

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF FLORIDA  
TALLAHASSEE DIVISION

JANE DOE, et al.,

Plaintiffs,

v.

Case No. 4:23-cv-00114-RH-MAF

JOSEPH A. LAPADO, et al.,

Defendants.

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**THE STATE'S AMENDED<sup>1</sup> RESPONSE IN OPPOSITION  
TO THE PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION  
AND MEMORADUM OF LAW**

The State Defendants oppose the Plaintiffs' motion for preliminary injunction for the reasons set forth in the accompanying memorandum.

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<sup>1</sup> Amended as to exhibits only.

Dated: August 7, 2023

Respectfully submitted by:

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### **CERTIFICATE OF COMPLIANCE**

As required by Local Rule 7.1(F), I certify that this response in opposition to the Plaintiffs' motion for preliminary injunction contains 35 words.

/s/ Mohammad O. Jazil  
Mohammad O. Jazil

### **CERTIFICATE OF SERVICE**

I certify that, on August 7, 2023, this response in opposition to the Plaintiffs' motion for preliminary injunction was filed through the Court's CM/ECF system, which will send a notice of electronic filing to all counsel of record.

/s/ Mohammad O. Jazil  
Mohammad O. Jazil

## INTRODUCTION

Despite the Plaintiffs’ assertions to the contrary, the informed-consent provisions they challenge do not “deny[] transgender patients medical care.” ECF No. 116, at 21. They do not discriminate by “prevent[ing] transgender adults in Florida from obtaining established medical care because they are transgender.” ECF No. 116, at 21. And they do not, nor were they ever intended to, “scare” patients with gender dysphoria “from getting needed care.” ECF No. 116, at 9.

Instead, each provision challenged by the Plaintiffs exists to ensure that any person seeking sex-modification procedures benefits from “the doctrine of informed consent,” a principle with common-law roots that imposes upon “physician[s] . . . an obligation to advise [their] patient[s] of the material risks of undergoing a medical procedure.” *State v. Presidential Women’s Ctr.*, 937 So. 2d 114, 116 (Fla. 2006). Florida codified the doctrine as a general matter back in the 1970s, *see* Fla. Stat. § 766.103, and—particularly relevant here—has routinely enacted more granular informed-consent provisions when a particular medical procedure has counseled in favor of doing so, *see, e.g., id.* § 458.324, (breast cancer); *id.* § 458.325 (electroconvulsive and psychosurgical procedures); *id.* § 945.48 (inmates receiving psychiatric treatment).

The Constitution, moreover, authorizes Florida, not the World Professional Association for Transgender Health, the Endocrine Society, or any other medical group, to regulate medical care within its borders. *Andino v. Middleton*, 141 S. Ct. 9, 10 (2020) (Kavanaugh, J., concurral); *see also L.W. v. Skermetti*, 73 F. 4th 408, 418 (6th Cir. 2023)

(explaining that the Constitution does not require state legislatures to agree with “the majority” of medical professionals or organizations). States, through their elected representatives accountable to the people—not “experts” or the courts—are the institutions tasked with deciding issues of health and welfare in our republic. *Skermetti*, 73 F. 4th 408 at 420. Florida’s decision to protect its citizens by requiring informed consent and creating additional guidelines for procuring and performing these procedures was well within its constitutional powers.

Even this Court has explicitly acknowledged that the “medications” at issue in this case “have attendant risks.” *See* ECF No. 90, at 11. It has further reiterated (several times) that decisions to begin such treatment should be made “in consultation with properly trained practitioners,” and that patients must be “fully apprised of the current state of medical knowledge and all attendant risks” before beginning sex-modification procedures. *E.g.*, ECF No. 90, at 11. Ensuring that individuals are so apprised is necessary if they are to have the “ability to evaluate the benefits and risks” of undergoing certain treatment. ECF No. 90, at 11. Simply put, the benefits and risks cannot be weighed in any sense of the word if the benefits and risks remain unknown.

That is all these provisions do. They ensure that the benefits and risks of sex-modification treatments are communicated in person by a physician—an individual with the training and credentials necessary to provide fulsome information and answer any questions that arise. In other words, they ensure that individuals seeking sex-modification procedures have the information that they need to make a fully informed

decision about treatment that has not yet been accepted universally and that carries ascertainable risks.

Read as a whole (instead of in the piecemeal fashion offered by the Plaintiffs), the informed-consent forms are neither incorrect nor confusing. If an individual has questions about something in the forms, the in-person-consultation requirement facilitates the give-and-take between doctor and patient that helps ensure a fully informed decision. And if the doctor and patient decide on a course of hormonal or surgical treatment, then the doctor-as-prescriber requirement provides an additional layer of expertise and protection so that, for instance, a schedule-III controlled substance like testosterone is administered responsibly, or the full ramifications of sex-modification procedures are explained by the most knowledgeable medical professional.

All these requirements are reasonable, rational, and responsible. None discriminate based on sex or gender identity. None bar an individual experiencing gender dysphoria from seeking medical intervention. Accordingly, none should be preliminarily enjoined under the Fourteenth Amendment's Equal Protection Clause.

## **STATEMENT OF CASE & FACTS**

### **I. FLORIDA LAW ENSURES THAT INDIVIDUALS EXPERIENCING GENDER DYSPHORIA ARE AS FULLY INFORMED AS THEY CAN BE.**

In earlier filings in both this case and in *Dekker v. Weida*, 4:22-cv-325 (N.D. Fla. 2022) ("*Dekker* Doc."), the State set out its position regarding gender dysphoria and the

lack of medical consensus regarding the appropriate course of treatment for it. *See, e.g.*, ECF No. 55, at 3-9. Given the Court’s familiarity with the issues and the State’s position, the State will limit its discussion here to the regulations giving rise to the Plaintiffs’ current motion for a preliminary injunction. The State does, however, incorporate by reference its previously stated assertions. *See, e.g.*, ECF No. 55, at 3-9.

The provisions of Senate Bill 254 that the Plaintiffs ask the Court to preliminary enjoin are straightforward, uncontroversial, and commonsensically in accord with other informed-consent provisions. Specifically, Florida law provides that “[i]f sex-reassignment prescriptions or procedures are prescribed for or administered or performed,” then “consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine.” Fla. Stat. § 456.52. Informed consent is defined as arising “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.

*Id.* Finally, “[s]ex-reassignment prescriptions or procedures may not be prescribed, administered, or performed except by a physician.” *Id.*

On July 7, 2023, the Florida Board of Medicine complied with Senate Bill 254 by creating three standard informed-consent forms for individuals seeking treatment for gender dysphoria. One form, titled “Surgical Treatment for Adults with Gender Dysphoria,” opens with the following language:

Before having surgery to treat gender dysphoria, you need to be aware of the effects and possible risks of these procedures. Your surgeon will make a medical decision, in consultation with you, about the procedures that are best for you, keeping in mind your overall health.

Your surgeon will discuss with you all the information relating to the surgery. You are asked to read and understand the following information and to discuss any questions you have with your surgeon. After your questions or concerns are addressed and you have decided to have surgery you must initial the statements below and sign this form in person with your surgeon.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient’s psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

Exh. A. The two other forms are titled “Feminizing Medications for Patients with Gender Dysphoria” and “Masculinizing Medications for Patients with Gender Dysphoria,” both of which begin with the following language.

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with the use of these medications.

The prescribing physician will make a medical decision, in consultation with you, about the medications that are best for you, keeping in mind your overall health during your gender transition process. The effects and possible risks associated with the use of these medications will be discussed with you. It is your responsibility to read and understand the following information and raise any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue hormones or hormone antagonists, you will need to initial the statements below and sign this form.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

Exhs. B, C.

None of the foregoing is inaccurate or misleading. Throughout the *Dekker* Trial, the Court heard testimony that the quality of the scientific data underlying the transgender standards of care remain "very low or low," even though the standards nonetheless "recommend," e.g., "hormonal treatment." *Dekker* Trial Tr. at 978 (Testimony of Dr. Stephen B. Levine). The "very low or low" categorization is based on "[t]he GRADE system," which "is a systematic way of rating the quality of evidence that is present within clinical practice guidelines." *Dekker* Trial Tr. at 154 (Testimony of Dr. Paul Hruz). "By definition, studies that are of very low[-]quality mean that it is very likely that the recommendations will change as new information becomes available." *Dekker* Trial Tr. at 154 (Testimony of Dr. Paul Hruz). Indeed, even the Court expressly

acknowledged that “[i]t seems—and that’s true, I think. I think the record shows that it is low-quality evidence.” *Dekker* Trial Tr. at 1035. At no point have either the Plaintiffs here or those in *Dekker* disputed this. Simply put, “the evidence-base is” indeed “low quality, and that is consistent with all of the reviews.” *Dekker* Trial Tr. at 1110 (Testimony of Dr. Kristopher Kaliebe).

## **II. THE PLAINTIFFS’ CHERRY-PICKED, OUT-OF-CONTEXT OBJECTIONS TO THE STATE’S INFORMED CONSENT REQUIREMENTS.**

Despite the self-evident benefit inherent in the very notion of informed consent, the Plaintiffs nonetheless assert that the State’s attempt to fully inform individuals experiencing gender dysphoria is somehow a bad thing. In addition to their objections to the in-person consent requirement, the physician-as-prescriber requirement, and the low-quality research disclaimer, the Plaintiffs pluck out the following concerns:

- “Both cross-sex hormone forms state that the use of hormones to treat gender dysphoria is considered ‘off label’ because they are not being used for their intended purpose.” ECF No. 116, at 11.
- The forms ask the patient to affirm that he or she “know[s] that the medicine and dose that is recommended is based solely on the judgment and experience of my prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT.” ECF No. 116, at 12.
- “Both cross-sex hormone forms state that ‘psychological therapy with a mental health provider’ is an ‘option’ for patients who do not wish to start or continue hormone therapy.” ECF No. 116, at 13.

- “Both cross-sex hormone forms state: ‘Treatment with feminizing [or masculinizing] medications will not prevent serious psychiatric events, including suicide.’” ECF No. 116, at 13.
- “[T]he form for feminizing hormones includes information about cyproterone acetate. . . . Similarly, the form for masculinizing hormones gratuitously mentions testosterone pills, despite noting that testosterone is typically ‘not given in pill form because the body may not absorb it properly which may cause potentially fatal liver problems.’” ECF No. 116, at 14.
- “[T]he form for masculinizing hormones falsely states that finasteride is a treatment for gender dysphoria in transgender men, whereas in fact is a treatment for baldness in both transgender and non-transgender men. In contrast, finasteride may be prescribed to treat gender dysphoria in transgender women.” ECF No. 116, at 14.
- “[T]he form for masculinizing hormones falsely states that ‘treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts,’ and ‘taking testosterone causes or worsens migraines.’ . . . This form also states that taking testosterone may cause certain changes that ‘could be permanent,’ but stating that any of the listed changes could be permanent is incorrect as they are all non-permanent effects of testosterone. . . . The form for feminizing hormones states: ‘My risk of breast cancer may significantly increase.’” ECF No. 116, at 15.
- “Both cross-sex hormone forms state: ‘HRT, the use of androgen blockers and antiandrogens, and the treatment process can affect your mood. Therefore, you must be under the care of a licensed mental health care professional while undergoing treatment.’” ECF No. 116, at 16.
- “[T]he recommendation that patients may be required to undergo annual bone scans has no medical basis whatsoever. . . . [T]here is no medical reason for either transgender men or transgender women to undergo annual bone scans. Doing so is not only

unnecessary but serves no medical purpose whatsoever.” ECF No. 116, at 18.

Based on foregoing (misguided) disagreement with Florida’s informed-consent requirements, the Plaintiffs have asked the Court to conclude that Florida has violated their Fourteenth Amendment Equal Protection rights by discriminating on the basis of sex. ECF Nos. 115, 116.

### **RELEVANT LEGAL STANDARD**

The Court may grant the “extraordinary and drastic remedy” of a preliminary injunction, *McDonald’s Corp. v. Robertson*, 147 F.3d 1301, 1306 (11th Cir. 1998), only if the Plaintiffs demonstrate that: (1) they have “a substantial likelihood for success on the merits”; (2) they will suffer irreparable injury “unless the injunction issues”; (3) “the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party”; and (4) “if issued, the injunction would not be adverse to the public interest.” *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (*en banc*). The non-moving party doesn’t have “the burden of coming forward and presenting its case against a preliminary injunction.” *Ala. v. U.S. Army Corps of Eng’rs*, 424 F.3d 1117, 1136 (11th Cir. 2005) (quoting *Granny Goose Foods, Inc. v. Bhd. of Teamsters & Auto Trust Drivers Local No. 70*, 415 U.S. 423, 442 (1974)). And because courts adjudicate only the case or controversy before them, absent class certification, “injunctive relief should be limited in scope to the extent necessary to protect the interests of the *parties*.” *Ga. Advoc. Off. v. Jackson*, 4 F.4th 1200, 1209 (11th Cir. 2021) (cleaned up) (emphasis added).

## ARGUMENT

Plaintiffs cannot meet any of the four prongs for a preliminary injunction. Their equal-protection challenge has no likelihood of success. None have established that they will experience irreparable harm unless the Court grants their requested injunction now, particularly since none of the informed-consent requirement provisions they challenge prohibit any treatment for gender dysphoria. And both the equities and public interest tilt decidedly in the State’s favor.

### **I. THE PLAINTIFFS’ EQUAL-PROTECTION CHALLENGE CANNOT SUCCEED.**

#### **A. The Plaintiffs are not likely to prevail on their claim that transgender status is a protected class.**

The Plaintiffs assert that they are likely to succeed on their equal protection claim because the challenged regulations “single out transgender patients because of their . . . transgender status.” ECF 116, at 21. “But neither the Supreme Court nor [the Eleventh Circuit] has recognized transgender status as a quasi-suspect class.” *L.W. v. Skarmetti*, 73 F. 4th 408, 419 (6th Cir. 2023). “The bar for recognizing a new quasi-suspect class, moreover, is a high one.” *Id.* Accordingly, the novelty of this claim, alone, precludes the Plaintiffs from establishing that they are likely to succeed on its merits. *Id.*; see also *Adams ex rel. Kasper v. St. Johns Cnty.*, 57 F.4th 801, 805 n.5 (11th Cir. 2022) (“[W]e have grave doubt that transgender persons constitute a quasi-suspect class).

#### **B. The challenged regulations do not discriminate based on sex.**

The Plaintiffs also assert that they are likely to succeed on their equal protection claim because the challenged regulations discriminate against them “because they are transgender and, therefore, because of their sex.” ECF 116, at 21. The regulations, however, apply to both sexes equally—whether an individual is a biological male seeking sex-modification surgery, or a biological female seeking sex-modification surgery, the informed-consent requirements apply equally to all. Accordingly, the challenged regulations do not discriminate based upon sex. *Skermetti*, 73 F. 4th at 419.

Neither *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), nor *Glenn v. Brumby*, 663 F.3d 1312 (11th Cir. 2011), requires this Court to apply heightened scrutiny. Both cases are limited in scope and do not control in a *medical* context where the sexes are *not* similarly situated. See *Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985) (“The Equal Protection Clause” “is essentially a direction that all persons *similarly situated* should be treated alike”) (emphasis added).

*Bostock* construed “discriminate” “because of” “sex” in a workplace discrimination law and not under the Equal Protection Clause. *Bostock*, 140 S. Ct. at 1739 (quoting 42 U.S.C. § 2000e-2.(a)(1)); see also *Students for Fair Admission v. Harvard Coll.*, 141 S. Ct. 2141, 2219-20 (2023) (Gorsuch, J., concurring); *Skermetti*, 73 F. 4th at 420. It read the statute to mean that “[a]n individual’s homosexuality or transgender status is not relevant to employment decisions.” *Id.* at 1741. Its reasoning was that an employer who “penalizes a person identified as female at birth” discriminates based on sex under the statute because those persons are “similarly situated” for employment

purposes. *Id.* at 1740-41. And it expressly reserved answering “[w]hether other policies and practices might or might not qualify as unlawful discrimination.” *Id.* at 1753.

*Glenn* too was a workplace discrimination case. There, the Eleventh Circuit subjected to intermediate scrutiny certain governmental employment decisions made “based upon gender stereotypes,” explaining that “we are beyond the day when an employer could evaluate employees by assuming or insisting that they matched the stereotypes associated with their group.” *Glenn*, 663 F.3d at 1320 (cleaned up).

The reasoning in *Bostock* and *Glenn* does not translate to the informed-consent context because Florida’s informed-consent regulations are entirely gender and sex neutral. Whether a person is a transgender male seeking sex-modification procedures, or a transgender woman seeking the same, he or she must comply with Senate Bill 254’s informed-consent requirements and the regulations implementing them. In other words, one *need not* “know the sex of a person to know whether or how [these] provision[s] appl[y] to the person.” *Dekker* Final Order 30. So long as a person is seeking certain treatments for gender dysphoria, it matters not the sex of that individual—the informed-consent requirements apply regardless. *See Skermetti*, 73 F. 4th at 419.

**C. The Plaintiffs are not treated dissimilarly from anyone “similarly situated.”**

The Plaintiffs neglect to show how Florida’s informed-consent requirements treat them any differently from individuals who are “similarly situated” to them. For at least three decades, the Eleventh Circuit has ascribed to the rule that “[d]ifferent

treatment of *dissimilarly situated* persons does not violate the equal protection clause.” *Griffin Indus. v. Irvin*, 496 F.3d 1189, 1207 (11th Cir. 2007) (citing *E & T Realty v. Strickland*, 830 F.2d 1107, 1109 (11th Cir. 1987)). “The reason that there is a ‘similarly situated’ requirement in the first place is that at their heart, equal protection claims . . . are basically claims of discrimination.” *Id.* (quoting *McDonald v. Vill. of Winnetka*, 371 F.3d 992, 1009 (7th Cir. 2004)). Indeed, “[t]o maintain this focus on discrimination, and to avoid constitutionalizing every state regulatory dispute,” courts of this Circuit “are obliged to apply the ‘similarly situated’ requirement with rigor.” *Id.*

The Plaintiffs make virtually no attempt to demonstrate how Senate Bill 254’s informed-consent provisions treat them any differently than a *similarly situated* individual. And the reason is obvious: a person experiencing gender dysphoria is self-evidently *not* similarly situated to any other patient. The reasons why an individual suffering from hypogonadism would opt for hormonal therapy are not the same as a person seeking to transition from one gender to another. The risks associated with hormonal therapy between the two are quite distinct as well; with the former, the treatment seeks to bring hormone levels in line with those that are naturally occurring, while the latter far exceeds what his or her body would otherwise naturally produce. The Plaintiffs make no real attempt to reconcile this apples-to-oranges comparison, and their failure to do so dooms their Equal Protection Claim.

**D. Even assuming that the Plaintiffs have shown that Florida’s informed-consent requirement treats them differently than similarly situated individuals, rational-basis review applies.**

The Supreme Court has recently clarified that the “regulation of a medical procedure . . . does not trigger heightened constitutional scrutiny unless the regulation is mere pretext designed to effect an invidious discrimination against members of one sex or the other.” *Dobbs*, 142 S. Ct. 2245-46 (cleaned up). The reason is clear—regulation of medical care (particularly informing patients of the risks and benefits of one procedure versus another) involves a number of considerations that States, and not courts, are best positioned to decide. *Skermetti*, 73 F. 4th at 417 (noting the important role states play in regulating health and cautioning federal courts to “be vigilant not to substitute their views for those of legislatures”). And because the Plaintiffs have offered nothing other than rank conjecture to suggest that Florida’s informed-consent requirements are a mere pretext to hide animus against the transgender community, *Dobbs* commands that rational-basis review applies.

**E. Florida’s informed-consent requirements satisfy both heightened scrutiny and rational-basis review.**

Even if the Court disagrees and applies heightened scrutiny, Florida’s informed-consent regulations are still plainly constitutional. This level of scrutiny requires the State to note (1) “important governmental objectives,” and to show that its chosen regulation is (2) “substantially related to the achievement of those objectives.” *Nguyen*, 533 U.S. at 61 (cleaned up). And “like other health and welfare laws,” Florida’s regulation “is entitled to a ‘strong presumption of validity.’” *Dobbs*, 142 S. Ct. at 2284 (citations omitted).

At the outset, the Plaintiffs’ constant characterizations of the challenged regulations as “deny[ing] essential medical care to transgender patients,” ECF 116, at 21, or “preventing transgender patients from receiving necessary medical care,” ECF 116, at 23, are flatly incorrect. At no point do the informed-consent requirements that the Plaintiffs challenge here prohibit them (or anyone else) from obtaining the procedures they desire. The challenged regulations merely provide guidelines for receiving the desired procedures, which are similar to guidelines the State provides in a myriad of other medical contexts. Furthermore, the Plaintiffs’ concerns about their ability to find qualified physicians or psychologists to perform the necessary evaluations for these procedures are undermined by their unwavering insistence that these procedures are widely accepted within the medical community.

Florida, of course, has a *compelling* interest in ensuring that its residents are fully informed and validly consent to any medical procedure. Indeed, the Florida Supreme Court has emphasized that “[u]nless a person knows the risks and dangers of such a procedure, ‘a ‘consent’ does not represent a choice and is ineffectual.” *Presidential Women’s Ctr.*, 937 So. 2d at 116 (quoting *Bowers v. Talmage*, 159 So. 2d 888, 889 (Fla. 3d DCA 1963)). Simply put, “[t]he doctrine of informed consent is well recognized, has a long history, and is grounded in the common law and based in the concepts of bodily integrity and patient autonomy.” *Id.* The State’s interest in protecting it is one of the highest order, let alone “important.” Each provision challenged by the Plaintiffs is also “substantially related to the achievement of [its] objective[],” *Nguyen*, 533 U.S. at 61—

i.e., ensuring that individuals experiencing gender dysphoria are fully apprised of the risks, and that they provide valid consent to such procedures irrespective of those risks.

In the Plaintiffs' telling, some of the information could cause confusion. Setting aside that their objections say *nothing* about the sort of disparate treatment that could support an equal-protection challenge, they're simply wrong that there is anything in Florida's informed-consent rules that are misleading, arbitrary, or gratuitous. Indeed, unrebutted testimony elicited during, and the Court's conclusions after, the *Dekker* Trial establish these points beyond any reasonable dispute.

***The physical presence requirement.*** The first objection that the Plaintiffs lodge is to the requirement that a physician be “physically present in the same room” when a patient provides his or her informed consent to undergo gender-affirming care. Fla. Stat. § 456.52. In their view, “[a] physical presence requirement needlessly prevents the use of telehealth and serves as an insurmountable barrier for patients who do not live in proximity to their provider or who lack access to transportation.” ECF No. 116, at 10. But testimony from the *Dekker* Trial reveals that the physical-presence requirement serves a profoundly important function.

Specifically, a telehealth appointment is not adequate to assess the complexity that goes into determining whether an individual is an appropriate candidate for sex-modification treatment. According to Dr. Aron Janssen, “[t]he primary components of an assessment” include “a full diagnostic evaluation,” since physicians “want to understand . . . that the presence, the diagnosis of gender dysphoria has been persistent,

and that the diagnostic criteria are met.” *Dekker* Trial Tr. at 84 (Testimony of Dr. Aron Janssen). Critically, “[t]his diagnosis is made not just with an interview with the patient themselves but also looking at other criteria, other informants.” *Dekker* Trial Tr. at 84 (Testimony of Dr. Aron Janssen). Providers will also want to assess “any co-occurring mental health and psychiatric disorders, how they may or may not influence the diagnosis of gender dysphoria.” *Dekker* Trial Tr. at 84 (Testimony of Dr. Aron Janssen). Then, the provider is in a better position to “make sure” that everyone has “a very clear understanding . . . of the specific risks, benefits, and alternatives, which include both the known and unknown risks of whatever that intervention is.” *Dekker* Trial Tr. at 84 (Testimony of Dr. Aron Janssen).

This sort of in-depth process cannot occur as productively over a video link. This is particularly true given that “adult individuals living transgender lives suffer much higher rates of suicidal ideation, completed suicide, and negative physical and mental health conditions than does the general population,” which “is true before and after transition, hormones, and surgery.” Expert Report of Dr. Stephen B. Levine, at 11. An in-person informed-consent requirement ensures that a physician can assess non-verbal indications of comorbidities that he or she might miss over a video link. And given the stakes attendant to sex-modification procedures—including possible irreversible loss of bodily organs/functionality, sterility, and hormonal changes—the sort of open, trusting, give-and-take informational exchange that occurs more naturally in person than over a

telehealth session is a critical part of ensuring full understanding and valid consent to these sorts of medical procedures.

The State's decision to require in-person informed consent is both abundantly rational and more than substantially related to the compelling interest it has in assuring that those seeking treatment for gender dysphoria understand the costs and benefits of their course of treatment. It should not be enjoined.

*The information in the informed-consent forms.* Next, the Plaintiffs take issue with several of the disclaimers listed in the informed-consent forms. In their view, the forms are “likely to cause confusion, to overwhelm a patient with irrelevant information, prevent a patient from understanding the individualized risks and benefits of the medication that is being recommended or prescribed, and generally make it more difficult for the patient to focus on the information relevant to their health.” ECF No. 116, at 13. Rather than acquiescing to the Plaintiffs' exaggeration, the State invites the Court to read the three forms (which the State attaches as Exhibits A, B, and C) and to assess for itself whether they are confusing, ambiguous, or likely to cause *less* of an understanding regarding the costs and benefits of sex modification procedures. And the State would be remiss if it didn't note that the in-person informed-consent requirement exists so that a patient can have all of his or her questions answered regarding the forms.

In any event, the information on the informed-consent forms is neither false nor misleading. As noted above, *supra*, the scientific data underlying the standards of care

for gender dysphoria remain “very low or low,” even though the standards nonetheless “recommend,” e.g., “hormonal treatment.” *Dekker* Trial Tr. at 978 (Testimony of Dr. Stephen B. Levine). Indeed, this Court expressly acknowledged that “[i]t seems—and that’s true, I think. I think the record shows that it is low-quality evidence.” *Dekker* Trial Tr. at 1035. This is information that a person seeking gender-affirming treatment is entitled to have if he or she is going to be fully informed and provide valid consent to that treatment.

The Plaintiffs’ other objections fare no better. Prescribing hormones for gender-affirming treatment is indeed an “off-label” use of those pharmaceuticals. This means, quite literally, that the drugs were “originally approved for some other purpose.” *Dekker* Trial Tr. at 1017 (Testimony of Dr. Stephen B. Levine). This is precisely the message that the informed-consent forms provide.

It is similarly true that there are no “*controlled* research studies that support the timing, dosing, and type of administration of HRT,” Exhs. B, C, and that the judgment of the prescribing physician controls. Throughout the *Dekker* Trial, experts testified that there was a lack of *controlled* research studies pinning down the correct ways in which to administer cross-sex hormones for purposes of bringing a person’s gender identity in line with their biological sex. *See generally, e.g., Dekker* Trial Tr. at 228 (Testimony of Dr. Paul Hruz); *Dekker* Trial Tr. at 1069 (Testimony of Dr. Patrick Lappert); Expert Report of Dr. Michael K. Laidlaw ¶ 308; Expert Report of Dr. Kristopher Kaliebe ¶ 162. And “psychological therapy” does indeed remain an option for individuals who

might not want to start hormonal therapy or undergo surgery. Gender dysphoria is a psychological diagnosis that manifests by “marked incongruence between one’s experienced/expressed gender and assigned gender” of at least six months duration. Diagnostic and Statistical Manual of Mental Disorders, Ed. 5. (DSM-V). It follows, then, that psychological therapy remains a potential route. Indeed, even the Plaintiffs note that “psychotherapy can be beneficial for many people, including transgender people.” ECF No. 116, at 12.

Informing a person with gender dysphoria that “[t]reatment with femininizing [or masculinizing] medications will not prevent serious psychiatric events, including suicide,” is entirely true. Exhs. B, C. Contrary to the Plaintiffs’ suggestion, this sentence does not “suggest[] that hormone therapy” has *no* “positive impact on a transgender patient’s mental health.” ECF No. 116, at 13. That said, “adult individuals living transgender lives suffer much higher rates of suicidal ideation, completed suicide, and negative physical and mental health conditions than does the general population. *This is true before and after transition, hormones, and surgery.*” Expert Report of Dr. Stephen B. Levine at 11 (emphasis added). It remains accurate that the suicide rate among those receiving cross-sex hormones to treat gender dysphoria remains frighteningly high, and even the Plaintiffs admit that “no treatment can provide an absolute guarantee against ‘psychiatric events, including suicide.’” ECF No. 116, at 13. This warning, then, is part of the information that someone struggling with gender dysphoria *and* other

comorbidities *should* understand before beginning hormonal treatment that they might expect to improve their well-being in all aspects of their lives.

Relatedly, anyone embarking on hormonal treatment should be made aware of the physical and mental effects such treatment can inflict. “Testosterone is an anabolic steroid,” and one “of high potency.” Expert Report of Dr. Michael K. Laidlaw ¶ 114. It is hazardous enough to be “classified as a Schedule 3 controlled substance by the DEA,” which means abuse of it “may lead to moderate or low physical dependence or *high psychological dependence*.” Expert Report of Dr. Michael K. Laidlaw ¶ 114 (emphasis added). For this reason, “[a] licensed physician with a valid DEA registration is required to prescribe testosterone,” and dose “must be carefully considered and monitored to avoid excess levels in the male as there are a number of serious concerns when prescribing testosterone.” Expert Report of Dr. Michael K. Laidlaw ¶¶ 114, 115. The labeling itself states that:

Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication . . . . Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions . . . . Abuse and misuse of testosterone are seen in female adults and adolescents . . . . There have been reports of misuse by men taking higher doses of legally obtained testosterone than prescribed and continuing testosterone despite adverse events or against medical advice.  
(Actavis Pharma, 2018)

Expert Report of Dr. Michael K. Laidlaw ¶ 116 (underscore in original). “Adverse events with respect to the nervous system include: ‘Increased or decreased libido, headache, anxiety, depression, and generalized paresthesia,’” while “[p]rolonged use of

high doses of androgens . . . has been associated with development of hepatic adenomas [benign tumors], hepatocellular carcinoma [cancer], and peliosis hepatis [generation of blood-filled cavities in the liver that may rupture]—all potentially life-threatening complications.” Expert Report of Dr. Michael K. Laidlaw ¶¶ 117, 122. And “[a]ccording to research[,] anabolic steroid abuse has been shown to predispose individuals towards mood disorders, psychosis, and psychiatric disorders,” with “[t]he ‘most prominent psychiatric features’” including “manic-like presentations defined by irritability, aggressiveness, euphoria, grandiose beliefs, hyperactivity, and reckless or dangerous behavior,” as well as “acute psychoses, exacerbation of tics and depression, and the development of acute confusional/delirious states.” Expert Report of Dr. Michael K. Laidlaw ¶ 140. This, then, is more than ample support for the requirement that “you must be under the care of a licensed mental health care professional while undergoing treatment.” Exh. B, C.

Research demonstrating these potential side effects typically examine male use of testosterone. “The use of high dose testosterone in females is experimental.” Dr. Michael K. Laidlaw ¶ 115. “[I]here are,” however, “greater attendant risks when you give testosterone to a female above and beyond that which you would see in giving that same hormone to a male.” *Dekker* Trial Tr. at 151 (Testimony of Dr. Paul Hruz). Similarly, “[t]he effects that actually have been shown to occur in males that are given estrogen as part of a gender affirmation can increase risk of a thromboembolic stroke three to fivefold.” *Dekker* Trial Tr. at 152 (Testimony of Dr. Paul Hruz).

Finally, the informed-consent forms' discussion of cyproterone acetate, finasteride, and the potential for bone scans cannot conceivably cause the sort of confusion that rises to the level of a constitutional violation. If an individual is not prescribed either cyproterone acetate or finasteride as part of his or her sex-modification procedure, it beggars belief to think that listing these substances in the informed-consent forms will somehow confuse, dissuade, or prevent him or her from receiving that treatment. If he or she experiences confusion, the physical-presence requirement provides the opportunity to alleviate it with the prescribing physician.

\* \* \*

According to the Court, it is crucial to take into account “[t]he risk of all of these medicines,” and then “make a benefit analysis.” *Dekker* Trial Tr. at 234. “Risks attend many kinds of medical treatment, perhaps most,” and “it is the patient, in consultation with the doctor, who weighs the risks and benefits and chooses a course of treatment.” *Dekker* Final Order at 43. “If a medicalized approach with hormones such as testosterone or medications to stop menstruation is being considered then a clear description of the risks and benefits needs to be conveyed to the patient,” and “[i]t needs to be verified that they fully understand these risks.” Expert Report of Dr. Michael K. Laidlaw ¶ 228.d. Similarly, “[i]f surgical procedures such as mastectomy, hysterectomy, ovariectomy, orchiectomy, or vaginoplasty are being considered then clear descriptions of the risks and benefits need to be conveyed to the patient.” Expert Report of Dr. Michael K. Laidlaw ¶ 228.e.

The informed-consent forms exist to make sure that patients answer “the key question”;—i.e., “whether the risk that is assumed relative is acceptable to the purported benefit.” *Dekker* Trial Tr. at 234. The forms do so accurately and effectively. Accordingly, they do not violate the Equal Protection Clause.

***The recurring mental-health evaluation.*** The Plaintiffs also take issue with the fact that “[b]oth cross-sex hormone forms require transgender patients to ‘undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist’ before beginning hormone therapy and ‘every two years thereafter.’” ECF No. 116, at 15-16. Their protestations that “[t]here is no medical basis for these requirements,” ECF No. 116, at 16, ignores that “[g]ender dysphoria is a psychiatric diagnosis” that is identified “purely by psychological methods of behavioral observation and questioning.” Expert Report of Dr. Michael K. Laidlaw ¶ 23.

It also ignores that “co-occurrence of mental illness” in this group is “widely recognized and widely documented.” *Dekker* Doc. ECF No. 49, at 4 (quoting App. 139). Indeed, gender dysphoric adults “continue to show high rates of mental health issues after transition” to the other gender. *Dekker* Doc. ECF No. 49, at 4 (quoting App. 139). And “[i]n working with this population,” doctors “treat the whole gamut of co-occurring psychiatric disorders.” *Dekker* Trial Tr. at 68 (Testimony of Dr. Aron Janssen). And as noted above, hormonal treatments (particularly, testosterone) are documented to cause or aggravate certain mental disorders. *Supra*. This

requirement, then, is abundantly rational and more than substantially related to the compelling interest the State has in assuring that those seeking gender-affirming care continue to understand the costs and benefits of their course of treatment.

*The physician-as-prescriber requirement.* Finally, the Plaintiffs object to Florida’s requirement that “[s]ex-reassignment prescriptions or procedures may not be prescribed, administered, or performed except by a physician,” Fla. Stat. § 456.52, which means that autonomous-practice certified Advanced Practice Registered Nurses can no longer do the same, *see* ECF No. 116, at 18. Contrary to their assertion that “[t]here is no medically valid basis or rationale for” limiting the provision of this treatment to physicians, *see* ECF No. 116, at 18-20, the record is replete with reasons establishing why the State’s decision to create this limitation serves its compelling interest.

Simply put, physicians are better trained to deal with the complexities inherent in treating gender dysphoria. At the *Dekker* Trial, there was testimony about an individual who “went to a nurse practitioner, and in 45 minutes at the first visit to the nurse practitioner got an estrogen prescription.” *Dekker* Trial Tr. at 1009 (Testimony of Dr. Stephen B. Levine). This apparently “is very common.” *Dekker* Trial Tr. at 1009 (Testimony of Dr. Stephen B. Levine). So too, “the risk of over-diagnosis.” Expert Report of Kristopher Kaliebe ¶ 57. Given the stakes inherent in gender-affirming treatment and the State’s compelling interest in ensuring that those seeking such care are fully informed of the costs and benefits of their choices, the State’s decision to

restrict prescribing authority to those with the greatest training and credentials plainly and substantially supports this goal.

**II. NOT ONE OF THE PLAINTIFFS WILL SUFFER IRREPARABLE HARM IN THE ABSENCE OF A PRELIMINARY INJUNCTION.**

None of the Plaintiffs have, or can, establish the requisite irreparable harm. We address each in turn.

*Kai Pope*, a 51-year old transgender man, argues that he was supposed to have “genital surgery” on “September 14, 2023,” but “on July 13, 2023, he was informed by his surgeon during a phone call that his surgery was cancelled because of SB 254.” Mr. Pope does not explain how or why the informed-consent provisions he is challenging caused the cancellation of his surgery, nor has he argued how enjoining the informed-consent provisions will result in it being rescheduled. Moreover, he has failed to explain why he will experience irreparable harm by waiting for this case to proceed to final judgment, given that he “was diagnosed with gender dysphoria many years ago,” which means he waited “many years” to schedule his genital surgery.

*Lucien Hamel*, 27-year old transgender man, argues that he can no longer “get[] his hormone therapy” from “an autonomous-practice certified Advanced Practice Registered Nurse—Nurse Practitioner.” By the Plaintiffs’ own telling, however, there are nearly 100,000 doctors in the State who can prescribe sex-modification surgery. *See* ECF No. 116, at 19. Mr. Hamel’s role as a CVS manager, moreover, strongly suggests

that it is far from impossible that he will be able to reestablish his hormonal therapy absent a preliminary injunction from this Court.

*Olivia Noel*, a transgender woman, has also reported difficulty in finding a physician to continue prescribing the estrogen she was prescribed by a nurse practitioner at Planned Parenthood. She reports, however, that she has a prescription refill. And with roughly 100,000 doctors in State who can continue to prescribe her the medicine she requires for her treatment, *see* ECF No. 116, at 19, she has not established the irreparable injury necessary to justify preliminary injunctive relief.

*Rebecca Cruz Evia*, a transgender woman, was scheduled to have a vaginoplasty surgery on August 15, 2023. Her surgeon informed her that Senate Bill 254 forced a cancellation of her surgery. Like Mr. Pope, however, Ms. Evia has not explained how or why the informed-consent provisions she is challenging caused the cancellation of her surgery, nor has she argued how enjoining the informed-consent provisions will result in it being rescheduled.

### **III. BALANCE OF THE EQUITIES.**

The remaining preliminary-injunction factors weigh against granting a preliminary injunction. The public benefits from the State ensuring that robust informed consent will remain the policy of the State, especially in the context of inherently risky medical treatment. *See Presidential Women's Ctr.*, 937 So. 2d at 116; *see also Dobbs*, 142 S. Ct. at 2282 (noting the State's strong role in making health, safety, and welfare decisions). The public is also served when the State gets to enforce its laws, and

the State is harmed when it's prevented from doing so. *See Hand v. Scott*, 888 F.3d 1206, 1214 (11th Cir. 2018) (The State is “harmed” when it can’t “apply its own laws.”); *see also Maryland v. King*, 567 U.S. 1301, 1301 (2012) (Roberts, C.J., in chambers) (“Any time a State is enjoined by a court from effectuating” its laws, “it suffers a form of irreparable harm.” (cleaned up)).

Because the Plaintiffs haven’t established a constitutional violation, haven’t shown irreparable harm, and haven’t shown that the balance of the equities and the public interest favor enjoining the State’s informed-consent requirements, these factors tilt decidedly in the State’s favor.

### **CONCLUSION**

The Plaintiffs themselves acknowledge that “transition-related medication and surgeries have attendant risks.” ECF No. 116, at 8. The provisions they challenge do no more than ensure that individuals seeking sex-modification treatment are fully informed of these risks. They do not violate the Equal Protection Clause, and for that reason (along with all the foregoing reasons), the Court should deny Plaintiffs’ motion for a preliminary injunction.

Dated: August 7, 2023

**Ashley Moody**  
ATTORNEY GENERAL

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### **CERTIFICATE OF COMPLIANCE**

As required by Local Rule 7.1(F), I certify that this memorandum of law contains  
7,116 words.

/s/ Mohammad O. Jazil  
Mohammad O. Jazil

### **CERTIFICATE OF SERVICE**

I certify that, on August 7, 2023, this memorandum of law was filed through the  
Court's CM/ECF system, which will send a notice of electronic filing to all counsel of  
record.

/s/ Mohammad O. Jazil  
Mohammad O. Jazil

## Feminizing Medications for Patients with Gender Dysphoria

### Patient Information and Informed Consent

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with use of these medications.

Your prescribing physician will make a medical decision in consultation with you about the medications that are best for you, keeping in mind your overall health during the treatment process. Your prescribing physician will discuss with you all of the available information relating to hormone therapy. You are asked to read and understand the following information and to discuss any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue treatment with hormones or hormone antagonists, you must initial the statements below and sign this form in person with your prescribing physician.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

#### **What are the different medications that can feminize one's appearance?**

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking estrogen, as well as medicines to block the body from producing or utilizing testosterone. Use of these medications, even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval and its use to treat gender dysphoria is considered "off label" because they are not being used for their intended purpose

Different forms of estrogen are used to feminize a person's appearance. Estrogen can be given as an injection either weekly or every other week, as a pill that is taken daily or twice a day, or as a patch that is changed weekly or every three or four days.

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**Please initial below to acknowledge your understanding of the information on this page.**

<b>Patient</b>

Medications that block the production or effects of testosterone are called androgen blockers. Spironolactone is the androgen blocker that is most commonly used in the United States. In some cases, Bicalutamide, an antiandrogen, is used to block the effects of testosterone, though it will not reduce testosterone levels. Bicalutamide (brand name Casodex) is a cancer drug approved for the treatment of prostate cancer. Fulminant hepatotoxicity, a severe liver injury often resulting in death, has been noted with bicalutamide use.

Cyproterone acetate, a synthetic progestogen with strong antiandrogen activity, is commonly used in many countries. When paired with estrogen, cyproterone acetate is associated with elevated prolactin, decreased HDL cholesterol, and rare meningiomas (tumors). Cyproterone acetate has also been associated with uncommon episodes of fulminant hepatitis.

The administration of finasteride blocks the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved uses of finasteride include the treatment benign prostatic hypertrophy and androgenic alopecia. Finasteride is not recommended for routine use in treating populations with gender dysphoria.

Various forms of progestins may also be used. This class includes micronized bioidentical progesterone (Prometrium) as well as oral medroxyprogesterone acetate (Provera). Although there are anecdotal reports of progesterone use for breast development and mood management, there is currently insufficient evidence that the potential benefits of progesterone administration outweigh the potential risks. There is also a theoretical risk of breast cancer associated with long-term exogenous progesterone.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to your prescribing physician to make sure that there are no negative medical or mental health effects.

HRT, the use of androgen blockers and antiandrogens, and the treatment process can affect your mood. Therefore, you must be under the care of a licensed mental health care professional while undergoing treatment.

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**Please initial below to acknowledge your understanding of the information on this page.**

<b>Patient</b>

**What are my other options if I do not wish to start or continue treatment with hormones, hormone antagonists, or antiandrogens?**

One option available is psychological therapy with a mental health provider. This is recommended regardless of whether or not the person undergoes treatment with hormones, hormone antagonists, or antiandrogens due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

**What are the requirements to receive hormone replacement therapy (HRT)?**

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor your medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Before beginning HRT and every two years thereafter, you must undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

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**Please initial below to acknowledge your understanding of the information on this page.**

<b>Patient</b>

The specific requirements for you to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
4. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Has psychological and social support during treatment;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery; and
7. Understands the effect of hormone treatment on reproduction and they have explored reproductive options;

The following may also be recommended by your prescribing physician:

1. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter;
3. Undergoes relevant laboratory testing at least every 6 months;
4. Annual bone density scan (DEXA) once a year for the first 5 years to allow monitoring of your bone density (bone strength) during treatment, which can be altered by HRT;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
6. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

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**Please initial below to acknowledge your understanding of the information on this page.**

<b>Patient</b>

**Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with taking feminizing medications.**

### Effects of Feminizing Medications

Patient	Statement
	Feminizing medications, including estrogen, androgen blockers, or antiandrogens, given singularly or in combination, may be prescribed to make me appear less like a male and more like a female.
	It can take several months or longer for the effects of feminizing medications to become noticeable and no one can predict how fast or how much change will occur.
	This treatment will not change my biological sex or chromosomes.
	<p>If I take estrogen, the following changes in my breasts will occur:</p> <ul style="list-style-type: none"> <li>• Breasts will develop but will not reach their full size for several years</li> <li>• Breasts will remain even if estrogen treatment is discontinued</li> <li>• A milky discharge from the nipples may appear, which should be reported to my prescribing physician</li> <li>• My risk of breast cancer may significantly increase</li> </ul>
	<p>If I take feminizing medications, my body will make less testosterone, which may affect my sex life in different ways, including:</p> <ul style="list-style-type: none"> <li>• My testicles may shrink</li> <li>• My penis may never fully develop, particularly if I previously took puberty blockers</li> <li>• I will have fewer spontaneous erections</li> <li>• My sperm may no longer mature causing infertility which may be permanent even if treatment is discontinued, the risk of which is increased if I took puberty blockers prior to starting feminizing medications</li> <li>• Conversely, it is possible that my sperm could still mature while taking feminizing medications and I may cause someone to get pregnant</li> </ul>
	The options for sperm banking have been explained.
	<p>If I take feminizing medications, some parts of my body will not change much, including:</p> <ul style="list-style-type: none"> <li>• If present, my facial hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years</li> <li>• If present, my body hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years</li> <li>• If I went through puberty and have a deep voice, the pitch of my voice will not rise and my speech patterns will not become more like a woman's</li> <li>• If present, my Adam's apple will not shrink</li> </ul>

	<p>Even if I stop taking feminizing medications, the following changes may occur:</p> <ul style="list-style-type: none"> <li>• My body fat may be redistributed with less fat on the abdomen and more on the buttocks, hips, and thighs creating a more female shape</li> <li>• I may have decreased muscle mass and strength in the upper body</li> <li>• My skin may become softer</li> </ul>
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to feminize my body is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of my prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications.

### Risks of Feminizing Medications

Patient	Statement
	The medical effects and the safety of taking feminizing medications are not completely known and there may be unknown long-term risks.
	Taking feminizing medications causes changes that other people will notice.
	Treatment with feminizing medications will not prevent serious psychiatric events, including suicide.
	I must not take more feminizing medication than prescribed. Taking too much medication: <ul style="list-style-type: none"> <li>• Will increase health risks</li> <li>• Will not make changes happen more quickly or more significantly</li> </ul>
	Taking feminizing medication can damage the liver and possibly lead to liver disease.

### Risks of Estrogen

Patient	Statement
	Estrogen <b>SHOULD NOT</b> be used by anyone who has: <ul style="list-style-type: none"> <li>• Any estrogen-dependent cancer</li> <li>• Any disorder that makes them more likely to get blood clots that could travel to the lungs unless they are also taking blood thinners and are being followed by a specialist</li> </ul>
	Estrogen should be used <b>WITH CAUTION</b> and only after a full discussion of risks by anyone who: <ul style="list-style-type: none"> <li>• Has a family history of breast cancer or other cancers that grow more quickly when estrogens are present</li> <li>• Has a family history of heart disease</li> </ul>

	<ul style="list-style-type: none"> <li>• Has diabetes</li> <li>• Has chronic hepatitis or other liver disease</li> <li>• Has high levels of cholesterol</li> <li>• Has migraines or seizures</li> <li>• Is obese</li> <li>• Smokes cigarettes or uses tobacco products</li> </ul>
	<p>Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in:</p> <ul style="list-style-type: none"> <li>• Chronic problems with veins in the legs, which may require surgery</li> <li>• Heart attack which may cause permanent heart damage or death</li> <li>• Pulmonary embolism (blood clot in the lungs), which may cause permanent lung damage or death</li> <li>• Stroke, which may cause permanent brain damage or death</li> </ul>
	<p>The risk of blood clots while take estrogen is much greater if you smoke cigarettes. The danger is so high that you should stop smoking completely while taking estrogen.</p>
	<p>Taking estrogen can increase the deposits of fat around internal organs, which increases the risk for diabetes and heart disease, which in turn increases the risk of heart attack and stroke.</p>
	<p>Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.</p>
	<p>Taking estrogen increases the risk of gallstones (stones in the gallbladder). Any long-term abdominal pain you experience while taking estrogen must be reported to your prescribing physician.</p>
	<p>Taking estrogen increases the risk of elevated prolactin levels and prolactinomas, which are non-cancerous tumors of the pituitary gland. While not typically life threatening, prolactinomas can damage your vision and cause headaches if not treated properly. Any changes in your vision, the occurrence of headaches that are worse when waking up in the morning, or any milky discharge from the nipples must be reported to your prescribing physician.</p>
	<p>Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to your prescribing physician.</p>
	<p>Taking estrogen can cause migraines or can make them worse if you already have them.</p>
	<p>Taking estrogen can cause hot flashes.</p>
	<p>Taking estrogen can cause you to feel tired and have difficulty focusing.</p>

**Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)**

<b>Patient</b>	<b>Statement</b>
	<p>Taking Spironolactone affects the balance of water and salt in the kidneys, which may:</p> <ul style="list-style-type: none"> <li>• Increase the amount of urine produced by your kidneys, making it necessary to urinate more frequently</li> <li>• Increase your thirst</li> <li>• Increase your risk of dehydration, which can be evidenced by less frequent urination than usual, dark and strong-smelling urine, thirst, and light-headedness</li> </ul>
	<p>Taking Spironolactone affects the balance of potassium in the kidneys, which may result in you experiencing high potassium levels resulting in:</p> <ul style="list-style-type: none"> <li>• Changes in heart rhythms that may be life threatening</li> <li>• Low blood pressure, which can cause: <ul style="list-style-type: none"> <li>○ Fatigue</li> <li>○ Lightheadedness</li> <li>○ Tingling feelings</li> <li>○ Muscle weakness</li> <li>○ Shortness of breath</li> </ul> </li> <li>• Your need for regular blood tests to monitor risks while on the medication</li> </ul>
	<p>Taking Bicalutamide may cause numerous side effects which should be reported to your prescribing physician, including:</p> <ul style="list-style-type: none"> <li>• Hot flashes or flushing</li> <li>• Bone, back, or pelvic pain</li> <li>• Muscle weakness</li> <li>• Muscle or joint pain</li> <li>• Headaches</li> <li>• Shortness of breath</li> <li>• Chest pain</li> <li>• Elevated blood pressure</li> <li>• Swelling of the hands, feet, ankles, or lower legs</li> <li>• Cough</li> <li>• Constipation</li> <li>• Nausea</li> <li>• Vomiting</li> <li>• Abdominal pain</li> <li>• Diarrhea</li> <li>• Gas</li> <li>• Changes in weight (loss or gain)</li> <li>• Loss of appetite</li> </ul>

	<ul style="list-style-type: none"> <li>• Dizziness</li> <li>• Pain, burning, or tingling in the hands or feet</li> <li>• Difficulty sleeping</li> <li>• Feeling of uneasiness or dread</li> <li>• Rash</li> <li>• Sweating</li> <li>• Need to urinate frequently during the night</li> <li>• Bloody urine</li> <li>• Painful or difficult urination</li> <li>• Frequent and urgent need to urinate</li> <li>• Difficulty emptying bladder</li> <li>• Painful or swollen breasts</li> <li>• Yellowing of the skin or eyes</li> <li>• Pain in the upper right part of the abdomen</li> <li>• Extreme tiredness</li> <li>• Unusual bleeding or bruising</li> <li>• Lack of energy</li> <li>• Upset stomach</li> <li>• Loss of appetite</li> <li>• Flu-like symptoms</li> <li>• Dull or sharp side pain</li> </ul>
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**Requirements of Treatment with Feminizing Medications**

Patient	Statement
	Compliance with the requirements explained above is a prerequisite for you to receive treatment with feminizing medications.
	The prescribing physician may stop prescribing feminizing medications if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
	I can change my mind and stop treatment at any time.

**Prevention of Complications while under Treatment with Feminizing Medications**

Patient	Statement
	I agree to notify the prescribing physician if I suffer from any side effects during treatment or are unhappy with the treatment in any way, particularly if I have any concerns about worsening signs of depression or anxiety or if I desire to harm myself or attempt suicide.

	<p>I acknowledge that taking feminizing medications is only a part of my overall health, and that a range of preventative health activities are necessary so that remain healthy. These include, but are not limited to:</p> <ul style="list-style-type: none"> <li>• Monthly breast self-examination (report any new lumps to the prescribing physician)</li> <li>• Regular age-appropriate breast mammograms</li> <li>• Regular age-appropriate prostate examinations</li> <li>• Appropriate immunizations</li> <li>• Regular STI screening depending on my level of risk</li> <li>• HIV prevention depending on my level of risk</li> <li>• Regular physical activity, including resistance exercise for bone health</li> <li>• Healthy eating</li> <li>• Quitting smoking</li> </ul>
	<p>The prescribing physician is required to monitor me for any side effects during treatment and may refer me to another physician or specialist for treatment. I agree to go to any physicians and specialists recommended by the prescribing physician.</p>

**CONSENT:**

**The signature below confirms the following:**

1. The prescribing physician has fully informed me about:
  - a. the benefits and risks of taking feminizing medications;
  - b. the possible or likely consequences of hormone therapy; and
  - c. potential alternative treatments.
2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with feminizing medications. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.
3. I have had sufficient time and opportunity to discuss relevant treatment options with the prescribing physician.
4. All my questions have been answered to my satisfaction by the prescribing physician.
5. I know enough to give informed consent for me to take, refuse, or postpone taking feminizing medications.
6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.
7. My signature below attests to my consent to begin treatment with feminizing medications.

---

Patient's printed name (required)

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Patient's signature (required)

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Date

**PRESCRIBING PHYSICIAN SIGNATURE:**

My signature below attests to my compliance with section 456.52, Florida Statutes.

\_\_\_\_\_  
Prescribing physician's printed name (required)

\_\_\_\_\_  
Prescribing physician's signature (required)

\_\_\_\_\_  
Date

**WITNESS:**

\_\_\_\_\_  
Witness' printed name (required)

\_\_\_\_\_  
Witness' signature (required)

\_\_\_\_\_  
Date

**FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:**

I certify that I am fluent in English and in the native language of the person indicating consent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

\_\_\_\_\_  
Interpreter's printed name

\_\_\_\_\_  
Interpreter's signature

\_\_\_\_\_  
Date

## **Masculinizing Medications for Patients with Gender Dysphoria**

### **Patient Information and Informed Consent**

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with the use of these medications.

The prescribing physician will make a medical decision, in consultation with you, about the medications that are best for you, keeping in mind your overall health during your gender transition process. The effects and possible risks associated with the use of these medications will be discussed with you. It your responsibility to read and understand the following information and raise any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue hormones or hormone antagonists, you will need to initial the statements below and sign this form.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient’s psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

#### **What are the medications that can masculinize one’s appearance?**

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking testosterone, which increases muscle mass and causes the development of facial hair and a deeper voice. Testosterone when used by biological women, even when the criteria listed below are followed, does not have the U.S. Food and Drug Administration (FDA) approval to be used in the treatment of gender dysphoria and is considered “off label” use because they are not being used for their intended purpose.

---

**Please initial below to acknowledge your understanding of the information on this page.**

<b>Patient</b>

**How is testosterone taken?**

Testosterone is usually injected every one to four weeks. Typically, it is not used as a pill because the body may not absorb it properly and may cause potentially fatal liver problems. The doses used for injection differ from product to product and from patient to patient. The injections are given in the muscle (intramuscular) or can be given with a smaller needle under the skin (subcutaneous). Taking testosterone may cause unwanted swings in hormone levels based on the amount and how often doses are given. Skin creams and patches may also be used. Both testosterone and the treatment process can affect mood. Therefore, individuals must be under the care of a licensed mental health care professional while undergoing treatment.

**Finasteride** is a treatment option for individuals experiencing bothersome alopecia resulting from higher dihydrotestosterone levels. The administration of 5 $\alpha$ -reductase inhibitors block the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved indications of finasteride administration include benign prostatic hypertrophy and androgenetic alopecia. The use of 5 $\alpha$ -reductase inhibitors may impair clitoral growth and the development of facial and body hair. Future studies are needed to assess the efficacy and safety of 5 $\alpha$ -reductase inhibitors in treatment for gender dysphoria.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the prescribing physician to make sure that there are no negative medical or mental health effects.

**What are my other options if I do not wish to start or continue medical treatments?**

One option available is psychological therapy with a mental health care provider. This is recommended regardless of whether the individual undergoes treatment with hormones or hormone antagonists or not, due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

---

**Please initial below to acknowledge your understanding of the information on this page.**

<b>Patient</b>

**What are the requirements to receive hormone replacement therapy?**

To receive hormone replacement therapy, there are specific requirements that need to be met before and during the treatment. These requirements will allow the prescribing physician to monitor medical as well as mental health wellbeing during HRT. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Before beginning HRT and every two years thereafter, the individual needs to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

The specific requirements for an individual to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
4. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Has psychological and social support during treatment;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery; and
7. Understands the effect of hormone treatment on reproduction and they have explored reproductive options.

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**Please initial below to acknowledge your understanding of the information on this page.**

<b>Patient</b>

The following may also be recommended by your prescribing physician:

1. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter;
3. Undergoes relevant laboratory testing, at least every 6 months;
4. Annual bone scan (DEXA) once a year for the first 5 years to allow monitoring of bone density (bone strength) during treatment, which can be altered by HRT;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
6. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

**Summary of Testosterone Benefits and Risk**

BENEFITS	RISKS
<ul style="list-style-type: none"> <li>• Appear more like a man</li> <li>• Bigger clitoris</li> <li>• Coarser skin</li> <li>• Lower voice</li> <li>• More body hair</li> <li>• More facial hair</li> <li>• More muscle mass</li> <li>• More strength</li> <li>• No or minimal menstrual periods</li> <li>• More physical energy</li> <li>• More sex drive</li> </ul>	<ul style="list-style-type: none"> <li>• Acne (may permanently scar)</li> <li>• Blood clots (thrombophlebitis), risk significantly increased by smoking</li> <li>• Emotional changes, for example, more aggression</li> <li>• Headache</li> <li>• High blood pressure (hypertension)</li> <li>• Increased red-blood-cell count</li> <li>• Infertility</li> <li>• Inflamed liver</li> <li>• Interaction with drugs for diabetes and blood thinning — for example Coumadin and Warfarin</li> <li>• Male pattern baldness</li> <li>• More abdominal fat — redistributed to a male shape</li> <li>• Risk of heart disease</li> <li>• Swelling of hands, feet, and legs</li> <li>• Weight gain</li> </ul>

Please initial below to acknowledge your understanding of the information on this page.

<b>Patient</b>

Please initial each statement on this form to show that you understand the benefits, risks, and changes that may occur from taking testosterone.

**Masculinizing Effects**

Patient	Statement
	Testosterone may be prescribed to make me appear less like a female and more like a male.
	It can take several months or longer for the effects of testosterone to become noticeable and no one can predict how fast or how much change will occur.
	<p>The following changes are likely to be permanent even if testosterone is discontinued:</p> <ul style="list-style-type: none"> <li>• Bigger clitoris - typically about half an inch to a little more than an inch</li> <li>• Deeper voice</li> <li>• Gradual growth of moustache and beard</li> <li>• Hair loss at the temples and crown of the head and the possibility of being completely bald</li> <li>• More, thicker, and coarser hair on abdomen, arms, back, chest, and legs</li> </ul>
	<p>The following changes could be permanent, but may improve if I stop taking testosterone:</p> <ul style="list-style-type: none"> <li>• Acne (although there may be permanent scars)</li> <li>• Menstrual periods (if present), typically stop one to six months after starting</li> <li>• More abdominal fat – redistributed to a male shape: decreased on buttocks, hips, and thighs; increased in abdomen – changing from “pear shape” to “apple shape”</li> <li>• More muscle mass and strength</li> <li>• More sexual interest</li> <li>• Vaginal dryness</li> <li>• Vaginal Tearing</li> <li>• Vaginal Bleeding</li> <li>• Vaginal Pain</li> <li>• Vaginal infection</li> <li>• Painful intercourse</li> </ul>
	This treatment will not change the individual’ s biological sex or chromosomes.
	Testosterone may reduce the ability to become pregnant, but it will not eliminate the risk of pregnancy. A person may become pregnant while on testosterone. I agree to inform the prescribing physician if I become pregnant.
	Some aspects of my body will not change:

	<ul style="list-style-type: none"> <li>• Fat loss may make breasts appear slightly smaller</li> <li>• The voice will deepen, but other aspects of the way I speak may not sound more masculine</li> </ul>
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to masculinize is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT.

**Risks of Testosterone**

Patient	Statement
	Testosterone <b>SHOULD NOT</b> be used by anyone who: <ul style="list-style-type: none"> <li>• Is pregnant</li> <li>• Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack</li> </ul>
	It should be used <b>WITH CAUTION</b> and only after a full discussion of risks by anyone who: <ul style="list-style-type: none"> <li>• Has acne</li> <li>• Has a family history of heart disease or breast cancer</li> <li>• Has had a blood clot</li> <li>• Has high levels of cholesterol</li> <li>• Has liver disease</li> <li>• Has a high red blood cell count</li> <li>• Is obese</li> <li>• Smokes cigarettes</li> </ul>
	The medical effects and the safety of testosterone are not completely known and there may be unknown long-term risks.
	Taking testosterone causes changes that other people will notice.
	Treatment with testosterone will not prevent serious psychiatric events, including suicide.
	Taking more testosterone than prescribed: <ul style="list-style-type: none"> <li>• Will increase health risks;</li> <li>• Will not make changes happen more quickly or more significantly; and</li> <li>• May cause the body to convert extra testosterone into estrogen that can slow down or stop me from appearing more masculine.</li> </ul>
	Taking testosterone can cause changes that increase the risk of heart disease. These changes include:

	<ul style="list-style-type: none"> <li>• Less good cholesterol (HDL) that may protect against heart disease and more bad cholesterol (LDL) that may increase the risk of heart disease;</li> <li>• Higher blood pressure; and</li> <li>• More deposits of fat around the internal organs</li> </ul>
	Taking testosterone can damage the liver and possibly lead to liver disease.
	Taking testosterone can increase red blood cells and hemoglobin, which may increase my risk of life-threatening problems such as stroke or heart attack.
	Taking testosterone can increase the risk for diabetes (high blood sugars), which decrease the body's response to insulin, cause weight gain, and increase deposits of fat around internal organs increasing the risk of heart disease and stroke.
	Treatment with testosterone can cause ovaries to not release eggs and may cause infertility.
	Treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts. It is unclear if taking testosterone plays any role in HPV infection or cervical cancer.
	Taking testosterone causes or worsens migraines.
	Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.

### Risks of Finasteride

Patient	Statement
	Finasteride may be an appropriate treatment option in individuals experiencing bothersome alopecia resulting from testosterone treatment.
	Finasteride may have side effects which include: <ul style="list-style-type: none"> <li>• decreased libido</li> <li>• dry skin</li> <li>• acne</li> <li>• Breast swelling and tenderness</li> <li>• headache</li> <li>• irregular menstruation</li> <li>• dizziness</li> <li>• increased body hair</li> </ul>
	Finasteride is not approved by the FDA for use in biological women and is forbidden in pregnant women due to birth defects.

**Requirements of Treatment with HRT**

Patient	Statement
	Compliance with the requirements explained above is a prerequisite to receive treatment with testosterone.
	The prescribing physician may stop prescribing testosterone if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
	I understand that I may decide to stop treatment at any time.

**Prevention of Complications while under Treatment of HRT**

Patient	Statement
	I agree to notify the prescribing physician if I suffer from any side effects during treatment or am unhappy with the treatment in any way, and if I have any concerns that I have worsening signs of depression or anxiety or wants to harm myself or attempt suicide or attempt suicide.
	The prescribing physician is required to monitor me for any side effects during treatment and may refer me to another physician or specialist for treatment.

**CONSENT:****My signature below confirms that:**

1. My prescribing physician has talked with me about:
  - a. the benefits and risks of taking testosterone;
  - b. the possible or likely consequences of hormone therapy; and
  - c. potential alternative treatments.
2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with testosterone. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.
3. I have had sufficient time and opportunity to discuss relevant treatment options with my prescribing physician.
4. All my questions have been answered to my satisfaction by my prescribing physician.
5. I know enough to give informed consent to take, refuse, or postpone taking testosterone.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.
7. My signature below attests to my consent to begin treatment with testosterone.

**Based on all this information:**

- \_\_\_\_\_ I want to begin or continue taking testosterone
- \_\_\_\_\_ I want to begin or continue taking finasteride
- \_\_\_\_\_ I do not wish to begin or continue taking masculinizing medication

\_\_\_\_\_  
Patient's printed name (required)

\_\_\_\_\_  
Patient's signature (required)

\_\_\_\_\_  
Date

**PRESCRIBING PHYSICIAN:**

My signature below attests to my compliance with 456.52, Florida Statutes.

\_\_\_\_\_  
Prescribing physician's printed name (required)

\_\_\_\_\_  
Prescribing physician's signature (required)

\_\_\_\_\_  
Date

**WITNESS:**

\_\_\_\_\_  
Witness' printed name (required)

\_\_\_\_\_  
Witness' signature (required)

\_\_\_\_\_  
Date

**FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:**

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

\_\_\_\_\_  
Interpreter's printed name

\_\_\_\_\_  
Interpreter's signature

\_\_\_\_\_  
Date

## Surgical Treatment for Adults with Gender Dysphoria

### Patient Information and Informed Consent

Before having surgery to treat gender dysphoria, you need to be aware of the effects and possible risks of these procedures. Your surgeon will make a medical decision, in consultation with you, about the procedures that are best for you, keeping in mind your overall health.

Your surgeon will discuss with you all the information relating to the surgery. You are asked to read and understand the following information and to discuss any questions you have with your surgeon. After your questions or concerns are addressed and you have decided to have surgery you must initial the statements below and sign this form in person with your surgeon.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

#### What are the types of surgery to treat gender dysphoria?

Surgery to treat gender dysphoria may involve procedures on the face, chest, or genitalia. Common surgery options include:

- **Facial reconstructive surgery** to make facial features more masculine or feminine.
- **Chest or "Top" surgery** to remove breast tissue for a more masculine appearance or enhance breast size and shape for a more feminine appearance.
- **Genital or "Bottom" surgery** to transform and reconstruct the genitalia.
  - **Orchiectomy:** A bilateral orchiectomy is a procedure performed by a urologist that involves surgical removal of the testicles through a small scrotal incision. This procedure is done with a particular technique that allows for vaginoplasty later, if desired. Afterward, patients may adjust their dose of estrogens downward and no longer require spironolactone. Recovery takes approximately 2 weeks. Individuals seeking orchiectomy may wish to consider semen banking to preserve future fertility options.

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**Please initial below to acknowledge your understanding of the information on this page.**

<b>Patient</b>

- **Vaginoplasty:** In addition to an orchiectomy, a person may elect to undergo a vaginoplasty, which is a surgical procedure that involves reconstructing the genitals to create external female genitalia with or without a vaginal cavity. For those patients treated with puberty blockers as a minor, such treatment may lead to insufficient penile tissue that could necessitate the use of other tissues, such as the colon, to create a vagina.
- **Phalloplasty:** This surgery involves a multi-staged procedure for the creation of a penis, urinary channel to allow urination, scrotum, and the obliteration of the vaginal cavity with closure. The removal of the female genital organs such as the uterus and ovaries and fallopian tubes are required and usually performed separately and prior to the phalloplasty surgery. The creation of the penis is performed with use of tissue from other parts of the body, which could include, more commonly the radial forearm free flap, or anterolateral thigh flap, and latissimus dorsi (MLD) flap. Prosthetics such as silicone or saline testicles can be placed as well as inflatable penile prosthetics in the final stage.
- **Metoidioplasty:** In this procedure, the surrounding tissue of the clitoris is released to achieve maximal length and a more natural-looking male position. A urethra is also reconstructed using either local skin tissue or a graft from the mouth depending on the amount of tissue present. Construction of a scrotum with testicular prosthetics can also be performed at the same time.
- **Hysterectomy:** Removal of the uterus and cervix via laparoscopic or vaginal techniques.
- **Salpingo-oophorectomy:** Removal of the fallopian tubes and ovaries.
- **Vaginectomy:** Obliteration of the vaginal canal and opening.

### Is surgery the only treatment for gender dysphoria?

Surgery is just one option. Not everyone who has gender dysphoria chooses to have surgery. Depending on your age and preferences, you may choose:

- Treatment by a licensed mental health care professional that has experience in treating people with gender dysphoria, which is recommended regardless of whether you undergo surgery due to the high risk of anxiety, depression, self-harm, and suicide.
- Hormone replacement therapy to increase masculine or feminine characteristics.  
Other options may be discussed with your prescribing physician.

---

**Please initial below to acknowledge your understanding of the information on this page.**

<b>Patient</b>

### What are some potential complications of surgery to treat gender dysphoria?

Potential complications include:

- Changes in sexual sensation
- Diminishment of bladder function
- Problems with urination
- Bleeding
- Infection
- Nerve damage
- Poor healing
- Scarring that can cause pain, firmness, asymmetry
- Side effects of anesthesia, including death

### What happens after surgery to treat gender dysphoria?

Recovery times vary based on what procedures or combination of procedures you have as follows:

- **Cheek and nose surgery:** Swelling lasts for around two to four weeks.
- **Chin and jaw surgery:** Most swelling fades within two weeks but may take up to four months for swelling to completely disappear.
- **Chest surgery:** Swelling and soreness lasts for one to two weeks with physical limitations lasting at least one month.
- **Bottom surgery:** Most people do not resume usual activities until at least six weeks after surgery and weekly follow-up visits with your surgeon for several months will be necessary.

### When should I see my surgeon?

After surgery, you should see your surgeon if you experience:

- Bleeding for more than a few days.
- Pain that does not go away after several weeks.
- Signs of infection, such as a wound that changes color or does not heal.

---

**Please initial below to acknowledge your understanding of the information on this page.**

<b>Patient</b>

Please initial each statement on this form to show that you understand the risks and changes associated with gender dysphoria surgeries.

Patient	Statement
	I understand that my surgeon will discuss with me during the preoperative process the available surgical procedures to treat gender dysphoria, the aftercare needs following surgery, and the importance of postoperative follow-up.
	I understand that these surgeries are permanent.
	I understand that if I have my breasts removed, I must undergo reconstructive surgery if I wish to have breasts in the future. If implants are used, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that if I have my breasts removed that breast feeding will never be possible.
	I understand that if I have breast augmentation surgery, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that my surgeon will assess me for risk factors associated with breast cancer prior to breast augmentation or mastectomy, including genetic mutations (e.g., BRCA1, BRCA2), family history, age, radiation, exposure to estrogen, and the amount of breast tissue anticipated to remain after surgery.
	I understand that if I undergo metoidioplasty/phalloplasty I will need lifelong urological treatment.
	<p>I understand that complications following metoidioplasty/phalloplasty include:</p> <ul style="list-style-type: none"> <li>• urinary tract strictures and fistulas</li> <li>• mucocoeles due to vaginal remnant</li> <li>• hair growth within the neourethra</li> <li>• compromised sexual function including absent tactile and/or erogenous sensation, difficulties achieving orgasm</li> <li>• complications with penile prosthetics</li> </ul>
	I understand that if I undergo vaginoplasty I will need lifelong treatment with my surgeon, primary care physician, and/or gynecologist.
	<p>I understand that if I undergo vaginoplasty, complications can include:</p> <ul style="list-style-type: none"> <li>• the formation of granulation tissue</li> <li>• intravaginal hair growth</li> <li>• delayed wound healing and/or wound disruption</li> <li>• introital stenosis (closing, narrowing, or closure)</li> </ul>

	<ul style="list-style-type: none"> <li>• painful sex</li> </ul>
	I understand that my surgeon may stop further treatment because the risks of treatment outweigh the benefits of treatment.
	I understand that this treatment will not prevent serious psychiatric events, including suicide.
	I agree to tell my surgeon if I have any problems or side effects or am unhappy with the surgery, including if I have worsening signs of depression or anxiety or want to harm myself or attempt suicide.
	I understand that my surgeon may be required to refer me to one or more specialists for surgery-related complications, and I agree to go to those specialists as recommended.
	<p>I acknowledge that surgery to treat gender dysphoria is only part of my overall health and that a range of preventative health activities are recommended including:</p> <ul style="list-style-type: none"> <li>• cervical/prostate screening tests at appropriate intervals as recommended by my doctor</li> <li>• regularly checking my breasts for lumps, even if I have had a mastectomy</li> <li>• regular mammograms from an appropriate age in consultation with my doctor</li> <li>• quitting smoking</li> <li>• immunizations</li> <li>• regular STI screening, depending on my level of risk</li> <li>• HIV prevention, depending on my level of risk</li> <li>• regular physical activity, including resistance exercise for bone health</li> <li>• healthy eating</li> </ul>

**CONSENT:**

My signature below confirms that:

1. My surgeon has talked with me about:
  - a. the benefits and risks of surgery to treat gender dysphoria;
  - b. the possible or likely consequences of surgery to treat gender dysphoria;
  - c. potential alternative treatments.
2. The information provided to me in this form and by the surgeon includes the known effects and risks of surgery to treat gender dysphoria. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.
3. I have had sufficient time and opportunity to discuss relevant treatment options with my surgeon.
4. All my questions have been answered to my satisfaction by my surgeon.
5. I know enough to give informed consent to have, refuse, or postpone surgery to treat gender dysphoria.
6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your surgeon.
7. My signature below attests to my consent to surgery to treat gender dysphoria.

My signature below confirms the following:

\_\_\_\_\_  
Patient's signature (required)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Patient's signature (required)

\_\_\_\_\_  
Date

**SURGEON:**

My signature below attests to my compliance with 456.52, Florida Statutes.

\_\_\_\_\_  
Surgeon's printed name (required)

\_\_\_\_\_  
Surgeon's signature (required)

\_\_\_\_\_  
Date

**WITNESS:**

\_\_\_\_\_  
Witness' printed name (required)

\_\_\_\_\_  
Witness' signature (required)

\_\_\_\_\_  
Date

**FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:**

I certify that I am fluent in English and in the native language of the person indicating consent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

\_\_\_\_\_  
Interpreter's printed name

\_\_\_\_\_  
Interpreter's signature

\_\_\_\_\_  
Date