

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION**

JANE DOE, et al.,

Plaintiffs,

vs.

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

JOSEPH A. LADAPO, et al.,

Defendants.

_____ /

PLAINTIFFS' NOTICE OF SUPPLEMENTAL AUTHORITY

Plaintiffs, pursuant to N.D. Fla. Local R 7.1(J), file this Notice of Supplemental Authority.

This case is currently under consideration on Plaintiffs' Motion for Preliminary Injunction (ECF 115). During the Scheduling Conference that took place on August 10, 2023, the Court raised a question regarding potential amendment of the Emergency Rules and Informed Consent Forms promulgated by the Medical Defendants in this case, and asked that the parties notify the Court of any such changes.

Pursuant to the Court's request, Plaintiffs file this Notice to inform the Court that Medical Defendants have published revised Emergency Rules and Revised Informed Consent forms for HRT treatment for adult patients with gender

dysphoria. (Notice of Emergency Rule No. 64B8ER23-11 and No. 64B15ER23-12, attached hereto as **Exhibits A and B**; and Forms DH5083-MQA (Rev. 08/23) and DH5082-MQA (Rev. 08/23), attached hereto as **Exhibits C and D**).

Dated: August 23, 2023

Respectfully submitted,

/s/ Simone Chriss

Counsel for Plaintiffs

SOUTHERN LEGAL COUNSEL

By: /s/ Simone Chriss

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CERTIFICATE OF WORD COUNT

Pursuant to Local Rule 7.1(F) and 7.1(J), the undersigned counsel certifies that, according to Microsoft Word, the word-processing system used to prepare this Notice, there are 147 total words contained within the Notice.

/s/ Simone Chriss
Simone Chriss

CERTIFICATE OF SERVICE

I hereby certify that, on August 23, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system.

/s/ Simone Chriss
Simone Chriss

Notice of Emergency Rule

DEPARTMENT OF HEALTH

Board of Medicine

RULE NO.: RULE TITLE:

64B8ER23-11 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states “[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section.”

Accordingly, the Board of Medicine, by emergency rule, hereby adopts the incorporated mandated consent forms for the treatment of gender dysphoria with hormone replacement therapy and surgical treatment for patients 18 years of age or older.

*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***

REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure used for the promulgation of this emergency rule is fair under the circumstances. CSSB 254 was signed into law on May 17, 2023. The Board of Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee’s June meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Medicine discussed the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Medicine published notice of its June 2, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.

The Joint Committee held yet another meeting on June 23, 2023, to discuss an emergency rule adopting draft consent forms that were under consideration. On June 6, 2023, the Board of Medicine published notice of the Joint Committee’s June 23 meeting to its website and in the Florida Administrative Register. On June 30, 2023, the Boards of Medicine and Osteopathic Medicine held a Joint Board meeting (Joint Board Meeting) to discuss the draft consent forms that were approved by the Joint Committee on June 23. The Joint Board meeting was held via Microsoft Teams and notice of the same was published to the Board of Medicine’s website and in the Florida Administrative Register on June 22, 2023. During the June 30, 2023, Joint Board Meeting, the Boards voted to approve consent forms and adopted them via emergency rule filed on July 5, 2023.

On July 21, 2023, the Board received correspondence from the Joint Administrative Procedures Committee (JAPC) questioning the Board’s statutory authority for requiring that adult patients “undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist” before beginning hormone replacement therapy and every two years thereafter. Accordingly, the Florida Board of Medicine and Osteopathic Medicine’s Joint Rules/Legislative Committee held a public meeting on August 3, 2023, and voted to remove the provision addressed by JAPC. The Board of Medicine discussed the Joint Committee’s report and affirmed the decision at its August 4, 2023, Board meeting.

The August 3 Joint Committee meeting was held in person in a public forum and was able to be attended by any interested parties. Notice of the Joint Committee meeting was published to the Board of Medicine’s website and in the Florida Administrative Register on July 13, 2023. The August 4 Board Meeting was also held in person in a

public forum and was able to be attended by any interested parties. Notice for the August 4 Board Meeting was published to the Board of Medicine's website on July 13, 2023, and in the Florida Administrative Register on July 12, 2023.

Public comment was accepted at all of the aforementioned board and committee meetings. Further, the Boards accepted written public comment on the initial proposed rules up and until 24 hours prior to the Joint Board Meeting. The Board also accepted written comments up and until 24 hours prior to the August 3, 2023, Joint Rules/Legislative Committee meeting as well. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with at all points during the rulemaking process and interested parties were given ample opportunity to participate at all points during this rulemaking process.

SUMMARY: The proposed emergency rule formally adopts the required consent forms for an adult patient to receive sex-reassignment prescriptions and/or procedures per section 456.52(2), Florida Statutes.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Paul Vazquez, Executive Director, Board of Medicine, 4052 Bald Cypress Way, Bin # C-03, Tallahassee, Florida 32399-3253.

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B8ER23-11 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults

Pursuant to Section 456.52, Florida Statutes, when sex-reassignment prescriptions or procedures are prescribed for or administered or performed on patients 18 years of age or older, the physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and the physician's patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(1) Informed Consent. The Board has approved the following mandatory informed consent forms for sex-reassignment prescriptions or procedures for patients 18 years of age or older:

(a) For patients prescribed sex-reassignment feminizing medication, form DH5082-MQA, (Rev. 08/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at <https://flboardofmedicine.gov/forms/Feminizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf>.

(b) For patients prescribed sex-reassignment masculinizing medications, form DH5083-MQA, (Rev. 08/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at <https://flboardofmedicine.gov/forms/Masculinizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf>.

(c) For patients undergoing surgical treatment, form DH5084-MQA, (06/23), entitled "Surgical Treatment for Adults with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at <https://flboardofmedicine.gov/forms/Surgical-Treatment-for-Adults-with-Gender-Dysphoria-Patients-Information-and-Informed-Consent.pdf>.

(2) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription or performing the procedure, while physically present in the same room as the patient, has informed the patient of the nature and risks of the prescription or procedure and has provided and received the patient's written acknowledgement before the prescription is prescribed, administered, or performed. The physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient is required to sign the informed consent form.

(c) A competent witness is also required to sign the informed consent form.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History – New 8-18-23.

THIS RULE TAKES EFFECT UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.

EFFECTIVE DATE: August 18, 2023

Notice of Emergency Rule

DEPARTMENT OF HEALTH

Board of Osteopathic Medicine

RULE NO.: RULE TITLE:

64B15ER23-12 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Osteopathic Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states “[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section.”

Accordingly, the Board of Osteopathic Medicine, by emergency rule, hereby adopts the incorporated mandated consent forms for the treatment of gender dysphoria with hormone replacement therapy and surgical treatment for patients 18 years of age or older.

*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***

REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure used for the promulgation of this emergency rule is fair under the circumstances. CSSB 254 was signed into law on May 17, 2023. The Board of Osteopathic Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee’s June meeting both on its website and in the Florida Administrative Register. On June 20, 2023, the Board of Osteopathic Medicine discussed the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Osteopathic Medicine published notice of its June 20, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.

The Joint Committee held another meeting on June 23, 2023, to discuss an emergency rule adopting draft consent forms that were under consideration. On June 6, 2023, the Board of Osteopathic Medicine published notice of the Joint Committee’s June 23, 2023, meeting to its website and in the Florida Administrative Register. On June 30, 2023, the Boards of Medicine and Osteopathic Medicine held a Joint Board meeting (Joint Board Meeting) to discuss the draft consent forms that were approved by the Joint Committee on June 23, 2023. The Joint Board meeting was held via Microsoft Teams and notice of the same was published to the Board of Medicine’s website and in the Florida Administrative Register on June 22, 2023. During the June 30, 2023, Joint Board Meeting, the Boards voted to approve consent forms and adopted them via emergency rule filed on July 5, 2023.

On July 21, 2023, the Board received correspondence from the Joint Administrative Procedures Committee (JAPC) questioning the Board’s statutory authority for requiring adult patients “undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist” before beginning hormone replacement therapy and every two years thereafter. Accordingly, the Florida Board of Medicine and Osteopathic Medicine’s Joint Rules/Legislative Committee held a public meeting on August 3, 2023, and voted to remove the provision addressed by JAPC. The Board of Osteopathic Medicine discussed the Joint Committee’s report and affirmed the decision at its August 11, 2023, Board meeting.

The August 3, 2023, Joint Committee meeting was held in person in a public forum and was able to be attended by any interested parties. Notice of the Joint Committee meeting was published to the Board of Osteopathic Medicine’s

website on July 19, 2023, and in the Florida Administrative Register on July 13, 2023. The August 11, 2023, Board Meeting was also held in person in a public forum and was able to be attended by any interested parties. Notice for the August 11, 2023, Board Meeting was published to the Board of Osteopathic Medicine's website on June 1, 2023, and in the Florida Administrative Register on May 24, 2023.

Public comment was accepted at all of the aforementioned board and committee meetings. Further, the Boards accepted written public comment on the initial proposed rules up and until 24 hours prior to the Joint Board Meeting. The Board also accepted written comments up and until 24 hours prior to the August 3, 2023, Joint Rules/Legislative Committee meeting as well. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with at all points during the rulemaking process and interested parties were given ample opportunity to participate at all points during this rulemaking process.

SUMMARY: The proposed emergency rule formally adopts the required consent forms for an adult patient to receive sex-reassignment prescriptions and/or procedures per section 456.52(2), Florida Statutes.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: : Danielle Terrell, Executive Director, Board of Osteopathic Medicine/MQA, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256, or by email at Danielle.Terrell@flhealth.gov.

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B15ER23-12 - Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults.

Pursuant to Section 456.52, Florida Statutes, when sex-reassignment prescriptions or procedures are prescribed for or administered or performed on patients 18 years of age or older, the physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and the physician's patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(1) Informed Consent. The Board has approved the following mandatory informed consent forms for sex-reassignment prescriptions or procedures for patients 18 years of age or older:

(a) For patients prescribed sex-reassignment feminizing medication, form DH5082-MQA, (Rev. 08/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at <https://flboardofmedicine.gov/forms/Feminizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf>.

(b) For patients prescribed sex-reassignment masculinizing medications, form DH5083-MQA, (Rev. 08/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at <https://flboardofmedicine.gov/forms/Masculinizing-Medications-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Informed-Consent.pdf>.

(c) For patients undergoing surgical treatment, form DH5084-MQA, (06/23), entitled "Surgical Treatment for Adults with Gender Dysphoria, Patient Information and Informed Consent," which is hereby incorporated by reference and available from the Board's website at <https://flboardofmedicine.gov/forms/Surgical-Treatment-for-Adults-with-Gender-Dysphoria-Patients-Information-and-Informed-Consent.pdf>.

(2) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription or performing the procedure, while physically present in the same room as the patient, has informed the patient of the nature and risks of the prescription or procedure and has provided and received the patient's written acknowledgement before the prescription is prescribed, administered, or performed. The physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient is required to sign the informed consent form.

(c) A competent witness is also required to sign the informed consent form.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History – New 8-18-23.

THIS RULE TAKES EFFECT UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.
EFFECTIVE DATE: August 18, 2023

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.

| |
|----------------|
| Patient |
| |

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 α -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 α -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 α -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.

| |
|----------------|
| Patient |
| |

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.

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.

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

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|----------------|
| Patient |
| |

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

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

| |
|----------------|
| Patient |
| |

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"> • Bigger clitoris - typically about half an inch to a little more than an inch • Deeper voice • Gradual growth of moustache and beard • Hair loss at the temples and crown of the head and the possibility of being completely bald • More, thicker, and coarser hair on abdomen, arms, back, chest, and legs |
| | <p>The following changes could be permanent, but may improve if I stop taking testosterone:</p> <ul style="list-style-type: none"> • Acne (although there may be permanent scars) • Menstrual periods (if present), typically stop one to six months after starting • More abdominal fat – redistributed to a male shape: decreased on buttocks, hips, and thighs; increased in abdomen – changing from “pear shape” to “apple shape” • More muscle mass and strength • More sexual interest • Vaginal dryness • Vaginal Tearing • Vaginal Bleeding • Vaginal Pain • Vaginal infection • Painful intercourse |
| | 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"> • Fat loss may make breasts appear slightly smaller • The voice will deepen, but other aspects of the way I speak may not sound more masculine |
| | 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 SHOULD NOT be used by anyone who: <ul style="list-style-type: none"> • Is pregnant • Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack |
| | It should be used WITH CAUTION and only after a full discussion of risks by anyone who: <ul style="list-style-type: none"> • Has acne • Has a family history of heart disease or breast cancer • Has had a blood clot • Has high levels of cholesterol • Has liver disease • Has a high red blood cell count • Is obese • Smokes cigarettes |
| | 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"> • Will increase health risks; • Will not make changes happen more quickly or more significantly; and • May cause the body to convert extra testosterone into estrogen that can slow down or stop me from appearing more masculine. |
| | Taking testosterone can cause changes that increase the risk of heart disease. These changes include: |

| | |
|--|---|
| | <ul style="list-style-type: none"> • Less good cholesterol (HDL) that may protect against heart disease and more bad cholesterol (LDL) that may increase the risk of heart disease; • Higher blood pressure; and • More deposits of fat around the internal organs |
| | 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"> • decreased libido • dry skin • acne • Breast swelling and tenderness • headache • irregular menstruation • dizziness • increased body hair |
| | 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

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.

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

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| Patient |
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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.

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

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| Patient |
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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.

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

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| Patient |
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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.

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

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| Patient |
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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"> • Breasts will develop but will not reach their full size for several years • Breasts will remain even if estrogen treatment is discontinued • A milky discharge from the nipples may appear, which should be reported to my prescribing physician • My risk of breast cancer may significantly increase |
| | <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"> • My testicles may shrink • My penis may never fully develop, particularly if I previously took puberty blockers • I will have fewer spontaneous erections • 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 • Conversely, it is possible that my sperm could still mature while taking feminizing medications and I may cause someone to get pregnant |
| | 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"> • If present, my facial hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If present, my body hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • 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 • If present, my Adam's apple will not shrink |

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| | <p>Even if I stop taking feminizing medications, the following changes may occur:</p> <ul style="list-style-type: none"> • 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 • I may have decreased muscle mass and strength in the upper body • My skin may become softer |
| | <p>Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.</p> |
| | <p>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.</p> |

Risks of Feminizing Medications

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

Risks of Estrogen

| Patient | Statement |
|---------|--|
| | <p>Estrogen SHOULD NOT be used by anyone who has:</p> <ul style="list-style-type: none"> • Any estrogen-dependent cancer • 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 |
| | <p>Estrogen should be used WITH CAUTION and only after a full discussion of risks by anyone who:</p> <ul style="list-style-type: none"> • Has a family history of breast cancer or other cancers that grow more quickly when estrogens are present • Has a family history of heart disease |

| | |
|--|--|
| | <ul style="list-style-type: none"> • Has diabetes • Has chronic hepatitis or other liver disease • Has high levels of cholesterol • Has migraines or seizures • Is obese • Smokes cigarettes or uses tobacco products |
| | <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"> • Chronic problems with veins in the legs, which may require surgery • Heart attack which may cause permanent heart damage or death • Pulmonary embolism (blood clot in the lungs), which may cause permanent lung damage or death • Stroke, which may cause permanent brain damage or death |
| | <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)

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

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

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. |

| | |
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| | <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">• Monthly breast self-examination (report any new lumps to the prescribing physician)• Regular age-appropriate breast mammograms• Regular age-appropriate prostate examinations• Appropriate immunizations• Regular STI screening depending on my level of risk• HIV prevention depending on my level of risk• Regular physical activity, including resistance exercise for bone health• Healthy eating• Quitting smoking |
| | <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)

Patient's signature (required)

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