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STATE OF FLORIDA
DEPARTMENT OF HEALTH
BOARD OF MEDICINE

In Re: Petition to Initiate Rulemaking Setting the Standard of Care for Treatment of Gender Dysphoria

FLORIDA DEPARTMENT OF HEALTH'S PETITION TO INITIATE RULEMAKING

Pursuant to Section 120.54(7), Florida Statutes, the Florida Department of Health (Department) hereby files this Petition to Initiate Rulemaking and in support thereof states as follows:

Standing and Authority

1. Pursuant to section 20.43, Florida Statutes, the purpose of the Department is to protect and promote the health of all residents and visitors in the state through organized state and community efforts.

2. Section 20.43(e), Florida Statutes, requires the Department to ensure the provision of quality health care and related services to identified populations in the state.

3. Section 20.43(g), Florida Statutes, requires the Department to regulate health practitioners for the preservation of the health, safety, and welfare of the public.

4. The Department has a substantial interest in the regulation of

physicians and the provision of effective, safe, and evidence-based medical care to the residents of the state.

5. The Board of Medicine (Board) is the state agency responsible for the regulation of physicians pursuant to chapters 456 and 458, Florida Statutes.

6. Section 458.331(1)(v), Florida Statutes, grants the Board authority to establish standards of care for particular practice settings, including, but not limited to, the performance of complex or multiple procedures and informed consent.

Gender Dysphoria

7. Gender dysphoria is clinically significant distress or functional impairment associated with an incongruence between a person's experienced or expressed gender and the person's sex.[1]

8. Only a minority of children who are diagnosed with gender dysphoria remain gender dysphoric as adults.[2] There is a lack of quality evidence and certainly no conclusive research to support the medical transition of children to the opposite gender as a treatment for gender

[1] George R. Brown, M.D., *Gender Dysphoria*, MERCK MANUAL (last modified May 2022), https://www.merckmanuals.com/professional/psychiatric-disorders/gender-dysphoria/gender-dysphoria.
[2] *See id.*

dysphoria.

Conflicting Guidance

9. The US Department of Health and Human Services has issued guidance encouraging early treatment for gender dysphoria with an array of services, including psychological, medical, and surgical interventions.[3]

10. The Endocrine Society[4] and the American Academy of Pediatrics[5] have issued similar guidance based on low quality evidence plagued with small sample sizes and high risks of bias.

11. These endorsements have permeated both the general public and health care community and created the false impression that chemical and surgical intervention is not only clinically proven, but the standard of care for treatment of gender dysphoria in Florida.

12. In an effort to resolve this confusion, on April 20, 2022, the Department issued an advisory and recommendation against the use of puberty blockers, hormone therapy, and sex reassignment surgery for the

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[3] *Gender Affirming Care and Young People*, U.S. DEP'T HEALTH & HUMAN SERVICES, https://opa.hhs.gov/sites/default/files/2022-03/gender-affirming-care-young-people-march-2022.pdf.
[4] Wylie C. Hembree, et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM, 3869-3903 (2017), https://www.endocrine.org/clinical-practice-guidelines/gender-dysphoria-gender-incongruence.
[5] Jason Rafferty, M.D., *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142 AMERICAN ACAD. PEDIATRICS 4 (Oct. 1, 2018), https://publications.aap.org/pediatrics/article/142/4/e20182162/37381/Ensuring-Comprehensive-Care-and-Support-for.

treatment of gender dysphoria in children, a copy of which is attached as Exhibit A.

Agency Report

13. Based on the Department's advisory, the Agency for Health Care Administration (Agency) conducted a study to determine whether such procedures are consistent with generally accepted professional medical standards. The Agency published its findings on June 2, 2022, a copy of which is attached as Exhibit B.

14. The Agency concluded that "[a]vailable medical literature provides insufficient evidence that sex reassignment through medical interventions is a safe and effective treatment for gender dysphoria."[6]

15. The Agency found that puberty blockers are not approved by the FDA for the treatment of gender dysphoria, are not medically efficacious for the treatment of gender dysphoria, and have permanent side effects.[7]

16. Similarly, the Agency found that hormonal treatments in adolescents can achieve their intended physical effects, but quality evidence regarding their psychological and cognitive impact are generally lacking.[8]

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[6] Exhibit B at 2.
[7] *See* Exhibit B at 14-16.
[8] *See* Exhibit B at 19.

These treatments can cause irreversible physical changes, including facial hair growth, voice deepening, and breast growth.[9]

17. Surgical interventions for gender dysphoria include multiple procedures to alter the appearance of the body to resemble the individual's desired gender. Sexual reassignment surgeries are not reversible.[10] The Agency concluded that the long-term mental health effects of these procedures are largely unknown.[11]

Danger to Public Health

18. The stark contrast between claims about the efficacy of so-called "gender-affirming" care for treating gender dysphoria and the lack of quality evidence supporting those claims has created confusion in the community.

19. This confusion has caused practitioners to forgo less invasive treatment options and rush patients into immediate chemical regimens and surgical procedures without full consideration of their efficacy, safety, and long-term repercussions.

20. Given the lack of quality evidence in support of gender transition treatments, the use of such treatments for gender dysphoria should be

[9] *See* Exhibit B at 18.
[10] *See* Exhibit B at 24.
[11] *See* Exhibit B at 24.

considered experimental and should require fully informed consent of the risks and limitations.

21. Children do not possess the cognitive or emotional maturity to comprehend the consequences of these invasive and irreversible procedures.

22. Even in adults, who possess the capacity to consent to experimental treatment, research supporting chemical and surgical interventions for treatment of gender dysphoria is insufficient to demonstrate long-term efficacy and safety, and there is a risk of irreversible physical changes, including infertility or sterility. Therefore, robust informed consent requirements are necessary.

Proposed Standard of Care

23. Due to the lack of quality evidence regarding the effectiveness of such treatments for gender dysphoria and in order to provide guidance to the medical community and protect the health, safety, and welfare of Floridians, the Department proposes the Board adopt a rule establishing that:

a. Sex reassignment surgery or any other procedure that alters primary or secondary sexual characteristics for the treatment of gender dysphoria is prohibited for patients under 18 years

of age.

b. Puberty blocking, hormone, and hormone antagonist therapies for the treatment of gender dysphoria are prohibited for patients under 18 years of age.

c. When any of the experimental treatments referenced above are used to treat gender dysphoria in adults, informed consent shall be in writing through forms approved by the Board at least 24 hours before treatment is provided. Proposed forms are attached as Exhibits C and D.

24. The Department further proposes that the Board issue guidance allowing physicians to provide appropriate care for patients currently undergoing hormone therapy at the time of the adoption of this rule or upon entry into this state.

WHEREFORE, the Department respectfully requests that the Board initiate rulemaking pursuant to section 120.54, Florida Statutes, for the purpose of adopting the proposed rules discussed herein.

Respectfully Submitted,

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