SUBJECT
Safeguarding Kids from Gender Surgeries & Drugs

SUMMARY ANALYSIS

In April 2022, the Florida Department of Health issued guidance regarding treatments for gender dysphoria. Immediately thereafter, the Florida Agency for Health Care Administration ("Agency") entered into a formal process to determine whether to cover under the Florida Medicaid program sex reassignment treatments for gender dysphoria. At that time, the Agency had not yet determined whether to cover such treatments under the Florida Medicaid program. The treatments at issue included (1) puberty blockers, (2) hormone therapy, and (3) sex reassignment surgery.

In June 2022, the Agency issued a report based on its research and analysis as well as five written assessments provided by subject-matter experts that the Agency retained for this purpose. The report recommended against covering sex reassignment treatments as reimbursable health services because they are not consistent with generally accepted professional medical standards and are experimentational and investigational.

In August 2022, the Agency promulgated a rule based on its report. The rule, codified in Rule 59G-1.050(7)(a), states that "Florida Medicaid does not cover," as "treatment of gender dysphoria," the use of (1) "puberty blockers," (2) "hormones or hormone antagonists," (3) "sex reassignment surgeries," or (4) "other procedures that alter primary or secondary sexual characteristics."

In September 2022, four Medicaid recipients sued the Agency in federal court seeking to enjoin the rule. To date, the plaintiffs' motion for a preliminary injunction is fully briefed. An evidentiary hearing is scheduled for Wednesday, October 12.

Gapms process

Generally Accepted Professional Medical Standards ("GAPMS") is a formal rule-based process that allows the Florida Medicaid program to determine whether health services will be covered. See generally Rule 59G-1.035, Florida Administrative Code. Anyone, including a member of the public, can request a review of a health service for coverage. In practice, the most common requestors tend to be pharmaceutical and other health care companies seeking coverage of their services and Florida Medicaid managed care plans seeking to pay or deny claims.

To quality for coverage, a health service must be "consistent with generally accepted professional medical standards and not experimental or investigational." The determination process requires the Deputy Secretary for Medicaid to make the final determination in a written report. The rule enumerates several factors that must be considered in making that determination. Those factors include consideration of evidence-based clinical guidelines, published medical and scientific literature, and effectiveness of the health service. The rule also contemplates the use of "recommendations or assessments by clinical or technical experts on the subject of field." In practice, experts tend not to be consulted during the GAPMS process, often because the inquiry is straightforward or under a tight deadline.

The Bureau of Medicaid Policy is responsible for drafting the GAPMS report. When a report is completed, it is routed for approval through the Bureau Chief, then to the Assistant Deputy Secretary for Medical Policy and Quality, and finally to the Deputy Secretary for Medicaid, who either concurs with the recommendation or does not concur. Once the Deputy Secretary signs the GAPMS report, a copy is delivered to the requestor. GAPMS reports generally are not considered confidential and do not fall under an exemption to public records laws. Still, they tend not to be made public to anyone other than the requestor, largely due to a lack of public interest.

Subject-matter experts

As contemplated by the GAPMS rule, the Agency retained seven subject-matter experts, including five experts that provided written assessments based on their respective expertise. While retaining experts is uncommon in the GAPMS process, doing so was necessary in this circumstance because of the politicization and ideological indoctrination of professional medical associations that have endorsed "gender affirming" treatment despite weak supporting evidence. A summary of the opinions of the five experts who submitted reports is below.

- **Dr. Romina Brignardello-Petersen**, together with a post-doctoral fellow, conducted a systematic review of medical studies published between 2020 and April 2022. They concluded that the evidence simply does not support the use of puberty blockers, cross-sex hormones, and reassignment surgeries as treatments for gender dysphoria. As they put it, there is "low and very low certainty evidence" to support these excluded treatments.

- **Dr. James Cantor**, editor-in-chief of the peer-reviewed journal Sexual Abuse, a professor, and a clinician, also looked at the medical literature and drew on his own experience. He found every one of the "11 outcome studies" that tracked pre-pubescent children showed that "the majority of children" "cease to feel dysphoric by puberty," thereby making the use of puberty blockers, cross-sex hormones, and surgeries inappropriate in this population. For adolescents, the medical literature showed some improvement with medical intervention and psychotherapy but could not show whether it was the medical intervention or psychotherapy that helped. For those with gender dysphoria, regardless of age, there was a greater likelihood of comorbidities—some other affliction—being the root cause of distress and even suicide. And Dr. Cantor concluded that the perspective of the leadership of medical trade groups in the United States was increasingly at odds with the current positions of European countries with formerly permissive regimes for the treatment of gender dysphoria.

- **Dr. Quentin Van Meter**, a pediatric endocrinologist who trained at Johns Hopkins, and is currently on the clinical faculties of Emory University and Morehouse College, discussed the effects of the excluded treatments on children. He cautioned against the "interruption of natural puberty," because it is puberty that "prepare[s] the body for reproduction and affects the bones, gonads, and brain." He further explained that "blocking puberty at the age of normal puberty prevents the needed accretion of calcium into the skeleton and prevents the maturation of the gonads." This contrasts with treatments for precocious puberty—the early onset of puberty—where puberty blockers are carefully used and the "end of treatment is carefully timed" so that natural puberty resumes at the appropriate age. He also rebutted the notion that the use of puberty-blockers and cross-sex hormones is reversible, noting, for example, that there can be "permanent infertility." And, recognizing that most of those with gender dysphoria later identify with their biological sex, he recommended against the very "permanent" surgical treatments.

- **Dr. Patrick Lappert,** a plastic surgeon with decades of experience, focused on the appropriateness of sex reassignment surgeries on a person's chest. He criticized the methods of those who have performed "breast removal surgery" on patients as young as thirteen, and distinguished sex reassignment surgeries from procedures like gynecomastia (an "objectively abnormal condition" that "makes males develop female-type breast gland tissue") and breast reduction (done when women suffer from "debilitating orthopedic" pain in their neck, back, or shoulders). He concluded that "the

> medical necessity of transgender chest surgery is not supported by scientific evidence and appears to be firmly in the category of cosmetic surgery." Worse yet, this type of procedure poses ethical concerns for surgeons because "[n]o other cosmetic procedure is expected to produce major functional loss."

Dr. G. Kevin Donovan, formerly the Director for the Center for Clinical Bioethics at Georgetown University School of Medicine, discussed ethical concerns associated with the excluded treatments. He found that "[v]ulnerable subjects such as children cannot legally or ethically participate in the consent process" needed for the excluded treatment "due to their age and maturity level." More broadly, he criticized the terminological wordplay used in recent years; he noted that the 2013 adoption of the phrase "gender dysphoria" to replace "gender identity disorder" in the DSM-V shifted the focus away from "correcting the underlying cause of the dysphoria" towards "transitioning to the preferred gender."

Gapms Report Summary

The June 2022 GAPMS Report summarized the findings of the consulting experts and concluded as follows: "the evidence shows that the [excluded] treatments pose irreversible consequences, exacerbate or fail to alleviate existing mental health conditions, and cause infertility or sterility," and, as such, the "treatments do not
conform to GAPMS and are experimental and investigational."

Specifically, the evidence relied upon by proponents of "gender affirming" treatment, including evidence of suicidality in the absence of such care, is either low or very low quality:

• Puberty Blockers: Evidence does not prove that puberty blockers are safe for treatment of gender dysphoria. Evidence that they improve mental health and reduce suicidality is low or very low quality.

• Cross-Sex Hormone Therapy: Evidence suggesting that hormone therapy provides benefits to mental health and prevents suicidality are low or very low quality. Rather, evidence shows that hormone therapy causes multiple irreversible consequences as well as infertility.

• Sex Reassignment Surgeries: Evidence of improvements in mental health and reductions in suicidality following sex reassignment surgery is low or very low quality. Sex reassignment surgeries result in irreversible physical changes, including sterility.

While professional medical associations like the American Academy of Pediatrics, the American Psychological Association, and the American Medical Association endorse the above treatments, none of those organizations relies on critically appraised evidence. Their prominence in the medical community alone does not validate their views in the absence of quality, supporting evidence. To the contrary, the evidence shows that the above treatments pose irreversible consequences, exacerbate existing mental health conditions, and cause infertility or sterility.

The Rulemaking

Following the report, the Agency entered into rulemaking. The text of the proposed rule, which was later finalized without modification, states that "Florida Medicaid does not cover," as "treatment of gender dysphoria," the use of (1) "puberty blockers," (2) "hormones or hormone antagonists," (3) "sex reassignment surgeries," or (4) "other procedures that alter primary or secondary sexual characteristics." Rule 59G-1.050(7)(a), Florida Administrative Code.

In July 2022, the Agency held a hearing on the proposed rule. During the hearing, the Agency took public comments concerning the GAPMS Report and Rule 59G-1.050(7)(a). Among those providing oral comments were two detransitioners—those who stopped and sought to reverse the effects of the excluded medical treatments. The comments received during the hearing were overwhelmingly supportive of the proposed rule. The Agency also accepted public comments in writing both before and after the hearing.

Florida finalized Rule 5G-1.050(7)(a), which became effective August 21, 2022. Even after the rule became final, the Agency continues to reimburse a long list of gender dysphoria treatments provided by clinical psychologists, child psychotherapists, psychiatrists, family therapists, and social workers. The rule only prohibits reimbursements for certain treatments specified in the text of the rule itself.

The Lawsuit

In September 2022, four Medicaid recipients sued the Agency and its Secretary in federal court in Tallahassee. While not representatives for a putative class, the four plaintiffs with gender dysphoria seek "preliminary and permanent injunctions prohibiting" the state from implementing Rule 59G-1.050(7)(a).

A separate motion for preliminary injunction also seeks relief beyond that necessary for the named plaintiffs. The only two bases for this broad, class-like request are the Equal Protection Clause, and the Affordable Care Act's non-discrimination provision. 42 U.S.C. § 18116(a).

At this time, the plaintiffs' motion for a preliminary injunction is fully briefed. An evidentiary hearing is scheduled for Wednesday, October 12, in Tallahassee.

SAFEGUARDED KIDS

FROM GENDER SURGERIES & DRUGS

LET KIDS BE KIDS

FLORIDA LEADS THE NATION AS THE FIRST STATE TO RELEASE EVIDENCE-BASED GUIDANCE RECOMMENDING AGAINST "GENDER AFFIRMING CARE" FOR CHILDREN EXPERIENCING GENDER DYSPHORIA

THIS RECOMMENDS AGAINST SURGERY, HORMONE THERAPY, AND THE USE OF PUBERTY BLOCKERS BEFORE THE AGE OF 18

THE AGENCY FOR HEALTH CARE ADMINISTRATION RELEASED A REPORT THAT FOUND GENDER DYSPHORIA TREATMENTS PROMOTED BY THE FEDERAL GOVERNMENT ARE NOT CONSISTENT WITH WIDELY ACCEPTED PROFESSIONAL MEDICAL STANDARDS AND ARE EXPERIMENTAL AND INVESTIGATIONAL WITH THE POTENTIAL FOR HARMFUL LONG-TERM EFFECTS

Safeguarding Kids from Gender Surgeries & Drugs

Key Points

- In June 2022, the Agency for Health Care Administration (AHCA) released a report recommending against covering sex reassignment treatments as reimbursable health services because they are not consistent with generally accepted professional medical standards and are experimentational and investigational.
- Following the report, the agency released a rule stating that "Florida Medicaid does not cover," as "treatment of gender dysphoria," the use of "puberty blockers," "hormones or hormone antagonists," "sex reassignment surgeries," or "other procedures that alter primary or secondary sexual characteristics."

Guidance Regarding Gender Dysphoria

In April 2022, the Florida Department of Health issued guidance regarding treatments for gender dysphoria. Immediately thereafter, the Florida Agency for Health Care Administration ("Agency") entered a formal process to determine whether to cover under the Florida Medicaid program sex reassignment treatments for gender dysphoria. At that time, the Agency had not yet determined whether to cover such treatments under the Florida Medicaid program. The treatments at issue included (1) puberty blockers, (2) hormone therapy, and (3) sex reassignment surgery.

In June 2022, the Agency issued a report based on its research and analysis as well as five written assessments provided by subject-matter experts that the Agency retained for this purpose. The report recommended against covering sex reassignment treatments as reimbursable health services because they are not consistent with generally accepted professional medical standards and are experimentational and investigational.

In August 2022, the Agency promulgated a rule based on its report. The rule, codified in Rule 59G-1.050(7)(a), states that "Florida Medicaid does not cover," as "treatment of gender dysphoria," the use of (1) "puberty blockers," (2) "hormones or hormone antagonists," (3) "sex reassignment surgeries," or (4) "other procedures that alter primary or secondary sexual characteristics."

In September 2022, four Medicaid recipients sued the Agency in federal court seeking to enjoin the rule. To date, the plaintiffs' motion for a preliminary injunction is fully briefed. An evidentiary hearing is scheduled for Wednesday, October 12.

GAPMS Process

Generally Accepted Professional Medical Standards ("GAPMS") is a formal rule-based process that allows the Florida Medicaid program to determine whether health services

will be covered. See generally Rule 59G-1.035, Florida Administrative Code. Anyone, including a member of the public, can request a review of a health service for coverage. In practice, the most common requestors tend to be pharmaceutical and other health care companies seeking coverage of their services and Florida Medicaid managed care plans seeking to pay or deny claims.

To quality for coverage, a health service must be "consistent with generally accepted professional medical standards and not experimental or investigational." The determination process requires the Deputy Secretary for Medicaid to make the final determination in a written report. The rule enumerates several factors that must be considered in making that determination. Those factors include consideration of evidence-based clinical guidelines, published medical and scientific literature, and effectiveness of the health service. The rule also contemplates the use of "recommendations or assessments by clinical or technical experts on the subject of field." In practice, experts tend not to be consulted during the GAPMS process, often because the inquiry is straightforward or under a tight deadline.

The Bureau of Medicaid Policy is responsible for drafting the GAPMS report. When a report is completed, it is routed for approval through the Bureau Chief, then to the Assistant Deputy Secretary for Medical Policy and Quality, and finally to the Deputy Secretary for Medicaid, who either concurs with the recommendation or does not concur. Once the Deputy Secretary signs the GAPMS report, a copy is delivered to the requestor. GAPMS reports generally are not considered confidential and do not fall under an exemption to public records laws. Still, they tend not to be made public to anyone other than the requestor, largely due to a lack of public interest.

Subject-Matter Experts

As contemplated by the GAPMS rule, the Agency retained seven subject-matter experts, including five experts that provided written assessments based on their respective expertise. While retaining experts is uncommon in the GAPMS process, doing so was necessary in this circumstance because of the politicization and ideological indoctrination of professional medical associations that have endorsed "gender affirming" treatment despite weak supporting evidence. A summary of the opinions of the five experts who submitted reports is below.

Dr. Romina Brignardello-Petersen, together with a post-doctoral fellow, conducted a systematic review of medical studies published between 2020 and April 2022. They concluded that the evidence simply does not support the use of puberty blockers, cross-sex hormones, and reassignment surgeries as treatments for gender dysphoria. As they put it, there is "low and very low certainty evidence" to support these excluded treatments.

Safeguarding Kids from Gender Surgeries & Drugs

Dr. James Cantor, editor-in-chief of the peer-reviewed journal Sexual Abuse, a professor, and a clinician, also looked at the medical literature and drew on his own experience. He found every one of the "11 outcome studies" that tracked pre-pubescent children showed that "the majority of children" "cease to feel dysphoric by puberty," thereby making the use of puberty blockers, cross-sex hormones, and surgeries inappropriate in this population. For adolescents, the medical literature showed some improvement with medical intervention and psychotherapy but could not show whether it was the medical intervention or psychotherapy that helped. For those with gender dysphoria, regardless of age, there was a greater likelihood of comorbidities—some other affliction—being the root cause of distress and even suicide. And Dr. Cantor concluded that the perspective of the leadership of medical trade groups in the United States was increasingly at odds with the current positions of European countries with formerly permissive regimes for the treatment of gender dysphoria.

Dr. Quentin Van Meter, a pediatric endocrinologist who trained at Johns Hopkins, and is currently on the clinical faculties of Emory University and Morehouse College, discussed the effects of the excluded treatments on children. He cautioned against the "interruption of natural puberty," because it is puberty that "prepare[s] the body for reproduction and affects the bones, gonads, and brain." He further explained that "blocking puberty at the age of normal puberty prevents the needed accretion of calcium into the skeleton and prevents the maturation of the gonads." This contrasts with treatments for precocious puberty—the early onset of puberty—where puberty blockers are carefully used and the "end of treatment is carefully timed" so that natural puberty resumes at the appropriate age. He also rebutted the notion that the use of puberty-blockers and cross-sex hormones is reversible, noting, for example, that there can be "permanent infertility." And, recognizing that most of those with gender dysphoria later identify with their biological sex, he recommended against the very "permanent" surgical treatments.

Dr. Patrick Lappert, a plastic surgeon with decades of experience, focused on the appropriateness of sex reassignment surgeries on a person's chest. He criticized the methods of those who have performed "breast removal surgery" on patients as young as thirteen, and distinguished sex reassignment surgeries from procedures like gynecomastia (an "objectively abnormal condition" that "makes males develop female-type breast gland tissue") and breast reduction (done when women suffer from "debilitating orthopedic" pain in their neck, back, or shoulders). He concluded that "the medical necessity of transgender chest surgery is not supported by scientific evidence and appears to be firmly in the category of cosmetic surgery." Worse yet, this type of procedure poses ethical concerns for surgeons because "[n]o other cosmetic procedure is expected to produce major functional loss."

Dr. G. Kevin Donovan, formerly the Director for the Center for Clinical Bioethics at Georgetown University School of Medicine, discussed ethical concerns associated with

Safeguarding Kids from Gender Surgeries & Drugs

the excluded treatments. He found that "[v]ulnerable subjects such as children cannot legally or ethically participate in the consent process" needed for the excluded treatment "due to their age and maturity level." More broadly, he criticized the terminological wordplay used in recent years; he noted that the 2013 adoption of the phrase "gender dysphoria" to replace "gender identity disorder" in the DSM-V shifted the focus away from "correcting the underlying cause of the dysphoria" towards "transitioning to the preferred gender."

GAPMS Report Summary

The June 2022 GAPMS Report summarized the findings of the consulting experts and concluded as follows: "the evidence shows that the [excluded] treatments pose irreversible consequences, exacerbate or fail to alleviate existing mental health conditions, and cause infertility or sterility," and, as such, the "treatments do not conform to GAPMS and are experimental and investigational."

Specifically, the evidence relied upon by proponents of "gender affirming" treatment, including evidence of suicidality in the absence of such care, is either low or very low quality:

Puberty Blockers: Evidence does not prove that puberty blockers are safe for treatment of gender dysphoria. Evidence that they improve mental health and reduce suicidality is low or very low quality.

Cross-Sex Hormone Therapy: Evidence suggesting that hormone therapy provides benefits to mental health and prevents suicidality are low or very low quality. Rather, evidence shows that hormone therapy causes multiple irreversible consequences as well as infertility.

Sex Reassignment Surgeries: Evidence of improvements in mental health and reductions in suicidality following sex reassignment surgery is low or very low quality. Sex reassignment surgeries result in irreversible physical changes, including sterility.

While professional medical associations like the American Academy of Pediatrics, the American Psychological Association, and the American Medical Association endorse the above treatments, none of those organizations relies on critically appraised evidence. Their prominence in the medical community alone does not validate their views in the absence of quality, supporting evidence. To the contrary, the evidence shows that the above treatments pose irreversible consequences, exacerbate existing mental health conditions, and cause infertility or sterility.

Safeguarding Kids from Gender Surgeries & Drugs

Rulemaking

Following the report, the Agency entered rulemaking. The text of the proposed rule, which was later finalized without modification, states that "Florida Medicaid does not cover," as "treatment of gender dysphoria," the use of (1) "puberty blockers," (2) "hormones or hormone antagonists," (3) "sex reassignment surgeries," or (4) "other procedures that alter primary or secondary sexual characteristics." Rule 59G-1.050(7)(a), Florida Administrative Code.

In July 2022, the Agency held a hearing on the proposed rule. During the hearing, the Agency took public comments concerning the GAPMS Report and Rule 59G-1.050(7)(a). Among those providing oral comments were two detransitioners—those who stopped and sought to reverse the effects of the excluded medical treatments. The comments received during the hearing were overwhelmingly supportive of the proposed rule. The Agency also accepted public comments in writing both before and after the hearing.

Florida finalized Rule 5G-1.050(7)(a), which became effective August 21, 2022. Even after the rule became final, the Agency continues to reimburse a long list of gender dysphoria treatments provided by clinical psychologists, child psychotherapists, psychiatrists, family therapists, and social workers. The rule only prohibits reimbursements for certain treatments specified in the text of the rule itself.

Lawsuit

In September 2022, four Medicaid recipients sued the Agency and its Secretary in federal court in Tallahassee. While not representatives for a putative class, the four plaintiffs with gender dysphoria seek "preliminary and permanent injunctions prohibiting" the state from implementing Rule 59G-1.050(7)(a).

A separate motion for preliminary injunction also seeks relief beyond that necessary for the named plaintiffs. The only two bases for this broad, class-like request are the Equal Protection Clause, and the Affordable Care Act's non-discrimination provision. 42 U.S.C. § 18116(a).

At this time, the plaintiffs' motion for a preliminary injunction is fully briefed. An evidentiary hearing is scheduled for Wednesday, October 12, in Tallahassee.

From: Strickland, Bettye C
To: Terrell, Danielle
Subject: RE: Updated agenda
Date: Wednesday, October 19, 2022 1:09:56 PM
Attachments: 10282022 Rule Workshop Agenda .docx
10282022 Rule Workshop Agenda .pdf
Importance: High

Updated/removed -

- Detransitioner Testimony

From: Terrell, Danielle <Danielle.Terrell@flhealth.gov>
Sent: Wednesday, October 19, 2022 12:47 PM
To: Strickland, Bettye C <Bettye.Strickland@flhealth.gov>
Subject: Updated agenda

Cherise,

Can you send me the updated agenda once you get it changed?

Thanks,

Danielle Terrell
Executive Director
Department of Health | Division of Medical Quality Assurance | Bureau of Health Care Practitioner Regulation
Boards of Osteopathic Medicine, Massage Therapy, Acupuncture, Speech Language Pathology and Audiology, and Council of Licensed Midwifery
4052 Bald Cypress Way Bin C-06
Tallahassee, FL 32399-1708
Phone: (850) 245-4162

From: Vazquez, Paul
To: Strickland, Bettye C
Subject: FW: Please add to public record
Date: Monday, October 24, 2022 8:43:45 AM
Attachments: B1937-ii-Interim-service-specification-for-specialist-gender-dysphoria-services-for-children-and-young-people-22.pdf.pdf
Importance: High

Please add to the materials with Chair approval and distribute accordingly.

Paul A. Vazquez, J.D.
Executive Director
Florida Board of Medicine
Florida Department of Health
Phone: 850-245-4130

From: Patrick Hunter <patrickhunter@mac.com>
Sent: Sunday, October 23, 2022 7:43 AM
To: Vazquez, Paul <Paul.Vazquez@flhealth.gov>
Subject: Please add to public record

Paul,

This is the latest out of England.

The board needs to consider what it says about

1) social transition not being a neutral act, but rather an active intervention
2) the need for any hormone use to be done within a research setting
3) need to track research data well into adulthood
4) and generally need for a system of care that provides regulation and oversight

Patrick

Classification: Official

Publication reference: PR1937_ii

NHS England

Public consultation

Interim service specification for specialist gender dysphoria services for children and young people

20 October 2022

Contents

Purpose of this document

NHS England is committed to working with a wide range of patients, patient groups and other stakeholders in the development of its commissioning of services. A public consultation is an opportunity to check whether proposals are right and supported, the public understand their impact, and identify any alternatives before decisions are made.

NHS England is the responsible commissioner for specialised services for individuals with gender dysphoria, and it is holding this consultation to seek views on a proposed interim service specification for services for children and young people with gender dysphoria- this represents phase 1 of our service transformation programme. Once agreed, this interim service specification will be operational for a limited time only until a new service specification is formed in 2023/24 following final advice from the independent Cass Review. This will be used by a new configuration of regional providers- representing phase 2 of our service transformation programme.

The public consultation will run for 45 days from 20 October to 4 December 2022.

This consultation guide summaries the proposals and sets out:

- How care is currently provided.
- How the interim service specification could change care and the way that services are delivered, and the reasons for these changes.
- How the proposed changes will be implemented.

The document also has information about how you can share your views with NHS England. At the end of the consultation period, all feedback will be considered before the interim service specification is published.

We recommend that you read this consultation guide alongside the other documents published as part of the consultation. While this single consultation guide has been produced to summarise the proposals, the other documents provide additional detail.

Documents included in this consultation:

- **Interim service specification** – The service specification is a contractual document that describes the clinical service and sets out appropriate standards and quality measures that provider organisations must satisfy.
- **Equality and Health Inequalities Impact Assessment** (EHIA) – This document assesses the potential impact of the interim service specification on population groups that may be disproportionately affected by changes and make appropriate recommendations to mitigate any inequity.

Background

The term used to describe a discrepancy between birth-assigned sex and gender identity is 'gender incongruence'. Gender incongruence is frequently, but not universally, accompanied by the symptom of gender dysphoria: *"a disorder characterized by a strong and persistent cross-gender identification (such as stating a desire to be the other sex or frequently passing as the other sex) coupled with persistent discomfort with his or her sex".*

There is currently only one provider of specialist services for children and young people (up to the 18th birthday) with gender dysphoria in England – this is the Gender Identity Development Service (GIDS) for children and adolescents, delivered by the Tavistock and Portman NHS Foundation Trust in London.

The GIDS is also directly commissioned by NHS Wales, and the changes described in this document will impact on patients who are the commissioning responsibility of NHS Wales.

Interim service specification: the case for change

In September 2020, NHS England commissioned an independent and wide-ranging review of gender identity services for children and young people. The Review, which is ongoing, is being led by Dr Hilary Cass, past president of the Royal College of Paediatrics and Child Health. It was established in response to a complex and diverse range of issues including:

1. A significant and sharp rise in referrals

In 2021/22 there were over 5,000 referrals into the Gender Identity Development Service (GIDS) run by the Tavistock and Portman NHS Foundation Trust. This compares to just under 250 referrals in 2011/12.

2. Marked changes in the types of patients being referred which are not well understood

There has been a dramatic change in the case-mix of referrals from predominantly birth-registered males to predominantly birth-registered females presenting with gender incongruence in early teen years. Additionally, a significant number of children are also presenting with neurodiversity and other mental health needs and risky behaviours which requires careful consideration and needs to be better understood.

3. Scarce and inconclusive evidence to support clinical decision making

This has led to a lack of clinical consensus on what the best model of care for children and young people experiencing gender incongruence and dysphoria should be; and a lack of evidence to support families in making informed decisions about interventions that may have life-long consequences.

4. Long waiting times for initial assessment and significant external scrutiny and challenge surrounding the clinical approach and operational capacity at GIDS

This has contributed to the current service being unable to meet the scale of rising demand and concerns being raised by healthcare regulators about the standard of care.

Next steps

In February 2022, Dr Cass published an interim report in which she set out initial findings and advice from her Review. She emphasised the need to urgently move away from the current model of a sole provider, and to establish regional services that work to a new clinical model that can better meet the holistic needs of a vulnerable group of children and young people. She began to describe the need for these new services to work as networked centres that connected with other local services including children and young people's mental health services and primary care to support all a patient's clinical needs.

In July, Dr Cass gave further advice on the core components of this model. You can read the advice in full here.

In summary, she has said:

- 'Regional centres should be led by experienced providers of tertiary paediatric care to ensure a focus on child health and development, with strong links to mental health services. These will generally be specialist children's hospitals.
- 'They should have established academic and education functions to ensure that ongoing research and training is embedded within the service delivery model'.
- 'The services should have an appropriate multi-professional workforce to enable them to provide an integrated model of care that manages the holistic needs of this population'.
- 'Staff should maintain a broad clinical perspective to embed the care of children and young people with gender uncertainty within a broader child and adolescent health context'.
- In view of the uncertainties surrounding their use, consideration should be given to the rapid establishment of the necessary research infrastructure to prospectively enroll young people being considered for puberty blocking drugs

into a formal research programme, with adequate follow-up into adulthood.

Establishing New (Phase 1) Services

Given the urgent need to stabilise service provision for patients and begin building a more resilient service by expanding provision, we are establishing two 'Phase 1'[1] services. Consistent with Dr Cass' advice, these services will be led by specialist children's hospitals and, once established, will take over clinical responsibility for and management of all current GIDS patients as part of a managed transition, and they will begin to see children and young people who are currently on the GIDS waiting list.

One Phase 1 service will be based in London and will be led by a partnership between Great Ormond Street Hospital for Children NHS Foundation Trust and Evelina London Children's Hospital (part of Guys and St Thomas' NHS Foundation Trust), with South London and Maudsley NHS Foundation Trust providing specialist CYP mental health support.

A second Phase 1 service will be based in the North West, led by a partnership between Alder Hey Children's NHS Foundation Trust and the Royal Manchester Children's Hospital (part of Manchester University NHS Foundation Trust), where both trusts also provide specialist CYP mental health services.

The Tavistock and Portman NHS Foundation Trust and the endocrine teams based at University College London Hospitals NHS Foundation Trust and Leeds Teaching Hospitals NHS Trust will play a vital role in supporting both Phase 1 services as they establish the new services building on their extensive experience of working with this patient group.

A single national transformation programme has been established to oversee a smooth and seamless transition for patients to the new Phase 1 services, including bringing the GIDS contract to a managed close because of these changes. The establishment of the Phase 1 services will happen as quickly as possible, but crucially at a pace that appreciates the complexity of the change, while minimising

[1] When NHS England announced plans in July 2022 to establish new services we referred to them as 'Early Adopter' service providers. We are now using the term 'Phase 1' service providers instead.

disruption and any additional anxiety for patients. The aim is for the Phase 1 services to be operational by Spring 2023.

The Phase 1 services will be commissioned against an interim service specification which will replace the current service specification used by the GIDS. There is now an urgent need to agree this specification to give the Phase 1 services time to recruit staff and set up the new services a quickly as possible.

The interim service specification builds out from the existing specification to both incorporate advice from the Cass Review following its extensive stakeholder engagement, and to provide points of clarification in certain areas. It has been worked up and endorsed by the Phase 1 providers, as well as senior clinical leads including the National Medical Director for Specialised Services, the National Clinical Director for Children and Young People and the Associate National Clinical Director for Children and Young People's Mental Health. It is important to note that this is an interim service specification to support the rapid mobilisation of the new Phase 1 services. It will be replaced in due course with a final service specification which will be subject to a further period of engagement and public consultation at a later date and once further advice has been received from Dr Cass as part of her ongoing independent review. This will mark the start of Phase 2 of our service transformation programme when additional regional services will be commissioned.

What are the proposed changes?

The interim service specification proposes the following changes and points of clarification over the current service specification.

1. **Composition of the clinical team – substantive change**

The current service specification for GIDS describes that the service is delivered through a specialist multidisciplinary team with contributions from specialist social workers, family therapists, psychiatrists, psychologists, psychotherapists, paediatric and adolescent endocrinologists and clinical nurse practitioners. *The new interim service specification proposes to extend the clinical team so that it is a more integrated multi-disciplinary team that, in addition to gender dysphoria specialists, will include experts in paediatric medicine, autism, neurodisability and mental health.*

The reason for this proposal is to respond to evidence that there is a higher prevalence of other complex presentations in children and young people who have gender dysphoria, that the Phase 1 services will also address, working with local services where appropriate. The proposal also responds to the findings of the Care Quality Commission's 2021 inspection report of GIDS, which highlighted the need for a better multi-disciplinary mix of care providers for some children and young people referred to the service. Furthermore, the interim advice of the Cass Review concluded (page 69) that "*a fundamentally different service model is needed which is more in line with other paediatric provision, to provide timely and appropriate care for children and young people needing support around their gender identity … this must include support for any other clinical presentations that they may have*".

2. **Clinical leadership – substantive change**

The current service specification for GIDS does not describe criteria for the clinical lead for the service. *The new interim service specification proposes that the clinical lead for the service will be a medical doctor*.

The reason for this change is to reflect that the new integrated clinical teams will have a broader range of clinical disciplines, including medical professionals, who will be addressing a broader range of medical conditions in addition to gender dysphoria;

and that oversight of the service by a medical doctor is appropriate given that the service may provide medical interventions to some children and young people..

3. **Collaboration with, and support for, referrers and local services – substantive change**

The current service specification for GIDS describes a tiered approach for progression through the clinical pathway: the first tier involves meetings between the GIDS team and local professionals involved in the care of the child or young person and the second tier involves the child or young person accessing local services for mental health needs with GIDS offering advice to local services. There are numerous references in the current GIDS service specification to joint working between GIDS and local services including through consultation and liaison. However, GIDS has struggled to provide this support to local services in a consistent way given the constraints on the service. *The new interim service specification proposes to retain this tiered approach to progression through the pathway and describes a more structured approach for collaboration with local services in the interests of the child and young person; a referral to The Service will require a consultation meeting between the Phase 1 service and the relevant local secondary healthcare team and / or the GP. Where the outcome of the initial professional consultation between the Service and the referrer is that the patient does not meet the access criteria for The Service, the child or young person will not be added to the waiting list - but the family and professional network will have been assisted to develop their formulation of the child or young person's needs and a local care plan and will be advised of other resources for support that are appropriate for individual needs. The proposed interim service specification also proposes that not all children and young people who meet the access criteria will need to be seen directly by The Service. A key intervention that will be delivered by The Service is the provision of consultation and active support to local professionals, including support in formulation of needs and risks and individualised care planning. The level and type of consultation offered to the professional network will be determined according to the individual needs of each case and through a process of clinical prioritisation.*

4. **Referral sources – substantive change**

The current service specification for GIDS states that referrals can be made by staff in health and social services, schools, colleges of further education and by voluntary organisations. *The new interim service specification proposes that referrals may be made by GPs and NHS professionals.* The reason for the proposal is to ensure that children and young people are already engaged with the local health system before a referral is considered by a local health professional into the highly specialist gender dysphoria service, including for the reason that a proposed core feature of the new pathway is a consultation meeting between the specialist service and local health professionals before a referral can be considered for acceptance. The proposal would impact on fewer than 5% of referrals at current referral patterns, in that around 65% of referrals into GIDS are currently made by GPs and around 30% are made by NHS professionals. This proposal relates only to the interim service specification for the Phase 1 services. The interim report of the Cass Review begins to describe a future clinical pathway approach that operates within a managed clinical network, including other statutory agencies, and this pathway will be worked up by NHS England in the coming months through engagement with the Cass Review and other stakeholders.

5. **Social transition – clarification**

The current GIDS service specification acknowledges that social transition in pre-pubertal children is a controversial issue, that divergent views are held by health professionals, and that the current evidence base is insufficient to predict the long-term outcomes of complete gender-role transition during early childhood.

The interim Cass Report has advised that although there are differing views on the benefits versus the harms of early social transition, it is important to acknowledge that it should not be viewed as a neutral act. Dr Cass has recommended that social transition be viewed as an ‘active intervention’ because it may have significant effects on the child or young person in terms of their psychological functioning.

In line with this advice, the interim service specification sets out more clearly that the clinical approach in regard to pre-pubertal children will reflect evidence that in most cases gender incongruence does not persist into adolescence; and that for

adolescents the provision of approaches for social transition should only be considered where the approach is necessary for the alleviation of, or prevention of, clinically significant distress or significant impairment in social functioning and the young person is able to fully comprehend the implications of affirming a social transition.

Endocrine Interventions

Building the research protocol

The interim service specification reads:

> "*Consistent with advice from the Cass Review highlighting the uncertainties surrounding the use of hormone treatments, NHS England is in the process of forming proposals for prospectively enrolling children and young people being considered for hormone treatment into a formal research programme with adequate follow up into adulthood, with a more immediate focus on the questions regarding GnRHa. On this basis NHS England will only commission GnRHa in the context of a formal research protocol. The research protocol will set out eligibility criteria for participation.*"

In due course NHS England will share details of this work, including plans for how stakeholders and the public will be engaged and consulted on eligibility criteria.

Placing the use of GnRHa in the context of clinical research will have several important benefits:

- It responds directly to Dr Cass' advice that *'Without an established research strategy and infrastructure, the outstanding questions will remain unanswered and the evidence gap will continue to be filled with polarised opinion and conjecture, which does little to help young people, and their families and carers, who need support and information on which to make decisions'*. In this respect the NHS has the opportunity to make a major international contribution to the evidence base in this area.

- Secondly, it will ensure that there is greater transparency for children and their parents / carers around the uncertain clinical benefits and longer-term health impacts surrounding their use.

- Thirdly, it will further strengthen the consent and information sharing process to support informed decision making by young people.

Unregulated drugs

The current service specification for GIDS states that GIDS does not offer shared care with private clinicians, and that in cases where puberty blocking drugs or hormone drugs are prescribed or accessed outside the service, the GIDS will make the young person and their family aware of the risks, contraindications and any irreversible or partly reversible effects of any interventions, and will be unable to provide ongoing clinical supervision for the management of these interventions.

The proposed interim specification reads:

> *"Children, young people and their families are strongly discouraged from sourcing GnRHa and masculinising / feminising hormone drugs from unregulated sources or from on-line providers that are not regulated by UK regulatory bodies. In such cases The Service will make the child or young person and their family aware of the risks, contraindications and any irreversible or partly reversible effects of the drugs and will advise the GP to initiate local safeguarding protocols.*
>
> *"Should a child or young person access GnRHa from unregulated sources or unregulated providers The Service will not assume responsibility for prescribing recommendations nor will it enter into shared cared arrangements in these circumstances.*
>
> *"Where a child or young person has obtained masculinising / feminising hormones from an unregulated source (such as the internet) The Service will not accept clinical responsibility for management of the endocrine intervention.*

> *"Where a child or young person has been prescribed masculinising / feminising hormones by an unregulated provider outside of the eligibility and readiness criteria described in the current NHS clinical commissioning policy The Service will not accept clinical responsibility for management of the endocrine intervention."*

The reason for the revised wording is to provide greater clarity and retain and strengthen current safeguards. Senior clinicians have advised NHS England on the need for the new interim service specification to have much clearer wording in this regard so that the interim service specification is less open to interpretation, so that young people, families and professionals are clear on the approach that will be adopted by the NHS in such cases.

How will the proposed changes be implemented?

The proposed interim service specification will inform how the Phase 1 services deliver care and support to young people referred into the gender identity service over the next year.

In parallel, the Cass Review will continue its work to describe the new clinical model to which the Phase 1 services and the new regional services will work in the future. Once Dr Cass has delivered this advice the NHS will build a new service specification and put it out for stakeholder engagement and formal public consultation.

Give us your views on the proposed changes

NHS England would like to hear what patients, parents and carers, clinicians, providers and other interested parties think about the proposed interim service specification for gender dysphoria services.

These are the questions we're asking as part of the public consultation:

1. **In what capacity are you responding?** (Patient / Parent / Clinician / Service Provider / Other; If you have selected 'Other', please specify.)

2. **Are you responding on behalf of an organisation?** (yes / no; If you have selected "yes", which organisation are you responding on behalf of?)

3. **To what extent do you agree with the four substantive changes to the service specification explained above?**

    A. **Composition of the clinical team**
    (Agree / Partially Agree / Neither Agree nor Disagree / Partially Disagree / Disagree; comments)

    B. **Clinical leadership**
    (Agree / Partially Agree / Neither Agree nor Disagree / Partially Disagree / Disagree; comments)

    C. **Collaboration with referrers and local services**
    (Agree / Partially Agree / Neither Agree nor Disagree / Partially Disagree / Disagree; comments)

    D. **Referral sources**
    (Agree / Partially Agree / Neither Agree nor Disagree / Partially Disagree / Disagree; comments)

4. **To what extent do you agree that the interim service specification provides sufficient clarity about approaches towards social transition?** (Agree / Partially Agree / Neither Agree nor Disagree / Partially Disagree / Disagree; comments)

5. **To what extent do you agree with the approach to the management of patients accessing prescriptions from un-regulated sources?**
   (Agree / Partially Agree / Neither Agree nor Disagree / Partially Disagree / Disagree; comments)

6. **Are there any other changes or additions to the interim service specification that should be considered in order to support Phase 1 services to effectively deliver this service?**
   (comments)

7. **To what extent do you agree that the Equality and Health Inequalities Impact Assessment reflects the potential impact on health inequalities which might arise as a result of the proposed changes?**
   (Agree / Partially Agree / Neither Agree nor Disagree / Partially Disagree / Disagree; comments)

You can provide your views with NHS England by completing the online survey: https://www.engage.england.nhs.uk/specialised-commissioning/specialist-gender-interim-specification

Your views will help NHS England to further shape and refine this interim service specification for gender dysphoria services, until a new service specification is agreed in 2023, which will be informed by a full consultation and engagement process.

NHS England
Wellington House
133-155 Waterloo Road
London
SE1 8UG

This publication can be made available in a number of alternative formats on request.

From: Vazquez, Paul
To: Strickland, Bettye C
Subject: Appearance Form
Date: Wednesday, November 2, 2022 3:05:39 PM
Attachments: Appearance Request Forms (Workshop) 9-20-22.docx

Paul A. Vazquez, J.D.
Executive Director
Florida Board of Medicine
Florida Department of Health
4052 Bald Cypress Way | Bin C-03
Tallahassee, FL 32399-3253
Phone: 850-245-4130

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

PLEASE NOTE: Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your e-mail communications may therefore be subject to public disclosure.

APPEARANCE REQUEST FORM

Florida Boards of Medicine and Osteopathic Medicine
Joint Rules/Legislative Committee

TAB 1 - Proposed Rulemaking on Standard of Care for Gender Dysphoria

Name:
Address (optional):
Telephone Number (optional):
Email Address (optional):
Affiliation or Organization (if any):
I am: ☐ **In Support of Rule** ☐ **In Opposition to Rule** ☐ **Neutral** ☐ **I wish to speak** ☐ **I DO NOT wish to speak**

APPEARANCE REQUEST FORM

Florida Boards of Medicine and Osteopathic Medicine
Joint Rules/Legislative Committee

TAB 1 - Proposed Rulemaking on Standard of Care for Gender Dysphoria

Name:
Address (optional):
Telephone Number (optional):
Email Address (optional):
Affiliation or Organization (if any):
I am: ☐ **In Support of Rule** ☐ **In Opposition to Rule** ☐ **Neutral** ☐ **I wish to speak**

APPEARANCE REQUEST FORM

☐ I **DO NOT** wish to speak