's request for members requesting temporary cash assistance from the DCF.

- The PCP agrees to attempt to obtain medical records on any member(s) receiving services from a nonnetwork provider with the proper release specific to any diagnosis signed by the member. These services include but are not limited to family planning, preventive services and sexually transmitted diseases.
- The PCP agrees to maintain vaccines safely and in accordance with specific guidelines, to provide member immunizations according to professional standards, and to maintain up-to-date member immunization records. PCP providers who render immunization to children are required to administer Vaccines in accordance with the Recommended Childhood and Adolescent Immunization Schedule for the United
 - Providers who render vaccines to Simply and Title XXI (MediKids and FHK) children are required to
 enroll with Florida's statewide online immunization registry, the Florida State Health Online Tracking
 System (SHOTS), and continue to keep the Simply member's immunization record updated in the
 SHOTS database
 - Providers must also registered with the Vaccines for Children Program to obtain vaccines free of charge for Simply members, excluding MediKids members (Medicaid program codes: MK A, MK B, MK C)
 - The Vaccines for Children (VFC) Program does not provide vaccines for the Title XXI (MediKids and FHK) members. Providers must utilize their purchased vaccines stock for this population.
 - All claims for immunizations rendered to MediKids, FHK and Medicaid members must be submitted to Simply for payment.
 - For all Medicaid members, excluding MediKids population, Simply will render payment for the administration of the vaccines only; as vaccines are expected to be obtained free of charge from the VFC Program.

For the Title XXI (MediKids and FHK) members, Simply

reimburses at a proprietary fee schedule

based on the CDC and Private Sector Pricing for FHK and Medikids vaccine reimbursement. Simply will review for pricing changes and will update its vaccine fee schedule twice a year. Payment for updated pricing changes will be applied prospectively. Simply pays a separate \$10.00 fee for the administration of vaccines. In order to be appropriately reimbursed, providers should bill for vaccine administration in addition to the vaccine product on the same claim.

<u>Immunization Schedules and Requirements:</u>

http://www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/schedules-and-requirements/index.html

CDC Vaccine Price List:

 $\underline{https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/pricelist/index.html}$

- The PCP agrees to reach out to members to schedule an appointment for post-discharge or after they are notified the member went to the emergency room.
- The PCP agrees to assist with Clear Health Alliance eligibility verification through provision of HIV status verification when available.
- The PCP agrees to make provisions to communicate in the language or fashion primarily used by his or her assigned members.

Simply allows immunizations to be administered at locations other than a PCP's office so long the treating provider submits the information to SHOTS or notifies the Enrollee's PCP of the immunization administration. However, Simply PCPs are prohibited from refusing to proactively offer or administer immunizations at their offices.

Role of the PCP

- Each Medicaid and Florida Healthy Kids member will select or be assigned a PCP at the time of enrollment.
 Medicaid membership is limited to 1,500 members per full-time PCP and may be increased by 750
 members for each advanced registered nurse practitioner (ARNP) or physician assistant (PA) affiliated with
 the physician. The maximum is a 3,000 active patient load for all populations (including but not limited to
 Medicaid FFS, children's medical services, other SMMC plans and Kidcare/Florida Healthy Kids).
- The PCP coordinates the member's health care needs through a comprehensive network of specialty, ancillary and hospital providers.
- For new members, the provider will contact each new member within 60 days of enrollment to perform an
 initial health risk assessment.
 - o The provider must notify Simply if he or she is unable to contact the member within the 90-day enrollment period. Simply will send a release form to Medicaid members for the purpose of Simply and state agency review. Once a release has been signed, the PCP will request records from previous care providers. The PCP will use the previous medical records and the health risk assessments to identify members who have not received age-appropriate preventive health screenings (Child Health Check-Ups) for children from birth through 20 years of age according to the standards established by the American Academy of Pediatrics and endorsed by AHCA. Health screenings for adults will meet Simply standards, including those standards established by the Centers for Disease Control and Prevention and the U.S. Preventive Services Task Force. When external regulating agencies impose more stringent health screening standards, the PCP is required to comply with those standards.
- The PCP is responsible 24/7 for providing or arranging all covered services, including prescribing, directing
 and obtaining appropriate authorizations of all care for members who have been assigned to the PCP.
 After-hours coverage consists of an answering service, call forwarding, provider call coverage or other
 customary means approved by Simply. The chosen method must connect the caller to someone who can
 render a clinical decision or reach the PCP for a clinical decision.
- To the extent necessary, the PCP is responsible for coordinating coverage for members with an alternate Simply network physician. All financial arrangements must be made between the PCP and covering physician. The PCP is also responsible for notifying Simply in writing two weeks prior to his or her absence of the duration of the absence and the physician who will be providing the coverage. The covering physician must be a Simply network physician.
- All PCPs must be credentialed by Simply or one of the Simply
 delegated credentialing entities. All personnel assisting in the provision of health care services to members
 are to be appropriately trained, qualified and supervised in the care provided.
- PCPs must notify their Provider Relations representative when a new provider joins the practice.
- Anytime a new provider joins a practice and members are directed to the provider that individual must be credentialed with the plan and cannot see members until the credentialing process is completed.
 Nonemergent services must not be provided by a noncredentialed physician, and such services will not be covered by Simply. The PCP is responsible for the direct training and supervision of medical assistants.
 Duties of the medical assistant will be strictly limited to those identified in F.S. Section 458.3485.
- All PCP facilities must have handicap accessibility, adequate space, supplies, good sanitation and fire safety procedures in operation.
- The PCP will only collect copays from Florida Healthy Kids members when applicable and permitted under state and federal law. The PCP must not charge any member for missed appointments.
- PAs and ARNPs may not be assigned as the PCP for Simply members.

Physician Extenders

Physician extenders (for example, ARNPs, PAs) must be credentialed prior to seeing Simply members. They must clearly and appropriately identify themselves as an ARNP or PA to the member. Office staff must appropriately refer to and identify physician extenders as ARNPs or PAs.

The supervision of services furnished while the supervising practitioner is in the building, and for which the supervising practitioner signs and dates the medical records (charts) within 24 hours of the provision of the service.

Background Checks

All Simply providers must have a Level 2 criminal history background screening completed prior to joining the Simply network. This includes the provider's subcontractors or any employees or volunteers of their subcontractors who meet the definition of "direct service provider" to verify that these individuals do not have disqualifying offenses as provided for in F.S. Section 430.0402 as created and F.S. Section 435.04. Any subcontractor, employee or volunteer of a subcontractor meeting the definition of a "direct service provider" who has a disqualifying offense is prohibited from providing services to the elderly as set forth in F.S. Section 430.0402.

Abuse, Neglect and Exploitation

All Simply providers are required to report elder abuse, neglect and exploitation of vulnerable adults to the statewide Elder Abuse Hotline at $\underline{1}$ -800-96ABUSE ($\underline{1}$ -800-962-2873).

- Simply direct-service providers are also required to complete abuse, neglect and exploitation training including training on how to identify victims of human trafficking.
- Per s.408.812, F.S., Simply providers are required to report suspected unlicensed assisted licensed facilities
 and adult family care homes to AHCA and Simply.

Abuse means any willful act or threatened act by a caregiver that causes or is likely to cause significant impairment to an enrollee's physical, mental or emotional health. Abuse includes acts and omissions.

Exploitation of a vulnerable adult means a person who:

- Stands in a position of trust and confidence with a vulnerable adult and knowingly, by deception or
 intimidation, obtains or uses or endeavors to obtain or use, a vulnerable adult's funds, assets or property
 for the benefit of someone other than the vulnerable adult.
- Knows (or should know) the vulnerable adult lacks the capacity to consent and obtains or uses, or
 endeavors to obtain or use, the vulnerable adult's funds, assets or property with the intent to temporarily
 or permanently deprive the vulnerable adult of the use, benefit or possession of the funds, assets or
 property for the benefit of someone other than the vulnerable adult.

Neglect of an adult means the failure or omission on the part of the caregiver to provide the care, supervision and services necessary to maintain the physical and behavioral health of the vulnerable adult, including but not limited to food, clothing, medicine, shelter, supervision and medical services that a prudent person would consider essential for the well-being of the vulnerable adult. The term neglect also means the failure of a caregiver to make a reasonable effort to protect a vulnerable adult from abuse, neglect or exploitation by others. Neglect is repeated conduct or a single incident of carelessness that produces or could reasonably be expected to result in serious physical or psychological injury or a substantial risk of death.

Identifying Victims of Human Trafficking

The following is a list of potential red flags and indicators of human trafficking. If you see any of these red flags, contact the National Human Trafficking Hotline at <u>1-888-373-7888</u> to report the situation or for specialized, victim services referrals.

The presence of these red flags is an indication that further assessment may be necessary to identify a potential human-trafficking situation. This list is not exhaustive and represents only a selection of possible indicators. Also, the red flags in this list may not be present in all trafficking cases and are not cumulative. Indicators reference conditions a potential victim might exhibit.

Common work and living conditions:

- Is not free to leave or come and go as they wish
- · Is in the commercial sex industry and has a pimp/manager
- Is unpaid, paid very little or paid only through tips
- Works excessively long and/or unusual hours
- Is not allowed breaks or suffers under unusual restrictions at work
- · Owes a large debt and is unable to pay it off
- Was recruited through false promises concerning the nature and conditions of their work
- High security measures exist in the work and/or living locations (i.e., opaque windows, boarded-up windows, bars on windows, barbed wire, security cameras, etc.)

Poor mental health or abnormal behavior:

- Is fearful, anxious, depressed, submissive, tense, nervous or paranoid
- Exhibits unusually fearful or anxious behavior after bringing up law enforcement
- Avoids eye contact

Poor physical health:

- Lacks medical care and/or is denied medical services by employer
- Appears malnourished or shows signs of repeated exposure to harmful chemicals
- Shows signs of physical and/or sexual abuse, physical restraint, confinement or torture

Lack of control:

- Has few or no personal possessions
- Is not in control of their own money, has no financial records or bank account
- Is not in control of their own identification documents (ID or passport)
- · Is not allowed or able to speak for themselves (a third party may insist on being present and/or translating)

Other:

- Claims of just visiting and inability to clarify where they're staying/address
- Lack of knowledge of whereabouts and/or of what city they're in
- Loss of sense of time
- Has numerous inconsistencies in their story

Note: According to federal law, any minor under the age of 18 engaging in commercial sex is a victim of sex trafficking, regardless of the presence of force, fraud or coercion.

Access and Availability

All providers are expected to meet the federal and state accessibility standards and those defined in the Americans with Disabilities Act of 1990. Health care services provided through Simply must be accessible to all members.

Simply is dedicated to arranging access to care for our members. The ability of Simply to provide quality access depends on the accessibility of network providers. Providers are required to adhere to the following access standards:

Service Service	Access Requirement	
Emergent or emergency visits	Immediately upon presentation	
Urgent care for non-life-	Florida Healthy Kids	•
threatening emergency, BH	• Within 624 hours	4
Urgent care for BH	Within 48 hours	-
Urgent, non-emergency visits,	MMA/Specialty	1
medical health and Behavioral	Within 48 hours of request for services that do not require prior	
Health (FHK)	authorization	
	Within 96 hours of request for services that do not require prior	
	authorization	
	Florida Healthy Kids	4
	Emergency care shall be provided immediately.	
	Urgently needed care shall be provided within twenty-four (24)	4
	hours. Within 24 hours	
Non-urgent medical	MMA/Specialty	
	Within 14 days of request for ancillary services for the diagnosis or	
	treatment of injury, illness or other health condition	
	Within 30 days of request for a primary care appointment	
	Within 60 days of request for a <u>pediatric</u> specialist appointment after	
	the appropriate referral is received by the specialist	
	Florida Healthy Kids	
	Routine care of enrollees who do not require emergency or urgent	
	care shall be provided within seven calendar days of the enrollee's	
	request for services. 7 days for routine care	
	← 4 weeks for routine physical exams	
	Routine physical examinations shall be provided within four weeks of	
	the enrollee's request.	
	Follow up care shall be provided as medically appropriate.	
Nonurgent, behavioral health	MMA/Specialty	
	 Seven7 days post discharge from an inpatient behavioral health 	
	admission for follow-up behavioral health treatment	
	1014 days for initial outpatient behavioral health treatment	
	Florida Healthy Kids	
	Seven calendar days for routine care	1
	 Four4 weeks for routine physical exams 	

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Service	Access Requirement	
	As medically appropriate for follow-up care	

Providers must also ensure member access to a follow-up appointment within seven days of discharge.

Providers may not use discriminatory practices, such as preference to other insured or private-pay patients, separate waiting rooms, or appointment days.

Simply will routinely (no less than quarterly) monitor adherence to the access care standards, including monitoring PCPs, specialists and behavioral health providers. We will report results for Medicaid PCPs to AHCA.

To ensure continuous 24-hour coverage, PCPs must maintain one of the following arrangements for their members to contact the PCP after normal business hours:

- Have the office telephone answered after hours by an answering service that can contact the PCP or another designated network medical practitioner; all calls answered by an answering service must be returned within 30 minutes.
- Have the office telephone answered after normal business hours by a recording in the language of each of
 the major population groups served by the PCP, directing the member to call another number to reach the
 PCP or another provider designated by the PCP; someone must be available to answer the designated
 provider's telephone; another recording is not acceptable.
- Have the office telephone transferred after office hours to another location where someone will answer
 the telephone and be able to contact the PCP or a designated Simply network medical practitioner who can
 return the call within 30 minutes.

The following telephone answering procedures are **not** acceptable:

- Only answering the office telephone during office hours
- Only answering the office telephone after hours by a recording that tells members to leave a message
- Answering the office telephone after hours by a recording that directs members to go to an emergency room for any services needed
- Answering the office telephone with an answering machine that does not explain what to do in an
 emergency (for example, dial 911, etc.)
- Returning after-hours calls outside of 30 minutes

Member Missed Appointments

Simply members may sometimes cancel or not appear for necessary appointments and fail to reschedule the appointment. This can be detrimental to their health. Simply requires providers to attempt to contact members who have not shown up for or canceled an appointment without rescheduling the appointment. The contact must be by telephone and should be designed to educate the member about the importance of keeping appointments and to encourage the member to reschedule the appointment.

Simply members who frequently cancel or fail to show up for an appointment without rescheduling the appointment may need additional education in appropriate methods of accessing care. Simply staff will contact the member and provide more extensive education and/or case management as appropriate. Our goal is for members to recognize the importance of maintaining preventive health visits and to adhere to a plan of care recommended by their PCP. Please note that the provider agrees not to charge a member for missed appointments.

Noncompliant Simply Members

Simply recognizes that providers may need help in managing noncompliant members. If you have an issue with a member regarding behavior, treatment cooperation and/or completion of treatment, and/or making or appearing for appointments, please call Provider Services at **844_405_4296**. Members should be referred to Simply for case management services.

PCP Transfers

To maintain continuity of care, Simply encourages members to remain with their PCP. However, members may request to change their PCP for any reason by contacting Member Services at **844-406-2396**. The member's name will be provided to the PCP on the membership roster.

Members can call to request a PCP change any day of the month. PCP change requests will be processed generally on the same day or by the next business day. Members will receive a new ID card within 10 days.

Covering Physicians

During a provider's absence or unavailability, the provider needs to arrange for coverage for his or her members. The provider will either: 1) make arrangements with one or more network providers to provide care for his or her members or 2) make arrangements with another similarly licensed and qualified provider who has appropriate medical staff privileges at the same network hospital or medical group, as applicable, to provide care to the members in question. Covering providers must have an active limited or fully enrolled Medicaid ID number.

In addition, the covering provider will agree to the terms and conditions of the network provider agreement, including without limitation, any applicable limitations on compensation, billing and participation. Providers will be solely responsible for a non-network provider's adherence to such provisions. Providers will be solely responsible for any fees or monies due and owed to any non-network provider providing substitute coverage to a member on the provider's behalf.

Specialist as a PCP

Under certain circumstances, when a member requires the regular care of the specialist, a specialist may be approved by Simply to serve as a member's PCP. The criteria for a specialist to serve as a member's PCP include the member having a chronic, life-threatening illness or condition of such complexity whereby:

- The need for multiple hospitalizations exists.
- The majority of care needs to be given by a specialist.
- The administrative requirements arranging for care exceed the capacity of the nonspecialist PCP. This
 would include members with complex neurological disabilities, chronic pulmonary disorders, HIV/AIDS,
 complex hematology/oncology conditions, cystic fibrosis, etc.

The specialist must meet the requirements for PCP participation, including contractual obligations and credentialing; provide access to care 24 hours a day, 7 days a week; and coordinate the member's health care, including preventive care. When such a need is identified, the member or specialist must contact the Simply Member Services department and complete a *Specialist as PCP Request Form*. A Simply case manager will review the request and submit it to the Simply medical director. Simply will notify the member and the provider of its determination in writing within 30 days of receiving the request. Should Simply deny the request, Simply will provide written notification to the member and provider outlining the reason(s) for the denial of the request within one day of the decision. Specialists serving as PCPs will continue to be paid fee-for-service while serving as the member's PCP. The designation cannot be retroactive.

Note: Clear Health Alliance allows Infectious Disease providers to serve as a PCPs for Clear Health Alliance members.

Specialty Referrals

To reduce the administrative burden on the provider's office staff, Simply has established procedures that are designed to permit a member with a condition that requires ongoing care from a specialist physician or other health care provider to request an extended authorization.

The provider can request an extended authorization by contacting the member's PCP. The provider must supply the necessary clinical information that will be reviewed by the PCP to complete the authorization review.

On a case-by-case basis, an extended authorization will be approved. In the event of termination of a contract with the treating provider, the continuity-of-care provisions in the provider's contract with Simply will apply. The provider may renew the authorization by submitting a new request to the PCP. Additionally, Simply requires the specialist physician or other health care provider to provide regular updates to the member's PCP (unless acting also as the designated PCP for the member). Should the need arise for a secondary referral, the specialist physician or other health care provider must contact Simply for a coverage determination.

If the specialist or other health care provider needed to provide ongoing care for a specific condition is not available in the Simply network, the referring physician will request authorization from Simply for services outside the network. Access will be approved to a qualified non-network health care provider within a reasonable distance and travel time at no additional cost if medical necessity is met.

If a provider's application for an extended authorization is denied, the member (or the provider on behalf of the member) may appeal the decision through the Simply medical appeal process.

Providers may contact case management to facilitate referrals to services outside our network or services provided through interagency agreements. The case manager will assist as needed to meet the member's additional supportive care needs such as food, bank, legal or housing assistance; support groups/psychosocial counseling; clinical trials; and outpatient substance abuse-related programs geared towards the issues and concerns of our members.

Second Opinions

A member, parent, and/or legally appointed representative or the member's PCP may request a second opinion in any situation where there is a question concerning a diagnosis or the options for surgery or other treatment of a health condition. The second opinion will be provided at no cost to the member.

The second opinion must be obtained from a network provider (see the provider referral directory) or with precertification from a non-network provider if there is not a network provider with the expertise required for the condition. Once approved, the PCP will notify the member of the date and time of the appointment and forward copies of all relevant records to the consulting provider. The PCP will notify the member of the outcome of the second opinion.

Simply may also request a second opinion at our own discretion. This may occur under the following circumstances:

- Whenever there is a concern about care expressed by the member or the provider
- Whenever potential risks or outcomes of recommended or requested care are discovered by the plan during its regular course of business
- Before initiating a denial of coverage of service

- · When denied coverage is appealed
- When an experimental or investigational service is requested

When we request a second opinion, we'll make the necessary arrangements for the appointment, payment and reporting. Simply will inform the member and the PCP of the results of the second opinion and the consulting provider's conclusion and recommendation(s) regarding further action.

Specialty Care Providers

To participate in our programs, providers must be enrolled in Florida Medicaid and have an active limited or fully enrolled Medicaid ID number. Providers must also be a licensed provider by the state before signing a contract with Simply.

Simply contracts with a network of provider specialty types to meet the medical specialty needs of members and provide all medically necessary covered services. The specialty care provider is a network physician who has the responsibility for providing specialized care for members, usually upon appropriate referral from a PCP within the network (see Role and Responsibility of the Specialty Care Provider). In addition to sharing many of the same responsibilities as the PCP (see Responsibilities of the PCP), the specialty care provider provides services that includes but is not limited to the following:

- Allergy and immunology services
- Burn services
- Community behavioral health (for example, mental health and substance abuse) services
- Cardiology services
- Clinical nurse specialists, psychologists and clinical social workers (that is, behavioral health)
- Critical care medical services
- Dermatology services
- Endocrinology services
- Gastroenterology services
- General surgery
- Hematology/oncology services
- Neonatal services
- Nephrology services
- Neurology services
- Neurosurgery servicesOphthalmology services
- Orthopedic surgery services
- Otolaryngology services
- Perinatal services
- Pediatric services
- Psychiatry (adult) assessment services
- Psychiatry (child and adolescent) assessment services
- Trauma services
- Urology services

Role and Responsibility of the Specialty Care Provider

Members may self-refer to a participating specialist provider, including mental health and substance abuse providers. Obligations of the specialist include but are not limited to the following:

- Complying with all applicable statutory and regulatory requirements of the Medicaid program
- Accepting all Simply members who self-refer or are directed to the specialist provider for care

- Submitting required claims information
- Arranging for coverage with network providers while off-duty or on vacation
- Verifying member eligibility and precertification of services (if required) at each visit
- Providing consultation summaries or appropriate periodic progress notes to the member's PCP on a timely basis, following a referral or routinely scheduled consultative visit
- Notifying the member's PCP when scheduling a hospital admission or scheduling any procedure
- Coordinating care, as appropriate, with other providers involved in providing care for members, especially
 in cases where there are medical and behavioral health comorbidities or co-occurring mental health and
 substance abuse disorders
- Making provisions to communicate in the language or fashion primarily used by his or her members

The specialist will:

- Manage the medical and health care needs of members, including monitoring and following up on care
 provided by other providers, including those engaged on a Fee-For-Service (FFS) basis; provide coordination
 necessary for referrals to other specialists and FFS providers (both in- and out-of-network); and maintain a
 medical record of all services rendered by the specialist and other providers.
- Provide 24/7 coverage and maintain regular hours of operation that are clearly defined and communicated to members.
- Provide services ethically and legally in a culturally competent manner and meet the unique needs of members with special health care requirements.
- Participate in the systems established by Simply that facilitate the sharing of records, subject to applicable
 confidentiality and HIPAA requirements.
- Participate and cooperate with Simply in any reasonable internal or external quality assurance, utilization review, continuing education, or other similar programs established by Simply.
- Make reasonable efforts to communicate, coordinate and collaborate with other specialty care providers, including behavioral health providers, involved in delivering care and services to members.
- Participate in and cooperate with the Simply complaint and grievance processes and procedures; Simply
 will notify the specialist of any member grievance brought against the specialist.
- Not balance bill members.
- Continue care in progress during and after termination of his or her contract for up to 60 days until a
 continuity of care plan is in place to transition the member to another provider or through postpartum care
 for pregnant members in accordance with applicable state laws and regulations.
- Comply with all applicable federal and state laws regarding the confidentiality of patient records.
- Develop and have an exposure control plan regarding blood-borne pathogens in compliance with OSHA
 standards.
- Make best efforts to fulfill the obligations under the ADA applicable to his or her practice location.
- Support, cooperate and comply with the Simply Quality Management Program initiatives and any related
 policies and procedures designed to provide quality care in a cost-effective and reasonable manner.
- Inform Simply if a member objects for religious reasons to the provision of any counseling, treatment or referral services.
- Treat all members with respect and dignity; provide members with appropriate privacy and treat member disclosures and records confidentially, giving the members the opportunity to approve or refuse their release as allowed under applicable laws and regulations.
- Provide members complete information concerning their diagnosis, evaluation, treatment and prognosis
 and give members the opportunity to participate in decisions involving their health care, except when
 contraindicated for medical reasons.

- Advise members about their health status, medical care or treatment options, regardless of whether benefits for such care are provided under the program, and advise members on treatments that may be self-administered.
- When clinically indicated, contact members as quickly as possible for follow-up regarding significant problems and/or abnormal laboratory or radiological findings.
- Have a policy or procedure to ensure proper identification, handling, transport, treatment and disposal of hazardous and contaminated materials and wastes to minimize sources and transmission of infection.
- Agree to maintain communication with the appropriate agencies such as local police, social services
 agencies and poison control centers to provide quality patient care.
- Agree that any notation in a patient's clinical record indicating diagnostic or therapeutic intervention that is
 part of a clinical research study is clearly distinguished from entries pertaining to nonresearch-related care.

Specialty Care Providers Access and Availability

Simply will maintain a specialty network to ensure access and availability to specialists for all members. A provider is considered a specialist if he or she has a provider agreement with Simply to provide specialty services to members. For more information on our access and availability guidelines, refer to the **Access and Availability** section.

Open-Access Specialist Providers

Members may self-refer to the network providers listed below without a PCP referral. Providers should establish processes for the identification of the member's PCP and forward information concerning the member's evaluation and treatment to the PCP after obtaining consent from the member as appropriate under legal requirements.

- Chiropractors
- Podiatrists
- Dermatologists
- OB/GYN

Culturally and Linguistically Appropriate Services

Patient panels are increasingly diverse and needs are becoming more complex. It is important for providers to have the knowledge, resources, and tools to offer culturally competent and linguistically appropriate care. Simply wants to help, as we all work together to achieve health equity.

The Cultural Competency

Cultural competency refers to the ability of individuals and systems to provide services effectively to people of all cultures, races, ethnic backgrounds and religions in a manner that recognizes values, affirms and respects the worth of individuals, and protects and preserves the dignity of each. This includes individuals with limited English proficiency and those with disabilities regardless of gender, sexual orientation or gender identity. Simply promotes cultural competency by providing training opportunities to staff and network providers, to increase their knowledge of, and ability to support, the values, beliefs, and needs of diverse members Staff and provider cultural competency is monitored as part of the Quality Improvement process.

Simply has a comprehensive, written Cultural Competency Plan describing how we ensure:

 Services are provided in a culturally competent manner to all members, including those with limited English proficiency. U.S. Department of Health and Human Services (HHS) defines cultural competence as the ability to honor and respect the beliefs, languages, interpersonal styles, and behaviors of individuals and families receiving services, as well as staff members who are providing such services. It is a dynamic, ongoing developmental process requiring long-term commitment. The Agency for Healthcare Research and Quality (AHRQ) Patient Safety Network explains that healthcare is defined through a cultural lens for both patients and providers. A person's cultural affiliations can influence:

For more information on our cultural competency program, please refer to the provider website.

U.S. Department of Health and Human Services (HHS) defines cultural competence as the ability to honor and respect the beliefs, languages, interpersonal styles, and behaviors of individuals and families receiving services, as well as staff members who are providing such services. It is a dynamic, ongoing developmental process requiring long-term commitment. The Agency for Healthcare Research and Quality (AHRQ) Patient Safety Network explains that healthcare is defined through a cultural lens for both patients and providers. A person's cultural affiliations can influence:

- Where and how care is accessed, how symptoms are described,
- Expectations of care and treatment options,
- Adherence to care recommendations.

Providers also bring their own cultural orientations, including the culture of medicine.

Offering culturally and linguistically appropriate care incorporates a variety of skills and knowledge, including, but not limited to, the ability to:

- Recognize the cultural factors (norms, values, communication patterns and world views) that shape personal and professional behavior.
- Develop understanding of others' needs, values and preferred means of having those needs met
- Formulate culturally competent treatment plans.
- Understand how and when to use language support services, including formally trained interpreters and auxiliary aids and services, to support effective communication.
- Avoid use of family members, especially minors, to act as interpreters for limited English proficient
 natients
- Understand and adhere to regulations to support the needs of diverse patients, such as the Americans with Disabilities Act (ADA).
- Use culturally appropriate community resources as needed to support patient needs and care.

Simply ensures providers have access to resources to help support delivery of culturally and linguistically appropriate services. Simply encourages providers to access and utilize the following resources.

MyDiversePatients.com: The My Diverse Patient website offers resources, information, and techniques, to help provide the individualized care every patient deserves regardless of their diverse backgrounds. The site also includes learning experiences on topics related to cultural competency and disparities that offer free Continuing Medical Education (CME) credit. Current CME offerings include:

- Caring for Children with ADHD: Promotes understanding of and adherence to diagnosis and treatment guidelines; use of AAP's Resource Toolkit for Clinicians; awareness of and strategies for addressing disparities.
- Creating an LGBT-Friendly Practice: Helps providers understand the fears and anxieties LGBT patients
 often feel about seeking medical care, learn key health concerns of LGBT patients, & develop strategies
 for providing effective health care to LGBT patients.

- Improving the Patient Experience: Helps providers identify opportunities and strategies to improve patient experience during a health care encounter.
- Medication Adherence: Helps providers identify contributing factors to medication adherence disparities for diverse populations & learn techniques to improve patient-centered communication to support needs of diverse patients.
- Moving Toward Equity in Asthma Care: Helps providers understand issues often faced by diverse patients with asthma & develop strategies for communicating to enhance patient understanding.
- Reducing Health Care Stereotype Threat (HCST): Helps providers understand HCST and the implications
 for diverse patients as well as the benefits of reducing HCST to both providers' patients and practices,
 and how to do so.
- Cultural Competency Training (Cultural Competency and Patient Engagement): A training resource to increase cultural and disability competency to help effectively support the health and health care needs of your diverse patients.
- Caring for Diverse Populations Toolkit: A comprehensive resource to help providers and office staff
 increase effective communication by enhancing knowledge of the values, beliefs, and needs of diverse
 patients.

Simply appreciates the shared commitment to ensuring Members receive culturally and linguistically appropriate services to support effective care and improved health outcomes.

Marketing

When it comes to marketing, you need to be aware of and comply with the following:

- Providers are permitted to make available and/or distribute Simply-approved marketing materials as long
 as the provider and/or the facility distributes or makes available marketing materials for all managed care
 plans with which the provider participates.
- Providers are permitted to display posters or other materials in common areas such as the provider's
 waiting room. Marketing may not be conducted in areas where patients primarily intend to receive health
 care services or are waiting to receive health care services.
- Long-term care facilities are permitted to provide materials in admission packets announcing all managed care plan contractual relationships.

We will provide education, outreach and monitoring to ensure you are aware of and comply with the following:

- To the extent a provider can assist a recipient in an objective assessment of his or her needs and potential
 options to meet those needs, the provider may do so. Providers may engage in discussions with recipients
 should a recipient seek advice. However, providers must remain neutral when assisting with enrollment
 decisions.
- Providers may not:
 - o Offer marketing/appointment forms.
 - Make phone calls or direct, urge or attempt to persuade recipients to enroll in a managed care plan based on financial or any other interests of the provider.
 - o Mail marketing materials on behalf of a managed care plan.
 - o Offer anything of value to induce recipients/enrollees to select them as their provider.
 - $\circ\quad$ Offer inducements to persuade recipients to enroll in the managed care plan.
 - Conduct health screening as a marketing activity.
 - $\circ \quad \text{Accept compensation directly or indirectly from the managed care plan for marketing activities}.$
 - o Distribute marketing materials within an exam room setting.

- Furnish the managed care plan with lists of their Medicaid patients or the membership of any managed care plan.
- Providers may:
 - o Provide the names of the managed care plans with which they participate.
 - o Make available and/or distribute managed care plan marketing materials.
 - Refer their patients to other sources of information, such as the managed care plan, the enrollment broker or the local Medicaid area office.
 - o Share information with patients from the Agency's website or the CMS website.
 - Distribute printed information provided by the managed care plan to their patients comparing the benefits of all of the different managed care plans with which the providers contract.
- · Provider affiliation information
 - Providers may announce new or continuing affiliations with the managed care plan through general advertising (for example, radio, television, websites).
 - Providers may make new affiliation announcements within the first 30 calendar days of the new provider agreement.
 - Providers may make one announcement to patients of a new affiliation that names only the managed care plan when such announcement is conveyed through direct mail, email or phone.
 - Additional direct mail and/or email communications from providers to their patients regarding affiliations must include a list of all managed care plans with which the provider contracts.
 - Any affiliation communication materials that include managed care plan-specific information (for example, benefits, formularies) must be prior approved by the Agency.

Member Records

Providers are required to maintain medical records for each patient in accordance with the medical record requirements below and with 42 CFR 431 and 42 CFR 456. A permanent medical record will be maintained at the primary care site for every member and be available to the PCP and other physicians. Medical records shall include the quality, quantity, appropriateness and timeliness of services performed.

Providers are required to have a designated person in charge of medical records. This person's responsibilities include but are not limited to:

- The confidentiality, security and physical safety of records.
- The timely retrieval of individual records upon request.
- The unique identification of each patient's record.
- The supervision of the collection, processing, maintenance, storage and appropriate access to the usage of records.
- The maintenance of a predetermined, organized and secured record format.

Medical Record Standards

Except when otherwise required by law, the content and format of clinical records, including the sequence of information, are uniform. Records are organized in a consistent manner that facilitates continuity of care. All patient medical records are to reflect all aspects of patient care, including ancillary services. Providers must follow the medical record standards set forth below for each member's medical records as appropriate:

- Include the enrollee's identifying information, including name, enrollee identification number, date of birth, gender, and legal guardianship or responsible party if applicable
- Include information relating to the enrollee's use of tobacco, alcohol, and drugs/substances
- Maintain each record legibly and in detail
- Include a summary of significant surgical procedures, past and current diagnoses or problems, allergies, untoward reactions to drugs and current medications and any other health conditions

- Include all services provided (this includes but is not limited to family planning services, preventive services
 and services for the treatment of sexually transmitted diseases)
- Record the presence or absence of allergies and untoward reactions to drugs, current medications and/or
 materials in a prominent and consistent location in all clinical records; this information should be verified at
 each patient encounter and updated whenever new allergies or sensitivities are identified
- Ensure all entries are dated and signed by the appropriate party
- Indicate in all entries the chief complaint or purpose of the visit, the objective, diagnoses, and medical findings or impression of the provider
- Indicate in all entries the studies ordered (for example, laboratory, X-ray, electrocardiogram) and referral
 reports
- Indicate in all entries the therapies administered and prescribed
- Record all medications prescribed and documentation or medication reconciliation, including any changes in prescription and nonprescription medication with name and dosage when available
- Include in all entries the name and profession of the provider rendering services (for example, MD, DO), including the provider's signature or initials
- Include in all entries the disposition, recommendations, instructions to member, evidence of follow-up and outcome of services
- <u>Documentation</u> of <u>the express written and informed</u> consent of the enrollee's <u>authorized representative prescriptions</u> for <u>psychotropic medication (i.e., antipsychotics, antidepressants, antianxiety medications, and mood stabilizers) prescribed</u> for <u>an enrollee</u> under the age of <u>thirteen (13) years</u>
- Documentation of the child's consent and proof that a signed attestation has been provided to the pharmacy
- Ensure all records contain an immunization history and documentation of body mass index
- Ensure all records contain information relating to the member's use of tobacco products and alcohol and/or substance abuse
- Ensure all records contain summaries of all emergency services and care and hospital discharges with appropriate and medically indicated follow-up
- Document referral services in all members' medical records
- Include all services provided such has family planning services, preventive services and services for the treatment of sexually transmitted diseases
- Ensure all records reflect the primary language spoken by the member and any translation needs of the member
- Ensure all records identify members needing communication assistance in the delivery of health care services
- Ensure all records contain documentation of the member being provided with written information
 concerning his or her rights regarding advance directives (that is, written instructions for living will or
 power of attorney) and whether or not he or she has executed an advance directive.
 - Note: Neither the health plan nor any of its providers can require, as a condition of treatment, the
 member to execute or waive an advance directive. The health plan must maintain written policies
 and procedures for advance directives.
- Maintain copies of any advance directives executed by the member
- Enter in the patient's clinical record and appropriately sign or initial significant medical advice given to a
 patient by telephone or online, including medical advice provided after hours
- Clearly contrast any notation in a patient's clinical record indicating diagnostic or therapeutic intervention
 as part of clinical research with entries regarding the provision of non-research-related care
- Review and incorporate into the record in a timely manner all reports, histories, physicals, progress notes
 and other patient information such as laboratory reports, X-ray readings, operative reports and
 consultations

- Document a summary of past and current diagnoses or problems, including past procedures if a patient has
 had multiple visits/admissions or the clinical record is complex and lengthy
- Include a notation concerning cigarettes if present for patients ages 12 and older (abbreviations and symbols may be appropriate)
- Provide health education to the member
- Screen patients for substance abuse and document in the medical record as part of a prevention evaluation during the following times:
 - o Initial contact with a new member
 - o Routine physical examinations
 - Initial prenatal contact
 - When the member evidences serious overutilization of medical surgical, trauma or emergency services
 - o When documentation of emergency room visits suggests the need

The following requirements must also be met regarding the patient's medical records:

- Consultations, referrals and specialist reports Notes from any referrals and consultations must be in the
 record. Consultation, lab and X-ray reports filed in the chart must have the ordering physician's initials or
 other documentation signifying review. Consultation and any abnormal lab and imaging study results must
 have an explicit notation in the record of follow-up plans, including timely notification with patient or
 responsible party (adult).
- Emergencies All emergency care provided directly by the contracted provider or through an emergency
 room and the hospital discharge summaries for all hospital admissions while the patient is part of the PCP's
 panel must be noted.
- 3. Hospital discharge summaries Discharge summaries must be included as part of the medical record for all hospital admissions that occur while the patient is enrolled and for prior admissions as appropriate. Prior admissions pertaining to admissions that may have occurred prior to the patient being enrolled may be pertinent to the patient's current medical condition.
- Security Providers must maintain a written policy and are required to ensure medical records are safeguarded against loss, tampering, alteration, destruction, or unauthorized or inadvertent use.
- 5. **Storage** Providers must maintain a system for the proper collection, processing, maintenance, storage, retrieval and distribution of patient's records. Also, the records must be easily accessible to personnel in the provider's office and readily available to authorized personnel any time the organization is open to patients.
- Release of information Written procedures are required for releasing information and obtaining consent for treatment.
- 7. **Documentation** Documentation is required setting forth the results of medical, preventive and behavioral health screenings as well as all treatment provided and the outcome of such treatment, including significant medical advice given to a patient by telephone.
- Multidisciplinary teams Documentation is required of the team members involved in the multidisciplinary team of a patient needing specialty care.
- 9. **Integration of clinical care** Documentation of the integration of clinical care in both the physical and behavioral health records is required. Such documentation must include:
 - Screening for behavioral health conditions, including those which may be affecting physical health care and vice versa, and referral to behavioral health providers when problems are indicated.
 - Screening and referral by behavioral health providers to PCPs when appropriate.
 - Receipt of behavioral health referrals from physical medicine providers and the disposition/outcome
 of those referrals.
 - At least quarterly, or more often if clinically indicated, a summary of the status/progress from the behavioral health provider to the PCP.
 - A written release of information that will permit specific information-sharing between providers.

- Documentation that behavioral health professionals are included in primary and specialty care service teams when a patient with disabilities or chronic or complex physical or developmental conditions has a co-occurring behavioral disorder.
- 10. **Domestic violence** Documentation of screening and referral to the applicable community agencies is required.
- 11. **Consent for psychotherapeutic medications** Pursuant to *F.S. 409.912(13)*, providers must document informed consent from the parent or legal guardian of members younger than age 13 who are prescribed psychotherapeutic medications and must provide the pharmacy with a signed attestation of this documentation. Pharmacies are required to obtain and keep these consents on file prior to filing a psychotherapeutic medication.
- 12. **Behavioral health services provided through telemedicine** Documentation of behavioral health services provided through telemedicine is required. Such documentation must include:
 - o A brief explanation of the use of telemedicine in each progress note.
 - o Documentation of telemedicine equipment used for the particular covered services provided.
 - A signed statement from the enrollee or the enrollee's representative indicating the choice to receive services through telemedicine. This statement may be for a set period of treatment or for a one-time visit, as applicable to the service(s) provided.
 - o For telepsychiatry the results of the assessment, findings and practitioner(s) plan for next steps.

Simply will periodically review medical records to ensure compliance with these standards. Simply will institute actions, including corrective actions for improvement, when standards are not met.

Patient Visit Data

At a minimum, documentation of individual encounters must provide adequate evidence of the following:

- Date of service; name, signature and profession (for example, MD, OD, RN) of the person(s) providing the service; type of service provided; department of facility (if applicable); chief complaint; changes in medications with name and dosage; disposition; recommendations or instructions provided; and documentation of missed or cancelled appointments
- A history and physical exam that includes appropriate subjective and objective information obtained for the presenting complaints
- 3. For patients receiving behavioral health treatment:
 - Documentation that includes at-risk factors such as danger to self and/or others, ability to care for self, affect, perceptual disorders, cognitive functioning, and significant social health concerns.
 - A documented assessment that is done with each visit relating to client status/symptoms and that
 may indicate initial symptoms of the behavioral health condition as decreased, increased or
 unchanged during the treatment period, along with the type and units of service provided.
 - A treatment plan that includes the member and/or parent or guardian's preferences for treatment, identifies reasonable and appropriate objectives, provides the necessary services to meet the objectives, and includes a retrospective review to confirm that care provided and its outcomes were consistent with the approved treatment and member's needs.
 - Documented therapies and other prescribed regimens; and show evidence of family involvement as applicable and include evidence that the family was included in therapy sessions when appropriate.
- 4. An admission or initial assessment that includes current support systems or lack of support systems
- 5. A plan of treatment that includes activities/therapies to be carried out and goals to be met
- 6. Diagnostic tests
- 7. For follow-up care encounter forms or notes with a notation indicating follow-up care, a call or a visit that must note in weeks, months or PRN (as needed) the specific time to return with unresolved problems from any previous visits being addressed in subsequent visits
- 8. Referrals and results, including all other aspects of patient care, such as ancillary services

Simply will systematically review medical records to ensure compliance with these standards. We will share the results of our audits and institute actions for improvement when standards are not met.

We maintain an appropriate record-keeping system for services to members. This system will collect all pertinent information relating to the medical management of each member and make that information readily available to appropriate health professionals and appropriate state agencies. All records will be retained in accordance with the record retention requirements of 45 CFR 438.3110, which states that records must be retained for ten years from the date of termination of Simply's SMMC contract with AHCA and retained further if records are under review or audit until the audit or review is complete. Prior approval from Simply is required for the disposition of records if subcontract is continuous, per 438.4.u.

Misrouted Protected Health Information

Providers and facilities are required to review all member information received from Simply to ensure no misrouted protected health information (PHI) is included. Misrouted PHI includes information about members that a provider or facility is not treating. PHI can be inadvertently misrouted to providers and facilities by mail, fax, email or electronic remittance advice. Providers and facilities are required to immediately notify Simply upon receipt of the information, not forward or copy the documents, and destroy the misrouted PHI or safeguard the PHI for as long as it is retained. In no event are providers or facilities permitted to misuse or redisclose misrouted PHI. If providers or facilities cannot destroy or safeguard misrouted PHI, they should call Provider Services at 1-844-405-4296 for help.

Advance Directives

Simply respects the right of the member to control decisions relating to his or her own medical care, including the decision to have provided, withheld or withdrawn the medical or surgical means or procedures calculated to prolong his or her life. This right is subject to certain interests of society, such as the protection of human life and the preservation of ethical standards in the medical profession.

Simply adheres to the Patient Self-Determination Act and maintains written policies and procedures regarding advance directives. Advance directives are documents signed by a competent person giving direction to health care providers about treatment choices in certain circumstances. There are two types of advance directives. A durable power of attorney for health care (that is, durable power) allows the member to name a patient advocate to act on behalf of the member. A living will allows the member to state his or her wishes in writing but does not name a patient advocate.

Member Services and Outreach associates encourage members to request an advance directive form and education from their PCP at their first appointment.

Members over age 18 and emancipated minors are able to make an advance directive. His or her response is to be documented in the medical record. Simply will not discriminate or retaliate based on whether a member has or has not executed an advance directive.

While each member has the right without condition to formulate an advance directive within certain limited circumstances, a facility or an individual physician may conscientiously object to an advance directive. Member Services and Outreach associates will assist members regarding questions about advance directives; however, no Simply associate may serve as witness to an advance directive or as a member's designated agent or representative.

Simply notes the presence of advance directives in the medical records when conducting medical chart audits.

Telemedicine

Florida defines telemedicine as the practice of health care delivery by a practitioner who is located at a site other than the site where a recipient is located for the purposes of evaluation, diagnosis, or treatment (59G-1.057, F.A.C.).

If we approve you to provide services through telemedicine <u>as exhibited in your Participating Provider Agreement or Amendment</u>, you must implement telemedicine fraud and abuse protocols that address:

- Authentication and authorization of users.
- Authentication of the origin of the information.
- The prevention of unauthorized access to the system or information.
- System security, including the integrity of information that is collected, program integrity and system
 integrity.
- Maintenance of documentation about system and information usage.

When providing services through telemedicine:

 The telecommunication equipment and telemedicine operations must meet the technical safeguards required by 45 CFR 164.312, and Rule 59G-1.057 F.A.C. where applicable.

We educate the patient, obtain consent, document the choice for telemedicine in the patient's medical record, and include detailed notes from each visit.

You must comply with HIPAA and other state and federal laws pertaining to patient privacy.

8 MEDICAL MANAGEMENT

Medical Review Criteria

Simply has its own nationally recognized medical policy process. Simply medical policies, which are publicly accessible on the provider-subsidiary websites, are the primary benefit plan policies for determining whether services are considered to be 1) investigational/experimental, 2) medically necessary, and 3) cosmetic or reconstructive.

A list of the specific *Clinical Utilization Management Guidelines* used is posted and maintained on the Simply provider website and can be obtained in hard copy by written request. Providers can also contact Provider Services at <u>1</u>-844-405-4296 for more information. These policies will support precertification requirements, clinical-appropriateness claims edits and retrospective review.

Federal and state law as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first when determining eligibility for coverage. As such, in all cases, state Medicaid contracts or CMS requirements will supersede Simply medical policy criteria. Medical technology is constantly evolving, and we reserve the right to review and periodically update medical policy and clinical utilization management criteria.

Simply uses MCG care guidelines for inpatient concurrent reviews except for those hospitals where the contract states differently. Unless superseded by state Medicaid or CMS requirements, all nonbehavioral health, behavioral health outpatient precertification requests, and behavioral health concurrent reviews will be determined using Simply Medical Policies and Clinical Utilization Management Guidelines.

We work with network providers to develop clinical guidelines of care for our membership. The medical advisory committee assists us in formalizing and monitoring guidelines.

If we utilize noncommercial criteria, the following standards apply to the development of the criteria:

- Criteria are developed with involvement from appropriate providers with current knowledge relevant to the content of treatment guidelines under development.
- Criteria are based on review of market practice and national standards/best practices.
- Criteria are evaluated at least annually by appropriate, actively practicing physicians and other providers
 with current knowledge relevant to the criteria of treatment guidelines under review and updated, as
 necessary. The criteria must reflect the names and qualifications of those involved in the development, the
 process used in the development, and when and how often the criteria will be evaluated and updated.

Precertification/Notification Process

Simply may require members to seek a referral from their PCP prior to accessing nonemergency specialty physical health services.

Precertification is defined as the **prospective** process whereby licensed clinical associates apply designated criteria against the intensity of services to be rendered and a member's severity of illness, medical history and previous treatment to determine the medical necessity and appropriateness of a given coverage request. **Prospective** means the coverage request occurred prior to the service being provided.

Notification is defined as faxed, telephonic or electronic communication received from a provider informing Simply of the intent to render covered medical services to a member. There is no review against medical necessity criteria; however, member eligibility and provider status (network and non-network) are verified.

Notification should be provided prior to rendering services. For services that are emergent or urgent, notification should be given within 24 hours or the next business day.

Utilization Management Decision Making

Simply, as a corporation and as individuals involved in utilization management (UM) decisions, is governed by the following statements:

- UM decision-making is based only on appropriateness of care and service and existence of coverage.
- Simply does not specifically reward practitioners or other individuals for issuing denial of coverage or care.
 Decisions about hiring, promoting or terminating practitioners or other staff are not based on the likelihood or perceived likelihood that they support, or tend to support, denials of benefits.
- Financial incentives for UM decision-makers do not encourage decisions that result in underutilization or create barriers to care and service.

Access to UM Staff

- UM staff is available at least eight hours a day during normal business hours for inbound collect or toll-free
 calls at <u>1</u>-844_405_4296. Staff are available Monday to Friday, 8 a.m. to 7 p.m. ET (excluding state
 holidays) to assist with inquiries and problems related to the provision of services and claims. The helpline
 is additionally staffed after-hours to respond to authorization requests.
- Staff can receive inbound communication regarding UM issues after normal business hours at
 1-844-405-4296. Our after-hours answering service will ensure providers can leave a message for our
 managers, nurses or the medical director as appropriate.
- Staff identify themselves by first name/first initial of last name, title and organization name when initiating
 or returning calls regarding UM Issues.
- TDD/TTY services are available by dialing 711.
- Language assistance, such as interpreter services, is available by calling Provider Services at 1-844-405-4296.

Preventive Care Guidelines

Simply uses nationally recognized preventive care, evidence-based clinical practice information, guidelines and protocols. This information is on the provider website to ensure fair, consistent and quality health care services and treatments are provided to members. Our clinical practice and preventive care guidelines: https://provider.simplyhealthcareplans.com/docs/FLFL_SMH_ClinicalPracticeGuidelines_June2019.pdf

The following are links to the HIV/AIDS-specific guidelines:

Adult HIV	http://www.aidsinfo.nih.gov/Guidelines	U.S. Dept. of Health
		and Human
Primary Care		Services, Clin.
Guidelines for the		Guidelines
Management of	http://www.patan.org/2013/HIV/ClinDis2013Aborgcid_cit665.ndf	Site Guidelines
Persons Infected	https://academic.oup.com/cid/advance-	updated: July 10,
with HIV	article/doi/10.1093/cid/ciaa1391/5956736	2015 August 16,
	ai ticle/ uoi/ 10:1035/ ciu/ ciaa1531/ 5350/ 50	<u>2021</u>
		2013 2020 Update
		by the HIV Medicine
		Association of the
		Infectious Diseases
		Society of America

Guidelines for	https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdfhtt	National Institutes
Prevention and	ps://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-	of Health, AIDS
Treatment of	opportunistic-infection/whats-new-guidelines	Information
Opportunistic		updated Nov 18,
Infections in HIV-		<u>2021</u>
Infected Adults		
and Adolescents		

Treatment adherence services are available through Simply. Case managers communicate the information to members, and information is made available to all PCPs.

Clinical Practice Guidelines

Clinical practice guidelines are resources to assist with the management of chronic medical conditions for the care of our membership. The medical advisory committee (MAC) oversees and directs Simply in adopting and monitoring guidelines. We must review and revise the guidelines at least every two years or whenever the guidelines change.

The clinical criteria are guidelines developed by industry specialty associations and organizations, including but not limited to:

- American Academy of Child and Adolescent Psychiatry
- American Academy of Family Physicians
- American Academy of Pediatrics
- American Cancer Society
- American College of Obstetricians and Gynecologists (ACOG)
- American College of Physicians
- American Diabetes Association
- American Lung Association
- American Medical Association
- Centers for Disease Control and Prevention
- Department of Health and Human Services Commission
- National Institutes of Health
- U.S. Preventive Services Task Force

Visit our provider website at https://medicalpolicy.simplyhealthcareplans.com to review and download a copy of the clinical practice guidelines. You may also call Provider Services at <u>1</u>-844-405-4296 to request a hard copy, and we will gladly mail it to you.

Clinical Criteria

The criteria provide a system for screening proposed medical care based on member specific best medical care practices and rule-based systems to match appropriate services to member needs based upon clinical appropriateness. Criteria include:

- Acute care (adult and pediatric)
- Rehabilitation
- Subacute care
- Home care
- Surgery and procedures
- Imaging studies and X-rays

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Simply utilization reviewers use these criteria as part of the precertification of scheduled admission, concurrent review and discharge planning process to determine clinical appropriateness and medical necessity for coverage of continued hospitalization. These criteria are reviewed at least annually.

Simply is available 24/7 to accept precertification requests. When a request is received from the physician via telephone, online submission or fax for medical services, the care specialist will verify eligibility and benefits. This information will be forwarded to the precertification nurse. The precertification nurse will review the coverage request and the supporting medical documentation to determine the medical appropriateness of diagnostic and therapeutic procedures. When appropriate, the precertification nurse will assist the physician in identifying alternatives for health care delivery as supported by the medical director.

When the clinical information received is in accordance with the definition of medical necessity and in conjunction with our *Clinical UM Guidelines* criteria, a Simply reference number will be issued to the referring physician. All utilization guidelines must be supported by an individualized determination of medical necessity based on the member's needs and medical history. Decisions on urgent requests (that is, expedited service authorizations) will be made within two calendar days.

If medical necessity criteria for the admission are not met on the initial review, the medical director will contact the requesting physician upon request to discuss the case.

If the precertification documentation is incomplete or inadequate, the precertification nurse will not approve coverage of the request but will notify the referring provider to submit the additional necessary documentation. Two requests for additional information will be made over a 48-hour period. If information is not received within the specified time period, the request will be denied. If the medical director denies coverage of the request, the appropriate denial letter (including the member's appeal rights) will be mailed to the requesting provider, the member's PCP and the member.

If the medical director denies the request for coverage, the appropriate notice of proposed action will be mailed to the requesting provider, the member's PCP, the facility and the member.

Our Interactive Care Reviewer (ICR), which is accessed online through the Availity Portal at https://www.availity.com, is the preferred method for submitting preauthorization requests; it offers a streamlined and efficient experience for providers requesting inpatient and outpatient medical or behavioral health services for our members. Additionally, providers can use this tool to make inquiries and check on the status of previously submitted requests, regardless of how they were sent (phone, fax, ICR or other online tool). Capabilities and benefits of the ICR include:

- Initiating preauthorization requests online eliminating the need to fax. The ICR allows detailed text, photo images and attachments to be submitted along with your request.
- Making inquiries on previously submitted requests via phone, fax, ICR or other online tool.
- Having instant accessibility from almost anywhere, including after business hours.
- Utilizing a dashboard that provides a complete view of all utilization management requests with real-time status updates, including email notifications if requested using a valid email address.
- Viewing real-time results for common procedures with immediate decisions.
- Requesting and checking the status of clinical appeals for denied authorizations.
- Viewing letters affiliated with the case.
- Submit an appeal for a UM denial

You can access the ICR under **Authorizations and Referrals** on the Availity Portal. For an optimal experience with the ICR, use a browser that supports 128-bit encryption. This includes Internet Explorer, Chrome, Firefox and Safari

The ICR is not currently available for:

- Transplant services.
- Services administered by vendors, such as AIM Specialty Health and Health Network One (HN1). For these
 requests, follow the same preauthorization process you use today.

We'll update our website as additional functionality is added throughout the year.

Hospital and Elective Admission Management

Simply requires precertification of all inpatient elective admissions. The referring primary care provider (PCP) or specialist physician is responsible for precertification. The referring physician identifies the need to schedule a hospital admission and must submit the request to the Simply Medical Management department.

Requests for precertification with all supporting documentation should be submitted immediately upon identifying the inpatient request or at least 72 hours prior to the scheduled admission. This will allow Simply to verify benefits and process the precertification request. For services that require precertification, Simply makes case-by-case determinations that consider the individual's health care needs and medical history in conjunction with medical necessity criteria.

The hospital can confirm that an authorization is on file by calling the Simply automated Provider Inquiry Line at <u>1</u>-844-405-4296 or accessing our secure website. If coverage of an admission has not been approved, the facility should call Simply at <u>1</u>-844-405-4296. Simply will contact the referring physician directly to resolve the issue.

Emergent Admission Notification Requirements

Simply prefers immediate notification by network hospitals of emergent admissions. Network hospitals must notify Simply of emergent admissions within one business day. Simply Medical Management staff will verify eligibility and determine benefit coverage. No prior authorization is required for emergency admissions.

Simply is available 24/7 to accept emergent admission notification at $\underline{\textbf{1}}$ -844-405-4296.

Coverage of emergent admissions is authorized based on review by a concurrent review nurse. When the clinical information received meets the criteria, a Simply reference number will be issued to the hospital. Two requests for clinical information will be made over a 48-hour period if clinical information was not provided with notification. If information is not received within 72 hours of the initial request, the request will be denied. If the notification documentation provided is incomplete or inadequate, Simply will not approve coverage of the request and will notify the hospital to submit the additional necessary documentation. If the medical director denies coverage of the request, the appropriate denial letter will be mailed to the hospital, member's PCP and the member.

Nonemergent Outpatient and Ancillary Services: Precertification and Notification Requirements

Simply requires precertification for coverage of selected nonemergent outpatient and ancillary services. To ensure timeliness of the authorization, the expectation is for the facility and/or provider to provide the following:

- Member name, DOB and ID
- Name, phone and fax number, TIN (or NPI and address) of the physician performing the elective service
- Name of the facility and telephone number where the service is to be performed

- Date of service
- Member ICD-10 diagnosis
- Name of elective procedure to be performed with CPT code
- Medical information to support requested services (medical information includes current signs/symptoms, past and current treatment plans, response to treatment plans, and medications)

For more information on prior authorization and notification requirements, refer to the Simply Health Care Benefits and Copays and our provider website.

Inpatient Reviews

Inpatient Admission Review

We'll review all inpatient hospital admissions, including urgent and emergent admissions, within 24 hours of admission notification. The Simply utilization review clinician determines the member's medical status through communication with the hospital's utilization review department. Appropriateness of stay is documented and concurrent review is initiated. Cases may be referred to the medical director, who renders a decision on the coverage of hospitalization. Diagnoses meeting specific criteria are referred to the medical director for possible coordination by the Care Management program.

Inpatient Concurrent Review

Each network hospital will have an assigned Utilization Management (UM) nurse. Each UM nurse will conduct a utilization review of the hospital medical record using EMR, phone or onsite at the facility if indicated, to determine the authorization of coverage for a continued stay.

When a Simply UM nurse reviews the medical record, he or she works closely with the hospital case management team and contacts the member or member representative as needed to discuss any discharge planning needs and verify that the member or family is aware of the PCP's name, address and telephone number. The UM nurse will conduct continued stay reviews and review discharge plan needs.

When the clinical information received meets medical necessity criteria, approved continued stay days will be communicated to the hospital. The request for the clinical information needed will be communicated to the designated department within the hospital. Simply asks that the hospital reviewer provide only the necessary information being requested.

Upon discharge Simply UM clinician will help coordinate discharge planning needs with the hospital utilization review staff and attending physician. The attending physician is expected to coordinate with the member's PCP regarding follow-up care after discharge. The PCP is responsible for contacting the member to schedule all necessary follow-up care. In the case of a behavioral health discharge, the attending physician is responsible for ensuring the member has secured an appointment for a follow-up visit with a behavioral health provider to occur within seven calendar days of discharge.

Simply will authorize covered length of stay one day at a time based on the clinical information that supports the continued stay. Exceptions to the one-day length of stay authorization are made for confinements when the severity of the illness and subsequent course of treatment is likely to be several days or is predetermined by state law. Examples of confinement and/or treatment include the following: ICU, CCU, behavioral health rehabilitation, and C-section or vaginal deliveries. Exceptions are made by the medical director.

If the medical director denies coverage for an inpatient stay request based on appropriate criteria and after offering a peer-to-peer discussion, the appropriate notice of action will be mailed to the hospital, the member's PCP and the member.

Discharge Planning

Discharge planning is designed to assist the provider in the coordination of the member's discharge when acute care (that is, hospitalization) is no longer necessary.

When long-term care is necessary, Simply works with the provider to plan the member's discharge to an appropriate setting for extended services. These services can often be delivered in a nonhospital facility, such as:

- A hospice facility
- A convalescent facility
- A home health care program (for example, home IV antibiotics)

When the provider identifies medically necessary and appropriate services for the member, we will assist the provider and the discharge planner in providing a timely and effective transfer to the next appropriate level of care.

Discharge plan authorizations follow <u>Simply</u> Clinical UM Guidelines. Authorizations include, but are not limited to, home health, durable medical equipment, pharmacy, follow-up visits to practitioners or outpatient procedures.

Confidentiality of Information

Utilization Management (UM), case management, disease management, discharge planning, quality management and claims payment activities are designed to ensure patient-specific information, particularly protected health information obtained during review, is kept confidential in accordance with applicable laws, including the HIPAA. Information is used for the purposes defined above. Information is shared only with entities who have the authority to receive such information and only with those individuals who need access to such information in order to conduct UM and related processes.

Emergency Services

Simply provides a 24/7 NurseLine with clinical staff to provide triage advice and referral and, if necessary, to make arrangements for treatment of the member. The staff has access to qualified behavioral health professionals to assess behavioral health emergencies.

Simply does not discourage members from using the 911 emergency system or deny access to emergency services. Emergency services are provided to members without requiring precertification. Any hospital or provider calling for an authorization for emergency services will be granted one immediately upon request. Emergency services coverage includes services that are needed to evaluate or stabilize an emergency medical condition. Criteria used to define an emergency medical condition are consistent with the prudent layperson standard and comply with federal and state requirements:

An emergency medical condition is defined as a physical or behavioral condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson who possesses an average knowledge of health and medicine could reasonably expect the absence of immediate medical attention to result in the following: 1) place the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, 2) serious impairment to bodily functions, or 3) serious dysfunction of any bodily organ or part.

Emergency response is coordinated with community services, including the police, fire and EMS departments, juvenile probation, the judicial system, child protective services, chemical dependency, and local mental health authorities, if applicable.

When a member seeks emergency services at a hospital, the determination as to whether the need for those services exists will be made for purposes of treatment by a physician licensed to practice medicine or, to the extent permitted by applicable law, by other appropriately licensed personnel under the supervision of, or in collaboration with, a physician licensed to practice medicine. The physician or other appropriate personnel will indicate in the member's chart the results of the emergency medical screening examination. Simply will compensate the provider for the screening, evaluations and examination that are reasonable and calculated to assist the health care provider in determining whether or not the patient's condition is an emergency medical condition.

If there is concern surrounding the transfer of a patient (that is, whether the patient is stable enough for discharge or transfer or whether the medical benefits of an unstable transfer outweigh the risks), the judgment of the attending physician(s) actually caring for the member at the treating facility prevails and is binding on Simply. If the emergency department is unable to stabilize and release the member, Simply will assist in coordination of the inpatient admission, regardless of whether the hospital is network or non-network. All transfers from non-network to network facilities are to be conducted only after the member is medically stable and the facility is capable of rendering the required level of care.

If the member is admitted, the Simply concurrent review nurse will implement the concurrent review process to ensure coordination of care.

Urgent Care

Simply requires its members to contact their PCP in situations where urgent, unscheduled care is necessary. Precertification with Simply is not required for a member to access a participating urgent care center.

9 QUALITY MANAGEMENT

Quality Management Program

Overview

Simply maintains a comprehensive Quality Management (QM) program to objectively monitor and systematically evaluate access to care and the quality and appropriateness of care and services rendered, to promote quality of care and patient outcomes (see 42 CFR 438.340 and 438.330). The scope and content of the program reflects the demographic and epidemiological needs of the population served. Studies are planned across the continuum of care and service with ongoing proactive evaluation and refinement of the program.

Members and providers have opportunities to make recommendations for areas of improvement. The QM program goals and outcomes are available, upon request, to providers and members. The easiest way for providers to access this information is by going to the provider website, and members can go to the member website.

The initial program development was based on a review of the needs of the population served. Systematic re-evaluation of the needs of the plan's specific population occurs on an annual basis. This includes not only age and gender distribution, but also a review of utilization data — inpatient; emergent/urgent care; and office visits by type, cost and volume. This information is used to define areas that are high-volume or problem-prone.

There is a comprehensive committee structure in place with oversight from the Simply governing body. Not only are the traditional medical advisory committee (MAC) Peer Review Committee (PRC) and Credentialing committee in place, but a community/enrollee advisory committee are also integral components of the quality management committee (QMC) structure.

Quality of Care

All physicians, advanced registered nurse practitioners and physician assistants are evaluated for compliance with pre-established standards as described in the Simply credentialing program.

Review standards are based on medical community standards, external regulatory and accrediting agencies requirements, and contractual compliance.

Reviews are accomplished by Florida licensed nurses and associate professionals who strive to develop relationships with providers and hospitals that will positively impact the quality of care and services provided to our members.

Results are submitted to the Simply QM department and incorporated into a profile.

The Simply quality program includes review of quality-of-care issues identified for all care settings. QM staff use peer review, performance improvement projects (PIP), medical/case record audits, performance measures, surveys, member complaints, and other information to evaluate the quality of service and care provided to our members. In addition, Simply reviews and analyzes adverse or critical incidents to identify and work to eliminate potential and actual quality of care and/or health and safety issues.

Use of Performance Data

Practitioners and providers must allow Simply to use performance data in cooperation with our quality improvement program and activities.

Quality Management Committee

The purpose of the QMC is to maintain quality as a cornerstone of Simply culture and to be an instrument of change through demonstrable improvement in care and service. The QMC's responsibilities are to:

- Establish strategic direction and monitor and support implementation of the QM program.
- Establish processes and structure that ensure accreditation compliance.
- Review and accept corporate and local QM policies and procedures as appropriate.
- Analyze, review and make recommendations regarding the planning, implementation, measurement and outcomes of clinical/service quality improvement studies.
- Address and resolve any problems/issues identified but not included in a process improvement program.
- Coordinate communication of QM activities throughout the health plans.
- Review and analyze HEDIS® and CAHPS® data and action plans for improvement.
- Review, monitor and evaluate program compliance against Simply, state, federal and accreditation standards.
- Review and approve the annual QM Program Description and work plan.
- Provide oversight and review of delegated services.
- Provide oversight and review of operational indicators.
- Assure interdepartmental collaboration, coordination and communication of quality improvement activities.
- Measure compliance to medical and behavioral health practice guidelines.
- Monitor continuity of care between medical and behavioral health services.
- Monitor accessibility and availability with cultural assessment.
- Make information publicly available to members and practitioners about our actions to improve patient safety.
- Make information available about our quality improvement program to members and practitioners; members and providers can request the program by calling Customer Service.
- Assure practitioner involvement through direct input from our MAC or other mechanisms that allow practitioner involvement.
- Provide communication to and from the BOD regarding strategic direction for the QM plan.

Medical Advisory Committee

The MAC has multiple purposes. It:

- Assesses levels and quality of care provided to members and recommends, evaluates and monitors standards of care.
- Monitors practice patterns to identify appropriateness of care and for improvement/risk prevention activities.
- Identifies opportunities to improve services and clinical performance by establishing, reviewing and
 updating clinical practice guidelines based on review of demographics and epidemiologic information to
 target high-volume, high-risk and problem-prone conditions.
- Oversees the peer review process, which provides a systematic approach for the monitoring of quality and the appropriateness of care.
- Conducts a systematic process for network maintenance through the credentialing/recredentialing process.
- Advises health plan administration in any aspect of health plan policy or operation affecting network providers or members.
- Approves and provides oversight of the peer review process, the QM program and the utilization review program.
- Oversees and makes recommendations regarding health promotion activities.

HEDIS is a registered trademark of the National Committee for Quality Assurance (NCQA). CAHPS is a registered trademark of the Agency for Healthcare Research and Quality.

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The MAC's responsibilities are to:

- Utilize an ongoing peer review system to assess levels of care and quality of care provided.
- Monitor practice patterns to identify risk prevention activities and the appropriateness of care.
- Review, provide input and approve evidence-based clinical protocols and guidelines to facilitate the
 delivery of quality care and appropriate resource utilization.
- · Review clinical study designs and results.
- Develop and approve action plans and recommendations regarding clinical quality improvement studies.
- Consider and act in regard to physician sanctions.
- Review, provide input for, and approve policies and procedures for credentialing/recredentialing, QM, utilization management and disease/case management.
- Review and provide feedback regarding new technologies.
- Oversee the compliance of delegated services.
- Review and provide input to credentialing and recredentialing policies and procedures; clinically oriented
 quality management policies and procedures; utilization management policies and procedures; and
 disease/case management policies and procedures.
- · Review and provide feedback regarding new technologies.
- Oversee compliance of delegated services.

Peer Review Committee (PRC)

Purpose

As a subcommittee of the QMC, the goal of the Peer Review Committee is to continually improve the quality of care and service provided to members and to ensure that care is consistent with appropriate medical practice standards.

Responsibilities

- The Peer Review is responsible for evaluating the appropriateness of care rendered by the plan's contracted providers;
- Reviewing provider's practice methods and patterns.
- Evaluating provider performance, trends in quality of care and service issues.
- Developing and analyzing plan wide audits.
- It may also serve as the plan's provider advisory council providing input and recommendations to the plan
 concerning, but not limited to, the clinical guidelines adopted, QM Trilogy documents, Credentialing report,
 PIPS, process improvements, quality indicators, performance measures, HEDIS, and Provider Satisfaction
 Survey tools and results

Provider Orientation and Education

Medical Reviewer nurses are available to provide a thorough orientation of Simply review standards. Educational sessions can be scheduled at a provider's convenience. The QM staff is also available to furnish providers with a thorough explanation of review findings during an exit conference on the day of the medical record review. If a provider's schedule does not allow for sufficient time on the day of the review, we can schedule a follow-up appointment. Experience has taught that provider participation in orientation and education sessions helps improve standards' compliance, and therefore decreases the frequency for required reviews.

Medical Record Documentation Review Standards

Administrative Component

This applies to the Medicaid programs for Simply Healthcare Plans, Inc. (Simply) and Clear Health Alliance (CHA) as well as the Florida Healthy Kids (FHK) program for Simply.

Elements and References	Guidelines •	Deleted Cells
Administrative Compo	nent (A)	Formatted: Tab stops: 0.9", Left + 3.68
<u>Element</u>	<u>Standard</u>	Centered
	d organized and legible and easily accessible to the health care practitioners	\ \
	re fastened with contents organized in a logical, consistent manner to facilit	ate
to the healthcare information information legible.	on retrieval. There is individual record for each member. The record must b	Formatted: Font: 12 pt, Font color: White
	ersonnel	Formatted Table
guidelines		Formatted: Font: Bold
AHCA contract	•	Formatted: Font: Bold
	er ID of file	Formatted: Font: 12 pt, Underline
NCQA guidelines AHCA contract	al identifying data (name, gender, DOB)	\ <u> </u>
	/ language	Formatted: Tab stops: 0.38", Left + 3.5
	ce of access to an interpreter, or translator if evidence of a gap	Left
	rage communication	Formatted: Font: 12 pt, Underline
AHCA contract	All records for members 21 years and older must contain:	Formatted: Tab stops: 0.38", Left + 3.5
FL Statute 765.110 Member ID on fil	Documentation the member was provided written information of	μ Left
	their rights regarding advanced directives (written instructions for	Formatted Table
	living will or durable power of attorney). Documentation of whether or not the member has executed an	Formatted: Font: 12 pt, Underline
	advance directive. When an advance directive exists, a copy must be	\ <u></u>
	maintained in the record. A copy of membership card on file or in the	- Cilia Court i de Coper Cies / Este i Cie
	medical record and written office policy to verify member eligibility	
	before rendering service.	
	*	Formatted: Font: 12 pt, Underline
	f advance directives	Formatted: Indent: First line: 0.25", Add
Simply Patient NCQA guidelines	ID on each page	space between paragraphs of the same
NCQA guidelines	All entries dates and signed by appropriate partyRequired	style, No bullets or numbering, Tab stops:
AHCA contract	information: Name, DOB, sex, address, and telephone number. For	0.38", Left + 3.5", Left
FL Regulation 64B8 30.012Personal	pediatric members (under 21 years old) names of parents or legal	Formatted Table
Identifying data. Legal Guardian.	guardian are required.	Formatted: Tab stops: 0.38", Left + 3.5
		Left
NCQA guidelines	All entries include the name and profession of the provider	Formatted: Font: 12 pt, Underline
AHCA contract FL Regulation 64B8-30.012 Primary	rendering the services, including the signature or initials of the	Formatted: Font: 12 pt, Underline
language and translation	provider. Applies to both licensed and non-licensed personnel.	
anguage and translation	All physician assistant signatures must be reviewed, cosigned an	Formatted: Tab stops: 0.38", Left + 3.5
	dated by a supervising physician within seven days. ARNP notes do n	not
	require cosigning. All records must reflect the member's primary	Formatted: Tab stops: 0.38", Left + 3.5
	spoken language and translation needs, to include services for the	Left
	deaf/hearing impaired, as well as evidence of access to a translator.	Formatted: Font: 12 pt, Underline
	English is the primary language, this must be documented.	Formatted: Font: 12 pt, Underline
AHCA contract	All entries include the disposition, recommendations, instruction	Formatted
SimplyAdvance Directives adviseme		
Simply Advance Directives adviseine	of services All records member's 18 years and older must contain	
	T. T. Hoos, and Contain the Market of the Years and Older mast contain	Formatted

		<u>Document that the member was provided written information</u> concerning Advance Directive.	
		concerning Advance Directive.	
AHCA contract Copy of Adva	ince	Documentation of the express written and informed consent of the	Formatted: Tab stops: 0.38", Left + 3.5
Directives		member's authorized representative prescriptions for psychotropic	Left
		medication (that is, antipsychotics, antidepressants, antianxiety	Formatted: Font: 12 pt, Underline
		medications and mood stabilizers) prescribed for a member under	Tornatted: Forc. 12 pt, oriderine
		the age of 13 years	
		The prescriber must document the consent in the child's medical record and provide the pharmacy with a signed attestation of the	
		consent with the prescription. If the patient chose to make an Advance	
		Directive, there should be a copy of it in the MR.	
		Brective, there should be a copy of te in the wint.	
		◆ The prescriber must ensure completion of an appropriate ◆	Formatted: Indent: First line: 0.25", Add
		attestation form.	space between paragraphs of the same
Simply	Test accompli	ished and filed	style, No bullets or numbering, Tab stops
Patient ID on each page NCQ	A guidelines	Follow up on missed/cancelled appointment Patient name, first &	0.38", Left + 3.5", Left
		last, and/or identification number are on ALL pages, reports,	Formatted: Font: 12 pt, Underline
		documents in the record. Pages that are used on both sides require	Formatted: Font: Bold
		identification on each side.	
Cincola	Cian od LUDAA	Information Form	Formatted: Font: 12 pt, Underline
Simply Simply	- 0	email communications	Formatted: Tab stops: 0.38", Left + 3.5
		r other communication assistance needs	Left
AHCA contract Entries dated		Legal guardian/responsible party (If applicable) All entries are	Formatted Table
		signed and dated with month, day and year. All entries contain author	Formatted: Font: 12 pt, Underline
		identification and professional status (MD, DO, ARNP, PA) when	Formatted: Tab stops: 0.38", Left + 3.5
		applicable.	Left
	No white out	or alterations in documentation	Formatted: Font: 12 pt, Underline
NCOA guidolinos		or atterations in documentation	
NCQA guidelines		led timely for review	Formatted: Tab stops: 0.38", Left + 3.5
NCQA guidelines Simply Simply	Record provid	led timely for review active records/retirement of inactive records	Left
Simply	Record provid		Left Formatted Table
Simply Simply	Record provid		

Elements and References		idelines	Deleted Cells
<u>Administrativ</u>	e Component (A) - cont'd.		Formatted: Don't keep with next, Tab
<u>Element</u>	<u>Standard</u>		stops: 0.9", Left + 3.68", Centered
Assessment	 Medical history and physical exam 	Formatted Table	
AHCA contract	Chief complaint/subjective	(
USPSTFAll entries shall include the disposition,	Past medical history	Formatted: Font: 12 pt, Font color: White	
recommendations,	Past surgical history Past social history (tobacco, ETOH, drugs)		Formatted Table
instructions to the enrollee,	Family history		Formatted: Widow/Orphan control, Don't
evidence of whether there	Blood transfusion history		keep with next, Tab stops: 0.38", Left
was follow-up and	Health risk assessments, if applicable		
outcome of services;	Allergies or absence of allergies and untoward relationships.	eactions to drugs and materials is	Formatted: Font: 12 pt, Underline
	recorded in a prominent and consistent location	ı, verified at each patient encounte	er
	and updated to reflect new allergies and sensitiv	vities.	
	 Diagnosis or medical impression consistent with 		
	 Medications, including over-the-counter produce 	ts and dietary supplements	
	recorded.		
	 As described Evidence that the needs of the car addressed (if applicable). 	egiver have been assessed and	Formatted: Font: Bold
	Documentation of emergency care encounters	in the member record with	F N T-b -b 0 2011 1 -
	appropriate medically indicated follow up.	the member record with	Formatted: Normal, Tab stops: 0.38", Le + 3.5", Left
Copies of consent or	As described		· · · · · · · · · · · · · · · · · · ·
attestation or Court Order	<u></u>		Formatted: Font: 12 pt, Underline
to prescribed			
<u>psychotherapeutic</u>			
medications to children			
under 13 years old			
Treatment plan Test Accomplished and filed	 Treatment plansProcess are consistent with diag The working diagnoses are consistent with finding 		Formatted: Tab stops: 0.38", Left + 3.5
Accomplished and med	physical exam.	ngs in the current history and	Left
	 Plan of care, studies ordered, testing and process 	Formatted Table	
	clinical needs.	Formatted: Font: 12 pt, Underline	
	Documentation of patient participation in treatr		
	recommendations.		
	• Absence of clinically unnecessaryon diagnostic or therapeutic procedures studies		Formatted: Normal, Tab stops: 0.38", Let
	i.e., log book, computer log, copies of all diagnostic st		Formatted: Font: 12 pt
F/U on	Documentation of follow-up for missed and of	cancelled app. Is required.	I omittee i one 12 pe
missed/cancelled app			
Signed HIPAA	Signed HIPAA Privacy Statement Form and place	in the Medical Record.	
information form			
Patient visit/patient	Date and department if department applicable	-	Formatted: Tab stops: 0.38", Left + 3.5
notes documentation	Chief complaint or purpose of the visit		Left
Telephone or e-mail	Clinical objective findings/vital signs/BMI (If BMI)		Formatted Table
<u>communication</u>	diagnosis of obesity and subsequent treatment		101111111111111111111111111111111111111
	 Current review and reconciliation of current me 	disations (proscription and	Formatted: Font: 12 pt
		The second secon	
	nonprescription, including over the counter and	The second secon	

Elements and Reference		Guidelines	Deleted Cells
<u>Administrativ</u>	<u>re Component (A) - cont'd.</u>		Formatted: Don't keep with next, Tab
	 Diagnosis or impression 		stops: 0.9", Left + 3.68", Centered
	 Studies ordered (i.e., labs, EKGs, X-rays) 		
	 Care rendered and therapies administe 		Formatted Table
	 Disposition, recommendations and inst 	ructions Significant medical advice or	Formatted: Font: 12 pt, Font color: White
	<u>prescriptions</u> given to <u>a</u> patient		
	Authentication and verification of conte		
	Documentation regarding missed/cancer		
	Signature of health care professional		
	Problems with service providers, with a	•	
	Documentation of all services provided	if any (that is, family planning, STD	
	treatment)		
	Any notationphone or internet should be a second to the second to t		
	indicating diagnosticand signed or there	· · · · · · · · · · · · · · · · · · ·	
	research is clearly contrasted with entri	les regarding the provision on	
		the processity appropriately as and visite a	•
		s the necessity, appropriateness and risks o ng medical advice provided after hours or	*
		atment alternatives and advanced directive	e e
		intain documentation that the member was	**
	provided with written information on the		'
	·	ower of attorney) and whether or not the	
	member has executed an advance direct	**	
		education and wellness promotion services	
	have occurred within the context of a c	·	
		nt or acute care documentationtelephone	Formatted: Normal, Tab stops: 0.38", Le
	triage.		
Translation or other	If translation is needed must be docume	nted and included services for the	Formatted: Font: 12 pt, Underline
ommunication needs	deaf/hearing impaired.		
Legal Guardian (if	As described		
pplicable)	AS described		
No white out or	Are consultants used appropriately?	1	Formatted: Font: Bold
Ilterations Coordination of	 Consultations promptly reviewed and for 	ollowed	(
are/follow-up/outreach	 Evidence of follow-up when significant 		Formatted: Tab stops: 0.38", Left + 3.5
	radiologic findings have been identified		Left
	Obtained medical record/OV from PCP/	/specialties	Formatted Table
	 Provided medical record to a health car 	e professional	Formatted: Font: 12 pt
	All records must contain record of ER ar	nd hospital D/C summaries, with appropriate	te
	medical indication for follow up (if appl		
	Evidence of appropriate and timely reference	errals	
	For records with multiple visits/admissi	ons or complex and lengthy: diagnostic	
	summaries utilized in accordance with o	organization policies and procedures	
		able to authorized personnel any time the	
	organization is open to patients		
		inad if applicable	
	 Evidence community resources are utili 	иген, и аррисаріе	
	*	ted last office encounters or visits to other	

Elements and References	- Guidelines	Deleted Cells
Administrativ	e Component (A) - cont'd.	
	Evidence of incorporation of records from previous providers, transitions of care and summaries when a member is being transferred to a new provider or consultant.	Formatted: Don't keep with next, Tab stops: 0.9", Left + 3.68", Centered
	Evidence of attempts to collect records from previous providers, specialists or	Formatted Table
	consultants The Medical Record must not contain any alterations or the use of	Formatted: Font: 12 pt, Font color: White
	white out for legal purposes, if an error is done a single line is drawn through the	Formatted: Normal
Record provided timely	error with "error" written above with initials and date. Problem list maintained, including significant illnesses and medical conditions.	Formatted: Font: 12 pt
for reviewSupporting	Immunization history included	Formatted: Font: Bold
documentation	Reports, histories and physicals, progress notes, and other patient information (lab reports, X ray readings, op reports and consultations) were reviewed	Formatted: Tab stops: 0.38", Left + 3.5", Left
	 Significant problems followed up on and incorporated in the record All Medical Records will be provided in a timely manner 	Formatted: Font: 12 pt
	Significant patient advice given by phone, online and/or provided after hours is	Formatted: Font: 12 pt
	entered in the date of the clinical records and appropriately signed or initialed Release of information contained in medical record	Formatted: Font: 12 pt
	• Treatment records from another current or transferring provider are present review	Formatted: Font: 12 pt
	if applicable Evaluation or member participation with provider recommendations	
	Documentation/evidence of preventive care	
	Evidence of end-of life care if applicable you have not inconvenient.	Formatted: Font: 12 pt
Retention of active	As described.	Formatted: Normal
records/retirement of inactive records		
If telemedicine,	If applicable.	
documentation that the		
member had a choice of		
whether to access services		
through a face-to-face or		
telemedicine encounter.		
Medicaid services	Evidence that the member had a choice of whether to receive Medicaid covered	
	service or an in lieu of service.	

Adult Preventive Component

PCPs are responsible for contacting new members and conducting preventive health care within 90 days of enrollment. Member contacts and attempted contacts must be documented.

Elements and References Adult Preventive Components (B)	Guidelines	Deleted Cells
<u>Element</u> <u>Standard</u>		Formatted Table
Adult preventive component Complete Medical History for New Members/Complete PE for New Members	Complete medical history for new members	Formatted: Font color: Auto
	Complete physical exam for new members All new member s should have a	Formatted: Don't keep with next, Tab stops: 1.35", Centered + 4.85", Centered
	complete Medical History that includes: CC/HIP/PMH/PSxHx/PSocial Hx/Tobacco Hx ETOH/Drugs/ Allergies/ROS and must	Formatted: Don't keep with next, Tab stops: 0.38", Left + 3.5", Left
	be updated when necessary. All new members should have a complete Physical Exam: Vital Signs/General/HEENT/Chest/Lungs/Heart, Abdomen Extremities/Skin/GU/Nodes/Neurology.	Formatted: Font: 12 pt
	• ,	Formatted: Font: 12 pt
High risk behaviors Risk Behaviors and anticipatory guidance	Screening to identify high risk	Formatted: Normal
AHCA contractAnticipatory Guidance.	individuals and documented in the chart. Teaching specific topics.◆	Formatted: Font: Bold, Font color: Auto
	Obtain consent for tests for the	Formatted: Font: Bold, Font color: Auto
	clinical findings or referred to appropriate treatment;	Formatted: Font: 12 pt
	Tobacco/ cigarette query Alcohol query	Formatted: Tab stops: 0.38", Left + 3.
	-/HIV/STD/hepatitis risk query - Hepatitis Risk/Safe sex practices - Sex Practices/Nutrition-guidance -/Injury/safety, Safety prevention -/Violence/abuse query - Abuse/Social/emotional health/depression Emotional Health/ Depression/Activity/exercise query Exercise.	Formatted: Font: 12 pt Formatted: Normal
Measurements/vitals	BP/pulse/respiration/temperature	Formatted: Font: 12 pt
AAP AHCA contract Measurement/Vital Signs	Document Vital signs: BP/HR/RR/Wt/ /Ht. on each visit. Adult Body Mass Index	Formatted: Tab stops: 0.38", Left + 3.5 Left
	• Weight • Height	Formatted: Font: Bold
	◆ BMI	Formatted: Font: 12 pt
Screening	• Cholesterol	Formatted: Normal
AAP AHCA contract	EKG Diabetes screening	Formatted: Font: Bold
ATTOM CONTRACT	Abdominal aortic aneurysmAll	Formatted: Font: 12 pt, Underline
	screening preventive tests must be documented in the MR. Cholesterol:	Formatted: Tab stops: 0.38", Left + 3.9 Left

	Starting at 20 years, obtained once every 5
	years. EKG: Test to be done for patient at
	high risk.
	<u>Diabetes Screening: Starting at age 45</u>
	every 3 years.
	AAA Screening: One time screening
	by U/S for men 65-75 smokers. TB Formatted: Font: Bold
	• : Skin testing for asymptomatic Formatted: Normal
	high risk patients. Osteoporosis
	Screening/Testing: Age 65 and older, Formatted: Font: Bold
	<u>routine</u> screening <u>every 2 years or patient</u>
	at high risk.
	Menopause Screening: Screening at
	physician discretion.
	Vision Screening: Annually. Hearing
	Screening: Starting at 20 years,
	Screening: Annually Hearing Formatted: Font: Bold
	sereening
	◆— <u>Screening: Starting at 20 years,</u>
	obtained once every 10 yr. Dental Formatted: Font: Bold
	health screening
	• Health Screening: Annually. Formatted: Normal
	Chlamydia (all: All sexually active females Formatted: Font: Bold
	under_<26 years, as well as othersother at
	risk).
	Breast Exam/Mammography:
	Annually for ages 40 and older.
	Pap smear Breast From Manuscapular Appropriate for each
	Exam/Mammography: Annually for ages 40 and older.
	PAP Smear: Annually. Colorectal CA
	Screening: At 50 both men and women
	start Colorectal CA screening Colonoscopy/
	Sigmoidoscopy every 5 years or at
	physician discretion. The choice of specific
	screening strategy should be based on
	patient preferences (FOBT), medical
	contraindications, patient adherence, and
	available resources for testing (FOBT) and
	follow-up. Prostate Exam/PSA: Annually
	beginning at age 50. Skin Cancer: Regular
	Checkup. HIV Testing: HIV counseling and
	offer of HIV Testing for Females of
	Childbearing age and Males. Copy of
	completed screening Instruments in the
	enrollee record and proof that a copy has
	been provided to the enrollee.
<u> </u>	

Pediatric and Adolescent Component

Elements and References Diabetes Component (C)	Guidelines	Deleted Cells
Element Standard Nutritional Status, Wt. Hx.	Eating pattern, Nutritional status, Chec	Formatted Table
Nutritional Status, Wt. Fix.	Wt. Hx on each visit.	Formatted: Font: Bold, Font color: Auto
DKA frequency, Hypoglycemia	Document Diabetes complications,	
	DKA, Low BS.	Formatted: Right: -0.08", Don't keep with next, Tab stops: 1.36", Centered + 5.24",
BP at every routine visit	BP at each visit lower 130/80.	Centered
Dilated eye exam	Dilated retinal exam annually.	
Thyroid palpation annually	Thyroid palpation or T3-T4-TSH annually	
Skin examinations.	At every routine visit.	
Neurology/foot examination	At every routine visit/ annually for	
	neuropathy.	
Hb A1C Test	Hb A1C Test every 3 months for	
	abnormal results (>7), every 6 months for	
	normal result (<7).	
Liver function test	<u>Liver function test annually.</u>	
Micro albuminuria	Micro albuminuria test annually.	
Serum creatinine/GFR	A baseline serum creatinine level is	
	indicated for all Diabetes patients.	
LDL Control	Fasting lipid profiles are indicated	
	annually. Goals: <100	
	mg/dL.	
Influenza Vaccine	Influenza Vaccine every year.	
Pneumococcal Vaccination	The Pneumococcal Vaccine is indicated	
	for all patients with Diabetes.	
	Revaccination every 5 years.	
Pediatric and adolescent preventive guidelines	 Complete history and physical exam 	Formatted: Normal, Tab stops: 0.38", Le
AHCA contract	for new members Medical Nutrition Therap	+ 3.5", Left
APA	(MNT) involving a nutritional assessment to	Formatted Table
USPSTE	evaluate the patient's food intake,	
AAP immunizations Obesity Management for BMI >24	metabolic status, lifestyle, readiness to	Formatted: Font: 12 pt, Underline, Font
	make changes, and goal setting dietary	color: Auto
High-risk behaviors and anticipatory guidance Education on Nutrition	instruction and evaluation.	Formatted: Don't keep with next, Tab
High-risk behaviors and anticipatory guidance Education on Nutrition	Nutrition guidelines Dental referral	stops: 0.38", Left + 3.5", Left
	Injury/safety prevention	Formatted: Font: 12 pt, Not Bold, Underli
	Violence/abuse guery	Formatted: Font: 12 pt, Underline, Font
	Social/emotional health/depression	color: Auto
	Tobacco/cigarette query	
	Alcohol query	Formatted: Tab stops: 0.38", Left + 3.5
	Activity/exercise query	Left
	• Illness prevention	
	Sleep positioning counseling	

		Document patient Education on	
		Nutrition, Plan should be individualized	land
		take into account cultural. life style and	
		financial considerations. Refer to a Dia	-
		educator if necessary.	
		HIV/STD/hepatitis risk guery	
		 Screening for autism 	
		 Nutrition guidelines 	
		Dental referral Document patient	Formatted: Normal, Tab stops: 0.38", Le
		Education on Nutrition, Plan should be	i dilliattedi Normal, rab stops. 0.50 , Le
		individualized and take into account	1 SIS / Leit
		cultural, life style and financial	
		considerations. Refer to a Diabetic edu	cator
		if necessary.	Formatted: Font: 12 pt, Underline
All required immunization	ensEducation on Physical Activity	Evidence of provider participation	n in
		FL SHOTSEncourage Physical Activity.	Formatted: Font: 12 pt, Underline, Font color: Auto
		Referrals if needed. Documented.	
<u>Weight</u> Measurements		• Height	Formatted: Tab stops: 0.38", Left + 3.5
		Weight	Left
		 BMI (annually) 	Formatted: Font: 12 pt, Underline
		 Head circumference Encourage*for 	
		Weight control. Referrals if needed to	Pormatted: Polit: bold
		Nutritionist as needed.	Formatted: Font: 12 pt, Underline, Font
Sensory screening Advis	e all patients not to Smoke	Vision screening	color: Auto
	-	 Hearing screening Document and 	Formatted: Tab stops: 0.38", Left + 3.5
		advise all patients not to smoke.	Left
Advise all patients on a	lcohol consumption	Document and advise all patients of	Formatted: Normal, Tab stops: 0.38", Le
		alcohol consumption.	+ 3.5", Left
Referrals		<u>Document any Referrals if needed.</u>	
General screeningComo	rhidities:	Lead testing at 12 months and 24	Formatted: Font: 12 pt, Underline
General sercening <u>come</u>	Total Cico.	months of age	Formatted: Font: 12 pt, Underline, Font
		H&H at 12 months of age	color: Auto
		Urinalysis	Formatted: Tab stops: 0.38", Left + 3.5
		Hereditary and metabolic	\\\ Left
		screeningProvider addresses impact of	Formattada Namaal Tab atama, 0 2011 La
		comorbidities and treatments.	Formatted: Normal, Tab stops: 0.38", Le + 3.5", Left
Procedures: at risk	TB testing		
	Cholesterol screening		Formatted: Font: 12 pt, Underline
	● HIV/STD/hepatitis		Formatted: Font: 12 pt, Underline, Font
	Pelvic exam/Pap smear		color: Auto
	Sickle cell test		Formatted: Tab stops: 0.38", Left + 3.5
Child abuse	• Screening		Left
	Suspected and reported		Formatted Table
			Formatted: Normal, Tab stops: 0.38", Let + 0.88", Left + 3.5", Left

Gener	al Medical Component (D)	
<u>Element</u>	<u>Standard</u>	
ASSESSMENT:		
Elements and References Medical History & Physical Exam	Guidelines A complete medical, psychosocial, and medical- surgical history must be documented in the MR, including a	Formatted: Tab stops: 0.38", Left + 3.5" Left
	Review of systems. A complete Physical Exam (General, Heart, Lungs, Abdomen, Extremities, HEENT, Neck and GU). Include g all VS. Updated as needed.	Formatted: Tab stops: 0.38", Left + 0.88", Left + 3.5", Left
Chief Complain/Subjective	Describe the symptom, problem, condition or other factor	Formatted Table
cinci complany suspective	that is the reason for a medical encounter.	Formatted: Font: Bold, Font color: Auto
Past Medical History	Should contain the total sum of a patient's health status prior to the presenting problem and must include: Past illnesses, Hospitalizations, Injuries, Surgeries, Blood Transfusions.	Formatted: Font color: Auto
Past Surgical History.	See General Medical Component #1.	
Past Social History	These must include: occupational and recreational aspects of the patient's personal life i.e. Alcohol, Tobacco, Illicit drugs.	
Family History	A family history consists of information about disorders from which the direct blood relatives of the patient suffered, i.e. DM/Cardiovascular disease/Cancer/Autoimmune Disorders.	
Blood Transfusion History	See General Medical Component #1.	
Health Risk Assessment, if applicable	A Health Risk Assessment is to be completed on all Medicare members and all high-risk members	_
Allergies/untoward reactions Diabetes	Elements Allergies or absence of the baseline medical history	Formatted: Font: Calibri, Bold
component exam ADA, Standards of Medical Care in Diabetes, 2005	include the following: - Current symptoms	Formatted Table
A	History of glucose control (results of prior A1C	Formatted: Font: Bold
	recordsallergies and lab studies relateduntoward reactions to the diagnosis of diabetes) Results of glucose self-monitoring	Formatted: Tab stops: 0.38", Left + 3.5" Left
	Exercise history Eating patterns, nutritional status, weight history, growthdrugs and development materials recorded in childrena prominent and adolescentsconsistent location, verified at each patient encounters Previous treatment programs and diabetic education All current medications, including over the counter Frequency, severity of acute complications such as ketoacidosisupdated to reflect new allergies and hypoglycemia Symptoms and treatment of chronic eye, kidney, nerve, foot, GI, GU, heart and vascular complications Risk factors to include smoking, alcohol use, hypertension, obesity, dyslipidemia and family history	

Element	Lifestyle, cultural, psychological and economic factors t might affect management of diabetes Eating pattern, nutritional status, weight, height DKA frequency, hypoglycemia	hat
	might affect management of diabetes Eating pattern, nutritional status, weight, height	hat
	Eating pattern, nutritional status, weight, height	
	DKA trequency hypoglycemia	
	1 11 01	
	BP at every routine visit and below 130/80	
	Annual dilated eye exam	
	Thyroid palpation annually	
	Skin examination	
	Neurologic/foot examination annually	
	Obesity management for BMI > 24sensitivities.	Formatted: Normal, Tab stops: 0.38", Le
Education Diagnosis or medical impressions	Education on nutrition	+ 0.88", Left + 3.5", Left
	 Education on physical activity At the end of each Office 	
	you must document a Diagnosis or a Clinical impression that	
	congruent with H&P and the symptoms/presenting complain	
Laboratory examination Medication list	HbA1C every three months for abnormal results, every	SIX \
	months for normal results	Formatted: Normal, Tab stops: 0.38", Le
	Liver function tests (annually)	+ 0.88", Left + 3.5", Left
	Test for micro albuminuria (annually)	Formatted: Font: Bold
	Serum creatinine and GFR	Formatted: Tab stops: 0.38", Left + 3.5
	◆ LDL control (< 100 mg/dL)A medication profile docume	Left
	all past, present medications including those for chronic	
	conditions, over-the-counter products and dietary suppleme	- I dimatedan maman, ras atapar and , an
	Medications must document dosage, route frequency, and s	
	and stop dates. Documentation of acute medications canno	t be
	documented solely on the progress notes.	
nmunization • Influenza vac		
	al vaccine (per guidelines)	
Evidence that the needs of the caregiver have	◆ Advise all patients not to smoke ◆	Formatted: Font: Bold
en assessed and addressed (if	 Advise all patients on alcohol consumption 	Formatted: Tab stops: 0.38", Left + 3.5
plicable). High risk screening annual	Referrals if needed As described	Left
		F
sternity Component		Formatted Table
		Formatted: Font: Bold
		Formatted: Normal, Tab stops: 0.38", Let + 0.88", Left + 3.5", Left

General M Element	l <u>edical Component (D) – cont'd.</u> Standard	
TREATMENT PLAN:		
Treatment Plan is consistent with diagnosis	The rationale for which a plan is formulated, the diagnostic impression, is required. Appropriateness based on the findings in the History and Physical. Please refer to General Medical Component #9.	1
The working Dx. are consistent with findings	Addresses each chief complaint (subjective/objective) and clinical finding with a working Diagnosis.	
Plan of Care/Studies ordered	Every Office Visit must document: Plan of Care/Studies ordered (if applicable) for the clinical findings and/or diagnosis stated.	
<u>Documentation of patient participation in</u> reatment and follow up with recommendations	Evidence of discussion of treatment with the patient and his/her active participation or lack of it thereof.	
Absence of clinically unnecessary diagnostic/therapeutic procedures	As described.	
Opioid Medications	Opioid Medication prescribed for the treatment of Acute Pair listed in Schedule II-limited to 3 day supply.(pain related to cance terminal illness, palliative care and serious traumatic injury are excluded from theses prescribing limits)	-
Acute Pain Exemption	Pain listed in Schedule II –limited to 7 day supply. (pain related to cancer, terminal illness, palliative care and serious traumatic injury are excluded from these prescribing limits)	
Prescription for Controlled Substance	Controlled substances in Schedule III, IV, V for treatment of acute pain is limited to 14 day supply. Pain related to cance terminal illness, palliative care and serious traumatic injury are excluded from these prescribing limits.	er,
PATIENT VISIT/PROGRESS NOTES DOCUMENTA	ATION:	
Date and Department, if department applicable	The complete date and time when services were rendered. If a department is applicable, include the department's name	
Chief Complaint/Purpose of Visit	As described.	
Clinical Objective Findings/VS/BMI	Each Office Visit must contain a Complete Objective Finding including Vital Signs and Body Mass Index documented in the MR If BMI is over 29.9 an appropriate diagnosis of Obesity and subsequent treatment documented.	
Elements and References Current review of medications/Reconciliation	Guidelines Current review of medications (prescription & non prescription including over-the-counter and dietary supplements) Medications must document dosage, route frequency, and start	Left
	and stop dates.	Formatted: Tab stops: 0.38", Left + 0.88", Left + 3.5", Left
Diagnosis or medical impression	See General Medical Component #9.	Formatted Table
<u>Studies ordered</u>	Studies ordered such as laboratory tests, X-rays studies, etc. reviewed and incorporated in the record in a timely manner.	Formatted: Font color: Auto
General M	ledical Component (D) – cont'd.	Formatted: Font: Not Bold, Font color: A

Element	<u>Standard</u>
Care rendered and therapies	Addresses therapies administered and prescribed according to
administered/prescribed	<u>clinical findings.</u>
Disposition, recommendations and	Documentation of case disposition, recommendations and
instructions given to patient	instructions to the patient must be documented in all progress
	notes.
Authentication and verification of contents by	All documentation is to be authenticated and verified by a
health care professional	healthcare professional.
Documentation regarding missed/cancelled	Documentation of patient cancelations, if applicable.
apt.	Security of patient cancerations, in applicable.
Signature of healthcare professional.	All progress notes must be signed and dated the day that
	services were rendered. Signatures should legible with the name
	and credentials of the health care professional who rendered the
	services.
Unresolved problems from previous visits are	Documentation of follow up care is present: Unresolved
addressed in subsequent visits.	Problems from previous visits are addressed in subsequent visits.
	Follow up of high risk issues identified in the history, physical, or
	at subsequent visits.
Documentation of all services provided if any.	Document in the MR any services provided to the patient i.e.,
	Family Planning, STD Treatment.
Any notation in the clinical record indicating	Documentation of services provided as part of clinical
diagnostic or therapeutic intervention as part of	research is clearly identified and contrasted with entries related to
clinical research is clearly contrasted with entries	non-research care.
regarding the provision of non-research related	Hon research care.
care.	
Discussions with the patient concerning the	All discussions with the patient concerning the necessity,
necessity, appropriateness and risks of proposed	appropriateness and risks of proposed care, surgery or procedure,
care, surgery or procedure, as well as discussions	as well as discussions of treatment alternatives and A.D. must be
of treatment alternatives and advanced	clearly documented, if applicable.
directives, if applicable.	
Documentation supporting that health and	All discussions regarding health education and wellness,
wellness promotion services have occurred within	whether they occurred within the context of a visit or a discussion
the context of a clinical visit or not.	with office staff.
Evidence of chronic illness management or	All Progress Notes regarding chronic illness treatment
acute care documentation	THE TO PERSON TO LOS TO GALLANIA GILLONIO INTEGS TO CALLINGTO
COORDINATION OF CARE/FOLLOW UP AND OU	
Are consultants used appropriately?	<u>Document in the Medical Record Referrals to Consultants The</u>
	MR reflects an appropriate utilization of Consultants.
Consultations promptly reviewed and	All consultations reports, labs, imaging reports must be filed,
followed.	reviewed, dated and signed by a PCP.
Obtained Medical Records and Office Visits	Evidence of documentation from other providers present on
from PCP/specialties, if applicable.	the medical record, if applicable.
General Mi Element	edical Component (D) – cont'd. Standard
Liement	StatiualU

Provided MR to health care professionals, if applicable.	Provider met record requests, as required.
Follow-up after an ER visit or hospitalization.	If a member was seen in ER or was Inpatient Status a f/u must be done in the PCP's office and also a copy of the Hospital and D/C Summaries must be place in the Medical Record and dated.
Appropriate and timely referrals	Referrals made within a reasonable time frame depending on condition.
For records with multiple visits/admissions or complex and lengthy history diagnostic summaries are utilized in accordance with P&P.	All Medical Records with the annexed description must contain diagnostic summaries, updated, as needed.
Documentation of referral	Documentation of referral services in the enrollee Record, including reports resulting from the referral
All clinical information is available to authorized personnel any time the provider is open to patients.	Evidence that all clinical information is available to authorized personnel any time the office is open to patients.
Community resources are utilized, if applicable.	Any documentation of referrals to social services agencies, support groups, etc.
Provider has read/consulted last office encounters or visits to other providers	Evidence that last office visit or visits to other providers have been read and reviewed.
Incorporation of records from previous transitions of care and summaries when a member is being transferred to a new provider or consultant. Evidence of attempts to collect records from previous providers or consultants.	Evidence of copies of previous records or attempts to providers, obtain them.
Supporting documentation:	
Problem List maintained	An Active problem list is included and updated as needed
Record contains Immunization History.	An immunization record for children is up to date, or an appropriate history has been made in the record for adults. For children, there is a completed immunization history in the chart. See schedule for vaccinations.
Reports, histories and physicals/progress notes reviewed	Lab reports, x-ray readings, op reports, and consultations) were reviewed, followed up significant problems and incorporated in the record in a timely manner.
Documentation of Emergency care	Documentation of emergency care encounters in the Enrollee record with appropriate medially indicated Follow-up.
Significant patient advice given by telephone, online, provided after-hours is entered in the clinical records and appropriately signed or initialed	Progress note with this information included, if applicable.
	edical Component (D) – cont'd.
Element Release of information contained in MR	Standard If applicable

<u>Treatment records from another current or</u> transferring provider is present.	<u>If applicable</u>	
Evaluation or member participation with Provider recommendations.	<u>Progress note indicating members participation with</u> providers' recommendation.	
·		
Evidence of preventive care ID documented in the record.	1	
Evidence of End-of-Life care if applicable.	Progress Notes indication that end-of life care has been addressed, if applicable.	
	rnity Medical Component (E)	
Element Initial prenatal prenatal care	Standard Pregnancy test and nursing assessment with	Formatted: Font: Bold
Visit	referrals Document when the first PN visit was rendered; 1s	t \
	trim.	Formatted: Font: Bold
	42 days of Plan enrollment/3 wks. after dx/ 1 wk. of a	Formatted Table
	pregnancy Dx. Referrals for comprehensive evaluation	Formatted: Font: Bold
	Firstand Florida's Healthy Start prenatal risk screening. 1st trimester visit within first trimester	Formatted: Tab stops: 0.38", Left + 3.5" Left
	 First prenatal visits within 42 days of Simply enrollment First trimester visit within three weeks weeks within three weeks within three weeks weeks within three weeks within the weeks within three weeks within the weeks w	
	diagnosis via +human chorionic gonadotropin Human	·Y
	Chorionic G Gonadotropin (HCG)-or US	
	• First	Formatted: Normal, Tab stops: 0.38", Le
	2nd trimester visit within three weeks 2 wks. of a pregnancy	+ 0.88", Left + 3.5", Left
	diagnosis via ++ HCG or US	
	Second3rd trimester visit within two weeks1 wk, of a programmed diagnosis via LHCC or HS	Formatted: Font color: Black
	pregnancy diagnosis via + HCG or US Third trimester visit within one week of a pregnancy	Formatted: Font color: Black
	diagnosis via +HCG or US	Formatted: Font color: Black
	Evidence of contact if the memberenrollee fails to keep	
	appointment and arrange for continued prenatal care as	
	soon as possible • Evidence of care coordination—of—/case management	Formattad Normal Tab stone: 0.30" Lo
	through the gestational period according to depending on the	Formatted: Normal, Tab stops: 0.38", Let + 0.88", Left + 3.5", Left
	needs of the memberenrollee	0.00 / Ecit 1 3.3 / Ecit
Pregnancy historyHx and risks.	◆ GravidaPregnancy history and para	Formatted: Font: Bold
	• (/or risks must include: G/P/Rh) status	Formatted: Font: Bold
	Type of delivery	Formatted: Font: Bold
	Gestational age at delivery	
	(Anesthesia/ Length of labor	Formatted: Tab stops: 0.38", Left + 3.5"
	-/Birth outcome/risks	LCIL
	Maternal complications	
	 /Sex/weight of child. Risk and management counseling 	Formatted: Normal, Tab stops: 0.38", Let
	concerning Diabetes-Type I/Type II/ Gestational	+ 0.88", Left + 3.5", Left

Medical/surgical-Surgical and psychosocial	These must include: Serious accidents	Formatted: Font: Bold
historyPsychosocial Hx.	•—/Operations	Formatted: Font: Bold
	•—_/Infections •—/ Illness	Formatted: Tab stops: 0.38", Left + 3.5",
	✓/Inness ✓/Substance abuse	Left
	/Mental health	Formatted: Font: Bold
	←_/Screening for depression	Formatted: Fortt. Bold
	Gynecological conditions	
	← /Gyn. Conditions/Infertility	
	◆—_/Stress	
	◆—	
	 <u>situation/</u> Socioeconomic evaluation. 	Formatted: Normal, Tab stops: 0.38", Left
Prenatal care Care	Genetic screening and counseling	+ 0.88", Left + 3.5", Left
	Provider documented preterm delivery risk assessments in	Formatted: Font: Bold
	the member's medical record by week 28 Evidence of any necessary referrals and follow up, if	Formatted: Font: Bold
	applicable	Formatted: Tab stops: 0.38", Left + 3.5",
	Evidence of assistance to member in making delivery	Left
	arrangements, if necessary A review of familial history of birth	\ <u></u>
	defect, deformities mental retardation, or inherited disease (e.g.	Formatted: Normal, Tab stops: 0.38", Left + 0.88", Left + 3.5", Left
	muscular dystrophy, hemophilia, cystic fibrosis). Maternal >35	+ 0.00 , Left + 3.3 , Left
	years/paternal >50 years at time of delivery. Ethnicity.	
Nutritional screening and counselingPreterm	Dietary intake	Formatted: Tab stops: 0.38", Left + 3.5",
Delivery Risk Assessment	Hydration	Left
	Prenatal vitamins	Formatted: Font: Bold
	Weight loss/gain Elimination	
	Food/shelter resources	
	Evidence provider promoted safe/adequate infant nutrition	
	by promoting breastfeeding and use of breast milk	
	substitutes	
	Provider offered midlevel assessment	
	Member provided individualized diet counseling and care	
	plan by a public health nutritionist, a nurse or physician	
	following the nutrition assessment	
	Documentation of nutrition care plan on medical preterm	
	<u>delivery risk assessment in the enrollee</u> record by the perse	on
	providing the counseling	
	WIC referral (children up to 5 years old, preg BF, postop) with the current height and weight taken within 60 days of the	ith
	WIC appointment and including Hb and Hct and nutritional	
	problems	
	• For subsequent WIC certifications, Simply ensures provider	·s
	coordinate with the local WIC office to provide the above	
	referral data from the most recent CHCUP	
	Copy to member provided each time a referral is made were	- Cilia decar itorniar, ras scoper cise , zere
	twenty-eight (28)	+ 0.88", Left + 3.5", Left

Ongoing/follow-up prenatal care visitsEvidence of any necessary referrals		 Schedule return visits every four weeks until 28/32 wegestation 	Formatted: Tab stops: 0.38", Left + 3.5"
		 Schedule every two weeks until 36 weeks gestation; every two weeks g	
		week thereafter until delivery, more frequent if requir	Formatted: Font: Bold
		Evidence of preterm risk assessments by week 28 Fullence of Deferrals and follows up to marchers who is	
		 Evidence of Referrals and follow-up-to-members who fappointments ASAP 	Talled
		 Evidence of offering assistance in making delivery arrangements if needed, if applicable 	Formatted: Normal, Tab stops: 0.38", Left + 0.88", Left + 3.5", Left
Obstetrical screening	Each ongoing prenat	al visit must include:	
	 Weeks' gestation 	n	
	 Fundal heights 		
	 Presentation 		
	◆ FHR		
	 Fetal movemen 	ŧ	
	 Preterm labor s 	/s	
	 Cervical exam 		
	 Blood pressure 		
	 Urine albumin/ 	zlucose	
	◆ Problems/comr	nents	
Immunizations (schedule)	 Document com 	municable disease(s)	
	• Immunization h	istory	
Treatment plans	High risk patien	ŧ	
	 Specialty physic 	ian care	
	Dental care		
	 Diagnostic testi 	ng and counseling	
	_	ration and counseling	
Healthy Start Prenatal Risk	0 /	ulthy Start instrument present on the medical	
Screen (DH Form 3134) record		, , , , , , , , , , , , , , , , , , , ,	
,		rprovided to the member	
		ne provider submitted the prenatal risk assessment	
		e county where the prenatal screen was	
		in 10 business days of completion	
	Referral for sen	vices regardless of score (member invited to	
	participate or d	irect referral based on risk factors)	
Prenatal Zika virus screen		men with a history of travel to an area with	
	1 0	us transmission should be tested for infection	
	If positive or inc	conclusive, consider serial fetal ultrasounds and	
	amniocentesis		
	 If negative, one 	fetal ultrasound should be performed to detect	
		r intracranial calcifications	
		or intracranial calcifications are present, retest	
	the state of the s	n and consider amniocentesis	
	1 0	nicrocephaly or intracranial calcifications, continue	
	with routine pro		

Postnatal risk screen	 Evidence of tran 	smission of Healthy Start (Postnatal) Risk
	Screening Instru	ment Certificate of Live Birth to the County CHD
	within five busin	ess days of the birth.
	 If the referral is 	made at the same time the Healthy Start risk
screen is a		stered, the provider may indicate on the risk
		hat the member or infant is invited to participate
	based on factors	other than score.
		tion is made subsequent to risk screening, the
	provider may re	er the member or infant directly to the Healthy
	Start care coord	nator based on assessment of actual or potential
	factors associate	d with high risk, such as HIV, hepatitis B,
	substance abuse	or domestic violence.
Delivery care	 If the provider d 	etermines the member's pregnancy is high risk,
•		will evidence that the provider's obstetrical care
	during labor and	delivery included preparation by all attendants
	for symptomatic	evaluation and that the member progresses
		I stages of labor and immediate postpartum care.
Postpartum-Evidence o	of delivery	• Postpartum Formatted: Tab stops: 0.38", Left + 3.5
rrangements		Date of Assistance to enrollee in making delivery Left
		a Infant's hirth weight and measuring
		• Gestational age at birth
		• Evidence of inspecting the newborn for abnormalities and/or
		complications
		Type of delivery: vaginal, Cesarean
		The postpartum visit occurs within 7 84 days (1 12 weeks)
		after the delivery date
		Postpartum physical assessment: BP, weight, pelvic exam.
		abdomen/breast exam
		Education and postpartum changes
		Personal health habits
		Family planning (including contraception methods as
		appropriate)
		Newborn care (that is, eye meds/APGAR, administration of 5
		mg of vitamin K) weight and measuring, inspection for
		abnormalities or complications
		Evidence of continuing care of the newborn is provided
		through the CHCUP program component and documented in
		the child's medical record
		If the mother is Rh negative: evidence of securing a cord
		blood sample for type Rh determination and direct Coombs
		test
		• Sexual activity
		• Nutrition
		◆—Depression addressed
		Referral for community resources for mother and child made

arrangements
Evidence the infants born to HBsAg positive members receive
hepatitis B immune globulin (HBIG) and the hepatitis B
vaccine once they are physiologically stable, preferably
within 12 hours of birth, and complete the hepatitis B vaccine
series according to the vaccine schedule established by the
Recommended Childhood Immunization Schedule for the
United States
Evidence that infants born to HBsAg positive members for
HBsAg and hepatitis B surface antibodies (anti-HBs) are
tested six months after the completion of the vaccine series
to monitor the success or failure of the therapy
Evidence the informant born to the member who tested
positive for HBsAG was referred to the Healthy Start
regardless of screening score
• Evidence of provider report to the local CHD of any positive Formatted: Normal, Tab stops: 0.38", Left
HBsAg results in any child age 24 months or less within 24 hours o + 0.88", Left + 3.5", Left
receipt of the positive test results arrangements
receipt of the positive test results arrangements

HIV/AIDS Component

Elements and References Maternity Medical Compo	onent (E) – Guidelines	Deleted Cells
<u>cont'd.</u> Element	Standard	Formatted Table
HIV/AIDS guidelines		cord contains date of first Formatted: Font: Calibri, Font color: Auto
—Initial history	positive HI	
HIV Medicine Association of the Infectious Diseases Soc	iety of Patient had	la previous HIV test? If so, 5.24", Centered
America (IDSA)	when was	the last test result?
Centers of Disease Control and Prevention	Patient rec	eived care for HIV?
	 Patient has 	s current CD4 (T cell)
(WHO) Nutritional screening and counseling.	count?	Formatted: Font: Bold
	 Chart cont 	Formatted: Normal, Indent: Left: 0", Tab
	count?	ctons: 0.38" Left + 3.5" Left
		ains first viral load countr
		ains current viral load
	count?	
		cords contain lab results
		IV/AIDS status?
		participating in research Formatted: Normal, Tab stops: 0.38", Le
		tritional screening and + 0.88", Left + 3.5", Left
		n/Prenatal vitamins/Wt.
	-	limination/Food/Shelter
		ence of provider promoted
		nfant nutrition by
		st-feeding and use of
	breast milk subs	
		d midlevel assessment.
	Member provid	ed individualized diet
	counseling and	care plan by a public health
	nutritionist, a nu	urse or physician following
	the nutrition ass	
	-	of nutrition care plan by
		iding the counseling. WIC
	· · · · · · · · · · · · · · · · · · ·	ritional counseling and
		ne Food and Nutrition
		men, Infants, and Children Referral Form) WIC Referral
		5 y/o, Preg BF, Postop) with
		tht and weight taken within
		VIC appointment and
	-	d Hct and nutritional
		to the enrollee. Evidence
	· · · · · · · · · · · · · · · · · · ·	WIC certifications the
	Managed Care F	Plan shall ensure that
	provider coordi	nated with the local WIC
		e the above referral data
	-	ecent CHCUP and copy to
	the enrollee.	
	A copy of comp	eted screening instrument

Eleme	ents and References Maternity Medical (Component (E) –	Guidelines	Deleted Cells
	<u>cont'd.</u> Element	Standard,		Formatted Table
	Licitott	Standard	is in the enrollee record and proof that a	Formatted: Font: Calibri, Font color: Auto
			copy has been provided to the enrollee.	Formatted: Tab stops: 1.37", Centered + 5.24", Centered
HIV-relate	ed illnessesRisk Behaviors/exposures.		Patient has had any opportunistic infection(s) (PCP, MAC, Cryptococcomeningitis, TB, etc.) Patient has had cancer(s)?	Formatted: Font: Calibri, Bold, Font color Auto Formatted: Tab stops: 0.38", Left + 3.5' Left
			TB Test TST or Interferon gamma release assay (IGRA) Patient has had a positive TB result: Patient is taking anti-TB medication Patient is taking HIV medications now? Patient has missed doses in the past three days? Present is expectations of side offers	2. 5 2
			 Patient is complaining of side effect HIV viral load or CD 4 counts while the patient was taking their medication? These must include an appropriate notation concerning: Tobacco/ETOH/Chemical Dependency/HIV/STD/Hepatitis HPV risks/Domestic violence/Safe sex practices/Sexual abuse/Safety risks, 	Formatted: Normal, Tab stops: 0.38", Let + 0.88", Left + 3.5", Left

Elements and References-Maternity Medical Component (E) –	Guidelines	Deleted Cells
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<u> </u>	HIV test. Infected member counseled and	Formatted: Font: Calibri, Font color: Auto
	offered latest recommended ART regime,	Formatted: Tab stops: 1.37", Centered +
	appropriate education and treatment	5.24", Centered
	referral/ If member HBsAg-positive report	J.Z.I., Centered
	to the local CDC, regardless of HS	
	score/Evidence that the provider	
	performed a second HBsAg test between	
	28 and 32 weeks of pregnancy for	
	enrollees who tested negative eat the first	
	pre-natal visit but who are considered to	
	be high-risk for Hepatitis B infection.	
	<u>Domestic Violence/Sexual abuse. Safe Sex</u> Safety risks/environmental/occupational.	
	HIV Test (initial visit/28 and 32 weeks.	
	Signed objection if HIV test declined. If	
	member infected she was counseled and	
	offered latest recommended ART regimen.	
	Offered appropriate education and	
	referrals, including smoking cessation.	
	Evidence of documentation of emergency	
	care encounters with appropriate	
	medically indicated follow-up.	
Complete past medical and surgical histories Physical Exam.	Evidence of documented	Formatted: Font: Calibri, Bold, Font color:
	information A Physical Exam must include:	Auto
	a comprehensive review of systems/a	Formatted: Tab stops: 0.38", Left + 3.5",
	focused Gyn. Safe sex practices. And OB	Left
	examination/ presenting complaints, if	
	any/EDD confirmation/18-20 week EDD	Formatted: Normal, Tab stops: 0.38", Left + 0.88", Left + 3.5", Left
OB/GYN/women's healthOngoing Prenatal Care Visits	update.	· · · · · · · · · · · · · · · · · · ·
OB/OTN/Women's nealth Ongoing Prenatal Care Visits	Pap test and result	Formatted: Font: Calibri, Bold, Font color:
	LMP Breast examination/mammogram	Auto
	Sreast examination/mammogram Yeast infections/UTI	Formatted: Tab stops: 0.38", Left + 3.5",
	G/P/A/LB history	Left
	HIV test during any pregnancy	
	 Positive HIV in children General Visit 	Farmer Manda Nameral Talantanan 0 2011 Laft
	Frequency: Every 4 weeks until 28/32	Formatted: Normal, Tab stops: 0.38", Left
	weeks* gestation/every 2 weeks until 36	+ 3.5", Left
	weeks gestation/every week thereafter	
	until delivery. Evidence of preterm risk	
	assessment by week 28/evidence to f/u to	
	members who fail appointment. Evidence	
	of offering assistance in making delivery	
	arrangements.	

Elements and References Maternity Medical Compor	<u>nent (E) –</u>	Guidelines	Deleted Cells
cont'd.	Standard		Formatted Table
Element Anorectal history OB screening/each Prenatal visit.	<u>Standard</u>	Anal Pap test and results	Formatted: Font: Calibri, Font color: Auto
		Anal warts historyEach ongoing prenatal visit must include weeks'	Formatted: Tab stops: 1.37", Centered + 5.24", Centered
		gestation Fundal height/Presentation/Fet Heart Rate/Fetal movement. Preterm labor signs and symptoms/Cervical	Termentiad: Font: Calibri Pold Font calor:
		exam/Weight/BP/Urine albumin, glucose/Problems/comments.	Formatted: Tab stops: 0.38", Left + 3.5", Left
Urologic historyImmunization.		Urinary tract infections Prostate infection or enlargement	Formatted: Normal, Tab stops: 0.38", Left + 0.88", Left + 3.5", Left
		PSA test and resultsAn appropriate immunization history has been made with notation that immunizations are up-to-	Formatted: Font: Calibri, Bold, Font color: Auto
		date/scheduled for catch up. Documentation of communicable disease	Formatted: Tab stops: 0.38", Left + 3.5", Left
Complete STD historyTreatment plans.		Oral health examination Treatment plans are clearly documented in the record and reflect. Use with potent (Specials)	Formatted: Normal, Tab stops: 0.38", Left + 0.88", Left + 3.5", Left
		and reflect: High risk patient/Specialty physician care/Dental care/Diagnostic Testing and counseling/Pregnancy	Formatted: Font: Calibri, Bold, Font color: Auto
Dental oral carePrenatal risk screen Form.		Education and counseling. Dentures Evidence of a DH Form	Formatted: Tab stops: 0.38", Left + 3.5", Left
		3134 completed and a copy given to the patient with referral services offered.	Formatted: Normal, Tab stops: 0.38", Left + 0.88", Left + 3.5", Left
		Evidence that the provider submitted the prenatal risk assessment to the CHD in the county where the prenatal screen was	Formatted: Font: Calibri, Bold, Font color: Auto
		completed within 10 business days of completion. Referral for services regardle	Formatted: Tab stops: 0.38", Left + 3.5", Left
Eye care Prenatal Zika Virus Screen		of score. Vision examination Dilated retinal examinationAll	Formatted: Normal, Tab stops: 0.38", Left + 0.88", Left + 3.5", Left
		pregnant women with a history of travel t an area with ongoing Zika virus	Formatted: Font: Calibri, Bold, Font color: Auto
		transmission should be tested for infection.	Formatted: Tab stops: 0.38", Left + 3.5", Left
		-If positive or inconclusive then consider serial fetal ultrasounds, and consider amniocentesis.	Formatted: Normal, Tab stops: 0.38", Left + 0.88", Left + 3.5", Left
		If negative, one fetal ultrasound should be performed to detect microcephaly of intracranial calcifications. If microcephaly or intracranial	
		calcifications are present, then retest pregnant women and consider amniocentesis.	

	Elements and References Maternity Medical Component (E) –	Guidelines	Deleted Cells
	<u>cont'd.</u> Element Standard.	*	Formatted Table
		-If negative for microcephaly or intracrania	Formatted: Font: Calibri, Font color: Auto
		calcifications, then continue with routine prenatal care.	Formatted: Tab stops: 1.37", Centered + 5.24", Centered
	Medication list maintained Post- Natal Screening Form	◆ Evidence of documented information	Formatted: Font: Calibri, Bold
		Evidence of transmission Healthy Start	Formatted: Tab stops: 0.38", Left + 3.5",
i		(Postnatal) Risk Screening Instrument	Left
		Certificate of Live Birth to the County CHD within 5 business days of the birth. If the	Formatted: Normal, Tab stops: 0.38", Left
		referral is made at the same time the	+ 0.88", Left + 3.5", Left
		Healthy Start risk screen is administered,	
		the provider may indicate on the risk	
		screening form that the enrollee or infant	
		is invited to participate based on factors	
		other than score. If the determination is	
		made subsequent to risk screening, the	
		provider may refer the enrollee or infant	
		directly to the Healthy Start care coordinator based on assessment of actua	
		or potential factors associated with high	
		risk, such as HIV, Hepatitis B, substance	
		abuse or domestic violence.	

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Element Delivery care inigh obsteration	Component (E) – cont'd. Standard the provider determines that the enrollee's press, documentation will evidence that the provider determines that the enrollee's press, documentation will evidence that the provider care during labor and delivery included presendants for symptomatic evaluation and that the end of the providence of labor and immediately and the final stages of labor and immediately and the final stages of labor and immediately and the post include: Date of delivery/Infant's birth weight birth, evidence of inspecting the newborn for complication. Type of birth: vaginal, C/S/Post fiter delivery date, PE: BP, weight, pelvic exam, exam, Education on postpartum change habits/Family planning to all women and their ers/Newborn care (eye medication, APGAR, adin K), Weight and measuring, inspection for abortications/Evidence of continuing care of the new led through the CHCUP program component and the child's medical records. If the move there is evidence of securing a cord blood such determination and direct Coomb test, /Sexusy/Nutrition/Signs of Depression Referral for concess for mother and child made as appropriate in that Hepatitis B Prevention Coordinator at the labor tested + for HBsAG, evidence of referral to the labor tested + for HBsAG, evidence of referral to the labor tested + for HBsAG, evidence of referral to the labor tested + for HBsAG, evidence of referral to the labor tested + for HBsAG, evidence of referral to the labor tested + for HBsAG, evidence of referral to the labor tested + for HBsAG, evidence of referral to the labor tested + for HBsAG, evidence of referral to the labor tested + for HBsAG, evidence of referral to the labor tested + for HBsAG, evidence of referral to the labor tested + for HBsAG, evidence of referral to the labor tested + for HBsAG, evidence of referral to the labor tested + for HBsAG, evidence of referral to the labor tested + for HBsAG, evidence of referral to the labor tested + for HBsAG, evidence of referral to the labor tested + for HBsAG, evidence of refe	vider's preparation by the enrollee diate it-partum visit Gestational rabnormalities tpartum 21-56 n, Abdomen, ges/Personal ir dmin 5 mg of mormalities or ewborn is and nother is RH sample for ual community set the local CHD, es receive	Formatted: Font: Calibri, Bold Formatted: Tab stops: 0.38", Left + 3.1 Left Formatted: Normal, Tab stops: 0.38", Left + 0.88", Left + 3.5", Left Formatted Table Formatted: Font: Calibri, Bold
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hour: accor Reco State HBsA (6) m the s	hey are physiologically stable, preferably withi		
accol Reco State HBsA (6) m the s	of birth, and shall complete the Hepatitis B vac		
Reco State HBsA (6) m the s	ling to the vaccine schedule established by the		
HBsA (6) m the s	nmended Childhood Immunization Schedule fo		
(6) m the s	. Evidence that infants born to HBsAg-positive	e enrollees for	
the s	and Hepatitis B surface antibodies (anti-HBs)	are tested six	
	onths after the completion of the vaccine series		
	ccess or failure of the therapy. Evidence that t		
	o the enrollee who tested positive for HBsAG v		
	Healthy Start regardless of screening score. Ev		
	<u>ler report to the local CHD of any positive HBsA</u> illd age 24 months or less within 24 hours of re		
	<u>nia age 24 months of less within 24 hours of re</u> /e test result.	eceipt of tile	
■ Pneumovax, Tdap, Fl	•		
● Hepatitis A, Hepatitis	B, Chicken Pox, MMR		
Health-related behaviors Tobacco use	atana ahusa		
• ETOH use/drug or su	estance abuse		
• Exercise	l I		
•— ыет (raw milk, raw e	gs, raw meat, raw fish, caffeine)		

Gender identity:	Evidence of documented information
male/female/sex change	
General sexual/sexual	 Sex with men, women or both/anal/vaginal/oral sex
practices	Protection used during sex?
HIV prevention	Patient's partner(s) have HIV?
	Patient uses condoms or some other barrier?
Family history	Evidence of documented information
Social history	Evidence of documented information
Mental health history	Evidence of documented information
ROS: (tired, fever, night	Evidence of documented information
sweats, anorexia) etc.	
PE:	Evidence of documented information
VS/BMI/nourishment/well	
or ill appearing	
Assessment	Evidence of documented information
Plan	Evidence of documented information
HIV education	Evidence of documented information

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Long-Term Care Component (Not Applicable to Florida Healthy Kids)

AIDS/UI	V Proventive Component /E\	Formatted: Normal
Element	<u>V Preventive Component (F)</u> Standard	
Elements and References-Initial History (HPI)	Guidelines MR with date of first positive HIV test, last negative	Formatted: Font: Calibri Font color: Aut
	HIV test documented, care received, current CD4 count, and chart	
	with lowest/highest CD4 count, chart with first and current viral	Formatted: Tab stops: 0.38", Left + 3.5
	load count, documentation if patient is participating in research	Left
	studies.	Formatted: Tab stops: 0.38", Left +
Long term care	Member demographic data, including emergency contact	0.88", Left + 3.5", Left
AHCA contract HIV - Related Illnesses	information; guardian contact data if applicable; permission	Formatted Table
	forms; and copies of assessments, evaluations, and medical	Formatted: Font: Calibri, Not Bold, Font
	and medication information	color: Auto
	 Copies of eligibility documentations, including level of care 	<u> </u>
	determinations by CARES	Formatted: Font: Calibri, Bold
	Identification of the member's PCP	Formatted: Tab stops: 0.38", Left + 3.5
		Left
	at least the following:	
	The member's current medical/functional/behavioral	
	health status, including strengths and needs	
	 Identification of family/informal support system or community resources and their availability to assist 	
	the member, including barriers to assistance	
	• The member's ability to participate in the review	
	and/or who case manager discusses service needs and	ı İ
	goals with if the member was unable to participate	
	 An assessment of the member's environment, 	
	including fall risk screening, and/or other special	
	needs	
	 Environmental and/or other special needs (i.e., safety 	
	risks, sanitation, need for physical adaptations,	
	general condition of the home, amount of space,	
	adequacy of sleeping area, access to the bathroom,	
	temperature)	
	Evidence of needs assessments	
	Evidence of plan of care	
	Documentation of member's responses to HCBS settings requirements queries.	
	requirements queries	
	Documentation of interaction and contacts (including telephone contacts and member-specific correspondence)	
	with member, family of members, PCP, service providers, or	
	other individuals related to provision of services	
	Documentation of issues relevant to the member remaining	
	in the community with supports and services consistent with	
	his or her capacities and abilities (includes monitoring	
	achievement of goals and objectives as set forth in the plan	
	of care)	
	Residential agreements between the facility(ies) and the	
	member	
	Problems with service providers, with a planned course of	
	action noted	

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	any opportunistic infections/cancer, documentation of TB test
	with results or IGRA, medications taken for anti-TB and HIV,
	documentation of missed doses and any side effects of
	medication, viral load or CD4 count while taking medications. Documentation the member received and signed, if
	Documentation the member received and signed, if applicable, all required plan and program information
	(including copies of the member handbook, provider
	directory, etc.)
	Documentation of the discussion with the member on the
	procedures for filing complaints and grievances
	Documentation of the choice of PDO, initially, annually and
	upon reassessment
	Documentation of the signed Participant Agreement for PDO
	(if applicable)
	Notices of adverse benefit determination sent to the
	member regarding denial, termination, reduction or
	suspension of services
	Proof of submission to DCF of the completed CF ES 2506A
	form (Client Referral/Change) and CF-ES 2515 form
	(Certification of Enrollment Status HCBS)
	Copy of any opportunistic infections/cancer, documentation
	that member/authorized representative was advised
	regarding how to report the contingency plan and other of TB
	test with results or IGRA, medications taken for anti-TB and
	HIV, documentation that indicates the unplanned gaps in
	authorized service delivery
	Copy of the disaster/emergency plan for the member's
	household that considers the special needs of the member
	Documentation of choice between institutional and HBCS Formatted: Normal, Tab stops: 0.38", Le
	services of missed doses and any side effects of medication, viral + 0.88", Left + 3.5", Left
	load or CD4 count while taking medications.
Past Medical History	Documentation of past medical history
GYN and Women's Health	Last pap smear test and result, LMP, breast examination/
	mammograms, UTI or yeast infection documented
Obstetric	History of G/P/A/LB, HIV test done during pregnancy, children
Obstetric	with positive HIV
Anorectal History	Anal Pap test and results, history of anal warts
<u>Urologic History</u>	UTI, prostate enlargement or infection, PSA test and results
STD History	Documented history of STD's
Dental Oral Care	Oral health examination, dentures
Eye Care	Vision examination, dilated retinal examination
Medication List maintained	List of current medications and side effects reviewed

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<u>Immunizations</u>	Pneumovax, Tdap, Flu, H1N1, Hepatitis A, Hepatitis B, Chicken Pox, MMR.
Health-Related Behaviors	Tobacco use, ETOH use, Drug or Substance Abuse, exercise, Diet (raw milk, raw eggs, raw meat, raw fish, caffeine).
Gender Identity	Male/Female/Sex change
Sexual Practices	Protection used during intercourse, sex with men/women/both, type of sex used such as anal/vaginal/oral sex
HIV prevention	Protection used to prevent transmission, whether partner also has HIV
Family History	Family history documented
Social History	Social History documented
Mental health History	History of mental health documented

Additional documentation requirements are Behavioral Health, Social Determinants of Health, Cognitive Assessment (as appropriate) and COVID-19 components. The COVID-19 component is not currently being scored. It is used for tracking purposes only. The complete Medical Record Review Tool is provided in all Medical Record Review assessment visits and during educational sessions. It is available upon request.

Medical Record Review Documentation Standards References

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	AIDS/HIV Preventive Component (F) – cont'd.	
Element	<u>Standard</u>	
ROS/Physical Exam	Presence of s/s: tired, fever, night sweats, anorexia, etc. Evidence of PE	
	done: VS/BMI/nourishment/well or ill.	
Assessment	Evidence of a complete assessment done	
Plan	Care plan completed and revised frequently according to condition	
	changes	
HIV Education	Information on testing, Rx., treatment adherence and prevention of HIV	
THY Eddedton	transmission to fetus or sexual partners	
AAP American	Academy of Pediatrics, Committee on Practice and Ambulatory Medicines	Deleted Cells
Recommendatio	ns for Preventive Pediatric Health Care, March 2000 Pediatric and Adolescent	Formatted Table
	Preventive Component (G)	roillatteu Table
	ement Standard ◆	Formatted: Tab stops: 1.36", Centered -
AAP Immunizations A Complete	American Academy of Pediatrics, Committee on Infectious Diseases,	5.25", Centered
story & Physical Examination.	Recommended Childhood and Adolescent Immunization Schedule: United	Formatted: Tab stops: 0.38", Left + 3.5
	States, 2005 A complete Medical History and Physical Exam must be done to	Left
	all new patient (CC/HPI/All/PMH/PSHX/PSURGICAL HXFAMILY HX/ROS/VITA	Formatted: Tab stops: 0.38", Left +
	SIGNS/PE: General/HEENT/Neck/Chest/Lungs/ Heart/Abdomen/Extremities/Nodes/Skin/Neurological evaluation/Gait/Hip.	0.88", Left + 3.5", Left
	abduction/Genitalia/Psychosocial Hx/Prenatal care/delivery/birth Hx.	<u> </u>
	The CHCUP schedule is: Birth or neonatal examination. Within 3-5 days of	Formatted: Font color: Auto
	birth and within 48-72 hours after discharge from a hospital, to include	
	evaluation for feeding and jaundice. For newborns discharged in less than 48	3
	hours after delivery, the infant must be examined within 48 hours of	-
	discharge. By 1 m/2m/4m/6m/9m/12m/15m/18m/24m/30m/Once per year	
	for 3 through 20 years old.	
ACSHigh Risk Behaviors and	American Cancer Society, Guidelines for Colorectal Cancer Screening for	
ticipatory Guidance.	Individuals at Average Risk, Reviewed 2003 Encourage patient on Nutritional	Left
	status/Dental care-3 yrs. old and or referral/Injury prevention/safety/Report	Formatted: Tab stops: 0.38", Left +
	any violence or abuse. Social/Emotional Health/Depression/Advise on ETQH	0.88", Left + 3.5", Left
	cigarette, E-cigarettes, drug abuse beginning at age 11/encourage	
	exercise/Illness. Prevention/Sleep Positioning/HIV/STD/Hepatitis Risk query	.(
	teaching instructions with the parent or guardian/18 months and 24 months	i
	Screening for Autism. Assessment of Parent/Guardian for Alcohol, Tobacco	
ALICA Control Income in the control	and Drug use/abuse. Florida Agency for Health Care Administration, Medicaid Contract An	Formatted: Font color: Auto
AHCA Contract Immunizations.	appropriate immunization history has been made with notation that	Formatted: Tab stops: 0.38", Left + 3.5
	immunizations are up to date/scheduled for catch up. Evidence of provider	Left
	participation in FL SHOTS.	Formatted: Tab stops: 0.38", Left +
Measurements.	Document Height/Wt./BMI /HC/BP for each routine visits. BMI annually	
<u>incusurementsi</u>	starting at age 2 yrs., BP annually starting at age 3 yrs.	Formatted: Font color: Auto
NCQASensory Screening.	National Committee of Quality Assurance Vision Screening starting at	
	age years then at 4, 5, 6, 8, 10, 12, 15, and 18 years of age. Hearing screening	Formatted: Tab stops: 0.38", Left + 3.5
	starting at age 4 years then at 5, 6, 8, and 10 years of age.	Left
		Formatted: Tab stops: 0.38", Left +
Simply Provider M		0.88", Left + 3.5", Left
SPSTF U.S. Preventive Se	rvices Task Force, Guide to Clinical Preventive Services, 3rd Edition	Formatted Table

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	lescent Preventive Component (G) – cont'd.	
<u>Element</u>	<u>Standard</u>	
General Screening.	<u>Lead Testing</u> at 12 months and 24 months of age. Children	
	between the ages of 36 and 72 mo. who have not been previously	
	screened for lead poisoning. H&H at 12 mo. of age. Urinalysis:	
	starting at 9 months of age and patient's at high risk. Hereditary	
	and Metabolic Screening processed through the State Public	
	Health Laboratory: Screening for PKU, Thyroid,	
	Hemoglobinopathies, Galactosemia.	
	If a child is found to have lead blood levels equal to or greater	
	than 10 micrograms per deciliter, providers should use their	
	medical discretion, with reference to the current Center for	
	<u>Disease Control and Prevention (CDC) guidelines covering patient</u>	
	management and treatment, including follow-up tests and	
	initiating investigations as to the source of lead where indicated.	
Procedures: At Risk.	TB Testing for all pediatric patients and at risk.	
	Dyslipidemia screening: To be done at ages 2-4-6-8-10 and each	
	year from 11-17 and or patients at risk.	
	HIV/STD/Hepatitis/Pelvic Exam/PAP Smear/Sickle Cell Test: For	
	all patients at risk/Family History.	
0.11.41		
Child Abuse.	Screening for child abuse is conducted/suspected and	
	reported to appropriate regulatory agencies and documented.	
Treatment Plan for Opioid Medications.	Opioid Medication prescribed for the treatment of Acute Pain	
	listed in Schedule II-limited to 3 day supply (pain related to cancer,	
	terminal illness, palliative care and serious traumatic injury are	
	excluded from theses prescribing limits)	
	Acute Pain Exemption: Pain listed in Schedule II –limited to 7 day	
	supply.(pain related to cancer, terminal illness, palliative care and	
	serious traumatic injury are excluded from these prescribing	
	limits).	
	Prescription for Controlled Substance: Controlled substances in	
	Schedule III, IV, V for treatment of acute pain is limited to 14 day	
	supply. (pain related to cancer, terminal illness, palliative care and	
	serious traumatic injury are excluded from theses prescribing	
	limits)	
Cofe	ty Preventive Component (H)	
		
Element Evidence of Staff training	Standard Staff training on infection control and universal procautions	
Evidence of Staff training	Staff training on infection control and universal precautions.	
	Evidence of boxes to dispose of hazardous materials and	
	contaminated materials and waste.	
Emergency disaster plan	Evidence of Emergency/Disaster Preparedness Plan addressing	
	internal/external emergencies for administrative offices and	
	ensures member safety and evacuation plan.	
After hours access	Evidence of accessibility to after hours convices by acting the	
After-hours access	Evidence of accessibility to after-hours services by asking the	
	appropriate office staff to show next available appointment.	

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	Preventive Component (H)	
<u>Element</u>	<u>Standard</u>	
Safety Program	Management of identified hazards, potential threats, near	
	misses, violence in the workplace, extreme threats like bomb	
	threats, firearms, terrorism and other safety concerns. Awareness	
	of, and a process for, the reporting of known adverse incidents to	
	appropriate state and federal agencies when required by law to	
	do so. Processes to reduce and avoid medication errors, including	
	expiration date monitoring on medications, reagents and	
	solutions. Evidence that the Thermometer log in the refrigerator	
	is being read. Evidence that opened medication in the refrigerator	
	is Not over 28 days. Prevention of falls or physical injuries	
	involving patients, staff and all others.	
Fire prevention	Evidence of staff education and fire drills (fire drills once a	
	year). Local/Federal fire prevention regulations for all sites, if	
	applicable. Compliance with applicable State/Local Building codes	
	and regulations. Contain fire-fighting equipment to control a	
	limited fire, including appropriately maintained and placed fire	
	extinguishers of the proper type. Have prominently displayed	
	illuminated signs with emergency power capability at all exits from	
	each floor or hall. Have emergency lighting, as appropriate to the	
	facility, to provide adequate evacuation of members and staff, in	
	case of an emergency. Have stairwells protected by fire doors, if	
	applicable.	
Member Privacy/Accessibility	Provide examination rooms, dressing rooms, and reception	
wichiser i macy recessionicy	areas that are constructed and maintained in a manner that	
	ensures member privacy during interviews, examinations,	
	treatment and consultation.	
		_
Have provisions to reasonably accommodate	<u>Self-Explanatory</u>	
disabled individuals.		
Evidence that Members' Rights poster is	<u>Self-Explanatory</u>	
prominently displayed.		
Posted information regarding lack of	Solf Evaluations	-
	<u>Self-Explanatory</u>	
malpractice insurance coverage, if applicable.		
Information is ported in a prominent location.		

RESIDENT RECORDS Bill of Rights/Proc. Lodging complaints with Complaints with Residents Discussion of House Rules Discussion of House Rules Documentation that show that House Rules were discussed Resident record on the premises by provider Resident Health Assessment (Form 1110) Residency Agreement ust have all required information filled out Documentation of a Resident Advised Grievance and hearing	
RESIDENT RECORDS Bill of Rights/Proc. Lodging complaints with Complaints with Residents Discussion of House Rules Documentation that show that House Rules were discussed Resident record on the premises by provider Documentation of the resident record on the premises kept by the provider Resident Health Assessment (Form 1110) Documented proof of a completed Resident Health Assessment (Form 1110) on file. Residency Agreement Residency Agreement Residency Agreement Residency Agreement Residency agreement must have all required information filled out	
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Residency Agreement Residency agreement must have all required information filled out	
<u>out</u>	
bocumentation of a Resident Advised Grievance and flearing	
process process, if applicable.	
Demographic information in each resident Documentation of Demographic info on each resident on file	
Demographic information in each resident	
Complete accounting of resident funds for File indicating that a complete account of resident funds is	
safekeeping being kept	
Resident's medication Documented record of each resident's Medication	
Annual Health Risk Assessment or when Documented Annual Health Assessment on file or when	
significant changes occur significant changes happen	
Health Risk Assessment (HRA) conducted and HRA must be conducted and signed by a physician or other	
signed by an authorized individual licensed practitioner of the healing arts defined as a Physician	
Assistant, Advanced Registered Nurse Practitioner or Registered	
Nurse acting within the scope of their practice under state law; documented and signed	
Service plan developed after the initial HRA Documentation of a Service Plan developed within 15 days after the initial HRA, based on HRA information and containing all	
required information; signatures of a resident/legal guardian/	
designated administrator must be present.	
Medication orders Documentation that medication orders are reviewed and	
<u>current</u>	
Nursing Progress Notes Documentation provided where it shows nursing progress	
notes are being kept when nursing services are provided	
<u>Special Diet for the member</u> <u>Copy in the member's file of any special diet order prescribed</u>	
by resident's health care provider.	
<u>Coordination of care</u> <u>Documentation of the coordination of care by</u>	
providers/licensed practitioner/nurse for the member	
Any major incidents or significant health Documentation of any major incidents or significant health	
<u>changes</u> <u>changes and action taken in response to such incidents or changes</u>	

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	<u>ly Care Home (AFCH) – cont'd.</u>	
<u>Element</u>	<u>Standard</u>	
Monthly weight record	<u>Documentation that monthly weights are being done for the</u>	
	member and in file; includes resident's name, admission weight,	
	weighing and recording of each resident on a monthly basis	
Resident discharge notices sent by provider	Resident records shall contain a copy of any notice of	
	discharge sent to the resident or the resident's representative	
Closed resident records kept 5 yrs.	Closed resident records shall be kept for a period of five years	
	after the resident leaves the AFCH. Ask the AFCH provider	
	whether or not resident records are being retained by the home	
	after a resident is discharged	
Personal Needs Allowance (PNA) for the	Evidence, if applicable, that the resident has been provided	•
esident	with a PNA in an amount equal to that set by rule 65A-2.036,	
<u>esident</u>	F.A.C.	
	I M.C.	-
FACILITY RECORDS/SAFETY		
Facility Records	Documentation of Facility Records shall be on file on the	
	premises and up-to-date	
		_
Resident Service Log (AHCA-Med Serv. Form	Evidence of a complete Resident Service Log (AHCA-Med Serv.	
37-Appendix D, July 2009)	Form 037-Appendix D, July 2009) on file; make sure log is filled out	
	properly (Resident name, Medicaid #, Facility name, month/year,	
	etc.)	
Certification of Medical Necessity for	ACS-AHCA-Med Ser., Form 035; this form needs to certify that	
vidence of a Certification of Medical necessity	the recipient is in need of an integrated set of assistive care	
or Medical Medicaid ACS-AHCA-Med Ser., Form	services on a 24-hour basis, which includes at least two of four	
<u>35</u>	service components on a daily basis; make sure that it is filled out	
<u></u>	completely.	
All the form		-
Admission/Discharge log	Evidence of an admission/discharge log on file for residents on	
	the premises.	
AFCH License	Evidence of an AFCH license available upon request to public.	
Current county health department inspection.	Evidence of a current county health department inspection on	
	<u>file.</u>	
Current fire safety inspection	Evidence of a current fire safety inspection for the AFCH must	
	be kept on file and ready for agency inspection.	
Radon Testing (If applicable)	Documentation of radon testing shall be kept on the premises	-
NAUGH TESTING (IT APPRICABLE)		
	by the provider and ready for agency inspection for AFCHs located	
	in counties requiring radon testing.	
Emergency Plan	Evidence of an emergency plan kept by provider on the	
	premises and in file; the AFCH shall have a written plan which	
	specifies emergency and evacuation procedures for fires and such	
	natural disasters as hurricanes, floods and tornadoes. There	
	Should also be an indication that the plan's emergency and	
	should also be an indication that the plan's emergency and	
	evacuation procedures have been reviewed with the residents, the relief person, all staff and all household members.	

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Adult Fami		Formatted: Normal
	ly Care Home (AFCH) – cont'd.	
Element	Standard Findence that the ASCU and ideas are because and the appropriate	
Survey, complaint investigation reports and	Evidence that the AFCH providers are keeping on the premises	
notices of sanctions and moratoriums issued to	all completed survey and complaint investigation reports, and	
the AFCH	notices of sanctions and moratoriums issued to the AFCH by the	
	agency within the last 3 years.	_
Emergency telephone numbers Emergency	Verify that the emergency telephone numbers are located by	
telephone numbers	a designated telephone and includes emergency # 911, police #,	
	fire dept. #, ambulance #, Florida Poison Info Ctr. #, Abuse	
	Hotline#, AHCA's Field Office, etc.	
Information regarding a resident's location to	Evidence that in the event of a disaster/ emergency, the AFCH	
essential medical services providers in	provider can make available all necessary information regarding a	
disaster/emergency situations	resident's location to essential medical service providers, both	
	during and after the disaster/emergency.	
Proof of fire safety inspection every 365 days	See Element and Standard #29	-
11001 of the safety hispection every 303 days	See Element and Standard #25	
Written emergency evacuation	See Element and Standard #31	
procedures/rev		
Emergency and first aid supplies	Check to see that the provider at all times maintains first aid	
	and emergency supplies including a 3-day supply of non-	
	perishable food based on the number of residents and household	
	members currently residing in the home, and 2 gallons of drinking	
	water per current resident and household member.	
Telephone available/accessible for residents'	Evidence that the ACFH, at a minimum, maintains a telephone	
use	in the home which is available and accessible for the resident's	
	use at all times and placed in an area that allows facilitated private	
	communication.	
Non-ambulatory/impaired residents on	Verify that residents who are non- ambulatory or who require	-
ground floor	assistance with, or supervision of, ambulation are housed on the	
<u></u>	ground floor.	
Grab bars for physically handicapped; hot	Verify that the bathrooms used by physically handicapped	-
water supervision	residents have grab bars for toilets, bathtubs and showers; verify	
water supervision	that hot water temperature is supervised for persons unable to	
	self-regulate water temperature.	
Safety cover on hot tub/spa	Evidence that if the home has a hot tub or spa that it has a	
	safety cover when not in use.	
Supervision/aware resident whereabouts/	Evidence that the AFCH provider is providing general	-
ensures safe/reminding of appointments and	supervision 24 hours per day, where the provider is aware of the	
unattended no more than 2 hours	resident's whereabouts and well-being while the resident is in	
	care of the AFCH. The resident may be with no supervision in an	
	AFCH for up to 2 hours in a 24 hour period, as long as approved by	
	the provider.	

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Adult Fami	ly Care Home (AFCH) – cont'd.	roi matteu. Noi mai
Element	Standard	
Report significant physical/mental changes,	Evidence that the AFCH provider is being responsible in	
weight loss	observing, recording and reporting any significant changes in the	
	resident's normal appearance, behavior or state of health;	
	significant changes include a sudden or major shift in behavior or	
	mood; a deterioration in health status, such as unplanned weight	
	change, stroke, heart condition, or stage 2 pressure sore. Evidence	
	of timeliness of LTC CM communication of all admissions,	
	discharges and ER visits within 48-hours.	
Medication Standards	Determine that correct assistance/supervision is being made	
	when meds are given; that self-administration of meds is being	
	encouraged verbally by trained staff; trained staff may also make	
	available such items as water, juice, cups and spoons; trained staff	
	must observe the resident take the medication; proof that for the	
	facilities that provide medication administration that there is a	
	staff member that has a license to administer meds in accordance	
	with a health provider's order or prescription label to meet	
	requirements; Documented proof that a list of all current	
	prescribed meds is in file; Documented proof that a nurse is	
	managing a pill organizer and/or list of centrally stored meds in	
	container.	
	Adult Living Facility	
Element	Standard	
RESIDENTS' RIGHTS		
Residents' rights posted.	Residents' rights must be visibly posted.	
		_
Residents informed of their rights.	Resident must be informed about their rights, documented in MR.	
Safe and Homelike environment.	Review if environment is homelike and safe for the resident.	-
Use of needed adaptive equipment.	If resident has and uses the adaptive equipment needed for	
	his/her condition and safety.	
Resident participating in activities.	Review if resident is participating in activities.	
Resident participation in selecting activities.	If resident was given opportunity to select activities.	
Member's opinion about his/her room &	Self explanatory.	
general Environment.		
Transportation arranged for medical	Review in Medical records notation about transportation for	
appointments	medical appointments.	
Encourage resident to participate on their	Notes about staff encouraging residents to participate in their	
care.	care.	
Resident funds for safekeeping	Staff keeps money or possessions for residents and give it	
nessuent funds for sufercephing	back when resident needs/wants them.	
Resident having his/her medicines all the	Resident never run out of medications.	
time		-
<u>Medication's assistance for residents</u>	Resident is receiving assistance with medications; type of assistance must be noted at MR.	

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<u>Adul</u>	t Living Facility – cont'd.	
Element	<u>Standard</u>	
Resident receiving assistance with other	Residents receiving assistance with other services as needed,	
<u>services</u>	must be documented at MR.	
Quality of food service	Resident opinion about food service in the Facility.	
Staff attention to residents	How does staff communicates with residents and responds to their concerns.	
RECORD REVIEW		
Height and weight	Documented correct height and weight on MR.	
<u>Diagnosis</u>	Documented correct diagnosis and is in member's chart.	
Allergies	<u>Documented all of the member's allergies.</u>	
ADLs assessment and score	Documented full ADL (Activities of Daily Living) assessments and scores.	
Evidence of special precautions taken	Documented all special precautions taken at this facility. (i.e. fall precautions, skin breakdown precautions, universal precautions, UTI precautions, precautions for PU).	
Evidence of cognitive and behavioral	Documented proof of assessment(s) done on member to	
<u>assessment</u>	determine his/her cognitive and behavioral levels.	
If evidence of Pressure Ulcer stage II present	Documented notes where it shows proof of wound care, any	1
in Member	observations made by the RN and any notations if the wound is	
	improving within 30 days.	
Any significant changes in member's health	Documented any significant changes in member's health on	
Fuldana of annualista annula astitis d'ef	MR.	_
Evidence of appropriate people notified of member's changes in his/her condition	<u>Documented evidence that indicates that if there are any</u> changes in the member's condition the significant people are	
member's changes in his/her condition	notified (Family, guardian, CM, PCP, Psych/SW.	
Medications		_
Medications	Indication that the medications ordered for the member are documented in the member's file	
Annual MD evaluation of medical restraints	Documentation of annual MD evaluation for restraints.	
Renewal of Restraints' Orders	Documented proof that Orders for Restraints have been renewed (if applicable).	
Form 1823 completion	Demonstrate that Form 1823 (Resident Health Assessment for Assisted Living Facilities) is Filled out completely.	
Photo ID of resident at elopement risk	Proof of a photo ID for resident if he/she is at risk of	
(if applicable)	elopement.	
Hospice services care plan on file (if applicable)	Proof of care plan for hospice services on file (if applicable).	
ALF House Rules and Bill of Rights	Proof of copy of ALF House Rules and Bill of Rights.	

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Adu	Ilt Living Facility – cont'd.	Formatted: Normal
Element	Standard	
Contract signed by the guardian/surrogate (if applicable)	Proof of a contract signed by a guardian/ surrogate for the member. Evidence of timeliness of LTC CM communication of all admissions, discharges and ER visits within 48-hours.	
LTC CM communication	Evidence of timeliness of LTC CM communication of all admissions, discharges and ER visits within 48 hours.	
Safety Component	Determine if the environment for the ALF is clean and comfortable, home-like; are there NO safety hazards observed; look at adaptive equipment to make sure that it is clean and well maintained; look at the resident's appearance to make sure that it is well overall. Documentation or observation of restraints use. Make sure all medications are stored and secured properly; analyze if the staff is able to perform their duties; no evidence of allegations or suspect of abuse/neglect or exploitation.	
<u>Medication Standards</u>	Determine that correct assistance/supervision is being made when medications are given; that self-administration of meds is being encouraged verbally by trained staff; trained staff may also make available such items as water, juice, cups and spoons; trained staff must observe the resident take the medication; proof that for facilities that provide medication administration that there is a staff member that has a license to administer meds in accordance with a health care provider's order or prescription label to meet requirements; Documented proof that a list of all current prescribed meds is in file; Documented proof that a nurse is managing a pill organizer and/or list of centrally stored meds in original container.	·
9	Skilled Nursing Facility	
<u>Element</u>	<u>Standard</u>	
RECORD REVIEW		
Member Name	Each page in the record contains member name of member ID number.	
Each page in the record contains member name of member ID number.	Each page in the record contains member name of member ID number. Personal data includes address, employer, telephone numbers, Emergency contact, marital status, etc.	
All entries signed/dated	Including dictation are signed or initiated by the licensed Professional. NA notes are to be cosigned by the supervising Professional. All verbal orders are cosigned by the physician. All entries are dated.	
The record is legible	All parts of the enrollee record are legible.	
Advanced directives	There is documentation of Advanced Directives being discussed and copy of the document if executed. DNR documentation if applicable.	

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Element	Skilled Nursing Facility Standard	
Medication list	Medication list is up-to-date. There is a medication list with	
Wedledton 113t	dosage and frequency of medication. Effectiveness of PRN	
	medications is documented.	
Administered medications	Evidence that all administered medications are recorded when	
<u>Manimistered inediederons</u>	Given. Entries have complete signatures.	
Medication Review	Evidence of medication review as required by member	
	condition. At a minimum medications are reviewed annually.	
Allergies	Allergies and adverse reactions are prominently displayed on	
	the member's chart.	
Past nursing history	Past nursing history including serious injuries, operations and	
<u>- uot natong motory</u>	illnesses, and secondary conditions and any other disorders that	
	impact on the members care.	
Past medical history	Past medical history including the physician's history,	
	member's physical exam, and the current need for care.	
Tobacco use	Tobacco use/non-use including tobacco, chew, pipe.	
Alcohol/drugs use	Alcohol/ Illicit drugs/Legally prescribed drugs assessment	
<u>Diagnosis</u>	<u>Diagnosis is clearly related to services being rendered and the</u>	
	symptoms described.	
Nutritional assessment	<u>Documentation of a nutritional assessment. Documentation of</u>	
	nutritional needs and responses at least quarterly.	
Functional assessment	Documentation of functional assessment. Documentation	
	includes skilled observations/assessment.	
Pain assessment	Documentation on pain assessment.	
Interdisciplinary team	There is documentation of an interdisciplinary team approach	
	to care.	
Physician's orders	Physician orders must be in writing and present in the record.	
Member seen by physician	Evidence that the member has been seen by a physician or another licensed professional acting within their scope of practice	
	at least 1X/30 days for the first 90 days and at least 1X/60 days	
	thereafter.	
LTC CM Communication	Evidence of Timelines of LTC CM communication of all	
ETC CIVI COMMUNICATION	admissions, discharges and ER visits within 48-hours	
Plan of care		
Plan of care	Plan of care completed 7 days after the assessment, within 14 days of admission and every 12 months thereafter. Plan of Care	
	reviewed every 3 months of promptly after a significant change.	
	Plan of care must include functional limitations and be written	
	collaboration with the member, family or responsible party at the	
	member's option.	
	Skilled Nursing Facility	
Element	Standard	

Discharge planning	There is desumentation of discharge planning and a discharge	
Discharge planning	There is documentation of discharge planning and a discharge summary signed by physician within 30 days of discharge.	
Social services	Evidence that social services are provided by a staff member	
	with the appropriate training and experience and who is	
	responsible for making integration arrangements so the member	
	can return back into the community, transfer to a home, or	
	transfer to another facility where appropriate level of care is	
	<u>available.</u>	
Relevant information	There is documentation of relevant information to the	
	PCP/ordering physician on a regular basis, and at discharge. There	
	is evidence of continuity and coordination of care between all	
	members of the treatment team.	
Designated FT employee	There is designated FT employee responsible and accountable	
	for the facility's medical records. If this employee is not a qualified	
	Medical Record Practitioner, then the facility shall have the	
	services of a qualified Medical Record Practitioner on a consultant	
	<u>basis.</u>	
MEMBERS' RIGHTS		
Statement posted	Statement of Member Rights posted	
Resident bills of rights copy	Evidence that members have been given a copy of the	
	resident's bill of rights and that these have been discussed with	
	the member.	
Right to private communication	Rights statement include the right to have private	
	communication with any person of his or her choice.	
Right to present grievances	The right to present grievances on behalf of himself, herself,	
rught to present grievances	or others to the facility's staff or administrator, to government	
	officials, or to any person without fear of reprisal, and to join with	
	other patients or individuals to work for improvements in patient	
	care.	
Right to be fully informed	The right to be fully informed in writing, prior to at the time of	
Right to be fully informed	admission and during his or her attendance, of fees and services	
	not covered.	
Billion I. I. I. I. I. I.		
Right to be adequately informed	The right to be adequately informed of his or her medical	
	condition and proposed treatment unless otherwise indicated in	
	the written medical plan of treatment by the physician, and to participate in the planning of all medical treatment, including the	
	right to refuse medication and treatment, unless otherwise	
	indicated in the written medical plan of treatment by the	
	physician, and to know the consequences of such actions.	
Dight of adequate care		
Right of adequate care	The right to receive adequate and appropriate health care	
	consistent with established and recognized practice standards within the community and with rules as promulgated by the	
	AHCA.	
	Skilled Nursing Facility – cont'd.	

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Right to privacy	The right to have privacy in treatment and in caring for personal needs, confidentiality in the treatment of personal and medical records.	
Right to be treated courteously	The right to be treated courteously, fairly, and with the fullest measure of dignity and to receive a written statement of the services provided by the facility.	
Right to freedom of choice	The right to freedom of choice in selecting a nursing home.	
Staff training	Evidence that staff has been trained regarding residents' rights.	
SAFETY		
Isolation	Members with communicable diseases are adequately and appropriately isolated.	
Incidents report	Evidence of a system to report accidents, adverse, critical or unusual incidents to the Plan and to AHCA.	
Staff Education	Staff Education plan contains prevention and control of infection, fire prevention, life safety and disaster preparedness, accident prevention and safety awareness program.	
<u>Environment</u>	Environment is safe, clean, comfortable and home-like and it allows the member to sue personal belongings to the extent possible.	
<u>Disaster preparedness</u>	Evidence of written Disaster Preparedness plan to be followed in the event of an internal or externally caused disaster.	
Evidence of procedures	Evidence of procedures that assure the accurate acquiring, receiving, dispensing and administering of all drugs and biologicals to meet the needs of the members	
Drugs and biologicals	Drugs and biologicals used in the facility shall be labeled in accordance with currently accepted professional principles, Chapter 499, F.S., and Chapter 64B16, F.A.C. Drugs and non-prescription medications requiring refrigeration shall be stored in a refrigerator. When stored in a general-use refrigerator, they shall be stored in a separate, covered, waterproof, and labeled receptacle.	
Controlled substances	All controlled substances shall be disposed of in accordance with state and federal laws. All non-controlled substances may be destroyed in accordance with the facility's policies and procedures. Records of the disposition of all substances shall be maintained in sufficient detail to enable an accurate reconciliation.	

	Chilled Nursing Facility contid
Floment	Skilled Nursing Facility – cont'd.
Element	<u>Standard</u>
dditional standards for SNF that a	idmit children 0-20
Evidence of assessment	Evidence of an assessment upon admission by licensed
	physical, occupational, and speech therapists who are experienced
	in working with children.
Determination of level of care	There is determination of LOC made a physician
	(intermediate/skilled/fragile nursing care).
vidence of written order	Evidence of a written order by the child's attending physician
	in consolation with parents/legal guardians.
Medicaid certification	For Medicaid certified nursing facilities, the recommendations
	for placement of a Medicaid applicant or recipient in the nursing
	facility shall be made by the Multiple Handicap Assessment Team.
	Consideration must be given to relevant medical, emotional,
	psychosocial, and environmental factors.
hysician's orders	Documentation of Physician's orders, diagnosis, medical
	history, physical examination and rehabilitative or restorative
	needs.
Preliminary evaluation	A preliminary nursing evaluation with physician orders for
	immediate care, completed on admission.
tandardized assessment	A comprehensive, accurate, reproducible, and standardized
	assessment of each child's functional capability which is
	completed within 14 days of the child's admission to the facility
	and every twelve months thereafter. Assessment reviewed no less
	than once every 120 days or promptly after a significant change.
lan of care	The plan of care should contain measurable objectives and
	timetables to meet the child's medical, nursing, mental and
	psychosocial needs identified in the comprehensive assessment.
	The Plan of care is completed within 7 days after the assessment
	and reviewed every 60 days.
ducation	For children 3-15 there is evidence of home-bound education
	or attempts made by the facility to engage the County School
	Board. Children 16 - 20 years are enrolled in an education program
	according to their ability to participate.
valuation and documentation	Evidence that evaluation and documentation on the status of
- Valuation and documentation	the child's condition is done at least monthly.
/erbal orders	Verbal orders are signed within 72 hours after the order was
erbai orders	given.
ctivities	There are indoor and outdoor activities designed to Encourage
Activities	exploration and maximize the child's capabilities and that
	accommodate mobile and non-mobile children. Outdoor activities
	are held in secure with areas of sun and shade, free of safety
	hazards; and equipped with age appropriate recreational
	equipment for developmental level of children and has storage
	space for same.
	space for suffic.

<u>Skill</u>	ed Nursing Facility – cont'd.
Element	<u>Standard</u>
mergency Medication Kit	The facility shall maintain an Emergency Medication Kit of
	pediatric medications, as well as adult dosages for those children
	who require adult doses.
<u> Fransportation</u>	The facility must provide access to emergency and other
	forms of transportation for children.
ife support certification	At least one licensed health care staff person with current Life
	Support certification for children shall be on the unit at all times where children are residing.
No diseasi	
Pediatric equipment	<u>Pediatric equipment and supplies shall be available as follows:</u> Suction machines, oxygen, thermometers, sphygmomanometers,
	apnea monitor and pulse oximeter.
Additional standards geriatric outpatient	nurse clinic
Maintain clinical record	The clinic shall maintain a clinical record for every patient
	receiving health services that contain the following: Identification
	data including name, address, telephone number, date of birth,
	sex, social security number, clinic case number if used, next of kin
	or guardian and telephone number, name and telephone number of patient's attending physician.
Loolth save when	Health Care Plan including diagnose, type, and frequency of
Health care plan	services and when receiving medications and medical treatments,
	the medical treatment plan and dated signature of the health
	professional licensed in this state to prescribe such medications
	and treatments.
Clinical notes	Clinical notes, signed and dated by staff providing service.
Progress notes	Progress notes with changes in the patient's condition.
Services rendered	Documentation of services rendered with progress
	reports/Observations.
<u>nstructions</u>	Instructions provided to the patient and family.
Consultations	Evidence of consultation reports
Case conferences	Documentation of case discussion
Report to physicians	Documentation of reports provided
Termination summary	Termination summary including the reasons on for the
Cimilation Summary	termination, dates of first and last visit, total number of visits by
	discipline, evaluation of achievements of previously established
	goals and condition of the member at discharge.
Confidentiality	All clinical records shall be maintained confidential according
<u></u>	to the law.
Prescriptions	All prescriptions for medications shall be noted on the patient
	record, and include the date, drug, dosage, frequency, method or
	site of administration, and the authorized health care
	professional's signature.

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	Skilled Nursing Facility – cont'd.	
Element	Standard	
Verbal orders	All verbal orders for medication or medication changes shall	
verbai orders	be taken by the clinic registered nurse or physician's assistant.	
	Such must be in writing and signed by the authorized health care	
	professional within eight (8) days and added to the member's	
	records.	
Administered medications	The clinic registered nurse or physician's assistant shall record	
	and sign for each medication administrated, by drug, dosage,	
	method, time and site on patient's record.	
Emergency plan/Kit	An emergency plan for reversal of drug reaction to include the	
	facility's PRN standing orders for medications available in the	
	emergency medication kit. If there is not a separate emergency	
	medication kit in the clinic, the facility's emergency medication kit	
	shall be immediately accessible for use in the outpatient clinic.	
Prescribed medications	<u>Prescribed medications for individual outpatients may be</u>	
	retained in clinic. These medications shall be stored separately	
	from those of the nursing home in-patients for preventive	
	measures and treatment of minor illnesses. Multi-dose containers	
	shall be limited to medications or biologicals commonly prescribed	
	for preventive measures and treatment of minor illnesses.	
	Long-term care	
Element	Standard	
Demographic Data	Complete Administrative Component.	
Contact Information	Emergency Contact Information Legal data; guardianship	
	papers, court orders, release forms.	
Permission/Consent	All permission, consent forms, assessments evaluations,	
<u> </u>	medical and medication information.	
Eligibility	Copies of eligibility documents, including level of care	
Eligibility		
	determination by CARES and LOC determinations.	
Healthcare Practitioner	Name and contact information of PCP.	
Current Medical Condition	Enrollee's current medical/functional/behavioral health status	
Carrent Wearear Contaction	including strengths and needs.	
Francisco de como esta contenta		
Enrollee's support system	Identification of family/informal support system or community	
	resources and their availability to assist the enrollee, including	
	barriers to assistance;	
	-Documentation of interaction and contacts (including telephone	
	contacts) with enrollee, family of enrollees, service providers or	
	others related to services	
	-Documentation of issues relevant to the enrollee remaining in the	
	community with supports and services consistent with his or her	
	capacities and abilities. This includes monitoring achievement of goals and objectives as set forth in the plan of care.	

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and the second	Long-term care – cont'd.	
<u>Element</u>	<u>Standard</u>	
Enrollee's Participation	Enrollee's ability to participate in the review and/or who case	
	manager discusses service needs and goals with if the enrollee was unable to participate.	
	-Environmental and/or other special needs, if applicable.	
A		
<u>Assessments</u>	Needs assessments, including all physician referrals.	
<u>Plan of Care</u>	Plan of care documented on medical record.	
ALF residents	For enrollees residing in ALFs and AFCHs or receiving ADHC	
	services, evidence of documentation of enrollee's response to HCB	
	Settings Requirements queries and enrollee limitations.	
Residential agreement	Agreement between facilities and the enrollee.	
<u>Authorizations</u>	Record of Services authorization.	
<u>Assessments</u>	CARES assessment documents.	
Enrollee's Program information	Documentation that the enrollee has received and signed, if	
	applicable, all required plan and program information (including	
	copies of the enrollee handbook, provider directory, etc.)	
	-Documentation of the discussion with the enrollee on the	
	procedures for filing complaints and grievances;	
	-Documentation of the choice of a participant-directed care	
	option;	
	-Documentation of the choice of PDO, initially, annually and upon	
	reassessment.	
	-Documentation of the signed participant agreement.	
Notices to Enrollee	Notices of Action sent to the enrollee regarding denial or	
	<u>changes to services (discontinuance, termination, reduction or</u>	
	suspension) if applicable	
	- Enrollee-Specific correspondence	
Submission to DCF	Proof of submission to DCF of the completed CF-ES 2506A	
	form.	
Physicians orders/evaluations	Physicians' orders for LTC services and equipment.	
	-Provider evaluations, assessments, and/or Progress Notes (Home	
	Health, Physical Therapy, Behavioral Health, etc.)	

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<u>Lo</u>	ng-term care – cont'd.	
<u>Element</u>	<u>Standard</u>	
Case Management	Case Management Files - Case management enrollee file	
	information is maintained by the Plan in compliance with state	
	regulations for record retention. Per 42 CFR 441.303(c) (3), written	
	and electronically retrievable documentation of all evaluations	
	and re-evaluations shall be maintained as required in 45 CFR	
	92.42. The Plan specifies in policy where records of evaluation and	
	re-evaluations of level of care are maintained and exchanged with	
	the CARES unit.	
	-Case notes including documentation of the type of contact made	
	with the enrollee and/or all other persons who may be involved	
	with the enrollee's care (e.g., providers)	
	-Copy of the contingency plan and other documentation that	
	indicates the enrollee/authorized representative has been advised	
	regarding how to report unplanned gaps in authorized service	
	delivery; copy of the disaster/emergency pan for the enrollee's	
	household that considers the special needs of the enrollee.	
	-Documentation of choice between institutional, home and	
	community based services (HCBS).	
	-Evidence of Care for Older Adults (COA) documentation	
	-Documentation of choice between institutional and home and	
	community based services.	
	-Evidence of Timelines of LTC CM communication of all	
	admissions, discharges and ER visits within 48-hours.	

	Behavioral Health
Element	Standard
emographic Data	Complete Administrative Component.
Contact information	Emergency Contact Information; Guardian Contact, if
	applicable. Consent for Behavioral Health treatment that is signed by the
Consent	recipient or the recipient's legal guardian. An explanation must be
	provided for signatures omitted in situations of exception.
- 1 /	
Evaluation/Assessment	<u>Evidence of evaluation or assessment that is signed by the</u> recipient or legal guardian, if applicable. Evaluation contains:
	Components of a brief behavioral health status exam; Evaluation
	is conducted by a physician, psychiatrist, a licensed practitioner of
	the healing arts (LPHA), or master's level certified addictions
	professional (CAP) for diagnostic and treatment planning
	purposes.
	-For new admissions, the evaluation or assessment by an LPHA for
	treatment planning purposes must have been completed within
	the past six months;
	-Copies of relevant assessments, reports, and tests;
	-Service notes (progress toward treatment plans and goals)
	-Documentation of service eligibility, if applicable.
	-Current treatment plans (within the last six months)
	-Current treatment Plan reviews and addenda.
	-Copies of all certification forms (e.g., comprehensive behavioral
	health assessment).
	-The practitioner's orders and results of diagnostic and laboratory
	tests.
	-Documentation of medication assessment, prescriptions and
	medication management
	-Copy of the Preadmission Screening and Resident Review (PASRR)
	Level I and II present on the record, if applicable.
Service Documentation	Recipient's Name; Date the service was rendered; Start and
	end times; Identification of the setting in which the service was
	rendered; Identification of the specific problem, behavior, or skill
	<u>deficit for which the service is being provided; Identification of the</u>
	service rendered.
	<u>Updates regarding the recipient's progress toward meeting</u>
	treatment related goals and objectives addressed during the
	provision of a service.
	-Dated signature of the individual who rendered the service
	-Printed or stamped name identifying the signature of the
	individual who rendered the service and the credentials (e.g., licensed clinical social worker) or functional title (e.g., treating
	practitioner)
<u> Felemedicine</u>	If telemedicine, services must be delivered from a facility
	enrolled in Medicaid as a community behavioral health services
	<u>provider.</u>

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	Behavioral Health – cont'd.	
Element	<u>Standard</u>	
Presenting Problems	Presenting problems, along with relevant psychological and	
	social conditions affecting the enrollee's medical and psychiatric	
	status, are documented in the treatment record; relevant medical	
	conditions are listed, prominently identified, and revised as	
	appropriate in the treatment record.	
	-Special status situation, such as suicidal ideation, or elopement	
	potential, are prominently noted, documented and revised in the	
	treatment record in compliance with Amerigroup Florida written	
	protocols.	
Allergies	Allergies, adverse reactions or no known allergies are clearly	
	documented in the treatment record.	
Modical History	A modical and psychiatric history is desumented in the	
Medical History	A medical and psychiatric history is documented in the treatment record, including previous treatment dates, provider	
	identification, therapeutic interventions and responses, sources of	
	clinical data, relevant family information, results of laboratory	
	tests, and consultation reports. This should include history of	
	trauma, assessment of suicide risk and risk for aggressive behavior	
	and history of psychiatric hospitalization and ED visits for	
	psychiatric issues.	
Enrollees 12 and older	<u>Documentation in the treatment record includes past and</u>	
	present use of cigarettes and alcohol as well as illicit, prescribed,	
	and over-the-counter drugs. N/A if the enrollee is under the age of	
	twelve.	
	-A mental status evaluation that includes the enrollee's affect,	
	speech, mood, thought content, judgment, insight, attention,	
	concentration, memory and impulse control is documented in the	
	treatment record.	
	-A DSM-V/ICD10 diagnosis, consistent with the presenting	
	problems, history, mental status examination, and/or other	
	assessment data is documented in the treatment record	
	-Treatment plans are consistent with diagnoses and have both	
	objective measurable goals and estimated time frames for goal	
	attainment or problem resolution. -The focus of treatment interventions is consistent with the	
	treatment plan goals and objectives.	
Records	Each treatment record indicates what medications have been	
NECUIUS	prescribed, the dosages of each, and the dates of initial	
	prescription or refills. For non-prescribing practitioners, each	
	treatment record indicates what medications have been	
	prescribed and the name of the prescriber. N/A is scored if	
	medications are not prescribed.	
Informed Consent		
Informed Consent	Informed consent for medication and the enrollee's level of	
	understanding is documented. N/A if medication is not prescribed	
	or the practitioner being reviewed is not a prescriber (e.g., MSW,	
	PhD)	

Standard In medication is prescribed, there is evidence of cy among the signs and symptoms, diagnosis, and on prescribed. N/A is scored if medication is not d or the practitioner being reviewed is not a prescriber (V, PhD) ess notes describe enrollee strengths and limitations in treatment plan goals and objectives. lees who become homicidal, suicidal, or unable to activities of daily living are promptly referred to the activities of daily living are promptly referred to the activities of daily living are promptly referred to the activities of daily living. It is scored if the enrollee is not activities of daily living. It is extended to conduct activities of daily living. It is extended to conduct activities of daily living. It is extended to comments preventive services, as a state (e.g. relapse prevention, stress management, programs, lifestyle changes, and referrals to community (s). It is the conduct activities of daily living the strength of the community of the community of the conduct activities of daily living. The activities of the conduct activities of daily living. The activities of the conduct activities of daily living. The activities of the conduct activities of daily living. The activities of the conduct activities of daily living. The activities of the conduct activities of daily living. The activities of the conduct activities of daily living. The activities of the conduct activities of daily living. The activities of the conduct activities of daily living. The activities of the conduct activities of daily living. The activities of the conduct activities of daily living. The activities of the conduct activities of the	
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ion of care between behavioral healthcare institutions,	
providers and or consultants; There is evidence in the	
coordination of care with the PCP or declination of this	
ion by the enrollee.;	
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r outpatient behavioral health practitioners	
rd reflects evidence of coordination with the	
<u>loyer if a referral was made; The record reflects linking to</u>	<u>)</u>
ty services or other support services.	
nce that suspected or reported vulnerable adult/child	
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the provider screened enrollees for signs of domestic	
the provider screened enrollees for signs of domestic and provided referral services to applicable domestic-	
e r	ence that suspected or reported vulnerable adult/child reported to the appropriate authorities.; Evidence that was notified within 24-hours of awareness of incident;

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<u>Beha</u>	avioral Health – cont'd.	
Element	<u>Standard</u>	
Child and adolescents		
Records Only	For children and adolescents, prenatal and perinatal events,	
	along with a complete developmental history including physical,	
	psychological, social, intellectual, and academic are documented	
	in the treatment record. N/A if the enrollee is over the age of 18.	
	-The record reflects the active involvement of the family/primary	
	caretakers in the assessment and treatment of the enrollee,	
	unless contraindicated.	
	-The record indicates the parent(s) or caretaker(s) have given	
	signed consent for the various treatments provided.	
	- The record shows evidence of an assessment of school	
	<u>functioning.</u>	
	-The record shows evidence of coordination with the youth's	
	school to achieve school related treatment goals.	
	-Documentation of the express written and informed consent of	
	the enrollee's authorized representative for prescriptions for	
	psychotropic medication (i.e., antipsychotics, antidepressants,	
	antianxiety medications, and mood stabilizers) prescribed for an	
	enrollee under the age of thirteen (13) years.	
Treatment Record-Based Adherence	Score these items if the diagnosis for any case reviewed is in	
Indicators	the 295, 296.2, 296.0x, 296.40, 296.4x, 296.5x, 296.6x, 296.7,	
	296.89 or 314 series. Data related to these adherence indicators	
	is used only in the aggregate – it does not enter into the total	
	score/evaluation of the records of this individual practitioner but	
	the results are shared with the practitioner.	
Major Depression – 296.2 or 296.3 Series	Evidence of a comprehensive assessment that takes into	
	account both the degree of functional impairment and /or	
	disability associated with the depression and the duration of	
	episode, history of depression and comorbid mental health or	
	physical disorders, any past history of mood elevation, any past	
	experience of, and response to treatments, the quality of	
	interpersonal relationships, living conditions and social isolation,	
	culture, social determinants and support system.	
	OB/GYN and maternity history, if applicable.	
	Evidence of substance use/abuse screening.	
	Mood symptoms and suicidality are assessed at every visit; Co-	
	morbid problems are assessed upon initial evaluation and at least	
	annually; When medication is prescribed, there is evidence of	
	consistency among the signs and symptoms, diagnosis, and	
	medication prescribed. N/A if medication is not prescribed or the	
	practitioner being reviewed is not a prescriber (e.g. MSW, PhD)	
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<u>Beha</u>	avioral Health – cont'd.	
<u>Element</u>	<u>Standard</u>	
Schizophrenia – 295 Series	There is evidence of an assessment of positive signs of	
	psychosis, e.g., delusions and/or hallucinations.	
	-Co-morbid problems are assessed upon initial evaluation and at	
	<u>least annually</u>	
	-When medication is prescribed, there is evidence of consistency	
	among the signs and symptoms, diagnosis, and medication	
	prescribed. N/A if medication is not prescribed or the practitioner	
	being reviewed is not a prescriber (e.g., MSW, PhD)	
	-When anti-psychotic medications are prescribed, there is	
	evidence of observation for side effects including EPS such as	
	dystonic reactions, akathisia, ("can't sit still"), or akinesia. {Note:	
	this applies to all discipline levels; N/A may not be checked)	
ADHD- 314.00; 314.01; 314.9	-The record reflects the active involvement of the	
	family/primary caregivers in the assessment and treatment of the	
	enrollee unless contraindicated. N/A is scored if contraindicated.	
	-Co-morbid problems are assessed upon initial evaluation and at	
	<u>least semi-annually.</u>	
	-The record reflects education about ADHD and parent training in	
	behavioral management.	
	-When medication is prescribed, there is evidence of consistency	
	among the signs and symptoms, diagnosis, and medication	
	prescribed. N/A is scored if medication is not prescribed or the	
	practitioner being reviewed is not a prescriber (e.g., MSW, PhD)	
	-When medication is prescribed, there is evidence of an evaluation	
	of the enrollee's response to medication and adjustments as	
	needed.	
Bipolar Disorder - 296.0x, 296.40, 296.4x,	Mood symptoms and suicidality are assessed at every visit;	
296.5x, 296.6x, 296.7, 296.89 Series	-Co-morbid problems are assessed upon initial evaluation and at	
	least annually.	
	-When medications are prescribed that require serum level	
	monitoring and/or laboratory tests to screen for medication side	
	effects, those tests are conducted as recommended by the drug	
	manufacturer. N/A is scored for non-prescribing practitioners (e.g.	
	MSW, PhD).	
Diabetes Screening/Monitoring and	-There is evidence of diabetes screening for people with	
Cardiovascular Disease for Patients with	schizophrenia or bipolar disorder who are using antipsychotic	
Schizophrenia or Bipolar Disorder	-There is evidence of care coordination with PCP/Specialist	
	treating the diabetes to ascertain appropriate monitoring -There is evidence of care coordination with PCP/Specialist	
	treating cardiovascular disease for patients with schizophrenia or	
	bipolar disorder.	
	<u>Dipolar disorder.</u>	

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	Behavioral Health – cont'd.	
Element	<u>Standard</u>	
Co-Occurring Psychiatric and Substance Relate		
List One – Psych Diagnoses	List Two – SA Diagnoses	
Major Depression – 296.XX	Psychoactive Substance	
Bipolar Disorder – 296.XX	Intoxication and Withdrawal 292.XX	
Schizophrenia – 295.XX	Psychoactive SA Induced Disorders 292.XX	
Depressive Disorder NOZ – 311	Psychoactive Substance Dependence 304.XX	
	Psychoactive Substance Abuse 305.XX	
	- Follow-up after discharge from inpatient care within 7 days	
	- Treatment plan includes identification of barriers to	
	adherence and interventions that address these barriers.	
	 Treatment plan includes relapse plan, including identification 	
	of relapse triggers, skills needed to deal with triggers, and	
	contingency plan for difficult instances	
	 Treatment plan includes both SA and psychiatric issues and 	
	<u>interventions</u>	
Opioid-Related Disorders –	Withdrawal evaluation completed within 24 hours to	
304.00, 305.50, 292.89x, 292.81x	determine the level of detoxification services needed (level I D	
	through level IV D, refer to ASAM PPC-2	
	-The evaluation includes the documentation of consideration of	
	appropriate pharmacotherapy for substance abuse disorder.	
	Rationale is provided for each component of the treatment plan	
	including additional medications	
	-Co-occurring) disorders should be assessed to identify both	
	medical and psychiatric symptoms, which may be masked by	
	substance abuse. If a co-occurring disorder is present, there must	
	be evidence of coordination of care with the medical provider.	
	<u>-Evaluation of behaviors correlated with continues use and abuse</u>	
	of illicit drugs	
	-Family/support system involvement in treatment, when	
	appropriate.	
Sc	ocial Determinants of Health	
Element	<u>Standard</u>	
Economic stability	Evidence of screening for financial problems, housing, living	
	situation, utility needs and employment. Food insecurity/	
	Transportation Needs.	
Education	Level of education, language and literacy.	
Social and community context	Civic participation, discrimination and incarceration.	
Health and health care	Medical problems/illnesses/Hospitalizations/Surgeries/	
	Infectious Diseases/Gynecological Conditions/Infertility/ Mental	
	Health disorders/Screening for Depression/ Stress/Substance	
	Abuse/Violence/Domestic Violence/ Serious accidents/	
	Disabilities/Access to primary care and health literacy. Physical	
	activity	
Neighborhood and built environment	Family and community support, environmental conditions,	
Technoon and bant chanolinent	crime and violence.	
	ornic and violence.	

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	<u>COVID-19</u>	
<u>Element</u>	<u>Standard</u>	
<u>Population</u>	Age 65 years or older	
Past medical history	Immunocompromised /Special Healthcare Needs/Disabilities	
Signs and Symptoms	Cough, fever, shortness of breath, mild/severe	
<u>Exposure</u>	Recent travel, hospitalization, facility/other exposure from family member/caregiver	
Testing	Type of test used (Viral/Antibody test), Result/Referral, Repeated test.	
Quarantine & Isolation	Advised to home quarantine	
Positive Covid-19	Confirmed positive result	
Hospitalization & treatment	Documentation of hospital admission, ER visit, treatment and a copy of the Hospital and D/C records must be place in the Medical Records	
Element	<u>Cognitive Assessment</u> <u>Standard</u>	
Cognitive Assessment	Evidence that cognitive assessment tools have been used to identify cognitive impairments and determine whether a full dementia evaluation is needed to assess for a possible dementia syndrome.	

References:

Condition/disease	Guideline title	Recognized source(s)	<u>URL</u>
ADULT HEALTH			
Alzheimer's Disease/Dementia	Practice Guideline for the Treatment of Patients with Alzheimer's Disease and Other Dementias (Guideline Watch October 2014)	American Psychiatric Association (APA)	https://psychiatryonline.org/pb/assets/raw/sit ewide/practice_guidelines/guidelines/alzheime rwatch.pdf
<u>Anxiety</u>	Anxiety Disorders (Last Revised July 2018)	National Institute of Mental Health (NIMH)	http://www.nimh.nih.gov/health/publications/ anxiety-disorders/treatment-of-anxiety- disorders.shtml
<u>Asthma</u>	Guidelines for the Diagnosis and Management of Asthma (EPR-3) (August 2007)	National Heart, Lung and Blood Institute (NHLBI)	https://www.nhlbi.nih.gov/health- topics/guidelines-for-diagnosis-management- of-asthma
<u>Asthma</u>	Asthma Clinical Practice Guidelines (2019)	Global Initiative for Asthma (GINA)	https://ginasthma.org/
Behavioral Health Screening, Assessment and Treatment	The American Psychiatric Association Practice Guidelines for the Psychiatric Evaluation of Adults 3rd edition [August 2015]	American Psychiatric Association (APA)	https://psychiatryonline.org/doi/full/10.1176/ appi.books.9780890426760.pe02
Bipolar Disorder* *addresses diagnosis and treatment of bipolar disorder in special populations such as children and adolescents	CANMAT and International Society for Bipolar Disorders (ISBD) 2018 guidelines for the management of patients with bipolar disorder	Canadian Network for Mood and Anxiety Treatments (CANMAT)	https://www.canmat.org/2019/03/27/2018- bipolar-guidelines
Coronary Artery	AHA / ACCF Secondary Prevention and Risk Reduction Therapy for Patients With Coronary and Other Atherosclerotic Vascular Disease (November 2011 Update)	American Heart Association/ American College of Cardiology Foundation (AHA/ACCF)	https://www.ahajournals.org/doi/pdf/10.1161 /CIR.0b013e318235eb4d
Disease (CAD)	Treatment of Hypertension in Patients With Coronary Artery Disease (March 2015)	American Heart Association, American College of Cardiology, and American Society of Hypertension	https://www.ahajournals.org/doi/pdf/10.1161 /CIR.00000000000000207 https://www.ahajournals.org/doi/pdf/10.1161 /CIR.0b013e318235eb4d

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Condition/disease	Guideline title	Recognized source(s)	<u>URL</u>	
ULT HEALTH - Cont'd				
<u>Disease (CAD)</u> (cont'd)	Effectiveness-Based Guidelines for the Prevention of Cardiovascular Disease in Women- 2011 Update (February 2011)	American Heart Association (AHA)	https://www.ahajournals.org/doi/pdf/10.1161 /CIR.0b013e31820faaf8	
	ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease (2019)	American College of Cardiology/American Heart Association (ACC/AHA)	http://www.onlinejacc.org/content/accj/74/10/e177.full.pdf? ga=2.181326051.571613739.1574282939-178208357.1556140440	
<u>Celiac Disease</u>	ACG Clinical Guidelines: Diagnosis and Management of Celiac Disease (April 2013)	American College of Gastroenterology	http://gi.org/wp- content/uploads/2013/05/ACG Guideline Celi acDisease May 2013.pdf	
	The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI)™ evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD) and related complications	National Kidney Foundation	https://www.kidney.org/professionals/guidelines/guidelines commentaries	
	Chronic Kidney Disease: Detection and Evaluation (2017)	American Academy of Family Physicians (AAFP)	https://www.aafp.org/afp/2017/1215/p776.ht ml	
Chronic Kidney	National Chronic Kidney Disease Fact Sheet (2017)	Centers for Disease Control and Prevention (CDC)	https://www.cdc.gov/diabetes/pubs/pdf/kidne y_factsheet.pdf	
Disease (CKD)	KDIGO (Kidney Disease Improving Global Outcomes) 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (January 2013)	International Society of Nephrology	http://www.kdigo.org/clinical practice guideli nes/pdf/CKD/KDIGO 2012 CKD GL.pdf	
	KDIGO (Kidney Disease Improving Global Outcomes) 2017 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (July 2017)	International Society of Nephrology	https://kdigo.org/wp- content/uploads/2017/02/2017-KDIGO-CKD- MBD-GL-Update.pdf	
Chronic Obstructive Pulmonary Disease (COPD)	Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2019)	Global Initiative for Chronic Obstructive Lung Disease (GOLD)	http://goldcopd.org/gold-reports/	

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Condition/disease	<u>Guideline title</u>	Recognized source(s)	<u>URL</u>	
ADULT HEALTH - Cont'd				
	Depression in Adults: Screening (January 2016) CANMAT Clinicians Guidelines 2016 Depression Guidelines	U.S. Preventive Services Task Force (USPSTF) Canadian Network for Mood and Anxiety Treatments (CANMAT)	https://www.uspreventiveservicestaskforce.o g/Page/Document/UpdateSummaryFinal/depi ession-in-adults-screening1 https://www.canmat.org/resources/	
<u>Depression</u>	Nonpharmacologic Versus Pharmacologic Treatment of Adult Patients With Major Depressive Disorder: A Clinical Practice Guideline From the American College of Physicians (2016)	American College of Physicians (ACP)	https://annals.org/aim/fullarticle/2490527/ng npharmacologic-versus-pharmacologic- treatment-adult-patients-major-depressive- disorder- clinical? ga=2.240375883.977749235.157652 219-1562492790.1557437793	
	Depression in adults: recognition and management Clinical Guideline CG90 (Updated April 2018).	National Collaborating Centre for Mental Health commissioned by the National Institute for Health & Clinical Excellence	https://www.nice.org.uk/guidance/cg90/resorces/depression-in-adults-recognition-and-management-pdf-975742638037	π.
<u>Diabetes</u>	Standards of Medical Care in Diabetes (January 2019)	American Diabetes Association (ADA)	http://care.diabetesjournals.org/content/42/5 upplement 1	
<u>Gender-Dysphoria/</u>	Endocrine Treatment of Gender-Dysphoric/Gender- Incongruent Persons: An Endocrine Society* Clinical Practice Guideline (September 2017)	The Endocrine Society	https://academic.oup.com/icem/article/102/1 1/3869/4157558	
<u>Incongruence</u>	Correction to Clinical Practice Guideline (February 2018)		https://academic.oup.com/icem/article/103/2699/4675081	21
	Correction to Clinical Practice Guideline (July 2018)		https://academic.oup.com/jcem/article/103/7 2758/5036711	<u>"</u>
	Falls Prevention in Community- Dwelling Older Adults: Interventions	U.S. Preventive Services Task Force (USPSTF)	https://www.uspreventiveservicestaskforce.o g/Page/Document/RecommendationStatement tFinal/falls-prevention-in-older-adults- interventions1	_
<u>Fall Risk</u>	Evidence –Based Falls Prevention Programs: Resources for Professionals and Advocates	National Council on Aging	https://www.ncoa.org/center-for-healthy- aging/falls-resource-center/falls-prevention- tools-and-resources/resources-for- professionals/	
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Condition/disease	Guideline title	Recognized source(s)	<u>URL</u>	offilacted: Normal
ADULT HEALTH - Cont'd				
Heart Failure (HF)	2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines (October 2013)	American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines/ Heart Failure Society of America (ACCF/ AHA/HFSA)	http://www.onlinejacc.org/content/62/16/e 7?ijkey=079f90818917662ed8e6c54bd132bb 0bede26a1&keytype2=tf_ipsecsha	
	ACCF/AHA/HFSA Guideline for the Management of Heart Failure (Focused Update 2017)		http://www.onlinejacc.org/content/70/6/77 ga=2.23313085.667318568.1514996759- 679389624.1511900706	<u>167</u>
<u>Hyperlipidemia</u>	2018 AHA/ACC/AACVPR/AAPA/ABC/ ACPM/ADA/AGS/APhA/ASPC,N LA/PCNA Guideline on the Management of Blood Cholesterol (October 2018)	American College of Cardiology/American Heart Association/ American Association of Cardiovascular and Pulmonary Rehabilitation/American Academy of Physician Assistants/Association of Back Cardiologists/American College of Preventive Medicine/American Diabetes Association/American Geriatrics Society/American Pharmacists Association/American Society of Preventive Cardiology/National Lipid Association/Preventive Cardiovascular Nurses Association (ACC/AHA/AACVPR/AAPA/ABC/AC PM/ADA/AGS/APhA/ASPC/NLA/PC NA)	https://www.acc.org/~/media/Non- Clinical/Files-PDFs-Excel-MS-Word- etc/Guidelines/2018/Guidelines-Made-Simpl Tool-2018-Cholesterol.pdf	l <u>e-</u>
<u>Hypertension</u>	ACC/AHA/AAPA/ABC/ACPM/A GS/APhA/ASH/ASPC/NMA/PCN A Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults (November 2017) Correction to Guideline (May 2018)	American College of Cardiology (ACC)/ American Heart Association (AHA)/ American Academy of Physician Assistants (AAPA)/ Association of Black Cardiologists (ABC)/ American College of Preventive Medicine (ACPM)/ American Geriatrics Society (AGS)/ American Pharmacists Association (APhA)/ American Society of Hypertension (ASH)/ American Society for Preventive Cardiology (ASPC)/ National Medical Association (NMA)/ Preventive Cardiovascular Nurses Association (PCNA)	http://www.onlinejacc.org/content/early/20/11/04/i.jacc.2017.11.006?sso=1&sso_redire_count=1&access_token= http://www.onlinejacc.org/content/71/19/25	ect

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Condition/disease	Guideline title	Recognized source(s)	<u>URL</u>	
ADULT HEALTH - Cont'd				
Low back Pain	Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians (2017)	American College of Physicians (ACP)	https://annals.org/aim/fullarticle/2603228/no ninvasive-treatments-acute-subacute-chronic- low-back-pain-clinical- practice? ga=2.247433220.1028399561.15754 92235-1562492790.1557437793	
<u>Obesity</u>	Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults(September 2018) AHA /ACC /TOS Guideline for the Management of Overweight and Obesity in Adults (November 2013)	U.S. Preventive Services Task Force (USPSTF) American College of Cardiology (ACC)/ American Heart Association (AHA) Task Force on Practice Guidelines and The Obesity Society	https://www.uspreventiveservicestaskforce.or g/Page/Document/UpdateSummaryFinal/obesi tv-in-adults-interventions1 http://circ.ahajournals.org/content/early/2013 /11/11/01.cir.0000437739.71477.ee	
Oppositional Defiant Disorder (ODD)	Common Questions About Oppositional Defiant Disorder [April 2016]	(TOS) American Academy of Family Physicians (AAFP)	https://www.aafp.org/afp/2016/0401/p586.pd f	
	Clinical Practice Guideline for the Treatment of Posttraumatic Stress Disorder (PTSD) in Adults (February 2017) VA/DOD Clinical Practice	American Psychiatric Association (APA) Department of Veterans Affairs	https://www.apa.org/ptsd-guideline/ptsd.pdf https://www.healthquality.va.gov/guidelines/	
Posttraumatic Stress Disorder	Guideline for the Management of Posttraumatic Stress Disorder and Acute Stress Disorder (V3.2017)	Department of Defense: The Management of Posttraumatic Stress Disorder Work Group	MH/ptsd	
	PTSD Screening Instruments	Department of Veterans Affairs: PTSD: National Center for PTSD	https://www.ptsd.va.gov/professional/assess ment/screens/index.asp	
Rheumatoid Arthritis	American College of Rheumatology: Referral Guidelines (August 2015) 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis (October 2015)	American College of Rheumatology (ACR)	https://www.rheumatology.org/Portals/0/Files/Referral%20Guidelines.pdf https://www.rheumatology.org/Portals/0/Files/ACR%202015%20RA%20Guideline.pdf	

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Condition/disease	Guideline title	Recognized source(s)	<u>URL</u>
DULT HEALTH - Cont'd			
<u>Schizophrenia</u>	Treatment Guidelines: Schizophrenia	Page maintained by the College of Psychiatric & Neurologic Pharmacists (CPNP). Sources include, but not limited to: • Agency for Health Research and Quality (AHRQ) • American Academy of Child & Adolescent Psychiatry • American Psychiatric Association (APA) • Canadian Psychiatric Association National Institute for Health and Clinical Excellence (NICE) Guidelines	https://cpnp.org/guideline/external/schizophrenia
Sickle Cell Anemia	Evidence-Based Management of Sickle Cell Disease: Expert Panel Report (September 2014)	National Heart, Lung, Blood Institute (NHLBI)	https://www.nhlbi.nih.gov/health- topics/evidence-based-management-sickle- cell-disease
Suicide Risk	SAFE-T: Suicide Assessment Five Step Evaluation and Triage Assessment and Management of Patients at Risk for Suicide (2019)	Suicide Prevention Resource Center (SPRC) Veterans Administration/ Department of Defense (VA/DoD)	https://www.integration.samhsa.gov/images/res/SAFE_T.pdf https://www.healthqualitv.va.gov/guidelines/mh/srb/index.asp
	Surgical technical evidence review for gynecologic surgery conducted for the Agency for Healthcare Research and Quality Safety Program for Improving Surgical Care and Recovery (December 2018) Surgical Technical Evidence Review for Colorectal Surgery	Agency for Healthcare Research and Quality (AHRQ)	https://www.aiog.org/article/50002- 9378(18)30583-0/pdf https://www.ncbi.nlm.nih.gov/pubmed/28797
<u>Surgery</u>	Review for Colorectal Surgery Conducted for the AHRQ Safety Program for Improving Surgical Care and Recovery (October 2017) Surgical Technical Evidence Review for Elective Total Joint Replacement Conducted for the AHRQ Safety Program for Improving Surgical Care and Recovery (February 2018)	<u>AHRQ</u>	https://iournals.sagepub.com/doi/pdf/10.1177 /2151458518754451

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ADULT HEALTH - Cont'd			<u> </u>	
Trauma Care	A Treatment Improvement Protocol: Trauma-Informed Care in Behavioral Health Services (2014)(2014)	Substance Abuse and Mental Health Services Administration (SAMHSA)	https://store.samhsa.gov/system/files/sma14- 4816 litreview.pdf	
	Trauma-Informed Care in Behavioral Health Services: Treatment Improvement Protocol (TIP) Series		https://store.samhsa.gov/series/tip-series- treatment-improvement-protocols-tips	
INFECTIOUS DISEASE – I	Return to Table of content			
<u>Chlamydia/ Human</u> <u>Papillomavirus (HPV)</u>	Sexually Transmitted Diseases Treatment Guidelines	Center for Disease Control and Prevention (CDC)	https://www.cdc.gov/std/tg2015/tg-2015- print.pdf	
	AASLD Guidelines for Treatment of Chronic Hepatitis B (August 2015)	American Association for the Study of Liver Diseases (AASLD)	http://www.aasld.org/sites/default/files/guidel ine_documents/hep28156.pdf	
<u>Hepatitis B</u>	Update on Prevention, Diagnosis, and Treatment of Chronic Hepatitis B: AASLD 2018 Hepatitis B Guidance (Jan 2018)		https://www.aasld.org/sites/default/files/2019 -06/HBVGuidance Terrault et al-2018- Hepatology.pdf	
Hepatitis C	HCV Guidance: Recommendations for Testing, Managing and Treating Hepatitis C	Infectious Diseases Society of America (IDSA)/ American Association for the Study of Liver Disease (AASLD)	http://www.hcvguidelines.org/	
inepatitis C	Guidelines for the Screening, Care and Treatment of Persons with Chronic Hepatitis C Infection (April 2016)	World Health Organization (WHO)	http://apps.who.int/iris/bitstream/handle/106 65/205035/9789241549615 eng.pdf;jsessionid =569946A6B8399B8CED0D09D7F7A9BD3C?seq uence=1	
	Primary Care Guidelines for the Management of Persons Infected With HIV: 2013 Update by the HIV Medicine Association of the Infectious Diseases Society of America (November 2013)	HIV Medicine Association of the Infectious Diseases Society of America (IDSA	https://www.idsociety.org/practice- guideline/primary-care-management-of- patients-infected-with-hiv/	
<u>HIV/AIDS</u>	Recommendations for HIV Prevention with Adults and Adolescents with HIV in the United States (December 2014)	Centers of Disease Control and Prevention (CDC)	https://stacks.cdc.gov/view/cdc/44064	
	2017 HIVMA of IDSA Clinical Practice Guideline for the Management of Chronic Pain in Patients Living With HIV (September 2017)	Infectious Diseases Society of America	https://www.idsociety.org/globalassets/idsa/p ractice-guidelines/2017-hivma-of-idsa-clinical- practice-guideline-for-the-management-of- chronic-pain-in-patients-living-with-hiv.pdf	
	HIV and Adolescents: Guidance for HIV testing and counselling and care for adolescents living with HIV (2013)	World Health Organization (WHO)	http://apps.who.int/iris/bitstream/handle/106 65/94334/9789241506168_eng.pdf?sequence =1	

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Condition/disease	Guideline title	Recognized source(s)	<u>URL</u>	
PEDIATRIC/ADOLESCENT	Г HEALTH (See ADULT HEALTH-Віро	olar Disorder for resources for bipolar	disorder in the pediatric and adolescent	
population) – Return to				
Attention Deficit Hyperactivity Disorder (ADHD)	Clinical Practice Guideline for the Diagnosis. Evaluation, and Treatment of Attention- Deficit/Hyperactivity Disorder in Children and Adolescents (October 2019)	American Academy of Pediatrics (AAP)	https://pediatrics.aappublications.org/content /144/4/e20192528	
<u>Autism</u>	Practice parameter: Screening and diagnosis of autism (Reaffirmed August 2014) Identification Evaluation and Management of Children With Autism Spectrum Disorder (January 2020)	American Academy of Neurology (AAN) and the Child Neurology Society (CNS) American Academy of Pediatrics (AAP)	https://n.neurology.org/content/neurology/55 /4/468.full.pdf https://pediatrics.aappublications.org/content /pediatrics/early/2019/12/15/peds.2019- 3447.full.pdf	
<u>Celiac Disease</u>	Guideline for the Diagnosis and Treatment of Celiac Disease in Children: Recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (January 2005)	North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN)	http://www.naspghan.org/files/documents/pd fs/position- papers/celiac guideline 2004 jpgn.pdf	
<u>Depression</u>	Depression in Children and Adolescents: Screening (February 2016) Depression in children and young people: identification and management (updated September 2017)	U.S. Preventive Services Task Force (USPSTF) National Institute for Health and Care Excellence (NICE)	https://www.uspreventiveservicestaskforce.or g/Page/Document/UpdateSummarvFinal/depr ession-in-children-and-adolescents-screening1 https://www.nice.org.uk/guidance/cg28/resou rces/depression-in-children-and-young-people- identification-and-management-pdf- 975332810437	
Hypertension in Children and Adolescents	Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents (September 2017)	American Academy of Pediatrics (AAP)	http://pediatrics.aappublications.org/content/ pediatrics/140/3/e20171904.full.pdf	
<u>Obesity</u>	Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report (December 2007)	American Academy of Pediatrics (AAP)	http://pediatrics.aappublications.org/content/ 120/Supplement_4/S164.full.pdf	
	Clinical Report: The Role of the Pediatrician in Primary Prevention of Obesity (July 2015)	American Academy of Pediatrics (AAP)	http://pediatrics.aappublications.org/content/ early/2015/06/23/peds.2015-1558	

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Condition/disease	Guideline title	Recognized source(s)	<u>URL</u>
EDIATRIC/ADOLESCEN			disorder in the pediatric and adolescent
Oppositional Defiant Disorder (ODD)	Table of Content. – Cont'd. Fifty years of preventing and treating childhood behavior disorders: a systematic review to inform policy and practice (April 2017)	National Institute of Health (NIH) PubMed	https://www.ncbi.nlm.nih.gov/pmc/articles/ MCS950520/
	rn to Table of Content. – Cont'd.		
	Medication-Assisted Treatment of Adolescents With Opioid Use Disorders (September 2016)	American Academy of Pediatrics (AAP)	http://pediatrics.aappublications.org/conterestry/2016/08/18/peds.2016-1893
	Unhealthy Alcohol Use in Adolescents and Adults: Screening and Behavioral Counseling Interventions (November 2018)	U.S. Preventive Services Task Force (USPSTF)	https://www.uspreventiveservicestaskforce. g/Page/Document/UpdateSummaryFinal/un althy-alcohol-use-in-adolescents-and-adults- screening-and-behavioral-counseling- interventions
	CDC Guideline for Prescribing Opioids for Chronic Pain — United States (March 2016)	Centers for Disease Control and Prevention (CDC)	http://www.cdc.gov/mmwr/volumes/65/rr/s 501e1.htm
Substance use	Medication-Assisted Treatment (MAT) (Last Updated February 2018)	Substance Abuse Mental Health Services Administration (SAMHSA)	http://dpt.samhsa.gov/
	Smoking & Tobacco Use	Center for Disease Control and Prevention (CDC)	https://www.cdc.gov/tobacco/index.htm
	Identifying and Treating Patients Who Use Tobacco (July 2017)	U.S. Department of Health and Human Services	https://millionhearts.hhs.gov/files/Tobacco- Cessation-Action-Guide.pdf
	ACC Expert Consensus Decision Pathway on Tobacco Cessation Treatment (2018)	American College of Cardiology (ACC)	http://www.onlinejacc.org/content/accj/ear 2018/11/29/j.jacc.2018.10.027.full.pdf? ga= 215406675.571613739.1574282939- 178208357.1556140440
Electronic Cigarettes	Electronic Cigarettes	Centers for Disease Control and Prevention (CDC)	https://www.cdc.gov/tobacco/basic informs on/e-cigarettes/index.htm
All states offer free smo	king cessation telephone quit line s	ervices. Dialing 1-800-QUIT NOW will	connect the caller to their state quit line.
	turn to Table of Contents		
Routine Antepartum Care	American Academy of Pediatrics, Guidelines for Perinatal Care, Eighth Edition (September 2017)	American Academy of Pediatrics (AAP) & American Congress of Obstetrics and Gynecology (ACOG)	https://shop.aap.org/guidelines-for-perinata care-8th-edition-ebook/
Preventive Care	Women's Preventive Services Guidelines. (Last Reviewed 2017)	Health Resources and Services Administration (HRSA)	https://www.hrsa.gov/womens-guidelines- 2016/index.html

	Guideline title	Recognized source(s)	<u>URL</u>
OMEN'S HEALTH – Re	eturn to Table of Contents – Cont'd.		
	Women's Health Care Physicians: Cervical Cancer FAQs (December 2015)	American Congress of Obstetrics and Gynecology (ACOG)	https://www.acog.org/Patients/FAQs/Cervical- Cancer
Cancer Screening	Cervical Cancer: Screening (August 2018)	U.S. Preventive Services Task Force (USPSTF)	https://www.uspreventiveservicestaskforce.or g/Page/Document/UpdateSummaryFinal/cervi cal-cancer-screening
	Management of Diabetes in Pregnancy (January 2019)	American Diabetes Association (ADA)	http://care.diabetesjournals.org/content/42/S upplement 1/S165
	Gestational Diabetes Mellitus, Screening (January 2014)	United States Preventive Services Task Force (USPSTF)	https://www.uspreventiveservicestaskforce.or g/Page/Document/UpdateSummaryFinal/gesta tional-diabetes-mellitus- screening?ds=1&s=gestational diabetes
<u>Diabetes and</u> <u>Pregnancy</u>	Gestational Diabetes	American Congress of Obstetrics and Gynecology (ACOG)	http://www.acog.org/Search?Keyword=gestati onal+diabetes
	Postpartum Screening for Abnormal Glucose Tolerance in Women Who Had Gestational Diabetes Mellitus	American Congress of Obstetrics and Gynecology (ACOG)	http://www.acog.org/Search?Keyword=Postpa rtum+Screening+for+Abnormal+Glucose+Toler ance+in+Women+Who+Had+Gestational+Diab etes+Mellitus&Topics=43d4646b-dc34-4c12- abeb-bb516387312f Members only
	Guidelines for Antenatal Care	American Congress of Obstetrics and Gynecology (ACOG)	https://www.acog.org/Search?Keyword=anten atal&Topics=906bff1e-0656-4579-a7df- 4a22f9bce483
Obstetrical Care	WHO recommendations for Prevention and treatment of pre-eclampsia and eclampsia (2011)	World Health Organization (WHO)	http://whqlibdoc.who.int/publications/2011/9 789241548335_eng.pdf
	Committee Opinion 455. Magnesium Sulfate Before Anticipated Preterm Birth for Neuroprotection (Reaffirmed 2018)	American Congress of Obstetrics and Gynecology (ACOG)/ Society for Maternal Fetal Health (SMFH)	https://www.acog.org/Clinical-Guidance-and- Publications/Committee-Opinions/Committee- on-Obstetric-Practice/Magnesium-Sulfate- Before-Anticipated-Preterm-Birth-for- Neuroprotection
	Pre-Gestational Diabetes Mellitus Number 201 (December 2018)	American Congress of Obstetrics and Gynecology (ACOG)	https://www.acog.org/Search?Keyword=prege stational+diabetes Members only
	Management of Preterm Labor Number 171 (Reaffirmed 2018)	American Congress of Obstetrics and Gynecology (ACOG)	http://www.acog.org/Search?Keyword=manag ement+of+preterm+labor Members only
	Gestational Hypertension and Preeclampsia (Jun 2020)	American Congress of Obstetrics and Gynecology (ACOG)	https://www.acog.org/clinical/clinical- guidance/practice- bulletin/articles/2020/06/gestational- hypertension-and-preeclampsia

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WOMEN'S HEALTH - Return	n to Table of Contents – Cont'd.			
Obstetrical Care	Alcohol Abuse and Other Substance Use Disorders: Ethical Issues in Obstetric and Gynecologic Practice. Number 633	American Congress of Obstetricians and Gynecologists (ACOG)	https://www.acog.org/clinical/clinical- guidance/committee- opinion/articles/2015/06/alcohol-abuse-and- other-substance-use-disorders-ethical-issues- in-obstetric-and-gynecologic-practice	
Cont'd.	Guidelines for the identification and management of substance use and substance use disorders in pregnancy (2014)	World Health Organization (WHO)	http://apps.who.int/iris/bitstream/10665/1071 30/1/9789241548731 eng.pdf?ua=1	
	Smoking Cessation During Pregnancy ACOG. Number 721 (October 2017)	American Congress of Obstetrics and Gynecology (ACOG)	https://www.acog.org/Clinical-Guidance-and- Publications/Committee-Opinions/ Committee- on-Obstetric-Practice/ Smoking-Cessation- During-Pregnancy	
Smoking Cessation during Pregnancy	Need Help Putting Out That Cigarette? Smoking Cessation During Pregnancy	American Congress of Obstetrics and Gynecology (ACOG) Obstetrics & Gynecology Journal	http://www.tobacco-cessation.org/ PDFs/NeedHelpBooklet.pdf https://journals.lww.com/greenjournal/Fulltex t/2017/10000/Committee Opinion No 721 Smoking Cessation.58.aspx	

Infection Prevention

For our providers to ensure members are treated in a safe and sanitary environment, you must implement nationally recognized infection control guidelines, such as those through the CDC. The infection prevention program's purpose is to identify and prevent infections and maintain a sanitary practice environment.

Your office staff must be educated on:

- A process for identifying and preventing infections through activities such as proper hand hygiene and safe injection practices.
- A process for the management of identified hazards, potential threats, near misses, and other safety
 concerns; this includes monitoring of products including medications, reagents and solutions that carry an
 expiration date.
- Being aware of and a process for the reporting of known adverse incidents to the appropriate state and federal agencies when required by law to do so.
- A process to reduce and avoid medication errors.
- Prevention of falls or physical injuries involving patients, staff and all others.

You must have a written emergency and disaster preparedness plan to address internal and external emergencies to ensure member safety, including an evacuation plan.

You must provide for accessible and available health services, ensuring information about services when provider practices are not open.

Simply and our providers must comply with applicable state and local building codes and regulations; applicable state and local fire prevention regulations, such as the NFPA 1010 Life Safety Code, 2000 edition, published by the National Fire Protection Association, Inc.; and applicable federal regulations.

Provider practice sites must:

- Contain fire-fighting equipment to control a limited fire, including appropriately maintained and placed fire
 extinguishers of the proper type for each potential type of fire.
- Have prominently displayed illuminated signs with emergency power capability at all exits, including exits
 from each floor or hall.
- Have emergency lighting, as appropriate to the facility, to provide adequate illumination for evacuation of member and staff, in case of an emergency.
- Have stairwells protected by fire doors when applicable.
- Provide examination rooms, dressing rooms and reception areas that are constructed and maintained in a manner ensuring member privacy during interviews, examinations, treatment and consultation.
- Operate in a safe and secure manner.
- Have provisions to reasonably accommodate disabled individuals.
- Have provisions to safeguard member privacy, accessibility and member rights.
- Ensure they have the necessary personnel, equipment, supplies and procedures to deliver safe care and handle medical and other emergencies that may arise.
- Hold periodic drills and have periodic instruction of all staff in the proper use of safety, emergency and fireextinguishing equipment.
- Ensure that staff has been trained on infection control, OSHA and Universal Precautions.
- Establish a safety program and an emergency disaster plan.

These items will be reviewed during site review for each cycle of credentialing and recredentialing. All items will be scored using the practitioner site office tool.

Risk Management

Risk management is defined as the identification, investigation, analysis and evaluation of risks and the selection of the most advantageous method of correcting, reducing or eliminating identifiable risks.

Our risk management program is intended to protect and conserve the human and financial assets, public image and reputation of the provider of care and/or the organization from the consequences of risks associated with members, visitors and employees at the lowest reasonable cost:

- To minimize the incidents of legal claims against the provider of care and/or organization.
- To enhance the quality of care provided to members.
- To control the cost of losses.
- To maintain patient satisfaction with the provider of care and the organization.

The scope of the risk management program is organization-wide. Each member of the medical care team has an equally important role to play in minimizing the occurrence of incidents. All providers of care, agents and employees of Simply have the affirmative duty to report adverse or untoward incidents (potential or actual) on an incident report form and to send that report to specific personnel for necessary follow-up.

The activities of the risk manager will contribute to the quality of care and a safer environment for members, employees, visitors and property, as well as to reduce the cost of risk to the provider of care and the organization.

These activities are categorized as those directed toward loss prevention (pre-loss) and those for loss reduction (post-loss).

The primary goal of pre-loss activity is to correct, reduce, modify or eliminate all identifiable risk situations, which could result in claims and litigation for injury or loss. This can be accomplished through:

- Providing ongoing education and training programs in risk management and risk prevention.
- Participating in safety, utilization review, quality assessment and improvement activities.
- Interfacing with the medical staff to ensure communication and cooperation in risk management.
- Exchanging information with professional organizations, peers and other resources to improve and update the program.
- Analyzing member grievances that relate to member care and the quality of medical services for trends and patterns.

The primary goal of post-loss activity is the selection of the most advantageous methods of correcting identifiable risks and claim control. This can be accomplished through an effective and efficient incident reporting system.

Internal Incident Reporting System

All Simply employees are educated on the Internal Incident Reporting System, which establishes the policy and procedure for reporting adverse incidents and includes: the definition of adverse incidents, access to the incident reporting form, appropriate routing and the required time frame for reporting incidents to the risk manager. Provider input and participation in the QM process further emphasizes the identification of potential risks in the clinical aspects of member care.

Definitions

Adverse incident — occurs during the delivery of managed care plan covered services that:

- Are associated in whole or in part with medical intervention rather than the condition for which such intervention occurred.
- Are not consistent with or expected to be a consequence of such service provision.
- Occur as a result of service provision to which the patient has not given his informed consent.
- Occur as a result of any other action or lack thereof on the part of the facility, staff or the provider.
- Causes injury to a member.

Injury — any of the following outcomes when caused by an adverse incident:

- Death
- Fetal death
- Brain damage
- Spinal damage
- Permanent disfigurement
- Fracture or dislocation of bones or joints
- Any condition requiring definitive or specialized medical attention that is not consistent
 with the routine management of the patient's case or patient's preexisting physical condition
- Any condition requiring surgical intervention to correct or control
- Any condition resulting in transfer of the patient, within or outside the facility, to a unit providing a more
 acute level of care

 ${f Critical incident}$ — events that negatively affect the health, safety or welfare of a member, including the following:

- Abuse/neglect/exploitation
- Altercations requiring medical intervention
- Elopement
- Escape

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- Homicide
- Major illness
- Medication errors
- Sexual battery
- Suicide
- Suicide attempt
- Unexpected death

Reporting Responsibilities

- All participating and direct service providers are required to report adverse incidents to the managed care
 plans within 48 hours of the incident. The managed care plan must ensure all participating and direct
 service providers are required to report adverse incidents to the Agency immediately but not more than 24
 hours of the incident. Reporting will include information such as the enrollee's identity, description of the
 incident and outcomes, including the current status of the enrollee.
- Simply will immediately report to the (DCF) any suspected cases of abuse, neglect or exploitation of
 enrollees, in accordance with s.39.201 and Chapter 415, F.S. The DCF Adult Protective Services Program has
 the responsibility for investigating allegations of abuse, neglect and exploitation of elders and individuals
 with disabilities. The Abuse Hotline number is 1-800-96-ABUSE (1-800-96-22873).
- Additionally, Simply reports any adverse and critical incidents to AHCA monthly.

Procedural Responsibilities

- The provider staff member involved in observing or first discovering the unusual incident or a Simply staff
 member who becomes aware of an incident is responsible for initiating the incident report. Reports will be
 fully completed on the incident report form and will provide a clear, concise, objective description of the
 incident. The director of the department involved in observing the risk situation will assist in the
 completion of the form, if necessary.
- All incident reports resulting in serious or potentially serious member harm will be forwarded to the risk manager or risk manager designee immediately.
- Incident reports are logged and date-stamped.
- The National Customer Care department associate is responsible for initiating incident reports for member grievances that relate to an adverse or untoward incident.
- Simply employees refer quality of care and quality of service issues to our QM department. The QM
 department may solicit information from other departments and/or providers during clinical reviews.
- The QM committee will review all pertinent safety-related reports.
- The QM committee, MAC and/or peer review committee will review pertinent member-related reports.
- Documentation related to the suspected abuse, neglect or exploitation, including the reporting of such, must be kept in a file, separate from the enrollee's case file, that is designated as confidential. Such file will be made available to the Agency upon request.
- A member incident report will be kept in a risk management computerized file, and the report will not be
 photocopied or carbon copied. Employees, providers and agents are prohibited from placing copies of an
 incident report in the medical record. Employees, providers and agents are prohibited from making a
 notation in the medical record referencing the filing of an incident report.
- The risk manager will communicate with department directors and managers to provide follow-up as appropriate. If corrective action is needed on the part of a Simply employee, the Human Resources department will execute it.
- The risk manager will follow up on all incidents pertinent to quality to determine causes and possible
 preventive interventions.
- The risk manager will keep statistical data of incidents for analysis purposes.

- The risk manager will keep incident reports in computerized files for no less than 10 years and longer for audits or litigation as specified elsewhere in the MMA contract.
 - Florida Healthy Kids records will be retained for a period of at least ten years following the term of Simply's Florida Healthy Kids contract with Florida Healthy Kids Corporation, except if an audit is in progress or audit findings are yet unresolved, in which case records will be kept until all tasks are completed.

Incident Report Review and Analysis

- The risk manager will review all incident reports and analyze them for trends and patterns. This includes the frequency, cause and severity of incidents by location, practitioner and type of incident.
- The risk manager will have free access to all health maintenance organization or provider medical records.
- The incident reports will be utilized to develop categories of incidents that identify problems.
- Once problems become evident, the risk manager will make recommendations for corrective actions, such as procedure revisions.

An incident report is an official record of the incident and is privileged and confidential in all regards. No copies will be made of any incident report for any reason, other than those situations authorized by applicable law.

Credentialing

Simply credentialing policies and procedures incorporate the current National Committee for Quality Assurance (NCQA) *Standards and Guidelines for the Accreditation of Managed Care Organizations* as well as the Florida Department of Health (FDOH) requirements for the credentialing and recredentialing of licensed independent providers and organizational providers with whom we contract.

Simply will accept the provider's copy of the Council for Affordable Quality Healthcare (CAQH) applications in lieu of a Simply application form.

Each provider agrees to submit for verification all requested information necessary to credential or recredential physicians providing services in accordance with the standards established by Simply. Each provider will cooperate with Simply as necessary to conduct credentialing and recredentialing pursuant to our policies, procedures and rules.

Credentialing Requirements

Each provider, applicable ancillary/facility and hospital will remain in full compliance with the Simply credentialing criteria as set forth in our credentialing policies and procedures and all applicable laws and regulations. Each provider, applicable ancillary/facility and hospital will complete the Simply application form upon request. Each provider will comply with other such credentialing criteria as may be established by Simply.

We're authorized to take whatever steps necessary to ensure each provider is recognized by the state Medicaid program, including its choice counseling/enrollment broker contractor(s) as a participating provider of Simply, and the provider's submission of encounter data is accepted by the Florida Medicaid Management Information Systems and/or the state's encounter data warehouse. Each provider must supply us with his or her active, enrolled or limited-enrolled Medicaid ID number.

Simply requires each provider to have a National Provider Identifier (NPI) in accordance with s. 1173(b) of the Social Security Act, as enacted by s. 4707(a) of the Balanced Budget Act of 1997.

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Credentialing Procedures

- Medical doctors
- Doctors of osteopathy
- Doctors of dental surgery
- Doctors of podiatric medicine
- Doctors of chiropractic
- Physician assistants
- Optometrists
- Dentists

Nurse

Health care practitioners:

Initial applicants must meet the following criteria in order to be considered for participation:

- A. Must not be currently federally sanctioned, debarred or excluded from participation in any of the following programs: Medicare, Medicaid or FEHBP;
- B. Possess a current, valid, unencumbered, unrestricted, and non-probationary license in the state(s) where he or she provides services to Members; and
- C. Possess a current, valid, and unrestricted Drug Enforcement Agency ("DEA") and/or Controlled Dangerous Substances ("CDS") registration for prescribing controlled substances, if applicable to his/her specialty in which he or she will treat Members; the DEA/CDS registration must be valid in the state(s) in which the practitioner will be treating Members. Practitioners who see Members in more than one (1) state must have a DEA/CDS registration for each state.

<u>Initial applications should meet the following criteria in order to be considered for participation, with exceptions reviewed and approved by the CC:</u>

- A. For MDs, DOs, DPMs, and DMDs/DDSs practicing oral and maxillofacial surgery, the applicant must have current, in force board certification (as defined by the American Board of Medical Specialties ("ABMS"), American Osteopathic Association ("AOA"), Royal College of Physicians and Surgeons of Canada ("RCPSC"), College of Family Physicians of Canada ("CFPC"), American Board of Foot and Ankle Surgery ("ABFAS"), American Board of Podiatric Medicine ("ABPM"), or American Board of Oral and Maxillofacial Surgery ("ABOMS") in the clinical discipline for which they are applying.
- B. If not certified, MDs and DOs will be granted five (5) years or a period of time consistent with ABMS or AOA board eligibility time limits, whatever is greater, after completion of their residency or fellowship training program to meet the board certification requirement.
- C. If not certified, DPMs will be granted five (5) years after the completion of their residency to meet this requirement for the ABPM. Non-certified DPMs will be granted seven (7) years after completion of their residency to meet this requirement for ABFAS.
- D. Individuals no longer eligible for board certification are not eligible for continued exception to this requirement.
 - As alternatives, MDs and DOs meeting any one (1) of the following criteria will be viewed as meeting the education, training and certification requirement:

- Previous board certification (as defined by one (1) of the following: ABMS, AOA, RCPSC, CFPC, ABFAS, ABPM, or ABOMS) in the clinical specialty or subspecialty for which they are applying which has now expired and a minimum of ten (10) consecutive years of clinical practice;
- Licensed professional counselors/social workers
- Psychologists
- Physical/occupational therapists
- Speech/language therapists
- Other applicable or appropriate mid-level providers
- Hospitals and allied services (ancillary) providers

During recredentialing, each provider must show evidence of satisfying policy requirements and must have satisfactory results relative to Simply measures of quality of health care and service.

We have a credentialing committee and MAC for the formal determination of recommendations regarding credentialing decisions. The credentialing committee will make decisions regarding participation of initial applicants and their continued participation at the time of recredentialing. The oversight rests with the MAC.

The Simply credentialing policy is revised periodically based on input from several sources, including but not limited to the credentialing committees, the health plan medical director, the Simply chief medical officer, and state and federal requirements. The policy will be reviewed and approved as needed but at a minimum annually.

The provider application contains the provider's actual signature that serves as an attestation of the credentials summarized on and included with the application. The provider's signature also serves as a release of information to verify credentials externally. We are responsible for externally verifying specific items attested to on the application. Any discrepancies between information included with the application and information obtained by Simply during the external verification process will be investigated and documented and may be grounds for refusal of acceptance into the network or termination of an existing provider relationship. The signed agreement documents compliance with Simply managed care policies and procedures.

All providers have the right to inquire about the status of their applications. They may do so by: 1) phone, 2) fax, 3) contact through their Provider Relations representative or 4) in writing.

As an applicant for participation with Simply, each provider has the right to review information obtained from primary verification sources during the credentialing process. Upon notification from Simply, the provider has the right to explain information obtained that may vary substantially from that provided and to provide corrections to any erroneous information submitted by another party. The provider must submit a written explanation or appear before the credentialing committee if deemed necessary.

- a. board certification (as defined by one (1) of the following: ABMS, AOA, RCPSC, CFPC, ABFAS, ABPM, or ABOMS) in the clinical specialty or subspecialty for which they are applying which has now expired and a minimum of ten (10) consecutive years of clinical practice;
- <u>b.</u> Training which met the requirements in place at the time it was completed in a specialty
 field prior to the availability of board certifications in that clinical specialty or
 subspecialty; or
- c. Specialized practice expertise as evidenced by publication in nationally accepted peer review literature and/or recognized as a leader in the science of their specialty and a faculty appointment of assistant professor or higher at an academic medical center and teaching facility in Simply network and the applicant's professional activities are spent at that institution at least fifty percent (50%) of the time.

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- Practitioners meeting one (1) of these three (3) alternative criteria (a, b, c) will be viewed as
 meeting all Simply education, training and certification criteria and will not be required to
 undergo additional review or individual presentation to the CC. These alternatives are subject to
 Simply review and approval. Reports submitted by delegates to Simply must contain sufficient
 documentation to support the above alternatives, as determined by Simply.
- E. For MDs and DOs, the applicant must have unrestricted hospital privileges at a The Joint Commission ("TJC"), National Integrated Accreditation for Healthcare Organizations ("NIAHO"), Center for Improvement in Healthcare Quality ("CIHQ"), a Healthcare Facilities Accreditation Program ("HFAP") accredited hospital, or a Network hospital previously approved by the committee. Some clinical disciplines may function exclusively in the outpatient setting, and the CC may at its discretion deem hospital privileges not relevant to these specialties. Also, the organization of an increasing number of physician practice settings in selected fields is such that individual physicians may practice solely in either an outpatient or an inpatient setting. The CC will evaluate applications from practitioners in such practices without regard to hospital privileges. The expectation of these physicians would be that there is an appropriate referral arrangement with a Network practitioner to provide inpatient care.
- F. For Genetic Counselors, the applicant must be licensed by the state to practice independently. If the state where the applicant practices does not license Genetic Counselors, the applicant must be certified by the American Board of Genetic Counseling or the American Board of Genetics and Genomics.

II. Criteria for Selecting Practitioners

- A. New Applicants (Credentialing)
 - Submission of a complete application and required attachments that must not contain intentional misrepresentations or omissions;
 - Application attestation signed date within one hundred eighty (180) calendar days of the date of submission to the CC for a vote;
 - Primary source verifications within acceptable timeframes of the date of submission to the CC for a vote, as deemed by appropriate accrediting agencies;
 - No evidence of potential material omission(s) on application;
 - Current, valid, unrestricted license to practice in each state in which the practitioner would provide care to Members;
 - 6. No current license action;
 - 7. No history of licensing board action in any state;
 - No current federal sanction and no history of federal sanctions (per System for Award Management ("SAM"), OIG and OPM report nor on NPDB report);
 - 9. Possess a current, valid, and unrestricted DEA/CDS registration for prescribing controlled substances, if applicable to his/her specialty in which he or she will treat Members. The DEA/CDS registration must be valid in the state(s) in which the practitioner will be treating Members. Practitioners who treat Members in more than one (1) state must have a valid DEA/CDS registration for each applicable state.

Initial applicants who have no DEA/CDS registration will be viewed as not meeting criteria and the credentialing process will not proceed. However, if the applicant can provide evidence that he or she has applied for a DEA/CDS registration, the credentialing process may proceed if all of the following are met:

It can be verified that this application is pending.

- The applicant has made an arrangement for an alternative practitioner to prescribe controlled substances until the additional DEA/CDS registration is obtained. If the alternate provider is a practice rather than an individual, the file may include the practice name. The Company is not required to arrange an alternative prescriber;
- c. The applicant agrees to notify Simply upon receipt of the required DEA/CDS registration.
- d. Simply will verify the appropriate DEA/CDS registration via standard sources.
 - The applicant agrees that failure to provide the appropriate DEA/CDS registration within a ninety (90) calendar day timeframe will result in termination from the Network.
 - i. Initial applicants who possess a DEA certificate in a state other than the state in which they will be seeing Simply's members will be notified of the need to obtain the additional DEA, unless the practitioner is delivering services in a telemedicine environment only and does not require a DEA or CDS registration in the additional location(s) where such telemedicine services may be rendered under federal or state law. If the applicant has applied for an additional DEA registration the credentialing process may proceed if all the following criteria are met:
 - (a) It can be verified that the applicant's application is pending; and
 - (b) The applicant has made an arrangement for an alternative provider to prescribe controlled substances until the additional DEA registration is obtained; and
 - (c) The applicant agrees to notify Simply upon receipt of the required DEA registration; and
 - (d) Simply will verify the appropriate DEA/CDS registration via standard sources; and
 - (e) The applicant agrees that failure to provide the appropriate DEA registration within a ninety (90) day timeframe will result in termination from the network.
 - <u>iii.</u> Practitioners who voluntarily choose to not have a DEA/CDS registration if that practitioner certifies the following:
 - (a) controlled substances are not prescribed within his/her scope of practice; or in their professional judgement, the patients receiving their care do not require controlled substances and
 - (b) he or she must provide documentation that an arrangement exists for an alternative provider to prescribe controlled substances should it be clinically appropriate. If the alternate provider is a practice rather than an individual, the file may include the practice name. The Company is not required to arrange an alternative prescriber; and
 - (c) DEA/CDS registration is or was not suspended, revoked, surrendered or encumbered for reasons other than those aforementioned.
- No current hospital membership or privilege restrictions and no history of hospital membership or privileges restrictions;
- 11. No history of or current use of illegal drugs or history of or current alcoholism;
- 12. No impairment or other condition which would negatively impact the ability to perform the essential functions in their professional field.
- 13. No gap in work history greater than six (6) months in the past five (5) years with the exception of those gaps related to parental leave or immigration where twelve (12) month gaps will be acceptable and viewed as "Level I". Other gaps in work history of six (6) months to five (5) years will be reviewed by the chair/vice-chair of the geographic CC and may be presented to the

- geographic CC if the gap raises concerns of future substandard Professional Conduct and Competence. In the absence of this concern the chair/vice-chair of the CC may approve work history gaps up to five (5) years:
- 14. No convictions, or pleadings of guilty or no contest to, or open indictments of, a felony or any offense involving moral turpitude or fraud. In addition, no other criminal or civil litigation history that together with any other relevant facts, raises a reasonable suspicion of future substandard professional conduct and/or competence. A minimum of the past ten (10) years of malpractice case history is reviewed.
- 15. Meets Credentialing Standards for education/training for the specialty(ies) in which practitioner wants to be listed in Simply's Network directory as designated on the application. This includes board certification requirements or alternative criteria for MDs and DOs and board certification criteria for DPMs, and oral and maxillofacial surgeons;
- 16. No involuntary terminations from an HMO or PPO;
- 17. No "yes" answers to attestation/disclosure questions on the application form with the exception of the following:
 - a. Investment or business interest in ancillary services, equipment or supplies;
 - Voluntary resignation from a hospital or organization related to practice relocation or facility utilization;
 - c. Voluntary surrender of state license related to relocation or nonuse of said license;
 - d. An NPDB report of a malpractice settlement or any report of a malpractice settlement that does not meet the threshold criteria;
 - Non-renewal of malpractice coverage or change in malpractice carrier related to changes in the carrier's business practices (no longer offering coverage in a state or no longer in business);
 - f. Previous failure of a certification exam by a practitioner who is currently board certified or who remains in the five (5) year post residency training window;
 - Actions taken by a hospital against a practitioner's privileges related solely to the failure to complete medical records in a timely fashion;
 - History of a licensing board, hospital or other professional entity investigation that was closed without any action or sanction.

National Provider Identifier (NPI) — Simply requires each provider to have a National Provider Identifier (NPI) in accordance with s. 1173(b) of the Social Security Act, as enacted by s. 4707(a) of the Balanced Budget Act of 1997.

Currently, the following verifications are completed, as applicable, prior to final submission of a practitioner file to the health plan medical director or credentialing committee. To the extent allowed under applicable law or state agency requirements, per NCQA standards and guidelines, the medical director has authority to approve clean files without input from the credentialing committee. All files not designated as a clean file will be presented to the credentialing committee for review and decision regarding participation.

In addition to the submission of an application and the execution of a Participating Provider Agreement, the following must be reviewed and approved by the credentialing committee or the medical director:

- 9. Board certification Verification by referencing the American Medical Association Provider Profile, American Osteopathic Association, the American Board of Medical Specialties, American Board of Podiatric Surgery, and/or American Board of Podiatric Orthopedics and Primary Podiatric Medicine. PCP does not achieve board certification within the first three years of initial credentialing for Florida Healthy Kids, insurer must remove the PCP from its FHKC panel and reassign any Florida Healthy Kids provider or present the provider to Florida Healthy Kids for review under the exemption process.
- 10. Verification of education and training Verification by referencing board certification or the appropriate state licensing agency. Proof of the provider's medical school graduation, completion of residency or other

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- 11. Verification of work history The practitioner must submit a curriculum vitae documenting work history for the past five years. Any gaps in work history greater than six months must be explained in written format and brought to the attention of the medical director and credentialing committee as applicable.
- 12. Hospital affiliations and privileges To the extent allowed under applicable law or state agency requirements, verification of clinical privileges in good standing at a Simply network hospital may be accomplished by the use of an attestation signed by the provider. If attestation is not acceptable, hospital admitting privileges in good standing are verified for the practitioner. This information is obtained in the form of a written letter from the hospital, roster format (multiple practitioners), internet access or by telephone contact. The date and name of the person spoken to at the hospital are documented.
- 13. State licensure or certification Verification of state license information to ensure that the practitioner maintains a current legal license or certification to practice in the state. This information can be verified by referencing data provided to Simply by the state via roster, telephone or the internet.
- 14. DEA number Verification of the Drug Enforcement Administration (DEA) number to ensure the practitioner is currently eligible to prescribe controlled substances. This information is verified by obtaining a copy of the DEA certificate or by referencing the National Technical Information Service (NTIS) data. If the practitioner is not required to possess a DEA certificate but does hold a state controlled substance certificate, the Controlled Dangerous Substance (CDS) certificate is verified to ensure the practitioner is currently eligible to prescribe controlled substances. This information is verified by obtaining a copy of the CDS certificate or by referencing CDS online or internet data, if applicable.
- 15. Professional liability coverage To the extent allowed under applicable law or state agency requirements, verification of malpractice coverage may be accomplished by the use of an attestation signed by the provider indicating the name of the carrier, policy number, coverage limits, and the effective and expiration dates of such malpractice coverage. If attestation is not acceptable, the practitioner's malpractice insurance information is verified by obtaining a copy of the professional liability insurance face sheet from the practitioner or from the malpractice insurance carrier. Practitioners are required to maintain professional liability insurance in specified amounts.
- 16. Professional liability claims history Verification of an applicant's history of professional liability claims, if any, reviewed by our credentialing committee to determine whether acceptable risk exposure exists. The review is based on information provided and attested to by the applicant and information available from the National Practitioner's Data Bank (NPDB). The credentialing committee's policy is designed to give careful consideration to the medical facts of the specific cases, total number and frequency of claims in the past five years, and the amounts of settlements and/or judgments.
- 17. CMS sanctions Verification that the practitioner's record is clear of any sanctions by CMS. This information is verified by accessing the NPDB.
 - 18. National Provider Identifier (NPI) Simply requires each provider to have a National Provider Identifier (NPI) in accordance with s. 1173(b) of the Social Security Act, as enacted by s. 4707(a) of the Balanced Budget Act of 1997.
 - 19. Verification of Medicaid Eligibility Simply will ensure that providers are eligible for participation in the Medicaid program, consistent with provider disclosure, screening, and enrollment requirements.
 - 20. Active_Patient Load Attestation Attestation that the total active patient load (all populations, including but not limited to Medicaid FFS, Children's Medical Services, SMMC plans, Medicare, KidCare, and commercial coverage) is no more than 3,000 patients per physician. An active patient is one that is seen by the provider a minimum of two times per year.
 - 23.21. Office location review At the time of initial credentialing, for PCPs and high-volume specialists, a Simply provider representative will complete a site visit for each office location of all providers to determine whether the provider's office can accommodate the members and meets all requirements.

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- 23.21. Office location review At the time of initial credentialing, for PCPs and high-volume specialists, a Simply provider representative will complete a site visit for each office location of all providers to determine whether the provider's office can accommodate the members and meets all requirements.
- a. Any history or current problems with chemical dependency or alcohol or substance abuse
- History of license revocations, suspension, voluntary relinquishment, probationary status, or other licensure conditions or limitations
- d. History of conviction of any criminal offense other than minor traffic violations
- e. History of loss or limitation of privileges or disciplinary activity, including denial, suspension, limitation, termination or nonrenewal of professional privileges
- f.— History of complaints or adverse action reports filed with a local, state or national professional society or licensing board
- g. History of refusal or cancellation of professional liability insurance
- History of suspension or revocation of a DEA or CDS certificate
- i. History of any CMS sanctions
- i. Attestation by the applicant of the correctness and completeness of the application
- c. Written explanation of any issue identified; these explanations are presented with the provider's application to the Credentialing Committee
- 22. NPDB The NPDB is queried against applicants and the Simply contracted providers. The NPDB will provide a report for every practitioner queried. These reports are shared with the medical director and the credentialing committee for review and action as appropriate. The Federation of State Medical Boards for doctors of medicine, doctors of osteopathy and physician assistants is queried to verify any restrictions/sanctions made against the practitioner's license. The appropriate state-licensing agency is queried for all other providers. All sanctions are investigated and documented, including the health plan's decision to accept or deny the applicant's participation in the network.
 - 23-21. Office location review At the time of initial credentialing, for PCPs and high-volume specialists, a Simply provider representative will complete a site visit for each office location of all providers to determine whether the provider's office can accommodate the members and meets all requirements.

Note: the CC will individually review any practitioner that does not meet one (1) or more of the criteria required for initial applicants.

- B. Additional Participation Criteria and Exceptions for Behavioral Health practitioners (Non Physician) Credentialing.
 - Licensed Clinical Social Workers ("LCSW") or other master level social work license type:
 - Master or doctoral degree in social work with emphasis in clinical social work from a program accredited by the Council on Social Work Education ("CSWE") or the Canadian Association on Social Work Education ("CASWE");
 - b. Program must have been accredited within three (3) years of the time the practitioner graduated;
 - c. Full accreditation is required, candidacy programs will not be considered; and
 - d. If master's level degree does not meet criteria and practitioner obtained PhD degree as a clinical psychologist, but is not licensed as such, the practitioner can be reviewed. To meet the criteria, the doctoral program must be accredited by the American Psychological Association ("APA") or be regionally accredited by the Council for Higher Education Accreditation ("CHEA"). In addition, a doctor of social work from an institution with at least regional accreditation from the CHEA

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will be viewed as acceptable.

Licensed professional counselor ("LPC") and marriage and family therapist ("MFT") or other master level license type:

- a. Master's or doctoral degree in counseling, marital and family therapy, psychology, counseling psychology, counseling with an emphasis in marriage, family and child counseling or an allied mental field. Master or doctoral degrees in education are acceptable with one (1) of the fields of study above;
- b. Master or doctoral degrees in divinity do not meet criteria as a related field of study;
- c. Graduate school must be accredited by one (1) of the Regional Institutional Accrediting Bodies and may be verified from the Accredited Institutions of Post-Secondary Education, APA, Council for Accreditation of Counseling and Related Educational Programs ("CACREP"), or Commission on Accreditation for Marriage and Family Therapy Education ("COAMFTE") listings. The institution must have been accredited within three (3) years of the time the practitioner graduated;
- d. Practitioners with PhD training as a clinical psychologist can be reviewed. To meet criteria this doctoral program must either be accredited by the APA or be regionally accredited by the CHEA. A Practitioner with a doctoral degree in one (1) of the fields of study noted will be viewed as acceptable if the institution granting the degree has regional accreditation from the CHEA and;
- e. Licensure to practice independently.

3. Clinical nurse specialist/psychiatric and mental health nurse practitioner:

- Master's degree in nursing with specialization in adult or child/adolescent
 psychiatric and mental health nursing. Graduate school must be accredited from
 an institution accredited by one (1) of the Regional Institutional Accrediting
 Bodies within three (3) years of the time of the practitioner's graduation;
- <u>Nurse Registered Nurse license and any additional licensure as an Advanced Practice Nurse/Certified Nurse Specialist/Adult Psychiatric Nursing or other license or certification as dictated by the appropriate State(s) Board of Registered Nursing, if applicable;</u>
- Certification by the American Nurses Association ("ANA") in psychiatric nursing. This may be any of the following types: Clinical Nurse Specialist in Child or Adult Psychiatric Nursing, Psychiatric and Mental Health Nurse Practitioner, or Family Psychiatric and Mental Health Nurse Practitioner; and
- d. Valid, current, unrestricted DEA/CDS registration, where applicable with appropriate supervision/consultation by a Network practitioner as applicable by the state licensing board. For those who possess a DEA registration, the appropriate CDS registration is required. The DEA/CDS registration must be valid in the state(s) in which the practitioner will be treating Members.

4. Clinical Psychologists:

- a. Valid state clinical psychologist license;
- Doctoral degree in clinical or counseling, psychology or other applicable field of study from an institution accredited by the APA within three (3) years of the time of the practitioner's graduation;
- c. Education/Training considered as eligible for an exception is a practitioner whose doctoral degree is not from an APA accredited institution, but who is listed in the National Register of Health Service Providers in Psychology or is a diplomat of the American Board of Professional Psychology; and
- d. Master's level therapists in good standing in the Network, who upgrade their license to clinical psychologist as a result of further training, will be allowed to

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continue in the Network and will not be subject to the above education criteria.

5. Clinical Neuropsychologist:

- Must meet all the criteria for a clinical psychologist listed in B.4 above and be Board certified by either the American Board of Professional Neuropsychology ("ABPN") or American Board of Clinical Neuropsychology ("ABCN");
- A practitioner credentialed by the National Register of Health Service Providers
 ("National Register") in psychology with an area of expertise in neuropsychology
 may be considered; and
- c. Clinical neuropsychologists who are not board certified, nor listed in the National Register, will require CC review. These practitioners must have appropriate training and/or experience in neuropsychology as evidenced by one (1) or more of the following:
 - Transcript of applicable pre-doctoral training;
 - Documentation of applicable formal one (1) year post-doctoral training (participation in CEU training alone would not be considered adequate);
 - iii Letters from supervisors in clinical neuropsychology (including number of hours per week); or
 - iv Minimum of five (5) years' experience practicing neuropsychology at least ten (10) hours per week.

6. Licensed Psychoanalysts:

- a. Applies only to practitioners in states that license psychoanalysts.
- b. Practitioners will be credentialed as a licensed psychoanalyst if they are not
 otherwise credentialed as a practitioner type detailed in Credentialing Policy (e.g.
 psychiatrist, clinical psychologist, licensed clinical social worker).
- <u>c. Practitioner must possess a valid psychoanalysis state license.</u>
 - Practitioner shall possess a master's or higher degree from a program
 accredited by one (1) of the Regional Institutional Accrediting Bodies and
 may be verified from the Accredited Institutions of Post-Secondary
 Education, APA, CACREP, or the COAMFTE listings. The institution must
 have been accredited within three (3) years of the time the practitioner
 graduates.
 - i. Completion of a program in psychoanalysis that is registered by the licensing state as licensure qualifying; or accredited by the American Board for Accreditation in Psychoanalysis (ABAP) or another acceptable accrediting agency; or determined by the licensing state to be the substantial equivalent of such a registered or accredited program.
 - (a) A program located outside the United States and its territories may be used to satisfy the psychoanalytic study requirement if the licensing state determines the following: it prepares individuals for the professional practice of psychoanalysis; and is recognized by the appropriate civil authorities of that jurisdiction; and can be appropriately verified; and is determined by the licensing state to be the substantial equivalent of an acceptable registered licensure qualifying or accredited program.
 - (b) Meet minimum supervised experience requirement for licensure as a psychoanalyst as determined by the licensing state.
 - (c) Meet examination requirements for licensure as determined by the licensing state.
- C. Additional Participation Criteria and Exceptions for Certified Nurse Midwives (Non Physician)
 Credentialing.

1. Process, Requirements and Verifications – Certified Nurse Midwives:

- a. The Certified Nurse Midwife (CNM) applicant will submit the appropriate application and supporting documents as required of any other practitioner with the exception of differing information regarding education, training and board certification.
- b. The required educational/training will be at a minimum that required for licensure as a registered nurse with subsequent additional training for licensure as a Certified Nurse Midwife by the appropriate licensing body. Verification of this education and training will occur either via primary source verification of the license, provided that state licensing agency performs verification of the education, or from the certification board if that board provides documentation that it performs primary verification of the professional education and training. If the state licensing agency or the certification board does not verify education, the education will be primary source verified in accordance with policy.
- c. The license status must be that of CNM as verified via primary source from the appropriate state licensing agency. Additionally, this license must be active, unencumbered, unrestricted and not subject to probation, terms or conditions. Any applicant whose licensure status does not meet these criteria, or who have in force adverse actions regarding Medicare or Medicaid will be notified of this and the applicant will be administratively denied.
- d. If the CNM has prescriptive authority, which allows the prescription of scheduled drugs, their DEA and/or state certificate of prescriptive authority information will be requested and primary source verified via normal Simply procedures. If there are current adverse actions against the DEA, the applicant will be notified and the applicant will be administratively denied.
- e. All CNM applicants will be certified by either:
 - i. The National Certification Corporation for Ob/Gyn and neonatal nursing; or
 - ii. The American Midwifery Certification Board, previously known as the American College of Nurse Midwifes.

This certification must be active and primary source verified. If the state licensing board primary source verifies one (1) of these certifications as a requirement for licensure, additional verification by Simply is not required. If the applicant is not certified or if their certification has expired, the application will be submitted for individual review by the geographic CC.

- f. If the CNM has hospital privileges, they must have unrestricted hospital privileges at a CIHQ, TJC, NIAHO, or HFAP accredited hospital, or a network hospital previously approved by the committee or in the absence of such privileges, must not raise a reasonable suspicion of future substandard professional conduct or competence. Information regarding history of any actions taken against any hospital privileges held by the CNM will be obtained. Any history of any adverse action taken by any hospital will trigger a Level II review. In the event the CNM provides only outpatient care, an acceptable admitting arrangement via the collaborative practice agreement must be in place with a participating OB/Gyn.
- g. The CNM applicant will undergo the standard credentialing process outlined in Simply's Credentialing Policies. CNMs are subject to all the requirements of the Credentialing Policies including (but not limited to): the requirement for CC review for Level II applicants, re-credentialing every three (3) years, and continuous sanction and performance monitoring upon participation in the network.

h. Upon completion of the credentialing process, the CNM may be listed in Simply's provider directories. As with all providers, this listing will accurately reflect their specific licensure designation and these providers will be subject to the audit process.
 i. CNMs will be clearly identified:

- i. On the credentialing file;
- ii. At presentation to the CC; and
- iii. Upon notification to network services and to the provider database.

24.-Currently

Participating Applicants (Re-credentialing)

Simply will fully enroll/onboard providers within 60 days of receipt of a complete and clean application. This means providers must complete and provide all required elements on our Florida Market Application Submission Checklist to establish a clean application receipt date, which will then determine our 60 day turnaround time for credentialing.

The provider will be notified by telephone or in writing if any information obtained in support of the assessment or reassessment process varies substantially from the information submitted by the provider. Providers have the right to review the information submitted in support of the credentialing and recredentialing process and to correct any errors in the documentation. This will be accomplished by submission of a written explanation or by appearance before the credentialing committee if so requested.

The decision to approve or deny initial participation will be communicated in writing within 60 days of the credentialing committee's decision, and for Medicaid, prior to the 60 days onboarding deadline. To the extent allowed under applicable law or state agency requirements, per NCQA standards and guidelines, the medical director may render a decision regarding the approval of clean files without benefit of input from the credentialing committee. In the event the provider's continued participation is denied, the provider will be notified by certified mail. If continued participation is denied, the provider will be allowed 30 days to appeal the decision.

- D. Participating Applicants (Re-credentialing)
 - Submission of complete re-credentialing application and required attachments that must not contain intentional misrepresentations;
 - Re-credentialing application signed date within one hundred eighty (180) calendar days of the date of submission to the CC for a vote;
 - 3. Must not be currently federally sanctioned, debarred or excluded from participation in any of the following programs; Medicare, Medicaid or FEHBP. If, once a practitioner participates in Simply's programs or provider Network(s), federal sanction, debarment or exclusion from the Medicare, Medicaid or FEHBP programs occurs, at the time of identification, the practitioner will become immediately ineligible for participation in the applicable government programs or provider Network(s) as well as Simply's other credentialed provider Network(s).
 - Current, valid, unrestricted, unencumbered, unprobated license to practice in each state in which the practitioner provides care to Members;
 - 5. No new history of licensing board reprimand since prior credentialing review;
 - *No current federal sanction and no new (since prior credentialing review) history of federal sanctions (per SAM, OIG and OPM Reports or on NPDB report);
 - Current DEA/CDS registration and/or state controlled substance certification without new (since prior credentialing review) history of or current restrictions;
 - 8. No current hospital membership or privilege restrictions and no new (since prior credentialing review) history of hospital membership or privilege restrictions; or for practitioners in a specialty defined as requiring hospital privileges who practice solely in

- the outpatient setting there exists a defined referral relationship with a Network practitioner of similar specialty at a Network HDO who provides inpatient care to Members needing hospitalization;
- No new (since previous credentialing review) history of or current use of illegal drugs or alcoholism;
- 10. No impairment or other condition which would negatively impact the ability to perform the essential functions in their professional field;
- 11. No new (since previous credentialing review) history of criminal/felony convictions, including a plea of no contest;
- 12. Malpractice case history reviewed since the last CC review. If no new cases are identified since last review, malpractice history will be reviewed as meeting criteria. If new malpractice history is present, then a minimum of last five (5) years of malpractice history is evaluated and criteria consistent with initial credentialing is used.
- 13. No new (since previous credentialing review) involuntary terminations from an HMO or PPO:
- 14. No new (since previous credentialing review) "yes" answers on attestation/disclosure guestions with exceptions of the following:
 - Voluntary resignation from a hospital or organization related to practice relocation or facility utilization;
 - Voluntary surrender of state license related to relocation or nonuse of said license;
 - An NPDB report of a malpractice settlement or any report of a malpractice settlement that does not meet the threshold criteria;
 - Monrenewal of malpractice coverage or change in malpractice carrier related to changes in the carrier's business practices (no longer offering coverage in a state or no longer in business);
 - Previous failure of a certification exam by a practitioner who is currently board certified or who remains in the five (5) year post residency training window;
 - Actions taken by a hospital against a practitioner's privileges related solely to the failure to complete medical records in a timely fashion;
 - g. History of a licensing board, hospital or other professional entity investigation that was closed without any action or sanction.
- 15. No quality improvement data or other performance data including complaints above the set threshold.
- 16. Re-credentialed at least every three (3) years to assess the practitioner's continued compliance with Simply standards.

*It is expected that these findings will be discovered for currently credentialed network practitioners and HDOs through ongoing sanction monitoring. Network practitioners and HDOs with such findings will be individually reviewed and considered by the CC at the time the findings are identified.

Note: the CC will individually review any credentialed Network practitioners and HDOs that do not meet one (1) or more of the criteria for re-credentialing.

III. HDO Eligibility Criteria

All HDOs must be accredited by an appropriate, recognized accrediting body or in the absence of such accreditation, Simply may evaluate the most recent site survey by Medicare, the appropriate state oversight agency, or site survey performed by a designated independent external entity within the past thirty-six (36) months. If a HDO has satellite facilities that follow the same policy and procedures, Simply may limit site visits to the main facility. Non-accredited HDOs are subject to individual review by the CC and will be considered for Member access need only when the CC

review indicates compliance with Simply standards and there are no deficiencies noted on the Medicare or state oversight review which would adversely affect quality or care or patient safety. HDOs are re-credentialed at least every three (3) years to assess the HDO's continued compliance with Simply standards.

A. General Criteria for HDOs:

- . Valid, current and unrestricted license to operate in the state(s) in which it will provide services to Members. The license must be in good standing with no sanctions.
- 2. Valid and current Medicare certification.
- 3. Must not be currently federally sanctioned, debarred or excluded from participation in any of the following programs; Medicare, Medicaid or the FEHBP. Note: If, once an HDO participates in Simply's programs or provider Network(s), exclusion from Medicare, Medicaid or FEHBP occurs, at the time of identification, the HDO will become immediately ineligible for participation in the applicable government programs or provider Network(s) as well as Simply's other credentialed provider Network(s).
- Liability insurance acceptable to Simply.
- If not appropriately accredited, HDO must submit a copy of its CMS, state site or a
 designated independent external entity survey for review by the CC to determine if
 Simply's quality and certification criteria standards have been met.

Additional Considerations

We encourage those providers who wish to be participating providers for Clear Health Alliance, and who are not credentialed by the American Academy of HIV Medicine (AAHIVM) or recognized by the Florida/Caribbean AIDS Education and Treatment Centers (AETC), to do so and refer them accordingly.

While all providers are required to undergo credentialing, we give particular focus to providers serving in the primary care role for our members with HIV/AIDS. We include an *Education/Training Attestation* for participation as an HIV/AIDS PCP in the credentialing packet, which includes the qualifications described

Participation as an HIV/AIDS-designated PCP requires that the provider attest that they meet the criteria to care for our members in one of the following ways:

- Be credentialed as an AAHIVM HIV specialist by the American Academy of HIV Medicine (www.aahivm.org)
- Be board-certified in the field of infectious disease and, if not certified in the past year through the
 American Board of Medical Specialties, has clinically managed a minimum of 25 patients in the preceding 12
 months as well as successfully completed a minimum of 10 hours of continuing medical education (CME)
 with at least five hours related to antiretroviral therapy in the past year
- Be recognized by the Florida/Caribbean AIDS Education and Training Center as having sufficient clinical
 experience and additional ongoing training in HIV/AIDS to be considered a specialist.

Delegated Credentialing

The provider application contains the provider's actual signature, which serves as an attestation that the health care facility agrees to the assessment requirements. Providers requiring assessments are as follows: hospitals; home health agencies; skilled nursing facilities; nursing homes; ambulatory surgical centers; and behavioral health facilities providing mental health or substance abuse services in an inpatient, residential or ambulatory setting. The provider's signature also serves as a release of information to verify credentials externally. Currently, the following steps are completed in addition to the application and network provider agreement before approval for participation of a hospital or organizational provider.

State licensure is verified by obtaining a current copy of the state license from the organization or by contacting the state licensing agency. Any restrictions to a license are investigated and documented, including the decision to accept or deny the organization's participation in the network.

We contract with facilities that meet the requirements of an unbiased and recognized authority. Hospitals (for example, acute, transitional or rehabilitation) should be accredited by The Joint Commission (TJC), Health Care Facilities Accreditation Program (HFAP) or the American Osteopathic Association (AOA). The Commission on Accreditation of Rehabilitation Facilities (CARF) may accredit rehabilitation facilities. Home health agencies should be accredited by TJC or the Community Health Accreditation Program (CHAP). Nursing homes should be accredited by TJC. TJC or the Accreditation Association for Ambulatory Health Care (AAAHC) should accredit ambulatory surgical centers.

If facilities, ancillaries or hospitals are not accredited, Simply will accept a copy of a recent state or CMS review in lieu of performing an onsite review. If accreditation or copy of a recent review is unavailable, an onsite review will be performed.

- A copy of the malpractice insurance face sheet is required. Organizations are required to maintain
 malpractice insurance in the amounts specified in the provider contract and according to Simply policy.
- We will track a facility's/ancillary's reassessment date and reassess every 36 months as applicable.
 Requirement for recredentialing of organizational providers are the same for reassessment as they are for the initial assessment.

The organization will be notified, either by phone or in writing, if any information obtained in support of the assessment or reassessment process varies substantially from the information submitted by the organization. Organizations have the right to review the information submitted in support of the assessment process and to correct any errors in the documentation. This will be accomplished by submission of a written explanation or by appearance before the credentialing committee, if so requested.

The decision to terminate an organization's participation will be communicated in writing via certified mail.

Delegated Credentialing

We will ensure the quality of our credentialing program through direct verification and through delegation of credentialing functions to qualified provider organizations. Where a provider group is believed to have a strong credentialing program, we may evaluate a delegation of credentialing and recredentialing. The provider group must have a minimum of 100 in scope practitioners.

The Enterprise Delegation Oversight & Management department will review the prospective delegate's written credentialing policies and a randomized sample of practitioner files to ensure compliance with contractual, state and federal, as well as NCQA standards. Steps, if any, are identified where the group's credentialing policy does not meet the Simply standards. We will perform or arrange for the group to perform the Simply credentialing steps not addressed by the group.

We will perform a pre-delegation audit of the group's credentialing program.

- A compliant score is between 95 percent and 100%. If the potential delegate has a compliant status and approved by the regional Credentialing Committee, they will be added to the annual audit schedule no more than 12 months from the pre-delegation date.
- A partial compliance score is between 80% and 94%. If the potential delegate has a partial compliance
 score and approved by the regional Credentialing Committee, any identified deficiencies will be tracked to
 closure via a corrective action plan (CAP). If the delegate contract is not executed within six months of the
 pre-delegation audit, the delegate must submit a new pre-delegation audit request.

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If the delegate scores below 80% and denied by the regional Credentialing Committee, the audit is considered a fail. The delegate can submit for reconsideration after a waiting period of six months from the pre-delegation audit date. When a final delegation decision has been made, notice of the audit findings and, if applicable, corrective action plan (CAP) request will be provided to the prospective delegate.

The group is expected to submit an acceptable corrective action plan within 30 days of receipt of the audit results and monitored monthly. The CAP must be acceptable to Simply and completed within the mutually agreed upon time frame but not to exceed 90 days of the submission.

If there are serious deficiencies, we will recommend the regional Credentialing Committee deny the delegation. Simply is responsible for oversight of any delegated credentialing arrangement and schedules appropriate reviews. The reviews are held annually at a minimum.

Peer Review

The peer review process provides a systematic approach for monitoring the quality and appropriateness of care. Peer review responsibilities are to:

- Participate in the implementation of the established peer review system, which reviews a provider's
 practice methods and patterns, morbidity and mortality rates, and all grievances filed relating to medical
 treatment
- Evaluate the appropriateness of the care rendered and implement corrective action if needed.
- Review and make recommendations regarding individual provider peer-review cases.
- Work in accordance with the executive medical director.

Should investigation of a member grievance or complaint result in concern about a physician's compliance with community standards of care or service, all elements of peer review will be followed.

Dissatisfaction severity codes and levels of severity are applied to quality issues. The medical director assigns a level of severity to the grievance. Peer review includes investigation of physician actions by or at the discretion of the medical director. The medical director takes action based on the quality issue and the level of severity, invites the cooperation of the physician, and consults and informs the Peer

Review Committee (PRC). The medical director informs the physician of the committee's decision, recommendations, follow-up actions and/or disciplinary actions to be taken. Outcomes are reported to the appropriate internal and external entities, which include the QM committee.

Simply has a peer review committee, which has the following responsibilities:

- Evaluating the appropriateness of care rendered by our contracted providers
- · Reviewing provider's practice methods and patterns
- Evaluating provider performance, trends in quality of care and service issues
- Developing and analyzing plan wide audits.

If the medical advisory committee cannot convene, the peer review committee may also serve as the Simply's provider advisory council, providing input and recommendations to the plan about clinical guidelines, QM trilogy documents, credentialing reports, PIPS, process improvements, quality indicators, performance measures, HEDIS, and provider satisfaction survey tools and results.

The peer review policy is available upon request.

Quality Measurement Standards for Providers and Requirements for Exchange of Data

Simply and Clear Health Alliance contract with an NCQA-certified software vendor, which produces eligible populations, analyzes compliance/noncompliance and reports rates, including but not limited to for the following measures:

Measure Indicator	Measure Description	
	AWC was combined with "Well-Child Visits in the Third, Fourth, Fifth and	
	Sixth Years of Life into WCV added at the end	
AAP	Adults' Access to Preventive/Ambulatory Health Services	
AMM	Antidepressant Medication Management	
BCS	Breast Cancer Screening	
CCS	Cervical Cancer Screening	
CIS	Childhood Immunization Status - Combo 2 and 3	
CDC	Comprehensive Diabetes Care	
	Hemoglobin A1c (HbA1c) Testing	
	HbA1c poor control	
	HbA1c control (<8%)	
	Eye exam (retinal) performed	
	•	
СВР	Controlling High Blood Pressure	
KED	<u>Kidney Health Evaluation for Patients with Diabetes</u>	
SSD	Diabetes Screening for People with Schizophrenia or Bipolar Disorder who are	
400	using Antipsychotic Medications	
ADD	Follow-up Care of Children Prescribed ADHD Medication	
IMA	Immunizations for Adolescents	
CHL	Chlamydia Screening in Women	
PPC	Prenatal and Postpartum Care	
AMR	Asthma Medication Ratio	
W30	Well-Child Visits in the First 30 Months of Life	
W15	Well-Child Visits in the First 15 Months of Life	
IET	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment	
AMB	Ambulatory Care	
LSC	Lead Screening in Children	
MPM	Annual Monitoring for Patients on Persistent Medications	
FPC	Frequency of Ongoing Prenatal Care	
SAA	Adherence to Antipsychotic Medications for Individuals With Schizophrenia	
APM	Metabolic Monitoring for Children and Adolescents on Antipsychotics	
APC	Use of Multiple Concurrent Antipsychotics in Children and Adolescents	
APP	Use of First-Line Psychosocial Care for Children and Adolescents on	
	Antipsychotics	
FUM	Follow-Up After Emergency Department Visit for Mental Illness	
PCR	Plan All-Cause-Readmissions	
UOD	Use of Opioids at High Dosage	

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Measure Indicator	Measure Description		
FUA	Follow up after emergency department visit for alcohol and other drug abuse or dependence		
HEDIS- and Agency-	Defined		
FHM	Follow-up after Hospitalization for Mental-Illness		
Agency-Defined			
RER	Mental Health Readmission Rate		
TRT	Transportation Timeliness		
TRA	Transportation Availability		
HAART	Highly Active Anti-Retroviral Treatment		
HIVV	HIV-Related Outpatient Medical Visits		
Child Core Set			
WCC	Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents: Body Mass Index Assessment for Children/Adolescents		
WCV	Child and Adolescent Well-Care Visits		
CCP-CH	Contraceptive Care – Postpartum Women Ages 15-20		
CCW-CH	Contraceptive Care – All Women Ages 15-20		
PC-01	Elective Delivery		
PC-02	Cesarean Section		
Adult Core Set			
VLS	HIV Viral Load Suppression		
MSC	Medical Assistance with Smoking and Tobacco Use Cessation	4	Formatted Table
CCP-AD	Contraceptive Care – Postpartum Women Ages 21-44		
CCW-AD	Contraceptive Care – All Women Ages 21-44		
OUDCOB-AD	Concurrent Use of Pharmacotherapy for Opioid Use Disorder Opioids and		
	Benzodiazepines		Formatted: Font: Calibri
CDF-AD	Screening for Depression and Follow-up Plan: Age 18 and Older		
OHD-AD	Use of Opioids at High Dosage in Persons without Cancer		

10 MEMBER APPEAL AND GRIEVANCE PROCEDURES

Overview

Simply has a formal appeal and grievance process to handle disputes pertaining to administrative issues and nonpayment-related matters. For payment disputes, see the **Provider Payment Disputes** section.

The appeal process is the procedure for addressing member appeals, which are requests for review of an adverse benefit determination. Adverse benefit determinations are defined as the following:

- The denial or limited authorization of a requested service, including the type or level of service pursuant to 42 CFR 438 400(b)
- The reduction, suspension or termination of a previously authorized service
- The denial, in whole or part, of a payment for a service
- The failure to provide services in a timely manner as defined by the state
- The failure of the plan to act within the time frames provided in Sec. 438.408(b)

Members have the right to tell Simply if they are not happy with their care or the coverage of their health care needs by calling Member Services Monday to Friday, 8 a.m. to 7 p.m. ET. These are called grievances and appeals:

- A grievance is when a member is unhappy about something besides his or her health benefits. A grievance
 could be about a doctor's behavior or about information the member should have received but did not.
- An appeal is a formal request from a member to seek a review of an adverse benefit determination made by Simply.

Complaints and Grievances

Simply has a process to solve complaints and grievances. If a member has a concern that is easy to solve and can be resolved within 24 hours, Member Services can help. If the concern cannot be handled within 24 hours and needs to be looked at by our grievance coordinator, the concern is noted and turned over to the grievance coordinator.

A complaint or grievance must be given orally or in writing any time after the event happened.

To file a complaint or grievance, the member can call Member Services at <u>1</u>-844-406-2396 (TTY 711) or write us a letter regarding the concern and mail it to:

Simply Healthcare Plans, Inc. Grievance Coordinator 4200 W. Cypress St., Suite 900 Tampa, FL 33607-4173

Members can have someone else help them with the grievance process. This person can be:

- A family member.
- A friend.
- A doctor.
- A lawyer.

The member must give written permission in order for someone else to file a grievance or an appeal on his or her behalf.

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If a member needs help filing the complaint, Simply can help. He or she can call Member Services at <u>1</u>_844-406-2396, (TTY **711**).

If the member or member's representative would like to speak with the grievance coordinator to give more information, they should tell Member Services when the complaint is filed or put it in a letter.

Once Simply gets the grievance (oral or written), we send the member a letter within three business days, telling them the date we received the grievance.

What happens next?

- 1. The grievance coordinator reviews the concern.
- 2. If more information is needed or you have asked to talk to the coordinator, the coordinator will call the member or the designated representative.
- 3. If you have more information to give us, you can bring it to us in person or mail it to: Simply Healthcare Plans, Inc.

Grievance Coordinator

4200 W. Cypress St., Suite 900

Tampa, FL 33607-4173

- 4. Medical concerns are looked at by medical staff.
- 5. Simply will tell the member the decision of the grievance within 90 calendar days from the date we received the grievance.

Medical Appeals

There may be times when Simply says it will not pay, in whole or in part, for care that a member's doctor recommended. If we do this, a member or someone on behalf of a member (with the member's written consent) can appeal the decision. A medical appeal is when Simply is asked to look again at the care being asked for that we said we will not pay for. Members must file for an appeal within 60 days from the date on the letter that says Simply has denied, limited, reduced, suspended or terminated services. Simply will not hold it against the member or the doctor for filling an appeal.

The member can have someone else help them with the appeal process. This person can be a family member, friend, doctor or lawyer. Write this person's name on the appeal form and fill out a request to designate a personal representative form.

Members can ask us to send you more information to help them understand why we would not pay for the service you requested.

I want to ask for an appeal. How do I do it?

An appeal may be filed verbally or in writing within 60 calendar days of when the member gets the notice of adverse benefit determination.

There are four ways to file an appeal:

- 1. Write us and ask to appeal.
- 2. Call Member Services at 1-844-406-2396 (TTY 711).
- 3. Send a fax to 1-866-216-3482.
- 4. Email us at flmedicaidgrievances@simplyhealthcareplans.com.

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What else do I need to know?

If the member wants someone else to help with the appeal process, let us know, and we will send the member a form for that.

When Simply receives an appeal, we will send the member a letter within <u>five</u> business days notifying them of the receipt of the appeal request.

The member or the representative may talk to the doctor who looks at the appeal to give more information. We can arrange for the member to talk to this person or you can mail it to us.

Members may ask for a free copy of the guidelines, records or other information used to make the denial and/or appeal decision.

We will notify the member of the decision within 30 calendar days of getting the appeal request. If we reduce coverage for a service a member is receiving and the member wants to continue to get the service during the appeal, the member can call Simply to ask for continuation of benefits. The member must call within 10 days of the date of the <u>initial denial</u> letter that tells him or her Simply will not pay for the service.

If you or the member has more information to give us, you can bring it in person or mail it to the address below. Also, the member can look at medical records and information on this decision before and during the appeal process.

The time frame for an appeal may be extended up to 14 calendar days if:

- · The member asks for an extension.
- Simply finds additional information is needed, and the delay is in the member's interest.

If the time frame of the appeal is extended other than at the member's request, Simply will call the member on the same day and notify the member in writing within two calendar days of when the ruling is made. If a member has a special need, Simply will give additional help to file the appeal.

Please call Simply Member Services at 844-406-2396 (TTY 711) or CHA Member Services at 844-406-2398, Monday to Friday, 8 a.m. to 7 p.m. ET.

Where do I mail my letter?

Mail all medical information and medical necessity appeals to: Simply Healthcare Plans, Inc. Medical Appeals P.O. Box 62429 Virginia Beach, VA 23466-2429

What can I do if Simply still will not pay?

The member, or representative on the member's behalf with the member's written consent, has a right to ask for a state fair hearing. Members must complete the appeal process before requesting a Medicaid fair hearing. If the member would like to request a fair hearing, he or she must do so no later than 120 <u>calendar</u> days from the date of the notice of plan appeal resolution letter.

The Medicaid Hearing Unit is not part of Simply. They look at appeals of Medicaid members who live in Florida. If you contact the Medicaid Hearing Unit, we will give them information about your case, including the information you have given us.

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Members have the right to ask to receive benefits while the hearing is pending. To do so, they can call Member Services toll free at 1-844-406-2396 (TTY 711).

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Note: Members cannot ask for a Medicaid fair hearing if they have MediKids or FHK. These members should request a review from the state.

How do I contact the state for a state fair hearing?

You can contact the Medicaid Hearing Unit at:
Agency for Health Care Administration
Medicaid Hearing Unit
P.O. Box 60127
Ft. Myers, FL 33906
1-877-254-1055 (toll-free)
1-239-338-2642 (fax)

MedicaidHearingUnit@ahca.myflorida.com

What can I do if I think I need an urgent or expedited appeal?

Members can ask for an urgent or expedited appeal if they or their physician think the time frame for a standard appeal process could seriously jeopardize the member's life or health or ability to attain, maintain or regain maximum function.

Members can also ask for an expedited appeal by calling Member Services toll free at <u>1-844-406-2396</u> (TTY **711**), Monday to Friday, 8 a.m. to 7 p.m. ET.

We must respond to the expedited request within 48 hours after we receive the appeal request, whether the appeal was made verbally or in writing.

If the request for an expedited appeal is denied, the appeal will be transferred to the time frame for standard resolution, and the member will be notified orally by close of business on the same day and a written notice will be sent within two calendar days.

If you have any questions or need help, please call Member Services toll free at <u>1-844-406-2396 (TTY 711)</u>, Monday to Friday, 8 a.m. to 7 p.m. ET.

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.1 CLAIM SUBMISSION AND ADJUDICATION PROCEDURES

Electronic Submission

Simply encourages the submission of claims electronically through Electronic Data Interchange (EDI). Providers must submit claims within 180 days from the date of discharge for inpatient services or from the date of service for outpatient services. Electronic claims submission is available through:

- Availity (formerly THIN) claim payer ID:
 - Simply = SMPLY
 - o Clear Health Alliance = CLEAR

Methods to exchange EDI transmissions with the Availity EDI Gateway:

- 1. Already exchanging EDI files? You can use your existing clearinghouse or billing company for your Simply transmissions. (Please work with them to ensure connectivity to the Availity EDI Gateway)
- 2. Become a direct trading partner with the Availity EDI Gateway
- 3. Use direct single claim entry through the Availity Portal

Providers, Billing services and Clearinghouses who are **not** currently exchanging EDI transactions can register for the Simply Plan with Availity.

Already registered with Availity?

Use your existing login and choose: My Providers > Enrollments Center.

Additionally, the following will guide you through the transition:

- Use the EDI Connectivity Services Startup Guide for detailed instructions.
- Use Availity's EDI Companion Guide

Your organization can exchange the following transactions through the Availity EDI Gateway:

- 275 Electronic Medical Attachments
- 278 Authorizations/Referrals
- 837- Institutional Claims
- 837- Professional Claims
- 835- Electronic Remittance Advice
- 276/277- Claim Status- Batch
- 270/271- Eligibility Request- Batch

The advantages of electronic claims submission are as follows:

- Facilitates timely claims adjudication
- Acknowledges receipt and rejection notification of claims electronically
- Improves claims tracking
- Improves claims status reporting
- Reduces adjudication turnaround
- Eliminates paper
- Improves cost-effectiveness
- Allows for automatic adjudication of claims

The guide for EDI claims submission is located on our provider website. The EDI claim submission guide includes additional information related to the EDI claim process. To initiate the electronic claims submission process or obtain additional information, please contact the Simply EDI Hotline at <u>1</u>_800-590-5745.

Paper Claims Submission

Providers also have the option of submitting paper claims. Simply uses optical character reading (OCR) technology as part of its front-end claims processing procedures. The benefits include the following:

- Faster turnaround times and adjudication
- Claims status availability within five days of receipt
- Immediate image retrieval by Simply staff for claims information allowing more timely and accurate response to provider inquiries

To use OCR technology, claims must be submitted on original red claim forms (not black-and-white or photocopied forms) and laser printed or typed (not handwritten) in a large, dark font. Providers must submit a properly completed *CMS-1450* or *CMS-1500* (08-05) within 180 days from the date of discharge for inpatient services or from the date of service for outpatient services, except in cases of coordination of benefits/subrogation or in cases where a member has retroactive eligibility. For cases of coordination of benefits/subrogation, the time frames for filing a claim will begin on the date the third party documents resolution of the claim.

Paper claims must be submitted **within 180 days** of the date of service and submitted to the following address: Simply Healthcare Plans, Inc.

Florida Claims P.O. Box 61010 Virginia Beach, VA 23466-1010

Encounter Data

Simply maintains a system to collect member encounter data. Due to reporting needs and requirements, network providers who are reimbursed by capitation must send encounter data to Simply for each member encounter. Encounter data can be submitted through EDI submission methods or on a CMS-1500 (08-05) claim form unless other arrangements are approved by Simply. Data will be submitted in a timely manner, but no later than 180 days from the date of service.

Encounter data should be submitted to the following address:

Simply Healthcare Plans, Inc. P.O. Box 61010 Virginia Beach, VA 23466-1010

Through claims and encounter data submissions, HEDIS information is collected. This includes but is not limited to:

- Preventive services (for example, childhood immunization, mammography, Pap smears).
- Prenatal care (for example, LBW, general first trimester care).
- Acute and chronic illness (for example, ambulatory follow-up and hospitalization for major disorders).

Compliance is monitored by the Simply utilization and quality improvement staff, coordinated with the medical director and reported to the quality management committee on a quarterly basis. The primary care provider (PCP) is monitored for compliance with reporting of utilization. Lack of compliance will result in training and follow-up audits and could result in termination from the network.

Claims Adjudication

Simply is dedicated to providing timely adjudication of provider claims for services rendered to members. All network and non-network provider claims that are submitted for adjudication are processed according to generally accepted claims coding and payment guidelines. These guidelines comply with industry standards as defined by the CPT-4 and ICD manuals. Institutional claims should be submitted using EDI submission methods or a *UB-04 CMS-1450* or successor forms; provider services should be submitted using the *CMS-1500*.

Providers must use HIPAA-compliant billing codes when billing Simply. This applies to both electronic and paper claims. When billing codes are updated, the provider is required to use appropriate replacement codes for submitted claims. Simply will not pay any claims submitted using noncompliant billing codes. Simply reserves the right to use code-editing software to determine which services are considered part of, incidental to or inclusive of the primary procedure.

For claims payment to be considered, providers must adhere to the following time limits:

- Submit claims within 180 days from the date the service is rendered; for inpatient claims filed by a hospital, submit claims within 180 days from the date of discharge unless contract timeframes state otherwise.
- In the case of other insurance (crossover claim submission), the claim must be received within 90 days of
 receiving a response from the primary payer's determination or three years for Medicare crossover claims.
- Claims for members whose eligibility has not been added to the state's eligibility system must be received
 within 180 days from the date the eligibility is added and Simply is notified of the eligibility/enrollment.
 Claims submitted after the 180-day filing deadline will be denied.

After filing a claim with Simply, review the Explanation of Payment (EOP). If the claim does not appear on an EOP within 30 business days as adjudicated or you have no other written indication that the claim has been received, check the status of your claim at https://www.availity.com or through the Provider Inquiry Line at 1-844-405-4296. If the claim is not on file with Simply, resubmit your claim within 180 days from the date of service. If filing electronically, check the confirmation reports for acceptance of the claim you receive from your EDI or practice management vendor.

International Classification of Diseases, 10th Revision (ICD-10) Description

As of October 1, 2015, ICD-10 became the code set for medical diagnoses and inpatient hospital procedures in compliance with HIPAA requirements and in accordance with the rule issued by the U.S. Department of Health and Human Services (HHS).

ICD-10 is a diagnostic and procedure coding system endorsed by the World Health Organization (WHO) in 1990. It replaces the International Classification of Diseases, 9th Revision (ICD-9), which was developed in the 1970s. Internationally, the codes are used to study health conditions and assess health management and clinical processes. In the United States, the codes are the foundation for documenting the diagnosis and associated services provided across health care settings.

Although we often use the term ICD-10 alone, there are actually two parts to ICD-10:

- Clinical modification (CM): ICD-10-CM is used for diagnosis coding.
- Procedure coding system (PCS): ICD-10-PCS is used for inpatient hospital procedure coding; this is a
 variation from the WHO baseline and unique to the United States.

ICD-10-CM replaces the code sets ICD-9-CM, volumes one and two for diagnosis coding, and ICD-10-PCS replaces ICD-9-CM, volume three for inpatient hospital procedure coding.

Clean Claims Payment

A clean claim is a request for payment for a service rendered by a provider that:

- Is submitted by the provider in a timely manner
- Is accurate
- Is submitted on a HIPAA-compliant standard claim form, including a CMS-1500 or CMS-1450, or successor forms thereto, or the electronic equivalent of such claim form
- Requires no further information, adjustment or alteration by the provider or by a third party in order to be processed and paid by Simply

Clean claims are adjudicated within 20 days (for electronic) or 40 days (for paper) of receipt. If Simply does not adjudicate the clean claim within the time frames specified above, we will pay all applicable interest as required by law.

We produce and mail an EOP Monday through Saturday, which delineates the status of each claim that has been adjudicated during the previous week. Upon receipt of the requested information from the provider, we must complete processing of the clean claim within 30 business days.

Paper claims that are determined to be unclean will be returned to the billing provider along with a letter stating the reason for the rejection. Electronic claims that are determined to be unclean will be returned to the Simply contracted clearinghouse that submitted the claim.

In accordance with state requirements, we will pay at least 90% of all clean claims from practitioners either in individual or group practice or who practice in shared health facilities within 30 days of the date of receipt. We will pay at least 99% of all clean claims from practitioners either in individual or group practice or who practice in shared health facilities within 90 days of the date of receipt. The date of receipt is the date Simply receives the claim as indicated by its date stamp on the claim. The date of payment is the date of the check or other form of payment.

Claims Status

You can visit the provider website or call the automated Provider Inquiry Line at <u>1</u>-844-405-4296 to check claims

High-dollar claims may be placed in a prepayment pending status to enable third-party vendor (Equian) claims review. An itemized bill may be requested for claims review, only if otherwise indicated in your contract.

Provider Reimbursement

Increased Medicaid Payments for Primary Care Physicians and Eligible Providers

In compliance with the Patient Protection and Affordable Care Act (PPACA), as amended by Section 1202 of the Health Care and Education Reconciliation Act, Simply reimburses eligible Medicaid primary care providers (PCPs) at parity with Medicare rates for qualified services in calendar years 2013 and 2014.

If you meet the requirements for the PPACA enhanced physician reimbursement and haven't yet submitted a completed attestation, you should do so as soon as possible to qualify for enhanced payments. Visit the provider website for links to information and instructions.

Simply Process for Supporting Enhanced Payments to Eligible Providers

As set forth in "Section 1202" of the PPACA:

- Conditioned upon the state of Florida requiring and providing funding to Simply, Simply will provide
 increased reimbursement to Medicare levels or some other federal or state-mandated level for specified
 CPT-4 codes for primary care services furnished with dates of service in 2013 and 2014 by providers who
 have attested to their eligibility to receive such increased reimbursement as set forth in "Section 1202" of
 the PPACA.
- Such CPT-4 codes will be paid in accordance with the requirements of PPACA, and the state and will not be subject to any further enhancements from Simply or any other source.

Provider Responsibilities with Regard to Payments

If you completed the attestation process as required by the state, the following procedures and guidelines apply to you regarding payments received from Simply:

- If you are a group provider, entity or any person other than the eligible provider who performed the
 service, you acknowledge and agree you will direct any and all increased reimbursements to such eligible
 providers or otherwise ensure such eligible providers receive direct and full benefit of the increased
 reimbursement in accordance with the final rule implementing PPACA.
- You also acknowledge and agree you will provide Simply with evidence of your compliance with this
 requirement upon request.

Electronic Remittance Advice (835)

Electronic Remittance Advice (835)

The 835 eliminates the need for paper remittance reconciliation.

Use Availity to register and manage ERA account changes with these three easy steps:

- 1. Log in to Availity https://apps.availity.com/availity/web/public.elegant.login
- 2. Select My Providers
- 3. Click on Enrollment Center and select Transaction Enrollment

Note: If you use a clearinghouse or vendor, please work with them on ERA registration and receiving your ERA's.

Electronic Funds Transfer (EFT)

Electronic claims payment through electronic funds transfer (EFT) is a secure and fastest way to receive payment reducing administrative processes. EFT deposit is assigned a trace number that is matched to the 835 Electronic Remittance Advice (ERA) for simple payment reconciliation.

Visit https://provider.simplyhealthcareplans.com/florida-provider/electronic-data-interchange for EFT registration instructions.

Maternity Coverage, Billing, Reimbursement Policies

Effective January 1, 2022, Simply Healthcare Plans will no longer reimburse postpartum visit Current Procedural Terminology (CPT) Code, 59430, Postpartum care only, if billed in conjunction with a global or bundled billed CPT code.

If CPT code "59430" is billed after a delivery claim using "59400, 59510, 59610, 59618, 59410, 59515,
 59614", then "59430" should be denied.

Also, effective January 1, 2022, Simply Healthcare Plans will begin down coding all bundled payments to delivery service only CPT codes if the postpartum CPT Category II Code (Table 1.2) is not submitted within timely filling (180 days) to verify postpartum visit completion.

- If cat II code "0503F" for postpartum visit is not submitted within 270 days (90 days postpartum window and 180 days timely filling) after the DOS on bundled delivery claims CPT codes "59410, 59515, 59614" then they should be down coded to the corresponding delivery service only code.
 - 59410 to 59409 Vaginal delivery only (with or without episiotomy and/or forceps)
 - 59510 to 59514 Cesarean delivery only
 - 59614 to 59612 Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps)

* Exception: when submitting bundle bill cpt code, 59622, provider's may also bill up to three postpartum visits (CPT code 59430) within 90 days following delivery, as delivery services only CPT code, 59620 -cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery, is not on the 2021 AHCA practitioner fee schedule (Florida Agency For Health Care Administration, 2021).

Routine inpatient Hospital postpartum CPT codes "99231, 99232, 99238" that have an ICD-10 diagnosis code of "239. 2 - routine postpartum follow-up" should be denied if provider billed a global/bundle CPT codes "59400, 59510, 59610, 59618, 59410, 59515, 59614" for the delivery.

PCP Reimbursement

Simply reimburses PCPs according to their contractual arrangement.

Specialist Reimbursement

Reimbursement to network specialty care providers and network providers not serving as PCPs is based on their contractual arrangement with Simply.

Specialty care providers will obtain PCP and Simply approval prior to rendering or arranging any treatment that is beyond the specific treatment authorized by the PCP's referral or beyond the scope of self-referral permitted under this program.

Specialty care provider services will be covered only when there is documentation of appropriate notification or precertification and receipt of the required claims and encounter information to Simply.

Overpayment Process

Refund notifications may be identified by two entities: 1) Simply and its contracted vendors or 2) the providers.

Once an overpayment has been identified by Simply, Simply will notify the provider of the overpayment. The overpayment notification will include instructions on how to refund the overpayment. Providers have up to 60 days to dispute an overpayment. If a refund check is not received, the identified overpayment will offset against future claims payments. Notification of overpayment will be submitted to facility claims within 30 months and to physician claims within 12 months.

The provider may also identify an overpayment and proactively submit a refund check to reconcile the overpayment amount. If a provider identifies an overpayment and submits a refund, a completed *Refund Notification Form* specifying the reason for the return must be included. This form is located on the provider website. The submission of the *Refund Notification Form* will allow us to process and reconcile the overpayment in a timely manner. For questions regarding the refund notification procedure, please call Provider Services at 1-844-405-4296 and select the appropriate prompt.

In instances where we are required to adjust previously paid claims to adhere to a new published rate, we will initiate a reconciliation of the affected claims. As such, we will determine the cumulative adjusted

reimbursement amount based on the new rates. In the event the outcome of this reconciliation results in a net amount owed to us, Simply will notify the provider of the overpayment, then commence recovery of such amounts through an offset against future claims payments. Such recoveries are not considered part of the overpayment recovery process described above or in the provider agreement.

Changes addressing the topic of overpayments have taken place with the passage of the Patient Protection and Affordable Care Act (PPACA), commonly known as the Healthcare Reform Act.

The provision directly links the retention of overpayments to false claim liability. The language of 42 U.S.C.A. § 1320a-7k makes explicit that overpayments must now be reported and returned to states or respective MCOs within 60 days of identification of the overpayment or by the date any corresponding cost report is due, whichever is later. After 60 days, the overpayment is considered a false claim, which triggers penalties under the False Claims Act, including treble damages. In order to avoid such liability, health care providers and other entities receiving reimbursement under Medicare or Medicaid should implement policies and procedures on reporting and returning overpayments that are consistent with the requirements in the PPACA.

The provision entitled "Reporting and Returning Overpayments – Deadline for Reporting and Returning Overpayments," codified at 42 U.S.C.A. § 1320a-7k, clarifies the uncertainty left by the 2009 Fraud Enforcement and Recovery Act. This provision of the HealthCare Reform Act applies to providers of services, suppliers, Medicaid managed care organizations, Medicare Advantage organizations and Medicare Prescription Drug Program sponsors. It does not apply to beneficiaries.

Reimbursement Policies

Reimbursement policies serve as a guide to assist you in accurate claim submissions and to outline the basis for reimbursement if the service is covered by a member's Simply benefit plan. These policies can be accessed on the provider site. Services must meet authorization and medical necessity guidelines appropriate to the procedure and diagnosis as well as to the member's state of residence. Covered services do not guarantee reimbursement unless specific criteria are met.

You must follow proper billing and submission guidelines, including using industry standard, compliant codes on all claim submissions. Services should be billed with Current Procedure Terminology (CPT) codes, Healthcare Common Procedure Coding System (HCPCS) codes and/or revenue codes which indicate the services and/or procedures performed. The billed code(s) are required to be fully supported in the medical record and/or office notes. Unless otherwise noted within the policy, our policies apply to participating providers and facilities; a non-contracting provider who accepts Medicare assignment will be reimbursed for services according to the original Medicare reimbursement rates.

If appropriate coding/billing guidelines or current reimbursement policies are not followed, Simply may:

- Reject or deny the claim
- Recover and/or recoup claim payment
- Adjust the reimbursement to reflect the appropriate services and/or procedures performed

The reimbursement policies are developed based on nationally accepted industry standards and coding principles. These policies may be superseded by mandates in provider, state, federal, or CMS contracts and/or requirements.

All documentation is subject to nationally and generally accepted general industry standards including, but not limited to the American Medical Association (AMA) Current Procedural Terminology (CPT) Code Set, the

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Healthcare Common Procedure Coding System (HCPCS), and the American Hospital Association (AHA) Coding Clinic Guidelines.

In addition to nationally and generally accepted industry standards, the primary authority for all coverage provisions for Medicare is the Social Security Act, the Code of Federal Regulations (CFR) and the Center for Medicare and Medicaid Services (CMS). Medicaid may be subject to requirements of your State agency responsible for operating the Medicaid program and/or health care laws in your state. In lieu of State-specific rules, Medicaid will defer to Medicare guidelines and other applicable provisions in the Provider Manual.

Reimbursement Hierarchy

Claims submitted for payments must meet all aspects of criteria for reimbursement. The reimbursement hierarchy is the order of payment conditions that must be met for a claim to be reimbursed. Conditions of payment could include benefits coverage, medical necessity/clinical criteria, authorization requirements and/or stipulations within a reimbursement policy. Neither payment rates nor methodology are considered to be conditions of payments.

Review Schedules and Updates to Reimbursement Policies

Reimbursement policies undergo reviews for updates to state contracts, federal or CMS requirements. Additionally, updates may be made at any time if we are notified of a mandated change or due to a business decision. We reserve the right to review and revise our policies when necessary. When there is an update, we will publish the most current policies to our provider website.

Medical Coding

The Medical Coding department ensures that correct coding guidelines have been applied consistently through Simply. Those guidelines include, but are not limited to:

- Correct modifier use
- Effective date of transaction code sets (CPT, HCPCS, ICD diagnosis/procedures, revenue codes, etc.)
- Code editing rules are appropriately applied and within regulatory requirements
- Analysis of codes, code definition and appropriate use

Reimbursement by Code Definition

Simply allows reimbursement for covered services based on their procedure code definitions or descriptor, as opposed to their appearance under particular CPT categories or sections, or descriptors unless otherwise noted by state or provider contracts or state, federal or CMS contracts and/or requirements. There are eight CPT contracts

- 1. Evaluation and management
- 2. Anesthesia
- 3. Surgery
- 4. Radiology (nuclear medicine and diagnostic imaging)
- 5. Pathology and laboratory
- 6. Medicine
- 7. Category II codes: supplemental tracking codes that can be used for performance measurement
- 8. Category III codes: temporary codes for emerging technology, services or procedures

Claim Payment Disputes

Provider Claim Payment Dispute Process

If you disagree with the outcome of a claim, you may begin the Simply provider payment dispute process. The simplest way to define a claim payment dispute is when the claim is finalized, but you disagree with the outcome.

Please be aware there are three common, claim-related issues that are not considered claim payment disputes. To avoid confusion with claim payment disputes, we've defined them briefly here:

- Claim inquiry: a question about a claim but not a request to change a claim payment
- Claims correspondence: when Simply requests further information to finalize a claim; typically includes medical records, itemized bills or information about other insurance a member may have
- Medical necessity appeals: a pre-service appeal for a denied service; for these, a claim has not yet been submitted

For more information on each of these, please refer to the appropriate section in this provider manual.

The Simply provider payment dispute process consists of two internal steps and a third external step. You will **not** be penalized for filing a claim payment dispute, and no action is required by the member.

- Claim payment reconsideration: This is the first step in the Simply provider payment dispute process. The
 reconsideration represents your initial request for an investigation into the outcome of the claim. Most
 issues are resolved at the claim payment reconsideration step.
- Claim payment appeal: This is the second step in the Simply provider payment dispute process. If you disagree with the outcome of the reconsideration, you may request an additional review as a claim payment appeal.
- Regulatory complaint: The state of Florida supports an external review process if you have exhausted both steps in the Simply payment dispute process but still disagree with the outcome.

A claim payment dispute may be submitted for multiple reason(s), including:

- · Contractual payment issues.
- Disagreements over reduced or zero-paid claims.
- Post-service authorization issues.
- Other health insurance denial issues.
- Claim code editing issues.
- Duplicate claim issues.
- Retro-eligibility issues.
- Experimental/investigational procedure issues.
- Claim data issues.
- Timely filing issues.*

* We will consider reimbursement of a claim that has been denied due to failure to meet timely filing if you can:
1) provide documentation the claim was submitted within the timely filing requirements or 2) demonstrate good cause exists.

Claim Payment Reconsideration

The first step in the Simply claim payment dispute process is called the reconsideration. It is your initial request to investigate the outcome of a finalized claim. Please note, we cannot process a reconsideration without a finalized claim on file.

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We accept reconsideration requests in writing, verbally and through our secure provider website within 90 days from the date on the *EOP* (see below for further details on how to submit). Reconsiderations filed more than 90 days from the *EOP* will be considered untimely and denied unless good cause can be established.

When submitting reconsiderations, please include as much information as you can to help us understand why you think the claim was not paid as you would expect. If a reconsideration requires clinical expertise, the appropriate clinical Simply professionals will review it.

Simply will make every effort to resolve the claims payment reconsideration within 30 calendar days of receipt. If additional information is required to make a determination, the determination date may be extended by 30 additional calendar days. We will mail you a written extension letter before the expiration of the initial 30 calendar days.

We will send you our decision in a determination letter, which will include:

- A statement of the provider's reconsideration request.
- A statement of what action Simply intends to take or has taken.
- The reason for the action.
- Support for the action, including applicable statutes, regulations, policies, claims, codes or provider manual references.
- An explanation of the provider's right to request a claim payment appeal within 30 calendar days of the date of the reconsideration determination letter.
- An address to submit the claim payment appeal.

If the decision results in a claim adjustment, the payment and EOP will be sent separately.

Claim Payment Appeal

If you are dissatisfied with the outcome of a reconsideration determination you may submit a claim payment appeal. Please note, we cannot process a claim payment appeal without a reconsideration on file.

We accept claim payment appeals through our provider website or in writing within 30 calendar days of the date on the reconsideration determination letter.

Claim payment appeals received more than 30 calendar days after the claims reconsideration determination letter will be considered untimely and upheld unless good cause can be established.

When submitting a claim payment appeal, please include as much information as you can to help us understand why you think the reconsideration determination was in error. If a claim payment appeal requires clinical expertise, it will be reviewed by appropriate clinical Simply professionals.

Simply will make every effort to resolve the claim payment appeal within 30 calendar days of receipt. If additional information is required to make a determination, the determination date may be extended by 30 additional calendar days. We will mail you a written extension letter before the expiration of the initial 30 calendar days.

We will send you our decision in a determination letter, which will include:

- A statement of the provider's claim payment appeal request.
- A statement of what action Simply intends to take or has taken.
- The reason for the action.

Support for the action, including applicable statutes, regulations, policies, claims, codes or provider manual references.

If the decision results in a claim adjustment, the payment and EOP will be sent separately.

How to Submit a Claim Payment Dispute

We have several options to file a claim payment dispute:

- Preferred Method: Online (for reconsiderations and claim payment appeals): Use the secure Provider Availity Payment Appeal Tool at https://www.availity.com. Through Availity, you can upload supporting documentation and will receive immediate acknowledgement of your submission.
- Verbally (for reconsiderations only): Call Provider Services at 1-844-405-4296.
- Written (for claim payment appeals only): Mail all required documentation (see below for more details), including the Claim Payment Appeal Form or the Reconsideration Form, to:

Payment Dispute Unit Simply Healthcare Plans, Inc. P.O. Box 61599 Virginia Beach, VA 23466-1599

Submit written claim payment appeals on the form *Claim Payment Appeal Form*, located in *Appendix A* of this manual.

If a provider is dissatisfied with the claim payment appeal resolution, the provider may appeal the Simply decision to Maximus (the vendor for AHCA for provider disputes).

Application forms and instructions on how to file claims are available from Maximus directly. For information updates, call Maximus at <u>1</u>-866-763-6395 and ask for the Florida Appeals Process department

Required Documentation for Claims Payment Disputes

Simply requires the following information when submitting a claim payment dispute (reconsideration or claim payment appeal):

- Your name, address, phone number, email, and either your NPI or TIN
- The member's name and his or her Simply or Medicaid ID number
- A listing of disputed claims, which should include the Simply claim number and the date(s) of service(s)
- All supporting statements and documentation

Claim Inquiries

A question about a claim or claim payment is called an inquiry. Inquiries do not result in changes to claim payments, but the outcome of the claim inquiry may result in the initiation of the claim payment dispute. In other words, once you get the answer to your claim inquiry, you may opt to begin the claim payment dispute process.

Our Provider Experience program helps you with claim inquiries. Just call <u>1-</u>844-405-4296 and select the *Claims* prompt within our voice portal. We connect you with a dedicated resource team, called the Provider Service Unit (PSU), to ensure:

- Availability of helpful, knowledgeable representatives to assist you.
- Increased first-contact, issue resolution rates.
- Significantly improved turnaround time of inquiry resolution.

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Increased outreach communication to keep you informed of your inquiry status.

The PSU is available to assist you in determining the appropriate process to follow for resolving your claim issue.

Claim Correspondence

Claim correspondence is different from a payment dispute. Correspondence is when Simply requires more information to finalize a claim. Typically, Simply makes the request for this information through the *EOP*. The claim or part of the claim may, in fact, be denied, but it is only because more information is required to process the claim. Once the information is received, Simply will use it to finalize the claim.

The following table provides examples of the most common correspondence issues along with guidance on the most efficient ways to resolve them.

Type of Issue	What Do I Need to Do?	
EDI Rejected Claim(s)	Contact Availity Client Services at 1-800-Availity (1-800-282-	
	4548). Availity Client Services at 1-800-Availity (1-800-282-	
	- 8 p.m. ET.	
EOP Requests for Supporting	Submit a Claim Correspondence Form, a copy of your EOP and	
Documentation (Sterilization/	the supporting documentation to:	
Hysterectomy/Abortion Consent	Claims Correspondence	
Forms, Itemized Bills and Invoices)	P.O. Box 61599	
	Virginia Beach, VA 23466-1599	
EOP Requests for Medical Records	Submit a Claim Correspondence Form, a copy of your EOP and	
	the medical records to:	
	Claims Correspondence	
	P.O. Box 61599	
No od to Colombia Compania d Claims	Virginia Beach, VA 23466-1599	
Need to Submit a Corrected Claim	Submit a Claim Correspondence Form and your corrected claim to:	
due to Errors or Changes on Original Submission	Claims Correspondence	
Original Submission	P.O. Box 61599	
	Virginia Beach, VA 23466-1599	
	Viigilia beacii, VA 23400-1333	
	Clearly identify the claim as corrected. We cannot accept claims	
	with handwritten alterations to billing information. We will	
	return claims that have been altered with an explanation of the	
	reason for the return. Provided the claim was originally received	
	timely, a corrected claim must be received within 365 days of	
	the date of service. In cases where there was an adjustment to a	
	primary insurance payment and it is necessary to submit a	
	corrected claim to Simply to adjust the other health insurance	
	(OHI) payment information, the timely filing period starts with	
Submission of Coordination of	the date of the most recent OHI EOB.	
	Submit a Claim Correspondence Form, a copy of your EOP and	
Benefits (COB)/Third-Party Liability (TPL) Information	the COB/TPL information to: Claims Correspondence	
(TFL) IIIIOIIIIalioii	P.O. Box 61599	
	F.O. DOX U1333	

Type of Issue	What Do I Need to Do?
	Virginia Beach, VA 23466-1599
Emergency Room Payment Review	Submit a Claim Correspondence Form, a copy of your EOP and
	the medical records to:
	Claims Correspondence
	P.O. Box 61599
	Virginia Beach, VA 23466-1599

Medical Necessity Appeals

Medical necessity appeals refer to a situation in which an authorization for a service was denied prior to the service. Medical necessity appeals/prior authorization appeals are different than claim payment disputes and should be submitted in accordance with the medical necessity appeal process.

Coordination of Benefits

State-specific guidelines will be followed when coordination of benefits (COB) procedures are necessary. Simply agrees to use covered medical and hospital services whenever available or other public or private sources of payment for services rendered to members in the Simply plan.

Simply and our providers agree the Medicaid program will be the payer of last resort when third-party resources are available to cover the costs of medical services provided to Medicaid members. When Simply is aware of these resources prior to paying for a medical service, we will avoid payment by either rejecting a provider's claim and redirecting the provider to bill the appropriate insurance carrier or, if Simply does not become aware of the resource until sometime after payment for the service was rendered, by pursuing postpayment recovery of the expenditure. Providers must **not** seek recovery in excess of the Medicaid payable amount.

Simply will avoid payment of trauma-related claims where third-party resources are identified prior to payment. Otherwise, we will follow a pay-and-pursue policy on prospective and potential subrogation cases. Paid claims are reviewed and researched postpayment to determine likely cases with multiple letters and phone calls being made to document the appropriate details. The filing of liens and settlement negotiations are handled internally and externally via our subrogation vendor, ACS Recovery Services.

We will require members to cooperate in the identification of any and all other potential sources of payment for services.

Any questions or inquiries regarding paid, denied or pended claims should be directed to Provider Services at <u>1</u>-844_405_4296.

Billing Members

Overview

Before rendering services, providers should always inform members that the cost of services not covered by Simply will be charged to the member.

A provider who chooses to provide services **not covered** by Simply:

- Understands Simply only reimburses for medically necessary services, including hospital admissions and other services
- Obtains the member's signature on the client acknowledgment statement, which specifies the member will be held responsible for payment of services.

 Understands he or she may not bill or take recourse against a member for denied or reduced claims for services that are within the amount, duration and scope of benefits of the Medicaid program.
 Simply members must not be balance-billed for the amount above that which is paid by Simply for covered services.

In addition, providers may **not** bill a member if any of the following occurs:

- · Failure to submit a claim timely, including claims not received by Simply
- · Failure to submit a claim to Simply for initial processing within the six-month filing deadline
- Failure to submit a corrected claim within the 180-day filing resubmission period
- Failure to appeal a claim within the 90 day administrative appeal period
- Failure to appeal a utilization review determination within 30 days of notification of coverage denial
- Submission of an unsigned or otherwise incomplete claim
- Errors made in claims preparation, claims submission or the appeal process

Client Acknowledgment Statement

A provider may bill a Simply member for a service that has been denied as not medically necessary or not a covered benefit **only if** both of the following conditions are met:

- The member requests the specific service or item
- The provider obtains and keeps a written acknowledgement statement signed by the member and the provider stating:

"I understand that, in the opinion of <u>(provider's name)</u>, the services or items that I have requested to be provided to me on <u>(dates of service)</u> may not be covered under Simply as being reasonable and medically necessary for my care or may not be a covered benefit. I understand that Simply has established the medical necessity standards for the services or items that I request and receive. I also understand that I am responsible for payment of the services or items I request and receive if these services or items are determined to be inconsistent with the Simply medically necessary standards for my care or are not a covered benefit."

Signature:	-
Date:	

Accessing Claim Status, Member Eligibility and Authorization Determinations

Simply recognizes that for you to provide the best service to our members, we must share with you accurate, up-to-date information. To access claim status, member eligibility and authorization determination (24 hours a day, 365 days a year):

- Access https://www.availity.com, your exclusive, secure multi-payer portal to access real-time claim status, eligibility verification and precertification status. You can also submit a claim or precertification or obtain a member panel listing. Detailed instructions for use of the provider online reporting tool are located on the provider website.
- Call the toll-free, automated Provider Inquiry Line at 1-844-405-4296 for real-time member status, claim status and precertification status. This option also offers the ability to be transferred to the appropriate department for other needs, such as seeking advice in case/care management.

APPENDIX A: FORMS

The following forms are available on the provider website. You may download them for your use as needed.

Referral and Claim Submission Forms

- Authorization Request Form
- Maternity Notification Form
- Child Health Check-Up 221 Form and Claim Instructions This form and instructions are available at www.fdhc.state.fl.us/medicaid or by calling 1_800-289-7799
- Specialist as a PCP Request Form
- CMS-1500 (08-05) Claim Form
- UB-04-Claim Form

Precertification Forms

- Precertification Information Required for Hysterectomy
- Precertification Information Required for Gastroplasty
- Precertification Information Required for Tonsillectomy, Adenoidectomy, Adenotonsillectomy

Provider Grievances and Appeals Forms

- Provider Payment Dispute and Correspondence Submission
- Provider Medical Necessity Appeal Form
- Grievance Form

Medical Record Documentation Forms

- Adult Health Form
- Oral Lead Risk Form English
- Oral Lead Risk Form Spanish
- Incident Report Form
- Inpatient Medical Review Form
- Advance Directive English
- Advance Directive Spanish
- Durable Power of Attorney English/Spanish
- Living Will English/Spanish
- Site Review Form

Other Forms

- Florida Assisted Living Facility Form
- Authorization Request Form
- Pharmacy Prior Authorization Form
- Medical Injectable Prior Authorization Form
- Incident Report Form
- Sterilization Consent Form
- Hysterectomy Acknowledgement Form
- Abortion Certificate Form
- Provider Payment Dispute Form

Pharmacy Synagis Order Form

• Synagis Enrollment Form

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Behavioral Health Forms

- Alzheimer's Mini-Cog Screening
- ASSIST SUD Screening
- AUDIT Alcohol Use Questionnaire
- CRAFFT Adolescent SUD Screening
- Functional Activities Questionnaire
- Michigan Alcohol Screening Test (MAST)
- Mood Disorder Questionnaire Bipolar Disorder Screening
- Pediatric Symptom Checklist
- PHQ-9 Depression Screening
- Vanderbilt Assessment Scales ADHD Screening
- Tip Sheet: PCP Toolkit & Telehealth Resource

Hysterectomy and Sterilization Forms

- Acknowledgement of Receipt of Hysterectomy Information
- Consent to Sterilization Form

Cost Containment Form

• Refund Notification Form



Simply Healthcare Plans, Inc. Medicaid Managed Care

Claim Payment Appeal — Submission Form

This form should be completed by providers for payment appeals only.

Member information		
Name:	DOB:	
Coverage: ☐ Medicaid ☐ Medicare	Member ID:	
Provider/provider representative informati	ion	
Name:	NPI:	
Street address:		
City:	State: ZIP:	
	am a nonparticipating provider.* ember has potential financial liability, you must include a	
completed Centers for Medicare & Medicaid	* ***	
•	agency 🗆 Law firm 🗆 Other:	
representative:		
Representative contact name:		
Email:	Phone:	
Street address:		
City:	State: ZIP:	
Claim information	was issue transported and form and attack a listing of the plains	
with each supporting document following be	me issue, you can use one form and attach a listing of the claims	
Claim number:	Billed amount:	
Amount received:	Start date of service:	
End date of service:	Authorization number:	
	, reconstruction manager	
Payment appeal		
, , , , , , , , , , , , , , , , , , , ,	om a health care provider to change a decision made by Simply	
A payment appeal is defined as a request fro	om a health care provider to change a decision made by Simply impayment for services already provided. A provider payment	
A payment appeal is defined as a request from Healthcare Plans, Inc. (Simply) related to cla		
A payment appeal is defined as a request from Healthcare Plans, Inc. (Simply) related to cla	im payment for services already provided. A provider payment er appeal on behalf of a member) of a denial or limited	

To ensure timely and accurate processing of your request, please complete the following **Payment dispute** section by checking the applicable determination provided on the Simply determination letter or *Explanation of Payment*.



Simply Healthcare Plans, Inc. Medicaid Managed Care

Payment dispute		
☐ Untimely filing	☐ Claim code editing denial	☐ Denied as duplicate
☐ No authorization	☐ Retrospective authorization issue	☐ Denial related to provider data issue
☐ Denied for other health insurance (OHI), but member doesn't have OHI	☐ Disagree that you were paid according to your contract	☐ Member retro-eligibility issue
☐ Experimental/investigational procedure denial	☐ Data elements on the claim on file do not match the claim originally submitted	☐ ER level of payment review
☐ Other:		

Mail this form, a listing of claims (if applicable) and supporting documentation to:

Simply Healthcare Plans, Inc. Attn: Payment Appeals P.O. Box 61599 Virginia Beach, VA 23466-1599

Case 4:22-cv-00325-RH-MAF Document 181-40 Filed 04/27/23 Page 1 of 1

From: Peoples, Leeanne

Subject: RE: Attention: A New Collateral Received for Filing: SFL-PM-0019-21 Simply CHA PM Annual Review

To: ""Gomez"","" Daralice; dgomez1@simplyhealthcareplans.com

Cc: dl-FL Regulatory Collaterals

Sent: February 14, 2022 9:02 AM (UTC-05:00)

Attached: Agency Comments 021422 SFL-PM-0019-21 Simply CHA PM Annual Review STATE.docx

Good morning,

Please see the attached document with Agency comments.

Thank you, Leeanne

From: Gomez, Daralice <dgomez1@simplyhealthcareplans.com>

Sent: Tuesday, January 18, 2022 5:25 PM

To: Peoples, Leeanne < Leeanne. Peoples@ahca.myflorida.com>

Cc: dl-FL Regulatory Collaterals <dl-FLRegulatoryCollaterals@anthem.com>

Subject: FW: Attention: A New Collateral Received for Filing: SFL-PM-0019-21 Simply CHA PM Annual Review

Hi Leeanne,

Please find the attached updated Provider Manual for your review. The TC and previous acknowledgement have been attached.

Material Name	SFL-PM-0019-21 Simply CHA PM Annual Review
Job Number ID	SFL-PM-0019-21
Description and	This is the annual update for the Simply CHA Provider Manual. This is a revision
Objective	of document SFL-PM-0017-21

Sincerely,

Simply Healthcare Plans, Inc.

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Daralice Gomez, FL Medicaid Compliance Consultant 9250 W. Flagler St. Suite 600, Miami, FL 33174

O: (561) 669-3216

<u>Dgomez1@simplyhealthcareplans.com</u>

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