Florida Senate - 2023 Bill No. CS for SB 254 COMMITTEE AMENDMENT



	LEGISLATIVE ACTION			
Senate		House		
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	•			
The Committee on Fisca	al Policy (Jones) rec	ommended the		
following:				
Senate Amendment				
Between lines 175	and 176			
insert:				
4. Treatment prov	rided by a health car	e practitioner to a		
minor if:				
a. The minor has been diagnosed as suffering from severe				
gender dysphoria by at	least two medical o	r mental health care		
practitioners, one of	whom is a mental hea	lth care practitioner		
or adolescent medicine	specialist, and bot	h of whom have		

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1 2 3

594-02886-23

PL011974



11	relevant training in the diagnosis and treatment of severe		
12	gender dysphoria in adolescents;		
13	b. The diagnosing health care practitioners express in		
14	written opinions that treatment with sex-reassignment		
15	prescriptions or procedures is medically necessary to treat the		
16	minor's psychiatric symptoms and limit self-harm, or the		
17	possibility of self-harm, by the minor;		
18	c. The minor, the minor's parents, legal guardians, or		
19	person or other persons charged with health care decisionmaking		
20	for the minor, and the minor's primary physician agree in		
21	writing with the treatment with sex-reassignment prescriptions		
22	or procedures for the minor; and		
23	d. Any use of sex-reassignment prescriptions or procedures		
24	is limited to the lowest titratable dosage necessary to treat		
25	the psychiatric condition and not for purposes of affirming a		
26	person's perception of his or her sex if that perception is		
27	inconsistent with the person's sex as defined in subsection (8).		
28			
29	Notwithstanding sub-subparagraphs ad., sex-reassignment		
30	prescriptions or procedures may not be provided to the minor if		
31	the minor is prepubescent.		

Florida Senate - 2023 Bill No. CS for SB 254 SENATOR AMENDMENT



	LEGISLATIVE ACTION			
Senate		House		
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Senator Jones moved the following:				
Senate Amendment				
Between lines 1	75 and 176			
insert:				
	ovided by a health care	e practitioner to a		
minor if:				
a. The minor ha	s been diagnosed as suf	fering from severe		
gender dysphoria by	at least two medical or	mental health care		
practitioners, one o	f whom is a mental heal	th care practitioner		
or adolescent medici	ne specialist, and both	of whom have		
relevant training in	the diagnosis and trea	tment of severe		

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Doe Pls' Trial Ex.

PL011976

34-03270-23



gender dysphoria in adolescents;
b. The diagnosing health care practitioners express in
written opinions that treatment with sex-reassignment
prescriptions or procedures is medically necessary to treat the
minor's psychiatric symptoms and limit self-harm, or the
possibility of self-harm, by the minor;
c. The minor, the minor's parents, legal guardians, or
person or other persons charged with health care decisionmaking
for the minor, and the minor's primary physician agree in
writing with the treatment with sex-reassignment prescriptions
or procedures for the minor; and
d. Any use of sex-reassignment prescriptions or procedures
is limited to the lowest dosage necessary to treat the
psychiatric condition and not for purposes of affirming a
person's perception of his or her sex if that perception is
inconsistent with the person's sex as defined in subsection (8).
Notwithstanding sub-subparagraphs ad., sex-reassignment
prescriptions or procedures may not be provided to the minor if
the minor is prepubescent.

Florida Senate - 2023 Bill No. CS for SB 254 COMMITTEE AMENDMENT



	LEGISLATIVE ACTION			
Senate		House		
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The Committee on Fisc	al Policy (Jones) rec	commended the		
The Committee on Fiscal Policy (Jones) recommended the following:				
TOTTOWING.				
Senate Amendment	(with title amendmen	ıt)		
Delete lines 200	- 216			
and insert:				
the pharmaceutical pr	oduct or perform the	procedure has:		
(a) Informed the	patient of the natur	re and risks of the		
prescription or proce	dure in order for the	e patient to make a		
<pre>prudent decision;</pre>				
(b) Provided the	informed consent for	rm, as approved by the		
department, to the pa	tient; and			

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594-02887-23

PL011978



Bill No. CS/SB 254, 1st Eng. (2023)

Amendment No.

CHAMBER ACTION

<u>Senate</u> <u>House</u>

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Representative Harris offered the following:

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Amendment to Amendment (256341)

Remove lines 69-95 and insert:

(1) For the purposes of this section, the term "gender clinical interventions" means surgical procedures that alter internal or external physical traits for the purpose of affirming a person's perception of his or her sex if that perception is inconsistent with the person's sex at birth.

(a) The term includes, but is not limited to, sex reassignment surgeries or any other surgical procedures that alter primary or secondary sexual characteristics.

(b) The term does not include:

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Doe Pls' Trial Ex.

PL011980

Bill No. CS/SB 254, 1st Eng. (2023)

Amendment No.

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- 1. Treatment provided by a physician who, in his or her good faith clinical judgment, performs procedures upon, or provides therapies to, a minor born with a medically verifiable genetic disorder of sexual development, including the following:
- <u>a. External biological sex characteristics that are</u> unresolvably ambiguous.
- b. A disorder of sexual development, in which the physician has determined through genetic or biochemical testing that the minor does not have normal sex chromosome structure, sex steroid hormone production, or sex steroid hormone action for a male or female.
- 2. Treatment of any infection, injury, disease, or disorder caused or exacerbated by the performance of gender clinical interventions regardless of whether such interventions were performed in accordance with state or federal law.
- 3. Puberty blocking, hormone, and hormone antagonistic therapies.

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Bill No. CS/SB 254, 1st Eng. (2023)

Amendment No.

CHAMBER ACTION

<u>Senate</u> <u>House</u>

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Representative Fine offered the following:

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Amendment (with title amendment)

Remove lines 83-370 and insert:

being subjected to gender clinical interventions, as defined in $\underline{s. 456.52(1)}$.

Section 2. Subsection (1) of section 61.534, Florida Statutes, is amended to read:

61.534 Warrant to take physical custody of child.-

(1) Upon the filing of a petition seeking enforcement of a child custody determination, the petitioner may file a verified application for the issuance of a warrant to take physical custody of the child if the child is likely to imminently suffer

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Doe Pls' Trial Ex.

PL011982

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Amendment No.

2.4

serious physical harm or removal from this state. <u>Serious</u> physical harm includes, but is not limited to, being subjected to gender clinical interventions, as defined in s. 456.52(1).

Section 3. Section 381.991, Florida Statutes, is created to read:

381.991 Public expenditures for gender clinical interventions; prohibition.—A state agency, political subdivision, public postsecondary institution as defined in 1000.04, or person providing services to or on behalf of any such agency, subdivision, or institution by contract or other agreement or relationship, may not expend funds to provide or reimburse for gender clinical interventions as defined in s. 456.52(1).

Section 4. Paragraph (f) is added subsection (1) of section 382.016, Florida Statutes, read:

382.016 Amendment of records.—The department, upon receipt of the fee prescribed in s. 382.0255; documentary evidence, as specified by rule, of any misstatement, error, or omission occurring in any birth, death, or fetal death record; and an affidavit setting forth the changes to be made, shall amend or replace the original certificate as necessary.

- (1) CERTIFICATE OF LIVE BIRTH AMENDMENT.-
- (f) The sex recorded on a birth certificate must be the person's biological sex at birth. The sex recorded on the birth certificate may only be changed in the case of a scrivener's

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Amendment No.

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error or in the case of a person born with external biological
sex characteristics that were unresolvably ambiguous at the time
of birth. The sex recorded on a birth certificate may not be
changed for the purpose of affirming a person's perception of
his or her sex if that perception is inconsistent with the
person's sex at birth. The department may change the sex
recorded on a birth certificate under this paragraph upon the
written request of a health care practitioner, as defined in s.
456.001, stating and providing evidence establishing the basis
for the correction. Misrepresenting or providing fraudulent
evidence in such a request is grounds for disciplinary action
under s. 456.072 and any applicable practice act.
     Section 5. Paragraphs (c) through (gg) of subsection (5)
of section 456.074, Florida Statutes, are redesignated as
paragraphs (d) through (hh), respectively, and a new paragraph
(c) is added to that subsection, to read:
     456.074 Certain health care practitioners; immediate
suspension of license.-
          The department shall issue an emergency order
suspending the license of any health care practitioner who is
arrested for committing or attempting, soliciting, or conspiring
to commit any act that would constitute a violation of any of
the following criminal offenses in this state or similar
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offenses in another jurisdiction:

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Section 456.52(6), relating to providing gender

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Amendment No.

64	clinical interventions to a minor.
65	Section 6. Section 456.52, Florida Statutes, is created to
66	read:
67	456.52 Prohibition on gender clinical interventions for
68	minors; physician requirements.—
69	(1) For the purposes of this section, "gender clinical
70	interventions" means procedures or therapies that alter internal
71	or external physical traits for the purpose of affirming a
72	person's perception of his or her sex if that perception is
73	inconsistent with the person's sex at birth.
74	(a) The term includes, but is not limited to:
75	1. Sex reassignment surgeries or any other surgical
76	procedures that alter primary or secondary sexual
77	characteristics.
78	2. Puberty blocking, hormone, and hormone antagonistic
79	therapies.
80	(b) The term does not include:
81	1. Treatment provided by a physician who, in his or her
82	good faith clinical judgment, performs procedures upon, or
83	provides therapies to, a minor born with a medically verifiable
8 4	genetic disorder of sexual development, including the following:
85	a. External biological sex characteristics that are
86	unresolvably ambiguous.
87	b. A disorder of sexual development, in which the
88	physician has determined through genetic or biochemical testing

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Amendment No.

that the minor does not have normal sex chromosome structure, sex steroid hormone production, or sex steroid hormone action for a male or female.

- 2. Treatment of any infection, injury, disease, or disorder caused or exacerbated by the performance of gender clinical interventions regardless of whether such interventions were performed in accordance with state or federal law.
- (2)(a) Gender clinical interventions may only be provided by a physician licensed under chapter 458 or chapter 459 or a physician practicing medicine or osteopathic medicine in the employment of the Federal Government.
- (b) A physician may not provide gender clinical interventions to a minor, except that a minor who was prescribed gender clinical interventions described in (1)(a)2. on or before January 1, 2023, and continuously received such therapies through July 1, 2023, may continue to receive such therapies through December 31, 2023, solely for the purpose of gradual discontinuation of such therapies.
- (3) Notwithstanding ss. 458.320(5) and 459.0085(5), a physician who provides gender clinical interventions for adults must obtain and maintain professional liability coverage in the amounts established in ss. 458.320(2)(b) and 459.0085(2)(b), as applicable.
- (4)(a) A physician must, while physically present in the same room as an adult patient, obtain informed written consent

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Amendment No.

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from the patient each time the physician provides gender clinical interventions. The physician must sign the consent and maintain the consent in the medical record. The patient must sign the informed consent acknowledging that the physician has sufficiently explained its content. The physician must use an informed consent form adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine, which must include, at a minimum, information related to the current state of research of: 1. The long-term and short-term effects of gender clinical interventions. 2. The impact of gender clinical interventions on physical and mental health. (b) The Board of Medicine and the Board of Osteopathic Medicine, as applicable, shall adopt emergency rules to implement this section. (c) Any emergency rules adopted under this section are exempt from s. 120.54(4)(c) and shall remain in effect until replaced by rules adopted under the nonemergency rulemaking procedures of the Administrative Procedure Act. (5) A board, or the department if there is no board, must revoke the license of a health care practitioner if the board, or the department if there is no board, determines that the

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health care practitioner violated this section.

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(6)(a) A health care practitioner who willfully or

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     actively participates in a violation of (2)(b) commits a felony
140
     of the third degree, punishable as provided in s. 775.082, s.
141
     775.083, or s. 775.084.
142
          (b) A health care practitioner who willfully or actively
     participates in a violation of (4)(a) commits a misdemeanor of
143
     the first degree, punishable as provided in s. 775.082 or s.
144
     775.083.
145
146
          Section 7. Section 627.6411, Florida Statutes, is created
     to read:
147
148
          627.6411 Coverage of certain treatment.—A health insurance
     policy may not provide coverage for gender clinical
149
     interventions as defined in s. 456.52(1).
150
151
          Section 8. Subsection (48) is added to section 641.31,
     Florida Statutes, to read:
152
153
          641.31 Health maintenance contracts.
154
          (48) A health maintenance contract may not include
155
     coverage for gender clinical interventions as defined in s.
156
     456.52(1).
157
          Section 9. Section 766.318, Florida Statutes, is created
158
     to read:
159
          766.318 Gender clinical interventions; liability.-
160
          (1) A physician who provides gender clinical
161
     interventions, as defined in s. 456.52, to a person is liable to
     the person for any physical, psychological, emotional, or
162
     physiological injury resulting from the gender clinical
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   256341
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Amendment No.

164	<u>intervention.</u>			
165	(2) A person who receives a gender clinical intervention			
166	from a physician may bring a civil action against such			
167	practitioner in a court of competent jurisdiction for:			
168	(a) Declaratory or injunctive relief.			
169	(b) Economic damages.			
170	(c) Noneconomic damages.			
171	(d) Punitive damages.			
172	(e) Attorney fees and costs.			
173	(3) In an action brought under this section, the			
174	limitations on punitive damages in s. 768.73, or any other			
175	provision of law that seeks to limit punitive damages, do not			
176	apply.			
177	(4) The estate of, or a legal guardian on behalf of, a			
178	person who received a gender clinical intervention from a			
179	physician, when the death of that person was caused by such			
180	gender clinical intervention, may bring a civil action against			
181	such practitioner in a court of competent jurisdiction for all			
182	of the following:			
183	(a) All remedies available under subsection (2).			
184	(b) All remedies available under s. 766.102.			
185	(c) Treble damages.			
186	(5) Notwithstanding s. 95.11, an action brought under			
187	subsection (2) must be commenced within 20 years after the date			
188	8 of the gender clinical interventions.			
	1 256341			

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Amendment No.

(6) An action brought under subsection (4) must be commenced within 5 years after the date of the person's death or the discovery of the person's death, whichever is later.

Section 10. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

TITLE AMENDMENT

Remove lines 6-67 and insert:

to or is threatened with being subjected to gender clinical interventions; amending s. 61.534, F.S.; providing that, for purposes of warrants to take physical custody of a child in certain child custody enforcement proceedings, serious physical harm to the child includes, but is not limited to, being subjected to gender clinical interventions; creating s. 381.991, F.S.; prohibiting certain persons and entities from expending funds for reimbursement for specified clinical interventions; amending s. 382.016, F.S.; prohibiting a person's biological sex from being changed on a birth certificate; providing an

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Amendment No.

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214
          exception; providing for disciplinary actions;
215
          amending s. 456.074, F.S.; requiring the department to
216
          immediately suspend the license of a health care
217
          practitioner who is arrested for committing or
218
          attempting, soliciting, or conspiring to commit
219
          specified violations related to gender clinical
220
          interventions for a minor; creating s. 456.52, F.S.;
221
          providing a definition for the term "gender clinical
          interventions"; prohibiting gender clinical
222
223
          interventions for minors; providing exceptions;
224
          requiring a physician to maintain specified
225
          professional liability coverage; requiring a physician
226
          to obtain informed written consent from a patient
227
          under certain circumstances; providing requirements
228
          for the informed consent form; authorizing certain
229
          persons to refuse to participate in gender clinical
230
          interventions; providing liability and penalties;
231
          creating s. 627.6411, F.S.; prohibiting a health
232
          insurance policy from providing coverage for gender
233
          clinical interventions; amending s. 641.31, F.S.;
234
          prohibiting a health maintenance contract from
235
          including coverage for gender clinical interventions;
236
          creating s. 766.318, F.S.; providing for physician
237
          liability; providing penalties for injuries and
238
          wrongful death caused by gender clinical
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Bill No. CS/SB 254, 1st Eng. (2023)

Amendment No.

239	interventions; authorizing the award of specified
240	damages and attorney fees and costs; providing statute
241	of limitations periods; providing severability;
242	providing

256341

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Bill No. CS/SB 254, 1st Eng. (2023)

Amendment No.

CHAMBER ACTION

Senate House

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Representative Rayner-Goolsby offered the following:

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Amendment to Amendment (256341)

Between lines 95 and 96, insert:

3. Treatment provided by a health care practitioner to a minor if:

a. The minor has been diagnosed as suffering from severe gender dysphoria by at least two medical or mental health care practitioners, one of whom is a mental health care practitioner or adolescent medicine specialist, and both of whom have relevant training in the diagnosis and treatment of severe gender dysphoria in adolescents;

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Bill No. CS/SB 254, 1st Eng. (2023)

Amendment No.

b. The diagnosing health care practitioners express in
written opinions that treatment with sex-reassignment
prescriptions or procedures is medically necessary to treat the
minor's psychiatric symptoms and limit self-harm, or the
possibility of self-harm, by the minor;
c. The minor, the minor's parents, legal guardians, or
other person or persons charged with health care decisionmaking
for the minor, and the minor's primary physician agree in
writing with the treatment with sex-reassignment prescriptions
or procedures for the minor; and
d. Any use of sex-reassignment prescriptions or procedures
is limited to the lowest dosage necessary to treat the
psychiatric condition and not for purposes of affirming the
minor's perception of his or her sex if that perception is
inconsistent with the minor's sex.
Notwithstanding sub-subparagraphs ad., sex-reassignment
prescriptions or procedures may not be provided to the minor if
the minor is prepubescent.

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Bill No. CS/SB 254, 1st Eng. (2023)

Amendment No.

CHAMBER ACTION

Senate House

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Representative Eskamani offered the following:

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Amendment to Amendment (256341)

Between lines 106 and 107, insert:

(c) An immediate family member of a person in any branch of the Armed Forces of the United States whose duty post is within this state may continue to have access to and insurance coverage of sex-reassignment prescriptions and procedures.

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Bill No. CS/SB 254, 1st Eng. (2023)

Amendment No.

	CHAMBER ACTION			
	<u>Senate</u> <u>House</u>			
	•			
1	Representative Eskamani offered the following:			
2				
3	Amendment to Amendment (256341) (with title amendment)			
4	Between lines 145 and 146, insert:			
5	(7) This section does not prohibit a cause of action			
6	against the state for mental, physical, or emotional damages			
7	based upon delayed or missed gender clinical interventions.			
8				
9				
10	TITLE AMENDMENT			
11	Between lines 230 and 231, insert:			
12	authorizing a private cause of action against the state under			
13	certain circumstances;			
	172969			

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Approved For Filing: 4/14/2023 5:15:28 PM

PL011996

Bill No. CS/SB 254, 1st Eng. (2023)

Amendment No.

CHAMBER ACTION

<u>Senate</u> <u>House</u>

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Representative Harris offered the following:

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Amendment to Amendment (256341)

Between lines 95 and 96, insert:

3. Nonsurgical treatments for the treatment of gender dysphoria in minors performed during an investigator-initiated clinical study approved by an institutional review board and conducted at a Florida medical school under s. 458.3145(1)(i). Such clinical trial must include long-term, longitudinal assessments of the patients' physiologic and psychologic outcomes.

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Doe Pls' Trial Ex.

PL011997

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Received: 6 June 2022 | Accepted: 7 June 2022

DOI: 10.1002/iac5.1691

LETTER TO THE EDITOR



Puberty blockers for gender dysphoric youth: A lack of sound science

Dear Editor,

The medical transition of children and adolescents with gender dysphoria remains highly debated and there is significant divergence in policy internationally. 1-7 Mills and colleagues' review the interventions that comprise the "gender-affirmative" care pathway, an approach currently promoted by many medical organizations in North America.⁶⁻⁸ We strongly agree with the authors that pharmacists have a responsibility to "understand the evidence," and "place the well-being of the patient over any personal cultural beliefs."8 However, we think the use of evidence to support the authors' claim that gonadotropin releasing hormone (GnRH)-analogs are fully reversible and have been shown to improve mental health, requires critical appraisal.

GnRH-analogs have been used for decades to successfully delay the early onset of puberty in children with precocious puberty. While generally considered safe for this indication, recent concern about impacts on polycystic ovarian disease, metabolic syndrome, and future bone density, have been raised. 10 Even less is known about the use of GnRH-analogs to halt normally timed puberty in youth with gender dysphoria; no long-term, longitudinal studies of GnRH-analogs for this indication exist.

Puberty-related hormones have wide ranging effects on brain structure, function, and connectivity. 11 Concerns have been raised that hormonal suppression of puberty may permanently alter neurodevelopment.^{2,11-13} The possible impact of puberty blockade on a young person's cognition has important implications for the decision to initiate exogenous cross-sex hormones and the capacity to give informed consent.¹⁴ Moreover, it has been suggested that pubertal suppression may alter the course of gender identity development, essentially "locking in" a gender identity that may have reconciled with biological sex during the natural course of puberty. 13 Over 95% of youth treated with GnRH-analogs go on to receive cross-sex hormones. 15 By contrast, 61-98% of those managed with psychological support alone reconcile their gender identity with their biological sex during puberty. 16-18 This lack of evidence to support the durability of a transgender identification is conceptually consistent with significant psychosocial determinants of cross-sex identity, while the belief in immutable biological influences can best be described as a "current hypothesis." 19

There are also concerns that GnRH-analogs may have irreversible effects on sexual function and bone development. In some youth

J Am Coll Clin Pharm. 2022;5:1005-1007.

pubertal blockade at Tanner stage 2 followed by exogenous cross-sex hormones has resulted in a complete absence of adult sexual function.²⁰ Profound effects on future sexual function may even occur when puberty is paused and later allowed to proceed, since the precise timing of hormone exposure during the peripubertal window is a determinative factor in adult sexual function.²¹ Finally, several studies have found that the expected pattern of bone mass accrual during adolescence does not occur when puberty is halted.²²⁻²⁵ The longterm clinical consequences of failure to accrue normal bone mass are unknown

Uncertainties about long-term risks of medical transition are often overshadowed by the most potent argument provided by advocates of the affirmative model: failure to affirm a young person's transgender identity may result in suicide. Suicidal ideation and self-harming behaviors have been found to be higher than age-matched peers, but comparable to nongender dysphoric youth referred for management of other mental health diagnoses.²⁶ However, the relevant question is whether affirmative care reduces suicide risk. Mills and colleagues assertion that GnRH-analogs have been shown to decrease lifetime suicidal ideation stems from a nonrepresentative, low-quality survey of transgender adults that has been thoroughly critiqued by others.^{27,28} Moreover, their claim that these drugs are effective for other mental health outcomes is at odds with recent systematic reviews that concluded there is little change from baseline to follow-up in depression, anxiety, body image, gender dysphoria, or psychosocial functioning.^{2,12,29} A seminal Dutch case-series of children with early-onset gender dysphoria is cited to support the assertion that GnRH-analogs improve psychological functioning. 15 The magnitude of posttreatment improvement in mental health outcomes in this study was small and of questionable clinical significance. Furthermore, the applicability of results to the most common demographic presenting today, that is, adolescent females with preexisting mental health problems or neurodevelopmental conditions and no prior history of gender dysphoria, is questionable.^{4,30} A recent attempt to replicate the results of the Dutch study in the United Kingdom found no psychological benefit with GnRH-analogs, but treatment was associated with adverse effects on bone development.31

Multiple European countries that were pioneers in youth medical transition are now adopting a more cautious approach to the use of

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Doe Pls' Trial Ex.

GnRH-analogs and cross-sex hormones after their own evidence reviews failed to show mental health benefits and highlighted a profound lack of knowledge about harms. The UK's Cass review emphasized the paucity of data in their interim report stating, "it is important that it is not assumed that outcomes for, and side effects in, children treated for precocious puberty will necessarily be the same in children or young people with gender dysphoria."13 The NHS updated guidance on treatment of gender dysphoria removed statements about the reversibility of GnRH-analogs and now states, "little is known about the long-term side effects of hormone or puberty blockers in children with gender dysphoria." ⁴ The Swedish Health Authority no longer offers GnRH-analogs to minors except in exceptional cases stating, "the risks of puberty suppressing treatment with GnRHanalogues and gender affirming hormonal treatment currently outweigh the possible benefits." Finland has severely restricted their use and now recommend psychotherapy as first-line treatment for gender-dysphoric youth.² Lastly, the French Académie Nationale de Médecine recently issued a press release stating, "great medical cau-ORCID tion must be taken in children and adolescents, given the vulnerability, particularly psychological, of this population and the many undesirable effects, and even serious complications, that some of the available **REFERENCES** therapies can cause."5 Although puberty-blockers and cross-sex hormones will still be available, the Académie emphasized, "the greatest reserve is required in their use, given side effects such as impact on cms/Documents/SOC%20v7/SOC%20V7_English.pdf growth, bone fragility, risk of sterility, emotional and intellectual con-

In summary, we believe the authors' review does not present a balanced assessment of the evidence and betrays a bias toward uncritically promoting medical transition. The widespread methodological weaknesses in the research coupled with the lack of certainty that benefits outweigh harms, should raise questions about affirmation being positioned as the "standard of care" in the United States and Canada.²⁹ Patients and their families rely on pharmacists to resist ideological influence and communicate transparently. To this end, we call on Mills and colleagues to revisit their important review and provide a more nuanced discussion of the evidentiary basis for genderaffirming care.

sequences and, for girls, symptoms reminiscent of menopause."5

ACKNOWLEDGEMENTS

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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From: Redfern, Jeremy T

Subject: Re: Fox News Media Request: Chloe Cole testimony, backstory To: ""ONei|"","" Tyler; Brock.Juarez@ahca.myflorida.com

Cc: Brock.Juarez@ahca.myflorida.com; Christina Pushaw; Bryan Griffin

Sent: July 10, 2022 4:38 PM (UTC-04:00)

I'm working on getting a quote from the Surgeon General. I will send it to you once I have it.

And yes, you are free to use the clip across all of your platforms. They were filmed by the Department of Health and are therefore available to use by anyone. I am currently in the process of editing other clips, and I will get them to you as I get them ready. Can you just let me know when you plan to have them air?

Jeremy Redfern Press Secretary Florida Department of Health 850-445-3260

On Jul 10, 2022, at 3:12 PM, ONeil, Tyler < Tyler. ONeil@FOX.COM> wrote:

You don't often get email from tyler.oneil@fox.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.

Thanks, Jeremy! Is there more of the event that I can watch? Would the surgeon general make a comment to Fox News on medicalizing minors with gender dysphoria and why is it important to push back on the "affirmative" care model? Is there testimony from an endocrinologist and/or a psychotherapist that you would share?

Finally, can we have permission to use the video of Cole that Ladapo shared on Fox News Channel, Fox Business Network, Fox Nation, Fox Weather and all Fox News Edge affiliates across all platforms until further notice with courtesy to you? Do we also need anyone else's permission? Thank you.

From: Redfern, Jeremy T < <u>Jeremy.Redfern@flhealth.gov</u>>

Sent: Sunday, July 10, 2022 4:02 PM **To:** ONeil, Tyler <<u>Tyler.ONeil@FOX.COM</u>>

<Bryan.Griffin@eog.myflorida.com>

Subject: Re: Fox News Media Request: Chloe Cole testimony, backstory

Hey Tyler,

The Surgeon General recently had the opportunity to sit down with detransitioners, parents, and experts in pediatric endocrinology and psychotherapy.

We are going to use this opportunity to educate the public on the unacceptable harm caused by the "affirmative" care model pushed by multiple professional and government institutions.

These conversations will also be included as part of our evidence gathering for when the Board of Medicine considers the Surgeon General's letter requesting an official practice standard.

Jeremy T. Redfern Press Secretary Florida Department of Health 850-445-3260

From: ONeil, Tyler < Tyler. ONeil@FOX.COM > Sent: Sunday, July 10, 2022 2:11 PM

To: Redfern, Jeremy T < <u>Jeremy.Redfern@flhealth.gov</u>>; Juarez, Brock < <u>Brock.Juarez@ahca.myflorida.com</u>>

Cc: zzzz Feedback, Health < Health@flhealth.gov >

Subject: Fox News Media Request: Chloe Cole testimony, backstory

Some people who received this message don't often get email from tyler.oneil@fox.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.

Jeremy, Brock,

I am writing a story about the testimony of Chloe Cole, a teenage detransitioner whose story Surgeon General Ladapo shared on Twitter this afternoon. I'd like to hear more about the testimony, if it was part of an event, and whether it is part of an effort to educate the public on transgender issues. Would Ladapo comment on the significance of testimony from former transgender people who have suffered due to what critics may claim is a rush to embrace transgender identity and champion medical interventions that may harm patients?

https://twitter.com/FLSurgeonGen/status/1546164557072187398

I am working on a deadline of 5:30 p.m. eastern and would appreciate a prompt response.

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Best,

Tyler O'Neil Digital Editor Fox News (303)956-8499

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Notice of Emergency Rule

Doe Pls' Trial Ex.

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://fiboardofmedicine.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:

64B15ER23-12 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:

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

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://fiboardofmedicine.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.*

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