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

Renaissance Orlando Airport Hotel
5445 Forbes Place
Orlando, FL 32812
407-240-1000

August 3, 2023

AGENDA

Participants in this public meeting should be aware that the proceedings are being recorded and that an audio file of the meeting will be posted to the boards' websites.

Roll call will be at 4:00 p.m. or shortly thereafter.

Old Business

Meeting Minutes

- Approval of June 23, 2023, Joint Rules/Legislative Committee meeting minutes

New Business

Rules 64B8-9.XXX and 64B15-14.XXX, F.A.C. – Standards of Practice for the Treatment of Gender Dysphoria in Minors **1**

- Discussion of permanent rule relating to the standard of care for the treatment of gender dysphoria in minors
- Discussion of permanent rule relating to informed consents for the treatment of gender dysphoria in minors

Rules 64B8-9.XXX and 64B15-14.XXX, F.A.C. – Informed Consent for the Treatment of Gender Dysphoria in Adults **2**

- Discussion of permanent rule relating to informed consents for the treatment of gender dysphoria in adults

CS/HB 1133 – Physician Assistant Licensure **3**

- Determine process for implementation of sections 458.347(6)(a)2.e. and 459.022(6)(a)2.e., F.S., in light of CS/HB 1133

Emergency Rules 64B8ER23-8 and 64B15ER23-10 – Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults **4**

- Consideration of JAPC correspondence dated 7/21/2023 for Board of Medicine
- Consideration of JAPC correspondence dated 7/21/2023 for Board of Osteopathic Medicine

Doe Pls' Trial Ex.
70

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Board of Medicine

The **Florida Boards of Medicine and Osteopathic Medicine's Joint Rules/Legislative Committee** announces a public meeting to which all persons are invited.

DATE AND TIME: (UPDATED) Thursday, August 3, 2023, beginning at 4:00 PM EST, or soon thereafter.

PLACE: Renaissance Orlando Airport Hotel, 5445 Forbes Place, Orlando, Florida 32812. The hotel's phone number is (407) 240-1000. The hotel's website is https://www.marriott.com/en-us/hotels/mcora-renaissance-orlando- airport-hotel/overview/. The public rate is $129 per night.

GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Committee. Committee meetings may be canceled prior to the meeting date. Please check the Board's website at https://flboardofmedicine.gov/meeting-information for cancellations or changes to the meeting date or time or call the Board at (850)245-4131 for more information.

A copy of the agenda may be obtained by contacting: https://flboardofmedicine.gov/meeting-information.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850) 245-4131.

If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: the Board at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850) 245-4131.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine

The Florida Boards of Medicine and Osteopathic Medicine's Joint Rules/Legislative Committee announces a public meeting to which all persons are invited.

DATE AND TIME: (UPDATED) Thursday, August 3, 2023, 4:00 p.m., EST, or soon thereafter.

PLACE: Renaissance Orlando Airport Hotel, 5445 Forbes Place, Orlando, Florida 32812. The hotel's phone number is (407)240-1000. The hotel's website is https://www.marriott.com/en-us/hotels/mcora-renaissance-orlando- airport-hotel/overview/. The public rate is $129 per night.

GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Committee. Committee meetings may be canceled prior to the meeting date. Please check the Board's website at https://floridasosteopathicmedicine.gov/meeting-information for cancellations or changes to the meeting date or time or call the Board at (850)245-4161 for more information.

A copy of the agenda may be obtained by contacting: https://floridasosteopathicmedicine.gov/meeting-information

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

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

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

MEETING MINUTES

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

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

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

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

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

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

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

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

Ms. Terrell did not provide any comments.

Old Business

There was no old business to discuss.

Action taken:

No action taken.

New Business

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SERC

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

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

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

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

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

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

Action taken:

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

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

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

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

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

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

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

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

Action taken:

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

SERC

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

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

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

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

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

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

The meeting adjourned at 4:54 p.m.

Notice of Emergency Rule

DEPARTMENT OF HEALTH
Board of Medicine
RULE NO.: RULE TITLE:
64B8ER23-7 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 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 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). ***
REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure used for the promulgation of this emergency rule is fair under the circumstances. CSSB 254 was signed into law on May 17, 2023. The Board of Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee's June meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Medicine discussed the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Medicine published notice of its June 2, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.
The Joint Committee held 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. 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 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: 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:

64B8ER23-7 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 7-5-23.

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

EFFECTIVE DATE: July 5, 2023

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). ***

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

The Joint Committee held 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 7-5-23.

THIS RULE TAKES EFFECT UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.
EFFECTIVE DATE: July 5, 2023

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). ***
REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure used for the promulgation of this emergency rule is fair under the circumstances. CSSB 254 was signed into law on May 17, 2023. The Board of Osteopathic Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of 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 7-5-23.

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

EFFECTIVE DATE: July 5, 2023

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). ***

REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure used for the promulgation of this emergency rule is fair under the circumstances. CSSB 254 was signed into law on May 17, 2023. The Board of Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee's June meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of 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 7-5-23.

THIS RULE TAKES EFFECT UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.
EFFECTIVE DATE: July 5, 2023

From: juanantoniobasteiro=gmail.com@mg.gospringboard.io on behalf of Juan Antonio Basteiro
To: BOM Public Comment
Subject: Reject rules to restrict access to gender affirming care
Date: Thursday, July 20, 2023 5:01:48 PM

Dear

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

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

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

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

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

I urge you to reject these rules.

Sincerely,

Juan Antonio Basteiro

From: Kristin Dayton
To: BOM Public Comment
Subject: Comment regarding Emergency Rule and Consents for Gender Care for Minors
Date: Friday, June 30, 2023 4:16:27 PM

Board of Medicine,

I am a physician who cares for hundreds of children with gender dysphoria, and this care many times includes providing gender affirming hormonal prescriptions. **I have spoken with you previously as an expert on the matter**, and have been providing this care for over 6 years. I provide thorough informed consent for all of my patients, both children and adults. I have several issues to bring up regarding the current proposed (and now passed) consent forms that you have created.

1. Requirement for mental health evaluation and suicide assessment by **licensed mental health professional** every 3 months - this is a barrier to care for many patients. We complete mental health assessments at each visit for our gender clinic patients, and include an assessment of suicidality. As physicians, it is well within our scope of practice to carry out this evaluation. So, requiring this to be done by a mental health professional is creating undue burden for our patients. Furthermore, many of our patients may not need that frequent of follow up visits with mental health professionals as they may be well adjusted and not experiencing significant emotional distress (especially once they are able to obtain the appropriate gender-affirming treatment). So, this may be taking away mental health resources from those that truly need it in order to "check a box" for continuing to receive gender care. Contrary to some of the comments made by board members, my experience practicing with this patient population is that it is VERY challenging for them to find mental health professionals and even then they may not be able to obtain appropriate insurance coverage for that continued mental health support.

2. Required labs, imaging studies: The requirements for lab studies and imaging studies should be changed to recommendations. This is not because we don't do these tests, but the frequencies of them are inappropriate and may lead to undue harm for patients. For instance, a bone age study is not required for someone undergoing gender care - it is only recommended if clinically indicated (see Endocrine Society Guidelines) and exposes them to radiation. It is an optional part of monitoring for certain patients, but should not be a yearly requirement as it does not have any added value to care for most patients. By guidelines, DEXA scans are recommended to be done every 1-2 years for patients on pubertal blocking medication but not for patients on gender affirming hormones (HRT as worded in your document). This is again exposing patients to unnecessary radiation with no evidence of the need for this to be done. Lastly, lab testing every 4 months is again an inappropriate frequency of testing. Patients on puberty blocking treatment, especially once they reach a steady state of suppression, typically do not need more than once yearly lab assessments and this would place them at undue financial and physical burden to make them do labs more often.

3. Language regarding the low quality evidence is misleading: The language in the BOM

consent forms that points to the "limited, poor quality research" and "speculative" nature of this treatment is misleading and false. Further, the use of the term "poor quality research" is in fact an opinion and not a medical fact - a more appropriate medical term using the GRADE evidence system (see GRADE system explained) may be "low quality evidence". You imply in this form that this may be unusual in medical practice, yet, low quality evidence is used every day to make important, life altering medical decisions. Therefore the fact that it is introduced at the beginning of every consent form is misleading to those not familiar with this commonality in medical practice.

Please feel free to reach out to me for any other questions or concerns,

Sincerely,
Kristin Dayton, MD

Public Comment Florida Boards of Medicine and Osteopathic Medicine Joint Meeting June 30 2023

Author: Jerrica Kirkley, MD

Organization: Plume

Title: Chief Medical Officer and co-founder

My name is Dr. Jerrica Kirkley, I am the co-founder and chief medical officer at Plume, and I'm also a trans woman. At Plume we focus entirely on serving the trans and gender non-conforming community and are the largest provider of gender affirming care in the country, and do that all via a telehealth platform. Our clinical team collectively brings several hundred years of experience and expertise in this space.

KEY POINTS

SB254 is in direct opposition of evidence-based care and undermines long-established medical standards of care and practice protocols.

Gender-affirming care, including gender-affirming hormone therapy, is supported by every major healthcare organization and expert in the field including the World Professional Association of Transgender Health, the American Academy of Pediatrics, the American Medical Association, the Endocrine Society, and many more.[1] In fact, just last week, the American Medical Association and the Endocrine Society passed a resolution opposing any criminal and legal penalties against patients seeking gender-affirming care, family members or guardians who support them in seeking medical care, and health care facilities and clinicians who provide gender-affirming care.[2] They reiterated that there is strong clinical research supporting gender-affirming care including over 2000 studies which have examined aspects of gender-affirming care since 1975. This is in direct contrast to the medical boards' claim that there is a paucity of clinical research and support or that gender-affirming care is "experimental".

[1] https://transhealthproject.org/resources/medical-organization-statements/
[2] https://www.endocrine.org/news-and-advocacy/news-room/2023/ama-gender-affirming-care

Having access to gender-affirming care improves health outcomes including decreasing rates of depression, anxiety, and suicidality.[3] This is supported by published clinical research and at Plume, we have seen rapid and significant reduction in depression scores with access to gender-affirming hormone therapy and virtual peer support groups. We know that gender affirming care saves lives and we're deeply concerned that SB254 actually puts real peoples' lives at risk -- many of whom are your neighbors, your co-workers or your family members.

The warnings around off-label prescription drug use in the consent forms is misleading: as practicing clinicians we're fully aware that there are over 500 off-label medications for youth alone that do not involve gender-affirming care and hundreds for adults as well outside of gender-affirming care.[4]

While our practice serves adults, we cannot ignore that the ban on youth gender affirming care is devastating and has serious implications for their future wellbeing and safety.

Finally and most importantly, SB254 sets a dangerous precedent as it fundamentally creates a two-tiered health system in Florida, where trans or gender diverse individuals will not be able or will be severely restricted in their ability to access the care they need, as compared to cisgender individuals.

Adult patients seeking gender affirming care will be segregated from the rest of the population and only be allowed to be seen by an MD or DO rather than an NP or PA, who we know provide the majority of primary care and gender-affirming care in Florida.[5]

In addition, these patients will be required to be initially seen in-person, imposing a major barrier for telehealth providers to prescribe gender-affirming medication, despite the fact that it's a

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[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5010234/#:~:text=Published%20in%202010%2C%20the%20review,and%20overall%20quality%20of%20life.

[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6677268/

[5] https://www.pbs.org/newshour/health/floridas-ban-on-gender-affirming-care-for-minors-also-limits-access-for-trans-adults

well-established care delivery platform for all people, and especially the gender diverse community - 85% of trans individuals did not go to a healthcare facility when they needed to in 2022 due to fear of discrimination and mistreatment.[6]

Furthermore, no other medical practice requires a written informed consent, including care for diabetes, hypertension, heart disease, erectile function, hormone replacement for cisgender men and cisgender women, body modifying surgeries for cisgender people or any other surgery, and many more conditions. The **requirement to have an evaluation and letter from a FL-licensed psychiatrist or psychologist to start or continue gender-affirming hormone therapy and annual assessment thereafter,** as noted in the drafted consent forms in the public book, is in direct opposition to the WPATH standards of care version 8, and is yet another barrier to lifesaving care.

Finally, these laws, which have no scientific basis, also threaten clinicians with severe penalties for looking after their patients' health care needs, sending a chilling message to the entire medical community.

This month alone, several bipartisan federally appointed judges around the country, including here in Florida, have made it clear that anti-trans legislation is unconstitutional, and this includes bans on and restriction to healthcare access.[7] [8]

As clinicians and as part of the broader community, I urge the Florida Board of Medicine and the Florida Board of Osteopathic Medicine to stand by evidence-based medicine, to stand by the Florida clinicians you represent, to stand by your community and permit individuals access to life saving gender-affirming care and specifically:

- Do not require an evaluation and/or a letter from a psychiatrist or psychologist to access gender-affirming care

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6 https://rockhealth.com/insights/startup-innovation-for-underserved-groups-2021-digital-health-consumer-adoption-insights/?mc_cid=0bfc248bda&mc_eid=bd247e782c

7 https://www.politico.com/news/2023/06/06/florida-gender-affirming-care-ruling-00100387

8 https://www.politico.com/news/2023/06/21/florida-gender-affirming-ban-00103067

- Do not require a diagnosis of gender dysphoria - gender incongruence is the recommendation from
- Do not require patients to sign an informed consent document - let the patient and the clinician navigate informed consent in the way that works best for them as is the case in all of medical practice
- Let all clinicians including nurse practitioners and physician assistants provide this lifesaving care to a community in need

Thank you,

Dr. Jerrica Kirkley

From: perseuslowe=gmail.com@mg.gospringboard.io on behalf of Perseus Lowe
To: BOM Public Comment
Subject: Reject rules to restrict access to gender affirming care
Date: Thursday, July 20, 2023 5:01:37 PM

Dear

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

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

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

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

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

Proposed policies such as this not only are an intrusion into the rights of trans individuals and their families, but it also directly inserts the state government into what healthcare is available based purely on partisan politics and demands that physicians ignore highly effective treatments in order to further a political agenda that demeans and dehumanizes a minority population and directly injects religion into state politics and state healthcare policies in direct violation of the Constitution.

I urge you to reject these rules.

Sincerely,

Perseus Lowe

From: laurieanderson7512=gmail.com@mg.gospringboard.io on behalf of Laurie Melton
To: BOM Public Comment
Subject: Reject rules to restrict access to gender affirming care
Date: Thursday, July 20, 2023 5:01:20 PM

Dear

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

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

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

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

By denying gender affirming care for youth, you are saying that you do not care at all for children's lives. By making it harder for adults to access care, you are invalidating them as adults and violating their right to privacy.

I urge you to reject these rules.

Sincerely,

Laurie Melton

An act relating to physician assistant licensure; amending ss. 458.347 and 459.022 F.S.; revising requirements for an applicant for licensure as a physician assistant; providing an effective date.

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

Section 1. Paragraph (a) of subsection (6) of section 458.347, Florida Statutes, is amended to read:

458.347 Physician assistants.—

(6) PHYSICIAN ASSISTANT LICENSURE.—

(a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met all of the following requirements:

1. Is at least 18 years of age.

2. Has completed ~~graduated from~~ an approved program.

a. For an applicant who matriculated ~~graduated~~ after December 31, 2020, has received a master's degree ~~in accordance with the Accreditation Review Commission on Education for the Physician Assistant or, before 2001, its equivalent or predecessor organization~~.

b. For an applicant who matriculated ~~graduated~~ on or before December 31, 2020, has received a bachelor's or master's

degree from an approved program.

c. For an applicant who graduated before July 1, 1994, has graduated from an approved program of instruction in primary health care or surgery.

d. For an applicant who graduated before July 1, 1983, has received a certification as a physician assistant from the boards.

e. The board may also grant a license to an applicant who does not meet the educational requirement specified in this subparagraph but who has passed the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants ~~before 1986~~.

3. Has obtained a passing score as established by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has been nationally certified. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants or its equivalent or successor organization to be eligible for licensure.

4. Has completed the application form and remitted an

application fee not to exceed $300 as set by the boards. An application for licensure as a physician assistant must include:

a. A diploma from an approved program.

b. Acknowledgment of any prior felony convictions.

c. Acknowledgment of any previous revocation or denial of licensure or certification in any state.

Section 2. Paragraph (a) of subsection (6) of section 459.022, Florida Statutes, is amended to read:

459.022 Physician assistants.—

(6) PHYSICIAN ASSISTANT LICENSURE.—

(a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met all of the following requirements:

1. Is at least 18 years of age.

2. Has completed ~~graduated from~~ an approved program.

a. For an applicant who matriculated ~~graduated~~ after December 31, 2020, has received a master's degree ~~in accordance with the Accreditation Review Commission on Education for the Physician Assistant or, before 2001, its equivalent or predecessor organization~~.

b. For an applicant who matriculated ~~graduated~~ on or before December 31, 2020, has received a bachelor's or master's degree from an approved program.

c. For an applicant who graduated before July 1, 1994, has graduated from an approved program of instruction in primary health care or surgery.

d. For an applicant who graduated before July 1, 1983, has received a certification as a physician assistant from the boards.

e. The board may also grant a license to an applicant who does not meet the educational requirement specified in this subparagraph but who has passed the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants ~~before 1986~~.

3. Has obtained a passing score as established by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has been nationally certified. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants or its equivalent or successor organization to be eligible for licensure.

4. Has completed the application form and remitted an application fee not to exceed $300 as set by the boards. An

application for licensure as a physician assistant must include:

a. A diploma from an approved program.

b. Acknowledgment of any prior felony convictions.

c. Acknowledgment of any previous revocation or denial of licensure or certification in any state.

Section 3. This act shall take effect upon becoming a law.

Select Year: 2022 Go

The 2022 Florida Statutes (including 2022 Special Session A and 2023 Special Session B)

Title XXXII REGULATION OF PROFESSIONS AND OCCUPATIONS | Chapter 458 MEDICAL PRACTICE | View Entire Chapter

458.347 Physician assistants.—

(1) LEGISLATIVE INTENT.—The purpose of this section is to authorize physician assistants, with their education, training, and experience in the field of medicine, to provide increased efficiency of and access to high-quality medical services at a reasonable cost to consumers.

(2) DEFINITIONS.—As used in this section, the term:

(a) "Approved program" means a physician assistant program in the United States or in its territories or possessions which is accredited by the Accreditation Review Commission on Education for the Physician Assistant or, for programs before 2001, accredited by its equivalent or predecessor entities the Committee on Allied Health Education and Accreditation or the Commission on Accreditation of Allied Health Education Programs formally approved by the boards for the education of physician assistants.

(b) "Boards" means the Board of Medicine and the Board of Osteopathic Medicine.

(c) "Continuing medical education" means courses recognized and approved by the boards, the American Academy of Physician Assistants, the American Medical Association, the American Osteopathic Association, or the Accreditation Council on Continuing Medical Education.

(d) "Council" means the Council on Physician Assistants.

(e) "Physician assistant" means a person who is a graduate of an approved program or its equivalent or meets standards approved by the boards and is licensed to perform medical services delegated by the supervising physician.

(f) "Physician assistant national certifying examination" means the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants or its successor agency.

(g) "Supervision" means responsible supervision and control. Except in cases of emergency, supervision requires the easy availability or physical presence of the licensed physician for consultation and direction of the actions of the physician assistant. For the purposes of this definition, the term "easy availability" includes the ability to communicate by way of telecommunication. The boards shall establish rules as to what constitutes responsible supervision of the physician assistant.

(h) "Trainee" means a person who is currently enrolled in an approved program.

(3) PERFORMANCE OF SUPERVISING PHYSICIAN.—Each physician or group of physicians supervising a licensed physician assistant must be qualified in the medical areas in which the physician assistant is to perform and shall be individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant. A physician may not supervise more than 10 currently licensed physician assistants at any one time. A physician supervising a physician assistant pursuant to this section may not be required to review and cosign charts or medical records prepared by such physician assistant.

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(a) The boards shall adopt, by rule, the general principles that supervising physicians must use in developing the scope of practice of a physician assistant under direct supervision and under indirect supervision. These

principles shall recognize the diversity of both specialty and practice settings in which physician assistants are used.

(b) This chapter does not prevent third-party payors from reimbursing employers of physician assistants for covered services rendered by licensed physician assistants.

(c) Licensed physician assistants may not be denied clinical hospital privileges, except for cause, so long as the supervising physician is a staff member in good standing.

(d) A supervisory physician may delegate to a licensed physician assistant, pursuant to a written protocol, the authority to act according to s. 154.04(1)(c). Such delegated authority is limited to the supervising physician's practice in connection with a county health department as defined and established pursuant to chapter 154. The boards shall adopt rules governing the supervision of physician assistants by physicians in county health departments.

(e) A supervising physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervising physician's practice unless such medication is listed on the formulary created pursuant to paragraph (f). A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that he or she is a physician assistant.

2. The supervising physician must notify the department of his or her intent to delegate, on a department-approved form, before delegating such authority and of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. A fully licensed physician assistant may procure medical devices and drugs unless the medication is listed on the formulary created pursuant to paragraph (f).

4. The physician assistant must complete a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal. Three of the 10 hours must consist of a continuing education course on the safe and effective prescribing of controlled substance medications which is offered by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit, designated by the American Academy of Physician Assistants as a Category 1 credit, or designated by the American Osteopathic Association as a Category 1-A credit.

5. The prescription may be in paper or electronic form but must comply with ss. 456.0392(1) and 456.42(1) and chapter 499 and must contain the physician assistant's name, address, and telephone number and the name of each of his or her supervising physicians. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465 and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

(f)1. The council shall establish a formulary of medicinal drugs that a fully licensed physician assistant having prescribing authority under this section or s. 459.022 may not prescribe. The formulary must include general anesthetics and radiographic contrast materials and must limit the prescription of Schedule II controlled substances as listed in s. 893.03 to a 7-day supply. The formulary must also restrict the prescribing of Schedule II psychiatric mental health controlled substances for children younger than 18 years of age to a 14-day supply, provided the physician assistant is under the supervision of a pediatrician, a family practice physician, an internal medicine physician, or a psychiatrist.

2. In establishing the formulary, the council shall consult with a pharmacist licensed under chapter 465, but not licensed under this chapter or chapter 459, who shall be selected by the State Surgeon General.

3. Only the council shall add to, delete from, or modify the formulary. Any person who requests an addition, a deletion, or a modification of a medicinal drug listed on such formulary has the burden of proof to show cause why such addition, deletion, or modification should be made.

4. The boards shall adopt the formulary required by this paragraph, and each addition, deletion, or modification to the formulary, by rule. Notwithstanding any provision of chapter 120 to the contrary, the formulary rule shall be effective 60 days after the date it is filed with the Secretary of State. Upon adoption of the formulary, the department shall mail a copy of such formulary to each fully licensed physician assistant having prescribing authority under this section or s. 459.022, and to each pharmacy licensed by the state. The boards shall establish, by rule, a fee not to exceed $200 to fund the provisions of paragraph (e) and this paragraph.

(g) A supervisory physician may delegate to a licensed physician assistant the authority to, and the licensed physician assistant acting under the direction of the supervisory physician may, order any medication for administration to the supervisory physician's patient in a facility licensed under chapter 395 or part II of chapter 400, notwithstanding any provisions in chapter 465 or chapter 893 which may prohibit this delegation.

(h) A licensed physician assistant may perform services delegated by the supervising physician in the physician assistant's practice in accordance with his or her education and training unless expressly prohibited under this chapter, chapter 459, or rules adopted under this chapter or chapter 459.

(i) Except for a physician certification under s. 381.986, a physician assistant may authenticate any document with his or her signature, certification, stamp, verification, affidavit, or endorsement if such document may be so authenticated by the signature, certification, stamp, verification, affidavit, or endorsement of a physician, except those required for s. 381.986. Such documents include, but are not limited to, any of the following:

1. Initiation of an involuntary examination pursuant to s. 394.463.
2. Do-not-resuscitate orders or physician orders for the administration of life-sustaining treatment.
3. Death certificates.
4. School physical examinations.
5. Medical examinations for workers' compensation claims, except medical examinations required for the evaluation and assignment of the claimant's date of maximum medical improvement as defined in s. 440.02 and for the impairment rating, if any, under s. 440.15.
6. Orders for physical therapy, occupational therapy, speech-language therapy, home health services, or durable medical equipment.

(j) A physician assistant may supervise medical assistants as defined in this chapter.

(k) This chapter authorizes third-party payors to reimburse employers of physician assistants for covered services rendered by licensed physician assistants. Payment for services within the physician assistant's scope of practice must be made when ordered or performed by a physician assistant if the same service would have been covered if ordered or performed by a physician. Physician assistants are authorized to bill for and receive direct payment for the services they deliver.

(5) PROGRAM APPROVAL.—

(a) The boards shall approve programs, based on recommendations by the council, for the education and training of physician assistants which meet standards established by rule of the boards. The council may recommend only those physician assistant programs that hold full accreditation or provisional accreditation from the Accreditation Review Commission on Education for the Physician Assistant or its successor entity or, before 2001, from the Committee on Allied Health Education and Accreditation or the Commission on Accreditation of Allied Health Programs.

(b) Notwithstanding any other law, a trainee may perform medical services when such services are rendered within the scope of an approved program.

(6) PHYSICIAN ASSISTANT LICENSURE.—

(a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met all of the following requirements:

1. Is at least 18 years of age.
2. Has graduated from an approved program.

a. For an applicant who graduated after December 31, 2020, has received a master's degree in accordance with the Accreditation Review Commission on Education for the Physician Assistant or, before 2001, its equivalent or predecessor organization.

b. For an applicant who graduated on or before December 31, 2020, has received a bachelor's or master's degree from an approved program.

c. For an applicant who graduated before July 1, 1994, has graduated from an approved program of instruction in primary health care or surgery.

d. For an applicant who graduated before July 1, 1983, has received a certification as a physician assistant from the boards.

e. The board may also grant a license to an applicant who does not meet the educational requirement specified in this subparagraph but who has passed the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants before 1986.

3. Has obtained a passing score as established by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has been nationally certified. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants or its equivalent or successor organization to be eligible for licensure.

4. Has completed the application form and remitted an application fee not to exceed $300 as set by the boards. An application for licensure as a physician assistant must include:

a. A diploma from an approved program.

b. Acknowledgment of any prior felony convictions.

c. Acknowledgment of any previous revocation or denial of licensure or certification in any state.

(b)1. The license must be renewed biennially. Each renewal must include:

a. A renewal fee not to exceed $500 as set by the boards.

b. Acknowledgment of no felony convictions in the previous 2 years.

c. A completed physician assistant workforce survey, which shall be administered in the same manner as the physician survey established in s. 458.3191 and must contain the same information required in s. 458.3191(1) and (2).

2. Beginning July 1, 2018, and every 2 years thereafter, the department shall report the data collected from the physician assistant workforce surveys to the boards.

3. The department shall adopt rules to implement this paragraph.

(c) Each licensed physician assistant shall biennially complete 100 hours of continuing medical education or shall hold a current certificate issued by the National Commission on Certification of Physician Assistants.

(d) Notwithstanding subparagraph (a)2., the department may grant to a recent graduate of an approved program, as specified in subsection (5), who expects to take the first examination administered by the National Commission on Certification of Physician Assistants available for registration after the applicant's graduation, a temporary license. The temporary license shall expire 30 days after receipt of scores of the proficiency examination administered by the National Commission on Certification of Physician Assistants. Between meetings of the council, the department may grant a temporary license to practice based on the completion of all temporary licensure requirements. All such administratively issued licenses shall be reviewed and acted on at the next regular meeting of the council. The recent graduate may be licensed before employment. An applicant who has passed the proficiency examination may be granted permanent licensure. An applicant failing the proficiency examination is no longer temporarily licensed but may reapply for a 1-year extension of temporary licensure. An applicant may not be granted more than two temporary licenses and may not be licensed as a physician assistant until he or she passes the examination administered by the National Commission on Certification of Physician Assistants. As prescribed by board rule, the council may require an applicant who does not pass the licensing examination after five or more attempts to complete additional remedial education or training. The council shall prescribe the additional requirements in a manner that permits the applicant to complete the requirements and be reexamined within 2 years after the date the applicant petitions the council to retake the examination a sixth or subsequent time.

(e) The Board of Medicine may impose any of the penalties authorized under ss. 456.072 and 458.331(2) upon a physician assistant if the physician assistant or the supervising physician has been found guilty of or is being investigated for any act that constitutes a violation of this chapter or chapter 456.

(f) An application or other documentation required to be submitted to the department under this subsection may be submitted electronically.

(7) DELEGATION OF POWERS AND DUTIES.—The boards may delegate such powers and duties to the council as they may deem proper.

(8) COUNCIL ON PHYSICIAN ASSISTANTS.—The Council on Physician Assistants is created within the department.

(a) The council shall consist of five members appointed as follows:

1. The chairperson of the Board of Medicine shall appoint one member who is a physician and member of the Board of Medicine who supervises a physician assistant in the physician's practice.

2. The chairperson of the Board of Osteopathic Medicine shall appoint one member who is a physician and member of the Board of Osteopathic Medicine who supervises a physician assistant in the physician's practice.

3. The State Surgeon General or his or her designee shall appoint three fully licensed physician assistants licensed under this chapter or chapter 459.

(b) Members shall be appointed to terms of 4 years, except that of the initial appointments, two members shall be appointed to terms of 2 years, two members shall be appointed to terms of 3 years, and one member shall be appointed to a term of 4 years, as established by rule of the boards. Council members may not serve more than two consecutive terms. The council shall annually elect a chairperson from among its members.

(c) The council shall:

1. Recommend to the department the licensure of physician assistants.

2. Develop all rules regulating the use of physician assistants by physicians under this chapter and chapter 459, except for rules relating to the formulary developed under paragraph (4)(f). The council shall also develop rules to ensure that the continuity of supervision is maintained in each practice setting. The boards shall consider adopting a proposed rule developed by the council at the regularly scheduled meeting immediately following the submission of the proposed rule by the council. A proposed rule submitted by the council may not be adopted by either board unless both boards have accepted and approved the identical language contained in the proposed rule. The language of all proposed rules submitted by the council must be approved by both boards pursuant to each respective board's guidelines and standards regarding the adoption of proposed rules. If either board rejects the council's proposed rule, that board must specify its objection to the council with particularity and include any recommendations it may have for the modification of the proposed rule.

3. Make recommendations to the boards regarding all matters relating to physician assistants.

4. Address concerns and problems of practicing physician assistants in order to improve safety in the clinical practices of licensed physician assistants.

(d) When the council finds that an applicant for licensure has failed to meet, to the council's satisfaction, each of the requirements for licensure set forth in this section, the council may enter an order to:

1. Refuse to certify the applicant for licensure;

2. Approve the applicant for licensure with restrictions on the scope of practice or license; or

3. Approve the applicant for conditional licensure. Such conditions may include placement of the licensee on probation for a period of time and subject to such conditions as the council may specify, including but not limited to, requiring the licensee to undergo treatment, to attend continuing education courses, to work under the direct supervision of a physician licensed in this state, or to take corrective action.

(9) INACTIVE AND DELINQUENT STATUS.—A license on inactive or delinquent status may be reactivated only as provided in s. 456.036.

(10) PENALTY.—Any person who has not been licensed by the council and approved by the department and who holds himself or herself out as a physician assistant or who uses any other term in indicating or implying that he or she is a physician assistant commits a felony of the third degree, punishable as provided in s. 775.082 or s. 775.084 or by a fine not exceeding $5,000.

(11) DENIAL, SUSPENSION, OR REVOCATION OF LICENSURE.—The boards may deny, suspend, or revoke a physician assistant license if a board determines that the physician assistant has violated this chapter.

(12) RULES.—The boards shall adopt rules to implement this section, including rules detailing the contents of the application for licensure and notification pursuant to subsection (6) and rules to ensure both the continued competency of physician assistants and the proper utilization of them by physicians or groups of physicians.

(13) EXISTING PROGRAMS.—This section does not eliminate or supersede existing laws relating to other paramedical professions or services and is supplemental to all such existing laws relating to the licensure and practice of paramedical professions.

(14) LIABILITY.—Each supervising physician using a physician assistant is liable for any acts or omissions of the physician assistant acting under the physician's supervision and control.

(15) LEGAL SERVICES.—Legal services shall be provided to the council pursuant to s. 456.009(1).

(16) FEES.—The department shall allocate the fees collected under this section to the council.

History.—ss. 1, 8, ch. 79-302; s. 301, ch. 81-259; ss. 2, 3, ch. 81-318; s. 8, ch. 84-543; s. 8, ch. 84-553; ss. 20, 25, 26, ch. 86-245; s. 29, ch. 88-1; s. 15, ch. 88-277; s. 3, ch. 88-361; s. 26, ch. 89-162; s. 2, ch. 90-60; ss. 33, 34, ch. 90-134; s. 2, ch. 91-22; s. 43, ch. 91-201; s. 4, ch. 91-429; s. 1, ch. 92-22; s. 108, ch. 94-218; s. 1, ch. 95-231; s. 1, ch. 96-197; s. 223, ch. 97-101; s. 1094, ch. 97-103; s. 27, ch. 97-264; s. 6, ch. 98-49; s. 49, ch. 98-166; s. 155, ch. 99-251; s. 1, ch. 99-370; s. 100, ch. 99-397; s. 107, ch. 2000-160; ss. 27, 42, ch. 2000-318; s. 1, ch. 2001-100; ss. 23, 55, ch. 2001-277; s. 75, ch. 2002-1; s. 76, ch. 2004-5; s. 15, ch. 2004-41; s. 1, ch. 2007-155; s. 75, ch. 2008-6; s. 1, ch. 2008-86; s. 2, ch. 2009-177; s. 1, ch. 2010-55; s. 1, ch. 2012-170; s. 1, ch. 2013-127; s. 15, ch. 2014-18; s. 1, ch. 2016-125; s. 2, ch. 2016-145; ss. 9, 10, 22, ch. 2016-224; s. 17, ch. 2016-230; s. 1, ch. 2017-154; s. 15, ch. 2020-133; s. 1, ch. 2021-204.

Select Year: 2022 Go

The 2022 Florida Statutes (including 2022 Special Session A and 2023 Special Session B)

Title XXXII REGULATION OF PROFESSIONS AND OCCUPATIONS | Chapter 459 OSTEOPATHIC MEDICINE | View Entire Chapter

459.022 Physician assistants.—

(1) LEGISLATIVE INTENT.—The purpose of this section is to authorize physician assistants, with their education, training, and experience in the field of medicine, to provide increased efficiency of and access to high-quality medical services at a reasonable cost to consumers.

(2) DEFINITIONS.—As used in this section, the term:

(a) "Approved program" means a physician assistant program in the United States or in its territories or possessions which is accredited by the Accreditation Review Commission on Education for the Physician Assistant or, for programs before 2001, accredited by its equivalent or predecessor entities the Committee on Allied Health Education and Accreditation or the Commission on Accreditation of Allied Health Education Programs formally approved by the boards for the education of physician assistants.

(b) "Boards" means the Board of Medicine and the Board of Osteopathic Medicine.

(c) "Continuing medical education" means courses recognized and approved by the boards, the American Academy of Physician Assistants, the American Medical Association, the American Osteopathic Association, or the Accreditation Council on Continuing Medical Education.

(d) "Council" means the Council on Physician Assistants.

(e) "Physician assistant" means a person who is a graduate of an approved program or its equivalent or meets standards approved by the boards and is licensed to perform medical services delegated by the supervising physician.

(f) "Physician assistant national certifying examination" means the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants or its successor agency.

(g) "Supervision" means responsible supervision and control. Except in cases of emergency, supervision requires the easy availability or physical presence of the licensed physician for consultation and direction of the actions of the physician assistant. For the purposes of this definition, the term "easy availability" includes the ability to communicate by way of telecommunication. The boards shall establish rules as to what constitutes responsible supervision of the physician assistant.

(h) "Trainee" means a person who is currently enrolled in an approved program.

(3) PERFORMANCE OF SUPERVISING PHYSICIAN.—Each physician or group of physicians supervising a licensed physician assistant must be qualified in the medical areas in which the physician assistant is to perform and shall be individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant. A physician may not supervise more than 10 currently licensed physician assistants at any one time. A physician supervising a physician assistant pursuant to this section may not be required to review and cosign charts or medical records prepared by such physician assistant.

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(a) The boards shall adopt, by rule, the general principles that supervising physicians must use in developing the scope of practice of a physician assistant under direct supervision and under indirect supervision. These

principles shall recognize the diversity of both specialty and practice settings in which physician assistants are used.

(b) This chapter does not prevent third-party payors from reimbursing employers of physician assistants for covered services rendered by licensed physician assistants.

(c) Licensed physician assistants may not be denied clinical hospital privileges, except for cause, so long as the supervising physician is a staff member in good standing.

(d) A supervisory physician may delegate to a licensed physician assistant, pursuant to a written protocol, the authority to act according to s. 154.04(1)(c). Such delegated authority is limited to the supervising physician's practice in connection with a county health department as defined and established pursuant to chapter 154. The boards shall adopt rules governing the supervision of physician assistants by physicians in county health departments.

(e) A supervising physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervising physician's practice unless such medication is listed on the formulary created pursuant to s. 458.347. A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that she or he is a physician assistant.

2. The supervising physician must notify the department of her or his intent to delegate, on a department-approved form, before delegating such authority and of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. A fully licensed physician assistant may procure medical devices and drugs unless the medication is listed on the formulary created pursuant to s. 458.347(4)(f).

4. The physician assistant must complete a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal. Three of the 10 hours must consist of a continuing education course on the safe and effective prescribing of controlled substance medications which is offered by a provider that has been approved by the American Academy of Physician Assistants and which is designated for the American Medical Association Physician's Recognition Award Category 1 credit, designated by the American Academy of Physician Assistants as a Category 1 credit, or designated by the American Osteopathic Association as a Category 1-A credit.

5. The prescription may be in paper or electronic form but must comply with ss. 456.0392(1) and 456.42(1) and chapter 499 and must contain the physician assistant's name, address, and telephone number and the name of each of his or her supervising physicians. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465, and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

(f) A supervisory physician may delegate to a licensed physician assistant the authority to, and the licensed physician assistant acting under the direction of the supervisory physician may, order any medication for administration to the supervisory physician's patient in a facility licensed under chapter 395 or part II of chapter 400, notwithstanding any provisions in chapter 465 or chapter 893 which may prohibit this delegation.

(g) A licensed physician assistant may perform services delegated by the supervising physician in the physician assistant's practice in accordance with his or her education and training unless expressly prohibited under this chapter, chapter 458, or rules adopted under this chapter or chapter 458.

(h) Except for a physician certification under s. 381.986, a physician assistant may authenticate any document with his or her signature, certification, stamp, verification, affidavit, or endorsement if such document may be so authenticated by the signature, certification, stamp, verification, affidavit, or endorsement of a physician, except those required for s. 381.986. Such documents include, but are not limited to, any of the following:

1. Initiation of an involuntary examination pursuant to s. 394.463.

2. Do-not-resuscitate orders or physician orders for the administration of life-sustaining treatment.

3. Death certificates.

4. School physical examinations.

5. Medical examinations for workers' compensation claims, except medical examinations required for the evaluation and assignment of the claimant's date of maximum medical improvement as defined in s. 440.02 and for the impairment rating, if any, under s. 440.15.

6. Orders for physical therapy, occupational therapy, speech-language therapy, home health services, or durable medical equipment.

(i) A physician assistant may supervise medical assistants as defined in chapter 458.

(j) This chapter authorizes third-party payors to reimburse employers of physician assistants for covered services rendered by licensed physician assistants. Payment for services within the physician assistant's scope of practice must be made when ordered or performed by a physician assistant if the same service would have been covered if ordered or performed by a physician. Physician assistants are authorized to bill for and receive direct payment for the services they deliver.

(5) PROGRAM APPROVAL.—

(a) The boards shall approve programs, based on recommendations by the council, for the education and training of physician assistants which meet standards established by rule of the boards. The council may recommend only those physician assistant programs that hold full accreditation or provisional accreditation from the Accreditation Review Commission on Education for the Physician Assistant or its successor entity or, before 2001, from the Committee on Allied Health Education and Accreditation or the Commission on Accreditation of Allied Health Programs.

(b) Notwithstanding any other law, a trainee may perform medical services when such services are rendered within the scope of an approved program.

(6) PHYSICIAN ASSISTANT LICENSURE.—

(a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met all of the following requirements:

1. Is at least 18 years of age.

2. Has graduated from an approved program.

a. For an applicant who graduated after December 31, 2020, has received a master's degree in accordance with the Accreditation Review Commission on Education for the Physician Assistant or, before 2001, its equivalent or predecessor organization.

b. For an applicant who graduated on or before December 31, 2020, has received a bachelor's or master's degree from an approved program.

c. For an applicant who graduated before July 1, 1994, has graduated from an approved program of instruction in primary health care or surgery.

d. For an applicant who graduated before July 1, 1983, has received a certification as a physician assistant from the boards.

e. The board may also grant a license to an applicant who does not meet the educational requirement specified in this subparagraph but who has passed the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants before 1986.

3. Has obtained a passing score as established by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has been nationally certified. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants or its equivalent or successor organization to be eligible for licensure.

4. Has completed the application form and remitted an application fee not to exceed $300 as set by the boards. An application for licensure as a physician assistant must include:

a. A diploma from an approved program.

b. Acknowledgment of any prior felony convictions.

c. Acknowledgment of any previous revocation or denial of licensure or certification in any state.

(b)1. The licensure must be renewed biennially. Each renewal must include:

a. A renewal fee not to exceed $500 as set by the boards.

b. Acknowledgment of no felony convictions in the previous 2 years.

c. A completed physician assistant workforce survey, which shall be administered in the same manner as the physician survey established in s. 459.0081 and must contain the same information required under s. 459.0081(1) and (2).

2. Beginning July 1, 2018, and every 2 years thereafter, the department shall report the data collected from the physician assistant workforce surveys to the boards.

3. The department shall adopt rules to implement this paragraph.

(c) Each licensed physician assistant shall biennially complete 100 hours of continuing medical education or shall hold a current certificate issued by the National Commission on Certification of Physician Assistants.

(d) Notwithstanding subparagraph (a)2., the department may grant to a recent graduate of an approved program, as specified in subsection (5), a temporary license to expire upon receipt of scores of the proficiency examination administered by the National Commission on Certification of Physician Assistants. Between meetings of the council, the department may grant a temporary license to practice to physician assistant applicants based on the completion of all temporary licensure requirements. All such administratively issued licenses shall be reviewed and acted on at the next regular meeting of the council. The recent graduate may be licensed before employment. An applicant who has passed the proficiency examination may be granted permanent licensure. An applicant failing the proficiency examination is no longer temporarily licensed, but may reapply for a 1-year extension of temporary licensure. An applicant may not be granted more than two temporary licenses and may not be licensed as a physician assistant until she or he passes the examination administered by the National Commission on Certification of Physician Assistants. As prescribed by board rule, the council may require an applicant who does not pass the licensing examination after five or more attempts to complete additional remedial education or training. The council shall prescribe the additional requirements in a manner that permits the applicant to complete the requirements and be reexamined within 2 years after the date the applicant petitions the council to retake the examination a sixth or subsequent time.

(e) The Board of Osteopathic Medicine may impose any of the penalties authorized under ss. 456.072 and 459.015(2) upon a physician assistant if the physician assistant or the supervising physician has been found guilty of or is being investigated for any act that constitutes a violation of this chapter or chapter 456.

(f) An application or other documentation required to be submitted to the department under this subsection may be submitted electronically.

(7) DELEGATION OF POWERS AND DUTIES.—The boards may delegate such powers and duties to the council as they may deem proper.

(8) COUNCIL ON PHYSICIAN ASSISTANTS.—The Council on Physician Assistants is created within the department.

(a) The council shall consist of five members appointed as follows:

1. The chairperson of the Board of Medicine shall appoint one member who is a physician and member of the Board of Medicine who supervises a physician assistant in the physician's practice.

2. The chairperson of the Board of Osteopathic Medicine shall appoint one member who is a physician and member of the Board of Osteopathic Medicine who supervises a physician assistant in the physician's practice.

3. The State Surgeon General or her or his designee shall appoint three fully licensed physician assistants licensed under chapter 458 or this chapter.

(b) Members shall be appointed to terms of 4 years, except that of the initial appointments, two members shall be appointed to terms of 2 years, two members shall be appointed to terms of 3 years, and one member shall be appointed to a term of 4 years, as established by rule of the boards. Council members may not serve more than two consecutive terms. The council shall annually elect a chairperson from among its members.

(c) The council shall:

1. Recommend to the department the licensure of physician assistants.

2. Develop all rules regulating the use of physician assistants by physicians under chapter 458 and this chapter, except for rules relating to the formulary developed under s. 458.347. The council shall also develop rules to ensure that the continuity of supervision is maintained in each practice setting. The boards shall consider adopting a proposed rule developed by the council at the regularly scheduled meeting immediately following the submission of the proposed rule by the council. A proposed rule submitted by the council may not be adopted by either board unless both boards have accepted and approved the identical language contained in the proposed rule. The language of all proposed rules submitted by the council must be approved by both boards pursuant to each respective board's guidelines and standards regarding the adoption of proposed rules. If either board rejects the council's proposed rule, that board must specify its objection to the council with particularity and include any recommendations it may have for the modification of the proposed rule.

3. Make recommendations to the boards regarding all matters relating to physician assistants.

4. Address concerns and problems of practicing physician assistants in order to improve safety in the clinical practices of licensed physician assistants.

(d) When the council finds that an applicant for licensure has failed to meet, to the council's satisfaction, each of the requirements for licensure set forth in this section, the council may enter an order to:

1. Refuse to certify the applicant for licensure;

2. Approve the applicant for licensure with restrictions on the scope of practice or license; or

3. Approve the applicant for conditional licensure. Such conditions may include placement of the licensee on probation for a period of time and subject to such conditions as the council may specify, including but not limited to, requiring the licensee to undergo treatment, to attend continuing education courses, to work under the direct supervision of a physician licensed in this state, or to take corrective action.

(9) INACTIVE AND DELINQUENT STATUS.—A license on inactive or delinquent status may be reactivated only as provided in s. 456.036.

(10) PENALTY.—Any person who has not been licensed by the council and approved by the department and who holds herself or himself out as a physician assistant or who uses any other term in indicating or implying that she or he is a physician assistant commits a felony of the third degree, punishable as provided in s. 775.082 or s. 775.084 or by a fine not exceeding $5,000.

(11) DENIAL, SUSPENSION, OR REVOCATION OF LICENSURE.—The boards may deny, suspend, or revoke a physician assistant license if a board determines that the physician assistant has violated this chapter.

(12) RULES.—The boards shall adopt rules to implement this section, including rules detailing the contents of the application for licensure and notification pursuant to subsection (6) and rules to ensure both the continued competency of physician assistants and the proper utilization of them by physicians or groups of physicians.

(13) EXISTING PROGRAMS.—This section does not eliminate or supersede existing laws relating to other paramedical professions or services and is supplemental to all such existing laws relating to the licensure and practice of paramedical professions.

(14) LIABILITY.—Each supervising physician using a physician assistant is liable for any acts or omissions of the physician assistant acting under the physician's supervision and control.

(15) LEGAL SERVICES.—Legal services shall be provided to the council pursuant to s. 456.009(1).

(16) FEES.—The department shall allocate the fees collected under this section to the council.

History.—ss. 1, 6, ch. 79-230; s. 309, ch. 81-259; ss. 2, 3, ch. 81-318; ss. 22, 27, 29, 31, ch. 86-290; s. 37, ch. 88-1; s. 16, ch. 88-277; s. 5, ch. 88-361; s. 28, ch. 89-162; s. 3, ch. 91-22; ss. 4, 5, ch. 91-429; s. 4, ch. 92-22; s. 91, ch. 92-149; s. 112, ch. 94-218; s. 2, ch. 95-231; s. 2, ch. 96-197; s. 224, ch. 97-101; s. 1101, ch. 97-103; s. 35, ch. 97-264; s. 7, ch. 98-49; s. 55, ch. 98-166; s. 156, ch. 99-251; s. 113, ch. 2000-160; ss. 27, 43, ch. 2000-318; s. 2, ch. 2001-100; ss. 26, 56, ch. 2001-277; s. 2, ch. 2007-155; s. 78, ch. 2008-6; s. 4, ch. 2009-177; s. 3, ch. 2010-55; s. 2, ch. 2012-170; s. 2, ch. 2013-127; s. 2, ch. 2016-125; s. 3, ch. 2016-145; ss. 22, 24, ch. 2016-224; s. 18, ch. 2016-230; s. 30, ch. 2017-3; s. 2, ch. 2017-154; s. 16, ch. 2020-133; s. 2, ch. 2021-204.

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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

Marjorie C. Holladay
Chief Attorney

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

MCH:df #190465

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 that has experience in treating minors with gender dysphoria. 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

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

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. Meets 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

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	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	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 • Weight gain • 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	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

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 provider that has experience in treating minors with gender dysphoria. 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

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. Meets 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

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	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 sex 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	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	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	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:
			  ○ Fatigue
			  ○ Lightheadedness
			  ○ Tingling feelings
			  ○ Muscle weakness
			  ○ 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	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	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

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 that has experience in treating minors with gender dysphoria. 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

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. Meets 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

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

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	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 sex 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	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	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	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

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

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 that has experience in treating people with gender dysphoria. 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 or continuing HRT, 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. Meets 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. Gender dysphoria is marked and sustained;
4. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
5. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
6. Has psychological and social support during treatment;
7. 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
8. 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 sex 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:
	  ○ Fatigue
	  ○ Lightheadedness
	  ○ Tingling feelings
	  ○ Muscle weakness
	  ○ 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

Masculinizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent

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

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

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

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

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

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

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

Patient

How is testosterone taken?

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

Finasteride is a treatment option for individuals experiencing bothersome alopecia resulting from higher dihydrotestosterone levels. The administration of 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 that has experience in treating people with gender dysphoria. 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 or continuing HRT, 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. Meets 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. Gender dysphoria is marked and sustained;
4. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
5. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
6. Has psychological and social support during treatment;
7. 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
8. 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 sex 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