No. 23-12159

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

Jane Doe et al.,
Plaintiffs-Appellees,

v.

Surgeon General, State of Florida et al.,
Defendants-Appellants.

U.S. District Court for the Northern District of Florida, No. 4:23-cv-114
(Hinkle, J.)

APPELLEES' SUPPLEMENTAL APPENDIX

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Dated: November 13, 2023

/s/ Thomas E. Redburn

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Dekker v. Weida: 4:22-cv-325

RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

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

Date: September 14, 2016

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:

- Lupron[44]
  - Indications for use: Palliative treatment of advanced prostatic cancer and central precocious puberty in children of both sexes.
- Synarel[47]
  - Indications for use: Central precocious puberty (gonadotropin-dependent precocious puberty) in children of both sexes and endometriosis.
- Supprelin[46]
  - 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:
  - Breast cancer
  - In vitro fertilization
  - Ovarian cancer
  - Premenstrual syndrome
  - Prostate cancer
  - Prostate cancer, Neoadjuvant treatment
  - Uterine leiomyoma
- Synarel:
  - Benign prostatic hyperplasia
  - Contraception, Female; prophylaxis
  - Contraception, Male; prophylaxis
  - Crohn's disease
  - Hirsutism
  - In vitro fertilization
  - Uterine leiomyoma
- Supprelin:
  - Acute intermittent porphyria
  - Endometriosis
  - Female infertility; Adjunct
  - Polycystic ovary syndrome
  - Uterine leiomyoma

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 age-matched 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.[95]

Gender Dysphoria

Gender dysphoria is an individual's affective or cognitive discontent with their assigned gender (gender at birth).[14] 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.[14]

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, 26, 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.[3] 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 System[1]

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."[5] 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:

Deputy Secretary for Medicaid (or designee)

Date

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RICK SCOTT
GOVERNOR

JUSTIN M. SENIOR
SECRETARY

CROSS-SEX HORMONE THERAPY
GAPMS DETERMINATION REPORT WITH RECOMMENDATION

Date: {DATE}
To: Beth Kidder, Deputy Secretary for Medicaid
From: Bureau of Medicaid Policy
Subject: **Cross-Sex Hormone Therapy**

PURPOSE

In order for the use of cross-sex hormone 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.

Pursuant to the criteria set forth in Rule 59G-1.010, F.A.C., the use of cross-sex hormone 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 cross-sex hormone therapy is consistent with generally accepted professional medical standards and not experimental or investigational.

If it is determined that cross-sex hormone 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.

RECOMMENDATION

This report recommends cross-sex hormone therapy as a health service that is consistent with generally accepted professional medical standards, and is supported in compendia as off-label use. There are clinical guidelines that have been published for the use of cross-sex hormones by the Endocrine Society, September 2009 and the World Professional Association for Transgender Health (WPATH 7th version). These guidelines are considered standards of care for transgender patients and provide parameters to determine the diagnosis of gender dysphoria, at what age to start treatment of cross-sex hormone therapy, and monitoring parameters that should be in place during treatment.

The Centers for Medicare and Medicaid Services (CMS), many commercial and Medicaid plans have protocols in place to provide access of the use of cross-sex hormone therapy in transgender patients.

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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).
- 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.
- Consensus of coverage policy from commercial and other state Medicaid insurers.

HEALTH SERVICE SUMMARY

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.

Cross-Sex Hormone Therapy

Cross-sex hormone therapy assists transgender patients to reflect the desired sex through physical changes. This is accomplished by increasing the testosterone in Female to Male (FTM) patients, in conjunction with suppressing the estrogen in their bodies. Male to Female (MTF) patients' testosterone levels are suppressed while their estrogen levels are increased.

Currently, there are drugs approved by the FDA that increases testosterone in men with hypogonadism and increase estrogen in women for various approved indications in addition to men with advanced prostate cancer (*Analytics, 2016*). Estrogen and testosterone are the medications mainly used in cross-sex hormone therapy. FTM patients, are prescribed testosterone, unless contraindicated. MTF patients, are prescribed estrogen, unless contraindicated (*Levine, 2013*). Anti-androgen agents may be used in conjunction with cross-sex hormone therapy, such as: progestins, gonadotropin releasing hormone agonists (GnRH), spironolactone, or 5-alpha reductase inhibitors.

Testosterone has a variety of routes of administration: buccal, intramuscular (IM), topical, transdermal, and intranasal. The oral formulation of testosterone is not available in the United States. FTM patients most commonly use transdermal/topical, or IM routes of administration because it provides better hormone levels. Estrogen also has various routes of administration

available: transdermal, vaginal, spray, oral and intramuscular. The most common route of administration for MTF: oral, IM or transdermal (*Tangpricha, 2016*). For the purposes of this report, an analysis is being performed on the use of cross-sex hormone therapy concentrating on testosterone and estrogen.

Government Regulatory Body Approval

The Food and Drug Administration (FDA) has approved testosterone for hypogonadism in men and estrogen is approved in women for various indications (see below) and for men with advanced prostate cancer. The available formulations of testosterone are testosterone cypionate, testosterone enanthate and testosterone undecanoate. The available formulations of estrogen are conjugated estrogens, esterified estrogens, estradiol, estradiol acetate, estradiol cypionate and estradiol valerate.

Testosterone:

- Indications for use: Primary hypogonadism or hypogonadotropic hypogonadism in men.
- Off Label Use: various doses used in clinical trials, including testosterone cypionate 200mg IM every 2 weeks for gender identity disorder FTM transsexual (*Analytics, 2016*).
- Possible side effects of testosterone FTM therapy: acne, polycythemia, dyslipidemia, transaminitis, weight gain, hypertension and mood lability. After 6 to 8 weeks of hormone treatment of testosterone, deepening of the voice occurs and is irreversible (*Gibson et al., 2010*).

Estrogen:

- Indications for use: Advanced prostate cancer- androgen dependent men, metastatic breast cancer, lower than normal estrogen levels in women, prevention of osteoporosis (postmenopausal),vulvovaginal atrophy (menopausal), and moderate to severe menopausal vasomotor symptoms.
- Off Label use: Conjugated estrogens, 17-beta estradiol and ethinyl estradiol may be effective in changing the physical external appearance for MTF transsexuals (*Analytics, 2016*).
- Side effects of estrogen in MTF therapy: decreased facial and body hair, fat redistribution, decreased spontaneous erections, softened skin, growth of breast tissue, and growth plate closure, increased risk of thromboembolic disease, liver dysfunction, cholelithiasis, hypertension, and hyperprolactinemia. Breast development will begin almost immediately upon estrogen administration, will proceed in a cyclical fashion, and will be as large as can be expected after approximately two years of treatment.

LITERATURE REVIEW

Gender Dysphoria

The Diagnostic and Statistical Manual of Mental Disorders defines gender dysphoria (GD) (formally referred to as gender identity disorder) as an individual's affective or cognitive discontent with their assigned gender at birth. GD 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 the 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 (*Association, 2014*).

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. Studies have shown that the majority of children (80%) diagnosed with gender dysphoria will not continue to be gender dysphoric after puberty (*Moller et al., 2009; Wallien & Cohen-Kettenis, 2008; and Drummond et al., 2008*).

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. It is generally introduced in children who have reached a minimum of Tanner Stage 2 (a scale used to determine physical development in children, adolescents and adults based on external primary and secondary sex characteristics) which is usually at the age of 12-16 (*Cohen-Kettenis et al., 2011*). Other drugs, such as progestins and antiandrogens (spironolactone and 5-alpha reductase inhibitors) have been used to suppress physical changes in puberty. 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 (*de Vries et al., 2011*).

Cross-sex hormone therapy is the primary medical intervention sought by transgender people***.*** Exogenous hormones have a clear impact on fertility. Patients must be informed and counseled regarding options for fertility and evaluation of medical conditions that can be exacerbated by hormone depletion, prior to treatment with sex hormones of the desired sex in both adolescents and adults. The patient must be made aware of the possibility of infertility/sterilization with the use of cross-sex hormone therapy. Fertility preservation options may include sperm, oocyte, embryo, ovarian tissue or testicular tissue cryopreservation. Transgender patients who undergo fertility preservation or assisted reproduction should be informed of the lack of data on outcomes. The use of cross-sex hormone therapy alone does not guarantee prevention of pregnancy, therefore if sexually active, contraception is required. Testosterone can cause birth defects and is contraindicated in pregnancy. The effects of long term exogenous testosterone and estrogen are unclear, but the possible side effects should be addressed (*Francisco, Center, and Information, 2016*).

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 (*Kaltiala-Heino et al., 2015; Jarin et al., 2016; Lee et al., 2016, March et al., 2015; Vance et al., 2014; Vrouenraets et al., 2015*).

Clinical Outcome

No perspective, randomized, controlled trials were located that have evaluated the safety and efficacy of the use of cross-sex hormones to produce physical effects in transgender patients. The current information used has been derived primarily from observational study or has been extrapolated from the use of hormones for the approved FDA indications (Tangpricha, 2016).

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

Recommendations from The Endocrine Society Guidelines are as follows:

- We recommend that the diagnosis of gender identity disorder (GID) be made by a mental health professional (MHP). For children and adolescents, the MHP should also have training in child and adolescent developmental psychopathology.
- Given the high rate of remission of GID after the onset of puberty, we recommend against a complete social role change and hormone treatment in pre-pubertal children with GID.
- We recommend that physicians evaluate and ensure that applicants understand the reversible and irreversible effects of hormone suppression (e.g. GnRH analog treatment) and cross-sex hormone treatment before they start hormone treatment.
- We recommend that all transsexual individuals be informed and counseled regarding options for fertility prior to initiation of puberty suppression in adolescents and prior to treatment with sex hormones of the desired sex in both adolescents and adults.
- We suggest that pubertal development of the desired opposite sex be initiated at about the age of 16 year, using a gradually increasing dose schedule of cross-sex steroids.
- We recommend referring hormone-treated adolescents for surgery when 1) the real-life experience (RLE) has resulted in a satisfactory social role change; 2) the individual is satisfied about the hormonal effects; and 3) the individual desires definitive surgical changes.
- We suggest that treatment with GnRH analogs be continued during treatment with cross-sex steroids to maintain full suppression of pituitary gonadotropin levels and, thereby, gonadal steroids. When puberty is initiated with a gradually increasing schedule of sex steroid doses, the initial levels will not be high enough to suppress endogenous sex steroid secretion.
- Baseline labs and scheduled routine monitoring for known risks throughout adulthood
- Maintain physiologic levels of appropriate sex hormones in the range of the desired gender and monitor for known risks of gender-appropriate sex hormones.
- Lifetime continuation of cross-sex hormone therapy usually required unless medically contraindicated (*Hembree et al., 2009*).

WPATH Version 7 Standard of Care recommendations for Cross-Sex Hormone therapy:

- Persistent, well-documented diagnosis of gender dysphoria.
- Capacity to make a fully informed decision and to consent for treatment.
- If significant medical or mental health concerns are present, they must be reasonably well controlled.
- A mental health professional competent in diagnosing and treating ordinary problems of children and adolescents; trained in childhood and adolescent developmental psychopathology; and must meet the competency requirements for mental health professionals working with adults.
- A staged process of physical interventions of adolescents is recommended to allow the adolescents and their parents to assimilate fully the effects of earlier interventions: fully reversible interventions (i.e. GnRH analogues, spironolactone, progestins) partially reversible interventions (i.e. hormone therapy to masculinize or feminize the body, cross-sex hormones) and irreversible interventions (surgical procedures).
- Adolescents may be eligible to begin feminizing/masculinizing hormone therapy preferably with parental consent at 16.
- Regimens for hormone therapy in gender dysphoric adolescents differ substantially from those used in adults (*Hembree et al., 2009*).
- The hormone regimen is adjusted to account for emotional, somatic and mental development that occurs throughout adolescence.

Possible risk Factors associated with Cross-Sex Hormone therapy:

- Adolescents undergoing partially reversible cross-sex hormone therapy should be monitored for progress in transition and for any potential medical complications.

- Male to Female (MTF) patients started on estrogen might develop deep venous thrombosis, prolactinomas, hypertension, hypertriglyceridemia, cardiovascular disease, type 2 diabetes, liver disease, and decreased libido and are at increased risk of breast cancer. Spironolactone can lead to hyperkalemia and decreased blood pressure.

- Female to Male (FTM) patients receiving testosterone may develop hyperlipidemia, polycythemia, male pattern baldness, acne, cardiovascular disease, hypertension, type 2 diabetes, breast cancer, cervical cancer, ovarian cancer, uterine cancer, destabilization of certain psychiatric disorders (i.e. bipolar, schizoaffective disorders (*Hembree et al., 2009; Tangpricha, 2016*).

Monitoring for FTM on hormone therapy:

- Monitor for virilizing and adverse effects every 3 months for first year and then every 6 – 12 months.
- Monitor serum testosterone at follow-up visits with a practical target in the male range (300 – 1000 ng/dl). Peak levels for patients taking parenteral testosterone can be measured 24 – 48 h after injection. Trough levels can be measured immediately before injection.
- Monitor hematocrit and lipid profile before starting hormones and at follow-up visits.

- Bone mineral density (BMD) screening before starting hormones for patients at risk for osteoporosis. Otherwise, screening can start at age 60 or earlier if sex hormone levels are consistently low.
- FTM patients with cervixes or breasts should be screened appropriately.
- Monitor renal function, liver function tests, fasting glucose, insulin, hemoglobin A1C, bone density and bone age.
- FTM patients should have axillary lymph nodes examined (*Gooren et al., 2008; Jain & Bradbeer, 2007; Sobralske, 2005*).

Monitoring for MTF on hormone therapy:

- Monitor for feminizing and adverse effects every 3 months for first year and then every 6– 12 months.
- Monitor serum testosterone and estradiol at follow-up visits with a practical target in the female range (testosterone 30 – 100 ng/dl; estradiol <200 pg/ml).
- Monitor prolactin and triglycerides before starting hormones and at follow-up visits.
- Monitor potassium levels if the patient is taking spironolactone.
- Bone mineral density screening before starting hormones for patients at risk for osteoporosis. Otherwise, start screening at age 60 or earlier if sex hormone levels are consistently low.
- MTF patients should be be advised to do breast self-exams and be screened for breast and prostate cancer appropriately. Breast self-exams should be advised (*Gooren et al., 2008; Jain & Bradbeer, 2007; Sobralske, 2005*).

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 or preferred drug list. 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:

- Compendia, consisting of the following:
  - American Hospital Formulary Service Drug Information;
  - United States Pharmacopeia-Drug Information (or its successor publications); and
  - the DRUGDEX Information System; and
- 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 may be 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).

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

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

Florida Medicaid covers hormone 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. Testosterone and estrogen are not FDA approved for cross-sex hormone therapy in patients with gender dysphoria. However, DRUGDEX Information System's compendia addresses off-label use of testosterone cypionate, conjugated estrogens, 17-beta estradiol and ethinyl estradiol in the use of cross-sex hormone therapy.

Children/adolescents diagnosed with gender dysphoria are also 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:

- Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
- 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;
- Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
- 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
- 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.

Centers for Medicare and Medicaid Services

A new rule by the Department of Health and Human Services implements Section 1557 of the Affordable Care Act (ACA), "Nondiscrimination in Health Programs and Activities." This rule applies to all health programs that receive federal funding or assistance, including state Medicaid agencies, as well as most health insurance issuers. On July 18, 2016, other provisions went into effect related to discrimination, based on gender identity, pregnancy, or transgender status. Individuals must be provided equal access to health services without discrimination related to gender or identity. Entities can still review for medical necessity as long as the review is not discriminatory towards these individuals and utilizes a neutral rule or principal. Categorical exclusion or limits on services related to gender transition are discriminatory as well.

Medicare

Transgender beneficiaries can use hormone therapy, which are reimbursable under the Medicare Part D prescription drug benefit program. 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." Medicare provides a special billing code (condition code 45) when gender mis-match claims may be a problem.

State Medicaid Programs

All state Medicaid programs cover hormone 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 cross-sex therapy in adolescents diagnosed with gender dysphoria. This report highlights the coverage policies for some Medicaid programs that do cover the service, as follows:

- Colorado Medicaid covers behavioral health services, GnRH analogs/agonists, cross-sex hormone therapy, gender confirmation surgery, and pre and post-operative care.
- Maryland Medicaid covers cross-sex hormone therapy for recipients 18 and older.
- 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.
- Washington State Medicaid covers behavioral health services, puberty suppression therapy, hormonal therapy, and gender reassignment surgery. Policy has been implemented since February 2014 regarding access to care.
- California, New York and Massachusetts Medicaid are obligated to pay for gender transition.
- Oregon Medicaid covers cross-sex hormone therapy for adolescents and adults who meet eligibility and readiness criteria.
- Montana Medicaid covers cross-sex hormone therapy for transgender recipients. Testosterone requires a prior authorization to ensure treatment is for appropriate diagnoses.
- Indiana Medicaid covers cross-sex hormone therapy for gender dysphoric recipients.
- Illinois Medicaid removed gender restrictions on estradiol and testosterone in April 2015 referencing the Endocrine Society recommendations.

Private Insurers:

The following private insurers have criteria in place to access medications for cross-sex hormone therapy:

- Moda Health Plan Inc., Gender Reassignment Medical Necessity:
- Fallon Health, Transgender Services Clinical Coverage Criteria
- Blue Regence Transgender Services Policy

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

Cross-sex hormone therapy may be considered a health service that is consistent with generally accepted professional medical standards for the approved FDA indications (i.e., hypogonadism, hypoestrogenism) and for off-label use when supported by citations in at least one of the compendia. Since Florida Medicaid already provides coverage of hormone therapy in the FDA approved indications 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, cross-sex hormone therapy should be 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 cross-sex hormone therapy in gender dysphoric children/adolescents have concluded that further systematic research is required to determine the long-term safety and efficacy of this approach.

The guidelines for transgender patients in the Endocrine Society and WPATH are controversial because they are based primarily on expert opinion rather than scientific data, given the paucity of the outcomes data on the effects of mental health and medical interventions (*Vance et al., 2014*). However, the standards of care for cross-sex hormone therapy seem to be consistent in the approach with diagnosis, monitoring and dosing of the transgender patients. Indeed, hormone therapy and surgery have been found to be medically necessary to alleviate gender dysphoria in many people (*Tangpricha, 2016).*

Regimens for hormone therapy in gender dysphoric adolescents differ substantially from those used in adults. The hormone regimens for youth are adapted to account for the somatic, emotional, and mental development that occurs throughout adolescence (*Hembree et al., 2009*). 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.

EPSDT Considerations:

Clinical guidelines from the Endocrine Society and WPATH recommend this therapy for certain adolescents, albeit based upon 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.

Testosterone cypionate, conjugated estrogens, 17-beta estradiol and ethinyl estradiol have documented off-label use in Micromedex compendia. Because of this supporting documentation in the compendia, the off-label criteria could be used to evaluate each patient on a case by case basis. This report recommends cross-sex hormone therapy as a health service that is consistent with generally accepted professional medical standards. 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:

_____

_____

_____

_____ _____
Signature Date
Deputy Secretary for Medicaid (or designee)

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Doc. 182-34, PX 294
Dekker v. Weida: 4:22-cv-325

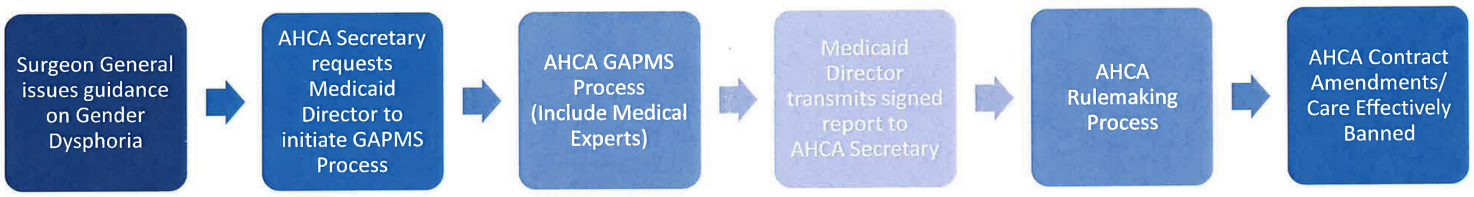
Projected Rulemaking Timeline

June 3	June 16	June 17	July 8	July 11	July 12	July 19	August 8
NORD published in FAR	Issue Response Letter	NOPR & Hearing information publishes in the FAR	Rulemaking Hearing	Hearing Comment Period	Adoption Package submitted to JAPC	File the rule for Adoption with DoS	Rule is Effective
Received Request for Workshop	Send NOPR to OFARR & FAR	Send Notice of Proposed Rule to JAPC					

Acronym Key	
GAPMS	Generally Accepted Professional Medical Standards
FAR	Florida Administrative Register
NORD	Notice of Rule Development
NOPR	Notice of Proposed Rule
JAPC	Joint Administrative Procedures Committee
DoS	Department of State

Doc. 182-35, PX 295
Dekker v. Weida: 4:22-cv-325

Gender Dysphoria/Transgender Health Care Non-Legislative Pathway

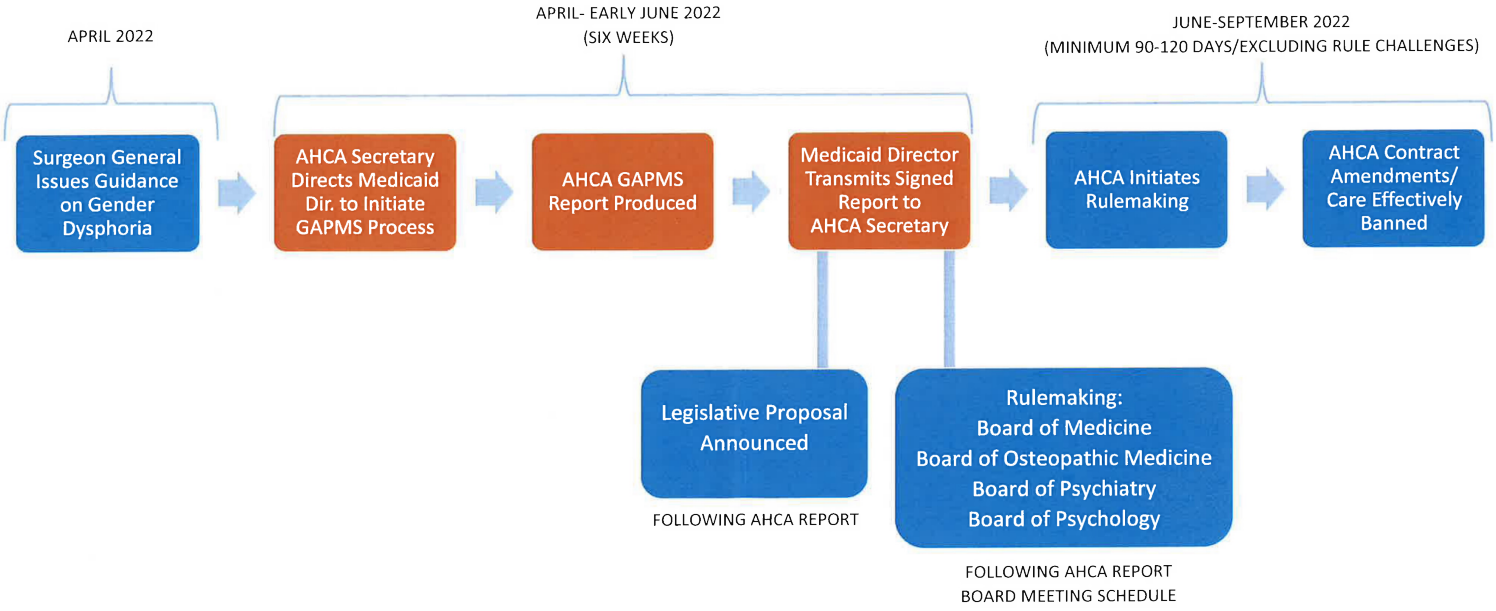


EOG_008240

Pl. Trial Ex. 295

Doc. 182-36, PX 296
Dekker v. Weida: 4:22-cv-325

Gender Dysphoria/Transgender Health Care Policy Pathway



^ GAPMS: Determining Generally Accepted Professional Medical Standards

EOG_008241

Pl. Trial Ex. 296

Doc. 193-5, DX 5
Dekker v. Weida: 4:22-cv-325

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Ron DeSantis
Governor

Joseph A. Ladapo, MD, PhD
State Surgeon General

Vision: To be the **Healthiest State** in the Nation

Treatment of Gender Dysphoria for Children and Adolescents

April 20, 2022

The Florida Department of Health wants to clarify evidence recently cited on a fact sheet released by the US Department of Health and Human Services and provide guidance on treating gender dysphoria for children and adolescents.

Systematic reviews on hormonal treatment for young people show a trend of low-quality evidence, small sample sizes, and medium to high risk of bias. A paper published in the International Review of Psychiatry states that 80% of those seeking clinical care will lose their desire to identify with the non-birth sex. One review concludes that "hormonal treatments for transgender adolescents can achieve their intended physical effects, but **evidence regarding their psychosocial and cognitive impact is generally lacking**."

According to the Merck Manual, “gender dysphoria is characterized by a strong, persistent cross-gender identification associated with anxiety, depression, irritability, and often a wish to live as a gender different from the one associated with the sex assigned at birth.”

Due to the lack of conclusive evidence, and the potential for long-term, irreversible effects, the Department's guidelines are as follows:

- Social gender transition should not be a treatment option for children or adolescents.
- Anyone under 18 should not be prescribed puberty blockers or hormone therapy.
- Gender reassignment surgery should not be a treatment option for children or adolescents.
    - Based on the currently available evidence, "encouraging mastectomy, ovariectomy, uterine extirpation, penile disablement, tracheal shave, the prescription of hormones which are out of line with the genetic make-up of the child, or puberty blockers, are all clinical practices which run an **unacceptably high risk of doing harm**."
- Children and adolescents should be provided social support by peers and family and seek counseling from a licensed provider.

These guidelines do not apply to procedures or treatments for children or adolescents born with a genetically or biochemically verifiable disorder of sex development (DSD). These disorders include, but are not limited to, 46, XX DSD; 46, XY DSD; sex chromosome DSDs; XX or XY sex reversal; and ovotesticular disorder.

The Department’s guidelines are consistent with the federal Centers for Medicare and Medicaid Services age requirement for surgical and non-surgical treatment. These guidelines are also in line with the guidance, reviews, and recommendations from Sweden, Finland, the United Kingdom, and France.

Parents are encouraged to reach out to their child’s health care provider for more information.

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Doc. 235-1
Dekker v. Weida: 4:22-cv-325

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA

CASE NO. 4:22-cv-00325-RH-MAF

AUGUST DEKKER, et al.,
Plaintiffs,
vs.
JASON WEIDA, et al.,
Defendants
_____/

	Volume 1, Pgs. 1 - 124
VIDEOTAPED DEPOSITION OF:	MATTHEW BRACKETT
AT THE INSTANCE OF:	THE PLAINTIFFS
DATE:	FEBRUARY 8, 2023
TIME:	COMMENCED: 10:00 A.M.
LOCATION:	AGENCY FOR HEALTH CARE ADMINISTRATION 2727 MAHAN DRIVE TALLAHASSEE, FLORIDA 32308
REPORTED BY:	DANA W. REEVES Court Reporter and Notary Public in and for State of Florida at Large

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ALSO PRESENT:

RL Minnich, Videographer

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*Uh-uh is a negative response
*Uh-huh is a positive response

D E P O S I T I O N

VIDEOGRAPHER: This is the video-recorded deposition of corporate representative for Agency for Healthcare Administration, in the matter of August Decker, et al. vs. Jason Weida, et al. Case No. 4:22-cv-00325, RH-MAF. This deposition is being held at 2727 Mahan Drive in Tallahassee, Florida. Today's date is February 8th, 2023 and the time is 10:08 a.m. The court reporter is Dana Reeves. My name is RL Minnich. I'm the videographer. Would counsel please introduce themselves and the court reporter please swear in the witness?

MS. DEBRIERE: Yes, Katy DeBriere and I represent the plaintiffs.

MS. CHRISS: Simone Chriss and I also represent the plaintiffs.

MS. DUNN: Chelsea Dunn. I also represent the plaintiffs.

MR. JAZIL: Mohammad Jazil for the defense.

MS. DEBRIERE: And we have a few people on the Zoom link from the plaintiff's side. That would be Catherine McKee and Omar Gonzalez-Pagan.

MR. PERKO: And Gary Perko on behalf of the defendants on the Zoom link.

MS. DEBRIERE: And Shani Rivaux has joined us from the plaintiff's side as well.

COURT REPORTER: All right, sir, if you would raise your right hand, please.

Whereupon,

MATTHEW BRACKETT

was called as a witness, having been first duly sworn to speak the truth, the whole truth, and nothing but the truth, was examined and testified as follows:

THE WITNESS: I do.

COURT REPORTER: Thank you.

EXAMINATION

BY MS. DEBRIERE::

Q All right. So we're just going to mark exhibits as they're discussed, if that's okay with you, Matt.

A That's fine.

Q As we walk through those exhibits, I'm going to read off the Bates numbers on the bottom of each page. So those are just the -- that line of numbers I'm reading out loud as we discuss exhibits, and that should help you track what page I'm on as we're discussing them. So we're going to go ahead and mark the notice of deposition as Exhibit 1. I saw that you brought the copy with you, as well, Mr. Brackett.

(Whereupon, Exhibit No. 1 was marked for identification.)

MR. JAZIL: Is this the court reporter's copy?

MS. CHRISS: The witness' copy that can become the court reporter's copy.

BY MS. DEBRIERE::

Q Okay. So just some preliminary stuff before we go over this notice. I'm going to be using the acronym GAPMS quite a bit. That stands for Generally Accepted Professional Medical Standards, and is the acronym that refers to the process described at Florida Administrative Code Rule 59-G-1.035. When I refer to the GAPMS or GAPMS process, do you understand what I mean?

A Yes.

Q I will also use the term gender dysphoria, which is defined as discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth and the associated gender role and/or primary and secondary sex characteristics. Can we agree that when I say gender dysphoria, that's the definition I'm using?

A Yes.

Q I will also be using a phrase categorical exclusion of treatment for gender dysphoria, which

refers to the exclusion in Florida Administrative Code Rule 59-G-1.050(7). Do you understand that that phrase refers to all the services in that particular portion of the rule when I say categorical exclusion?

A I do.

Q And then I will also be using the term EPSDT services, which stands for Early Periodic -- Early and Periodic Screening Diagnostic and Treatment Services. When I say EPSDT, do you know what I mean?

A Yes.

Q Have you ever been deposed before?

A Yes, I have.

Q Okay. So if there's at any point that you don't understand my question, what I want you to do is I want you to stop and ask me to rephrase it. I don't want you to try to attempt to ask -- answer the question if you don't understand it. Okay?

A Okay.

Q I have a problem sometimes of speaking over someone else, I don't know if you have the same problem, but what we need to try to do is just give each other space to pause in between the questions so we're not speaking over each other. Okay?

A I'm fine with that.

Q Okay. Verbal answers. Sounds like, you know,

you speak very clearly, so we shouldn't have a problem, but obviously -- although we do have a videographer here, it's better to speak your answer out loud.

A I do understand. Articulating hand gestures, the court reporter cannot get those into the transcripts.

Q Exactly. All right, if you need to take a break for any reason, totally fine, just let me know. I do ask that you answer my question before we take a break.

A Okay.

Q And then are you on any medications or other substances that could impact your memory today?

A No.

Q And state your name for the record.

A So my full name is John Matthew Brackett.

Q Okay. And it's your understanding that you're representing the Florida Agency for Health Care Administration in a 30(b)(6) deposition?

A That's correct.

Q Okay. What topics, looking at the notice, which is Exhibit 1, notice of 30(b)(6) deposition, what topics were you designated for? Were they all of them here?

A Yes.

Q And you're prepared to testify on behalf of the Agency on each of these topics?

A Yes.

Q Have you seen the 30(b)(6) deposition topics?

A You mean as those listed in the -- yes, I have seen them.

Q And who provided them to you?

A Those were provided to me by our outside counsel.

Q Okay. And did you consent to acting as the agency representative?

A Yes, I did.

Q What did you do to -- excuse me. What did you do to prepare for today?

A Mostly just familiarize myself with areas and topics that are on the list that are not familiar to my current job role, and that's pretty much it. So pretty much standard operating procedures here at the Agency that are -- that might fall under different divisions or different teams, et cetera. And just kind of, like, reviewed some of our coverage policies, some of our rules and some of our own materials.

Q Okay. Who did you speak to?

A Principally, consulted with Andrew Sheeran and for any questions that involved managed care, I

consulted my supervisor Devona Pickle.

Q Did you gather information from anyone, anyone besides counsel?

A I gathered a little bit of information from Devona Pickle, since one of the questions directly involved her role in the process.

Q Okay. I saw that you brought a document with you today, it looks like maybe you reviewed that to prepare. What is that?

A So that is pertinent to the question. I can provide you the exact one. Yeah, I think -- yeah, question three. It was -- since that asked about the process of how we looked at other states' Medicaid programs, which that spreadsheet was -- Devona Pickle administered that role of the GAPMS process. And since that question was on there, I did ask her to provide me with what she used to -- and the research methods used to go through each state Medicaid program to find out what their coverage criteria is, or if they have a statement prohibiting coverage, or if they just don't have any statement whatsoever.

MS. DEBRIERE: Okay. And, Mo, do you know if that was produced to us in discovery?

MR. JAZIL: I don't believe it was. So we'll make copies and get it to you.

BY MS. DEBRIERE::

Q How long did it take you to prepare for the deposition today?

A Well, given that we received these questions about a week ago, I'd probably say I spent probably off and on -- I mean, in between other projects, probably I'd say three, maybe four working days.

Q Okay. A little bit about you. Describe your educational background.

A So I received a -- my -- started off, I got my AA at Tallahassee Community College. I received my Bachelor of Arts in history at Florida University, 2003. I graduated magna cum laude. Received my Master of Arts in History from Florida University in 2005. During my time in graduate school, I did spend a few extra years working on a PhD, which I decided not to finish, but during my grad school years, I presented research papers on numerous topics at numerous conferences. And I also published scholarly articles in the Florida Historical Quarterly and Southern Studies and Interdisciplinary Journal of the South.

Q The conferences, what were those about?

A The conferences ranged. They could -- they were, I think, either conference on Florida history, conferences on environmental history. I think there

were, like, graduate symposiums. So often they're also, like, regional conferences. The topics I represented on ranged from anything from environmental history to public health history.

Q And your PhD, what -- what were you attempting to get it in?

A So I was actually looking at getting my PhD in the history of medicine and public health. And actually, I was -- my dissertation topic was on tuberculosis, on how during the late 19th century, how kind of the infancy of public health agencies and how public health was actually becoming a common concept and how -- and, of course, with the emerging sciences -- well, pretty much with the discovery of microbiology and discovery of the tuberculosis bacteria, how all that was coming together to affect changes in the south in public health, and looking at also how, since tuberculosis was very common, on how that shapes southern identity.

Q Okay. And what's your current position at the Agency for Health Care Administration?

A So my current position is Program Consultant. I work on the Canadian Drug Importation Program primarily.

MS. DEBRIERE: And, Court Reporter, just to note, we're going to refer to the Agency for Health

Care Administration's throughout as either AHCA or the Agency.

BY MS. DEBRIERE::

Q Prior to your role with the Canadian Drug Importation Program -- did I get that right?

A Yeah, close enough.

Q What was your role at the Agency?

A My role at the Agency, I was the Program Administrator over the Specialized Services and Behavioral Health teams. Of course, we oversaw the development and, of course, updating of policies, such as durable medical equipment, community behavioral health, non-emergency transportation, school-based services, hospice. There's actually quite a lengthy list.

Q And how long did you do that for?

A I was in that position for three and a half years.

Q Okay. And prior to that, were you at the Agency?

A Yes, I was.

Q And what was your role then?

A I was a Government Analyst II. And during that time period, that was from January 2017 to November 2017, I was -- my role specifically tasked with

completing the Generally Accepted Professional Medical Standards reports.

Q And prior to that time, were you at the Agency?

A Yes.

Q And what did you do then?

A I would -- I worked in the Office of the Deputy Secretary for Health Quality Assurance.

Q So your time in the Bureau of Medicaid policy was from December 2017 to --

A January 2017 to November 2017. But my job -- but becoming a program administrator, I was still in the same bureau.

Q So GAPMS -- working on GAPMS was January 2017 to November 2017, and then you shifted to another role in Bureau and Medicaid Policy?

A Yes.

Q And that was in December of 2017 through --

A November 2017 through April of 2021.

Q And so since May of 2021 or April 2021 you've been with the Canadian Drug --

A April 2021.

Q Okay. Let's look at the Florida definition of medical necessity. And that is in the Florida Medicaid Definitions Policy, which I'm sure you're intimately

familiar, at Section 2.83, and it's incorporated by reference into rule by Florida Administrative Code Rule 59-G-1.010.

MR. JAZIL: Simone, would you happen to have an extra copy?

MS. CHRISS: Yes.

MR. JAZIL: I'd rather just not lean over his shoulder.

MS. DEBRIERE: You know what, Mo, you can use mine. I basically have it committed to memory.

MR. JAZIL: Thank you.

MS. DEBRIERE: So we'll go ahead and mark this policy as Exhibit 2.

(Whereupon, Exhibit No. 2 was marked for identification.)

BY MS. DEBRIERE::

Q And, Mr. Brackett, if you want to turn to it, it's 2.83.

A Okay.

Q What's the purpose of the Medical Necessity standard listed here?

A So is -- kind of clarify -- can you clarify what's meant by purpose?

Q What does AHCA use that medical necessity standard for?

A So these prongs for medical necessity, as defined, these are our guidelines for determining whether or not Florida Medicaid should cover a service.

Q Okay. Is it correct to say that the standard is used to determine whether Medicaid service should be prior authorized?

A I don't -- I don't -- I don't think so.

Q Okay. Tell me why.

A Because for medical necessity, being medically necessary, this is generally -- this is a criteria for whether or not Medicaid should cover a service. The prior authorization process is just mostly more clinical review to determine whether or not delivery of that service, coverage of that service corresponds to the definition of medical necessity.

Q Okay. So when you're doing a prior authorization review, you do determine whether or not the service corresponds to the definition of medical necessity?

A So since our subcontractors and our managed care plans do our prior authorizations, they do have to make sure that the -- that with the service they're prior authorizing would, if subjected to the medical necessity guidelines and definition, yeah, they have to make sure it corresponds.

Q Okay. And that's part of the prior authorization process?

A That's part of the prior authorization process, yes.

Q If a Medicaid service is found to be experimental by AHCA, would AHCA or its contractors, subcontractors like a managed care plan, still review whether the service meets any other portion of AHCA's medical necessity rule?

A No.

Q Okay. Why not?

A Because it does have to meet the five prongs of medical necessity, and one of those prongs is it has to be in alignment with GAPMS.

Q Okay. So if it's not in alignment with GAPMS, would you analyze it under any other portion of that definition?

A No, we wouldn't.

Q If a Medicaid service has not been determined experimental, using like GAPMS process, can a Medicaid managed care plan use the portion of the medical necessity standard that reads, be consistent with Generally Accepted Professional Medical Standards?

A Once the Agency deemed that it's not consistent, and often these requests usually come to us

from the plans, the plan is not going to cover it.

Q Okay. Is the plan able to make an independent determination of whether those services are experimental in nature, or must that come from -- decision come from AHCA?

A It does not necessarily have to come from AHCA. We do grant our managed care plans a great deal of flexibility when it comes down to the services they wish to cover, but sometimes when they get a service that they're not sure about, they do often -- sometimes will ask us to do a GAPMS review of it to determine whether or not that -- if they should cover it. So sometimes we're kind of more of a reference point, but the plans function pretty independently in these areas.

Q Okay. So the plan can make an independent determination as to whether or not a service is experimental or investigational?

A No. Whether or not to cover -- we don't allow them to do -- we don't allow them to do independent GAPMS reviews, if that's what you're asking.

Q What I'm asking is looking at the prong about whether this service is consistent with GAPMS, whether the plan can deny coverage of a service on that basis without AHCA's initial determination?

A No, they need to consult with us before

they -- they need to consult with us before they use experimental and investigational as a basis for denial, which they will -- we do get requests from the health plans.

Q Okay. All right. So moving on to what's Bates-stamped as defendant DEF_000126105. This is the GAPMS report on cross-sex hormone therapy, which is dated --

MS. CHRISS: May '22.

BY MS. DEBRIERE::

Q May 20th, 2022.

VIDEOGRAPHER: Counsel, can you put that mic on, please? They placed it right beside you.

MS. DEBRIERE: Yes. Yes.

VIDEOGRAPHER: The one to your right. Thank you.

MS. DEBRIERE: I should have worn my suit jacket tonight.

THE WITNESS: It might get hot here shortly, so I may be taking mine off.

MS. DEBRIERE: Should I mark this as 3?

MS. CHRISS: Yes, the one for him.

MS. DEBRIERE: I think we got it split up. I'm sorry. Mo, do you want to copy?

MR. JAZIL: Sure. Do you really have all these

committed to memory?

MS. DEBRIERE: Well, not this one, no, no, but somewhat.

MR. JAZIL: Here's the last one, Katy.

MS. DEBRIERE: Thanks.

MR. JAZIL: That's pretty impressive if you do.

MS. DEBRIERE: Well, not these, but definitely, you know, you practice Medicaid in Florida for seven years, you know what the medical necessity definition is.

(Whereupon, Exhibit No. 3 was marked for identification.)

MS. DEBRIERE: All right. Not a day past seven years, either.

BY MS. DEBRIERE::

Q Okay. So looking at -- do you have a copy, Mr. Brackett?

A Yes.

Q Okay. Looking at -- if you'll flip to what's marked as DEF_000126112, it's page eight.

A Okay.

Q Starting under coverage policy, there's some discussion about federal regulations, and then moving through to the Florida Medicaid section that ends on the top of page 10, if you could just review that for me.

A Okay.
Q So is this an accurate portrayal of the standard to determine Florida Medicaid coverage for prescription drugs?
A Yes, this is.
Q Do all prescription drugs require prior authorization to be reimbursed by Florida Medicaid?
A I can't speak fully to that one. I don't -- I don't believe so, but often our managed care plans, we grant them a lot more flexibility when it comes down to prior authorizations, so they may require prior authorization for every drug. But as far as, like, every single drug, as far as the fee for service system goes, I'm not a hundred percent certain, but I believe that we do not require prior authorization for every single drug.
Q Okay. Do you know if anybody at the Agency would have a hard answer to that question?
A One of our staff pharmacists probably would.
Q So can you briefly describe the process a Medicaid recipient undertakes in seeking prior authorization for a drug?
A Usually, that's taken by the provider usually, or in the case of pharmacy, I'm not sure who would submit the prior authorization. I don't think that

that's -- process is not initiated by the recipient themselves, it's usually initiated by the provider. Of course, it goes through, like, a one-two level review process. That first level is usually done by, like, a nurse or an RN. They just determine whether or not it's medically necessary. If it is, then that one level stops. If it's a denial, it has to go -- I think it goes to a second-level review.

Q Okay. And what is -- what is involved in that review? What is being reviewed?

A Well, I'm not intimately familiar with it because we used it a long, long time ago, prior to SM's. We did that stuff in-house. That was before my time with the Agency, but now that's outsourced to EQ Health Solutions in the fee-for-service system. But they do review the medical records, et cetera, and then, I think, any other materials that are submitted by the doctor, so --

Q Do they compare it to coverage policies or guidelines?

A Well, for children, I don't -- it wouldn't be necessary to because of EPSDT, but for adults, I don't know. That's information that we would have to ask our vendors. I assume they would, but that's an assumption.

Q Okay. Tell me a bit more about what you mean

by coverage guidelines when it needs to be reviewed for children because of EPSDT.

A Well, because of EPSDT, in which, since you're familiar with all this, of course, even regardless of what something says on the coverage policies -- because our coverage policies and our fee schedules are very prescriptive, they list out what services can be covered, what services can't be covered. Our fee schedules, of course, outline the amount of money that we pay for each service and our perimeter service gaps, most importantly, the service gaps. So for children, if it's deemed medically necessary, and usually it does have to go through the prior authorization process for an EPSDT consideration, if it's determined medically necessary, regardless of whether it's on a fee schedule or not, or in excess of our fee schedule, or if it's not listed in that coverage policies, because of EPSDT requirements from the feds, we do have to cover it.

Q Okay. Okay. And how do you define medical necessity for EPSDT?

A It's the same as listed in definitions policy.

Q Okay. What would be the process for obtaining Medicaid coverage for a drug where prior authorization is not required?

A Well, so the thing about Medicaid coverage for

drugs is that we do cover all drugs that are FDA approved. So if -- unless it has a prior authorization requirement and if that FDA approved covered drug can be covered by Medicaid.

Q Okay. What if it's not FDA approved?

A If it's not FDA approved or if it's -- so are we talking about, like, complete non-FDA approval or are we talking about like our off-label usage?

Q Actually, let's back up. So if it's FDA approved, does that mean it does not need to go through the prior authorization process for Medicaid to authorize it?

A If it's not FDA approved, we -- I mean, we're not going to cover it if it's not FDA approved.

Q Okay. If it is FDA approved, does the Medicaid recipients still have to undertake the prior authorization process to --

A If it's FDA approved, and it's a drug that we've required prior authorization, then, yes.

Q Okay. If it's a drug that does not require prior authorization, what does that process look like for coverage?

A I generally -- I think it just -- the pharmacy fills the prescription, they file a claim, agency pays the claim and the dispensing fee.

Q Okay. So there's no review in medical necessity under that --

A Providing the drug does not -- does not have prior authorization criteria, yes.

Q Okay. So if it's a drug that does not require authorization, AHCA does not determine if it's being prescribed for a medically necessary use; is that correct?

A Can you repeat that?

Q Yep. If a drug does not require prior authorization, AHCA does not -- AHCA or its contractors does not undertake a determination as to whether it's being prescribed for a medically necessary use?

MR. JAZIL: Object to form.

THE WITNESS: We covered -- we cover services that are medically necessary. So if it's -- that would be in violation of policy if drugs are being covered -- if drugs are being prescribed and covered, when for -- when medical records and the documentation -- when medical necessity is not being met, that is that -- no, we would not cover in those circumstances.

BY MS. DEBRIERE::

Q How would you make that determination that you would not cover if you're not doing a prior

authorization review?

A So generally when issues like that, when providers are billing Medicaid for services that are not medically necessary, that's usually when our Medicaid -- Medicaid program Integrity, they start getting involved in looking at -- looking at such claims.

Q How would that rise to the surface of triggering an investigation with Medicaid Integrity?

A Well, there are lots of tip-offs. I mean, we do have a -- we do have a fraud hotline. So somebody could report a provider for fraud. There -- it could be result from an on-site survey. Our Bureau of Recipient Provider Assistance does -- they often do Medicaid surveys on providers. It could also potentially result from a -- one of our health quality assurance surveys, if they're going in and looking at, like, their compliance with licensure rules. So it really depends on where the fraud's detected. So there are multiple avenues for reporting Medicaid fraud.

Q Does AHCA have a pharmacy coverage policy for every prescription drug?

A We do have our outpatient prescribed drugs services coverage policy. And that, of course, is for our covered outpatient drug benefit.

Q Does that policy list every potential

prescription drug prescribed under -- prescribed to a Florida Medicaid recipient?

A No. So -- because Florida Medicaid covers any drug that's FDA approved, when these medical necessity guidelines, that's kind of an encompassing umbrella. And then, of course, we do have the preferred drug list which is assembled by the Pharmaceutical and Therapeutics Committee. We always just call P&T, so -- but because the list is so vast we don't actually reproduce it in any kind of a form. So the prescribed drug services policy, the way it's worded is supposed to be all-encompassing, but there are exclusions in Section 5.2 of non-covered service -- of drugs that we won't cover under certain circumstances.

Q Okay. So it lists some drugs you won't cover, but it doesn't list all the drugs you will potentially cover?

A Right. But it's also -- but it's not -- it doesn't specifically state drugs, it's just -- it's more specific to conditions. Like we don't say we won't cover -- well, let me use it -- Viagra, but we say that we will not cover drugs for ED.

Q Okay. So there's some general descriptions of what you won't -- will and won't cover?

A Yes.

Q Is there a pharmacy -- is there an AHCA pharmacy coverage policy for estradiol? And I'm happy to spell it for you if you need it.

A Oh, are we talking about estradiol.

Q Estradiol. Thank you.

A No, we don't have specific coverage policies for specific drugs. And by estradiol, I mean, that's an -- that's a kind of name brand estrogen.

Q Okay. And how about for medroxyprogesterone acetate, or Provera?

A We don't have specific coverage policies for those.

Q Okay. How about micronized progesterone?

A Those would all be encompassed under the prescribed drug services policy.

Q Okay, but not specifically named?

A We don't specifically name drugs.

Q I'm just going to run down the list. Spiro -- and you're going to correct me when I say it wrong -- Spironolactone.

A Spironolactone. That one, I mean, once again, the previous answer applies. It's enveloped by our prescribed drug services coverage policy. We don't have, like, an individual policy addressing that specific drug.

Q Okay. Finasteride.

A I think that's close enough. Same as before it's covered -- it's enveloped by the prescribed drug services coverage policy. We do not have an individual coverage policy for that drug.

Q Dutasteride.

A We do not have an individual coverage policy for that drug, but it is covered. It is -- it is addressed through the prescribed drug services coverage policy.

Q Okay. Testosterone.

A The same as before, we don't have an individual coverage policy for it, but it is covered through the prescribed drug services coverage policy.

Q Testosterone enanthate.

A Same as before, as in, we don't have a specific coverage policy, but it is covered through the prescribed drug services coverage policy.

Q Okay. Two more. Testosterone undecanoate.

A We do not have an individual coverage policy for that, but it is enveloped by our prescribed drug services policy.

Q Gonadotropin-releasing hormone antagonists.

A Gonadotropin, yeah. So, yeah, we do not have an individual coverage policy for GnRH. And that, of

course, would be covered through the prescribed drug services coverage policy, is how it would be addressed.

Q Okay. You do not have a policy, a pharmacy policy for GnRH antagonists?

A Not promulgated into rule.

Q Okay. Do you have any coverage policies -- I didn't realize that when I asked whether there was a coverage policy that you interpreted that to mean that it had to be promulgated into rule. Do you have any coverage policies regarding these drugs that are not promulgated into rule?

A As far as the policy goes, we don't really have a policy so for it -- so much. There was a guideline produced, I think, in 2016 that was given to Magellan for guidance on the prior authorization process, but as far as a policy goes, no, we don't have -- we don't have a specific policy for these drugs.

Q Okay. So there was some guidance that AHCA provided to Magellan regarding GnRH antagonists.

MS. DEBRIERE: Simone, can I have that coverage guidance?

MS. CHRISS: This one?

MS. DEBRIERE: Yes, please. Thank you. We'll mark that as Exhibit 4. You definitely need a copy of this one.

(Whereupon, Exhibit No. 4 was marked for identification.)

THE WITNESS: I've seen it enough times.

BY MS. DEBRIERE::

Q Well, so is that what you're referring to when you said the guidance provided to Magellan?

A Yes.

Q That's all I needed to know. Okay. So I'm sure we'll come back to that. And so you referenced FDA approval in Medicaid coverage earlier. When making decisions about individual claims for coverage for Medicaid recipients, does AHCA or its contractor determine whether the use the drug is being prescribed for is FDA approved?

A Well, absolutely, yes. I mean -- I mean, if it doesn't have FDA approval, I mean, it's still -- I mean, it's either not FDA-approved, it's still going through clinical trials. It's not FDA-approved, then no, it's not eligible for coverage.

Q Okay. How does AHCA do that on an individualized basis?

A So for an individualized basis, generally this is a prior authorization process, the request is put in. The recipients, or health care plan enrollees, the specific condition is evaluated and determination of

medical necessity is made.

Q Okay. What if the drug does not require prior authorization, then how does AHCA determine whether the use it's being prescribed for is FDA-approved?

A That would normally have to involve a retrospective claims review.

Q Okay. So at the time it'd be covered, but then AHCA would go back and look to see if it should have been covered?

A That's correct.

Q And how do they do that?

A How do they do that?

Q Yeah.

A I don't know the specifics, generally either MPI or another bureau. Often people in the field will often look at review claims, and this has happen frequently, that if claims are found to be paid in error or paid for services that were not necessarily -- not medically necessary, but the Agency does have the ability and frequently does gather recoupments on providers.

Q Okay. MPI stands for --

A Medicaid Program Integrity.

Q So that's like a fraud investigation?

A Yes, there are two fraud investigation teams

of the state. For MPI, they're specifically here for Medicaid. Every Medicaid program in the country is required to have a program integrity team, but we also have Medicaid Fraud Control Unit over at the Attorney General's Office.

Q Okay. Just turning back quickly to Exhibit 4, why is this not considered a coverage policy?

A Because coverage policies are generally -- well, first of all, it's not promulgated in a rule. So all of our coverage policies go through the rulemaking process, which is, of course, allows for public input and everything like that. This is mostly more -- these are guidelines developed in-house and provided to our PBM subcontractor.

Q Okay. For use in determining whether or not to prescribe GN -- strike that.

Are there other coverage guidelines like this not promulgated into rule for other drugs?

A For other -- I am not aware of whether or not we have any other guidelines like this.

Q Okay. What about for cross-sex hormone therapy?

A There was -- to my knowledge, there was no guidance or for cross-sex hormones.

Q Okay. So going back to the MPI post-claim

reviews, how often does that happen? Can you quantify?

A I don't have enough numbers of how often it happens, because obviously we have thousands of Medicaid providers. Then we do hear about cases of recoupment, so I couldn't tell you what the percentage of providers that had to pay back to the Agency money, but I can tell -- I can definitely tell -- like, I know -- well, for instance, I know -- like, I think Miami-Dade or Broward County have -- like, their school district actually they had -- after they had received a Federal Audit from HHS, they ended up having to pay back, I think, a million or so dollars in funds because they were delivering services that weren't properly documented and weren't meeting that medical necessity criteria. So as far as the larger numbers go, I don't have those.

Q Is there somewhere publicly the public can access that information, or where we can access that information?

A So a public records request can always be put in. We don't have that information available on our website, but anyone can put in a public records request and find out, like, how often recoupments do occur.

Q Do you know what a drug compendium is?

A Yes. Yeah, I'm aware of three.

Q Which three are you aware of?
A Drug Index is one. There are two others whose names do not -- whose names I do not recall immediately offhand. I believe they are listed. And, of course, they do usually consist of, like, a very large amount of information on each specific drug, and it talks about, like, appropriate uses and so forth. So, for each of these compendia -- and I -- they are -- we do utilize them when evaluating whether or not we can use an FDA-approved drug for an off-label purpose.
Q Okay. Do you know if those three compendia are Drug Text Information System, United States Pharmacopoeia Drug Information and American Hospital Formulate -- Formulary Service Drug --
A That sounds correct.
Q And those are the three compendia listed in the Federal Medicaid Act?
A Yes.
Q Okay. So when I'm using compendium, or compendia for next set of questions, I'm referring only to those three listed in the Federal Medicaid Act.
A Okay, that's fine.
Q For drugs that do not require prior authorization, when making decisions about individual claims for coverage, does AHCA or its contractors

determine whether the use that drug is being prescribed for is supported by citation in one of the compendia?

A So is this for drugs that do not require prior authorization, or drugs that do require prior authorization?

Q Do not require.

A We really don't because we don't require prior authorization. We're not able to check.

Q So that means where AHCA does not require prior authorization for a Medicaid recipient to obtain coverage of a particular drug, it covers the drug without knowing in advance whether the use it's being prescribed for is supported by citation in one of the compendia?

A If we're not requiring prior authorization, there's no way for us to know in advance.

Q Okay. So I know you mentioned it earlier. I'm just going to reference it on my computer, and that is the prescription drug list. And the website link -- I'll turn it so both you and counsel can see it, without spilling my drinks. That URL is HTTPS://AHCA.myflorida -- Florida is spelled out -- .com//Medicaid/prescribed_drug/pharm -- P-H-A-R-M -- _thera -- T-H-E-R-A -- /PDF/PDL.pdf. So I'm showing you what is AHCA's preferred drug list. Do you recognize

it?

A Yes, I recognize that.

Q What is the PDL?

A So the preferred drug list -- so even though we have everything that's FDA-approved, our Pharmaceutical and Therapeutics Committee, they do place drugs on the preferred drug list. I don't know the -- necessarily all the details. I think often it has to do with the ability for the agency to obtain rebates and so forth, so -- but they do put this together. It is publicly available on our website. And, of course, it does -- it does, of course, have age -- it does have age, minimum age, maximum age, clinical care required.

I would like to clarify, though. I know for our -- in our Medicaid Management Information System, which we often dub as FMMIS, we do program for procedure codes and so forth, corresponding diagnosis codes. So if a claim does not correspond to a diagnosis code, and -- that claim can be denied automatically in the system.

Q Okay. Okay.

A Which, I'm sorry, I forgot --

Q No, no, no. It's helpful. I just want to make a note of it.

A And we do program our system with ICD-10

codes, so we do have a build in our system for claims to deny if they don't necessarily correspond to a specific diagnosis code.

Q And that's regardless of whether the drug requires prior authorization?

A If it's prior authorized, the prior -- there's a different process for entering claims into the system that are prior authorized. So I think if it was prior authorized, that would override the automatic denials, but I would have to confirm that, but I believe that's how the system does work.

Q So FMMIS can be programmed to deny a certain service if it's associated with a particular diagnostic code, and that's done automatically?

A That's automatic. Yeah. Claims can deny automatically in the system, so we do have a fail-safe there.

Q Okay. And that's even if the drug does not require prior authorization?

A That's correct.

Q Okay.

A So I know it's definitely the case for the procedure codes that I administered when I was over -- when I was over specialized services. I'm going to assume that we have the same in place for NDC's,

National Drug Codes.

Q Okay. Because the services you were previously working on were not prescription drugs, is that correct, they were other Medicaid services?

A No, they were a little of everything.

Q Do you have a diagnostic code for every drug in the system?

A I can't speak to that at the moment.

Q Okay. Is there some way we can find that information out?

A Yeah, we can -- we can find that out for you.

MS. DEBRIERE: Okay. Can we flag that as a question, follow-up question?

BY MS. DEBRIERE::

Q If a drug is on the PDL, does it mean it's on the fee schedule?

A So we don't -- so with drugs, and this is one of the things with having worked -- working on the Canadian Drug Importation Program is that drug pricing is not a transparent process, so we don't actually list rates, we just list what we cover, or we list what's on the PDL. We don't actually say what we'll reimburse.

Q Okay, but if it's listed on the PDL, even if the rate's not on the fee schedule, AHCA is going to cover it?

A Yeah.

Q Okay. Does the PDL apply to managed care plan coverage of prescription drugs?

A Yes, that's actually -- well, yes, actually. I think -- I think -- I believe it does. That we wouldn't -- I would need to verify, but as far as -- like, I know that's the way our pharmacy benefit works. So with pharmacy benefit managers, generally the law ensures subcontract, that's the pharmacy benefit managers, who handle both their prior authorization of drugs and also negotiating rebates with manufacturers to help, of course, lower expenses. And so -- but for Medicaid, the SMC health plans, they have PBM's that they're really only there for the prior authorization process of prescription drugs. So their PBM's do not negotiate rebates. All that's done on the Agency side. So the agencies have contracted PBM, which is another branch of Magellan. They're the ones that negotiate all the rebates.

Q Okay. Just for clarity of the record, PBM stands for --

A Pharmacy Benefit Manager.

Q Okay. And then SMC PBM's, they're using the PDL to determine whether or not to authorize coverage for a prescription drug?

A Well, since with Medicaid we'll cover anything that's FDA-approved, they're going to be reviewing primarily medical necessity.

Q Okay. Are they going to match up the request for drug coverage to the PDL?

A I don't know if they do that or not.

Q Okay. So you don't know if Medicaid managed care plans rely on the PDL to authorize coverage?

A I don't. I can't speak to that.

Q All right. Let's look at a few specific drugs. Say this one for me again.

A Estradiol.

Q Estradiol. Thank you. Okay. So the PDL indicates that AHCA covers estradiol in each of these formulations, there's many listed here, for at least one indication, but we don't know what the indication is, or at least the PDL doesn't indicate it, correct?

A That's correct.

Q Okay, but AHCA does not cover estradiol to treat gender dysphoria?

A That's correct.

Q For what uses or indications does AHCA authorize coverage for estradiol?

A So for -- well, when estradiol needs to be covered, generally, as I speak very generally, of

course, usually it's used for hormonal imbalances, but I mean, but still we go back -- we defer back to the medical necessity guidelines.

Q So what does the no -- let's look at the very first list -- listed formulation of estradiol, which is associated with Climara 0.025-milligrams-per-day patch. And looking over at the clinical PA required, it says no. What does that mean?

A That means if the provider wants to prescribe it, that, of course, they can prescribe it without having to have a clinical review process.

Q So that means no prior authorization is ever required?

A Not under fee-for-service. Managed care plans, however, they have the flexibility to make it go through prior authorization.

Q Okay. So in fee-for-service, estradiol will be covered without AHCA or its contractor first determining for what purpose it's being used?

A Right, not until the claim comes in.

Q Okay. So that would mean that Medicaid could cover this drug if it were prescribed for non-FDA-approved uses?

A That's, of course, where our claim system comes in. So our claim -- our claim system was

programmed -- and, of course, I'm speaking generally of our CPT codes, et cetera, that if it doesn't -- if the diagnosis code doesn't align with what's in the system, that can come back as a denial.

Q Okay. So for estradiol, let's use this as an example, but not a hypothetical, in real life.

A Okay.

Q If estradiol is prescribed for treatment of gender dysphoria, is FMMIS programmed to automatically deny that claim?

A I would have to confirm with our -- with our Medicaid fiscal agent operations to make sure -- to know whether or not that the system has been updated for -- to deny that.

Q Is it possible to program a system to do that?

A To program it to deny it?

Q Based on -- based on the diagnostic code --

A From my experience, it's pretty -- it's a pretty simple affair to update the system to -- when we -- because we are uploading new and deleting diagnosis codes or uploading new procedure codes, I mean, it's generally a pretty straightforward process.

Q Okay. Can you provide us a list of those diagnostic codes at some point?

A For estradiol?

Q I think -- well the diagnostic codes would be -- are you using CPT codes? What are you using?
A So we use ICD-10 for --
Q ICD. Okay.
A -- because it's going to be primarily -- those are going to be like your -- well, those are your service codes. Those aren't drug codes.
Q Okay. So you use -- for your diagnostic codes, it's associated with ICD-10?
A That's correct.
Q Okay. So, looking at testosterone, this indicates that -- we've got to get there first, don't we? So this indicates that AHCA covers testosterone, and each of these formulations listed on the PDL for at least one indication, although based on the PDL, we don't know which indications for which it covers; is that correct?
A Yeah. I mean, there's a very large number of FDA-approved clinical indications for testosterone.
Q Okay. Just for clarity, AHCA will never cover testosterone when used to treat gender dysphoria, is that correct?
A Yes.
Q And it looks like, at least some of these formulations, including, for example, Andrew Durham,

four milligrams, 24-hour patch, that there is a clinical prior authorization that's required. Is that correct?

A Yes. Yeah. Based on the PDL? Yes, there would be a PA required.

Q For what uses or indications does AHCA provide prior authorization or approve coverage?

A So that goes back to our definition of medical necessity.

Q Okay. Would it also be governed by AHCA's drug criteria? And I'll just -- I'll pull that up. So when I say AHCA's drug criteria, I'm referring to that criteria listed at https://AHCA -- A-H-C-A --.myflorida.com/Medicaid/prescribed_ drug/drug _criteria.shtml.

And so would the drug criteria -- I'm looking at the screen. It says testosterone criteria updated 6-16-2022. Would the indications for which testosterone will be prior authorized -- prior authorized, would it be contained in this criteria?

A It would be contained in that criteria. That's correct.

Q Okay. Is this list exhaustive of all prescription drugs that AHCA will cover?

A I think -- I mean, I haven't seen the entire list, so -- but, I mean, for any drugs that we deem that

criteria is necessary, I imagine that would be an exhaustive list.

Q Okay. This applies in fee-for-service, correct?

A Those would apply for fee-for-service, yes.

Q How about for managed care?

A Managed care plans would need to be able to -- they would -- they would need to mirror their criteria and align it with the agency's.

Q So it can't -- my understanding is the managed care plan criteria cannot be more restrictive than what AHCA --

A That's correct. So they can be less restrictive, they can't be more restrictive.

Q Okay. Would the drug criteria listed here at the link to testosterone provide all the instances in which testosterone would be covered after prior authorization review?

A On the criteria?

Q Uh-huh?

A After --

Q Yes.

A Well, I would -- I'd have to -- I haven't actually had a chance to physically look at the criteria, so -- but I would assume that what we have the

criteria is accurate, especially given that it was updated in June 2022.

Q Okay. Turning back to EPSDT briefly. If the drug was being prescribed to a child under age 21, when AHCA or its contractor was undertaking the prior authorization process, could AHCA or that contract -- would AHCA or that contractor deviate from this criteria if the drug was otherwise prescribed for a medically necessary use?

A I have trouble following that question.

MR. JAZIL: Object to form.

BY MS. DEBRIERE::

Q So where testosterone was prescribed to a child under 21.

A Okay.

Q And EPSDT applies, then could AHCA or its contractor in its prior authorization review deviate from the criteria listed here? If medically necessary.

A As long as it meets medical necessity criteria, whether or not there's criteria involved and it meets -- if it's for an off-label use and it meets our off-label criteria, I mean, under EPSDT, I mean, yes, Florida Medicaid can cover it, but -- I mean, that would, of course, require significantly in-depth review, et cetera, but, I mean, hypothetically speaking, yes.

Q And one of the requirements -- just to circle back -- one of the requirement under that medical necessity review is that the prescribed drug cannot be for an experimental or investigational use, correct?

A That's correct.

Q All right. Just turning quickly back to FMMIS programming of the ICD-10 codes, what ICD-10 codes are programmed into the system for estradiol?

A What ICD-10 codes?

Q Yes.

A We would have to check the system. I would -- because I know pharmacy codes are set up a little differently than our procedure codes. So I'm kind of using the procedure code as analogous to the drug codes, but we would need to speak with one of our pharmacists.

MS. DEBRIERE: Can we flag that as a follow-up question, too? I had one more. So if you -- can we take a break for two minutes? I just want to confer -- or we can do longer if you need a second to go to the bathroom.

THE WITNESS: If you need a break, you can go ahead and take the break. That's fine.

MS. DEBRIERE: Thank you. Okay.

VIDEOGRAPHER: This concludes video one. The time is 11:05 a.m.

(Brief recess.)

VIDEOGRAPHER: This is the beginning of video two. The time is 11:08 a.m.

BY MS. DEBRIERE::

Q All right. So turning back to the preferred drug list, AHCA's preferred drug list, and looking at the formulation of testosterone cypionate -- did I say that correctly?

A I really don't know.

Q The PDL indicates that AHCA covers testosterone cypionate for at least one indication, although it doesn't say what indication, correct?

A Not on the PDL, no.

Q Does it say it anywhere? Is there anywhere we can find that information?

A Unless there's that criteria, unless we have a criteria listed on the website, generally, no, that's like one of the things -- I mean, we do have our claim system set up, which -- but like all that information is -- I mean, I suppose it could be obtained through public records request. That's usually the process.

Q Okay. So AHCA will never cover testosterone cypionate, or any formulation of testosterone for treatment of gender dysphoria, is that correct?

A That's correct.

Q So looking at the formulation of testosterone cypionate of testosterone CYP 1000 milligrams per 10 milliliters, that indicates there's no clinical prior authorization required, correct?

A That's correct.

Q So that means that AHCA will cover the drug or reimburse for the drug without determining for what use it's being prescribed?

A Well, based on my understanding of how our system works, through my experience is that the claim would deny.

Q Because why?

A Because the diagnosis code that'd be associated with that drug would trigger the system to do a denial.

Q Okay. So you're looking not at the indication of the -- what indication the drug's being prescribed for, but instead you're looking at the diagnostic code?

A So -- that's correct. Part of the process requires the procedure code, diagnostic code and place of service. Of course, those are for our health services, but those three all have to be programmed into the system. So say you're delivering a -- doing a checkup in a other setting, or you're doing like a setting that's not approved by us, it's not in our

policy, that claim would deny.

Q Okay. What if it wasn't for the treatment of gender dysphoria? What if it was for a diagnostic code that was not programmed to automatically deny?

A If it was for -- so if it was for a diagnosis code that was not programmed to deny?

Q Right.

A If it's programmed in the system -- we don't -- so we program the codes that it will approve. So all the other codes, it's not loaded in the system would automatically deny. So each -- so there'll be a set of ICD-10 codes that are -- that would link up with a particular service. As long as the diagnostic code corresponds to that service, the claim will pay.

Q Okay. So with the formulation of testosterone cypionate that we've been discussing that no clinical prior authorization is required, if the diagnostic code is programmed into the system, then it's going to automatically approve without looking at the indication for which the drug is prescribed?

A Provide that the claim form is -- it's a clean claim and all the pertinent information corresponds with the physician requirements, they will pay.

Q What is involved in a clean claim?

A No errors.

Q Errors of what?
A Someone might type in the wrong code by accident. Maybe they -- human error.
Q Okay. But you're -- but in that clean claim, there's no requirement to submit the indication for which it's being prescribed or AHCA undertaking a review of that?
A I mean, we do do retrospective review of claims.
Q At the time the coverage is being requested.
A Okay. Can we go back a little bit?
Q Yeah, yeah. Yeah. So looking at this formulation of testosterone cypionate, where no clinical prior authorization is required, when the claim is submitted and -- when the claim is submitted, AHCA is not doing a review of whether the indication it's being prescribed for -- sorry. Scratch that.
Looking at testosterone cypionate, in the formulation that we've been discussing where no clinical prior authorization was required, when the claim is submitted, AHCA -- neither AHCA nor its contractors does a review to determine for what indication the drug is being prescribed for?
A Right, there'd be no manual clinical review process or prior authorization process, if that's what

you're asking.

Q And when you said AHCA will only cover drugs that are FDA-approved, does that mean that AHCA never covers off-label use of a drug?

A We do have a -- no, we definitely would never -- we have a procedure for covering FDA-approved drugs for non-approved clinical indications, AKA off-label use. We do have a procedure for that. So we wouldn't necessarily -- no, we would never say never. That's --

Q Okay. I thought you said earlier that AHCA will only cover FDA-approved drugs?

A Right. But, I mean, like, let's say there's a drug that -- okay. Let's say it's been manufactured by European pharmaceutical or, you know, it's a pharmaceutical and it hasn't gone through the FDA review process, brand new drug. It's not FDA-approved. It's really not even approved -- it's not even approved for sale on the market. We won't cover those.

Q Okay. Okay. But you will cover drugs that are FDA-approved for uses that in and of themselves are not FDA-approved, for off-label uses?

A Yes, we have a procedure for that.

Q Okay. Do you ever program into the system the use of a drug for a condition for which the drug is not

FDA-approved?

A I can't speak to a hundred percent for that, but it seems it'd be counter to the process we have in place for reviewing off-label use for drugs.

Q Okay. And what is that process?

A So, it's a three-prong process. Step one is that there has to be a trial period for FDA-approved drugs for that clinical indication to have tried to have been used. And, of course, if the FDA-approved drugs for that kind of indication are not successful, then the -- then it moves to the second prong, which, you know, that requires like phase-three clinical trials having had to be completed on that drug. Then the third step is that the peer-review literature and one of the three drug compendia that we mentioned earlier has to pass the list or support it.

Q So you're looking at when determining whether or not you'll authorize coverage for a prescribed drug, you're looking at more than just whether the indication for which it's being prescribed is listed in the compendia?

A Yes, it's a little bit more comprehensive, correct.

Q Yeah. And so first you look at the individual Medicaid recipient and you determine whether or not they

tried other drugs?
A That's correct, yeah.
Q Okay.
A It would be an individualized basis.
Q Okay. And then the second step was what?
A A phase-three -- the drug had to have completed phase three clinical trials.
Q And then the third step is you look to see if the indication that's being prescribed for is listed in the compendia plus --
A Plus support in the peer-reviewed literature.
Q Okay. Let's look back at Exhibit 3.
MS. DEBRIERE: Simone, do you have that handy? That's the cross-sex hormone therapy GAPMS.
MS. CHRISS: You should still have those two versions.
MS. DEBRIERE: I might have it. I have a notice of deposition and I have a cross-sex hormone therapy. Here it is.
BY MS. DEBRIERE::
Q Is there anywhere on this GAPMS that describes the process for the criteria used?
A It's on page nine, if you're referring to the off-label use.
Q Okay. And that starts with the criteria that

utilized under the Florida Medicaid program and authorization for drugs for off-label purposes are as follows?

A Uh-huh.

Q Okay. And that's what you just described to me?

A Yes.

Q Yeah. Okay. All right. Turning to past GAPMS regarding gender dysphoria.

A Okay.

Q We are aware, plaintiff's counsel is aware of three pre-2022, at least draft GAPMS reports regarding Medicaid coverage of the treatment for gender dysphoria. One we've already marked as Exhibit 3, and that is the May 20th, 2022 version of the GAPMS for cross-sex hormone therapy. We actually know of two other versions, one dated June 23rd, 2017 and one dated April 19th, 2022. So we're going to mark the June 23rd one as Exhibit 5?

MS. DUNN: Yes.

(Whereupon, Exhibit No. 5 was marked for identification.)

THE WITNESS: Yeah. I have to apologize for the auto-dating on those documents, so I can probably give you more accurate dates --

BY MS. DEBRIERE::

Q Yeah, let's get the documents in front of you, and then that's exactly what we were wondering about. It can get confusing.

A I can give you more --

Q That would be -- that's exactly what we're after. We appreciate that.

MR. JAZIL: They're identical except for the date, right?

MS. DEBRIERE: Yes. Yeah -- well, that's not true. Yeah --

THE WITNESS: Well, I have this one. I mean, it's fine. There's one -- there should be one for surgeries.

MS. DEBRIERE: No, no. We're just looking at the versions of cross-sex hormone therapy right now. We have three different versions, at least, that we've found so far.

MR. JAZIL: Thank you.

BY MS. DEBRIERE::

Q Okay. So let's first look at the one with the June 23rd date.

A Okay.

Q June 23rd, 2017. Who authored the version of this report?

A So listed in our assignment writing and tracking page in SharePoint, the author of this was Sarah Craig.

Q Okay. And do we have that routing form?

MR. JAZIL: You should.

THE WITNESS: They should have it. We -- I did produce it for everybody.

BY MS. DEBRIERE::

Q Okay. And then that was back in 2017 when she authored this?

A She authored it in 2016. This is actually -- so to provide a little context.

Q Please.

A So in 2016, this was before I came to the Bureau of Medicaid Policy, there wasn't -- there wasn't a GAPMS position. Because they were accumulating a lot of services, a lot of requests for coverage, they created two GAPMS positions in the fall of 2016. They were filled in January 2017. So GAPMS reports often went to subject matter experts. So that's -- so in 2016 when this one was completed, the person who completed it, their primary job was not GAPMS.

Q Okay. What was Sarah Craig a subject matter expert in?

A She was one of our pharmacists.

Q Okay. And right now, just for clarity of the record, we're looking at June 23rd, 2017. That's labeled Exhibit 6.

(Whereupon, Exhibit No. 6 was marked for identification.)

BY MS. DEBRIERE::

Q Who -- so saying that, let's move on to the April 19th, 2022, which is labeled as Exhibit 5, who authored this report -- or made the revisions, I should say, in the April 19th, 2022 version?

A The only person I'm aware of who worked on this one was Sarah Craig. Since this was done before my entrance into the Bureau, and she's the only author listed in our system.

Q And were any changes made on the April 19th, 2022?

A No. That may have been a day when it was pulled out to be printed.

Q Okay. Why would it have been pulled out to be printed?

A I think -- because there had been some questions about the history of whether the Agency had previously done any work on this subject.

Q Okay. And why did those questions arise?

A Those questions had arisen as part of the

request process for the GAPMS report we did, and that was approved on June 2nd.

Q And that's related to the treatment of gender dysphoria?

A That's correct.

Q Okay. Does Sarah Craig still work at the Agency?

A Sarah Craig, I think, left in 2020.

Q Okay. Do you know where she went?

A I do not.

Q Were there any changes -- looking back at Exhibit 3, which is dated May 20th, 2022, there are some revisions on this one.

A Okay.

Q For example, Beth Kidder is crossed out and Ashley Peterson's name is put in. And the subject line is crossed out and there's just some edits and comments. And it looks like some text was added, for example, on page three.

A I was not privy to any edits or changes being made after -- I was not privy to any changes being made to that document.

Q Okay. Well, just to be clear, you're here as the Agency representative and not in your individual capacity, so you should have some knowledge about any

revisions to these reports, based on your designation as the Agency representative. Can you not speak in that capacity to it?

A As far as the work goes during the time period that we were working on the June 2nd GAPMS?

Q Uh-huh.

A That -- the work for the determination of the transgender dysphoria in relation to consistency with GAPMS, that task was specifically designated to myself, and Nai Chen and Devona Pickle in supporting roles.

Q Okay. Right now, though, I'm just asking about revisions made to the May 20th, 2022 version. You do not know who made these revisions, is that correct?

A I do not know who made those revisions, because -- as the Agency witness. Nobody was requiring revisions to that document.

Q But there were revisions made based on what I'm looking at.

A Whoever did so was doing so on their own accord.

Q Okay. Who had access to this document?

A Well, given that any -- actually, anybody has access to that document because the documents -- it's available on our SharePoint site. It doesn't require a password. Anyone in the bureau, anyone who's

knowledgeable of our repository could go through and pull up that document.

Q Okay. Could it have been Ashley Peterson who made the revisions?

A It's possible. We would have to find out from our IT department.

Q Okay. I think we do need that information. And then who's GS? There's some comments on the side there on the front page, Exhibit 3. It says GS 1.

A Well, GS would be initials. Would usually like last name first, first name second. I might -- might occur to me later on. I can't --

Q Would it be Sheena Grantham?

A It's possible. I don't know.

Q Okay. Can you track who has access to this document?

A Yeah, our IT department can track whoever had made edits to that.

Q Okay. Okay. So we can find out the answer to that question?

A Yes.

MS. DEBRIERE: Let's flag that.

BY MS. DEBRIERE::

Q Was this report ever finalized?

A To my knowledge, and I did actually do some

history -- do historical digging on this one. Since our pharmacy manager at the time, and I do need to add it because I forgot to add, that I did consult Arlene Elliot, who was the pharmacy manager at the time that this report was initially prepared, I did confer with her to determine whether or not it was finalized. And what I mean by finalized, it went through the review process and was signed off by the deputy secretary. She let me know that it had not.

Q Okay. Do you know why or why not? Why was it never finalized?

A Well, generally, and this is often the case with GAPMS reports, is that because it's -- well, Medicaid is a -- it's very busy -- we're a very busy division. We have lots of requests, lots of asks, lots of projects, and often GAPMS reports, usually, for those of us who like to be very detailed and very analytical, we, you know, it's -- it's a craft. It's almost like each one is like a seminar paper or scholarly article. It takes time to read and review. And usually it's -- and sometimes often, because unless somebody's asking for it, or if it's deemed a low priority, often it just -- it just often waits. And that may have been why. That's speculation, though.

Q Okay.

A But it's not surprising that a GAPMS draft is out there and didn't complete the review process. Solely it's because there's just too many other projects going on.

Q And GAPMS is generally low priority?

A It depends.

Q What does it depend on?

A Depends on the situation, because often when the managed care plan requests for the GAPMS, that's usually -- those usually have to be addressed quickly.

Q Okay. Let's set expedited GAPMS aside. Just traditional GAPMS, are they generally low priority?

A A traditional GAPMS? Well, like I said -- like I said, it often depends on the context. It depends on the request. Sometimes it could be -- sometimes it's a stakeholder who made their voice known downtown. Sometimes -- I mean, it really depends on the context.

Q Okay. When you're referencing downtown, what do you mean by that?

A The Capitol.

Q Okay. So sometimes GAPMS will get bumped up if the Capitol is the person who's raising --

A It just depends on the situation/I just don't want to commit to an absolute answer saying that they're

all low priority, because not every single circumstance or every single GAPMS means that it will be.

Q Okay, but with the cross-sex hormone therapy GAPMS, you're guessing that one reason why it was never finalized is because it was low priority?

A That's a guess in relation to my experience when I had the role.

Q Okay. And what was your experience when you had the role?

A When I -- when I had the role, I had it for about 10 months, and I think I drafted ten reports and two of them made through the review process. Those two I reviewed in January. They weren't finalized and signed off on until July of that year. So often, it was more trying to -- you know, reminding supervisors at different levels to review them so they can move forward. And given how busy everything was, especially with legislative session going on or other special projects taking precedence, often if it could be done -- put on hold until the next day or later, it was.

Q Okay. And so for the two of the ten reports that were finalized, it took seven months for the reports to be finalized, reviewed and finalized?

A Yes.

Q Prior to its adoption, prior to AHCA's

adoption of the categorical exclusion of treatment for gender dysphoria, did Florida Medicaid -- were there any instances where Florida Medicaid ever authorized coverage for cross-sex hormone therapy to treat gender dysphoria?

A Were there any circumstances? The Agency didn't have a policy or criteria regarding cross-sex hormones or, like, hormones for that clinical indication.

Q So that wasn't quite my question. My question is prior to the adoption of the categorical exclusion of treatment for gender dysphoria, were there any instances, so --

A Under -- so, well --

Q Did Florida Medicaid ever cover treatment of gender -- use of -- did Florida Medicaid ever authorize coverage for cross-sex hormone therapy to treat gender dysphoria?

A So by Florida Medicaid, are you referring to the Agency?

Q AHCA or any of its contractors, Medicaid managed care plans or EQ Health or --

A Under fee-for-service, that was -- no, it was not an approved clinical indication. Obviously, with managed care plans, since they have the flexibility to

cover services that, you know, that are not necessarily clarified in our coverage policies so -- I mean, it's possible that we could have done that, yes.

Q Okay. So, to be clear, in fee -- under fee-for-service, prior to the adoption of the categorical exclusion for the treatment of gender dysphoria, there was never an instance of Florida Medicaid covering cross-sex hormone therapies to treat gender dysphoria?

A Are you referring to the fee-for-service?

Q Fee-for-service only.

A We don't necessarily have that information available.

Q Why?

A Well, not offhand.

Q Why?

A Well, going -- because we want to go back several years. We're assessing an extensive data pull.

Q Or even just six months prior to August 21st, 2022.

A So I think we did do a data pull for the past year. And that data pull, of course, show the results of what services we were covering, had the number of recipients with the diagnosis for gender dysphoria, and those who received treatment. So I'll defer to that

data.

Q So we don't have that data in front of us. And, again, you were produced as the 30(b)(6) representative, so what did that data show?

A That data did show that some -- that there were a handful of recipients who were receiving the services.

Q In fee-for-service?

A I think fee-for-service. I think managed care.

Q Okay. So there were times, prior to the adoption of the categorical exclusion for the treatment of gender dysphoria, that Florida Medicaid covered cross-sex hormone therapy for treatment of gender dysphoria?

A Cumulatively for the whole program, yes, there were.

Q Okay. So another previous GAPMS regarding gender dysphoria is the GAPMS entitled puberty suppression therapy, and that begins at DEF_ 000288776. Although, for clarity of the record, I do want to say we received multiple versions of this document, as well.

MS. DEBRIERE: Do we have the final one, by any chance? I'm positive it was my mistake in terms of listing exhibits.

MS. DUNN: The one that was signed?
MS. DEBRIERE: Yeah.
MS. DUNN: That's a whole different -- it has a different name.
MS. DEBRIERE: I'm sorry, guys. That's my fault. My fault.
MR. JAZIL: Counsel, do you want him to clarify that date issue? I think he mentioned it as you were --
MS. DEBRIERE: Oh, yeah, I thought he did. I'm sorry if -- please, go ahead and clarify the date issue.
THE WITNESS: So both of these GAPMS were initiated in 2016.
BY MS. DEBRIERE::
Q Okay. When you say both of these GAPMS, you're referring to --
A Referring to the one on the cross-sex hormone therapy.
Q Okay.
A And the one on the puberty suppression.
Q Okay. Let's not talk about the puberty suppression one just yet, because I want to get the right exhibit into the record first.
A Okay, but as far as the date goes, these were

projects from 2016.

Q Okay. Okay.

MR. JAZIL: Counsel, if you'd like me to just make additional copies of that, I'm sure we can.

MS. DEBRIERE: So there are multiple versions that were provided to us of this document. We are looking for another version that has a signature on it, although I'm sure Mr. Brackett can speak to it being finalized. But just to make everyone's life easier in the long run, we are going to try to -- yeah, this is great. Okay.

Chelsea, should we mark it?

MS. DUNN: Yeah. Do you want that Exhibit 7?

MS. DEBRIERE: Are we on 7? Okay.

(Whereupon, Exhibit No. 7 was marked for identification.)

BY MS. DEBRIERE::

Q All right. We have only one copy of this, and it's DEF_000288776, entitled puberty suppression therapy, dated September 14th, 2016. And the reason we were -- and that's going to be marked as Exhibit 7. The reason we wanted that one is because if you turn to the back page, it's signed by Mr. Senior. So we assume then that's the final report?

A This would be the final report if he signed

it.

Q Okay. So it was adopted by the Agency?

A The recommendations in this GAPMS were -- yes, they would be adopted.

Q Who authored this report?

A So in the --in our system, our SharePoint system, that was the individual listed for this report was Monique Johnson.

Q Okay. And who was Ms. Johnson? What was her subject matter expertise?

A So she was a program administrator and she oversaw the primary care services team, which is primarily like surgeries, inpatient -- inpatient services, dental services. Like, I think like surgical procedures, things like that. Of course, child health checkup procedures. Generally be like primary care and preventive, anything that would fall into those categories.

Q Why would she then look at puberty suppression therapy?

A So this was, at the time before we had the defined GAPMS individuals, so I can only speculate as to why she was selected. It may have been she had bandwidth at the time to do it, but since there was no one who actually did GAPMS full time, I don't -- I can't

speak as to -- because I'm not that familiar with her background, I can't -- and, of course, this was 2016, but more or less, there may have been a number of reasons for why she was selected for this.

Q Okay. Why wouldn't it have gone to a pharmacist?

A We don't have the -- an answer for that.

Q Was Ms. Johnson a pharmacist or pharmacy tech or had any --

A I think she was an RN.

Q Okay.

MR. JAZIL: Counsel, just so the record's clear, this copy of Exhibit 7 has highlights on it. Did you --

MS. DEBRIERE: It would have not been -- it would have been highlighted by us. Is that right? Yeah. So my apologies.

MS. DUNN: It's the only copy we have, but we can potentially print a clean copy.

MS. DEBRIERE: And it's Bates-stamped.

MR. JAZIL: It's fine. I just want the record to be clear that it's highlighted and the highlights were added by counsel for plaintiffs, not the witness.

MS. DEBRIERE: Yes. Thank you for that, Mo.

BY MS. DEBRIERE::

Q Okay. So going back to Exhibit 4, pubertal suppression -- yep. This is the special services criteria. This was developed only six days after the puberty suppression therapy GAPMS report. Is that correct?

A You mean the criteria?

Q Yes. Yes. Exhibit 4.

A Based -- I'm going to defer to the dates on this, because it predates my time in the Bureau of Medicaid Policy. So if the dates say 30 days, then that would be --

Q The dates say six days.

A The dates say six days?

Q Yeah.

A I'll defer to that.

Q Okay. Are these two documents related?

A Can you provide some context on what related means?

Q Is one based off another?

A It seems -- it would appear that following the completion and approval of the GAPMS process, that this document was completed, routed and then approved, based on the time stamps.

Q Okay. So was the special services criteria at

Exhibit 3, was it drafted based on the information contained in the GAPMS report related to puberty suppression therapy?

MR. JAZIL: Exhibit 4?

MS. DEBRIERE: Did I say 3? I'm sorry. Exhibit 4. Thank you, Mo.

THE WITNESS: It looks like it's fairly consistent.

MS. DEBRIERE: Okay.

THE WITNESS: Based on the EPSDT consideration portion.

BY MS. DEBRIERE::

Q So based on your understanding of office operations, then it's likely that the special services criteria was drafted in response to the puberty suppression therapy GAPMS?

A Yes.

Q Okay. And this is the -- this policy, Exhibit 4, is the criteria that AHCA used prior to its adoption of the categorical exclusion of treatment for gender dysphoria to determine whether gonadotropin-releasing hormone analog would be prior authorized for pubertal suppression and treating gender dysphoria, correct?

A Yes, correct.

Q Okay. Between the time this policy was

adopted, which was October 6th, 2016, and the time AHCA adopted the categorical exclusion of treatment for gender dysphoria in August of 2022, if an individual's condition met the criteria laid out in this policy, then Florida Medicaid would cover the cost of the drug for pubertal suppression and the treatment of gender dysphoria, is that correct?

A Providing that the criteria, and prior to the challenge exclusion, yes.

Q Okay. Between October 6, 2016, and the time AHCA adopted its categorical exclusion of treatment for gender dysphoria, how many times did AHCA authorize the drug set forth in this policy for the treatment of gender dysphoria?

A We would have to defer at least -- at least prior to the challenge exclusion being implemented, we'd have to defer that data for that time period, but we'd have to go all the way back to 2016 as far as the data goes, at least in fee-for-service, to determine how many recipients actually received the -- actually received authorization for it.

Q Do you have any knowledge of any time period in which fee-for-service covered it, based on the criteria in this policy?

A So this -- so once this policy -- so once this

criteria was released to Magellan, Magellan was our PBM for fee-for-service. So they did the prior authorizations for fee-for-service. So Magellan would review each case individually.

Q Okay. Do you know how many times Magellan authorized it based on the criteria?

A I do not have those numbers.

Q Okay. Can we get those numbers?

A We can try to find them. We can try to get those numbers. It's a very long time period.

Q But it is your understanding that in certain instances, Magellan did authorize it?

A We would have to -- we would have to look at those numbers.

Q Okay. Because previously, when we were discussing cross-sex hormone therapy, you did know that in some instances fee-for-service had covered the drug to treat gender dysphoria, but you don't have that same information for pubertal suppression?

A That's speaking more about Medicaid, cumulatively as far as the differences between fee-for-service and managed care encounters, I would have to take a look at the data to get the exact numbers of what was in the fee-for-service system versus the encounters for the managed care were. But we would --

have we would have to go ahead and get this information from Magellan going back to find out exactly how many times that they get pre-authorization requests versus how many approval/how many denials.

Q Okay. Let's just look quickly at exhibit -- it's going to take me a second to find it.

MS. DEBRIERE: Simone, is the list of Medicaid recipients and discussion of their authorizations -- yeah. I don't know. Yeah, that's it. Not surgery, though. There should be a drug one. Maybe I'm wrong. They probably didn't include it.

BY MS. DEBRIERE::

Q Mr. Brackett, while we're looking for that, let's go back to the notice of deposition. In the deposition topics, we do list the number of Florida Medicaid recipients who -- participants who have sought any form of care for gender dysphoria from January 1st, 2015 until the enactment of the challenged exclusion. And so as we're sitting here today, you're telling me you can't answer whether -- or how many times AHCA or one of its contractors authorized coverage of pubertal suppression therapy for treatment of gender dysphoria, is that correct?

A That's correct, as of now, but we can get that

information.

Q And you will provide us that information?

A We will obtain that information.

Q Okay.

MS. DEBRIERE: So I think that given that there are a few places where we have follow-up questions I do, at this point, just want to say that once those questions are answered, we're going to reserve some time for this deposition so that we can do follow-up questions based on the information that's provided to us, because right now there's some holes that Mr. Brackett is not able to fill, and once that information is provided to us, of course, we will probably have follow-up questions. So we just need to reserve some time for --

MR. JAZIL: Okay. And just so the record's clear, I think I provided objections to the last set of depo topics. There may have been an objection to this particular topic, going back to 2015, but we'll work with you. If we can gather the information, we'll provide it.

MS. DEBRIERE: Okay.

BY MS. DEBRIERE::

Q So looking at the final GAPMS report related to treatment of gender dysphoria, it's entitled gender

confirmation surgery.

MS. DEBRIERE: Oh, gosh. Do we have it from the past deposition? I'm sorry. We had, like, over 50 exhibits and clearly it's completely my fault not putting them in the list. We can always pull back around to them and print it out at lunch, too. There it is. Okay. We're going to mark this one as Exhibit 8, and it's entitled GAPMS gender confirmation surgery, dated July 19th, 2017.

(Whereupon, Exhibit No. 8 was marked for identification.)

BY MS. DEBRIERE::

Q And this one does have markups on it that are not our markups, they're from the Agency. Who authored this report?

A So this report is authored by Rebecca Buceo.

Q Okay. When?

A This was authored in the summer of 2017.

Q How do you know who was authored by?

A I was in the bureau at the time and was present when the project was being assigned out.

Q Okay. Why weren't you assigned the project?

A I was actually being assigned -- I was working on another project related to designated state health programs and getting approval for those through the

Centers for Medicaid -- Medicare and Medicaid Services. So I was actually on a kind of a legislative priority project. And so I was not assigned to this one.

Q It's my understanding that there's only one hard copy of this report, is that correct?

A That's correct.

Q Okay. Whose office was it found in?

A So, I -- this report, I did -- it was in a binder with -- so this report was found in Rebecca Buceo's old office. So she had an office in the bureau. I know she maintained her GAPMS materials there.

Q Okay. And what else was in that binder?

A I think some of the research articles she used.

Q Is that it?

A That was it.

Q Okay. Is Rebecca Buceo still with AHCA?

A No, she's not.

Q When did she leave?

A I believe she left in 2019.

Q Okay. And what was her subject matter expertise?

A She had a behavioral health background. That was her -- that was her subject matter expertise.

Q Did she have any expertise in surgery?

A Not professionally, no.
Q What about not professionally?
A In other words, she's never worked as a surgeon or anything like that. But, I mean -- but I mean -- or in the formal education in that area.
Q Okay. But did she have any experience with surgery that would help her inform the drafting of this GAPMS?
A I couldn't speak to that.
Q Did AHCA ever rely on the conclusions in this report?
A So this report did not get past her immediate supervisor, so, no.
Q Okay. Prior to its adoption of the categorical exclusion of treatment for gender dysphoria, did Florida Medicaid ever cover gender confirmation surgery for the treatment of gender dysphoria?
A Under fee-for-service, to the best of my knowledge, we didn't. In managed care, there were a few instances where the managed care plan did approve the procedure.
MS. DEBRIERE: Okay. Can we look at those exhibits now? The -- I forget what they're called. They're a weird name. ATTB, ATTA. It's a weird name. It wouldn't come to me.

BY MS. DEBRIERE::

Q Okay. So I'm handing you -- these were natives, so they were not Bates-stamped, but I'm handing you documents produced to plaintiffs in discovery. They were also not labeled, and I just want to ask you some questions about what they mean. We'll mark that as exhibit -- actually, I'll take those copies. I'm sorry. Well mark this as Exhibit 9 and 10. And, I'm sorry, because they're natives, they don't have Bates stamps.

(Whereupon, Exhibit Nos. 9 - 10 were marked for identification.)

BY MS. DEBRIERE::

Q So looking at Exhibit 9 first, which is two pages total, front and back.

MS. DEBRIERE: Seems like they -- yeah, it printed out -- I see. Do I put it together? What do we do?

BY MS. DEBRIERE::

Q Let's look at under service type, outpatient surgery. Line item status is approve. Does that mean that Florida Medicaid approved outpatient surgery?

A Yes, that would mean it was approved.

Q Okay. And the product description was mastectomy with a primary diagnosis code of F649?

A Uh-huh.

Q So that means that the outpatient surgery was approved for a mastectomy for a diagnosis code of F649, is that correct?
A That's correct.
Q Okay. And F649, what is that diagnosis code?
A That's gender dysphoria.
Q Do you know if -- can you tell by this document whether -- it appears that it was approved by children's medical services under product roll-up.
A So based on these two -- so based on these two, I can't tell if the recipient is in managed care or if they're in fee-for-service. So in Exhibit 10 --
Q Yeah.
A -- this looks like this would be managed care.
Q Okay. And how do you know that?
A Because it has, like, the member effective category.
Q Okay. If the title of both of these documents had the term CMS on it, would that mean that it's managed care?
A Children's Medical Services is overseen by Sunshine Health. So, yes, it's managed care.
Q And looking at Exhibit 10, the Medicaid ID, does that correspond to individual Medicaid recipients?
A Each Medicaid recipient has a unique Medicaid

ID assigned to them. That's correct.

Q Okay. And these documents are indicating that there were authorizations of surgeries for primary diagnosis codes of F640 and F649, is that correct?

A Yeah, that's correct.

Q Okay. And F640 is a diagnostic code for what?

A So F64, generally, there is a decimal point after the 4. So it was F64. The way ICD-10 codes work, it's kind of like a taxonomy. So F64, categorically, is gender dysphoria. So F64.9 would be like a -- like a subcategory of that general diagnosis.

Q So these documents are showing that, at least in managed care, prior to the categorical exclusion -- prior to AHCA's adoption of the categorical exclusion for the treatment of gender dysphoria, there were times in which Florida Medicaid covered surgery to treat gender dysphoria; is that correct?

A That would be correct.

Q Okay. Let's turn to the June 2022 GAPMS. We have this exhibit. And Exhibit 11 will be the June 2nd, 2022 GAPMS related to the treatment of gender dysphoria.

(Whereupon, Exhibit No. 11 was marked for identification.)

BY MS. DEBRIERE::

Q I'm going to refer to this throughout as the

June 2022 GAPMS.

A That's fine.

Q When was the request to initiate this GAPMS made?

A So the formal request was made on April 20th. That was the date of the Secretary's letter.

Q Were there any informal requests prior to that time?

A There were some informal, I guess, indicators of, you know, trying -- when they were trying to determine whether or not we had bandwidth, you know, and so there was some informal indicators that this project would be coming down the pipeline because they were trying to figure out who to do it. So we were aware of the Secretary's letter it would be coming to us.

Q Okay. When you say they were trying to figure out. Who is they?

A Our Agency leadership.

Q And who is that comprised of?

A So that was primarily for the Bureau of Medicaid Policy, Ann Dalton was our bureau -- is still our bureau chief at the time.

Q So Ann Dalton had knowledge of the potential for this project coming down prior to April 20th, 2022; is that correct?

A Yes.
Q Okay. Who else in leadership was aware that this would be coming to AHCA prior to April 20th, 2022?
A At the time, Secretary Weida was serving as Assistant Deputy Secretary. He did have knowledge.
Q Okay. Anybody else?
A To my --to my knowledge, those two were the ones with the knowledge of this project.
Q Okay. When did you have knowledge of the project?
A Just probably a few days before we were given the letter.
Q Okay. So, like, April 17th?
A Something around there. Yeah, I don't remember the exact date.
Q Okay. Who did you gain the knowledge -- who did AHCA leadership gain the knowledge from?
A As far as the project goes, the decision to do a GAPMS to my -- so that was to do a GAPMS report, that was determined by our legal as the best route to evaluate the medical necessity for treatments for gender dysphoria. It was that -- it was subjected to the GAPMS process.
Q Okay. And which counsel was that?
A Andrew Sheeran, who's now our General Counsel.

Q Okay. And who contacted -- was Mr. Sheeran the first point of contact related to what eventually became the June 2022 GAPMS?

A No, I don't think he would have been the first point of contact.

Q Who would have been the first point of contact?

A Generally, our first point of contact would have been our General Counsel at the time.

Q And that was?

A Josephina Tamayo.

Q Okay. And who contacted Josephina Tamayo about this project?

A So this project, about the GAPMS in particular --

Q No.

A -- or about requesting a Medicaid review?

Q Requesting a Medicaid review.

A So that, of course, that did come down from the Governor's office.

Q Okay. Who in the Governor's office made the request?

A So that is -- so it was a multi-party meeting. So the three staffers from the Governor's office that were involved were, I think, Katie Strickland, Ryan

Newman and Maureen Farino.

Q Okay. What other agencies were involved?

A As far as the decision for Medicaid's review?

Q No, as far as that initial request coming from the Governor's office. You said there was a multi-party meeting.

A Well, between AHCA's staff and Governor's office staff.

Q I see. Okay. What other AHCA staff were present at that meeting besides Ms. Tamayo?

A I think at that meeting, I think Deputy Secretary Weida may have been present, I think the General Counsel, I think, Andrew Sheeran, may have been present as well.

Q Okay. Anybody else present at that meeting, besides those people that you just named?

A I can't name them with any specificity.

Q Okay. Were they from other agencies other than the Governor's office or AHCA?

A So in regards specifically to this project?

Q Are there other projects we should be aware of?

A Well, I -- there were, I think, some people present from the Department of Health.

Q Regarding what project?

A But that was regarding their review of treatments for gender dysphoria.

Q Based on actions related to the Board of Medicine or based on CMS guidance?

A What do you mean -- when you say CMS, are you referring to Children's Medical Services or --

Q No. Centers for Medicare. Great question.

A That guidance was actually not by CMS, it was from HHS.

Q Excuse me, HHS.

A It was in regard to that guidance.

Q Okay. So there was some presence of Department of Health there, as well, but not related to Medicaid?

A Right.

Q Okay. And what was the date of that initial meeting?

A I don't have -- know the date offhand. I think it was like early April.

Q Okay. And at that meeting, it had not yet been determined that AHCA would use the GAPMS process to evaluate whether treatment for gender dysphoria was experimental, is that correct?

A I think that -- yes, I believe that is correct, based on -- based on the information we've

gathered, is that the decision is to route it to the GAPMS process was done after that conversation.

Q Okay. So what was the Governor's office request for the meeting?

A The Governor's office request was to -- in response to the HHS documents, the Department of Justice documents, Department of Education documents regarding gender dysphoria, designing treatments for gender dysphoria, the evidence for gender dysphoria, it was that the Department of Health and AHCA both undertake reviews.

Q Did the Governor's office instruct AHCA to find -- did the Governor's office instruct AHCA to ensure that Florida Medicaid would not cover treatment for gender dysphoria?

A No.

Q Okay. Did the Governor's office make any specific requests about Florida Medicaid coverage as it related to the treatment of gender dysphoria?

A The Governor's office wanted the Agency to undertake the review.

Q But what type of review did it want the Agency to undertake?

A It wanted to take a look at -- a detailed look at the available medical evidence, or at least the

peer-reviewed literature, and to see what it says.

Q Okay. You referenced earlier the Florida Department of Health's investigation on the HHS fact sheet. What did that investigation find?

A So the Department of Health's fact sheet, of course, provide some cursory information, like go into some snapshots of some literature out there, you know, stating that the evidence for support -- that was supporting gender dysphoria treatment was too weak for this to be considered a standard treatment for that condition.

Q Okay. And so at the time of this initial meeting in early April, when there was a discussion of DOH's findings, at that point there was a conclusion that the information or evidence to support treatment of gender dysphoria was weak?

MR. JAZIL: Object to form.

MS. DEBRIERE: I can strike that.

BY MS. DEBRIERE::

Q Why did the Governor's office want AHCA to review Medicaid coverage for treatments of gender dysphoria?

A So in response to these documents, there were questions about whether or not the evidence supported what HHS, DOJ and DOE was -- at least the United States

DOJ, United States DOE, the claims they were making. They wanted to do a review to see whether or not this -- the evidence that's supporting was -- actually sufficiently supported those claims.

Q Did the Governor have a specific position on whether HHS' findings were accurate, prior to AHCA's review?

MR. JAZIL: Object to form.

THE WITNESS: No.

BY MS. DEBRIERE::

Q Did DOH have a position on whether HHS' findings were accurate prior to AHCA's review?

MR. JAZIL: Object to form.

THE WITNESS: Can you rephrase that question?

BY MS. DEBRIERE::

Q Yeah. Did DOH -- at that initial meeting, what conclusions had DOH drawn about the HHS report?

A So DOH, they didn't -- they didn't release their opinions until April 20th, the day we got the letter.

Q Okay. But had they -- at that meeting, had they formulated those opinions?

A To my -- based on the information given to me, they had not yet formulated those.

Q So why did AHCA general counsel decide that

the best process to undertake the review was the GAPMS process?

A Because, well, I'm speaking based on our -- on how policy works is that, of course, the medical necessity definition does have a prong saying that the service has to be consistent with generally accepted professional medical standards. So the best way to do a review to either -- to determine whether or not something is consistent with GAPMS is to do that, undertake that review process, and that really provides the best opportunity to go through the literature on a large scale and to make a conclusion.

Q Okay. To your knowledge, had there ever been a time previous where a GAPMS was used to determine the experimental nature of services previously covered by Florida Medicaid?

A To my knowledge, there was not.

Q So this is the first time the GAPMS process was used to determine whether services that were already being covered by Florida Medicaid were experimental?

A To my knowledge, yes.

Q The folks at the initial early April meeting, did they reach out to HHS to get the info they relied on before conducting their own review?

A Are you talking about the Florida Department

of Health folks?

Q Or the Governor's office, anyone involved in that meeting.

A No, we -- with the releases, the document releases from those -- from those federal agencies was sufficient.

Q So AHCA did not reach out to HHS either?

A No, we had their documents. We didn't -- we didn't have any need to question them on them.

Q In the letter you're referring to from Secretary Marstiller dated April 20th, 2022, is that correct?

A Uh-huh.

Q That's the letter that directed Tom Wallace, the Director -- I'm sorry --

A State Medicaid Director, Deputy Secretary.

Q Thank you. That was the letter directing him to undertake GAPMS related to treatment of gender dysphoria, right?

A Yes.

Q Why did Secretary Marstiller's letter say that she was making the request in response to DOH guidance rather than a request from the Governor?

A Because the DOH guidance had just been published.

Q Okay. But she was asking Mr. Wallace to undertake that GAPMS process because it was a request from the Governor's office, correct?

A A request for the state agencies to look at the existing evidence and making recommendations, that initially came from the Governor's office. Since I wasn't physically -- since I personally was not present for those meetings, I can't exactly speak to the sequence, but DOH would undertake its review. And, of course, once they published their guidance, we undertook ours.

Q Okay. Just to be clear, there's a few times that you said to your knowledge, but, again, you're testifying as an Agency representative?

A Yes.

Q So this is to the knowledge of the Agency, correct?

A To the knowledge of the Agency, yes.

Q When did AHCA begin work on the 2022 GAPMS? What date?

A We started work on April 20th.

Q You didn't do anything prior to that?

A No. I mean, I may have done, like, an article search, just to see what was out there, but as far as any large-scale work goes, no, we didn't do -- we didn't

do anything like that.

Q Okay. And, again, just to be clear, no one at the Agency, because you're in the capacity as an Agency representative. So my question is not just about whether you started anything related to the 2022 GAPMS.

A The Agency did not -- did not start work until April 20th.

Q Who worked on the 2022 GAPMS at the Agency?

A You mean the June 2022 GAPMS?

Q Yes.

A So I was primarily the author. It was myself, Devona Pickle prepared the maps of the United State Medicaid programs. Nai Chen prepared the maps for the internet -- for the European countries to classify who covered what, but that was it. It was the three of us.

Q Okay. And I apologize. Can you just one more time run through what everybody's roles were? You were the primary author. Mr. Chen worked on the maps.

A Worked on the maps for Western Europe.

Q Okay. And what did Dede Pickle do?

A The maps for the State Medicaid programs.

Q Okay. And as primary author -- so you wrote everything else except for the maps in the state Medicaid coverage, then?

A That's correct.

Q Okay. And did you have any assistance?
A It's -- GAPMS are a solitary project, any extensive research project is, because once you immerse yourself in the literature, it's very difficult to have assistance because you're trying to get up to -- you have to transplant knowledge from yourself to them. It's actually just easier to do it, to kind of sail the waters on your own. And this is coming from speaking from experience on, like, a myriad of research projects, from scholarly articles, master's theses for, like, works -- other works for the Agency, previous GAPMS reports. Once you under -- once you reach a certain understanding of that knowledge, it comes a point where you -- it makes sense -- it's more efficient for you to do it in a solitary fashion.
Q Okay. So you were the only one involved in outlining and reviewing the literature that became the June 2022 GAPMS?
A Yes.
Q Okay. Was there anyone else at the Agency -- so you didn't work with Mr. Chen on the literature or --
A Nai, he did -- he occasionally he'd find an article and give it to me, but other than give me the occasional article, that was -- that was it. I went through, reviewed the article, like, broke it down. As

far as any content or analysis, he just gave me copies of articles.

Q Okay. Okay. And so no one else at the Agency -- did anybody else at the Agency take on that role to where they were sending you articles or anything related to that? I guess what I'm trying to determine is whether anyone else assisted you with drafting?

A Nobody assisted me with the drafting.

Q Inside or outside the Agency?

A We did have a few consultations with some of our contracted experts --

Q Were they a verbal consultations?

A They were verbal.

Q Only verbal?

A Yeah, but as far as drafting went, they weren't involved in that process.

Q Okay. So they didn't write any of the main report?

A They did not write any of the main report.

Q Or outline it or anything?

A No.

Q Okay. Looking at -- I have another exhibit, the Van Mol ATF. We're going to mark this as Exhibit -- Exhibit 12. What is wrong with me today? And it's entitled Agency for Health Care Administration

after-the-fact request form under 35k.

(Whereupon, Exhibit No. 12 was marked for identification.)

BY MS. DEBRIERE::

Q So, reason for occurrences, where I'm reading and second sentence to the last, due to the need to start work quickly, all of the purchase order elements were not available until May 6th. Why was there a need to start work quickly?

A Since this is -- since we did have a request, and since we were writing in response to the Department of Health, which had already had published their findings, the Agency, of course, we considered this a priority project, and this was mostly that's -- that's pretty much, it was a priority project.

Q I'm sorry. Why was it a priority project?

A It was priority project because in relation to -- in relation to the Department Health guidelines, which had been released, then, of course, because, you know, as the state of Florida wanted to respond to the HHS documents, which had also been released, because we didn't want a significant amount of time, like, five or six or seven months to elapse before the Agency had gotten its response out.

Q Okay. So you wanted to make sure that there

would be a quick response to the HHS guidance?

A Yes.

Q Okay. When I say a decision tree checklist for GAPMS, do you know what I mean?

A Are you referring to, like, to a checklist?

Q Yes.

A Yes, I do know what you're referring to.

Q Okay. Did AHCA do a decision tree checklist for this report?

A So that decision tree checklist, that was a -- is an internal process, and each person who does GAPMS often kind of brought their own unique perspective or unique approach to them, since these are research projects and there's not really a formula for it, but I believe -- I think Jeffrey English, I think, helped to develop a checklist, which I think he used when making evaluations. I kind of have my own mental checklist when I did them. And also, actually, I actually wanted to kind of help refine, to help cut down the number of GAPMS requests we had. As we started going through requests, we started realizing, well, some of these really aren't GAPMS, these are just coverage determinations.

Q What -- How did you know that?

A Generally -- okay, well, FDA approval for the

clinical indication.

Q Okay.

A If a national coverage determination's been released by Medicare, things like that.

Q Okay. What about if it was already listed on AHCA's fee schedule?

A Not necessarily.

Q Why?

A Because -- just because it's listed on AHCA's fee schedule, it does not necessarily mean that it's -- wouldn't be experimental or investigational for another clinical indication.

Q So based on the checklist, if it was listed on the fee schedule, that one isn't going to determine whether or not it should go through GAPMS?

A It shouldn't, no. And that was -- when I -- when I did GAPMS, that was not part of my criteria.

Q After the checklist was developed, how many GAPMS did you do?

A The checklist was developed well after I had left that role.

Q Okay. So -- but we know you did the June 2022 GAPMS, so at least one right?

A Uh-huh.

Q Okay. After the checklist was developed, for

any other time that AHCA undertook a GAPMS, was a checklist completed?

A I think there were some completed checklists that I was able to find in our PDM, but that was after the fact. When I embarked on this one, I was not aware a checklist even existed. Not that I didn't apply kind of a mental checklist when I was going through it to check to see if there were certain elements in there that would either come to the conclusion that this shouldn't be that way through GAPMS or not.

Q What was your mental checklist?

A FDA approval for a clinical indication, which would mean that there was already substantiating research for it, which had been done by federal agency, which would kind of render GAPMS point moot, or a national coverage determination by Medicare. And the national coverage determination is pretty much -- it's like a Medicare GAPMS, and it's -- there aren't that many NCD's out there because there's a risk involved in getting an NCD, but if -- but Medicare NCD's are backed by substantial amounts of research. So if there's an NCD out there supporting a treatment and mandating coverage for a specific service, and all the research they do behind it, it kind of also -- it renders doing the GAPMS moot.

Q Okay. Any other -- anything else on your checklist?

A No, those were the two items I usually look for.

Q So that's it. And then if they didn't pass those two tests, they went to a GAPMS?

A Went to a GAPMS.

Q Okay. So -- I'm sorry. I just need to find my place in the outline. When was the checklist developed? Remind me. 2017?

A No, the checklist would have been developing in 2019.

Q 2019. Okay. During the 2022 -- the start of the 22 -- 2022 GAPMS, you mentioned that you were having conversations with the Governor -- or there was an initial meeting with the Governor's office when the request was made and DOH was also present?

A Prior to the request being made.

Q After the request was made, was there any communication with the Governor's office?

A No.

Q After the request was made, was there any communication with the Department of Health?

A No.

Q What about HHS?

A No.
Q And what about Alliance Defending Freedom?
A No.
Q Liberty Counsel?
A No.
Q Okay. What consultants were used by AHCA in the development of the GAPMS.
A So during the development, we have a few verbal conversations with Doctors Miriam Grossman and Andre Van Mol.
Q Okay. And what did those conversations entail?
A Well, Dr. Van Mol, he just offered suggestions for articles and research for us to look at. He did provide us with a bibliography for our consideration, as far as -- mostly just leads on research to help save time in finding resources. And Dr. Grossman, of course, she provide us with some history of gender dysphoria treatments, and gave us more reviews of some scientific techniques.
Q How did you get connected with Dr. Van Mol?
A So Dr. Van Mol, like all of our experts, who also provide published reports, so the process for those was that we did get a name at the very outset of the process, which was Michelle Cretella. And by contacting

her, she led us to other providers -- or other practitioners who had expertise in the fields, and that's how AHCA made contact with these individuals.

Q So Michelle was the only person who connected AHCA to the consultants it relied on for the 20 -- June 2022 GAPMS?

A Yeah.

Q Okay. And who Michelle?

A Michelle -- Dr. Michelle Cretella?

Q Uh-huh.

A She's a physician. I think she has some affiliations with, like, a couple of -- I think American College of Pediatrics, I think. I'm not sure what her other affiliations are.

Q How did you find her?

A Well, her name was passed on to us from the Department of Health.

Q Okay. What's her relationship with to the Department of Health?

A I -- the Agency does not know what her relation to the Department of Health is.

Q Okay. So you just accepted this recommendation by the Department of Health as the person who would connect you to the consultants you would use to develop the 2022 GAPMS?

A Yes.
Q You didn't do any outside research on whether you should seek out other consultants?
A Well, we were vouching for our -- for the consultants. I mean and so we did want individuals who had expertise in their respective fields of medicine, and who also were going to take an evidence-based approach.
Q Okay. Who at Department of Health recommended Dr. Cretella?
A Don't -- we don't have the name of the individual.
Q Because it was sent in an anonymous email? Why don't you have the name?
A We can get that information for you.
Q So you don't have the name, but the Agency has the name, correct?
A The Agency might have a name. We need to confirm that.
Q And who at the Agency was this communication sent to? I mean, how was it communicated?
A To my knowledge, it was verbal. It was a verbal exchange.
Q Okay. So who at AHCA was part of that conversation?

A So I think when it came down to, you know, reaching out to experts and determining who the experts we should use were, I think Andrew Sheeran and Jason Weida were involved.

Q Okay. So it was either Andrew Sheeran or Jason Weida who received that information from the Department of Health related to Dr. Cretella?

A Yes.

Q Could it have been anybody else at the Agency?

A I don't think so. I mean --

Q It seems like you have a name in mind.

A Well, I mean, there were other senior leaders. The Secretary may have been given the name, or Chief of Staff may have been given the name, so, but --

Q Who was the chief of staff?

A Cody Farrell.

Q And who was the person who spoke with Dr. Cretella about her recommendations?

A I think -- I think Andrew Sheeran and Jason spoke about that -- spoke to them about the recommendations.

Q And she recommended everyone, is that correct?

A Well, she -- from what I gathered, there was, like, recommendations. She gave some names. And not everyone she recommended, of course, we decided to go

with. So there were some that we did turn down.
Q Who did you turn down?
A We can get that -- we can get that -- we can get those names for you.
Q With Dr. Cretella, was there any consideration given to the associations, the medical associations of which she was a member?
A No.
Q Okay. So you didn't look to see if she was associated with any particular medical association?
A No.
Q You just went off the recommendation of Department of Health?
A Yes.
Q Was Dr. Cretella paid for her assistance with -- to AHCA?
A No.
Q So DOH didn't pay her or anything?
A Well, I don't know at DOH, that's a question for the Department of Health. AHCA did not -- we did not establish a financial arrangement with her.
Q Okay. Are you -- are you personally aware of any financial arrangement between Dr. Cretella and Department of Health?
A No.

Q Okay. I'm sorry. Who did you turn down?
A We would have to get those for you.
Q Okay. And so Dr. Grossman and Dr. Van Mol just gave you some article leads, and that's all?
A Gave some article leads, some background information. Yeah, it was -- I mean, as far as providing us with content to include in the report, they did not.
Q Why not?
A Because it was an independent assessment by the Agency.
Q Okay. Did -- but they didn't write any of the reports that were in the attachments to the June 2022 GAPMS either?
A Right?
Q Why not?
A I think because we had experts. We already had a psych -- one psychologist who was writing one. We already had -- we, of course, we had physicians for, like, plastic surgery. We had a bioethicist, as well. Since those bases were covered, we felt they would best benefit us by helping provide guide -- guidance with research.
Q Were they ever given the option of writing a report for one of the attachments?

A No, we didn't ask them to write a report.
Q Okay. Did they ask if they could write a report?
A No, they did not.
Q How did you identify Dr. Romina Brignardello-Petersen?
A So through the contacts we were making, her name was passed on to us as someone at McMaster University who had some experience in doing evidence evaluation.
Q Did Dr. Cretella pass on that name?
A As far as the actual contact that gave us that name?
Q Uh-huh.
A Dr. Cretella was kind of the head of the tree of the contacts. We would have to go back and get that information on who gave us the exact name for Dr. Brignardello-Petersen.
Q Okay. But Dr. Cretella was the one who -- so what -- if Dr. Cretella didn't recommend Dr. Brignardello-Petersen, who would have?
A We would have to get that information for you.
Q Would it have been another physician?
A Yes, it likely -- yes, it would have probably been another physician.

Q What other physicians provided recommendations for consultants?
A We would have to get that information.
Q What all physicians did you talk to you prior to -- or in the process of drafting the --
A So in the process of drafting the report, we really -- we talked to Doctors Grossman, Van Mol. There were a couple conference calls with the experts who provided the reports, but those weren't about our report, that was just mostly more -- that was talking to them about them doing their reports.
Q Okay. So who recommended Dr. Cantor?
A We -- that may have been Dr. Cretella who had recommended him. We would need to confirm that.
Q Okay. So, again, just pointing to topic 24 in the notice of deposition, we asked for an Agency representative who was knowledgeable as to --
MS. DEBRIERE: No, no. I just don't know what -- I have no idea where it is.
BY MS. DEBRIERE::
Q So looking at topic 24, and we asked very specifically about the identification of Dr. Brignardello-Petersen, Dr. Cantor, Dr. Van Meter, Dr. Lappert, Dr. Donovan, in the inclusion of the written assessment. So I don't know what to say. I mean, it

seems like you're not able to answer the question.

MR. JAZIL: So, counsel, the topic says the process by which AHCA prepared the memo, and I read that to mean the process by which we identify these experts. And so he's detailed the process. It was an initial consultation with one physician, and then it was -- one person recommends another, recommends another. And I think he said that a lot of these were oral. To the extent that we have any written records of who specifically said, hire Dr. Romina Brignardello-Petersen, we'll supplement the production with that.

MS. DEBRIERE: Other than written records, Mo, can you get us -- can you just do an investigation of who spoke with these individuals and collected this?

MR. JAZIL: So who -- so I think he's answered that, it was General Counsel's Office, and it's now Secretary Weida, who spoke to these individuals. If the question is who specifically recommended each expert --

MS. DEBRIERE: Yes.

MR. JAZIL: -- I'll ask. And if there's a written record, it would have been turned over to you already. If there's an oral record, beyond

what he's talked about, well --

MS. DEBRIERE: If someone knows. Because if someone knows at the Agency --

MR. JAZIL: -- you know, Bob talked to Jill, Jill talked to Jane, Jane talked to Jason and said, hey, hire Brignardello-Petersen, I'll get that information for you.

MS. DEBRIERE: Thank you.

BY MS. DEBRIERE::

Q Whose decision was it to engage with Dr. Van Meter? I'm sorry. Who recommended Dr. Van Meter? I apologize.

A That's information we would have to --

Q So you don't know who recommended any of these individuals other than Dr. Cretella?

A Right.

Q Okay. When did AHCA first become aware of the HHS fact sheet on gender-affirming care in young people?

A We became aware of it, since we do follow HHS publications, much of our staff in Medicaid, so forth, they are actually on -- they receive automatic updates, so we became aware of them as they came out.

Q What was AHCA's independent reaction to the fact sheet?

A Well, as the Agency initially didn't -- didn't

have a reaction. There was -- we didn't -- we don't react publicly to HHS documents.

Q Okay. So did AHCA -- you stated in your declaration filed with the court on January 23rd -- are you aware of what I'm talking about? I can get you a copy, if not.

A I should be aware of it. I've reviewed it.

Q Okay. That litigation was highly likely because in drafting the GAPMS report, the GAPMS determination might conflict with federal standards. Do you remember saying that?

A Yeah. If I -- yeah, I mean, it's written and signed off on, then, yes.

Q Okay. With what federal standards, did you think it might conflict?

A Well, it might -- it would probably conflict with that guidance that was released from HHS.

Q Any other federal standards?

A No.

Q Why did you think it would conflict with the guidance from HHS?

A Because the guidance from HHS, the conclusions we made -- that we made following an independent assessment, conflicted with the HHS guidance. The HHS guidance did state that these were, like, medically

necessary treatments, that evidence supporting them, so that they would alleviate mental health systems symptoms, et cetera. Our concluded -- our conclusions and our assessment of literature deemed otherwise, so we knew that there would be a potential conflict.

Q At what point did you realize that there would be a potential conflict?

A When we -- during the drafting process. So we realized that the evidence was inadequate to support the claims that HHS was making, or that -- that's when we realized that there would be -- there would be a conflict.

Q Okay. Did you anticipate that the GAPMS report would conclude that the relevant services were experimental?

A When I started working on it, I did not know where the evidence would take me.

Q At what point did you realize that you were going to conclude that the services were experimental?

A As -- the more and more I read the articles that focused on the mental health benefits, the methods and so forth, the more I realized that all those articles left way too many unanswered questions. This -- there was also -- there wasn't any evidence available to answer those outstanding questions. I

realized that I couldn't -- that there was not going to be -- that the conclusion was going to be, no, it was not consistent.

Q Okay. So your analysis of those services. So I think one of your concerns related to the treatment of services for gender dysphoria that is now excluded under 59-G-1.050(7), was that the services were not supported by randomized controlled trials, is that correct?

A That was one element of many elements.

Q Okay. Does AHCA ever require that -- does every -- does AHCA require that every treatment or procedure it covers be supported by randomized controlled trials?

A So to contextualize that question, every medical service is unique. So we don't apply a uniform set of standards to every single medical service, because every single medical service is for a specific condition, every medical service carries its own pros and cons, risks versus benefits. So we don't necessarily -- we don't have a one-size-fits-all model for evaluating each and every medical service.

Q You mentioned unanswered questions as you were reviewing the literature for treatment of gender dysphoria, or the services you were analyzing. What were those?

A So those are iterated in the GAPMS report, but generally like -- well, number one, long-term. And other unanswered questions, like a lot of these studies were based on anonymous surveys. How are we supposed to know whether or not these responses are credible, if we don't have any longitudinal history of these individuals? I mean, one of the things that we came up with when we were doing the literature review is the etiology. There are lots of potential causes and associations with gender dysphoria, not -- not including but not limited to autism, trauma, neglect, abuse, abandonment, things like that. So because there was so many unanswered questions, I mean, how are we supposed to know whether or not a one-time survey is going to accurately capture all of that, especially if it's done -- being taken by anonymous people, or if the survey -- or for those that weren't anonymous, the sample sizes were very, very small. So and, of course, you're talking about one- or two-year periods. These -- the changes prompted by these treatments are permanent.

Q Did you adopt any of the conclusions about treatment for gender dysphoria relied upon by the American Academy of Child and Adolescent Psychiatry?

A The American College of -- can you repeat that?

Q American Academy of Child and Adolescent Psychiatry. I think it's AACAP.
A No, I don't recall we -- us using their recommendations.
Q What about the American Academy of Family Physicians?
A No, we didn't use theirs.
Q What about the American Academy of Pediatrics?
A We did do an evaluation of theirs.
Q Did you rely on them, their conclusions?
A So what do you mean by --
Q Did you -- did you lend credence to their conclusions?
A Yeah, yeah. It was -- their conclusions required thoughtful analysis and probing of the evidence. We do take the recommendations of clinical organizations very seriously, but we also do reserve the right to question those recommendations and we did review those and we did analyze them.
Q And after you reviewed and analyzed them, did you adopt them?
A No, we found that they were based on very weak evidence.
Q Okay. What about the American College of Obstetricians and Gynecologists?

A No. I mean -- I mean, there -- we didn't -- so, aside from AAP, we did notice, like most of the recommendations, guidelines, were very, very similar, very straightforward, and they usually are based on Endocrine Society and WPATH guidelines.

Q And did you adopt the recommendations from the Endocrine Society and the Pediatric Endocrine Society?

A No, we did not. We did review those in close detail, though, and analyze them.

Q What about -- I'm sorry. The other WPATH?

A Yes. So the World Professional Association for Transgender Health, we did closely review their guidelines. We did -- we did analyze them. And, of course, we do discuss them in lengthy detail in multiple areas of the GAPMS report.

Q And ultimately you disagreed with their standards?

A Ultimately, yes.

Q What about the American Psychiatric Association?

A I think we actually didn't make reference to them in the GAPMS report.

Q Did you adopt their conclusions related to the treatment of gender dysphoria?

A No, we did not.

Q What about the American Psychological Association?
A No, we did not.
Q American Medical Association?
A We did not.
Q When you say we, you mean --
A The Agency.
VIDEOGRAPHER: Excuse me, counsel. Sometime soon, I need to take a short --
MS. DEBRIERE: Oh, yes.
VIDEOGRAPHER: -- to start the next video. Do you want to take a break? We could take a -- do you want to take a 30-minute lunch break or --
THE WITNESS: I'm good with that, yeah.
VIDEOGRAPHER: Okay. This concludes video two. The time is 12:42 p.m.
(Whereupon, the deposition resumes in Volume 2.)

CERTIFICATE OF OATH

STATE OF FLORIDA)
COUNTY OF LEON)

I, the undersigned authority, certify that the above-named witness personally appeared before me and was duly sworn.

WITNESS my hand and official seal this 21st day of February, 2023.

_____

DANA W. REEVES
NOTARY PUBLIC
COMMISSION #GG970595
EXPIRES MARCH 22, 2024

CERTIFICATE OF REPORTER

STATE OF FLORIDA)
COUNTY OF LEON)

I, DANA W. REEVES, Professional Court Reporter, certify that the foregoing proceedings were taken before me at the time and place therein designated; that my shorthand notes were thereafter translated under my supervision; and the foregoing pages, numbered 5 through 120, are a true and correct record of the aforesaid proceedings.

I further certify that I am not a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

DATED this 21st day of February, 2023.

_____.

DANA W. REEVES
NOTARY PUBLIC
COMMISSION #GG970595
EXPIRES MARCH 22, 2024

Gary V. Perko, Esq.
gperko@holtzmanvogel.com

February 21, 2023

RE: August Dekker, et al. vs. Jason Weida, et al.
February 8, 2023/Matthew Brackett/5696545

The above-referenced transcript is available for review. The witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason on the attached Errata Sheet. The witness should, please, date and sign the Errata Sheet and email to the deposing attorney as well as to Veritext at Transcripts-fl@veritext.com and copies will be emailed to all ordering parties. It is suggested that the completed errata be returned 30 days from receipt of testimony, as considered reasonable under Federal rules*, however, there is no Florida statute to this regard. If the witness fail(s) to do so, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions
*Federal Civil Procedure Rule 30(e)/Florida Civil Procedure Rule 1.310(e).

August Dekker, et al. vs. Jason Weida, et al.

February 8, 2023/Matthew Brackett

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Under penalties of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.

_____ _____

Matthew Brackett DATE

p

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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CERTIFICATE OF SERVICE

I hereby certify that on November 13, 2023, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Thomas E. Redburn

Thomas E. Redburn, Jr.
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