Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with providing puberty suppression treatment to the minor.

Effects of Treatment of Suppression of Puberty

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Puberty blockers are used to temporarily suspend or block the physical changes of puberty for minors
			If a minor stops treatment with puberty blockers, in a few months their body may restart the changes of puberty at the developmental stage they were before starting medication. However, the effects of these medications could be permanent.
			It can take several months for the medications to be effective. It cannot be predicted how quickly or slowly or even if a minor's body will respond to the medication.
			Taking these medications, will cause a minor's body to stop producing testosterone or estrogen.
			These medications will not change a minor's sex (chromosomes), and it will not change a minor's internal or external reproductive structures.
			Puberty blockers can interfere with fertility.
			Puberty blockers do not affect the minor's ability to contract a sexually transmitted infection.
			The use of puberty blockers in minors for the treatment of gender dysphoria is an off-label use. This means these medications are not approved by the FDA to treat this specific diagnosis.

Risks of Treatment of Suppression of Puberty

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The adverse effects and safety of puberty blockers used for the treatment of gender dysphoria in minors is not well known.
			Treatment with puberty blockers will not prevent serious psychiatric events such as a suicide.
			Treatment with puberty blockers may cause new or worsened psychiatric problems, including: • Crying • Irritability • Restlessness (impatience)

			• Anger • Acting aggressive
			It is the responsibility of the parent/guardian to notify the prescribing physician if the minor has any new or worsening physical or psychiatric problems while taking this medication.
			During the first 4 weeks of treatment, puberty blockers can cause an increase in some hormones. During this time, a minor may notice more signs of puberty, including vaginal bleeding.
			Seizures are a risk associated with taking puberty blockers. The risk of seizures may be higher in people who: • Have a history of seizures • Have a history of epilepsy • Have a history of brain or brain vessel (cerebrovascular) problems or tumors • Are taking a medicine that has been connected to seizures, such as bupropion or selective serotonin reuptake inhibitors (SSRIs).
			It is the responsibility of the parent/guardian to immediately notify the appropriate health care providers including the minor's prescribing physician if the minor has a seizure while taking puberty blockers.
			Increased pressure in the fluid around the brain is a risk associated with taking puberty blockers. It is the responsibility of the parent/guardian to notify the minor's prescribing physician if the minor has any of the following symptoms while taking puberty blockers: • Headache • Eye problems including blurred vision, double vision, and decreased eyesight • Eye pain • Ringing in the ears • Dizziness • Nausea
			Puberty blockers should not be used if a minor is: • Allergic to GnRH, GnRH agonist medicines, or Progesterones. • Pregnant or becomes pregnant because puberty blockers can cause birth defects or loss of the baby. It is the responsibility of the parent/guardian to notify the prescribing physician if a minor becomes pregnant while taking puberty blockers.
			The most common side effects of puberty blockers include: • Injection site reactions such as pain, swelling, and abscess which may result in surgery

			• Weight gain • Pain throughout body • Headache • Acne or red, itchy rash and white scales (seborrhea) • Serious skin rash (erythema multiforme) • Mood changes • Swelling of vagina (vaginitis), vaginal bleeding, and vaginal discharge • Upper stomach pain • Diarrhea • Bleeding • Nausea and vomiting • Fever • Itching • Pain in extremities • Rash • Back pain • Ligament sprain • Fracture • Breast tenderness • Difficulty sleeping • Chest pain • Excessive sweating
			Puberty blockers may decrease bone density.
			Minors may grow less than their peers while taking puberty blockers.
			Puberty blockers may cause stalling of typical cognitive or brain development in minors.

Requirements of Treatment of Suppression of Puberty

I understand the following:

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite to receive treatment for puberty suppression.
			The prescribing physician may stop prescribing puberty blockers 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.

			The parent/guardian or the minor can change their mind and stop treatment at any time.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed me about:
   a. the benefits and risks of treatment with puberty blockers;
   b. the possible or likely consequences of treatment with puberty blockers and puberty suppression; 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 puberty blockers. 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 minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for my minor to take, refuse, or postpone using puberty blocking 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 for my minor to begin treatment for suppression of puberty.

_____
Parent/legal guardian's name (required)

_____ _____
Parent/legal guardian's signature (required) Date

Parent/legal guardian's name (optional)

Parent/legal guardian's signature (optional) Date

PRESCRIBING PHYSICIAN SIGNATURE:

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

Prescribing physician's name (required)

Prescribing physician's signature (required) Date

ASSENT OF MINOR:

I have discussed the benefits and risks of treatment to suppress puberty with my prescribing physician and my parent(s) or legal guardian(s), and I wish to receive it.

Minor's name (required)

Minor's signature (required) Date

WITNESS:

Witness printed name

Witness signature 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 and/or adult(s) legally responsible for the minor child 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 Parental Consent and Assent for Minors

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

After your questions or concerns are addressed and you have decided to have the minor start or continue treatment with hormones or hormone antagonists, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

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 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 by minors even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval to be used by minors and its use in this population is considered "off label" because they are not being used for their intended purpose.

Different forms of estrogen are used to feminize one'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.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

DH5080-MQA (Rev. 06/23)
Rules 64B8ER23-7 and 64B15ER23-9

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.

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 minor's 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 a minor's mood. Therefore, minors must be under the care of a licensed mental health care professional while undergoing treatment. This professional can work with the minor, your family and friends, and your school staff.

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

One option available is psychological therapy with a mental health. This is recommended regardless of whether or not the minor 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 the minor's 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.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

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

The specific requirements for a minor 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. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (first stage of puberty), which must be confirmed by a physician;
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;
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing at least every 4 months;
10. X-ray of the hand (bone age) at least once a year if the minor is still growing;
11. Annual bone density scan (DEXA) which will allow monitoring of the minor's bone density (bone strength) during treatment, which can be altered by HRT;
12. Annual mental health assessments by a Board-certified Florida licensed psychiatrist or psychologist; and
13. 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.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

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

Effects of Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Feminizing medications, including estrogen, androgen blockers, or antiandrogens, given singularly or in combination, may be prescribed to make a minor appear less masculine and more feminine
			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 the minor's biological sex or chromosomes.
			If a minor takes estrogen, the following changes in a minor's breasts will occur: • 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 the minor's prescribing physician • The minor's risk of breast cancer may significantly increase
			If a minor takes feminizing medications, the minor's body will make less testosterone, which may affect the minor's sex life in different ways, including: • The minor's testicles may shrink • The minor's penis may never fully develop, particularly if the minor has previously taken puberty blockers • The minor will have fewer spontaneous erections • The minor's sperm may no longer mature causing infertility which may be permanent

			even if treatment is discontinued, the risk of which is increased if the minor took puberty blockers prior to starting feminizing medications • Conversely, it is possible that a minor's sperm could still mature while taking feminizing medications and the minor may cause someone to get pregnant
			To improve the possibility that the minor may have biological children in the future, the options for sperm banking by the minor have been explained.
			If a minor takes feminizing medications, some parts of the minor's body will not change much, including: • If present, the minor's facial hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If present, the minor's body hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If the minor went through puberty and has a deep voice, the pitch of the minor's voice will not rise and the minor's speech patterns will not become more like a woman's • If present, the minor's Adam's apple will not shrink
			Even if a minor stops taking feminizing medications, the following changes may occur: • The minor's body fat may be redistributed with less fat on the abdomen and more on the buttocks, hips, and thighs creating a more female shape • The minor may have decreased muscle mass and strength in the upper body • The minor's skin may become softer
			Mood changes may be caused by these medicines, and the minor will continue therapy with a licensed mental health care professional during treatment.
			Using these medicines to feminize a minor 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 minor's 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 for minors.

Risks of Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The medical effects and the safety of minors taking femininizing medications are not completely known and there may be unknown long-term risks.
			Taking feminizing medications causes changes that other people will notice.
			Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
			The minor must not take more feminizing medication than prescribed. Taking too much medication: • Will increase health risks • Will not make changes happen more quickly or more significantly
			Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Estrogen **SHOULD NOT** be used by anyone who has a history of: • 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

			Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • 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 • 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
			Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • 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
			The risk of blood clots while take estrogen is much greater if the minor smokes cigarettes. The danger is so high that the minor should stop smoking completely while taking estrogen.
			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.
			Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
			Taking estrogen increases the risk of gallstones (stones in the gallbladder). Any long-term abdominal pain experience by the minor while taking estrogen must be reported to the minor's prescribing physician.
			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 the

			minor's vision and cause headaches if not treated properly. Any changes in the minor's 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 the minor's prescribing physician.
			Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to the minor's prescribing physician.
			Taking estrogen can cause migraines or can make them worse if the minor already has them.
			Taking estrogen can cause hot flashes.
			Taking estrogen can cause the minor to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • Increase the amount of urine produced by the minor's kidneys, making it necessary to urinate more frequently • Increase the minor's thirst • Increase the minor's risk of dehydration, which can be evidenced by less frequent urination than usual, dark and strong-smelling urine, thirst, and light-headedness
			Taking Spironolactone affects the balance of potassium in the kidneys, which may result in the minor experience high potassium levels resulting in: • Changes in heart rhythms that may be life threatening • Low blood pressure, which can cause: o Fatigue o Lightheadedness o Tingling feelings o Muscle weakness o Shortness of breath

			• The minor's need for regular blood tests to monitor risks while on the medication
			Taking Bicalutamide may cause numerous side effects which should be reported to the minor's prescribing physician, including: • 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 • 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

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite for a minor 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.
			The parent/guardian or the minor can change their mind and stop treatment at any time although some effects of HRT may be permanent.

Prevention of Complications while under Treatment with Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The undersigned parent(s)/legal guardian(s) agree(s) to notify the minor's prescribing physician if the minor suffers from any side effects during treatment or is unhappy with the treatment in any way, particularly if the parent(s)/legal guardian(s) has/have any concerns that the minor has worsening signs of depression or anxiety or expresses a desire harm themselves or attempt suicide.
			The prescribing physician is required to monitor the minor for any side effects during treatment and may refer the minor to another physician or specialist for treatment. The undersigned

			parent(s)/legal guardian(s) agree(s) to take the minor to physicians and specialists as recommended by the prescribing physician.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's 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 minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for the minor 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 for the minor to begin treatment with feminizing medications.

_____

Parent/legal guardian's printed name (required)

_____ _____

Parent/legal guardian's signature (required) Date

Parent/legal guardian's printed name (optional)

Parent/legal guardian's signature (optional) 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

ASSENT OF A MINOR:

I have discussed the benefits and risks of treatment with feminizing medications with my prescribing physician, parent(s) or legal guardian(s), and I wish to receive them.

Minor's printed name (required)

Minor'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 and/or adult(s) legally responsible for the minor child 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 Parental Consent and Assent for Minors

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

After your questions or concerns are addressed and you have decided to have the minor start or continue treatment with hormones or hormone antagonists, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

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 minors, even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval to be used by minors and its use in this population is considered "off label" because they are not being used for their intended purpose.

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

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

DH5081-MQA (Rev. 06/23)
Rules 64B8ER23-7 and 64B15ER23-9

What are my other options if I do not wish to start or continue my minor's treatment with hormones or hormone antagonists?

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

How is testosterone taken?

Testosterone is usually injected every one to four weeks. Typically, it is not given in pill form because the body may not absorb it properly which 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). A minor taking testosterone may experience unwanted swings in hormone levels based on the amount and how often doses are given.

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 minor's prescribing physician to make sure that there are no negative medical or mental health effects.

Both testosterone and the treatment process can affect a minor's mood. Therefore, minors must be under the care of a licensed mental health care professional while undergoing treatment. This professional can work with the minor, your family and friends, and your school staff.

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 the minor's 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.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

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

The specific requirements for a minor 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. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (first stage of puberty), which must be confirmed by a physician;
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;
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing, at least every 4 months;
10. X-ray of the hand (bone age) at least once a year if the minor is still growing;
11. Annual bone density scan (DEXA) which will allow monitoring of the minor's bone density (bone strength) during treatment, which can be altered by HRT
12. Annual mental health assessments by a Board-certified Florida licensed psychiatrist or psychologist; and
13. 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.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Summary of Testosterone Benefits and Risks

BENEFITS	RISKS
• 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	• 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 such as 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.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with a minor taking testosterone.

Masculinizing Effects

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Testosterone may be prescribed to make a minor 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.
			Changes from testosterone may not be complete for 2 to 5 years after treatment is started.
			The following changes are likely to be permanent even if testosterone is discontinued: • 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
			The following changes could be permanent, but may improve if I stop taking testosterone: • 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 minor's biological sex or chromosomes.
			Testosterone may reduce the minor's ability to become pregnant, but it will not eliminate the risk of pregnancy. A person can become pregnant while on testosterone. I agree to inform the minor's prescribing physician if the minor becomes pregnant.
			Some aspects of the minor's body will not change: • Fat loss may make breasts appear slightly smaller (if present) • The voice will deepen, but other aspects of the way the minor speaks may not sound more masculine
			Mood changes may be caused by these medicines, and the minor will continue therapy with a licensed mental health care professional during treatment.
			Using these medicines to masculinize a minor 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 minor's 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 for minors.

Risks of Testosterone

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Testosterone **SHOULD NOT** be used by anyone who: • Is pregnant • Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack
			Testosterone should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • 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 or uses tobacco products
			The medical effects and the safety of minors taking 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.
			The minor must not take more testosterone than prescribed. Taking too much testosterone: • 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 the minor appearing more masculine
			Taking testosterone can cause changes that increase the risk of heart disease into adulthood. These changes include: • 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 worsen migraines.

			Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.

Requirements of Treatment with HRT

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite for a minor 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.
			The parent/guardian or the minor can change their mind and stop treatment at any time although some effects of HRT may be permanent.

Prevention of Complications while under Treatment with HRT

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The undersigned parent(s)/legal guardian(s) agree(s) to notify the minor's prescribing physician if the minor suffers from any side effects during treatment or is unhappy with the treatment in any way, particularly if the parent(s)/legal guardian(s) has/have any concerns that the minor has worsening signs of depression or anxiety or expresses a desire harm themselves or attempt suicide.
			The prescribing physician is required to monitor the minor for any side effects during treatment and may refer the minor to another physician or specialist for treatment. The undersigned parent(s)/legal guardian(s) agree(s) to take the minor physicians and specialists as recommended by the prescribing physician.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed 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 the minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for the minor 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 for the minor to begin treatment with testosterone.

_____

Parent/legal guardian's printed name (required)

_____ _____

Parent/legal guardian's signature (required) Date

Parent/legal guardian's printed name (optional)

Parent/legal guardian's signature (optional) 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

ASSENT OF A MINOR:

I have discussed the benefits and risks of treatment with masculinizing medication with my prescribing physician, parent(s) or legal guardian(s), and I wish to receive it.

Minor's printed name (required)

Minor'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 and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's signature Date

FLORIDA DEPARTMENT of STATE

RON DESANTIS
Governor

CORD BYRD
Secretary of State

July 6, 2023

Angela Southwell
Paralegal Specialist
Office of the Attorney General
PL 01, The Capitol
Tallahassee, FL 32399

Dear Angela Southwell:

Your adoption package for Emergency Rule 64B8ER23-8 was received, electronically, by the Florida Department of State, Administrative Code and Register at 5:37 p.m. on July 5, 2023. After review, it appears that the package meets statutory requirements and those of Rule 1-1.010, F.A.C. and is deemed filed for adoption at the time received, as indicated above. The effective date is July 5, 2023.

Sincerely,

Anya C. Owens
Administrative Code and Register Director

Owens, Anya C.

From: Angela Southwell <Angela.Southwell@myfloridalegal.com>
Sent: Wednesday, July 5, 2023 5:37 PM
To: RuleAdoptions
Cc: Owens, Anya C.; Donna McNulty; Christopher Dierlam; Cassandra Fullove
Subject: Adoption Packet for Emergency Rule 64B8ER23-8
Attachments: Adoption Pkt 64B8ER23-8.pdf; THE FULL TEXT OF THE EMERGENCY RULE IS.docx

Good Afternoon:

Attached please find the adoption packet and text.

Angela M. Southwell
Paralegal Specialist
Office of the Attorney General
Administrative Law
PL-01 The Capitol
Bin #4100
Tallahassee, Florida 32399-1050
Telephone: (850) 414-3772
angela.southwell@myfloridalegal.com

ASHLEY MOODY
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Administrative Law

Angela Southwell
Paralegal Specialist
PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3772
Fax (850) 922-6425
angela.southwell@myfloridalegal.com

MEMORANDUM

TO: Anya Owens, Program Administrator
Administrative Code and Register

FROM: Angela Southwell, Paralegal Specialist

RE: Department of Health
Board of Medicine
Emergency Rule 64B8ER23-8

DATE: July 5, 2023

Attached are the following documents regarding the above-referenced emergency rule adoption packet for the above-referenced emergency rule:

- Notice of Emergency Rule
- Adoption text for Emergency Rule 64B8ER23-8 (double spaced)
- Certification of Board of Medicine Emergency Rule Filed With the Department of State
- Designation of Rule the Violation of Which is a Minor Violation Certification
- Certification of Materials Incorporated by Reference in Rules Filed with the Department of State
- Form DH5082-MQA, (06/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent"
- Form DH5083-MQA, (06/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent,"
- Form DH5084-MQA, (06/23), entitled "Surgical Treatment for Adults with Gender Dysphoria, Patient Information and Informed Consent"

Should you have any questions regarding the rule, please contact me at angela.southwell@myfloridalegal.com or by telephone at 850-414-3772.

Thank you for your attention to this matter.

Attachments

CERTIFICATION OF BOARD OF MEDICINE

EMERGENCY RULE FILED WITH THE

DEPARTMENT OF STATE

I hereby certify that pursuant to Ch 2023-90 Laws of Florida, Section 5, section 456.52, Florida Statutes was created and pursuant to subparagraphs 456.52(1)(a) and (6)(a), F.S., the Board of Medicine is required to adopt emergency rules to implement the section. I further certify that the procedures used in the promulgation of this emergency rule were fair under the circumstances and that the rule otherwise complies with subsection 120.54(4), F.S. The adoption of this rule was authorized by the head of the agency and this rule is hereby adopted upon its filing with the Department of State.

Rule No.

64B8ER23-8

Under the provision of subparagraph 120.54(4)(d), F.S., this rule takes effect upon filing unless a later time and date less than 20 days from filing is set out below:

Effective: _____
(Month) (Day) (Year)

Signature, Person Authorized
To Certify Rules

Executive Director for Scot Ackerman, M.D., Chair
Title

_____
Number of Pages Certified

CERTIFICATION OF DEPARTMENT OF STATE
DESIGNATION OF RULE THE VIOLATION OF WHICH IS A MINOR VIOLATION

Pursuant to Section 120.695(2)(c)3, Florida Statutes, I certify as agency head, as defined by section 20.05(1)(b), F.S., that:

[x] All rules covered by this certification are not rules the violation of which would be minor violation pursuant to Section 120.695, F.S.

[ ] The following parts of the rules covered by this certification have been designated as rules the violation of which would be a minor violation pursuant to Section 120.695, F.S.:

Rule No(s).

Rules covered by this certification:

Rule No(s).:

64B8ER23-8

Signature of Agency Head

Paul Vazquez, Executive Director for
Scot Ackerman, M.D., Chair
Title

Form: DS-FCR-6
Rule 1-1.010(3)(f), F.A.C.; effective 10-17

NOTICE OF EMERGENCY RULE

DEPARTMENT OF HEALTH

Board of Medicine

RULE NO.: RULE TITLE:

64B8ER23-8 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(1), F.S., sex-reassignment prescriptions are prohibited for patients younger than 18 years of age upon the effective date of the act; however, pursuant to section 456.52(1)(a), F.S., the Board of Medicine shall within 60 days after the effective date of the act, adopt emergency rules pertaining to standards of practice by which minors may continue to be treated if such treatment was commenced before, and is still active on, the effective date of the act. Section 456.52(1)(b), F.S., also provides a minor patient meeting the criteria outlined in section 456.52(1)(a), F.S., may continue to be treated by a physician with such prescriptions according to rules adopted pursuant to paragraph (1)(a).

Further, 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.

*** 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). ***

REASONS FOR CONCLUDING THAT THE PROCEDURE USED 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 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, 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.

Each Joint Committee meeting was held in person in a public forum and was able to be attended by any interested persons. The Joint Board Meeting was held via Microsoft Teams and also was able to be attended by any interested persons. Public comment was accepted at all of the aforementioned meetings. Further, the Board's accepted written public comment on the proposed rules up and until 24 hours prior to the Joint Board Meeting. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with and interested persons were given ample opportunity to participate in this rulemaking process.

SUMMARY: The proposed emergency rule formally adopts the required consent forms for a 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, Paul.Vazquez@flhealth.gov

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B8ER23-8 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, (06/23), 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, (06/23), 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 ____.

CERTIFICATION OF MATERIALS INCORPORATED

BY REFERENCE IN EMERGENCY RULES FILED WITH THE DEPARTMENT OF STATE

I hereby certify pursuant to Rule 1-1.013, Florida Administrative Code, that materials incorporated by reference in Emergency Rule 64B8ER23-8 have been:

[x] (1) Filed with the Department of State and included as part of the Emergency Rule adoption packet.

[ ] (2) That because there would be a violation of federal copyright laws if the submitting agency filed the incorporated materials as described in option (1) above, a true and complete copy of the incorporated materials has been provided to the Department of State as outlined in paragraph 1-1.013(5)(c), F.A.C.

Copies of the incorporated materials below may be obtained at the agency by [include address(es)/location(s)].

List form number(s) and form title(s), or title of document(s) below:

DH5082-MQA Feminizing Medications for Patient with Gender Dysphoria-Patient Information and Informed Consent

DH5083-MQA Masculinizing Medications for Patients with Gender Dysphoria-Patient Information and Informed Consent

DH5084 Surgical Treatment for Adults with Gender Dysphoria-Patients Information and Informed Consent

Under the provisions of Section 120.54(4)(d), F.S., the attached material(s) take effect upon filing with the Department of State, or a date less than 20 days thereafter if specified in the rule if the adopting agency finds that such effective date is necessary because of immediate danger to the public health, safety, or welfare.

Signature, Person Authorized to Certify Rules

Paul Vazquez, Executive Director for
Scot Ackerman, M.D., Chair
Title

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.

Patient

DH5082-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

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.

Patient

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

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

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

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

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

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

Patient

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.

Patient

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.
	If I take estrogen, the following changes in my breasts will occur: • 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
	If I take feminizing medications, my body will make less testosterone, which may affect my sex life in different ways, including: • 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.
	If I take feminizing medications, some parts of my body will not change much, including: • 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

	Even if I stop taking feminizing medications, the following changes may occur: • 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
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to feminize my body is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of my prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications.

Risks of Feminizing Medications

Patient	Statement
	The medical effects and the safety of taking femininizing medications are not completely known and there may be unknown long-term risks.
	Taking femininizing medications causes changes that other people will notice.
	Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
	I must not take more feminizing medication than prescribed. Taking too much medication: • Will increase health risks • Will not make changes happen more quickly or more significantly
	Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Patient	Statement
	Estrogen **SHOULD NOT** be used by anyone who has: • 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
	Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • 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

	• 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
	Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • 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
	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.
	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.
	Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
	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.
	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.
	Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to your prescribing physician.
	Taking estrogen can cause migraines or can make them worse if you already have them.
	Taking estrogen can cause hot flashes.
	Taking estrogen can cause you to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Patient	Statement
	Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • 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
	Taking Spironolactone affects the balance of potassium in the kidneys, which may result in you experiencing high potassium levels resulting in: • Changes in heart rhythms that may be life threatening • Low blood pressure, which can cause: o Fatigue o Lightheadedness o Tingling feelings o Muscle weakness o Shortness of breath • Your need for regular blood tests to monitor risks while on the medication
	Taking Bicalutamide may cause numerous side effects which should be reported to your prescribing physician, including: • 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

	• 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.

	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: • 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
	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.

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

DH5082-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

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

DH5083-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

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 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.

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.

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

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

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

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

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
• 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	• 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.
	The following changes are likely to be permanent even if testosterone is discontinued: • 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
	The following changes could be permanent, but may improve if I stop taking testosterone: • 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:

	• 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: • 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: • 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: • 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:

	• 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: • 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

DH5083-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

WITNESS:

_____

Witness' printed name (required)

_____ _____

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

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

_____

Interpreter's printed name

_____ _____

Interpreter's signature Date

Surgical Treatment for Adults with Gender Dysphoria

Patient Information and Informed Consent

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

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

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

What are the types of surgery to treat gender dysphoria?

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

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

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

Patient

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

- **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.
- **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.

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

Patient

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

Potential complications include:

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

What happens after surgery to treat gender dysphoria?

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

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

When should I see my surgeon?

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

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

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

Patient

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

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

Patient	Statement
	I understand that my surgeon will discuss with me during the preoperative process the available surgical procedures to treat gender dysphoria, the aftercare needs following surgery, and the importance of postoperative follow-up.
	I understand that these surgeries are permanent.
	I understand that if I have my breasts removed, I must undergo reconstructive surgery if I wish to have breasts in the future. If implants are used, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that if I have my breasts removed that breast feeding will never be possible.
	I understand that if I have breast augmentation surgery, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that my surgeon will assess me for risk factors associated with breast cancer prior to breast augmentation or mastectomy, including genetic mutations (e.g.., BRCA1, BRCA2), family history, age, radiation, exposure to estrogen, and the amount of breast tissue anticipated to remain after surgery.
	I understand that if I undergo metoidioplasty/phalloplasty I will need lifelong urological treatment.
	I understand that complications following metoidioplasty/phalloplasty include: • urinary tract strictures and fistulas • mucoceles due to vaginal remnant • hair growth within the neourethra • compromised sexual function including absent tactile and/or erogenous sensation, difficulties achieving orgasm • complications with penile prosthetics
	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: • the formation of granulation tissue • intravaginal hair growth • delayed wound healing and/or wound disruption • introital stenosis (closing, narrowing, or closure) • painful sex
	I understand that my surgeon may stop further treatment because the risks of treatment outweigh the benefits of treatment.
	I understand that this treatment will not prevent serious psychiatric events, including suicide.
	I agree to tell my surgeon if I have any problems or side effects or am unhappy with the surgery, including if I have worsening signs of depression or anxiety or want to harm myself or attempt suicide.
	I understand that my surgeon may be required to refer me to one or more specialists for surgery-related complications, and I agree to go to those specialists as recommended.
	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: • cervical/prostrate screening tests at appropriate intervals as recommended by my doctor • regularly checking my breasts for lumps, even if I have had a mastectomy • regular mammograms from an appropriate age in consultation with my doctor • quitting smoking • 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

CONSENT:

My signature below confirms that:

1. My surgeon has talked with me about:
   a. the benefits and risks of surgery to treat gender dysphoria;
   b. the possible or likely consequences of surgery to treat gender dysphoria;
   c. potential alternative treatments.

2. The information provided to me in this form and by the surgeon includes the known effects and risks of surgery to treat gender dysphoria. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my surgeon.

4. All my questions have been answered to my satisfaction by my surgeon.

5. I know enough to give informed consent to have, refuse, or postpone surgery to treat gender dysphoria.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your surgeon.

7. My signature below attests to my consent to surgery to treat gender dysphoria.

My signature below confirms the following:

_____ _____

Patient's signature (required) Date

_____ _____

Patient's signature (required) Date

SURGEON:

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

_____

Surgeon's printed name (required)

_____ _____

Surgeon's signature (required) Date

WITNESS:

_____

Witness' printed name (required)

_____ _____

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

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

_____

Interpreter's printed name

_____ _____

Interpreter's signature Date

FLORIDA DEPARTMENT of STATE

RON DESANTIS
Governor

CORD BYRD
Secretary of State

July 6, 2023

Angela Southwell
Paralegal Specialist
Office of the Attorney General
PL 01, The Capitol
Tallahassee, FL 32399

Dear Angela Southwell:

Your adoption package for Emergency Rule 64B15ER23-9 was received, electronically, by the Florida Department of State, Administrative Code and Register at 5:38 p.m. on July 5, 2023. After review, it appears that the package meets statutory requirements and those of Rule 1-1.010, F.A.C. and is deemed filed for adoption at the time received, as indicated above. The effective date is July 5, 2023.

Sincerely,

Anya C. Owens
Administrative Code and Register Director

R. A. Gray Building • 500 South Bronough Street • Tallahassee, Florida 32399-0250
Telephone: (850) 245-6270

Owens, Anya C.

From: Angela Southwell <Angela.Southwell@myfloridalegal.com>
Sent: Wednesday, July 5, 2023 5:38 PM
To: RuleAdoptions
Cc: Owens, Anya C.; Donna McNulty; Christopher Dierlam; Cassandra Fullove
Subject: Adoption Packet for Emergency Rule 64B15ER23-9
Attachments: Adoption pkt 64B15ER23-9.pdf; THE FULL TEXT OF THE EMERGENCY RULE IS.docx

Good Afternoon:

Attached please find the adoption packet and text.

Angela M. Southwell
Paralegal Specialist
Office of the Attorney General
Administrative Law
PL-01 The Capitol
Bin #4100
Tallahassee, Florida 32399-1050
Telephone: (850) 414-3772
angela.southwell@myfloridalegal.com

ASHLEY MOODY
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Administrative Law

Angela Southwell
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Tallahassee, FL 32399-1050
Phone (850) 414-3772
Fax (850) 922-6425
angela.southwell@myfloridalegal.com

MEMORANDUM

TO: Anya Owens, Program Administrator
Administrative Code and Register

FROM: Angela Southwell, Paralegal Specialist

RE: Department of Health
Board of Osteopathic Medicine
Emergency Rule 64B15ER23-9

DATE: July 5, 2023

Attached are the following documents regarding the above-referenced emergency rule adoption packet for the above-referenced emergency rule:

- Notice of Emergency Rule
- Adoption text for Emergency Rule 64B15ER23-9 (double spaced)
- Certification of Board of Osteopathic Medicine Emergency Rule Filed With the Department of State
- Designation of Rule the Violation of Which is a Minor Violation Certification
- Certification of Materials Incorporated by Reference in Rules Filed with the Department of State
- Form DH5079-MQA, (06/23), entitled "Puberty Suppression Treatment for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors"
- Form DH5080-MQA, (06/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors"
- Form DH5081-MQA, (06/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors"

Should you have any questions regarding the rule, please contact me at angela.southwell@myfloridalegal.com or by telephone at 850-414-3772.

Thank you for your attention to this matter.

Attachments

CERTIFICATION OF BOARD OF OSTEOPATHIC MEDICINE

EMERGENCY RULE FILED WITH THE

DEPARTMENT OF STATE

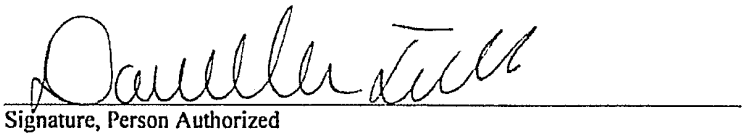
I hereby certify that pursuant to Ch 2023-90 Laws of Florida, Section 5, section 456.52, Florida Statutes was created and pursuant to subparagraphs 456.52(1)(a) and (6)(a), F.S., the Board of Osteopathic Medicine is required to adopt emergency rules to implement the section. I further certify that the procedures used in the promulgation of this emergency rule were fair under the circumstances and that the rule otherwise complies with subsection 120.54(4), F.S. The adoption of this rule was authorized by the head of the agency and this rule is hereby adopted upon its filing with the Department of State.

Rule No.

64B15ER23-9

Under the provision of subparagraph 120.54(4)(d), F.S., this rule takes effect upon filing unless a later time and date less than 20 days from filing is set out below:

Effective: _____
(Month) (Day) (Year)



Signature, Person Authorized
To Certify Rules

Executive Director for Tiffany Sizemore Di Pietro , DO, FACC, FACOI, Chair
Title

_____
Number of Pages Certified

CERTIFICATION OF DEPARTMENT OF STATE
DESIGNATION OF RULE THE VIOLATION OF WHICH IS A MINOR VIOLATION

Pursuant to Section 120.695(2)(c)3. Florida Statutes, I certify as agency head, as defined by section 20.05(1)(b), F.S., that:

[x] All rules covered by this certification are not rules the violation of which would be minor violation pursuant to Section 120.695, F.S.

[ ] The following parts of the rules covered by this certification have been designated as rules the violation of which would be a minor violation pursuant to Section 120.695, F.S.:

Rule No(s).

Rules covered by this certification:

Rule No(s).:

64B15ER23-9

Signature of Agency Head

Danielle Terrell, Executive Director for Tiffany Sizemore Di Pietro, DO, FACC, FACOI, Chair
Title

Form: DS-FCR-6
Rule 1-1.010(3)(f), F.A.C.; effective 10-17

NOTICE OF EMERGENCY RULE

DEPARTMENT OF HEALTH

Board of Osteopathic Medicine

RULE NO.: RULE TITLE:

64B15ER23-9 Sex-reassignment Standards of Practice in Minors.

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(1), F.S., sex-reassignment prescriptions are prohibited for patients younger than 18 years of age upon the effective date of the act; however, pursuant to section 456.52(1)(a), F.S., the Board of Osteopathic Medicine shall within 60 days after the effective date of the act, adopt emergency rules pertaining to standards of practice by which minors may continue to be treated if such treatment was commenced before, and is still active on, the effective date of the act. Section 456.52(1)(b), F.S., also provides a minor patient meeting the criteria outlined in section 456.52(1)(a), F.S., may continue to be treated by a physician with such prescriptions according to rules adopted pursuant to paragraph (1)(a).

Further, 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 standards of practice and mandated consent forms for the treatment of gender dysphoria with puberty blockers and hormone replacement therapy in minors.

*** 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). ***

REASONS FOR CONCLUDING THAT THE PROCEDURE USED 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 Osteopathic 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 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 2, 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. Prior to conclusion of the Joint Board Meeting, the Boards each separately voted to approve the draft consent forms via emergency rule. The Joint Board Meeting was held via Microsoft Teams and notice of the same was published to the Board of Osteopathic Medicine's website and in the Florida Administrative Register on June 22, 2023.

Each Joint Committee meeting was held in person in a public forum and was able to be attended by any interested persons. The Joint Board Meeting was held via Microsoft Teams and also was able to be attended by any interested persons. Public comment was accepted at all of the aforementioned meetings. Further, the Boards accepted written public comment on the proposed rules up and until 24 hours prior to the Joint Board Meeting. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with and interested persons were given ample opportunity to participate in this rulemaking process.

SUMMARY: The proposed emergency rule formally adopts the required consent forms that must be executed for a minor patient who was already receiving sex-reassignment prescriptions to continue to receive said prescriptions per section 456.52(1), 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:

64B15ER23-9 Sex-reassignment Standards of Practice in Minors.

The standards of practice in this rule do not supersede the level of care, skill, and treatment recognized in general law related to healthcare licensure.

(1) Pursuant to Section 456.52, Florida Statutes, sex-reassignment prescriptions and procedures are prohibited for patients younger than 18 years of age, except that a physician may continue to treat such patient with a prescription if such treatment for sex-reassignment was commenced before, and is still active on, May 17, 2023. 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 his or her 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.

(2) Informed Consent. The Board has approved the following mandatory informed consent forms for the continued treatment of minors with sex-reassignment prescriptions:

(a) For patients prescribed puberty blocking medications, form DH5079-MQA, (06/23), entitled "Puberty Suppression Treatment for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors," which is hereby incorporated by reference and available from the Board's website at https://flboardofmedicine.gov/forms/Puberty-Suppression-Treatment-for-Patients-with-Gender-Dysphoria-Patient-Information-and-Parental-Consent-and-Assent-for-Minors.pdf.

(b) For patients prescribed sex-reassignment feminizing medications, form DH5080-MQA, (06/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors," 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-Parental-Consent-and-Assent-for-Minors.pdf.

(c) For patients prescribed sex-reassignment masculinizing medications, form DH5081-MQA, (06/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors," 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-Parental-Consent-and-Assent-for-Minors.pdf.

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

(a) The physician issuing the prescription, while physically present in the same room as the patient, has informed the patient and the patient's parent or legal guardian of the nature and risks of the prescription, and has provided and received the written acknowledgement of the patient and the patient's legal guardian before the prescription is prescribed or administered. 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's parent or legal guardian is required to sign the informed consent form.

(c) The patient is required to assent to the informed consent form.

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

(4) Standards of Practice. The nature and extent of the requirements set forth below will vary depending on the practice setting and circumstances presented to the prescribing physician. A prescribing physician who continues to treat a minor patient with sex-reassignment prescriptions pursuant to section 456.52(1)(a), Florida Statutes, shall comply with the following:

(a) Patient Evaluation. An in-person thorough medical history and physical examination of the patient conducted by the physician must be documented in the patient's medical record prior to prescribing any new sex-reassignment prescription.

(b) Clinical Determinations. Based on the patient evaluation, the following must be confirmed:

1. The patient 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. The patient has pubertal changes resulting in an increase in gender dysphoria;

3. The patient does not suffer from a psychiatric comorbidity that interferes with the diagnostic work-up or treatment;

4. The patient will have psychological and social support during treatment;

5. The patient has experienced puberty to at least Tanner Stage 2; and

6. The patient demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of puberty suppression, future cross-sex hormone treatment, as well as the medical and social risks and benefits of sex reassignment surgery based on the patient's current treatment status.

(c) Patient Visit. The physician or their designated covering physician must meet with the patient in-person every six (6) months for the purpose of monitoring the patient and must document each visit in the patient's medical records.

(d) Suicide Risk Assessment. A suicide risk assessment by a licensed mental health care professional must be performed every three (3) months.

(e) Laboratory Testing. Relevant laboratory testing must be performed every four (4) months.

(f) X-rays. X-rays of the hand must be performed each year to monitor and document the patient's bone age progression.

(g) Bone Density Scan. An annual bone density (DEXA) scan must be performed to monitor the patient's bone density during treatment.

(h) Mental Health Assessment. The physician must have the patient undergo an annual mental health assessment to be performed by a board-certified Florida licensed psychiatrist or psychologist.

(i) Counseling. The physician must refer the patient for counseling with a licensed mental health care professional during the treatment period, with a frequency as recommended by the licensed mental health care professional.

(j) Additional Consultations. The physician must refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History – New ____.

CERTIFICATION OF MATERIALS INCORPORATED

BY REFERENCE IN EMERGENCY RULES FILED WITH THE DEPARTMENT OF STATE

I hereby certify pursuant to Rule 1-1.013, Florida Administrative Code, that materials incorporated by reference in Emergency Rule 64B15ER23-9 have been:

[x] (1) Filed with the Department of State and included as part of the Emergency Rule adoption packet.

[ ] (2) That because there would be a violation of federal copyright laws if the submitting agency filed the incorporated materials as described in option (1) above, a true and complete copy of the incorporated materials has been provided to the Department of State as outlined in paragraph 1-1.013(5)(c), F.A.C.

Copies of the incorporated materials below may be obtained at the agency by [include address(es)/location(s)].

List form number(s) and form title(s), or title of document(s) below:

DH5079-MWA Puberty Suppession Treatment for Patients with Gender Dysphoria-Patient Information and Parental Consent and Assent for Minors

DH5080-MQA Feminizing Medications for Patients with Gender Dysphoria-Patient Information and Partental Cosnent and Assent for Minors

DH5081-MQA Masculinizing Medications for Patients with Gender Dysphoria-Patient Information and Parental Consent and Assent for Minors

Under the provisions of Section 120.54(4)(d), F.S., the attached material(s) take effect upon filing with the Department of State, or a date less than 20 days thereafter if specified in the rule if the adopting agency finds that such effective date is necessary because of immediate danger to the public health, safety, or welfare.

Signature, Person Authorized
To Certify Rules

Danielle Terrell, Executive Director for Tiffany Sizemore Di Pietro, DO, FACC, FACOI, Chair
Title

Puberty Suppression Treatment for Patients with Gender Dysphoria

Patient Information and Informed Parental Consent and Assent for Minors

Before a minor continues treatment to suppress puberty with puberty blockers, you and the minor need to be aware of the effects and possible risks associated with the use of these medications. After your questions or concerns are addressed and you have decided to have the minor continue treatment with puberty blockers, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

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 other options if I do not wish to have the minor continue treatment with puberty blockers?

One option available is psychological therapy with a mental health provider. This is recommended regardless of whether the minor undergoes suppression of puberty 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 different medications that are used to suppress puberty?

The main mechanism by which physical changes of puberty can be put on hold is by using medication to block the signal from the brain to the organs that make hormones. These hormones are estrogen and testosterone. Estrogen is made by the ovaries. Testosterone is made by the testicles.

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

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

DH5079-MQA (Rev. 06/23)
Rules 64B8ER23-7 and 64B15ER23-9

Pediatric endocrinologists (children's doctors who specialize in hormones and puberty) use these medications frequently to suppress puberty in children with precocious (early) puberty, which is the U.S. Food and Drug Administration (FDA) approved use. None of the medications have been approved by the FDA to be used in minors with gender dysphoria. In other words, using these medications for gender dysphoria is considered "off label" use because they are not being used for their intended purpose.

Lupron and Histrelin are called GnRH analogs and are the most effective forms of treatment for puberty suppression. When used for precocious puberty, Lupron is given as a monthly or every 3-month intramuscular injection. When used for precocious puberty, Histrelin (brand name Supprelin) is an implant that is surgically placed under the skin and needs to be replaced every 1 to 2 years.

Provera is a pill that needs to be taken twice a day and is approved to be used in female adolescents with abnormal uterine bleeding. Provera is less effective than Lupron and Histrelin. Depo-Provera injections are approved for the use in females with abnormal bleeding and as birth control.

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

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

What are the requirements to receive puberty suppression for gender dysphoria?

To receive treatment with puberty blockers, there are specific requirements that must be met before and during treatment. These requirements will allow the prescribing physician to monitor the minor's medical and mental health status during treatment. If these requirements are not met, treatment with puberty blockers may be discontinued by the prescribing physician.

The specific requirements for a minor to receive and continue 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. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (this is the first stage of puberty and refers to breast or testicle growth), which must be confirmed by a physician;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of puberty suppression, future cross-sex hormone treatment, as well as the medical and social risks and benefits of sex reassignment surgery.
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing at least every 4 months;
10. X-ray of the hand (bone age) no less than once a year;
11. Annual bone density scan (DEXA) which will allow monitoring of the minor's bone density (bone strength) during treatment, as puberty blockers may decrease bone density if given for long periods of time;
12. Annual mental health assessment by a Board-certified Florida-licensed psychiatrist or psychologist; and
13. 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.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with providing puberty suppression treatment to the minor.

Effects of Treatment of Suppression of Puberty

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Puberty blockers are used to temporarily suspend or block the physical changes of puberty for minors
			If a minor stops treatment with puberty blockers, in a few months their body may restart the changes of puberty at the developmental stage they were before starting medication. However, the effects of these medications could be permanent.
			It can take several months for the medications to be effective. It cannot be predicted how quickly or slowly or even if a minor's body will respond to the medication.
			Taking these medications, will cause a minor's body to stop producing testosterone or estrogen.
			These medications will not change a minor's sex (chromosomes), and it will not change a minor's internal or external reproductive structures.
			Puberty blockers can interfere with fertility.
			Puberty blockers do not affect the minor's ability to contract a sexually transmitted infection.
			The use of puberty blockers in minors for the treatment of gender dysphoria is an off-label use. This means these medications are not approved by the FDA to treat this specific diagnosis.

Risks of Treatment of Suppression of Puberty

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The adverse effects and safety of puberty blockers used for the treatment of gender dysphoria in minors is not well known.
			Treatment with puberty blockers will not prevent serious psychiatric events such as a suicide.
			Treatment with puberty blockers may cause new or worsened psychiatric problems, including: • Crying • Irritability • Restlessness (impatience)

			• Anger • Acting aggressive
			It is the responsibility of the parent/guardian to notify the prescribing physician if the minor has any new or worsening physical or psychiatric problems while taking this medication.
			During the first 4 weeks of treatment, puberty blockers can cause an increase in some hormones. During this time, a minor may notice more signs of puberty, including vaginal bleeding.
			Seizures are a risk associated with taking puberty blockers. The risk of seizures may be higher in people who: • Have a history of seizures • Have a history of epilepsy • Have a history of brain or brain vessel (cerebrovascular) problems or tumors • Are taking a medicine that has been connected to seizures, such as bupropion or selective serotonin reuptake inhibitors (SSRIs).
			It is the responsibility of the parent/guardian to immediately notify the appropriate health care providers including the minor's prescribing physician if the minor has a seizure while taking puberty blockers.
			Increased pressure in the fluid around the brain is a risk associated with taking puberty blockers. It is the responsibility of the parent/guardian to notify the minor's prescribing physician if the minor has any of the following symptoms while taking puberty blockers: • Headache • Eye problems including blurred vision, double vision, and decreased eyesight • Eye pain • Ringing in the ears • Dizziness • Nausea
			Puberty blockers should not be used if a minor is: • Allergic to GnRH, GnRH agonist medicines, or Progesterones. • Pregnant or becomes pregnant because puberty blockers can cause birth defects or loss of the baby. It is the responsibility of the parent/guardian to notify the prescribing physician if a minor becomes pregnant while taking puberty blockers.
			The most common side effects of puberty blockers include: • Injection site reactions such as pain, swelling, and abscess which may result in surgery

			• Weight gain • Pain throughout body • Headache • Acne or red, itchy rash and white scales (seborrhea) • Serious skin rash (erythema multiforme) • Mood changes • Swelling of vagina (vaginitis), vaginal bleeding, and vaginal discharge • Upper stomach pain • Diarrhea • Bleeding • Nausea and vomiting • Fever • Itching • Pain in extremities • Rash • Back pain • Ligament sprain • Fracture • Breast tenderness • Difficulty sleeping • Chest pain • Excessive sweating
			Puberty blockers may decrease bone density.
			Minors may grow less than their peers while taking puberty blockers.
			Puberty blockers may cause stalling of typical cognitive or brain development in minors.

Requirements of Treatment of Suppression of Puberty

I understand the following:

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite to receive treatment for puberty suppression.
			The prescribing physician may stop prescribing puberty blockers 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.

			The parent/guardian or the minor can change their mind and stop treatment at any time.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed me about:
   a. the benefits and risks of treatment with puberty blockers;
   b. the possible or likely consequences of treatment with puberty blockers and puberty suppression; 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 puberty blockers. 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 minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for my minor to take, refuse, or postpone using puberty blocking 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 for my minor to begin treatment for suppression of puberty.

_____
Parent/legal guardian's name (required)

_____ _____
Parent/legal guardian's signature (required) Date

Parent/legal guardian's name (optional)

Parent/legal guardian's signature (optional) Date

PRESCRIBING PHYSICIAN SIGNATURE:

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

Prescribing physician's name (required)

Prescribing physician's signature (required) Date

ASSENT OF MINOR:

I have discussed the benefits and risks of treatment to suppress puberty with my prescribing physician and my parent(s) or legal guardian(s), and I wish to receive it.

Minor's name (required)

Minor's signature (required) Date

WITNESS:

_____
Witness printed name

_____ _____
Witness signature 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 and/or adult(s) legally responsible for the minor child 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 Parental Consent and Assent for Minors

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

After your questions or concerns are addressed and you have decided to have the minor start or continue treatment with hormones or hormone antagonists, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

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 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 by minors even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval to be used by minors and its use in this population is considered "off label" because they are not being used for their intended purpose.

Different forms of estrogen are used to feminize one'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.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

DH5080-MQA (Rev. 06/23)
Rules 64B8ER23-7 and 64B15ER23-9

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.

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 minor's 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 a minor's mood. Therefore, minors must be under the care of a licensed mental health care professional while undergoing treatment. This professional can work with the minor, your family and friends, and your school staff.

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

One option available is psychological therapy with a mental health. This is recommended regardless of whether or not the minor 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 the minor's 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.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

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

The specific requirements for a minor 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. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (first stage of puberty), which must be confirmed by a physician;
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;
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing at least every 4 months;
10. X-ray of the hand (bone age) at least once a year if the minor is still growing;
11. Annual bone density scan (DEXA) which will allow monitoring of the minor's bone density (bone strength) during treatment, which can be altered by HRT;
12. Annual mental health assessments by a Board-certified Florida licensed psychiatrist or psychologist; and
13. 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.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

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

Effects of Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Feminizing medications, including estrogen, androgen blockers, or antiandrogens, given singularly or in combination, may be prescribed to make a minor appear less masculine and more feminine
			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 the minor's biological sex or chromosomes.
			If a minor takes estrogen, the following changes in a minor's breasts will occur: • 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 the minor's prescribing physician • The minor's risk of breast cancer may significantly increase
			If a minor takes feminizing medications, the minor's body will make less testosterone, which may affect the minor's sex life in different ways, including: • The minor's testicles may shrink • The minor's penis may never fully develop, particularly if the minor has previously taken puberty blockers • The minor will have fewer spontaneous erections • The minor's sperm may no longer mature causing infertility which may be permanent

			even if treatment is discontinued, the risk of which is increased if the minor took puberty blockers prior to starting feminizing medications • Conversely, it is possible that a minor's sperm could still mature while taking feminizing medications and the minor may cause someone to get pregnant
			To improve the possibility that the minor may have biological children in the future, the options for sperm banking by the minor have been explained.
			If a minor takes feminizing medications, some parts of the minor's body will not change much, including: • If present, the minor's facial hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If present, the minor's body hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If the minor went through puberty and has a deep voice, the pitch of the minor's voice will not rise and the minor's speech patterns will not become more like a woman's • If present, the minor's Adam's apple will not shrink
			Even if a minor stops taking feminizing medications, the following changes may occur: • The minor's body fat may be redistributed with less fat on the abdomen and more on the buttocks, hips, and thighs creating a more female shape • The minor may have decreased muscle mass and strength in the upper body • The minor's skin may become softer
			Mood changes may be caused by these medicines, and the minor will continue therapy with a licensed mental health care professional during treatment.
			Using these medicines to feminize a minor 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 minor's 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 for minors.

Risks of Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The medical effects and the safety of minors taking femininizing medications are not completely known and there may be unknown long-term risks.
			Taking feminizing medications causes changes that other people will notice.
			Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
			The minor must not take more feminizing medication than prescribed. Taking too much medication: • Will increase health risks • Will not make changes happen more quickly or more significantly
			Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Estrogen **SHOULD NOT** be used by anyone who has a history of: • 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

			Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • 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 • 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
			Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • 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
			The risk of blood clots while take estrogen is much greater if the minor smokes cigarettes. The danger is so high that the minor should stop smoking completely while taking estrogen.
			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.
			Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
			Taking estrogen increases the risk of gallstones (stones in the gallbladder). Any long-term abdominal pain experience by the minor while taking estrogen must be reported to the minor's prescribing physician.
			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 the

			minor's vision and cause headaches if not treated properly. Any changes in the minor's 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 the minor's prescribing physician.
			Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to the minor's prescribing physician.
			Taking estrogen can cause migraines or can make them worse if the minor already has them.
			Taking estrogen can cause hot flashes.
			Taking estrogen can cause the minor to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • Increase the amount of urine produced by the minor's kidneys, making it necessary to urinate more frequently • Increase the minor's thirst • Increase the minor's risk of dehydration, which can be evidenced by less frequent urination than usual, dark and strong-smelling urine, thirst, and light-headedness
			Taking Spironolactone affects the balance of potassium in the kidneys, which may result in the minor experience high potassium levels resulting in: • Changes in heart rhythms that may be life threatening • Low blood pressure, which can cause: o Fatigue o Lightheadedness o Tingling feelings o Muscle weakness o Shortness of breath

			• The minor's need for regular blood tests to monitor risks while on the medication
			Taking Bicalutamide may cause numerous side effects which should be reported to the minor's prescribing physician, including: • 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 • 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

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite for a minor 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.
			The parent/guardian or the minor can change their mind and stop treatment at any time although some effects of HRT may be permanent.

Prevention of Complications while under Treatment with Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The undersigned parent(s)/legal guardian(s) agree(s) to notify the minor's prescribing physician if the minor suffers from any side effects during treatment or is unhappy with the treatment in any way, particularly if the parent(s)/legal guardian(s) has/have any concerns that the minor has worsening signs of depression or anxiety or expresses a desire harm themselves or attempt suicide.
			The prescribing physician is required to monitor the minor for any side effects during treatment and may refer the minor to another physician or specialist for treatment. The undersigned

			parent(s)/legal guardian(s) agree(s) to take the minor to physicians and specialists as recommended by the prescribing physician.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's 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 minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for the minor 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 for the minor to begin treatment with feminizing medications.

_____
Parent/legal guardian's printed name (required)

_____ _____
Parent/legal guardian's signature (required) Date

Parent/legal guardian's printed name (optional)

Parent/legal guardian's signature (optional) 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

ASSENT OF A MINOR:

I have discussed the benefits and risks of treatment with feminizing medications with my prescribing physician, parent(s) or legal guardian(s), and I wish to receive them.

Minor's printed name (required)

Minor'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 and/or adult(s) legally responsible for the minor child 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 Parental Consent and Assent for Minors

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

After your questions or concerns are addressed and you have decided to have the minor start or continue treatment with hormones or hormone antagonists, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

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 minors, even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval to be used by minors and its use in this population is considered "off label" because they are not being used for their intended purpose.

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

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

DH5081-MQA (Rev. 06/23)
Rules 64B8ER23-7 and 64B15ER23-9

What are my other options if I do not wish to start or continue my minor's treatment with hormones or hormone antagonists?

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

How is testosterone taken?

Testosterone is usually injected every one to four weeks. Typically, it is not given in pill form because the body may not absorb it properly which 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). A minor taking testosterone may experience unwanted swings in hormone levels based on the amount and how often doses are given.

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 minor's prescribing physician to make sure that there are no negative medical or mental health effects.

Both testosterone and the treatment process can affect a minor's mood. Therefore, minors must be under the care of a licensed mental health care professional while undergoing treatment. This professional can work with the minor, your family and friends, and your school staff.

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 the minor's 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.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

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

The specific requirements for a minor 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. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (first stage of puberty), which must be confirmed by a physician;
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;
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing, at least every 4 months;
10. X-ray of the hand (bone age) at least once a year if the minor is still growing;
11. Annual bone density scan (DEXA) which will allow monitoring of the minor's bone density (bone strength) during treatment, which can be altered by HRT
12. Annual mental health assessments by a Board-certified Florida licensed psychiatrist or psychologist; and
13. 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.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Summary of Testosterone Benefits and Risks

BENEFITS	RISKS
• 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	• 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 such as 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.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with a minor taking testosterone.

Masculinizing Effects

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Testosterone may be prescribed to make a minor 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.
			Changes from testosterone may not be complete for 2 to 5 years after treatment is started.
			The following changes are likely to be permanent even if testosterone is discontinued: • 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
			The following changes could be permanent, but may improve if I stop taking testosterone: • 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 minor's biological sex or chromosomes.
			Testosterone may reduce the minor's ability to become pregnant, but it will not eliminate the risk of pregnancy. A person can become pregnant while on testosterone. I agree to inform the minor's prescribing physician if the minor becomes pregnant.
			Some aspects of the minor's body will not change: • Fat loss may make breasts appear slightly smaller (if present) • The voice will deepen, but other aspects of the way the minor speaks may not sound more masculine
			Mood changes may be caused by these medicines, and the minor will continue therapy with a licensed mental health care professional during treatment.
			Using these medicines to masculinize a minor 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 minor's 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 for minors.

Risks of Testosterone

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Testosterone **SHOULD NOT** be used by anyone who: • Is pregnant • Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack
			Testosterone should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • 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 or uses tobacco products
			The medical effects and the safety of minors taking 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.
			The minor must not take more testosterone than prescribed. Taking too much testosterone: • 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 the minor appearing more masculine
			Taking testosterone can cause changes that increase the risk of heart disease into adulthood. These changes include: • 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 worsen migraines.

			Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.

Requirements of Treatment with HRT

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite for a minor 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.
			The parent/guardian or the minor can change their mind and stop treatment at any time although some effects of HRT may be permanent.

Prevention of Complications while under Treatment with HRT

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The undersigned parent(s)/legal guardian(s) agree(s) to notify the minor's prescribing physician if the minor suffers from any side effects during treatment or is unhappy with the treatment in any way, particularly if the parent(s)/legal guardian(s) has/have any concerns that the minor has worsening signs of depression or anxiety or expresses a desire harm themselves or attempt suicide.
			The prescribing physician is required to monitor the minor for any side effects during treatment and may refer the minor to another physician or specialist for treatment. The undersigned parent(s)/legal guardian(s) agree(s) to take the minor physicians and specialists as recommended by the prescribing physician.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed 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 the minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for the minor 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 for the minor to begin treatment with testosterone.

_____

Parent/legal guardian's printed name (required)

_____ _____

Parent/legal guardian's signature (required) Date

Parent/legal guardian's printed name (optional)

Parent/legal guardian's signature (optional) 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

ASSENT OF A MINOR:

I have discussed the benefits and risks of treatment with masculinizing medication with my prescribing physician, parent(s) or legal guardian(s), and I wish to receive it.

Minor's printed name (required)

Minor'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 and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's signature Date

FLORIDA DEPARTMENT of STATE

RON DESANTIS
Governor

CORD BYRD
Secretary of State

July 6, 2023

Angela Southwell
Paralegal Specialist
Office of the Attorney General
PL 01, The Capitol
Tallahassee, FL 32399

Dear Angela Southwell:

Your adoption package for Emergency Rule 64B15ER23-10 was received, electronically, by the Florida Department of State, Administrative Code and Register at 5:39 p.m. on July 5, 2023. After review, it appears that the package meets statutory requirements and those of Rule 1-1.010, F.A.C. and is deemed filed for adoption at the time received, as indicated above. The effective date is July 5, 2023.

Sincerely,

Anya C. Owens
Administrative Code and Register Director

Owens, Anya C.

From: Angela Southwell <Angela.Southwell@myfloridalegal.com>
Sent: Wednesday, July 5, 2023 5:39 PM
To: RuleAdoptions
Cc: Owens, Anya C.; Donna McNulty; Christopher Dierlam; Cassandra Fullove
Subject: Adoption Packet for Emergency Rule 64B15ER23-10
Attachments: Adoption pkt 64B15ER23-10.pdf; THE FULL TEXT OF THE EMERGENCY RULE IS.docx

Good Afternoon:

Attached please find the adoption packet and text.

Angela M. Southwell
Paralegal Specialist
Office of the Attorney General
Administrative Law
PL-01 The Capitol
Bin #4100
Tallahassee, Florida 32399-1050
Telephone: (850) 414-3772
angela.southwell@myfloridalegal.com

ASHLEY MOODY
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Administrative Law

Angela Southwell
Paralegal Specialist
PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3772
Fax (850) 922-6425
angela.southwell@myfloridalegal.com

MEMORANDUM

TO: Anya Owens, Program Administrator
Administrative Code and Register

FROM: Angela Southwell, Paralegal Specialist

RE: Department of Health
Board of Osteopathic Medicine
Emergency Rule 64B15ER23-10

DATE: July 5, 2023

Attached are the following documents regarding the above-referenced emergency rule adoption packet for the above-referenced emergency rule:

- Notice of Emergency Rule
- Adoption text for Emergency Rule 64B15ER23-10 (double spaced)
- Certification of Board of Osteopathic Medicine Emergency Rule Filed With the Department of State
- Designation of Rule the Violation of Which is a Minor Violation Certification
- Certification of Materials Incorporated by Reference in Rules Filed with the Department of State
- Form DH5082-MQA, (06/23), entitled "Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent"
- Form DH5083-MQA, (06/23), entitled "Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent,"
- Form DH5084-MQA, (06/23), entitled "Surgical Treatment for Adults with Gender Dysphoria, Patient Information and Informed Consent"

Should you have any questions regarding the rule, please contact me at angela.southwell@myfloridalegal.com or by telephone at 850-414-3772.

Thank you for your attention to this matter.

Attachments

CERTIFICATION OF BOARD OF OSTEOPATHIC MEDICINE

EMERGENCY RULE FILED WITH THE

DEPARTMENT OF STATE

I hereby certify that pursuant to Ch 2023-90 Laws of Florida, Section 5, section 456.52, Florida Statutes was created and pursuant to subparagraphs 456.52(1)(a) and (6)(a), F.S., the Board of Osteopathic Medicine is required to adopt emergency rules to implement the section. I further certify that the procedures used in the promulgation of this emergency rule were fair under the circumstances and that the rule otherwise complies with subsection 120.54(4), F.S. The adoption of this rule was authorized by the head of the agency and this rule is hereby adopted upon its filing with the Department of State.

Rule No.

64B15ER23-10

Under the provision of subparagraph 120.54(4)(d), F.S., this rule takes effect upon filing unless a later time and date less than 20 days from filing is set out below:

Effective: _____
(Month) (Day) (Year)

Signature, Person Authorized
To Certify Rules

Executive Director for Tiffany Sizemore Di Pietro , DO, FACC, FACOI, Chair
Title

_____
Number of Pages Certified

CERTIFICATION OF DEPARTMENT OF STATE
DESIGNATION OF RULE THE VIOLATION OF WHICH IS A MINOR VIOLATION

Pursuant to Section 120.695(2)(c)3. Florida Statutes, I certify as agency head, as defined by section 20.05(1)(b), F.S., that:

[X] All rules covered by this certification are not rules the violation of which would be minor violation pursuant to Section 120.695, F.S.

[ ] The following parts of the rules covered by this certification have been designated as rules the violation of which would be a minor violation pursuant to Section 120.695, F.S.:

Rule No(s).

Rules covered by this certification:

Rule No(s)..

64B15ER23-10

Signature of Agency Head

Danielle Terrell, Executive Director for Tiffany Sizemore Di Pietro, DO, FACC, FACOI, Chair
Title

Form: DS-FCR-6
Rule 1-1.010(3)(f), F.A.C.; effective 10-17

NOTICE OF EMERGENCY RULE

DEPARTMENT OF HEALTH

Board of Osteopathic Medicine

RULE NO.: RULE TITLE:

64B15ER23-10 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(1), F.S., sex-reassignment prescriptions are prohibited for patients younger than 18 years of age upon the effective date of the act; however, pursuant to section 456.52(1)(a), F.S., the Board of Osteopathic Medicine shall within 60 days after the effective date of the act, adopt emergency rules pertaining to standards of practice by which minors may continue to be treated if such treatment was commenced before, and is still active on, the effective date of the act. Section 456.52(1)(b), F.S., also provides a minor patient meeting the criteria outlined in section 456.52(1)(a), F.S., may continue to be treated by a physician with such prescriptions according to rules adopted pursuant to paragraph (1)(a).

Further, 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.

*** 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). ***

REASONS FOR CONCLUDING THAT THE PROCEDURE USED 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 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 2, 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 Osteopathic Medicine's website and in the Florida Administrative Register on June 22, 2023.

Each Joint Committee meeting was held in person in a public forum and was able to be attended by any interested persons. The Joint Board Meeting was held via Microsoft Teams and also was able to be attended by any interested persons. Public comment was accepted at all of the aforementioned meetings. Further, the Board's accepted written public comment on the proposed rules up and until 24 hours prior to the Joint Board Meeting. Accordingly, all notice requirements contained in Rule 28-102.001, F.A.C., were properly complied with and interested persons were given ample opportunity to participate in this rulemaking process.

SUMMARY: The proposed emergency rule formally adopts the required consent forms for a 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:

64B15ER23-10 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, (06/23), 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, (06/23), 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____.

CERTIFICATION OF MATERIALS INCORPORATED
BY REFERENCE IN EMERGENCY RULES FILED WITH THE DEPARTMENT OF STATE

I hereby certify pursuant to Rule 1-1.013, Florida Administrative Code, that materials incorporated by reference in Emergency Rule 64B15ER23-10 have been:

[x] (1) Filed with the Department of State and included as part of the Emergency Rule adoption packet.

[ ] (2) That because there would be a violation of federal copyright laws if the submitting agency filed the incorporated materials as described in option (1) above, a true and complete copy of the incorporated materials has been provided to the Department of State as outlined in paragraph 1-1.013(5)(c), F.A.C.

Copies of the incorporated materials below may be obtained at the agency by [include address(es)/location(s)].

List form number(s) and form title(s), or title of document(s) below:

DH5082-MQA Feminizing Medications for Patient with Gender Dysphoria-Patient Information and Informed Consent

DH5083-MQA Masculinizing Medications for Patients with Gender Dysphoria-Patient Information and Informed Consent

DH5084 Surgical Treatment for Adults with Gender Dysphoria-Patients Information and Informed Consent

Under the provisions of Section 120.54(4)(d), F.S., the attached material(s) take effect upon filing with the Department of State, or a date less than 20 days thereafter if specified in the rule if the adopting agency finds that such effective date is necessary because of immediate danger to the public health, safety, or welfare.

Signature, Person Authorized to Certify Rules

Danielle Terrell, Executive Director for Tiffany Sizemore Di Pietro, DO, FACC, FACOI, Chair
Title

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.

Patient

DH5082-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

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.

Patient

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

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

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

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

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

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

Patient

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.

Patient

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.
	If I take estrogen, the following changes in my breasts will occur: • 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
	If I take feminizing medications, my body will make less testosterone, which may affect my sex life in different ways, including: • 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.
	If I take feminizing medications, some parts of my body will not change much, including: • 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

	Even if I stop taking feminizing medications, the following changes may occur: • 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
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to feminize my body is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of my prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications.

Risks of Feminizing Medications

Patient	Statement
	The medical effects and the safety of taking femininizing medications are not completely known and there may be unknown long-term risks.
	Taking femininizing medications causes changes that other people will notice.
	Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
	I must not take more feminizing medication than prescribed. Taking too much medication: • Will increase health risks • Will not make changes happen more quickly or more significantly
	Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Patient	Statement
	Estrogen **SHOULD NOT** be used by anyone who has: • 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
	Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • 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

	• 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
	Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • 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
	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.
	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.
	Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
	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.
	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.
	Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to your prescribing physician.
	Taking estrogen can cause migraines or can make them worse if you already have them.
	Taking estrogen can cause hot flashes.
	Taking estrogen can cause you to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Patient	Statement
	Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • 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
	Taking Spironolactone affects the balance of potassium in the kidneys, which may result in you experiencing high potassium levels resulting in: • Changes in heart rhythms that may be life threatening • Low blood pressure, which can cause: o Fatigue o Lightheadedness o Tingling feelings o Muscle weakness o Shortness of breath • Your need for regular blood tests to monitor risks while on the medication
	Taking Bicalutamide may cause numerous side effects which should be reported to your prescribing physician, including: • 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

	• 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.

	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: • 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
	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.

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

DH5082-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

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

DH5083-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

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 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.

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.

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

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

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

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

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
• 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	• 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.
	The following changes are likely to be permanent even if testosterone is discontinued: • 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
	The following changes could be permanent, but may improve if I stop taking testosterone: • 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:

	• 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: • 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: • 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: • 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:

	• 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: • 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

Surgical Treatment for Adults with Gender Dysphoria

Patient Information and Informed Consent

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

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

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

What are the types of surgery to treat gender dysphoria?

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

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

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

Patient

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-8 and 64B15ER23-10

- **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.
- **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.

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

Patient

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

Potential complications include:

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

What happens after surgery to treat gender dysphoria?

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

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

When should I see my surgeon?

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

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

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

Patient

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

Patient	Statement
	I understand that my surgeon will discuss with me during the preoperative process the available surgical procedures to treat gender dysphoria, the aftercare needs following surgery, and the importance of postoperative follow-up.
	I understand that these surgeries are permanent.
	I understand that if I have my breasts removed, I must undergo reconstructive surgery if I wish to have breasts in the future. If implants are used, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that if I have my breasts removed that breast feeding will never be possible.
	I understand that if I have breast augmentation surgery, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that my surgeon will assess me for risk factors associated with breast cancer prior to breast augmentation or mastectomy, including genetic mutations (e.g.., BRCA1, BRCA2), family history, age, radiation, exposure to estrogen, and the amount of breast tissue anticipated to remain after surgery.
	I understand that if I undergo metoidioplasty/phalloplasty I will need lifelong urological treatment.
	I understand that complications following metoidioplasty/phalloplasty include: • urinary tract strictures and fistulas • mucoceles due to vaginal remnant • hair growth within the neourethra • compromised sexual function including absent tactile and/or erogenous sensation, difficulties achieving orgasm • complications with penile prosthetics
	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: • the formation of granulation tissue • intravaginal hair growth • delayed wound healing and/or wound disruption • introital stenosis (closing, narrowing, or closure)

	• painful sex
	I understand that my surgeon may stop further treatment because the risks of treatment outweigh the benefits of treatment.
	I understand that this treatment will not prevent serious psychiatric events, including suicide.
	I agree to tell my surgeon if I have any problems or side effects or am unhappy with the surgery, including if I have worsening signs of depression or anxiety or want to harm myself or attempt suicide.
	I understand that my surgeon may be required to refer me to one or more specialists for surgery-related complications, and I agree to go to those specialists as recommended.
	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: • cervical/prostrate screening tests at appropriate intervals as recommended by my doctor • regularly checking my breasts for lumps, even if I have had a mastectomy • regular mammograms from an appropriate age in consultation with my doctor • quitting smoking • 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

CONSENT:

My signature below confirms that:

1. My surgeon has talked with me about:
   a. the benefits and risks of surgery to treat gender dysphoria;
   b. the possible or likely consequences of surgery to treat gender dysphoria;
   c. potential alternative treatments.

2. The information provided to me in this form and by the surgeon includes the known effects and risks of surgery to treat gender dysphoria. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my surgeon.

4. All my questions have been answered to my satisfaction by my surgeon.

5. I know enough to give informed consent to have, refuse, or postpone surgery to treat gender dysphoria.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your surgeon.

7. My signature below attests to my consent to surgery to treat gender dysphoria.

My signature below confirms the following:

_____ _____

Patient's signature (required) Date

_____ _____

Patient's signature (required) Date

SURGEON:

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

_____
Surgeon's printed name (required)

_____ _____
Surgeon's signature (required) Date

WITNESS:

_____
Witness' printed name (required)

_____ _____
Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

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

_____

Interpreter's printed name

_____ _____

Interpreter's signature Date

FLORIDA DEPARTMENT of STATE

RON DESANTIS
Governor

CORD BYRD
Secretary of State

August 18, 2023

Cassandra P. Fullove
Senior Legal Assistant
Office of the Attorney General
PL-01, The Capitol
Tallahassee, FL 32399-1050

Dear Cassandra P. Fullove:

Your adoption package for Emergency Rule 64B8ER23-11 was received, electronically, by the Florida Department of State, Administrative Code and Register 3:49 p.m. on August 18, 2023. After review, it appears that the package meets statutory requirements and those of Rule 1-1.010, F.A.C. and is deemed filed for adoption at the time received, as indicated above. The effective date is August 18, 2023.

Sincerely,

Anya C. Owens
Administrative Code and Register Director

ACO/al

R. A. Gray Building • 500 South Bronough Street • Tallahassee, Florida 32399-0250
Telephone: (850) 245-6270

Leijon, Alexandra

From: Cassandra Fullove <Cassandra.Fullove@myfloridalegal.com>
Sent: Friday, August 18, 2023 3:49 PM
To: Owens, Anya C.; Leijon, Alexandra; RuleAdoptions
Subject: 64B8ER23-11, F.A.C.
Attachments: 64B8ER23-11 emergency rule packet.pdf; Text.docx

Hello,

Attached is the emergency rule filing for 64B8ER23-11, F.A.C. If you have any questions do not hesitate to contact me. Thank you.

Cassandra P. Fullove
Senior Legal Assistant
Administrative Law Bureau
Office of the Attorney General
PL-01, The Capitol
Tallahassee, FL 32399-1050
Office: (850) 414-3766
Fax: (850) 922-6425
Cassandra.Fullove@myfloridalegal.com

ASHLEY MOODY
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
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http://www.myfloridalegal.com

M E M O R A N D U M

TO: Anya C. Owens, Program Administrator
Bureau of Administrative Code

FROM: Cassandra P. Fullove, Senior Legal Assistant

RE: Department of Health
Board of Medicine
Emergency Rule 64B8ER23-11

DATE: August 18, 2023

Attached are the following documents regarding the above-referenced emergency rule adoption packet.

1. Notice of Emergency Rule
2. Adoption text for Emergency Rule 64B8ER23-11
3 Certification of Board of Medicine Emergency Rule
3. Designation of Rule the Violation of Which is a Minor Violation
4. Certification of Materials Incorporated by Reference in Emergency Rules
5. Form DH-5082-MQA (08/23)
6. Form DH-5083-MQA (08/23)
7. Form DH-5084-MQA (08/23)

Should you have any questions regarding the rule do not hesitate to contact me.

Thank you.

CERTIFICATION OF BOARD OF MEDICINE

EMERGENCY RULE FILED WITH THE

DEPARTMENT OF STATE

I hereby certify that pursuant to Ch 2023-90 Laws of Florida, Section 5, section 456.52, Florida Statutes was created and pursuant to subparagraphs 456.52(1)(a) and (6)(a), F.S., the Board of Medicine is required to adopt emergency rules to implement the section. I further certify that the procedures used in the promulgation of this emergency rule were fair under the circumstances and that the rule otherwise complies with subsection 120.54(4), F.S. The adoption of this rule was authorized by the head of the agency and this rule is hereby adopted upon its filing with the Department of State.

Rule No.

64B8ER23-11

Under the provision of subparagraph 120.54(4)(d), F.S., this rule takes effect upon filing unless a later time and date less than 20 days from filing is set out below:

Effective: _____
(Month) (Day) (Year)

Signature, Person Authorized
To Certify Rules

Executive Director for Scot Ackerman, M.D., Chair
Title

_____
Number of Pages Certified

CERTIFICATION OF DEPARTMENT OF STATE
DESIGNATION OF RULE THE VIOLATION OF WHICH IS A MINOR VIOLATION

Pursuant to Section 120.695(2)(c)3, Florida Statutes, I certify as agency head, as defined by section 20.05(1)(b), F.S., that:

[x] All rules covered by this certification are not rules the violation of which would be minor violation pursuant to Section 120.695, F.S.

[ ] The following parts of the rules covered by this certification have been designated as rules the violation of which would be a minor violation pursuant to Section 120.695, F.S.:

Rule No(s).

Rules covered by this certification:

Rule No(s).:

64B8ER23-11

Signature of Agency Head

Paul Vazquez, Executive Director for
Scot Ackerman, M.D., Chair
Title

Form: DS-FCR-6
Rule 1-1.010(3)(f), F.A.C.; effective 10-17

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). ***

REASONS FOR CONCLUDING THAT THE PROCEDURE USED 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.

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____.

CERTIFICATION OF MATERIALS INCORPORATED

BY REFERENCE IN EMERGENCY RULES FILED WITH THE DEPARTMENT OF STATE

I hereby certify pursuant to Rule 1-1.013, Florida Administrative Code, that materials incorporated by reference in Emergency Rule 64B8ER23-11 have been:

[x] (1) Filed with the Department of State and included as part of the Emergency Rule adoption packet.

[ ] (2) That because there would be a violation of federal copyright laws if the submitting agency filed the incorporated materials as described in option (1) above, a true and complete copy of the incorporated materials has been provided to the Department of State as outlined in paragraph 1-1.013(5)(c), F.A.C.

Copies of the incorporated materials below may be obtained at the agency by [include address(es)/location(s)].

List form number(s) and form title(s), or title of document(s) below:

DH5082-MQA Feminizing Medications for Patient with Gender Dysphoria-Patient Information and Informed Consent

DH5083-MQA Masculinizing Medications for Patients with Gender Dysphoria-Patient Information and Informed Consent

DH5084-MQA Surgical Treatment for Adults with Gender Dysphoria-Patients Information and Informed Consent

Under the provisions of Section 120.54(4)(d), F.S., the attached material(s) take effect upon filing with the Department of State, or a date less than 20 days thereafter if specified in the rule if the adopting agency finds that such effective date is necessary because of immediate danger to the public health, safety, or welfare.

Signature, Person Authorized to Certify Rules

Paul Vazquez, Executive Director for
Scot Ackerman, M.D., Chair
Title

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.

Patient

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Rules 64B8ER23-11 and 64B15ER23-12

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.

Patient

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.

Patient

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.

Patient

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.
	If I take estrogen, the following changes in my breasts will occur: • 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
	If I take feminizing medications, my body will make less testosterone, which may affect my sex life in different ways, including: • 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.
	If I take feminizing medications, some parts of my body will not change much, including: • 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

	Even if I stop taking feminizing medications, the following changes may occur: • 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
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to feminize my body is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of my prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications.

Risks of Feminizing Medications

Patient	Statement
	The medical effects and the safety of taking femininizing medications are not completely known and there may be unknown long-term risks.
	Taking femininizing medications causes changes that other people will notice.
	Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
	I must not take more feminizing medication than prescribed. Taking too much medication: • Will increase health risks • Will not make changes happen more quickly or more significantly
	Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Patient	Statement
	Estrogen **SHOULD NOT** be used by anyone who has: • 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
	Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • 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

	• 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
	Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • 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
	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.
	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.
	Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
	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.
	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.
	Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to your prescribing physician.
	Taking estrogen can cause migraines or can make them worse if you already have them.
	Taking estrogen can cause hot flashes.
	Taking estrogen can cause you to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Patient	Statement
	Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • 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

	Taking Spironolactone affects the balance of potassium in the kidneys, which may result in you experiencing high potassium levels resulting in:
	• Changes in heart rhythms that may be life threatening
	• Low blood pressure, which can cause:
	  o Fatigue
	  o Lightheadedness
	  o Tingling feelings
	  o Muscle weakness
	  o Shortness of breath
	• Your need for regular blood tests to monitor risks while on the medication

	Taking Bicalutamide may cause numerous side effects which should be reported to your prescribing physician, including: • 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

	• 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.

	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: • 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
	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.

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

DH5082-MQA (Rev. 08/23)
Rules 64B8ER23-11 and 64B15ER23-12

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

DH5082-MQA (Rev. 08/23)
Rules 64B8ER23-11 and 64B15ER23-12

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

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Rules 64B8ER23-11 and 64B15ER23-12

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 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.

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.

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
• 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	• 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.
	The following changes are likely to be permanent even if testosterone is discontinued: • 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
	The following changes could be permanent, but may improve if I stop taking testosterone: • 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:

	• 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: • 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: • 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: • 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:

	• 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: • 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

Surgical Treatment for Adults with Gender Dysphoria

Patient Information and Informed Consent

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

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

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

What are the types of surgery to treat gender dysphoria?

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

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

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

Patient

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-11 and 64B15ER23-12

- **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.
- **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.

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

Patient

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-11 and 64B15ER23-12

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

Potential complications include:

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

What happens after surgery to treat gender dysphoria?

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

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

When should I see my surgeon?

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

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

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

Patient

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

Patient	Statement
	I understand that my surgeon will discuss with me during the preoperative process the available surgical procedures to treat gender dysphoria, the aftercare needs following surgery, and the importance of postoperative follow-up.
	I understand that these surgeries are permanent.
	I understand that if I have my breasts removed, I must undergo reconstructive surgery if I wish to have breasts in the future. If implants are used, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that if I have my breasts removed that breast feeding will never be possible.
	I understand that if I have breast augmentation surgery, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that my surgeon will assess me for risk factors associated with breast cancer prior to breast augmentation or mastectomy, including genetic mutations (e.g.., BRCA1, BRCA2), family history, age, radiation, exposure to estrogen, and the amount of breast tissue anticipated to remain after surgery.
	I understand that if I undergo metoidioplasty/phalloplasty I will need lifelong urological treatment.
	I understand that complications following metoidioplasty/phalloplasty include: • urinary tract strictures and fistulas • mucoceles due to vaginal remnant • hair growth within the neourethra • compromised sexual function including absent tactile and/or erogenous sensation, difficulties achieving orgasm • complications with penile prosthetics
	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: • the formation of granulation tissue • intravaginal hair growth • delayed wound healing and/or wound disruption • introital stenosis (closing, narrowing, or closure)

	• painful sex
	I understand that my surgeon may stop further treatment because the risks of treatment outweigh the benefits of treatment.
	I understand that this treatment will not prevent serious psychiatric events, including suicide.
	I agree to tell my surgeon if I have any problems or side effects or am unhappy with the surgery, including if I have worsening signs of depression or anxiety or want to harm myself or attempt suicide.
	I understand that my surgeon may be required to refer me to one or more specialists for surgery-related complications, and I agree to go to those specialists as recommended.
	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: • cervical/prostrate screening tests at appropriate intervals as recommended by my doctor • regularly checking my breasts for lumps, even if I have had a mastectomy • regular mammograms from an appropriate age in consultation with my doctor • quitting smoking • 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

CONSENT:

My signature below confirms that:

1. My surgeon has talked with me about:
    a. the benefits and risks of surgery to treat gender dysphoria;
    b. the possible or likely consequences of surgery to treat gender dysphoria;
    c. potential alternative treatments.

2. The information provided to me in this form and by the surgeon includes the known effects and risks of surgery to treat gender dysphoria. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my surgeon.

4. All my questions have been answered to my satisfaction by my surgeon.

5. I know enough to give informed consent to have, refuse, or postpone surgery to treat gender dysphoria.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your surgeon.

7. My signature below attests to my consent to surgery to treat gender dysphoria.

My signature below confirms the following:

_____ _____

Patient's signature (required) Date

_____ _____

Patient's signature (required) Date

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-11 and 64B15ER23-12

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

FLORIDA DEPARTMENT of STATE

RON DESANTIS
Governor

CORD BYRD
Secretary of State

August 18, 2023

Cassandra P. Fullove
Senior Legal Assistant
Office of the Attorney General
PL-01, The Capitol
Tallahassee, FL 32399-1050

Dear Cassandra P. Fullove:

Your adoption package for Emergency Rule 64B15ER23-12 was received, electronically, by the Florida Department of State, Administrative Code and Register 3:54 p.m. on August 18, 2023. After review, it appears that the package meets statutory requirements and those of Rule 1-1.010, F.A.C. and is deemed filed for adoption at the time received, as indicated above. The effective date is August 18, 2023.

Sincerely,

Anya C. Owens
Administrative Code and Register Director

ACO/al

Leijon, Alexandra

From: Cassandra Fullove <Cassandra.Fullove@myfloridalegal.com>
Sent: Friday, August 18, 2023 3:54 PM
To: Owens, Anya C.; Leijon, Alexandra; RuleAdoptions
Subject: 64B15ER23-12, F.A.C.
Attachments: 64B15ER23-12 emergency rule adoption packet.pdf; DH5082-MQA.pdf; DH5083-MQA.pdf; DH5084-MQA.pdf; Text.docx

Hello,

Attached are the emergency rule documents for 64B15ER23-12, F.A.C. If you have any questions do not hesitate to contact me. Thank you.

Cassandra P. Fullove
Senior Legal Assistant
Administrative Law Bureau
Office of the Attorney General
PL-01, The Capitol
Tallahassee, FL 32399-1050
Office: (850) 414-3766
Fax: (850) 922-6425
Cassandra.Fullove@myfloridalegal.com

ASHLEY MOODY
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Cassandra P. Fullove
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http://www.myfloridalegal.com

M E M O R A N D U M

TO: Anya C. Owens, Program Administrator
Bureau of Administrative Code

FROM: Cassandra P. Fullove, Senior Legal Assistant

RE: Department of Health
Board of Osteopathic Medicine
Emergency Rule 64B15ER23-12

DATE: August 18, 2023

Attached are the following documents regarding the above-referenced emergency rule adoption packet.

1. Notice of Emergency Rule
2. Adoption text for Emergency Rule 64B15ER23-12
3 Certification of Board of Osteopathic Medicine Emergency Rule
3. Designation of Rule the Violation of Which is a Minor Violation
4. Certification of Materials Incorporated by Reference in Emergency Rules
5. Form DH5082-MQA (08/23)
6. Form DH5083-MQA (08/23)
7. Form DH5084-MQA (08/23)

Should you have any questions regarding the rule do not hesitate to contact me.

Thank you.

CERTIFICATION OF BOARD OF OSTEOPATHIC MEDICINE

EMERGENCY RULE FILED WITH THE

DEPARTMENT OF STATE

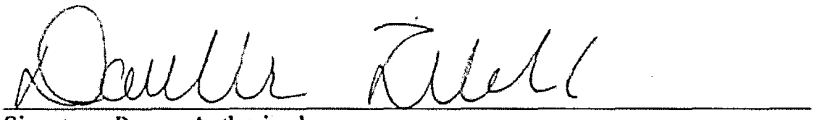
I hereby certify that pursuant to Ch 2023-90 Laws of Florida, Section 5, section 456.52, Florida Statutes was created and pursuant to subparagraphs 456.52(1)(a) and (6)(a), F.S., the Board of Osteopathic Medicine is required to adopt emergency rules to implement the section. I further certify that the procedures used in the promulgation of this emergency rule were fair under the circumstances and that the rule otherwise complies with subsection 120.54(4), F.S. The adoption of this rule was authorized by the head of the agency and this rule is hereby adopted upon its filing with the Department of State.

Rule No.

64B15ER23-12

Under the provision of subparagraph 120.54(4)(d), F.S., this rule takes effect upon filing unless a later time and date less than 20 days from filing is set out below:

Effective: _____
(Month) (Day) (Year)



Signature, Person Authorized
To Certify Rules

Executive Director for Tiffany Sizemore Di Pietro , DO, FACC, FACOI, Chair
Title

_____
Number of Pages Certified

CERTIFICATION OF DEPARTMENT OF STATE
DESIGNATION OF RULE THE VIOLATION OF WHICH IS A MINOR VIOLATION

Pursuant to Section 120.695(2)(c)3, Florida Statutes, I certify as agency head, as defined by section 20.05(1)(b), F.S., that:

[x] All rules covered by this certification are not rules the violation of which would be minor violation pursuant to Section 120.695, F.S.

[ ] The following parts of the rules covered by this certification have been designated as rules the violation of which would be a minor violation pursuant to Section 120.695, F.S.:

Rule No(s).

Rules covered by this certification:

Rule No(s).:

64B15ER23-12

Signature of Agency Head

Executive Director for Tiffany Sizemore Di Pietro , DO, FACC, FACOI, Chair
Title

Form: DS-FCR-6
Rule 1-1.010(3)(f), F.A.C.; effective 10-17

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). ***

REASONS FOR CONCLUDING THAT THE PROCEDURE USED 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.

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____.

CERTIFICATION OF MATERIALS INCORPORATED
BY REFERENCE IN EMERGENCY RULES FILED WITH THE DEPARTMENT OF STATE

I hereby certify pursuant to Rule 1-1.013, Florida Administrative Code, that materials incorporated by reference in Emergency Rule 64B15ER23-12 have been:

[x] (1) Filed with the Department of State and included as part of the Emergency Rule adoption packet.

[ ] (2) That because there would be a violation of federal copyright laws if the submitting agency filed the incorporated materials as described in option (1) above, a true and complete copy of the incorporated materials has been provided to the Department of State as outlined in paragraph 1-1.013(5)(c), F.A.C.

Copies of the incorporated materials below may be obtained at the agency by [include address(es)/location(s)].

List form number(s) and form title(s), or title of document(s) below:

DH5082-MQA Feminizing Medications for Patient with Gender Dysphoria-Patient Information and Informed Consent

DH5083-MQA Masculinizing Medications for Patients with Gender Dysphoria-Patient Information and Informed Consent

DH5084-MQA Surgical Treatment for Adults with Gender Dysphoria-Patients Information and Informed Consent

Under the provisions of Section 120.54(4)(d), F.S., the attached material(s) take effect upon filing with the Department of State, or a date less than 20 days thereafter if specified in the rule if the adopting agency finds that such effective date is necessary because of immediate danger to the public health, safety, or welfare.

Signature, Person Authorized to Certify Rules

Danielle Terrell, Executive Director for Tiffany Sizemore Di Pietro, DO, FACC, FACOI, Chair
Title

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.

Patient

DH5082-MQA (Rev. 08/23)
Rules 64B8ER23-11 and 64B15ER23-12

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.

Patient

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.

Patient

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.

Patient

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.
	If I take estrogen, the following changes in my breasts will occur: • 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
	If I take feminizing medications, my body will make less testosterone, which may affect my sex life in different ways, including: • 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.
	If I take feminizing medications, some parts of my body will not change much, including: • 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

	Even if I stop taking feminizing medications, the following changes may occur: • 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
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to feminize my body is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of my prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications.

Risks of Feminizing Medications

Patient	Statement
	The medical effects and the safety of taking femininizing medications are not completely known and there may be unknown long-term risks.
	Taking femininizing medications causes changes that other people will notice.
	Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
	I must not take more feminizing medication than prescribed. Taking too much medication: • Will increase health risks • Will not make changes happen more quickly or more significantly
	Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Patient	Statement
	Estrogen **SHOULD NOT** be used by anyone who has: • 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
	Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • 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

	• 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
	Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • 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
	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.
	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.
	Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
	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.
	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.
	Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to your prescribing physician.
	Taking estrogen can cause migraines or can make them worse if you already have them.
	Taking estrogen can cause hot flashes.
	Taking estrogen can cause you to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Patient	Statement
	Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • 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
	Taking Spironolactone affects the balance of potassium in the kidneys, which may result in you experiencing high potassium levels resulting in: • Changes in heart rhythms that may be life threatening • Low blood pressure, which can cause: o Fatigue o Lightheadedness o Tingling feelings o Muscle weakness o Shortness of breath • Your need for regular blood tests to monitor risks while on the medication
	Taking Bicalutamide may cause numerous side effects which should be reported to your prescribing physician, including: • 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

	• 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.

	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: • 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
	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.

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

DH5082-MQA (Rev. 08/23)
Rules 64B8ER23-11 and 64B15ER23-12

PRESCRIBING PHYSICIAN SIGNATURE:

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

_____
Prescribing physician's printed name (required)

_____ _____
Prescribing physician's signature (required) Date

WITNESS:

_____
Witness' printed name (required)

_____ _____
Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

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

_____
Interpreter's printed name

_____ _____
Interpreter's signature Date

Masculinizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent

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

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

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

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

What are the medications that can masculinize one's appearance?

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

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

Patient

DH5083-MQA (Rev. 08/23)
Rules 64B8ER23-11 and 64B15ER23-12

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 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.

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.

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
• 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	• 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.
	The following changes are likely to be permanent even if testosterone is discontinued: • 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
	The following changes could be permanent, but may improve if I stop taking testosterone: • 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:

	• 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: • 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: • 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: • 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:

	• 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: • 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

Surgical Treatment for Adults with Gender Dysphoria

Patient Information and Informed Consent

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

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

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

What are the types of surgery to treat gender dysphoria?

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

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

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

Patient

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-11 and 64B15ER23-12

- **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.
- **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.

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

Patient

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

Potential complications include:

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

What happens after surgery to treat gender dysphoria?

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

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

When should I see my surgeon?

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

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

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

Patient

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

Patient	Statement
	I understand that my surgeon will discuss with me during the preoperative process the available surgical procedures to treat gender dysphoria, the aftercare needs following surgery, and the importance of postoperative follow-up.
	I understand that these surgeries are permanent.
	I understand that if I have my breasts removed, I must undergo reconstructive surgery if I wish to have breasts in the future. If implants are used, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that if I have my breasts removed that breast feeding will never be possible.
	I understand that if I have breast augmentation surgery, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that my surgeon will assess me for risk factors associated with breast cancer prior to breast augmentation or mastectomy, including genetic mutations (e.g.., BRCA1, BRCA2), family history, age, radiation, exposure to estrogen, and the amount of breast tissue anticipated to remain after surgery.
	I understand that if I undergo metoidioplasty/phalloplasty I will need lifelong urological treatment.
	I understand that complications following metoidioplasty/phalloplasty include: • urinary tract strictures and fistulas • mucoceles due to vaginal remnant • hair growth within the neourethra • compromised sexual function including absent tactile and/or erogenous sensation, difficulties achieving orgasm • complications with penile prosthetics
	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: • the formation of granulation tissue • intravaginal hair growth • delayed wound healing and/or wound disruption • introital stenosis (closing, narrowing, or closure)

	• painful sex
	I understand that my surgeon may stop further treatment because the risks of treatment outweigh the benefits of treatment.
	I understand that this treatment will not prevent serious psychiatric events, including suicide.
	I agree to tell my surgeon if I have any problems or side effects or am unhappy with the surgery, including if I have worsening signs of depression or anxiety or want to harm myself or attempt suicide.
	I understand that my surgeon may be required to refer me to one or more specialists for surgery-related complications, and I agree to go to those specialists as recommended.
	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: • cervical/prostrate screening tests at appropriate intervals as recommended by my doctor • regularly checking my breasts for lumps, even if I have had a mastectomy • regular mammograms from an appropriate age in consultation with my doctor • quitting smoking • 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

CONSENT:

My signature below confirms that:

1. My surgeon has talked with me about:
    a. the benefits and risks of surgery to treat gender dysphoria;
    b. the possible or likely consequences of surgery to treat gender dysphoria;
    c. potential alternative treatments.

2. The information provided to me in this form and by the surgeon includes the known effects and risks of surgery to treat gender dysphoria. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my surgeon.

4. All my questions have been answered to my satisfaction by my surgeon.

5. I know enough to give informed consent to have, refuse, or postpone surgery to treat gender dysphoria.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your surgeon.

7. My signature below attests to my consent to surgery to treat gender dysphoria.

My signature below confirms the following:

_____ _____

Patient's signature (required) Date

_____ _____

Patient's signature (required) Date

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-11 and 64B15ER23-12

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

KENNETH J. PLANTE
COORDINATOR
Room 680, Pepper Building
111 West Madison Street
Tallahassee, Florida 32399-1400
Telephone (850) 488-9110
Fax (850) 922-6934
www.japc.state.fl.us
japc@leg.state.fl.us

July 21, 2023

Mr. Christopher Dierlam
Senior Assistant Attorney General
Office of the Attorney General
PL-01, The Capitol
Tallahassee, Florida 32399-1050

RE: Department of Health: Board of Medicine
Emergency Rule 64B8ER23-8

Dear Mr. Dierlam:

I have reviewed the above-referenced emergency rule, which was effective on July 5, 2023, and advertised in the Florida Administrative Register on July 7, 2023. I have the following comments.

64B8ER23-8: The board may want to consider citing section 458.331(1)(v) as rulemaking authority and as a law implemented.

64B8ER23-8(1)(a): DH5082-MQA, Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent
Page 3: Please explain the board's statutory authority for requiring that adults receiving these medications "to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist" before beginning HRT and every two years thereafter. *See* § 120.52(8)(c), Fla. Stat.

Also, please explain why this informed consent contains substantive requirements for adults to receive hormone replacement therapy. Section 456.52(2) requires the consent form to provide information regarding the nature and risks of the prescription and an acknowledgment from the patient. It appears that substantive requirements for hormone replacement therapy should be in the rule text, not in the informed consent form. *See* § 120.52(8)(c), Fla. Stat.

64B8ER23-8(1)(b): DH5083-MQA, Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent
See comments to 64B8ER23-8(1)(a) regarding form DH5082.

Please let me know if you have any questions. Otherwise, I look forward to your response.

Sincerely,

Marjorie C. Holladay
Chief Attorney

cc: Mr. Edward A. Tellechea, Chief Assistant Attorney General

MCH:df #190463

KATHLEEN PASSIDOMO
President

PAUL RENNER
Speaker

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July 21, 2023

Ms. Donna McNulty
Special Counsel
Office of the Attorney General
PL-01, The Capitol
Tallahassee, Florida 32399-1050

RE: Department of Health: Board of Osteopathic Medicine
Emergency Rule 64B15ER23-10

Dear Ms. McNulty:

I have reviewed the above-referenced emergency rule, which was effective on July 5, 2023, and advertised in the Florida Administrative Register on July 7, 2023. I have the following comments.

64B15ER23-10: The board may want to consider citing section 459.015(1)(z) as rulemaking authority and as a law implemented.

64B15ER23-10(1)(a): DH5082-MQA, Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent
Page 3: Please explain the board's statutory authority for requiring that adults receiving these medications "to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist" before beginning HRT and every two years thereafter. *See* § 120.52(8)(c), Fla. Stat.

Also, please explain why this informed consent contains substantive requirements for adults to receive hormone replacement therapy. Section 456.52(2) requires the consent form to provide information regarding the nature and risks of the prescription and an acknowledgment from the patient. It appears that substantive requirements for hormone replacement therapy should be in the rule

text, not in the informed consent form. *See* § 120.52(8)(c), Fla. Stat.

64B15ER23-10(1)(b): DH5083-MQA, Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent
See comments to 64B15ER23-10(1)(a) regarding form DH5082.

Please let me know if you have any questions. Otherwise, I look forward to your response.

Sincerely,

Marjorie C. Holladay
Chief Attorney

cc: Mr. Edward A. Tellechea, Chief Assistant Attorney General

MCH:df #190465