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

Rosen Plaza Hotel
1900 International Drive
Orlando, FL 32819
407-996-9700

November 30, 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 3:00 p.m. EST or soon thereafter.

- Permanent rulemaking relating to the standard of care for the treatment of gender dysphoria in minors
- Permanent rulemaking relating to informed consent for the treatment of gender dysphoria in minors

- Permanent rulemaking relating to informed consent for the treatment of gender dysphoria in adults

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 workshop to which all persons are invited.

DATE AND TIME: (UPDATED) Thursday, November 30, 2023, beginning at 3:00 PM EST, or soon thereafter.

PLACE: Rosen Plaza Hotel, 9700 International Dr., Orlando, FL 32819. The hotel's phone number is (407) 996-9700. The hotel's website is https://www.rosenplaza.com

GENERAL SUBJECT MATTER TO BE CONSIDERED: (UPDATED) A rule workshop to discuss rules 64B8-9.0191, 64B8-9.0192, 64B15-14.0141, and 64B15-14.0142, F.A.C. 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: the Board of Medicine at https://flboardofmedicine.gov/meeting-information, or the Board of Osteopathic Medicine at https://floridaosteopathicmedicine.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 workshop to which all persons are invited.

DATE AND TIME: Thursday, November 30, 2023, 3:00 p.m., EST, or soon thereafter.

PLACE: Rosen Plaza Hotel, 9700 International Dr., Orlando, FL 32819. The hotel's phone number is (407)996-9700. The hotel's website is https://www.rosenplaza.com

GENERAL SUBJECT MATTER TO BE CONSIDERED: **(UPDATED)** A rule workshop to discuss rules 64B8-9.0191, 64B8-9.0192, 64B15-14.0141, and 64B15-14.0142, F.A.C. 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.

This notice will replace notice # 27748322

A copy of the agenda may be obtained by contacting: the Board of Medicine at https://flboardofmedicine.gov/meeting-information, or the Board of Osteopathic Medicine at https://floridaosteopathicmedicine.gov/meeting-information/.

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For more information, you may contact: 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 MEDICINE

RULE NO.: RULE TITLE:
64B8-9.0191 Sex-reassignment Standards of Practice in Minors
64B8-9.0192 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults

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

DATE AND TIME: Thursday, November 30, 2023, 3:00 p.m. EST or soon thereafter.

PLACE: Rosen Plaza Hotel, 9700 International Drive, Orlando, FL 32819, (407) 996-9700.

GENERAL SUBJECT MATTER TO BE CONSIDERED: A rule workshop to discuss rules 64B8-9.0191 and 64B8-9.0192, F.A.C. Please check the Board website at https://flboardofmedicine.gov/meeting-information/ for cancellations or changes or call the Board of Medicine at (850) 245-4131 for information.

A copy of the agenda may be obtained by contacting: the Board of Medicine at https://flboardofmedicine.gov/meeting-information/. or the Board of Osteopathic Medicine and Medicine at www.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 of Medicine by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board of Medicine 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.

Notice of Meeting/Workshop Hearing

DEPARTMENT OF HEALTH
BOARD OF OSTEOPATHIC MEDICINE

RULE NO.: RULE TITLE:
64B15-14.0141 Sex-reassignment Standards of Practice in Minors
64B15-14.0142 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults

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

DATE AND TIME: Thursday, November 30, 2023, 3:00 p.m. EST or soon thereafter.

PLACE: Rosen Plaza Hotel, 9700 International Drive, Orlando, FL 32819, (407) 996-9700.

GENERAL SUBJECT MATTER TO BE CONSIDERED: A rule workshop to discuss rules 64B15-14.0141 and 64B15-14.0142, F.A.C. Please check the Board website at https://flboardofmedicine.gov/meeting-information/ for cancellations or changes or call the Board of Medicine at (850) 245-4131 for information.

A copy of the agenda may be obtained by contacting: the Board of Medicine at https://flboardofmedicine.gov/meeting-information/. or the Board of Osteopathic Medicine and Medicine at www.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 of Medicine by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board of Medicine at (850) 245-4131.

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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.

Vazquez, Paul

From: Jon Harris Maurer <jonharris@equalityflorida.org>
Sent: Thursday, October 5, 2023 3:09 PM
To: Vazquez, Paul
Cc: Quinn Diaz
Subject: Request for Rule Development Workshop - Rule 64B8-9.0191

Dear Director Vazquez,

Please accept this email as a written request for a rule development workshop on proposed rule 64B8-9.0191 (Sex-reassignment Standards of Practice in Minors).

Please advise when and where the meeting will take place, and whether public testimony will be accepted. Please also advise whether you anticipate that draft rule language will be available before the rule development workshop and how it can be accessed by the public.

Thank you,
Jon Harris

--

Jon Harris Maurer

PUBLIC POLICY DIRECTOR

pronouns: he/him

954.494.1863

Vazquez, Paul

From: Jon Harris Maurer <jonharris@equalityflorida.org>
Sent: Thursday, October 5, 2023 3:09 PM
To: Vazquez, Paul
Cc: Quinn Diaz
Subject: Request for Rule Development Workshop - Rule 64B8-9.0192

Dear Director Vazquez,

Please accept this email as a written request for a rule development workshop on proposed rule 64B8-9.0192 (Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults).

Please advise when and where the meeting will take place, and whether public testimony will be accepted. Please also advise whether you anticipate that draft rule language will be available before the rule development workshop and how it can be accessed by the public.

Thank you,
Jon Harris

--

Jon Harris Maurer

PUBLIC POLICY DIRECTOR

pronouns: he/him

954.494.1863

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 Medicine
RULE NO.: RULE TITLE:
64B8ER23-11 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults
SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section."
Accordingly, the Board of Medicine, by emergency rule, hereby adopts the incorporated mandated consent forms for the treatment of gender dysphoria with hormone replacement therapy and surgical treatment for patients 18 years of age or older.
*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***
REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure used for the promulgation of this emergency rule is fair under the circumstances. CSSB 254 was signed into law on May 17, 2023. The Board of Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee's June meeting both on its website and in the Florida Administrative Register. On June 2, 2023, the Board of Medicine discussed the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Medicine published notice of its June 2, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.
The Joint Committee held yet another meeting on June 23, 2023, to discuss an emergency rule adopting draft consent forms that were under consideration. On June 6, 2023, the Board of Medicine published notice of the Joint Committee's June 23 meeting to its website and in the Florida Administrative Register. On June 30, 2023, the Boards of Medicine and Osteopathic Medicine held a Joint Board meeting (Joint Board Meeting) to discuss the draft consent forms that were approved by the Joint Committee on June 23. The Joint Board meeting was held via Microsoft Teams and notice of the same was published to the Board of Medicine's website and in the Florida Administrative Register on June 22, 2023. During the June 30, 2023, Joint Board Meeting, the Boards voted to approve consent forms and adopted them via emergency rule filed on July 5, 2023.
On July 21, 2023, the Board received correspondence from the Joint Administrative Procedures Committee (JAPC) questioning the Board's statutory authority for requiring that adult patients "undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist" before beginning hormone replacement therapy and every two years thereafter. Accordingly, the Florida Board of Medicine and Osteopathic Medicine's Joint Rules/Legislative Committee held a public meeting on August 3, 2023, and voted to remove the provision addressed by JAPC. The Board of Medicine discussed the Joint Committee's report and affirmed the decision at its August 4, 2023, Board meeting.
The August 3 Joint Committee meeting was held in person in a public forum and was able to be attended by any interested parties. Notice of the Joint Committee meeting was published to the Board of Medicine's website and in the Florida Administrative Register on July 13, 2023. The August 4 Board Meeting was also held in person in a

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

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

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

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

THE FULL TEXT OF THE EMERGENCY RULE IS:

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

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

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

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

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

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

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

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

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

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

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

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

Notice of Emergency Rule

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine
RULE NO.: RULE TITLE:
64B15ER23-9 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

Notice of Emergency Rule

DEPARTMENT OF HEALTH
Board of Osteopathic Medicine
RULE NO.: RULE TITLE:
64B15ER23-12 Mandatory Standardized Informed Consent for Sex-reassignment Prescriptions or Procedures in Adults
SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 17, 2023, Florida Governor, Ronald DeSantis, signed CSSB 254 into law creating Ch. 2023-90, Laws of Florida and section 456.52, Florida Statutes. Pursuant to section 456.52(2), F.S., if sex reassignment prescriptions or procedures are prescribed for or administered to patients 18 years of age or older, consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Osteopathic Medicine. Pursuant to section 456.52(4), F.S., the consent required for sex-reassignment prescriptions does not apply to renewals of sex-reassignment prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription. Section 456.52(6)(a), F.S., states "[t]he Board of Medicine and the Board of Osteopathic Medicine shall adopt emergency rules to implement this section."
Accordingly, the Board of Osteopathic Medicine, by emergency rule, hereby adopts the incorporated mandated consent forms for the treatment of gender dysphoria with hormone replacement therapy and surgical treatment for patients 18 years of age or older.
*** This emergency rule does not apply to Susan Doe, Gavin Goe, or Lisa Loe, or their parents or healthcare providers (see Jane Doe et al., v. Joseph A. Ladapo, et al, Preliminary Injunction, Filed June 6, 2023, Case No. 4:23cv114-RH-MAF, United States District Court for the Northern District of Florida). ***
REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure used for the promulgation of this emergency rule is fair under the circumstances. CSSB 254 was signed into law on May 17, 2023. The Board of Osteopathic Medicine was contacted by multiple licensed physicians and physician groups seeking clarification regarding the exception contained in section 465.52(4), F.S., and a timeframe for the required emergency rules shortly thereafter. In response, the Board of Medicine and the Board of Osteopathic Medicine held a Joint Rules/Legislative Committee (Joint Committee) meeting on June 1, 2023, to discuss the emergency rule. On May 19, 2023, the Board of Medicine published notice of the Joint Committee's June meeting both on its website and in the Florida Administrative Register. On June 20, 2023, the Board of Osteopathic Medicine discussed the report of the Joint Committee and voted upon emergency rule language that would allow for the renewal of previous prescriptions while the Board worked on consent forms. The Board of Osteopathic Medicine published notice of its June 20, 2023, meeting in the Florida Administrative Register on May 5, 2023, and on its website on May 12, 2023.
The Joint Committee held another meeting on June 23, 2023, to discuss an emergency rule adopting draft consent forms that were under consideration. On June 6, 2023, the Board of Osteopathic Medicine published notice of the Joint Committee's June 23, 2023, meeting to its website and in the Florida Administrative Register. On June 30, 2023, the Boards of Medicine and Osteopathic Medicine held a Joint Board meeting (Joint Board Meeting) to discuss the draft consent forms that were approved by the Joint Committee on June 23, 2023. The Joint Board meeting was held via Microsoft Teams and notice of the same was published to the Board of Medicine's website and in the Florida Administrative Register on June 22, 2023. During the June 30, 2023, Joint Board Meeting, the Boards voted to approve consent forms and adopted them via emergency rule filed on July 5, 2023.
On July 21, 2023, the Board received correspondence from the Joint Administrative Procedures Committee (JAPC) questioning the Board's statutory authority for requiring adult patients "undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist" before beginning hormone replacement therapy and every two years thereafter. Accordingly, the Florida Board of Medicine and Osteopathic Medicine's Joint Rules/Legislative Committee held a public meeting on August 3, 2023, and voted to remove the provision addressed by JAPC. The Board of Osteopathic Medicine discussed the Joint Committee's report and affirmed the decision at its August 11, 2023, Board meeting.
The August 3, 2023, Joint Committee meeting was held in person in a public forum and was able to be attended by any interested parties. Notice of the Joint Committee meeting was published to the Board of Osteopathic Medicine's

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

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

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

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

THE FULL TEXT OF THE EMERGENCY RULE IS:

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

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

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

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

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

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

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

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

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

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

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

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

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 children~~people~~ with gender dysphoria is based on very limited, poor-quality research. . Even the World Professional Association for Transgender Health acknowledges the limited science to support these treatments in children in their recently published Standards of Care version 8 (S45-46) where they state the following:
"A key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments over time. Given the lifelong implications of medical treatment and the young age at which treatments may be started, adolescents, their parents, and care providers should be informed about the nature of the evidence base. It seems reasonable that decisions to move forward with medical and surgical treatments should be made carefully. Despite the slowly growing body of evidence supporting the effectiveness of early medical intervention, the number of studies is still low, and there are few outcome studies that follow youth into adulthood."~~with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.~~

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

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

What are different medications that are used to suppress puberty?

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

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

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

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

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

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

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

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

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

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

The specific requirements for a minor to receive and continue treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (this is the first stage of puberty and refers to breast or testicle growth), which must be confirmed by a physician;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of puberty suppression, future cross-sex hormone treatment, as well as the medical and social risks and benefits of sex reassignment surgery.
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment such as PHQ-9 by their physician ~~a licensed mental health care professional~~ at least every 3 months; positive screens will be sent to their Florida licensed psychologist or psychiatrist.
9. Undergoes relevant laboratory testing at least every 3-~~6~~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 is strongly encouraged 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	Parent/legal guardian	Minor (required)

(required)	(optional)	

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

Effects of Treatment of Suppression of Puberty

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

Risks of Treatment of Suppression of Puberty

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

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

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

Requirements of Treatment of Suppression of Puberty

I understand the following:

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite to receive treatment for puberty suppression.
			The prescribing physician may stop prescribing puberty blockers if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or

			the requirements in this consent are not met.

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

PARENTAL CONSENT:

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

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

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with puberty blockers. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my minor's prescribing physician.

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

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

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

7. My signature below attests to my consent for my minor to begin treatment for suppression of puberty.

_____
Parent/legal guardian's name (required)

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

Parent/legal guardian's name (optional)

Parent/legal guardian's signature (optional) Date

PRESCRIBING PHYSICIAN SIGNATURE:

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

Prescribing physician's name (required)

Prescribing physician's signature (required) Date

ASSENT OF MINOR:

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

Minor's name (required)

Minor's signature (required) Date

WITNESS:

_____
Witness printed name

_____ _____
Witness signature Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

_____
Interpreter's printed name

_____ _____
Interpreter's signature Date

Feminizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Parental Consent and Assent for Minors

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

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

Medical treatment of children ~~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.~~ Even the World Professional Association for Transgender Health acknowledges the limited science to support these treatments in children in their recently published Standards of Care version 8 (S45-46) where they state the following:

"A key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments over time. Given the lifelong implications of medical treatment and the young age at which treatments may be started, adolescents, their parents, and care providers should be informed about the nature of the evidence base. It seems reasonable that decisions to move forward with medical and surgical treatments should be made carefully. Despite the slowly growing body of evidence supporting the effectiveness of early medical intervention, the number of studies is still low, and there are few outcome studies that follow youth into adulthood." ~~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.~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (first stage of puberty), which must be confirmed by a physician;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery;
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment such as PHQ-9 by their physician ~~a licensed mental health care professional~~ at least every 3 months; any positive screens will be referred as quickly as indicated to their Florida licensed psychologist or psychiatrist for treatment.
9. Undergoes relevant laboratory testing at least every 3-~~6~~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 is strongly encouraged with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

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

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

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

Effects of Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Feminizing medications, including estrogen, androgen blockers, or antiandrogens, given singularly or in combination, may be prescribed to make a minor appear less masculine and more feminine
			It can take several months or longer for the effects of feminizing medications to become noticeable and no one can predict how fast or how much change will occur.
			This treatment will not change the minor's biological sex or chromosomes.
			If a minor takes estrogen, the following changes in a minor's breasts will occur: • Breasts will develop but will not reach their full size for several years • Breasts will remain even if estrogen treatment is discontinued • A milky discharge from the nipples may appear, which should be reported the minor's prescribing physician • The minor's risk of breast cancer may significantly increase

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

			If a minor takes feminizing medications, the minor's body will make less testosterone, which may affect the minor's sex life in different ways, including: • The minor's testicles may shrink • The minor's penis may never fully develop, particularly if the minor has previously taken puberty blockers • The minor will have fewer spontaneous erections • The minor's sperm may no longer mature causing infertility which may be permanent even if treatment is discontinued, the risk of which is increased if the minor took puberty blockers prior to starting feminizing medications • Conversely, it is possible that a minor's sperm could still mature while taking feminizing medications and the minor may cause someone to get pregnant
			To improve the possibility that the minor may have biological children in the future, the options for sperm banking by the minor have been explained.
			If a minor takes feminizing medications, some parts of the minor's body will not change much, including: • If present, the minor's facial hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If present, the minor's body hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If the minor went through puberty and has a deep voice, the pitch of the minor's voice will not rise and the minor's speech patterns will not become more like a woman's • If present, the minor's Adam's apple will not shrink
			Even if a minor stops taking feminizing medications, the following changes may occur:

			• The minor's body fat may be redistributed with less fat on the abdomen and more on the buttocks, hips, and thighs creating a more female shape • The minor may have decreased muscle mass and strength in the upper body • The minor's skin may become softer
			Mood changes may be caused by these medicines, and the minor will continue therapy with a licensed mental health care professional during treatment.
			Using these medicines to feminize a minor is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the minor's prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications for minors.

Risks of Feminizing Medications

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

Risks of Estrogen

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Estrogen **SHOULD NOT** be used by anyone who has a history of: • Any estrogen-dependent cancer • Any disorder that makes them more likely to get blood clots that could travel to the lungs unless they are also taking blood thinners and are being followed by a specialist
			Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has a family history of breast cancer or other cancers that grow more quickly when estrogens are present • Has a family history of heart disease • Has diabetes • Has chronic hepatitis or other liver disease • Has high levels of cholesterol • Has migraines or seizures • Is obese • Smokes cigarettes or uses tobacco products
			Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • Chronic problems with veins in the legs, which may require surgery • Heart attack which may cause permanent heart damage or death • Pulmonary embolism (blood clot in the lungs), which may cause permanent lung damage or death • Stroke, which may cause permanent brain damage or death
			The risk of blood clots while take estrogen is much greater if the minor smokes cigarettes. The danger is so high that the minor should stop smoking completely while taking estrogen.
			Taking estrogen can increase the deposits of fat around internal organs, which increases the risk for diabetes and

			heart disease, which in turn increases the risk of heart attack and stroke.
			Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
			Taking estrogen increases the risk of gallstones (stones in the gallbladder). Any long-term abdominal pain experience by the minor while taking estrogen must be reported to the minor's prescribing physician.
			Taking estrogen increases the risk of elevated prolactin levels and prolactinomas, which are non-cancerous tumors of the pituitary gland. While not typically life threatening, prolactinomas can damage the minor's vision and cause headaches if not treated properly. Any changes in the minor's vision, the occurrence of headaches that are worse when waking up in the morning, or any milky discharge from the nipples must be reported to the minor's prescribing physician.
			Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to the minor's prescribing physician.
			Taking estrogen can cause migraines or can make them worse if the minor already has them.
			Taking estrogen can cause hot flashes.
			Taking estrogen can cause the minor to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • Increase the amount of urine produced by the minor's kidneys, making it necessary to urinate more frequently • Increase the minor's thirst • Increase the minor's risk of dehydration, which can be evidenced by less frequent urination than usual, dark and strong-smelling urine, thirst, and light-headedness