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

Thank you,

Dr. Jerrica Kirkley

From: perseuslowe=gmail.com@mq.gospringboard.io on behalf of Perseus Lowe

To: BOM Public Comment

Subject: Reject rules to restrict access to gender affirming care

**Date:** Thursday, July 20, 2023 5:01:37 PM

You don't often get email from perseuslowe@gmail.com. Learn why this is important

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

#### Dear

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

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

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

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

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

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

# Case 4:23-cv-00114-RH-MAF Document 200-4 Filed 12/11/23 Page 47 of 85

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1	urge	you	to	re	ect	these	rules.

Sincerely,

Perseus Lowe

From: <u>laurieanderson7512=qmail.com@mq.qospringboard.io</u> on behalf of <u>Laurie Melton</u>

To: BOM Public Comment

Subject: Reject rules to restrict access to gender affirming care

**Date:** Thursday, July 20, 2023 5:01:20 PM

You don't often get email from laurieanderson7512@gmail.com. Learn why this is important

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

Dear

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

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

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

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

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

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

I urge you to reject these rules.

Sincerely,

Laurie Melton

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CS/HB 1133 2023 Legislature

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

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

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

458.347 Physician assistants.-

- (6) PHYSICIAN ASSISTANT LICENSURE.-
- (a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met all of the following requirements:
  - 1. Is at least 18 years of age.
  - 2. Has completed graduated from an approved program.
- a. For an applicant who <u>matriculated</u> graduated after

  December 31, 2020, has received a master's degree in accordance

  with the Accreditation Review Commission on Education for the

  Physician Assistant or, before 2001, its equivalent or

  predecessor organization.
- b. For an applicant who <u>matriculated</u> graduated on or before December 31, 2020, has received a bachelor's or master's

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CS/HB 1133 2023 Legislature

26 degree from an approved program.

- c. For an applicant who graduated before July 1, 1994, has graduated from an approved program of instruction in primary health care or surgery.
- d. For an applicant who graduated before July 1, 1983, has received a certification as a physician assistant from the boards.
- e. The board may also grant a license to an applicant who does not meet the educational requirement specified in this subparagraph but who has passed the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants before 1986.
- 3. Has obtained a passing score as established by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has been nationally certified. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants or its equivalent or successor organization to be eligible for licensure.
  - 4. Has completed the application form and remitted an

Page 2 of 5

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CS/HB 1133 2023 Legislature

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

- a. A diploma from an approved program.
- b. Acknowledgment of any prior felony convictions.
- c. Acknowledgment of any previous revocation or denial of licensure or certification in any state.
- Section 2. Paragraph (a) of subsection (6) of section 459.022, Florida Statutes, is amended to read:
  - 459.022 Physician assistants.-
  - (6) PHYSICIAN ASSISTANT LICENSURE.
- (a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met all of the following requirements:
  - 1. Is at least 18 years of age.
  - 2. Has completed graduated from an approved program.
- a. For an applicant who <u>matriculated</u> graduated after December 31, 2020, has received a master's degree in accordance with the Accreditation Review Commission on Education for the Physician Assistant or, before 2001, its equivalent or predecessor organization.
- b. For an applicant who <u>matriculated</u> graduated on or before December 31, 2020, has received a bachelor's or master's degree from an approved program.

Page 3 of 5

CS/HB 1133 2023 Legislature

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

- d. For an applicant who graduated before July 1, 1983, has received a certification as a physician assistant from the boards.
- e. The board may also grant a license to an applicant who does not meet the educational requirement specified in this subparagraph but who has passed the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants before 1986.
- 3. Has obtained a passing score as established by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has been nationally certified. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants or its equivalent or successor organization to be eligible for licensure.
- 4. Has completed the application form and remitted an application fee not to exceed \$300 as set by the boards. An

Page 4 of 5

CODING: Words stricken are deletions; words underlined are additions.

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CS/HB 1133 2023 Legislature

100 application for licensure as a physician assistant must include:

- a. A diploma from an approved program.
- b. Acknowledgment of any prior felony convictions.
- 103 c. Acknowledgment of any previous revocation or denial of 104 licensure or certification in any state.
- Section 3. This act shall take effect upon becoming a law.

Page 5 of 5

CODING: Words stricken are deletions; words underlined are additions.

Select Year: 2022 **∨** Go

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

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

458.347 Physician assistants.—

- (1) LEGISLATIVE INTENT.—The purpose of this section is to authorize physician assistants, with their education, training, and experience in the field of medicine, to provide increased efficiency of and access to high-quality medical services at a reasonable cost to consumers.
  - (2) DEFINITIONS.—As used in this section, the term:
- (a) "Approved program" means a physician assistant program in the United States or in its territories or possessions which is accredited by the Accreditation Review Commission on Education for the Physician Assistant or, for programs before 2001, accredited by its equivalent or predecessor entities the Committee on Allied Health Education and Accreditation or the Commission on Accreditation of Allied Health Education Programs formally approved by the boards for the education of physician assistants.
  - (b) "Boards" means the Board of Medicine and the Board of Osteopathic Medicine.
- (c) "Continuing medical education" means courses recognized and approved by the boards, the American Academy of Physician Assistants, the American Medical Association, the American Osteopathic Association, or the Accreditation Council on Continuing Medical Education.
  - (d) "Council" means the Council on Physician Assistants.
- (e) "Physician assistant" means a person who is a graduate of an approved program or its equivalent or meets standards approved by the boards and is licensed to perform medical services delegated by the supervising physician.
- (f) "Physician assistant national certifying examination" means the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants or its successor agency.
- (g) "Supervision" means responsible supervision and control. Except in cases of emergency, supervision requires the easy availability or physical presence of the licensed physician for consultation and direction of the actions of the physician assistant. For the purposes of this definition, the term "easy availability" includes the ability to communicate by way of telecommunication. The boards shall establish rules as to what constitutes responsible supervision of the physician assistant.
  - (h) "Trainee" means a person who is currently enrolled in an approved program.
- (3) PERFORMANCE OF SUPERVISING PHYSICIAN.—Each physician or group of physicians supervising a licensed physician assistant must be qualified in the medical areas in which the physician assistant is to perform and shall be individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant. A physician may not supervise more than 10 currently licensed physician assistants at any one time. A physician supervising a physician assistant pursuant to this section may not be required to review and cosign charts or medical records prepared by such physician assistant.
  - (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—
- (a) The boards shall adopt, by rule, the general principles that supervising physicians must use in developing the scope of practice of a physician assistant under direct supervision and under indirect supervision. These

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

- (b) This chapter does not prevent third-party payors from reimbursing employers of physician assistants for covered services rendered by licensed physician assistants.
- (c) Licensed physician assistants may not be denied clinical hospital privileges, except for cause, so long as the supervising physician is a staff member in good standing.
- (d) A supervisory physician may delegate to a licensed physician assistant, pursuant to a written protocol, the authority to act according to s. <u>154.04(1)(c)</u>. Such delegated authority is limited to the supervising physician's practice in connection with a county health department as defined and established pursuant to chapter 154. The boards shall adopt rules governing the supervision of physician assistants by physicians in county health departments.
- (e) A supervising physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervising physician's practice unless such medication is listed on the formulary created pursuant to paragraph (f). A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:
  - 1. A physician assistant must clearly identify to the patient that he or she is a physician assistant.
- 2. The supervising physician must notify the department of his or her intent to delegate, on a department-approved form, before delegating such authority and of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276.
- 3. A fully licensed physician assistant may procure medical devices and drugs unless the medication is listed on the formulary created pursuant to paragraph (f).
- 4. The physician assistant must complete a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal. Three of the 10 hours must consist of a continuing education course on the safe and effective prescribing of controlled substance medications which is offered by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit, designated by the American Academy of Physician Assistants as a Category 1 credit, or designated by the American Osteopathic Association as a Category 1-A credit.
- 5. The prescription may be in paper or electronic form but must comply with ss. <u>456.0392(1)</u> and <u>456.42(1)</u> and chapter 499 and must contain the physician assistant's name, address, and telephone number and the name of each of his or her supervising physicians. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465 and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465.
- 6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.
- (f)1. The council shall establish a formulary of medicinal drugs that a fully licensed physician assistant having prescribing authority under this section or s. <u>459.022</u> may not prescribe. The formulary must include general anesthetics and radiographic contrast materials and must limit the prescription of Schedule II controlled substances as listed in s. <u>893.03</u> to a 7-day supply. The formulary must also restrict the prescribing of Schedule II psychiatric mental health controlled substances for children younger than 18 years of age to a 14-day supply, provided the physician assistant is under the supervision of a pediatrician, a family practice physician, an internal medicine physician, or a psychiatrist.
- 2. In establishing the formulary, the council shall consult with a pharmacist licensed under chapter 465, but not licensed under this chapter or chapter 459, who shall be selected by the State Surgeon General.
- 3. Only the council shall add to, delete from, or modify the formulary. Any person who requests an addition, a deletion, or a modification of a medicinal drug listed on such formulary has the burden of proof to show cause why such addition, deletion, or modification should be made.

- 4. The boards shall adopt the formulary required by this paragraph, and each addition, deletion, or modification to the formulary, by rule. Notwithstanding any provision of chapter 120 to the contrary, the formulary rule shall be effective 60 days after the date it is filed with the Secretary of State. Upon adoption of the formulary, the department shall mail a copy of such formulary to each fully licensed physician assistant having prescribing authority under this section or s. <u>459.022</u>, and to each pharmacy licensed by the state. The boards shall establish, by rule, a fee not to exceed \$200 to fund the provisions of paragraph (e) and this paragraph.
- (g) A supervisory physician may delegate to a licensed physician assistant the authority to, and the licensed physician assistant acting under the direction of the supervisory physician may, order any medication for administration to the supervisory physician's patient in a facility licensed under chapter 395 or part II of chapter 400, notwithstanding any provisions in chapter 465 or chapter 893 which may prohibit this delegation.
- (h) A licensed physician assistant may perform services delegated by the supervising physician in the physician assistant's practice in accordance with his or her education and training unless expressly prohibited under this chapter, chapter 459, or rules adopted under this chapter or chapter 459.
- (i) Except for a physician certification under s. <u>381.986</u>, a physician assistant may authenticate any document with his or her signature, certification, stamp, verification, affidavit, or endorsement if such document may be so authenticated by the signature, certification, stamp, verification, affidavit, or endorsement of a physician, except those required for s. <u>381.986</u>. Such documents include, but are not limited to, any of the following:
  - 1. Initiation of an involuntary examination pursuant to s. 394.463.
  - 2. Do-not-resuscitate orders or physician orders for the administration of life-sustaining treatment.
  - 3. Death certificates.
  - 4. School physical examinations.
- 5. Medical examinations for workers' compensation claims, except medical examinations required for the evaluation and assignment of the claimant's date of maximum medical improvement as defined in s. <u>440.02</u> and for the impairment rating, if any, under s. <u>440.15</u>.
- 6. Orders for physical therapy, occupational therapy, speech-language therapy, home health services, or durable medical equipment.
  - (j) A physician assistant may supervise medical assistants as defined in this chapter.
- (k) This chapter authorizes third-party payors to reimburse employers of physician assistants for covered services rendered by licensed physician assistants. Payment for services within the physician assistant's scope of practice must be made when ordered or performed by a physician assistant if the same service would have been covered if ordered or performed by a physician. Physician assistants are authorized to bill for and receive direct payment for the services they deliver.
  - (5) PROGRAM APPROVAL. -
- (a) The boards shall approve programs, based on recommendations by the council, for the education and training of physician assistants which meet standards established by rule of the boards. The council may recommend only those physician assistant programs that hold full accreditation or provisional accreditation from the Accreditation Review Commission on Education for the Physician Assistant or its successor entity or, before 2001, from the Committee on Allied Health Education and Accreditation or the Commission on Accreditation of Allied Health Programs.
- (b) Notwithstanding any other law, a trainee may perform medical services when such services are rendered within the scope of an approved program.
  - (6) PHYSICIAN ASSISTANT LICENSURE. -
- (a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met all of the following requirements:
  - 1. Is at least 18 years of age.
  - 2. Has graduated from an approved program.
- a. For an applicant who graduated after December 31, 2020, has received a master's degree in accordance with the Accreditation Review Commission on Education for the Physician Assistant or, before 2001, its equivalent or predecessor organization.

- b. For an applicant who graduated on or before December 31, 2020, has received a bachelor's or master's degree from an approved program.
- c. For an applicant who graduated before July 1, 1994, has graduated from an approved program of instruction in primary health care or surgery.
- d. For an applicant who graduated before July 1, 1983, has received a certification as a physician assistant from the boards.
- e. The board may also grant a license to an applicant who does not meet the educational requirement specified in this subparagraph but who has passed the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants before 1986.
- 3. Has obtained a passing score as established by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has been nationally certified. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants or its equivalent or successor organization to be eligible for licensure.
- 4. Has completed the application form and remitted an application fee not to exceed \$300 as set by the boards. An application for licensure as a physician assistant must include:
  - a. A diploma from an approved program.
  - b. Acknowledgment of any prior felony convictions.
  - c. Acknowledgment of any previous revocation or denial of licensure or certification in any state.
  - (b)1. The license must be renewed biennially. Each renewal must include:
  - a. A renewal fee not to exceed \$500 as set by the boards.
  - b. Acknowledgment of no felony convictions in the previous 2 years.
- c. A completed physician assistant workforce survey, which shall be administered in the same manner as the physician survey established in s. <u>458.3191</u> and must contain the same information required in s. <u>458.3191(1)</u> and (2).
- 2. Beginning July 1, 2018, and every 2 years thereafter, the department shall report the data collected from the physician assistant workforce surveys to the boards.
  - 3. The department shall adopt rules to implement this paragraph.
- (c) Each licensed physician assistant shall biennially complete 100 hours of continuing medical education or shall hold a current certificate issued by the National Commission on Certification of Physician Assistants.
- (d) Notwithstanding subparagraph (a)2., the department may grant to a recent graduate of an approved program, as specified in subsection (5), who expects to take the first examination administered by the National Commission on Certification of Physician Assistants available for registration after the applicant's graduation, a temporary license. The temporary license shall expire 30 days after receipt of scores of the proficiency examination administered by the National Commission on Certification of Physician Assistants. Between meetings of the council, the department may grant a temporary license to practice based on the completion of all temporary licensure requirements. All such administratively issued licenses shall be reviewed and acted on at the next regular meeting of the council. The recent graduate may be licensed before employment. An applicant who has passed the proficiency examination may be granted permanent licensure. An applicant failing the proficiency examination is no longer temporarily licensed but may reapply for a 1-year extension of temporary licensure. An applicant may not be granted more than two temporary licenses and may not be licensed as a physician assistant until he or she passes the examination administered by the National Commission on Certification of Physician Assistants. As prescribed by board rule, the council may require an applicant who does not pass the licensing examination after five or more attempts to complete additional remedial education or training. The council shall prescribe the additional requirements in a manner that permits the applicant to complete the requirements and be reexamined within 2 years after the date the applicant petitions the council to retake the examination a sixth or subsequent time.

- (e) The Board of Medicine may impose any of the penalties authorized under ss. <u>456.072</u> and <u>458.331(2)</u> upon a physician assistant if the physician assistant or the supervising physician has been found guilty of or is being investigated for any act that constitutes a violation of this chapter or chapter 456.
- (f) An application or other documentation required to be submitted to the department under this subsection may be submitted electronically.
- (7) DELEGATION OF POWERS AND DUTIES.—The boards may delegate such powers and duties to the council as they may deem proper.
  - (8) COUNCIL ON PHYSICIAN ASSISTANTS.—The Council on Physician Assistants is created within the department.
  - (a) The council shall consist of five members appointed as follows:
- 1. The chairperson of the Board of Medicine shall appoint one member who is a physician and member of the Board of Medicine who supervises a physician assistant in the physician's practice.
- 2. The chairperson of the Board of Osteopathic Medicine shall appoint one member who is a physician and member of the Board of Osteopathic Medicine who supervises a physician assistant in the physician's practice.
- 3. The State Surgeon General or his or her designee shall appoint three fully licensed physician assistants licensed under this chapter or chapter 459.
- (b) Members shall be appointed to terms of 4 years, except that of the initial appointments, two members shall be appointed to terms of 2 years, two members shall be appointed to terms of 3 years, and one member shall be appointed to a term of 4 years, as established by rule of the boards. Council members may not serve more than two consecutive terms. The council shall annually elect a chairperson from among its members.
  - (c) The council shall:
  - 1. Recommend to the department the licensure of physician assistants.
- 2. Develop all rules regulating the use of physician assistants by physicians under this chapter and chapter 459, except for rules relating to the formulary developed under paragraph (4)(f). The council shall also develop rules to ensure that the continuity of supervision is maintained in each practice setting. The boards shall consider adopting a proposed rule developed by the council at the regularly scheduled meeting immediately following the submission of the proposed rule by the council. A proposed rule submitted by the council may not be adopted by either board unless both boards have accepted and approved the identical language contained in the proposed rule. The language of all proposed rules submitted by the council must be approved by both boards pursuant to each respective board's guidelines and standards regarding the adoption of proposed rules. If either board rejects the council's proposed rule, that board must specify its objection to the council with particularity and include any recommendations it may have for the modification of the proposed rule.
  - 3. Make recommendations to the boards regarding all matters relating to physician assistants.
- 4. Address concerns and problems of practicing physician assistants in order to improve safety in the clinical practices of licensed physician assistants.
- (d) When the council finds that an applicant for licensure has failed to meet, to the council's satisfaction, each of the requirements for licensure set forth in this section, the council may enter an order to:
  - 1. Refuse to certify the applicant for licensure;
  - 2. Approve the applicant for licensure with restrictions on the scope of practice or license; or
- 3. Approve the applicant for conditional licensure. Such conditions may include placement of the licensee on probation for a period of time and subject to such conditions as the council may specify, including but not limited to, requiring the licensee to undergo treatment, to attend continuing education courses, to work under the direct supervision of a physician licensed in this state, or to take corrective action.
- (9) INACTIVE AND DELINQUENT STATUS.—A license on inactive or delinquent status may be reactivated only as provided in s. 456.036.
- (10) PENALTY.—Any person who has not been licensed by the council and approved by the department and who holds himself or herself out as a physician assistant or who uses any other term in indicating or implying that he or she is a physician assistant commits a felony of the third degree, punishable as provided in s. <u>775.082</u> or s. <u>775.084</u> or by a fine not exceeding \$5,000.

- (11) DENIAL, SUSPENSION, OR REVOCATION OF LICENSURE.—The boards may deny, suspend, or revoke a physician assistant license if a board determines that the physician assistant has violated this chapter.
- (12) RULES.—The boards shall adopt rules to implement this section, including rules detailing the contents of the application for licensure and notification pursuant to subsection (6) and rules to ensure both the continued competency of physician assistants and the proper utilization of them by physicians or groups of physicians.
- (13) EXISTING PROGRAMS.—This section does not eliminate or supersede existing laws relating to other paramedical professions or services and is supplemental to all such existing laws relating to the licensure and practice of paramedical professions.
- (14) LIABILITY.—Each supervising physician using a physician assistant is liable for any acts or omissions of the physician assistant acting under the physician's supervision and control.
  - (15) LEGAL SERVICES.—Legal services shall be provided to the council pursuant to s. 456.009(1).
  - (16) FEES.—The department shall allocate the fees collected under this section to the council.

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

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Select Year: 2022 **∨** Go

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

<u>Title XXXII</u> <u>Chapter 459</u> <u>View Entire Chapter</u>

REGULATION OF PROFESSIONS AND OCCUPATIONS OSTEOPATHIC MEDICINE

#### 459.022 Physician assistants.—

- (1) LEGISLATIVE INTENT.—The purpose of this section is to authorize physician assistants, with their education, training, and experience in the field of medicine, to provide increased efficiency of and access to high-quality medical services at a reasonable cost to consumers.
  - (2) DEFINITIONS.—As used in this section, the term:
- (a) "Approved program" means a physician assistant program in the United States or in its territories or possessions which is accredited by the Accreditation Review Commission on Education for the Physician Assistant or, for programs before 2001, accredited by its equivalent or predecessor entities the Committee on Allied Health Education and Accreditation or the Commission on Accreditation of Allied Health Education Programs formally approved by the boards for the education of physician assistants.
  - (b) "Boards" means the Board of Medicine and the Board of Osteopathic Medicine.
- (c) "Continuing medical education" means courses recognized and approved by the boards, the American Academy of Physician Assistants, the American Medical Association, the American Osteopathic Association, or the Accreditation Council on Continuing Medical Education.
  - (d) "Council" means the Council on Physician Assistants.
- (e) "Physician assistant" means a person who is a graduate of an approved program or its equivalent or meets standards approved by the boards and is licensed to perform medical services delegated by the supervising physician.
- (f) "Physician assistant national certifying examination" means the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants or its successor agency.
- (g) "Supervision" means responsible supervision and control. Except in cases of emergency, supervision requires the easy availability or physical presence of the licensed physician for consultation and direction of the actions of the physician assistant. For the purposes of this definition, the term "easy availability" includes the ability to communicate by way of telecommunication. The boards shall establish rules as to what constitutes responsible supervision of the physician assistant.
  - (h) "Trainee" means a person who is currently enrolled in an approved program.
- (3) PERFORMANCE OF SUPERVISING PHYSICIAN.—Each physician or group of physicians supervising a licensed physician assistant must be qualified in the medical areas in which the physician assistant is to perform and shall be individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant. A physician may not supervise more than 10 currently licensed physician assistants at any one time. A physician supervising a physician assistant pursuant to this section may not be required to review and cosign charts or medical records prepared by such physician assistant.
  - (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—
- (a) The boards shall adopt, by rule, the general principles that supervising physicians must use in developing the scope of practice of a physician assistant under direct supervision and under indirect supervision. These

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

- (b) This chapter does not prevent third-party payors from reimbursing employers of physician assistants for covered services rendered by licensed physician assistants.
- (c) Licensed physician assistants may not be denied clinical hospital privileges, except for cause, so long as the supervising physician is a staff member in good standing.
- (d) A supervisory physician may delegate to a licensed physician assistant, pursuant to a written protocol, the authority to act according to s. 154.04(1)(c). Such delegated authority is limited to the supervising physician's practice in connection with a county health department as defined and established pursuant to chapter 154. The boards shall adopt rules governing the supervision of physician assistants by physicians in county health departments.
- (e) A supervising physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervising physician's practice unless such medication is listed on the formulary created pursuant to s. <u>458.347</u>. A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:
  - 1. A physician assistant must clearly identify to the patient that she or he is a physician assistant.
- 2. The supervising physician must notify the department of her or his intent to delegate, on a department-approved form, before delegating such authority and of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276.
- 3. A fully licensed physician assistant may procure medical devices and drugs unless the medication is listed on the formulary created pursuant to s. 458.347(4)(f).
- 4. The physician assistant must complete a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal. Three of the 10 hours must consist of a continuing education course on the safe and effective prescribing of controlled substance medications which is offered by a provider that has been approved by the American Academy of Physician Assistants and which is designated for the American Medical Association Physician's Recognition Award Category 1 credit, designated by the American Academy of Physician Assistants as a Category 1 credit, or designated by the American Osteopathic Association as a Category 1-A credit.
- 5. The prescription may be in paper or electronic form but must comply with ss. <u>456.0392(1)</u> and <u>456.42(1)</u> and chapter 499 and must contain the physician assistant's name, address, and telephone number and the name of each of his or her supervising physicians. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465, and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465.
- 6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.
- (f) A supervisory physician may delegate to a licensed physician assistant the authority to, and the licensed physician assistant acting under the direction of the supervisory physician may, order any medication for administration to the supervisory physician's patient in a facility licensed under chapter 395 or part II of chapter 400, notwithstanding any provisions in chapter 465 or chapter 893 which may prohibit this delegation.
- (g) A licensed physician assistant may perform services delegated by the supervising physician in the physician assistant's practice in accordance with his or her education and training unless expressly prohibited under this chapter, chapter 458, or rules adopted under this chapter or chapter 458.
- (h) Except for a physician certification under s. <u>381.986</u>, a physician assistant may authenticate any document with his or her signature, certification, stamp, verification, affidavit, or endorsement if such document may be so authenticated by the signature, certification, stamp, verification, affidavit, or endorsement of a physician, except those required for s. <u>381.986</u>. Such documents include, but are not limited to, any of the following:
  - 1. Initiation of an involuntary examination pursuant to s. 394.463.
  - 2. Do-not-resuscitate orders or physician orders for the administration of life-sustaining treatment.

- 3. Death certificates.
- 4. School physical examinations.
- 5. Medical examinations for workers' compensation claims, except medical examinations required for the evaluation and assignment of the claimant's date of maximum medical improvement as defined in s. <u>440.02</u> and for the impairment rating, if any, under s. <u>440.15</u>.
- 6. Orders for physical therapy, occupational therapy, speech-language therapy, home health services, or durable medical equipment.
  - (i) A physician assistant may supervise medical assistants as defined in chapter 458.
- (j) This chapter authorizes third-party payors to reimburse employers of physician assistants for covered services rendered by licensed physician assistants. Payment for services within the physician assistant's scope of practice must be made when ordered or performed by a physician assistant if the same service would have been covered if ordered or performed by a physician assistants are authorized to bill for and receive direct payment for the services they deliver.
  - (5) PROGRAM APPROVAL. —
- (a) The boards shall approve programs, based on recommendations by the council, for the education and training of physician assistants which meet standards established by rule of the boards. The council may recommend only those physician assistant programs that hold full accreditation or provisional accreditation from the Accreditation Review Commission on Education for the Physician Assistant or its successor entity or, before 2001, from the Committee on Allied Health Education and Accreditation or the Commission on Accreditation of Allied Health Programs.
- (b) Notwithstanding any other law, a trainee may perform medical services when such services are rendered within the scope of an approved program.
  - (6) PHYSICIAN ASSISTANT LICENSURE.—
- (a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met all of the following requirements:
  - 1. Is at least 18 years of age.
  - 2. Has graduated from an approved program.
- a. For an applicant who graduated after December 31, 2020, has received a master's degree in accordance with the Accreditation Review Commission on Education for the Physician Assistant or, before 2001, its equivalent or predecessor organization.
- b. For an applicant who graduated on or before December 31, 2020, has received a bachelor's or master's degree from an approved program.
- c. For an applicant who graduated before July 1, 1994, has graduated from an approved program of instruction in primary health care or surgery.
- d. For an applicant who graduated before July 1, 1983, has received a certification as a physician assistant from the boards.
- e. The board may also grant a license to an applicant who does not meet the educational requirement specified in this subparagraph but who has passed the Physician Assistant National Certifying Examination administered by the National Commission on Certification of Physician Assistants before 1986.
- 3. Has obtained a passing score as established by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has been nationally certified. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants or its equivalent or successor organization and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants or its equivalent or successor organization to be eligible for licensure.
- 4. Has completed the application form and remitted an application fee not to exceed \$300 as set by the boards. An application for licensure as a physician assistant must include:
  - a. A diploma from an approved program.

- b. Acknowledgment of any prior felony convictions.
- c. Acknowledgment of any previous revocation or denial of licensure or certification in any state.
- (b)1. The licensure must be renewed biennially. Each renewal must include:
- a. A renewal fee not to exceed \$500 as set by the boards.
- b. Acknowledgment of no felony convictions in the previous 2 years.
- c. A completed physician assistant workforce survey, which shall be administered in the same manner as the physician survey established in s. <u>459.0081</u> and must contain the same information required under s. <u>459.0081(1)</u> and (2).
- 2. Beginning July 1, 2018, and every 2 years thereafter, the department shall report the data collected from the physician assistant workforce surveys to the boards.
  - 3. The department shall adopt rules to implement this paragraph.
- (c) Each licensed physician assistant shall biennially complete 100 hours of continuing medical education or shall hold a current certificate issued by the National Commission on Certification of Physician Assistants.
- (d) Notwithstanding subparagraph (a)2., the department may grant to a recent graduate of an approved program, as specified in subsection (5), a temporary license to expire upon receipt of scores of the proficiency examination administered by the National Commission on Certification of Physician Assistants. Between meetings of the council, the department may grant a temporary license to practice to physician assistant applicants based on the completion of all temporary licensure requirements. All such administratively issued licenses shall be reviewed and acted on at the next regular meeting of the council. The recent graduate may be licensed before employment. An applicant who has passed the proficiency examination may be granted permanent licensure. An applicant failing the proficiency examination is no longer temporarily licensed, but may reapply for a 1-year extension of temporary licensure. An applicant may not be granted more than two temporary licenses and may not be licensed as a physician assistant until she or he passes the examination administered by the National Commission on Certification of Physician Assistants. As prescribed by board rule, the council may require an applicant who does not pass the licensing examination after five or more attempts to complete additional remedial education or training. The council shall prescribe the additional requirements in a manner that permits the applicant to complete the requirements and be reexamined within 2 years after the date the applicant petitions the council to retake the examination a sixth or subsequent time.
- (e) The Board of Osteopathic Medicine may impose any of the penalties authorized under ss. <u>456.072</u> and <u>459.015(2)</u> upon a physician assistant if the physician assistant or the supervising physician has been found guilty of or is being investigated for any act that constitutes a violation of this chapter or chapter 456.
- (f) An application or other documentation required to be submitted to the department under this subsection may be submitted electronically.
- (7) DELEGATION OF POWERS AND DUTIES.—The boards may delegate such powers and duties to the council as they may deem proper.
  - (8) COUNCIL ON PHYSICIAN ASSISTANTS.—The Council on Physician Assistants is created within the department.
  - (a) The council shall consist of five members appointed as follows:
- 1. The chairperson of the Board of Medicine shall appoint one member who is a physician and member of the Board of Medicine who supervises a physician assistant in the physician's practice.
- 2. The chairperson of the Board of Osteopathic Medicine shall appoint one member who is a physician and member of the Board of Osteopathic Medicine who supervises a physician assistant in the physician's practice.
- 3. The State Surgeon General or her or his designee shall appoint three fully licensed physician assistants licensed under chapter 458 or this chapter.
- (b) Members shall be appointed to terms of 4 years, except that of the initial appointments, two members shall be appointed to terms of 2 years, two members shall be appointed to terms of 3 years, and one member shall be appointed to a term of 4 years, as established by rule of the boards. Council members may not serve more than two consecutive terms. The council shall annually elect a chairperson from among its members.
  - (c) The council shall:
  - 1. Recommend to the department the licensure of physician assistants.

- 2. Develop all rules regulating the use of physician assistants by physicians under chapter 458 and this chapter, except for rules relating to the formulary developed under s. 458.347. The council shall also develop rules to ensure that the continuity of supervision is maintained in each practice setting. The boards shall consider adopting a proposed rule developed by the council at the regularly scheduled meeting immediately following the submission of the proposed rule by the council. A proposed rule submitted by the council may not be adopted by either board unless both boards have accepted and approved the identical language contained in the proposed rule. The language of all proposed rules submitted by the council must be approved by both boards pursuant to each respective board's guidelines and standards regarding the adoption of proposed rules. If either board rejects the council's proposed rule, that board must specify its objection to the council with particularity and include any recommendations it may have for the modification of the proposed rule.
  - 3. Make recommendations to the boards regarding all matters relating to physician assistants.
- 4. Address concerns and problems of practicing physician assistants in order to improve safety in the clinical practices of licensed physician assistants.
- (d) When the council finds that an applicant for licensure has failed to meet, to the council's satisfaction, each of the requirements for licensure set forth in this section, the council may enter an order to:
  - 1. Refuse to certify the applicant for licensure;
  - 2. Approve the applicant for licensure with restrictions on the scope of practice or license; or
- 3. Approve the applicant for conditional licensure. Such conditions may include placement of the licensee on probation for a period of time and subject to such conditions as the council may specify, including but not limited to, requiring the licensee to undergo treatment, to attend continuing education courses, to work under the direct supervision of a physician licensed in this state, or to take corrective action.
- (9) INACTIVE AND DELINQUENT STATUS.—A license on inactive or delinquent status may be reactivated only as provided in s. 456.036.
- (10) PENALTY.—Any person who has not been licensed by the council and approved by the department and who holds herself or himself out as a physician assistant or who uses any other term in indicating or implying that she or he is a physician assistant commits a felony of the third degree, punishable as provided in s. <u>775.082</u> or s. <u>775.084</u> or by a fine not exceeding \$5,000.
- (11) DENIAL, SUSPENSION, OR REVOCATION OF LICENSURE.—The boards may deny, suspend, or revoke a physician assistant license if a board determines that the physician assistant has violated this chapter.
- (12) RULES.—The boards shall adopt rules to implement this section, including rules detailing the contents of the application for licensure and notification pursuant to subsection (6) and rules to ensure both the continued competency of physician assistants and the proper utilization of them by physicians or groups of physicians.
- (13) EXISTING PROGRAMS.—This section does not eliminate or supersede existing laws relating to other paramedical professions or services and is supplemental to all such existing laws relating to the licensure and practice of paramedical professions.
- (14) LIABILITY.—Each supervising physician using a physician assistant is liable for any acts or omissions of the physician assistant acting under the physician's supervision and control.
  - (15) LEGAL SERVICES.—Legal services shall be provided to the council pursuant to s. <u>456.009(1)</u>.
- (16) FEES.—The department shall allocate the fees collected under this section to the council. History.—ss. 1, 6, ch. 79-230; s. 309, ch. 81-259; ss. 2, 3, ch. 81-318; ss. 22, 27, 29, 31, ch. 86-290; s. 37, ch. 88-1; s. 16, ch. 88-277; s. 5, ch. 88-361; s. 28, ch. 89-162; s. 3, ch. 91-22; ss. 4, 5, ch. 91-429; s. 4, ch. 92-22; s. 91, ch. 92-149; s. 112, ch. 94-218; s. 2, ch. 95-231; s. 2, ch. 96-197; s. 224, ch. 97-101; s. 1101, ch. 97-103; s. 35, ch. 97-264; s. 7, ch. 98-49; s. 55, ch. 98-166; s. 156, ch. 99-251; s. 113, ch. 2000-160; ss. 27, 43, ch. 2000-318; s. 2, ch. 2001-100; ss. 26, 56, ch. 2001-277; s. 2, ch. 2007-155; s. 78, ch. 2008-6; s. 4, ch. 2009-177; s. 3, ch. 2010-55; s. 2, ch. 2012-170; s. 2, ch. 2013-127; s. 2, ch. 2016-125; s. 3, ch. 2016-145; ss. 22, 24, ch. 2016-224; s. 18, ch. 2016-230; s. 30, ch. 2017-3; s. 2, ch. 2017-154; s. 16, ch. 2020-133; s. 2, ch. 2021-204.

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# THE FLORIDA LEGISLATURE JOINT ADMINISTRATIVE PROCEDURES COMMITTEE



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Representative Tobin Rogers "Toby" Overdorf, Chair Senator Blaise Ingoglia, Vice Chair Senator Colleen Burton Senator Erin Grall Senator Rosalind Osgood Senator Darryl Ervin Rouson Representative Shane G. Abbott Representative Kimberly Berfield Representative Jervonte "Tae" Edmonds Representative Alina Garcia

Representative Yvonne Hayes Hinson

July 21, 2023

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

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

Dear Mr. Dierlam:

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

**64B8ER23-8:** The board may want to consider citing section 458.331(1)(v) as

rulemaking authority and as a law implemented.

64B8ER23-8(1)(a): DH5082-MQA, Feminizing Medications for Patients with Gender

Dysphoria, Patient Information and Informed Consent

Page 3: Please explain the board's statutory authority for requiring that adults receiving these medications "to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist" before beginning HRT and every two years thereafter. *See* § 120.52(8)(c), Fla. Stat.

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

Mr. Christopher Dierlam July 21, 2023 Page 2

64B8ER23-8(1)(b): DH5083-MQA, Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent

See comments to 64B8ER23-8(1)(a) regarding form DH5082.

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

Sincerely,
Mayoni l. Hollaslay

Marjorie C. Holladay Chief Attorney

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

MCH:df #190463



# THE FLORIDA LEGISLATURE JOINT ADMINISTRATIVE PROCEDURES COMMITTEE



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Representative Yvonne Hayes Hinson

July 21, 2023

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

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

Dear Ms. McNulty:

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

64B15ER23-10: The board may want to consider citing section 459.015(1)(z) as

rulemaking authority and as a law implemented.

DH5082-MQA, Feminizing Medications for Patients with Gender 64B15ER23-10(1)(a):

Dysphoria, Patient Information and Informed Consent

Page 3: Please explain the board's statutory authority for requiring that adults receiving these medications "to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist" before beginning HRT and every two years thereafter. See

§ 120.52(8)(c), Fla. Stat.

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

Ms. Donna McNulty July 21, 2023 Page 2

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

64B15ER23-10(1)(b):

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

Mayoni & Holladay

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

Sincerely

Marjorie C. Holladay Chief Attorney

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

MCH:df #190465

#### **Puberty Suppression Treatment for Patients with Gender Dysphoria**

#### **Patient Information and Informed Parental Consent and Assent for Minors**

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

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

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

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

# What are different medications that are used to suppress puberty?

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

guardian (required)	guardian (optional)	
------------------------	------------------------	--

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.

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

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

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

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

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

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

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

# **Effects of Treatment of Suppression of Puberty**

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

# **Risks of Treatment of Suppression of Puberty**

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

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

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

# **Requirements of Treatment of Suppression of Puberty**

# I understand the following:

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor	Statement
			Compliance with the requirements explained above is a
			prerequisite to receive treatment for puberty suppression.
			The prescribing physician may stop prescribing puberty
			blockers if the prescribing physician or mental health care
			professionals providing treatment pursuant to this consent
			determine the benefit of treatment no longer outweighs the
			risks, there is insufficient social or psychological support, or
			the requirements in this consent are not met.

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

#### **PARENTAL CONSENT:**

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

- 1. The minor's prescribing physician has fully informed me about:
  - a. the benefits and risks of treatment with puberty blockers;
  - b. the possible or likely consequences of treatment with puberty blockers and puberty suppression; and
  - c. potential alternative treatments.
- 2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with puberty blockers. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.
- 3. I have had sufficient time and opportunity to discuss relevant treatment options with my minor's prescribing physician.
- 4. All my questions have been answered to my satisfaction by the minor's prescribing physician.
- 5. I know enough to give informed consent for my minor to take, refuse, or postpone using puberty blocking medications.
- 6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.
- 7. My signature below attests to my consent for my minor to begin treatment for suppression of puberty.

Parent/legal guardian's name (required)	
Turono regui guarcatar o nume (requireu)	
Parent/legal guardian's signature (required)	——————————————————————————————————————

Parent/legal guardian's name (optional)		
Parent/legal guardian's signature (optional)	Date	
PRESCRIBING PHYSICIAN SIGNATURE:		
My signature below attests to my compliance with s	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 physician and my parent(s) or legal guardian(s), and		g
Minor's name (required)		
Minor's signature (required)	Date	

WITNESS:	
Witness printed name	-
Witness signature	- Date
FOR PATIENTS WHOSE PRIMARY LANGU	AGE IS NOT ENGLISH:
I certify that I am fluent in English and in the national and/or assent on the above form. I certify that I has contents of this form, and that the patient and/or ach has indicated understanding of the contents of this f	ve accurately and completely interpreted the hult(s) legally responsible for the minor child
Interpreter's printed name	-
Interpreter's Signature	Date

#### Feminizing Medications for Patients with Gender Dysphoria

#### **Patient Information and Informed Parental Consent and Assent for Minors**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 1. Meets the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
- 2. Has pubertal changes resulting in an increase in gender dysphoria;
- 3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
- 4. Has psychological and social support during treatment;
- 5. Has experienced puberty to at least Tanner Stage 2 (first stage of puberty), which must be confirmed by a physician;
- Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery;
- 7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
- 8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
- 9. Undergoes relevant laboratory testing at least every 4 months;
- 10. X-ray of the hand (bone age) at least once a year if the minor is still growing;
- 11. Annual bone density scan (DEXA) which will allow monitoring of the minor's bone density (bone strength) during treatment, which can be altered by HRT;
- 12. Annual mental health assessments by a Board-certified Florida licensed psychiatrist or psychologist; and
- 13. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

nal)

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

# **Effects of Feminizing Medications**

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

<ul> <li>even if treatment is discontinued, the risk of which is increased if the minor took puberty blockers prior to starting feminizing medications</li> <li>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</li> </ul>
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.
<ul> <li>If a minor takes feminizing medications, some parts of the minor's body will not change much, including:</li> <li>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</li> <li>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</li> <li>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</li> <li>If present, the minor's Adam's apple will not shrink</li> </ul>
<ul> <li>Even if a minor stops taking feminizing medications, the following changes may occur:</li> <li>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</li> <li>The minor may have decreased muscle mass and strength in the upper body</li> <li>The minor's skin may become softer</li> </ul>
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
measurations are not approved by the 1 D71 for this

purpose. I know that the medicine and dose that is
recommended is based solely on the judgment and
experience of the minor's prescribing physician
and there is no data in the medical literature or
controlled research studies that support the timing,
dosing, and type of administration of feminizing
medications for minors.

# **Risks of Feminizing Medications**

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

# Risks of Estrogen

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor	Statement
			Estrogen SHOULD NOT be used by anyone who has a history of:  • Any estrogen-dependent cancer  • Any disorder that makes them more likely to get blood clots that could travel to the lungs unless they are also taking blood thinners and are being followed by a specialist

Estrogen should be used WITH CAUTION and
only after a full discussion of risks by anyone who:
Has a family history of breast cancer or other
cancers that grow more quickly when
estrogens are present
<ul> <li>Has a family history of heart disease</li> </ul>
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