The record establishes that for some minors, including Susan Doe and K.F., a treatment regimen of mental-health therapy followed by GnRH agonists and eventually by cross-sex hormones is the best available treatment. They and their parents, in consultation with their doctors and multidisciplinary teams, have rationally chosen this treatment. The State of Florida's decision to ban payment for GnRH agonists and cross-sex hormones for transgender individuals is not rationally related to a legitimate state interest.

Dissuading a person from conforming to the person's gender identity rather than to the person's natal sex is not a legitimate state interest. The defendants apparently acknowledge this.[66] But the State's disapproval of transgender status—of a person's gender identity when it does not match the person's natal sex—was a substantial motivating factor in enactment of the challenged rule and statute.

Discouraging individuals from pursuing their gender identities, when different from their natal sex, was also a substantial motivating factor. In a "fact sheet," the Florida Department of Health asserted social transitioning, which involves no medical intervention at all, should not be a treatment option for children or adolescents.[67] Nothing could have motivated this remarkable intrusion into parental prerogatives other than opposition to transgender status itself.

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[66] Trial Tr., ECF No. 242 at 97–98.

[67] Defs.' Ex. 5, ECF No. 193-5 at 1; *see also* Pls.' Ex. 19, ECF No. 175-19 at 2.

State action motivated by purposeful discrimination, even if otherwise lawful, violates the Equal Protection Clause. *See Adams*, 57 F.4th at 810 (recognizing that an otherwise neutral law still violates the Equal Protection Clause when it is "motivated by 'purposeful discrimination'") (citing *Pers. Adm'r of Mass. v. Feeney*, 442 U.S. 256, 274 (1979)); *see also Greater Birmingham Ministries v. Sec'y of State for Ala.*, 992 F.3d 1299, 1321–22 (11th Cir. 2021). The rule and statute at issue were motivated in substantial part by the plainly illegitimate purposes of disapproving transgender status and discouraging individuals from pursuing their honest gender identities. This was purposeful discrimination against transgenders.

XII. The pretextual justifications for the rule and statute

In support of their position, the defendants have proffered a laundry list of purported justifications for the rule and statute. The purported justifications are largely pretextual and, in any event, do not call for a different result.

A. "Low quality" evidence

A methodology often used for evaluating medical studies—for evaluating research-generated evidence on the safety and efficacy of any given course of treatment—is known as Grading of Recommendations, Assessment, Development, and Evaluation ("GRADE"). The defendants stridently assert that the evidence supporting the treatments at issue is "low" or "very low" quality as those terms are

used in the GRADE system. But the evidence on the other side—the evidence purportedly showing these treatments are ineffective or unsafe—is far weaker, not just of "low" or "very low" quality. Indeed, evidence suggesting these treatments are ineffective is nonexistent.

The choice these plaintiffs face is binary: to use GnRH agonists and cross-sex hormones, or not. It is no answer to say the evidence on the yes side is weak when the evidence on the no side is weaker or nonexistent. There is substantial and persuasive, though not conclusive, research showing favorable results from these treatments.[68] A decision for the patients at issue cannot wait for further or better research; the treatment decision must be made now.

Moreover, the fact that research-generated evidence supporting these treatments gets classified as "low" or "very low" quality on the GRADE scale does not mean the evidence is not persuasive, or that it is not the best available research-generated evidence on the question of how to treat gender dysphoria, or that medical treatments should not be provided consistent with the research results and clinical evidence.

It is commonplace for medical treatments to be provided even when supported only by research producing evidence classified as "low" or "very low"

[68] *See, e.g.*, Trial Tr., ECF No. 228 at 41–42.

on this scale.[69] The record includes unrebutted testimony that only about 13.5% of accepted medical treatments across all disciplines are supported by "high" quality evidence on the GRADE scale.[70] The defendants' assertion that treatment should be banned based on the supporting research's GRADE score is a misuse of the GRADE system.

We put band-aids on cuts to keep dirt out not because there is "high" quality research-generated evidence supporting the practice but because we know, from clinical experience, that cuts come with a risk of infection and band-aids can reduce the risk.

Gender dysphoria is far more complicated, and one cannot know, with the same level of confidence, how to treat it. But there is now extensive clinical experience showing excellent results from treatment with GnRH agonists and cross-sex hormones. If these treatments are prohibited or Medicaid payment is unavailable, many patients will suffer needlessly.[71] The extensive clinical evidence is important and indeed persuasive evidence, even if the supporting research has produced only "low" or "very low" quality evidence on the GRADE scale.

When facing a binary decision to use or not use GnRH agonists or hormones, a reasonable decisionmaker would consider the evidence on the yes

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[69] *See* Trial Tr., ECF No. 227 at 98–101.
[70] Trial Tr., ECF No. 226 at 68–69.
[71] Trial Tr., ECF No. 226 at 64; Trial Tr., ECF No. 238 at 97–98.

side, as well as the weaker evidence on the no side. Calling the evidence on the yes side "low" or "very low" quality would not rationally control the decision.

B. Risks attendant to treatment

The defendants assert there are risks attendant to treatment with GnRH agonists and cross-sex hormones. Indeed there are. There are legitimate concerns about the effect on bone density; this calls for appropriate monitoring. There are legitimate concerns about fertility and sexuality that a child entering puberty is not well-equipped to evaluate and for which parents may be less-than-perfect decisionmakers. There is a risk of misdiagnosis, though the requirement in the standards of care for careful analysis by a multidisciplinary team should minimize the risk. There is a risk that a child later confronted with the bias that is part of our world will come to believe it would have been better to try to pass as cisgender.

There also are studies suggesting not that there *are* but that there *may be* additional medical risks. An unreplicated study found that sheep who took GnRH agonists became worse at negotiating a maze, at least for a time. Another study showed a not-statistically-significant but nonetheless-concerning decrease in IQ among cisgender children treated for central precocious puberty with GnRH agonists. These and other studies cited by the defendants would surely be rated low or very-low quality on the GRADE scale and, more importantly, are not very persuasive. The latter study has not led to a ban on the use of GnRH agonists to

treat central precocious puberty. One cannot know from these studies whether treating transgender adolescents with GnRH agonists will cause comparable adverse results in some patients. But the risk that they will is a risk a decisionmaker should reasonably consider.

That there are risks does not end the inquiry. There are also substantial benefits for the overwhelming majority of patients treated with GnRH agonists and cross-sex hormones. And there are risks attendant to *not* using these treatments, including the risk—in some instances, the near certainty—of anxiety and depression and even suicidal ideation. The challenged rule and statute ignore the benefits that many patients realize from these treatments and the substantial risk posed by foregoing the treatments—the risk from failing to pursue what is, for many, the most effective available treatment of gender dysphoria. Mr. Dekker attempted suicide four times before beginning successful treatment with cross-sex hormones; he is now thriving.[72]

If the plaintiffs do not continue appropriate treatments, the likelihood is very high that they will suffer attendant adverse mental-health consequences. If, on the other hand, they *do* continue appropriate treatments, they will avoid some of the adverse consequences. They also will face attendant risks.

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[72] Trial Tr., ECF No. 228 at 150 & 166–67.

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Risks attend many kinds of medical treatment, perhaps most. Ordinarily it is the patient, in consultation with the doctor, who weighs the risks and benefits and chooses a course of treatment. Florida's Medicaid program routinely covers treatments with greater risks than those involved here. What is remarkable about the challenged rule and statute is not that they address medical treatments with both risks and benefits but that they arrogate to the State the right to make the decision. And worse, the rule and statute make the same decision for everybody, without considering any patient's individual circumstances. The rule and statute do this in contravention of widely accepted standards of care.

That there are risks of the kind presented here is not a rational basis for denying patients the option to choose this treatment and to have Medicaid cover the cost.

C. Bias in medical organizations

The defendants say the many professional organizations that have endorsed treatment of gender dysphoria with GnRH agonists and hormones all have it wrong. The defendants say, in effect, that the organizations were dominated by individuals who pursued good politics, not good medicine.

If ever a pot called a kettle black, it is here. The statute and the rule were an exercise in politics, not good medicine.

This is a politically fraught area. There has long been, and still is, substantial bigotry directed at transgender individuals. Common experience confirms this, as does a Florida legislator's remarkable reference to transgender witnesses at a committee hearing as "mutants" and "demons."[73] And even when not based on bigotry, there are those who incorrectly but sincerely believe that gender identity is not real but instead just a choice. This is, as noted above, the elephant in the room.

Where there is bigotry, there are usually—one hopes, always—opponents of bigotry. It is hardly surprising that doctors who understand that transgender identity can be real, not made up—doctors who are willing to provide supportive medical care—oppose anti-transgender bigotry.

It sometimes happens that opponents of bigotry deem opposing viewpoints bigoted even when they are not. And it sometimes happens that those with opposing viewpoints are slow to speak up, lest they be accused of bigotry. These dynamics could affect a medical association's consideration of transgender

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[73] *Hearing on Facility Requirements Based on Sex*, CS/HB 1521 2023 Session (Fla. Apr. 10, 2023), https://www.myfloridahouse.gov/VideoPlayer.aspx?eventID=8804 (time stamp 2:30:35 to 2:34:10). Representative Webster Barnaby said to transgender Florida citizens who spoke at the hearing that they were "mutants living among us on Planet Earth." He raised his voice and said, "[T]his is Planet Earth, where God created men, male and women, female!" He continued: "[T]he Lord rebuke you Satan and all of your demons and imps that come parade before us. That's right I called you demons and imps who come and parade before us and pretend that you are part of this world." Finally, he said, you can "take [him] on" but he "promises [he] will win every time."

treatment. The record suggests these dynamics *have* affected the tone and quality of debate within WPATH. It is entirely possible that the same dynamics could have affected the tone and quality of debate within other associations.

Even so, it is fanciful to believe that all the many medical associations who have endorsed gender-affirming care, or who have spoken out or joined an amicus brief supporting the plaintiffs in this litigation, have so readily sold their patients down the river. The great weight of medical authority supports these treatments. The widely accepted standards of care require competent therapy and careful evaluation by a multidisciplinary team before use of GnRH agonists and cross-sex hormones for treatment of gender dysphoria. But the widely accepted standards of care support their use in appropriate circumstances. The standards have been unanimously endorsed by reputable medical associations, even though not unanimously endorsed by all the members of the associations.

The overwhelming majority of doctors are dedicated professionals whose first goal is the safe and effective treatment of their patients. There is no reason to believe the doctors who adopted these standards were motivated by anything else.

D. International views

The defendants have asserted time and again that Florida now treats GnRH agonists and cross-sex hormones the same as European countries. The assertion is false. And no matter how many times the defendants say it, it will still be false. No

country in Europe—or so far as shown by this record, anywhere in the world—entirely bans these treatments or refuses to pay for them. *See also Brandt v. Rutledge*, No. 4:21-cv-450, 2023 WL 4073727, at *30 (E.D. Ark. June 20, 2023) (rejecting the apparently identical assertion that a ban on gender-affirming care for minors was consistent with "nations around the world" and finding the evidence showed no other identified nation took that position).

To be sure, there are countries that ban gays and lesbians and probably transgender individuals, too. One doubts these treatments are available in Iran or other similarly repressive regimes. But the treatments are available in appropriate circumstances in all the countries cited by the defendants, including Finland, Sweden, Norway, Great Britain, France, Australia, and New Zealand.[74] Some or all of these insist on appropriate preconditions and allow care only in approved facilities—just as the Endocrine Society and WPATH standards insist on appropriate preconditions, and just as care in the United States is ordinarily provided through capable facilities. Had Florida truly joined the international consensus—making these treatments available in appropriate circumstances or in approved facilities—these plaintiffs would qualify, and this lawsuit would not be necessary.

[74] *See* Trial Tr., ECF No. 226 at 78–79; *see also* Trial Tr., ECF No. 227 at 134; Trial Tr., ECF No. 228 at 61–62.

E. Malpractice

The defendants assert, with no real evidentiary support, that GnRH agonists and cross-sex hormones have sometimes been provided in Florida without the appropriate mental-health therapy and evaluation by a multidisciplinary team.

If that were true, the solution would be to appropriately regulate these treatments, not to ban them. And there are, of course, remedies already in place in Florida for deficient medical care. AHCA is entitled to review any individual Medicaid claim and to pay only for medically necessary treatment. There is no evidence that this kind of care is routinely provided so badly that it should be banned outright.

Along the same lines, the defendants say gender dysphoria is difficult to diagnose accurately—that gender identity can be fluid, that there is no objective test to confirm gender identity or gender dysphoria, and that patients treated with GnRH agonists or cross-sex hormones have sometimes come to regret it. But the defendants ignore facts that do not support their narrative. Fluidity is common prior to puberty but not thereafter. Regret is rare; indeed, the defendants have offered no evidence of any Florida resident who regrets being treated with GnRH agonists or cross-sex hormones. And the absence of objective tests to confirm gender dysphoria does not set it apart from many other Medicaid-covered mental-

health conditions that are routinely diagnosed without objective tests and treated with powerful medications.

The difficulty diagnosing a patient calls for caution. It does not call for a one-size-fits-all refusal to cover widely accepted medical treatment.[75] It does not call for the State to make a binary decision not to cover the treatment even for a properly diagnosed patient.

F. Continuation of treatment

The defendants note that 98% or more of adolescents treated with GnRH agonists progress to cross-sex hormones. That is hardly an indictment of the treatment; it is instead consistent with the view that in 98% or more of the cases, the patient's gender identity did not align with natal sex, this was accurately determined, and the patient was appropriately treated first with GnRH agonists and later with cross-sex hormones. An advocate who denies the existence of genuine transgender identity or who wishes to make everyone cisgender might well fear progression to cross-sex hormones, but the defendants have denied that this is a basis for their current reference to this progression.

The defendants say, instead, that the high rate of progression rebuts an argument in support of GnRH agonists: that GnRH agonists give a patient time to

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[75] *See* Trial Tr., ECF No. 239 at 91–94 (defense expert Dr. Levine explaining that medical intervention such as puberty blockers and hormones should be carefully prescribed and monitored but not banned).

reflect on the patient's gender identity and, if still convinced of a gender identity opposite the natal sex, to reflect on whether to go forward socially in the gender identity or natal sex. But if that is a goal of treatment with GnRH agonists, it is certainly not the treatment's *primary* goal. The primary goal is to delay and eventually avoid development of secondary sex characteristics inconsistent with the patient's gender identity—and thus to avoid or reduce the attendant anxiety, depression, and possible suicidal ideation.

The high rate of progression from GnRH agonists to cross-sex hormones is not a reason to ban or refuse to cover the treatments.

G. Off-label use of FDA-approved drugs

The defendants note that while the Food and Drug Administration has approved GnRH agonists and the hormones at issue as safe and effective, the agency has not addressed their use to treat gender dysphoria. Quite so. Use of these drugs to treat gender dysphoria is "off label."

That the FDA has not approved these drugs for treatment of gender dysphoria says precisely nothing about whether the drugs are safe and effective when used for that purpose. Off-label use of drugs is commonplace and widely

accepted across the medical profession.[76] Florida Medicaid routinely covers such use.[77] The defendants' contrary implication is divorced from reality.

Obtaining FDA approval of a drug is a burdensome, expensive process.[78] A pharmaceutical provider who wishes to market a new drug must incur the burden and expense because the drug cannot be distributed without FDA approval. Once a drug has been approved, however, the drug can be distributed not just for the approved use but for any other use as well. There ordinarily is little reason to incur the burden and expense of seeking additional FDA approval.

That the FDA approved these drugs at all confirms that, at least for one use, they are safe and effective.[79] This provides some support for the view that they are safe when properly administered and that they effectively produce the intended results—that GnRH agonists delay puberty and that testosterone and estrogen have masculinizing or feminizing effects as expected. The FDA approval goes no further—it does not address one way or the other the question whether using these drugs to treat gender dysphoria is as safe and effective as on-label uses.

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[76] Trial Tr., ECF No. 227 at 121–23.
[77] *See* AHCA 30(b)(6) Dep., ECF No. 235-1 at 35, 53–56.
[78] Trial Tr., ECF No. 226 at 182–84; Trial Tr., ECF No. 227 at 120–23; Trial Tr., ECF No. 239 at 54–55.
[79] Trial Tr., ECF No. 226 at 182–84; Trial Tr., ECF No. 227 at 120–23.

That use of GnRH agonists and cross-sex hormones to treat gender dysphoria is "off-label" is not a reason to ban or refuse to cover their use for that purpose.

XIII. Ruling on the claims

What remains is to match the findings of fact and conclusions of law as set out above to the specific claims asserted in the first amended complaint.

Count I asserts a claim against Mr. Weida under 42 U.S.C. § 1983 and the Fourteenth Amendment's Equal Protection Clause. The plaintiffs are entitled to prevail because the denial of Medicaid coverage for transgender patients for the same drugs covered for others survives neither intermediate nor rational-basis scrutiny.

Count II asserts a claim against AHCA under the Affordable Care Act's prohibition of discrimination based on sex, 42 U.S.C. § 18116. The plaintiffs are entitled to prevail on this claim, just as on the Equal Protection claim.

Count III asserts a § 1983 claim for Mr. Rothstein, Susan Doe, and K.F. against Mr. Weida based on the Medicaid Act's requirement for early and periodic screening, diagnostic, and treatment services for beneficiaries under age 21, 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43)(C),1396d(a)(4)(B), and 1396d(r)(5). The plaintiffs are entitled to prevail because the treatments at issue comport with the

standards of care for their medical conditions and there are no alternative, equally effective treatments.

Count IV asserts a § 1983 claim against Mr. Weida based on the Medicaid Act's comparability requirement, 42 U.S.C. § 1396a(a)(10)(B)(i), under which assistance to an eligible individual cannot be less in "amount, duration, or scope" than assistance available to other Medicaid beneficiaries. The plaintiffs are entitled to prevail because cisgender Medicaid beneficiaries are covered for the same puberty blockers and hormones at issue. That cisgender patients receive the drugs for a different diagnosis does not make the different treatment permissible. Quite the contrary: federal law prohibits a state from denying or reducing a Medicaid-eligible patient's required services "solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230(c); *see also Rush*, 625 F.2d at 1156 n.12. Indeed, denying coverage for an illness suffered only or primarily by a disfavored group is the very paradigm of prohibited discrimination based on diagnosis.

XIV. Conclusion

Gender identity is real. Those whose gender identity does not match their natal sex often suffer gender dysphoria. The widely accepted standard of care calls for evaluation and treatment by a multidisciplinary team. Proper treatment begins with mental-health therapy and is followed in appropriate cases by GnRH agonists and cross-sex hormones. Florida has adopted a rule and statute that prohibit

Medicaid payment for these treatments even when medically appropriate. The rule and statute violate the federal Medicaid statute, the Equal Protection Clause, and the Affordable Care Act's prohibition of sex discrimination.

These plaintiffs are Medicaid beneficiaries who are entitled to payment, as a matter of medical necessity, for puberty blockers or cross-sex hormones as appropriately determined by their multidisciplinary teams of providers.

IT IS ORDERED:

1. It is declared that Florida Statutes § 286.31(2) and Florida Administrative Code rule 59G-1.050(7) are invalid to the extent they categorically ban Medicaid payment for puberty blockers and cross-sex hormones for the treatment of gender dysphoria.

2. The defendants Jason Weida, in his official capacity, and the Florida Agency for Health Care Administration (a) must approve Medicaid payment for services rendered from this date forward for the evaluation, diagnosis, and treatment of the plaintiffs August Dekker, Brit Rothstein, Susan Doe, and K.F. for gender dysphoria, including with puberty blockers and cross-sex hormones, as recommended by their multidisciplinary teams, and (b) must not take any steps to prevent the administration of cross-sex hormones to August Dekker or Brit Rothstein or to prevent the administration of puberty blockers or cross-sex hormones to Susan Doe or K.F. But this injunction does not preclude the

defendants from applying the professional standards that would apply to use of the same substances to treat patients with other medical conditions.

3. This injunction binds the defendants and their officers, agents, servants, employees, and attorneys—and others in active concert or participation with any of them—who receive actual notice of this injunction by personal service or otherwise.

4. The clerk must enter judgment and close the file.

5. Jurisdiction is retained to award costs and attorney's fees.

SO ORDERED on June 21, 2023.

s/Robert L. Hinkle
United States District Judge

From: Robin
To: BOM Public Comment
Subject: Transgender Rights
Date: Wednesday, June 21, 2023 3:07:42 PM

Dear board members,

My name is Robin, and I'm a 16 year old teenager transitioning from female to male. I've been taking testosterone through an injection format for 4 months, and wanted to voice my dissent against SB 254. Hundreds of trans people are being affected by SB 254, including adults. According to Plume, which is the largest telehealth service for trans and nonbinary people and operates in 45 states, about 80% of transgender adults receive care from a nurse practitioner. The law now mandates physicians can only provide gender affirming care, which forces trans adults to seek out new providers. Additionally, SB 254 makes it mandatory for the signing of the currently nonexistent informed consent form to occur in person. This directly targets transgender Floridians who live in rural areas and need access to transportation. I know this bill was created to harm people like me. It was created under the assumption that trans youth don't know what's best for them, that being trans is a "choice" and is something that must be eradicated. I can not stress enough how false this idea is. Prior to coming out, I struggled with severe depression and self hatred. I looked in the mirror and saw a stranger. But the first time I heard someone call me by my true name, the one that doesn't match my legal records, I cried tears of joy and recognition. I am so much happier now that I am on HRT. It was life saving for me, just like it is for the estimated 94,900 transgender adults living in Florida. How can people want to ban such a beautiful act of self-discovery, of transformation? I know the people pushing this bill aren't trans and most likely view transitioning with confusion, even disgust. Cis people are born feeling comfortable in their gender identities and bodies, and have trouble understanding the importance of HRT. But please listen to trans people, listen to the scientists who back us up with data, listen like the judges in other states who put a halt to these sex reassignment treatment bans. I'm a teenager like anyone else, and I just want to have the right to be myself and succeed like any other teen. Don't I deserve that right?

Sincerely,
Robin (they/them or he/him pronouns)

From: Tony Cooper
To: BOM Public Comment
Subject: Proposed Gender Affirming Care Rule
Date: Friday, June 23, 2023 10:07:53 AM

Hello Florida BOM,

I am writing to ask that at today's meeting in Jacksonville, you vote against the proposed rule concerning gender affirming care for trans folks. It is disrespectful towards both them and this week's court ruling on the matter.

With All Due Regard,

T.C.

From: Strickland, Bettye C
To: BOM Public Comment
Subject: FW: 64B15ER23-4 Sex-reassignment Prescriptions
Date: Wednesday, June 28, 2023 9:00:59 AM

From: info@parrislaw.org <info@parrislaw.org>
Sent: Tuesday, June 27, 2023 6:15 PM
To: Terrell, Danielle <Danielle.Terrell@flhealth.gov>
Subject: 64B15ER23-4 Sex-reassignment Prescriptions

Good afternoon Ms. Terrell,

Is there another hearing coming up soon on the informed consent form element of SB 254?

I'd like to make a comment under Chapter 120 regardless:

The form should be one page, very cursory, and should leave it to the physician to write what s/he discussed about the specific treatment. This would appear to comply with the plain language of the law.

The form should not contain specifics on the risks, hazards, and alternatives to any specific sex reassignment treatment(s) or procedure(s) but just blank lines for the date of consent, proposed treatment, date and location of proposed treatment, signatures, and blank lines for the doctor to fill in describing what s/he provided to the patient in terms of informed consent information.

Or if you wanted just a bit more detail, you could break it down to the following sections with blank lines for the doctor to complete:

1. Nature of treatment or procedure
2. Risks/hazards of the treatment of procedure
3. Alternatives

Otherwise the Boards would be in the position of having to constantly update the form to include new research or findings, and it could even create liability on the state if specific elements of informed consent are determined to be absent or insufficient.

Thanks,

Kendra Parris

From: WILLIAMS Madison
To: zzzz Feedback, MQA_Medicine
Subject: Regarding june 30th meeting
Date: Tuesday, June 27, 2023 10:15:40 AM

Dear Board of Medicine:

I am writing to inquire about the new business scheduled on this coming Friday's agenda: Rule for informed consent for treatment of gender dysphoria in adults (64B8-9, 64B15-14). I am requesting a copy of the full draft guidelines and proposed informed consent form which are to be raised for vote at the upcoming meeting. Would you be able to provide a copy of these materials, including any supplemental guidance around comorbid conditions and well-managed psychiatric conditions, including how that impacts adult transgender patients' access to informed consent hormone replacement therapy? Specifically, I would like to understand what type of documentation from a board-certified therapist is required to indicate that any other condition is well-managed and thus would not prevent a patient from accessing informed-consent care.

Respectfully yours,

Madison WILLIAMS
Technical Operations Manager
Tel.: : +1 (321) 361.8720

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

Aloft Jacksonville Tapestry Park
4812 Deer Lake Drive West
Jacksonville, FL 32246
904-998-4448

MEETING MINUTES

The meeting was called to order at 1:01 p.m. on June 23, 2023, by Mr. Nicholas Romanello. Roll call was conducted by Cherise Strickland, Program Operations Administrator.

Members Present:
Nicholas Romanello, Esq., Consumer Member, Acting Chair
Scot Ackerman, M.D.
Matthew Benson, M.D.
Amy Derick, M.D.
Tiffany Sizemore DiPietro, D.O.
William Kirsh, D.O.
Monica Mortensen, D.O.

Members Absent:
David Diamond, M.D.
Maria Garcia, Esq., Consumer Member
Patrick Hunter, M.D.
Luz Marina Pages, M.D.
Zachariah Zachariah, M.D.

Staff Present:
Paul Vazquez, J.D., Executive Director BOM
Danielle Terrell, Executive Director BOOM
Christopher Dierlam, Board Counsel
Cassandra Fullove, Certified Paralegal
Cherise Strickland, Program Operations Administrator
Cyra Williams, Regulatory Specialist III
Michelle DeVeas, Administrative Assistant II
Brad Dalton, Public Information Officer

Court Reporter:
Cynthia Green
Magnolia Court Reporting
407-896-1813

Mr. Vazquez provided opening remarks and instructions on the conduct of the meeting. Mr. Vazquez reminded everyone that this is a publicly noticed meeting, the proceedings are being recorded, and an audio file of the meeting will be posted to both Boards' websites.

Mr. Vazquez summarized SB 254, which was signed into law and became effective upon Governor DeSantis' signing on May 17, 2023. The law enacted requires the Board of Medicine and the Board of Osteopathic Medicine to adopt rules within 60 days establishing practice standards for the continuing treatment of minors already receiving treatment prior to the signing of the law, including the development of any necessary informed consent forms. The law also requires the Boards to adopt emergency rules establishing informed consent forms for adults; however, the 60-day time frame is not a requirement for the adult informed consent forms.

Mr. Vazquez advised today we will work on finalizing the practice standards for the treatment of gender dysphoria in minors, and on finalizing draft versions of the informed consent forms for the treatment of gender dysphoria in both minors and adults. Mr. Vazquez advised there will be a subsequent joint full board meeting on June 30, 2023, at 1:00 p.m.

Ms. Terrell did not provide any comments.

Old Business

There was no old business to discuss.

Action taken:

No action taken.

New Business

Mr. Romanello provided an overview of the related meetings already held on prior dates, noting the impressive number of public comments received to date. The next meeting being held will be a virtual joint board meeting on June 30, 2023. Mr. Romanello advised today, the committee has six different draft informed consent forms and two emergency rule drafts to review, the committee will take up discussion of the consent forms first and then discuss the two draft emergency rules. Mr. Romanello advised public comments will be taken until 4:30 p.m. and we will close the meeting at 5:00 p.m.

Dr. Ackerman provided welcoming remarks to the public in attendance, thanking them for being present today. Dr. Ackerman asked the public for constructive feedback and comments.

Mr. Romanello advised at the June 23, 2023, Joint Rules/Legislative Committee Meeting, the committee approved and delegated Drs. Benson and Mortensen to help develop informed consent drafts and present to the committee.

Discussion began on Bates page 264 reviewing draft consent form, Puberty Suppression Treatment for Patients with Gender Dysphoria in Minors. Dr. Derick asked will these forms be the mandatory minimum forms? Ms. McNulty answered, yes, a physician may have additional forms, if desired, but a physician must have our forms, as a minimum. Mr. Romanello, Drs. Benson, Derick, and DiPietro suggested amendments to the form, discussion continued. Motion was made, seconded, and approved unanimously to amend the form with changes as discussed on record.

Discussion began on Bates page 272 reviewing draft consent form, Feminizing Medications for Patients with Gender Dysphoria in Minors. Drs. DiPietro, Benson, and Mr. Romanello suggested amendments to the form, discussion continued. A motion was made, seconded, and approved unanimously to amend the form with all changes as discussed on record.

Discussion began on Bates page 284 reviewing draft consent form, Masculinizing Medications for Patients with Gender Dysphoria in Minors. Dr. Benson made comments and suggested amendments to the form, discussion continued. Ms. Terrell suggested a change to remove, requirement #2, from Bates page 285, it is a duplicate of requirement #1. A motion was made, seconded, and approved unanimously to amend the form with changes as discussed on record.

Discussion began on Bates page 298 reviewing draft consent form, Feminizing Medications for Patients with Gender Dysphoria in Adults. Dr. Derick made comments and suggested amendments

to the form. Discussion on this draft form will continue after public comments.

Discussion began on Bates page 308 reviewing draft consent form, Testosterone Treatment for Patients with Gender Dysphoria in Adults. Drs. DiPietro and Benson made comments and suggested amendments to the form, discussion continued. Mr. Vazquez suggested a change in the name of the form to mirror the other forms. The current name of the form reads Testosterone Treatment for Patients with Gender Dysphoria. The suggested amended name of the form would read Masculine Medications for Patients with Gender Dysphoria. A motion was made, seconded, and approved unanimously to amend the form with all changes as discussed on record.

Discussion began on Bates page 317 reviewing draft consent form, Surgical Treatment for Adults with Gender Dysphoria. Dr. Benson made comments and suggested amendments to the form, discussion continued. A motion was made, seconded, and approved unanimously to amend the form with all changes as discussed on record.

Mr. Romanello called a short break at 3:00 p.m. After the break, the draft emergency rules will be addressed, and we will take public comments until 4:30 p.m. Mr. Romanello reconvened and called the meeting back to order at 3:11p.m.

Mr. Romanello began discussion of the draft emergency rule for minors on Bates page 295, titled Sex-reassignment Standards in Minors. Ms. McNulty suggested a modification on Bates page 295 under subsection (4) Standards of Practice, to strike “Clinical determinations” from subsection (4) entirely, it is redundant. A motion to strike was made, seconded, and approved unanimously to amend as discussed on record.

Ms. McNulty suggested a modification on Bates page 296, subsection (4)(b) item #4, strike “adequate” from the sentence. A motion to strike was made, seconded, and approved unanimously to amend as discussed on record.

Ms. McNulty suggested a modification on Bates page 296 subsection (4)(g) currently reads “Bone (DEXA) Scan”, strike and replace with “Bone Density Scan (DEXA)”.

Dr. Derick suggested a modification of subsection (4)(c) Patient Visit. on Bates page 296 regarding the “physician or covering physician” verbiage addition. A motion to carry over the approved language from the informed consent forms was made, seconded, and approved unanimously to amend as discussed on record.

Dr. Benson asked questions regarding Bates 295 subsection (3)(a-d). What does assent to the informed consent form mean? Dr. Benson asked if this assent is the minor child signing to give permission? Ms. McNulty answered, yes that is correct.

Dr. Benson asked if it is standard to have a witness on the consent forms? Ms. McNulty answered, it is consistent with other types of consent forms. Dr. DiPietro indicated every consent form she has seen in the hospital has a witness signature.

Mr. Romanello began discussion of the draft emergency rule for adults on Bates page 323, titled Mandatory Standardized Informed Consent for Sex-reassignment Procedures in Adults. Mr. Dierlam indicated board counsel does not have any technical change amendments to request.

Mr. Romanello began the public comment portion of the meeting by inviting any public attendee to form a line who has any comments to provide on relevant scope issues related to the informed consent forms or the rules. Each speaker was given three minutes to speak. Mr. Romanello asked Dr. Ackerman to assist with the pronunciation of the drug names and four questions the public is being asked to comment on. Dr. Ackerman stated the four questions the committee would like addressed are:

1. Is there widespread use or any use of testosterone in any form?
2. Is there use of Bicalutamide (brand name Casodex) in the pediatric population?
3. Is there use of Finasteride (also more commonly known as Proscar) for hair loss for male pattern baldness in the pediatric population?
4. Is Cyproterone acetate available in the United States? Is it being prescribed by physicians? Is it being recommended by physicians?

Mr. Romanello recognized the first public speaker; a line was formed, and the public continued to make comments in that format. A total of twenty-three individuals spoke and provided public comment. Public comments continued until 4:30 p.m.

Mr. Romanello advised we will move towards consideration and vote on informed consent forms and the emergency rules.

Mr. Romanello asked the committee if they had any changes or responses to the public comments we have heard this afternoon. No comments were provided, or amendments requested by the committee.

A motion was made, seconded, and approved unanimously to adopt the informed consent forms for minors and emergency rule language as amended on record.

SERC

Will the proposed rule amendments have an adverse impact on small business? Is the proposed rule amendment likely to directly or indirectly increase regulatory costs to any entity, including government, in excess of $200,000 in the aggregate in Florida within one year after implementation?

A motion was made in the negative, seconded, and carried unanimously.

Will this rule amendment create an offense that would constitute a minor violation under the rule?

A motion was made in the negative, seconded, and carried unanimously.

Does the Board/Committee want to impose a sunset provision for this rule or rule amendment?

A motion was made in the negative, seconded, and carried unanimously not to impose a sunset provision.

Action taken:

Approved the informed consent forms for minors and the emergency rule language as amended on record.

Mr. Romanello asked the committee for any changes or responses to the public comments we have heard this afternoon.

Dr. Derick spoke on the informed consent forms for adults, she believes the audience had a lot of compelling comments. Beginning on Bates page 309 there are some items to address on both the Masculinizing Medication for Patients with Gender Dysphoria in Adults form and the Feminizing Medications for Patients with Gender Dysphoria in Adults form regarding HRT, #1 - #14. Dr. Derick indicates she thinks we should consider removing some of the requirements on the consent forms for adults. Discussion continued among the committee.

Dr. DiPietro provided a suggestion to add a recommendation statement for #9 - #14. Dr. Derick agreed this is a great compromise to separate the items and add a recommendation statement for

items #9 - #14. Dr. Derick stated it is important for us to not lose our transgender patients for lack of follow-up.

Mr. Romanello asked the committee to consider a new section that reads, “the following may also be recommended by the prescribing physician for an individual to receive or continue to receive HRT treatment”. This will apply to #9 - #14 and would be placed in its own subsection. This will apply to both the masculinizing and feminizing adult informed consent forms.

A motion was made, seconded, and approved unanimously to add an additional section after #8, the following may also be recommended by the prescribing physician for an individual to receive or continue to receive HRT treatment.

A motion was made, seconded, and approved unanimously to adopt the informed consent forms as amended and the emergency rule as amended.

Action taken:

Approved the informed consent forms for adults and the emergency rule language as amended on record.

SERC

Will the proposed rule amendments have an adverse impact on small business? Is the proposed rule amendment likely to directly or indirectly increase regulatory costs to any entity, including government, in excess of $200,000 in the aggregate in Florida within one year after implementation?

A motion was made in the negative, seconded, and carried unanimously.

Will this rule amendment create an offense that would constitute a minor violation under the rule?

A motion was made in the negative, seconded, and carried unanimously.

Does the Board/Committee want to impose a sunset provision for this rule or rule amendment?

A motion was made in the negative, seconded, and carried unanimously not to impose a sunset provision.

The meeting adjourned at 4:54 p.m.

64B8-9.019 Standards of Practice for the Treatment of Gender Dysphoria in Minors.

(1) The following therapies and procedures performed for the treatment of gender dysphoria in minors are prohibited.

(a) Sex reassignment surgeries, or any other surgical procedures, that alter primary or secondary sexual characteristics.

(b) Puberty blocking, hormone, and hormone antagonist therapies.

(2) Minors being treated with puberty blocking, hormone, or hormone antagonist therapies prior to the effective date of this rule may continue with such therapies.

Rulemaking Authority 458.331(1)(v) FS. Law Implemented 458.331(1)(v) FS. History–New 3-16-23.

64B15-14.014 Standards of Practice for the Treatment of Gender Dysphoria in Minors.

(1) The following therapies and procedures performed for the treatment of gender dysphoria in minors are prohibited.

(a) Sex reassignment surgeries, or any other surgical procedures, that alter primary or secondary sexual characteristics.

(b) Puberty blocking, hormone, and hormone antagonist therapies.

(2) Minors being treated with puberty blocking, hormone, or hormone antagonist therapies prior to the effective date of this rule may continue with such therapies.

Rulemaking Authority 459.015(1)(z) FS. Law Implemented 459.015(1)(z) FS. History–New 3-28-23.

CHAPTER 2023-90

Committee Substitute for Senate Bill No. 254

An act relating to treatments for sex reassignment; amending s. 61.517, F.S.; granting courts of this state temporary emergency jurisdiction over a child present in this state if the child has been subjected to or is threatened with being subjected to sex-reassignment prescriptions or procedures; amending s. 61.534, F.S.; providing that, for purposes of warrants to take physical custody of a child in certain child custody enforcement proceedings, serious physical harm to the child includes, but is not limited to, being subjected to sex-reassignment prescriptions or procedures; creating s. 286.31, F.S.; defining the term "governmental entity"; prohibiting certain public entities from expending state funds for the provision of sex-reassignment prescriptions or procedures; amending s. 456.001, F.S.; defining the terms "sex" and "sex-reassignment prescriptions or procedures"; creating s. 456.52, F.S.; prohibiting sex-reassignment prescriptions and procedures for patients younger than 18 years of age; providing an exception; requiring the Board of Medicine and the Board of Osteopathic Medicine to adopt certain emergency rules within a specified timeframe; requiring the boards to consider specified factors in developing such rules; requiring that such prescriptions and procedures for patients older than 18 years of age be prescribed, administered, or performed only with the voluntary and informed consent of the patient; providing criteria for what constitutes voluntary and informed consent; providing that only a physician may prescribe, administer, or perform such prescriptions and procedures; defining the term "physician"; providing applicability; providing for disciplinary action; providing criminal penalties; requiring the Board of Medicine and the Board of Osteopathic Medicine to adopt certain emergency rules; providing that such emergency rules remain in effect until they are replaced by nonemergency rules; amending s. 456.074, F.S.; requiring the department to immediately suspend the license of a health care practitioner who is arrested for committing or attempting, soliciting, or conspiring to commit specified violations related to sex-reassignment prescriptions or procedures for a patient younger than 18 years of age; creating s. 766.318, F.S.; creating a cause of action to recover damages for personal injury or death resulting from the provision of sex-reassignment prescriptions or procedures to a minor; providing that certain limitations on punitive damages do not apply to such actions; specifying the timeframe within which such actions may be commenced; providing construction and applicability; providing severability; providing a directive to the Division of Law Revision; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (1) of section 61.517, Florida Statutes, is amended to read:

61.517 Temporary emergency jurisdiction.—

(1) A court of this state has temporary emergency jurisdiction if the child is present in this state and:

(a) The child has been abandoned; ~~or~~

(b) It is necessary in an emergency to protect the child because the child, or a sibling or parent of the child, is subjected to or threatened with mistreatment or abuse; or

(c) It is necessary in an emergency to protect the child because the child has been subjected to or is threatened with being subjected to sex-reassignment prescriptions or procedures, as defined in s. 456.001.

Section 2. Subsection (1) of section 61.534, Florida Statutes, is amended to read:

61.534 Warrant to take physical custody of child.—

(1) Upon the filing of a petition seeking enforcement of a child custody determination, the petitioner may file a verified application for the issuance of a warrant to take physical custody of the child if the child is likely to imminently suffer serious physical harm or removal from this state. Serious physical harm includes, but is not limited to, being subjected to sex-reassignment prescriptions or procedures as defined in s. 456.001.

Section 3. Section 286.31, Florida Statutes, is created to read:

286.31 Prohibited use of state funds.—

(1) As used in this section, the term "governmental entity" means the state or any political subdivision thereof, including the executive, legislative, and judicial branches of government; the independent establishments of the state, counties, municipalities, districts, authorities, boards, or commissions; and any agencies that are subject to chapter 286.

(2) A governmental entity, a public postsecondary educational institution as described in s. 1000.04, the state group health insurance program, a managing entity as defined in s. 394.9082, or a managed care plan providing services under part IV of chapter 409 may not expend state funds as described in s. 215.31 for sex-reassignment prescriptions or procedures as defined in s. 456.001.

Section 4. Subsections (8) and (9) are added to section 456.001, Florida Statutes, to read:

456.001 Definitions.—As used in this chapter, the term:

(8) "Sex" means the classification of a person as either male or female based on the organization of the human body of such person for a specific reproductive role, as indicated by the person's sex chromosomes, naturally

occurring sex hormones, and internal and external genitalia present at birth.

(9)(a) "Sex-reassignment prescriptions or procedures" means:

1. The prescription or administration of puberty blockers for the purpose of attempting to stop or delay normal puberty in order to affirm a person's perception of his or her sex if that perception is inconsistent with the person's sex as defined in subsection (8).

2. The prescription or administration of hormones or hormone antagonists to affirm a person's perception of his or her sex if that perception is inconsistent with the person's sex as defined in subsection (8).

3. Any medical procedure, including a surgical procedure, to affirm a person's perception of his or her sex if that perception is inconsistent with the person's sex as defined in subsection (8).

(b) The term does not include:

1. Treatment provided by a physician who, in his or her good faith clinical judgment, performs procedures upon or provides therapies to a minor born with a medically verifiable genetic disorder of sexual development, including any of the following:

a. External biological sex characteristics that are unresolvably ambiguous.

b. A disorder of sexual development in which the physician has determined through genetic or biochemical testing that the patient does not have a normal sex chromosome structure, sex steroid hormone production, or sex steroid hormone action for a male or female, as applicable.

2. Prescriptions or procedures to treat an infection, an injury, a disease, or a disorder that has been caused or exacerbated by the performance of any sex-reassignment prescription or procedure, regardless of whether such prescription or procedure was performed in accordance with state or federal law.

3. Prescriptions or procedures provided to a patient for the treatment of a physical disorder, physical injury, or physical illness that would, as certified by a physician licensed under chapter 458 or chapter 459, place the individual in imminent danger of death or impairment of a major bodily function without the prescription or procedure.

Section 5. Section 456.52, Florida Statutes, is created to read:

456.52 Sex-reassignment prescriptions and procedures; prohibitions; informed consent.—

(1) Sex-reassignment prescriptions and procedures are prohibited for patients younger than 18 years of age, except that:

(a) The Board of Medicine and the Board of Osteopathic Medicine shall, within 60 days after the effective date of this act, adopt emergency rules pertaining to standards of practice under which a patient younger than 18 years of age may continue to be treated with a prescription consistent with those referenced under s. 456.001(9)(a)1. or 2. if such treatment for sex reassignment was commenced before, and is still active on, the effective date of this act. In developing rules under this paragraph, the boards shall consider requirements for physicians to obtain informed consent from such patient's parent or legal guardian, consistent with the parameters of informed consent under subsections (2) and (4), for such prescription treatment, and shall consider the provision of professional counseling services for such patient by a board-certified psychiatrist licensed under chapter 458 or chapter 459 or a psychologist licensed under chapter 490 in conjunction with such prescription treatment.

(b) A patient meeting the criteria of paragraph (a) may continue to be treated by a physician with such prescriptions according to rules adopted under paragraph (a) or nonemergency rules adopted under paragraph (6)(b).

(2) If sex-reassignment prescriptions or procedures are prescribed for or administered or performed on patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine. Consent to sex-reassignment prescriptions or procedures is voluntary and informed only if the physician who is to prescribe or administer the pharmaceutical product or perform the procedure has, at a minimum, while physically present in the same room:

(a) Informed the patient of the nature and risks of the prescription or procedure in order for the patient to make a prudent decision;

(b) Provided the informed consent form, as adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine, to the patient; and

(c) Received the patient's written acknowledgment, before the prescription or procedure is prescribed, administered, or performed, that the information required to be provided under this subsection has been provided.

(3) Sex-reassignment prescriptions or procedures may not be prescribed, administered, or performed except by a physician. For the purposes of this section, the term "physician" is defined as a physician licensed under chapter 458 or chapter 459 or a physician practicing medicine or osteopathic medicine in the employment of the Federal Government.

(4) Consent required under subsection (2) does not apply to renewals of prescriptions consistent with those referenced under s. 456.001(9)(a)1. and

2. if a physician and his or her patient have met the requirements for consent for the initial prescription or renewal. However, separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(5)(a) Violation of this section constitutes grounds for disciplinary action under this chapter and chapter 458 or chapter 459, as applicable.

(b) Any health care practitioner who willfully or actively participates in a violation of subsection (1) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c) Any health care practitioner who violates subsection (2), subsection (3), or subsection (4) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(6)(a) The Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section.

(b) Any emergency rules adopted under this section are exempt from s. 120.54(4)(c) and shall remain in effect until replaced by rules adopted under the nonemergency rulemaking procedures of the Administrative Procedure Act.

Section 6. Present paragraphs (c) through (gg) of subsection (5) of section 456.074, Florida Statutes, are redesignated as paragraphs (d) through (hh), respectively, and a new paragraph (c) is added to that subsection, to read:

456.074 Certain health care practitioners; immediate suspension of license.—

(5) The department shall issue an emergency order suspending the license of any health care practitioner who is arrested for committing or attempting, soliciting, or conspiring to commit any act that would constitute a violation of any of the following criminal offenses in this state or similar offenses in another jurisdiction:

(c) Section 456.52(5)(b), relating to prescribing, administering, or performing sex-reassignment prescriptions or procedures for a patient younger than 18 years of age.

Section 7. Section 766.318, Florida Statutes, is created to read:

766.318 Civil liability for provision of sex-reassignment prescriptions or procedures to minors.—

(1) A cause of action exists to recover damages for personal injury or death resulting from the provision of sex-reassignment prescriptions or procedures, as defined in s. 456.001, to a person younger than 18 years of age which are prohibited by s. 456.52(1).

(2) The limitations on punitive damages in s. 768.73(1) do not apply to actions brought under this section.

(3) An action brought under this section:

(a) May be commenced within 20 years after the cessation or completion of the sex-reassignment prescription or procedure.

(b) Is in addition to any other remedy authorized by law.

(4) The cause of action created by this section does not apply to:

(a) Treatment with sex-reassignment prescriptions if such treatment is consistent with s. 456.001(9)(a)1. or 2. and was commenced on or before, and is still active on, the effective date of this act.

(b) Sex-reassignment prescriptions or procedures that were ceased or completed on or before the effective date of this act.

Section 8. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

Section 9. The Division of Law Revision is directed to replace the phrase "the effective date of this act" wherever it occurs in this act with the date this act becomes a law.

Section 10. This act shall take effect upon becoming a law.

Approved by the Governor May 17, 2023.

Filed in Office Secretary of State May 17, 2023.

CHAPTER 2023-90

Committee Substitute for Senate Bill No. 254

An act relating to treatments for sex reassignment; amending s. 61.517, F.S.; granting courts of this state temporary emergency jurisdiction over a child present in this state if the child has been subjected to or is threatened with being subjected to sex-reassignment prescriptions or procedures; amending s. 61.534, F.S.; providing that, for purposes of warrants to take physical custody of a child in certain child custody enforcement proceedings, serious physical harm to the child includes, but is not limited to, being subjected to sex-reassignment prescriptions or procedures; creating s. 286.31, F.S.; defining the term "governmental entity"; prohibiting certain public entities from expending state funds for the provision of sex-reassignment prescriptions or procedures; amending s. 456.001, F.S.; defining the terms "sex" and "sex-reassignment prescriptions or procedures"; creating s. 456.52, F.S.; prohibiting sex-reassignment prescriptions and procedures for patients younger than 18 years of age; providing an exception; requiring the Board of Medicine and the Board of Osteopathic Medicine to adopt certain emergency rules within a specified timeframe; requiring the boards to consider specified factors in developing such rules; requiring that such prescriptions and procedures for patients older than 18 years of age be prescribed, administered, or performed only with the voluntary and informed consent of the patient; providing criteria for what constitutes voluntary and informed consent; providing that only a physician may prescribe, administer, or perform such prescriptions and procedures; defining the term "physician"; providing applicability; providing for disciplinary action; providing criminal penalties; requiring the Board of Medicine and the Board of Osteopathic Medicine to adopt certain emergency rules; providing that such emergency rules remain in effect until they are replaced by nonemergency rules; amending s. 456.074, F.S.; requiring the department to immediately suspend the license of a health care practitioner who is arrested for committing or attempting, soliciting, or conspiring to commit specified violations related to sex-reassignment prescriptions or procedures for a patient younger than 18 years of age; creating s. 766.318, F.S.; creating a cause of action to recover damages for personal injury or death resulting from the provision of sex-reassignment prescriptions or procedures to a minor; providing that certain limitations on punitive damages do not apply to such actions; specifying the timeframe within which such actions may be commenced; providing construction and applicability; providing severability; providing a directive to the Division of Law Revision; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (1) of section 61.517, Florida Statutes, is amended to read:

61.517 Temporary emergency jurisdiction.—

(1) A court of this state has temporary emergency jurisdiction if the child is present in this state and:

(a) The child has been abandoned; ~~or~~

(b) It is necessary in an emergency to protect the child because the child, or a sibling or parent of the child, is subjected to or threatened with mistreatment or abuse; or

(c) It is necessary in an emergency to protect the child because the child has been subjected to or is threatened with being subjected to sex-reassignment prescriptions or procedures, as defined in s. 456.001.

Section 2. Subsection (1) of section 61.534, Florida Statutes, is amended to read:

61.534 Warrant to take physical custody of child.—

(1) Upon the filing of a petition seeking enforcement of a child custody determination, the petitioner may file a verified application for the issuance of a warrant to take physical custody of the child if the child is likely to imminently suffer serious physical harm or removal from this state. Serious physical harm includes, but is not limited to, being subjected to sex-reassignment prescriptions or procedures as defined in s. 456.001.

Section 3. Section 286.31, Florida Statutes, is created to read:

286.31 Prohibited use of state funds.—

(1) As used in this section, the term "governmental entity" means the state or any political subdivision thereof, including the executive, legislative, and judicial branches of government; the independent establishments of the state, counties, municipalities, districts, authorities, boards, or commissions; and any agencies that are subject to chapter 286.

(2) A governmental entity, a public postsecondary educational institution as described in s. 1000.04, the state group health insurance program, a managing entity as defined in s. 394.9082, or a managed care plan providing services under part IV of chapter 409 may not expend state funds as described in s. 215.31 for sex-reassignment prescriptions or procedures as defined in s. 456.001.

Section 4. Subsections (8) and (9) are added to section 456.001, Florida Statutes, to read:

456.001 Definitions.—As used in this chapter, the term:

(8) "Sex" means the classification of a person as either male or female based on the organization of the human body of such person for a specific reproductive role, as indicated by the person's sex chromosomes, naturally

occurring sex hormones, and internal and external genitalia present at birth.

(9)(a) "Sex-reassignment prescriptions or procedures" means:

1. The prescription or administration of puberty blockers for the purpose of attempting to stop or delay normal puberty in order to affirm a person's perception of his or her sex if that perception is inconsistent with the person's sex as defined in subsection (8).

2. The prescription or administration of hormones or hormone antagonists to affirm a person's perception of his or her sex if that perception is inconsistent with the person's sex as defined in subsection (8).

3. Any medical procedure, including a surgical procedure, to affirm a person's perception of his or her sex if that perception is inconsistent with the person's sex as defined in subsection (8).

(b) The term does not include:

1. Treatment provided by a physician who, in his or her good faith clinical judgment, performs procedures upon or provides therapies to a minor born with a medically verifiable genetic disorder of sexual development, including any of the following:

a. External biological sex characteristics that are unresolvably ambiguous.

b. A disorder of sexual development in which the physician has determined through genetic or biochemical testing that the patient does not have a normal sex chromosome structure, sex steroid hormone production, or sex steroid hormone action for a male or female, as applicable.

2. Prescriptions or procedures to treat an infection, an injury, a disease, or a disorder that has been caused or exacerbated by the performance of any sex-reassignment prescription or procedure, regardless of whether such prescription or procedure was performed in accordance with state or federal law.

3. Prescriptions or procedures provided to a patient for the treatment of a physical disorder, physical injury, or physical illness that would, as certified by a physician licensed under chapter 458 or chapter 459, place the individual in imminent danger of death or impairment of a major bodily function without the prescription or procedure.

Section 5. Section 456.52, Florida Statutes, is created to read:

456.52 Sex-reassignment prescriptions and procedures; prohibitions; informed consent.—

(1) Sex-reassignment prescriptions and procedures are prohibited for patients younger than 18 years of age, except that:

(a) The Board of Medicine and the Board of Osteopathic Medicine shall, within 60 days after the effective date of this act, adopt emergency rules pertaining to standards of practice under which a patient younger than 18 years of age may continue to be treated with a prescription consistent with those referenced under s. 456.001(9)(a)1. or 2. if such treatment for sex reassignment was commenced before, and is still active on, the effective date of this act. In developing rules under this paragraph, the boards shall consider requirements for physicians to obtain informed consent from such patient's parent or legal guardian, consistent with the parameters of informed consent under subsections (2) and (4), for such prescription treatment, and shall consider the provision of professional counseling services for such patient by a board-certified psychiatrist licensed under chapter 458 or chapter 459 or a psychologist licensed under chapter 490 in conjunction with such prescription treatment.

(b) A patient meeting the criteria of paragraph (a) may continue to be treated by a physician with such prescriptions according to rules adopted under paragraph (a) or nonemergency rules adopted under paragraph (6)(b).

(2) If sex-reassignment prescriptions or procedures are prescribed for or administered or performed on patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine. Consent to sex-reassignment prescriptions or procedures is voluntary and informed only if the physician who is to prescribe or administer the pharmaceutical product or perform the procedure has, at a minimum, while physically present in the same room:

(a) Informed the patient of the nature and risks of the prescription or procedure in order for the patient to make a prudent decision;

(b) Provided the informed consent form, as adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine, to the patient; and

(c) Received the patient's written acknowledgment, before the prescription or procedure is prescribed, administered, or performed, that the information required to be provided under this subsection has been provided.

(3) Sex-reassignment prescriptions or procedures may not be prescribed, administered, or performed except by a physician. For the purposes of this section, the term "physician" is defined as a physician licensed under chapter 458 or chapter 459 or a physician practicing medicine or osteopathic medicine in the employment of the Federal Government.

(4) Consent required under subsection (2) does not apply to renewals of prescriptions consistent with those referenced under s. 456.001(9)(a)1. and

2. if a physician and his or her patient have met the requirements for consent for the initial prescription or renewal. However, separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(5)(a) Violation of this section constitutes grounds for disciplinary action under this chapter and chapter 458 or chapter 459, as applicable.

(b) Any health care practitioner who willfully or actively participates in a violation of subsection (1) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c) Any health care practitioner who violates subsection (2), subsection (3), or subsection (4) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(6)(a) The Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section.

(b) Any emergency rules adopted under this section are exempt from s. 120.54(4)(c) and shall remain in effect until replaced by rules adopted under the nonemergency rulemaking procedures of the Administrative Procedure Act.

Section 6. Present paragraphs (c) through (gg) of subsection (5) of section 456.074, Florida Statutes, are redesignated as paragraphs (d) through (hh), respectively, and a new paragraph (c) is added to that subsection, to read:

456.074 Certain health care practitioners; immediate suspension of license.—

(5) The department shall issue an emergency order suspending the license of any health care practitioner who is arrested for committing or attempting, soliciting, or conspiring to commit any act that would constitute a violation of any of the following criminal offenses in this state or similar offenses in another jurisdiction:

(c) Section 456.52(5)(b), relating to prescribing, administering, or performing sex-reassignment prescriptions or procedures for a patient younger than 18 years of age.

Section 7. Section 766.318, Florida Statutes, is created to read:

766.318 Civil liability for provision of sex-reassignment prescriptions or procedures to minors.—

(1) A cause of action exists to recover damages for personal injury or death resulting from the provision of sex-reassignment prescriptions or procedures, as defined in s. 456.001, to a person younger than 18 years of age which are prohibited by s. 456.52(1).

(2) The limitations on punitive damages in s. 768.73(1) do not apply to actions brought under this section.

(3) An action brought under this section:

(a) May be commenced within 20 years after the cessation or completion of the sex-reassignment prescription or procedure.

(b) Is in addition to any other remedy authorized by law.

(4) The cause of action created by this section does not apply to:

(a) Treatment with sex-reassignment prescriptions if such treatment is consistent with s. 456.001(9)(a)1. or 2. and was commenced on or before, and is still active on, the effective date of this act.

(b) Sex-reassignment prescriptions or procedures that were ceased or completed on or before the effective date of this act.

Section 8. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

Section 9. The Division of Law Revision is directed to replace the phrase "the effective date of this act" wherever it occurs in this act with the date this act becomes a law.

Section 10. This act shall take effect upon becoming a law.

Approved by the Governor May 17, 2023.

Filed in Office Secretary of State May 17, 2023.

Britain Limits Use of Puberty-Blocking Drugs to Research Only

By Azeen Ghorayshi

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The News

Britain's National Health Service announced on Friday that it would limit the use of puberty-suppressing drugs to children enrolled in clinical trials. The change comes as the agency's pediatric gender services have struggled to keep up with soaring demand.

A document explaining the N.H.S.'s reasoning stated that "there is not enough evidence to support their safety or clinical effectiveness as a routinely available treatment."

The N.H.S. had released a draft of this policy change in October, but Friday's announcement formally instituted the new approach after months of public comment. The policy will go into effect later this year.

The N.H.S. announced last year it would shut down the Tavistock Gender Identity Development Service in London after the clinic saw a sharp rise of referrals. Peter Nicholls/Reuters

Why It Matters: Other countries have limited the drugs, too

The change is part of a broader push in several countries to limit gender-related medical treatments for young people.

After conducting evidence reviews, Finland has begun limiting who can access gender-related treatments and Sweden has restricted the use of puberty blockers and hormones to clinical trials. A Norwegian health body and the French National Academy of Medicine have also urged caution.

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In the United States, more than 20 Republican-led states have passed laws banning the use of puberty-blocking drugs and hormones, with some making it a felony for doctors to prescribe them. Hundreds of clinicians across the country — including some who have raised concerns about which adolescents should receive gender-related treatments — have denounced the bans, saying such decisions should be made by patients, their families and their doctors.

Background: Data on the effect of blockers is sparse

Last year, the N.H.S. announced that it would be shutting down the country's only youth gender clinic after an external review showed that the Tavistock Gender Identity Development Service had been unable to provide appropriate care for the rapidly increasing number of adolescents seeking gender treatments. The clinic had seen a sharp rise in referrals, from 250 young people in 2011 to 5,000 in 2021.

Puberty blockers, which work by suppressing estrogen and testosterone, were first tested on children with gender dysphoria in the Netherlands in the 1980s. The Dutch researchers published their first study on 70 children in 2011, finding that the adolescents reported a decrease in depression and anxiety after taking the drugs.

But a British study of Tavistock patients published in 2021 showed that blockers had no effect on children's scores on psychological tests. The study found that 43 out of the 44 participants later chose to start testosterone or estrogen treatments. One interpretation of the data is that all were good candidates for hormone therapy. But the numbers raised concerns at the N.H.S. about whether the drugs served their intended purpose of giving adolescents time to think.

"The most difficult question is whether puberty blockers do indeed provide valuable time for children and young people to consider their options, or whether they effectively 'lock in' children and young people to a treatment pathway," Dr. Hilary Cass, the pediatrician overseeing the independent review of the N.H.S. gender service, wrote last year.

What's Next: Britain will start a trial of children taking blockers

The N.H.S. is organizing a clinical trial for all children receiving puberty blockers from the health service, which it expects will begin enrollment in 2024.

Although the Tavistock clinic has been closed, regional centers are opening across Britain to expand gender-related services for young people. The N.H.S. said that the new system for treating minors with gender-related issues will establish standardized assessments and incorporate much more mental health support.

"The main objective is to alleviate distress associated with gender incongruence and promote the individual's global functioning and well-being," the N.H.S. guidance said.

Azeen Ghorayshi covers the intersection of sex, gender and science for The Times.

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VIEW OFFER

NHS England

Consultation report for the interim service specification for specialist gender incongruence services for children and young people

9 June 2023

Contents

1. Background

In September 2020, NHS England commissioned an independent and wide-ranging expert review of gender identity services for children and young people. The Independent 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 natal males to predominantly natal 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 international evidence to support clinical decision making**
   This has led to a lack of clinical consensus and polarised opinion 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 all contributed to the service provided by the Tavistock and Portman NHS Foundation Trust being unable to meet the scale of rising demand and provide the level of appropriate care.

Next steps

In February 2022, the Independent Review published an interim report in which she set out initial findings and advice from her Review. She emphasised the need to 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 2022, the Independent Review sent further advice on the core components of this model. You can read the advice in full here.

In summary, she 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'.

Establishing Phase 1 service providers

Following the further advice the Independent Review provided in July 2022, NHS England set out plans for how it would start building a more resilient service by expanding provision and enhancing the focus on quality in terms of clinical effectiveness, safety, and patient experience. These plans were welcomed and supported by the Tavistock and Portman NHS Foundation Trust.

The first phase in these plans is to establish two new nationally networked services which, consistent with advice from the Independent Review, will be led by specialist children's hospitals.

These Phase 1 service providers will take over clinical responsibility for seeing children and young people on the national waiting list as well as providing continuity of care for the GIDS open caseload at the point of transfer. The Tavistock GIDS service itself will be decommissioned as part of a managed transition of the service to the new Phase 1 service providers.

One service – The Southern Hub – is being formed through a partnership between Great Ormond Street Hospital, Evelina London Children's Hospital (part of Guy's and St Thomas' NHS Foundation Trust) and South London and Maudsley NHS Foundation Trust.

The other service – The Northern Hub – is being formed through a partnership between Alder Hey Children's NHS Foundation Trust and the Royal Manchester Children's Hospital (part of Manchester University NHS Foundation Trust).

These new services will be commissioned against a new, interim service specification. The draft specification- which is the subject of this consultation- was developed by a clinically led Specification Working Group chaired by the NHS National Medical Director for Specialised Services and comprised of senior clinicians with expertise in gender incongruence, mental health and neurodiversity in children and young people, safeguarding and paediatric medicine.

NHS National Medical Director for Specialised Services
and senior clinicians with expertise in
—gender incongruence
—mental health
—neurodiversity
—safeguarding
—pediatrics

2. How we consulted

The public consultation on this draft interim service specification ran on the NHS England consultation website for 45 days from 20 October to 4 December 2022. It received 5,183 responses in total. NHS England thanks all those individuals and organisations who submitted responses to consultation.

NHS England commissioned TONIC - an independent organisation specialising in public consultation, social research and evaluation - to conduct analysis on all responses and report back on these findings. Their detailed analysis of the responses can be found on the consultation page.

During the consultation period, NHS England actively engaged with individuals, organisations and services who were most likely to be directly affected by the proposed changes, including patient groups, Royal Colleges, professional bodies, as well as some of the current patients and parents of patients within the GIDS. These groups were invited to virtual meetings and discussion groups throughout the course of the consultation period with the aims of:

1. increasing awareness about the constitution,
2. clarifying our proposals,
3. listening to the early thoughts and feedback and
4. encouraging a formal, written response.

3. How has feedback at consultation been considered?

The Specification Working Group considered the report of the independent analysis of consultation responses.

The consultation asked the following questions:

- To what extent do you agree with the four substantive changes to the service specification?
    - Composition of the clinical team
    - Clinical leadership
    - Collaboration with referrers and local services
    - Referral sources
- To what extent do you agree that the interim service specification provides sufficient clarity about approaches towards social transition?
- To what extent do you agree with the approach to the management of patients accessing prescriptions from un-regulated sources?
- 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?
- 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?

The following sections outline how our consideration of consultation feedback has informed the final version of the interim service specification.

Composition of the clinical team

The current service specification for the Gender Identity Development Service (GIDS) at the Tavistock and Portman NHS Foundation Trust describes a service that 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 proposed 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.

Rather than purely focused on gender specialists, it will now include them, but add specialists in pediatrics, autism, neurodiveersity, and mental health