

**Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide) N/A**

<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 lightheadedness</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><del>Taking Bicalutamide may cause numerous side effects which should be reported to your prescribing physician, including:</del></p> <ul style="list-style-type: none"> <li><del>• Hot flashes or flushing</del></li> <li><del>• Bone, back, or pelvic pain</del></li> <li><del>• Muscle weakness</del></li> <li><del>• Muscle or joint pain</del></li> <li><del>• Headaches</del></li> <li><del>• Shortness of breath</del></li> <li><del>• Chest pain</del></li> <li><del>• Elevated blood pressure</del></li> <li><del>• Swelling of the hands, feet, ankles, or lower legs</del></li> <li><del>• Cough</del></li> <li><del>• Constipation</del></li> <li><del>• Nausea</del></li> <li><del>• Vomiting</del></li> <li><del>• Abdominal pain</del></li> <li><del>• Diarrhea</del></li> <li><del>• Gas</del></li> <li><del>• Changes in weight (loss or gain)</del></li> <li><del>• Loss of appetite</del></li> </ul>

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

\_\_\_\_\_  
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

## Masculinizing Medications for Patients with Gender Dysphoria

### Patient Information and Informed Consent

The Endocrine Society and WPATH have published guidelines on the medical treatment of people with gender dysphoria. These are based on very limited, low-quality research and mostly based on expert opinions. There are conflicting results- some have studies have shown improvements seen in some patient's psychological functioning and other studies have not shown significant benefits. There is also limited data on the long-term effects of treatment.

The purpose of this form is to inform you of the risks and benefits and to provide an open dialogue with your physician about your individual risks based on your family and medical history. 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.

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

One option available is psychological therapy with a mental health 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.

#### **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.~~ HRT will require taking testosterone. Testosterone does not have U.S. Food and Drug Administration (FDA) approval to be used for gender dysphoria and is considered "off

label". Off-label prescribing is when a medical provider prescribes a drug that the U.S. Food and Drug Administration (FDA) has approved to treat a condition different than your condition. This practice is legal and common, but you must be informed that the medication is off-label. The medicine and dose that is recommended should follow the Endocrine Society guidelines. However, these suggestions are based on replacing testosterone in biological males who do not make testosterone and require testosterone to go through puberty or maintain normal testosterone levels. Further research studies are needed to support the timing, dosing, and type of administration of HRT for gender dysphoria.

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.

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**What are the expected changes on masculinising hormone therapy and how long will it take?**

*Typical changes from Testosterone (varies from person to person)*

Effect	Onset	Maximum
Skin oiliness/acne	1-6 mo	1-2 y
Facial/body hair growth	6-12 mo	4-5 y
Scalp hair loss	6-12 mo	
Increased muscle mass/strength	6-12 mo	2-5 y
Fat redistribution	1-6 mo	2-5 y
Cessation of menses	1-6 mo	
Clitoral enlargement	1-6 mo	1-2 y
Vaginal atrophy	1-6 mo	1-2 y
Deepening of voice	6-12 mo	1-2 y

The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the minor's prescribing physician to make sure that there are no negative medical or mental health effects.

**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 ~~should~~**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 5α-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 5α-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 5α-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.~~

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**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.

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 3-126 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; Screening for osteoporosis should be conducted in those who stop testosterone treatment, are not compliant with hormone therapy, or who develop risks for bone loss,~~
5. ~~5. If cervical tissue is present, monitoring as recommended by the American College of Obstetricians and Gynecologists.~~
- 4-6. ~~Conduct sub- and periareolar annual breast examinations if mastectomy performed. If mastectomy is not performed, then consider mammograms as recommended by the American Cancer Society.~~
- 5-7. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
- 6-8. 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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**Summary of Testosterone Benefits and Risk**

BENEFITS	RISKS
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<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>
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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 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 <u>for an individual</u> .
	The following changes are likely to be permanent even if testosterone is discontinued: <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> </ul>

	<ul style="list-style-type: none"> <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 <del>will likely be permanent, but may</del> 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>
	<p>This treatment will not change the individual’s <del>biological sex or</del> chromosomes (XX).</p>
	<p>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.</p>
	<p>Some aspects of my body will not change:</p> <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>
	<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><del>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.</del></p>

**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>
	<p>It should be used <b>WITH CAUTION</b> and only after a full discussion of risks by anyone who:</p> <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 <del>w</del> may <del>ill</del> not prevent serious psychiatric events, including suicide.
	<p>Taking more testosterone than prescribed:</p> <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>
	<p>Taking testosterone can cause changes that increase the risk of heart disease. These changes include:</p> <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.



	<p>Taking testosterone <del>can cause or worsens migraines, or cause headaches.</del>                  This could be a sign of increase red blood cell count, so I agree to inform my provider if I start having headaches or worsening of migraines.</p>
	<p>Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.</p>

**Risks of Finasteride**

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



**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 Surgical Treatment for Adults with Gender Dysphoria

### Patient Information and Informed Consent

The Endocrine Society and WPATH have published guidelines on the medical treatment of people with gender dysphoria. These are based on very limited, low quality research and mostly based on expert opinions. There are conflicting results- some have studies have shown improvements seen in some patients' psychological functioning in some patients and other studies have not shown significant benefits.

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. New techniques develop overtime. 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.



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 recommend 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.

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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?

All surgeries carry risk and potential complications that 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
- Blood clot (DVT, pulmonary embolism or stroke)
- Side effects of anesthesia, including death

For genital surgery, other complications can include:

- Changes in sexual sensation
- Diminishment of bladder function
- Problems with urination

What happens after surgery to treat gender dysphoria?

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

- **Cheek and nose surgery:** ~~Most~~ swelling ~~fades~~ lasts for ~~2-4~~ around two to four weeks but can last up to 4 months.
- **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 ~~but make take up to 6 months to fully recover~~ with physical limitations ~~lasting at least one month, based on your healing.~~
- **~~Genital~~Bottom surgery:** Most people do not resume usual activities until at least six weeks after surgery and ~~frequent~~ weekly follow-up visits with your surgeon for several months ~~may~~ will be necessary.

**When should I see my surgeon?**

You will be scheduled for routine follow up based on your procedure.

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~~However~~After surgery, you should informsee your surgeon- if you experience:

- Bleeding for more than a few days or excessive bleeding.
- Pain that does not go away after several weeks.
- Signs of infection, such as a wound that changes color or does not heal or fever.
- Signs of a blood clot such as pain or swelling in one leg, chest pain, difficulty breathing or signs of a stroke (headaches, change in vision, weakness/numbness in arms or legs, slurred speech).

**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.
	<del>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.</del>
	<del>I understand that if I have my breasts removed that breast feeding will never be possible.</del>
	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 <del>or mastectomy</del> ; including genetic mutations (e.g., BRCA1, BRCA2), family history, age, radiation, exposure to estrogen, and the amount of breast tissue, <del>anticipated to remain after surgery.</del>
	<del>I understand that if I undergo metoidioplasty/phalloplasty I will need lifelong urological treatment.</del>
	<del>I understand that complications following metoidioplasty/phalloplasty include:</del> <ul style="list-style-type: none"> <li><del>• urinary tract strictures and fistulas</del></li> <li><del>• mucoceles due to vaginal remnant</del></li> <li><del>• hair growth within the neourethra</del></li> <li><del>• compromised sexual function including absent tactile and/or erogenous sensation, difficulties achieving orgasm</del></li> <li><del>• complications with penile prosthetics</del></li> </ul>
	I understand that if I undergo vaginoplasty I will need lifelong treatment with my surgeon, primary care physician, and/or gynecologist.
	I understand that if I undergo vaginoplasty, complications can include: <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> <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 <del>may</del> 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.
	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: <ul style="list-style-type: none"> <li>• <del>cer</del>vical/prostate screening tests at appropriate intervals as recommended by my doctor</li> <li>• regularly checking my breasts for lumps, <del>even if I have had a mastectomy</del></li> </ul>

- |  |   |
|--|---|
|  | <ul style="list-style-type: none"><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:**

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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

## Masculinizing Surgical Treatment for Adults with Gender Dysphoria

### Patient Information and Informed Consent

~~The Endocrine Society and WPATH have published guidelines on the medical treatment of people with gender dysphoria. These are based on very limited, low quality research and mostly based on expert opinions. There are conflicting results- some have studies have shown improvements seen in some patients' psychological functioning and other studies have not shown significant benefits.~~

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.~~

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

<b>Patient</b>

- ~~o **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 other tissues, such as the colon, to create a vagina.~~
- o **Phalloplasty:** This surgery involves a multi-staged procedure for the creation of a penis which can also include a urinary channel to allow urination as well as a scrotum. This may also include the obliteration of the vaginal cavity with closure. These can be performed in a number of ways and stages depending on the patient's clinical needs and desired outcomes. The techniques used in staging these procedures also vary, 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 performed.~~ The creation of the penis is performed with use of tissue from other parts of the body, which could include but not limited to, more commonly the radial forearm free flap, or anterolateral thigh flap, and latissimus dorsi (MLD) (back) flap. Prosthetics such as silicone or saline testicles can be placed as well as both malleable inflatable and inflatable penile prosthetics, ~~in the final stage.~~
- o **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.~~
- o **Hysterectomy:** Removal of the uterus and cervix via laparoscopic or vaginal techniques.
- o **Salpingo-oophorectomy:** Removal of the fallopian tubes and ovaries.
- o **Vaginectomy:** Obliteration of the vaginal canal and opening.

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**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 recommend 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?

All surgeries carry risk and 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
- Blood clot (DVT, pulmonary embolism or stroke)
- Side effects of anesthesia, including death

For genital surgery, other complications can include:

- Changes in sexual sensation
- Diminishment of bladder function
- Problems with urination

What happens after surgery to treat gender dysphoria?

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

- **Check and nose surgery:** ~~Most swelling fades/lasts for 2-4 around two to four weeks but can last up to 4 months.~~
- **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 but make take up to 6 months to fully recover with physical limitations ~~lasting at least one month based on your healing.~~

- **Genital/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?**

You will be scheduled for routine follow up based on your procedure.

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However~~After surgery,~~ you should inform~~see~~ your surgeon if you experience:

- Bleeding for more than a few days or excessive bleeding.
- Pain that does not go away after several weeks.
- Signs of infection, such as a wound that changes color or does not heal or fever.
- Signs of a blood clot such as pain or swelling in one leg, chest pain, difficulty breathing or signs of a stroke (headaches, change in vision, weakness/numbness in arms or legs, slurred speech).

**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.

	<del>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.</del>
	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 <u>follow up treatment</u> .
	I understand that complications following metoidioplasty/phalloplasty include: <ul style="list-style-type: none"> <li>• urinary tract strictures and fistulas</li> <li>• mucoceles 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>
	<del>I understand that if I undergo vaginoplasty I will need lifelong treatment with my surgeon, primary care physician, and/or gynecologist.</del>
	I understand that if I undergo vaginoplasty, complications can include: <ul style="list-style-type: none"> <li>• <del>the formation of granulation tissue</del></li> <li>• <del>intravaginal hair growth</del></li> <li>• <del>delayed wound healing and/or wound disruption</del></li> <li>• <del>introital stenosis (closing, narrowing, or closure)</del></li> <li>• <u>painful sex</u></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 <u>may will</u> 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.
	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: <ul style="list-style-type: none"> <li>• cervical/<del>prostate</del>-screening tests <u>if warranted</u> at appropriate intervals as recommended by my doctor</li> </ul>

	<ul style="list-style-type: none"><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:**

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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

---

**From:** Allen Grossman <[a.grossman@gfblawfirm.com](mailto:a.grossman@gfblawfirm.com)>  
**Sent:** Thursday, October 26, 2023 11:40 AM  
**To:** Vazquez, Paul <[Paul.Vazquez@flhealth.gov](mailto:Paul.Vazquez@flhealth.gov)>  
**Cc:** Christopher Dierlam <[Christopher.Dierlam@myfloridalegal.com](mailto:Christopher.Dierlam@myfloridalegal.com)>; Donna McNulty <[Donna.McNulty@myfloridalegal.com](mailto:Donna.McNulty@myfloridalegal.com)>; Cassandra Fullove <[Cassandra.Fullove@myfloridalegal.com](mailto:Cassandra.Fullove@myfloridalegal.com)>  
**Subject:** RE: Notice of Rule Development for Sex Reassignment Rules

EXTERNAL EMAIL: DO NOT CLICK links or open attachments unless you recognize the sender and know the content is safe.

Paul,

On behalf of hospital clients, I had previously raised some issues in regard to the emergency rules on sex reassignment. As the Boards initiate permanent rulemaking, I have been asked to bring these issues back to the attention of the Joint Committee and the Boards.

There were a couple of issues regarding typos on the Adult Surgery Informed consent form. On page 2., under the options to surgery, there is a reference to mental health treatment that uses the word "recommend" when it should be "recommended". Also, on page 5., the first item in the last box refers to "cervical/prostrate" when it should be "cervical/prostate". Finally, on page 6., there are two lines identified as being for patient signature and one of them should be for the patient's printed name.

In addition, my clients are requesting further consideration of carveout language in the rules for patients who are hospitalized while already involved in treatment in compliance with statute and rules. The hospitals are concerned about whether and how to go about allowing/providing the same treatment during the hospital stay. Hospitals routinely take steps to avoid interruption of ongoing treatment or care for hospitalized patients who might be harmed by such interruption even though maintenance of such ongoing treatment or care would not impact whatever treatment is required for the condition that caused the patient to be hospitalized.

I have attached proposed draft language for consideration by the Joint Committee and the Boards.

Thank you very much for adding these suggestions to the consideration of the permanent rules.

Allen R. Grossman  
Grossman Furlow and Bayó, L.L.C.  
2022-2 Raymond Diehl Road  
Tallahassee, Florida 32308  
(850) 385-1314



(850) 385-4240 (fax)

[www.gfblawfirm.com](http://www.gfblawfirm.com)

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If this communication was received in error we apologize for the intrusion. Please notify us by reply e-mail or by telephone at (850) 385-1314 and delete the original message without reading same. Nothing in this e-mail message shall, in and of itself, create an attorney-client relationship with the sender.

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64B8ER23-7/64B15ER23-9 (64B8-9.0191/65B15-14.0141) Minors

(1)(a)

(b) A patient being treated with sex reassignment prescriptions prior to a hospitalization may continue the same treatment while hospitalized and treating physicians in the hospital may order such medication and its administration by personnel authorized to dispense and administer medications in the hospital. The ordering or administration of such medication during the hospitalization shall not be considered the initiation of a new treatment and does not require compliance with the informed consent process otherwise set forth in these rules.

64B8ER23-11/64B15ER23-12 (64B8-9.0192/64B15-14.0142) Adults

(3) A patient being treated with sex reassignment prescriptions prior to a hospitalization may continue the same treatment while hospitalized and treating physicians in the hospital may order such medication and its administration by personnel authorized to dispense and administer medications in the hospital. The ordering or administering of such medication for administration during the hospitalization shall not be considered the initiation of a new treatment and does not require compliance with the informed consent process otherwise set forth in these rules.

**From:** [hatsoffforhumanrights=comcast.net@mg.gospringboard.io](mailto:hatsoffforhumanrights=comcast.net@mg.gospringboard.io) on behalf of [Frank Cummings](#)  
**To:** [BOM Public Comment](#)  
**Subject:** Reject rules to restrict access to gender affirming care  
**Date:** Monday, September 25, 2023 9:26:49 PM

You don't often get email from [hatsoffforhumanrights@comcast.net](mailto:hatsoffforhumanrights@comcast.net). [Learn why this is important](#)

**EXTERNAL EMAIL: DO NOT CLICK** links or open attachments unless you recognize the sender and know the content is safe.

Dear

I am writing to you today to urge the Florida State Board of Medicine to reject rule 64B8-9.019 and the Florida State Board of Osteopathic Medicine to reject rule 64B15-14.014. Both proposed rules cover Standards of Practice for the Treatment of Gender Dysphoria in Minors, to restrict access to gender-affirming healthcare.

Care providers, doctors, and leading medical associations have been clear that gender-affirming care is safe, effective, evidence-based, and lifesaving.

The nation's leading health organizations support gender-affirming care for transgender and gender non-conforming people, including the American Academy of Pediatrics; the American Medical Association; The American College of Obstetricians and Gynecologists; The American College of Physicians; The American Psychiatric Association; The American Psychological Association; The American Academy of Family Physicians; The Endocrine Society; The Pediatric Endocrine Society; American Nurses Association; American Public Health Association; American Heart Association; National Association of Social Workers; World Medical Association; and The World Professional Association for Transgender Health, among others.

There is overwhelming evidence to support the positive mental health impacts of gender-affirming medical care for transgender adolescents - including in some of the very studies cited by the DOH and Board of Medicine. Prohibiting social transition is clear government intrusion on personal and parental decision-making. Numerous studies have found that after social transition, transgender youth report similar mental health levels to the general youth population, eliminating mental health disparities typically seen. When transgender youth are affirmed by people around them, reported rates of depression and suicidality drop significantly. This rule will deny them this life-saving treatment.

The Florida State Board of Medicine and the Florida Board of Osteopathic Medicine must reject proposed policies like these that are not grounded in science and research and are clearly based on prejudice and political agendas. The evidence is clear: denying transgender youth the ability to access critical healthcare is dangerous and life-threatening.

I urge you to reject these rules.

Sincerely,

Frank Cummings



**From:** [deloresbaker5000@gmail.com](mailto:deloresbaker5000@gmail.com)@mq.gospringboard.io on behalf of [Kermit Ty Poulson](#)  
**To:** [BOM Public Comment](#)  
**Subject:** Reject rules to restrict access to gender affirming care  
**Date:** Thursday, October 5, 2023 11:31:58 AM

You don't often get email from [deloresbaker5000@gmail.com](mailto:deloresbaker5000@gmail.com). [Learn why this is important](#)

**EXTERNAL EMAIL: DO NOT CLICK** links or open attachments unless you recognize the sender and know the content is safe.

Dear

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The Florida State Board of Medicine and the Florida Board of Osteopathic Medicine must reject proposed policies like these that are not grounded in science and research and are clearly based on prejudice and political agendas. The evidence is clear: denying transgender youth the ability to access critical healthcare is dangerous and life-threatening.

I urge you to reject these rules.

Sincerely,

Kermit Ty Poulson



**From:** [monsterclaire@gmail.com](mailto:monsterclaire@gmail.com)@mq.gospringboard.io on behalf of [CLAIRE MONESTERIO](#)  
**To:** [BOM Public Comment](#)  
**Subject:** Reject rules to restrict access to gender affirming care  
**Date:** Friday, October 20, 2023 12:03:05 PM

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**EXTERNAL EMAIL: DO NOT CLICK links or open attachments unless you recognize the sender and know the content is safe.**

Dear

I am writing to you today to urge the Florida State Board of Medicine to reject rule 64B8-9.019 and the Florida State Board of Osteopathic Medicine to reject rule 64B15-14.014. Both proposed rules cover Standards of Practice for the Treatment of Gender Dysphoria in Minors, to restrict access to gender-affirming healthcare.

Care providers, doctors, and leading medical associations have been clear that gender-affirming care is safe, effective, evidence-based, and lifesaving.

The nation's leading health organizations support gender-affirming care for transgender and gender non-conforming people, including the American Academy of Pediatrics; the American Medical Association; The American College of Obstetricians and Gynecologists; The American College of Physicians; The American Psychiatric Association; The American Psychological Association; The American Academy of Family Physicians; The Endocrine Society; The Pediatric Endocrine Society; American Nurses Association; American Public Health Association; American Heart Association; National Association of Social Workers; World Medical Association; and The World Professional Association for Transgender Health, among others.

There is overwhelming evidence to support the positive mental health impacts of gender-affirming medical care for transgender adolescents - including in some of the very studies cited by the DOH and Board of Medicine. Prohibiting social transition is clear government intrusion on personal and parental decision-making. Numerous studies have found that after social transition, transgender youth report similar mental health levels to the general youth population, eliminating mental health disparities typically seen. When transgender youth are affirmed by people around them, reported rates of depression and suicidality drop significantly. This rule will deny them this life-saving treatment.

The Florida State Board of Medicine and the Florida Board of Osteopathic Medicine must reject proposed policies like these that are not grounded in science and research and are clearly based on prejudice and political agendas. The evidence is clear: denying transgender youth the ability to access critical healthcare is dangerous and life-threatening.

As a member of our shared global community, I honor all the natural differences between all living species. As a curious, truth-seeking human being, I have learned that science and the scientific method are our species' best and most effective means by which to measure cause, effect, and correlation. I understand that "progress" is just another word for growth and evolution, the inevitable and sacred practices of expanding our understanding of the world we live in and the lives with whom we cohabitate. Science tells us that gender-affirming treatments save lives, the lives of children.

Loving and accepting people—especially our youth—as who they are, seeing them and honoring their truths has been scientifically proven to reinforce the necessary components for developing a healthy identity as both an individual and as a global community member. Love and acceptance in their truest forms do not hurt or punish or fear, they do not control. Love and acceptance only facilitate and scaffold the climb for our next generation’s ascension to a greater comprehension of this precious shared existence.

Listen to the youth.

Love thy neighbor.

If fear is holding you back from understanding this particular shape of the human struggle, please find a safe adult and ask them to gently enlighten you: there are no monsters hiding behind these young people, just as there were no monsters hiding in Elvis’ hip gyrations. Just listen to the music, the stories these young people have to share with us.

Operate from kindness.

Let people live their lives.

What would Jesus do?

He probably would have washed their feet and said, “I love you, child of God.”

I urge you to reject these rules.

Sincerely,

CLAIRE MONESTERIO



**From:** [caradomenici@gmail.com](mailto:caradomenici@gmail.com)@mq.gospringboard.io on behalf of [Cara Domenici](#)  
**To:** [BOM Public Comment](#)  
**Subject:** Reject rules to restrict access to gender affirming care  
**Date:** Monday, October 30, 2023 10:23:29 AM

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I urge you to reject these rules.

Sincerely,

Cara Domenici

**From:** [hill\\_alexandra@hotmail.com](mailto:hill_alexandra@hotmail.com) on behalf of [Alexandra Hill](#)  
**To:** [BOM Public Comment](#)  
**Subject:** Reject rules to restrict access to gender affirming care  
**Date:** Thursday, November 9, 2023 2:29:19 PM

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I urge you to reject these rules.

Sincerely,

Alexandra Hill



 Site Header Image



## **AAP reaffirms gender-affirming care policy, authorizes systematic review of evidence to guide update**

August 4, 2023

Alyson Sulaski Wyckoff, Associate Editor

Article type: [News](#)

Topics: [Advocacy](#), [Diversity, equity and inclusion](#)

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The AAP Board of Directors voted to reaffirm the 2018 AAP policy statement on gender-affirming care and authorized development of an expanded set of guidance for pediatricians based on a systematic review of the evidence.

An updated policy statement, plus companion clinical and technical reports, will reflect data and research on gender-affirming care since the original policy was released and offer updated guidance. The board recognized the value of additional detail with five more years of experience since the 2018 policy statement was issued.

The decision to authorize a systematic review reflects the board's concerns about restrictions to access to health care with bans on gender-affirming care in more than 20 states.

AAP CEO/Executive Vice President Mark Del Monte, J.D., is speaking today at the AAP Leadership Conference in Itasca, Ill.

He emphasizes that policy authors and AAP leadership are confident the principles presented in the original policy, [Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents](#), remain in the best interest of children.

As part of its mission, the AAP will continue to “ensure young people get the reproductive and gender-affirming care they need and are seen, heard and valued as they are,” Del Monte said.

The board reviews evidence and considers policy renewal on a regular schedule as authorizations expire. Based on the continuing review, the board reaffirmed the current guidance on transgender care until there is an updated version.

To ensure the policy update process is transparent and inclusive, the AAP will invite members and other stakeholders to share input.

The AAP and other major medical organizations — including the American Medical Association, the American College of Obstetricians and Gynecologists and the World Health Organization — support giving transgender adolescents access to the health care they need.

The AAP opposes any laws or regulations that discriminate against transgender and gender-diverse individuals, or that interfere in the doctor-patient relationship.

**Additional Leadership Conference coverage**

- [Leadership Conference: AAP pledges to address payment issues, support pediatrician wellness](#)
- [Leadership Conference: Top resolution calls for federal protections of gender-affirming care for patients, doctors](#)
- [Reform humanitarian system for migrant children: Leadership Conference speaker](#)



Interim Clinical Policy:

## **Puberty suppressing hormones (PSH) for the purpose of puberty suppression for children and adolescents who have gender incongruence/dysphoria [1927]**

### **Commissioning position**

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The proposal is: Puberty suppressing hormones (PSH) are not recommended to be available as a routine commissioning treatment option for treatment of children and adolescents who have gender incongruence/dysphoria within the criteria set out in this document.

This is an interim clinical policy which will be kept under review in light of any further emerging evidence and recommendations from the independent Cass Review and its research programme.

### **Background**

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Gender incongruence/dysphoria is a condition where a person experiences discomfort or distress that is caused by a discrepancy between a person's gender identity (how they see themselves<sup>1</sup> regarding their gender) and that person's natal sex (and the associated gender role, and/or primary and secondary sex characteristics). Diagnostic approaches have been described with reference to Diagnostic and Statistical Manual of Mental Disorders, version 5 published in 2013 (gender dysphoria) and International Statistical Classification of Diseases and Related Health Problems version 11 effective 2022 (gender incongruence).

The reason why some people experience gender incongruence/dysphoria is not fully understood and it is likely that the development of gender identity is multifactorial and influenced by both biological and social factors. Gender variant behaviours may start between ages 3 and 5 years, the same age at which most typically developing children begin showing gendered behaviours and interests (Fast et al, 2018). Gender atypical behaviour is common among young children and may be part of normal development (Young et al, 2019). Children who meet the criteria for gender incongruence/dysphoria may or may not continue to experience the conflict between their physical gender and the one with which they identify into adolescence and adulthood (Ristori et al, 2016).

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<sup>1</sup> "Gender refers to the roles, behaviours, activities, attributes and opportunities that any society considers appropriate for girls and boys, and women and men." [source: WHO website Health Topics: Gender, at <https://www.who.int/health-topics/gender> ]



Gender incongruence/dysphoria can become more distressing in adolescence due to the pubertal development of secondary sex characteristics and increasing social divisions between genders. Some studies have found that young people with gender incongruence/dysphoria may present to gender identity development services with a range of associated difficulties e.g., bullying, low mood / depression and self-harm and suicidality.

PSH competitively block puberty hormone receptors to prevent the spontaneous release of two puberty inducing hormones, Follicular Stimulating Hormone (FSH) and Luteinising Hormone (LH) from the pituitary gland. This arrests the progress of puberty, delaying the development of secondary sexual characteristics. In England, the puberty suppressor triptorelin (a synthetic decapeptide analogue of a natural puberty hormone, which has marketing authorisations for the treatment of prostate cancer, endometriosis and precocious puberty) is one of the puberty suppressing hormones used for this purpose. The use of triptorelin for children and adolescents with gender incongruence/dysphoria is off-label.

In January 2020, a policy working group (PWG) was established by NHS England to undertake a review of the published evidence on the use of PSH. As part of this NHS England-led process, the National Institute for Health and Care Excellence (NICE) was commissioned to review the published evidence. Nine observational studies were included in the evidence review (NICE 2020). Overall, there was no statistically significant difference in gender dysphoria, mental health, body image and psychosocial functioning in children and adolescents treated with PSH (2020). The quality of evidence for all these outcomes was assessed as very low certainty using modified GRADE. There remains limited short-term and long-term safety data for PSH. PSH may reduce the expected increase in lumbar or femoral bone density during puberty. A re-run of the search was undertaken in April 2023 to capture literature published after the NICE evidence review in 2020. Nine further studies were identified.

## **Current treatments**

Treatment of individuals with gender incongruence/dysphoria is recommended to be tailored to the specific needs of individual patients and aims to ameliorate the potentially negative impact of gender incongruence/dysphoria on general developmental processes, to support young people and their families in managing the uncertainties inherent in gender identity development and to provide ongoing opportunities for exploration of gender identity (Ristori et al, 2016).

The primary intervention will focus on psychosocial and psychological support; for some individuals, the use of PSH in adolescence to suppress puberty may be considered; this may be followed later with gender-affirming hormones of the desired sex (NHS England, 2013). If individuals fulfil additional criteria, they may have various types of gender affirming surgery from the age of 18 years through adult gender identity clinics (NHS England, 2013).

## **What we have decided**

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NHS England has carefully considered the evidence review conducted by NICE (2020) to treat children and young people who have gender dysphoria with PSH and has identified and reviewed any further published evidence available to date.



We have concluded that there is not enough evidence to support the safety or clinical effectiveness of PSH to make the treatment routinely available at this time. NHS England recommends that access to PSH for children and young people with gender incongruence/dysphoria should only be available as part of research.

On an exceptional, case by case basis any clinical recommendation to prescribe PSH for the purpose of puberty suppression outside of research and in contradiction to the routine commissioning position set out in this policy must be considered and approved by a national multidisciplinary team.

For children and young people who, at the point the proposed clinical commissioning policy takes effect, have been referred into an endocrine clinic but have not yet been assessed by a consultant endocrinologist for suitability of PSH, or who are already administering PSH through an NHS prescription, there is an expectation of consideration for treatment that would need to be clinically managed. In these cases it would be for the consultant endocrinologist to consider with the child or young person and their family whether to continue with off-label prescribing within the current clinical pathway.

The use of PSH as a precursor to a moving onto gender affirming hormones is covered by a separate clinical policy.

## Links and updates to other policies

NHS England has no other policies relating to the sole use of PSH for the treatment of children and adolescents who have gender incongruence/dysphoria.

This document relates to the specialised service for Children and Young People with Gender Incongruence:

[Gender identity development service for children and adolescent service specification](#)

This document is linked to the revised policy for gender affirming hormones.

## Policy review date

This document will be reviewed when information is received which indicates that the policy requires revision. If a review is needed due to a new evidence base then a new Preliminary Policy Proposal needs to be submitted by contacting [england.CET@nhs.net](mailto:england.CET@nhs.net).

## Equality statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are

provided in an integrated way where this might reduce health inequalities.

## Definitions

Gender incongruence	Gender incongruence is where a person experiences discomfort or distress because there is a mismatch between their experienced gender as compared with their assigned sex and its associated physical primary and secondary sex characteristics.
Puberty suppressing hormones	Synthetic (man-made) hormones that suppress the hormones naturally produced by the body and in doing so, suppress puberty, with the aim of reducing the level of puberty-related anxiety in an individual with gender incongruence/dysphoria.
Gender affirming hormones	Gender affirming hormones (also known as feminising/masculinising hormones and previously referred to as cross sex hormones) are hormones prescribed for an individual that are consistent with the experienced gender as compared to the assigned gender.
Diagnostic and Statistical Manual of Mental Disorders	The American diagnostic manual used to diagnose mental health disorders, and commonly used in UK practice.
GRADE	Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) is a transparent framework for developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations.