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December 5, 2022

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Re: Proposed Rule, 64B15-14.014, Standards of Practice for the Treatment of Gender Dysphoria in Minors

Dear Chair Schwemmer, Ms. Terrell, and Members of the Board of Osteopathic Medicine,

Southern Legal Counsel, Inc. (SLC) and Florida Health Justice Project (FHJP) submit the following comments in response to Proposed Rule, 64B15-14.014, Standards of Practice for the Treatment of Gender Dysphoria in Minors, the Notice of Proposed Rule for which was published in the Florida Administrative Register on November 14, 2022. We vehemently oppose the Proposed Rule based on both the evidence supporting the medical necessity of treatment for gender dysphoria, as well as our own extensive experience working with transgender minors and medical providers with clinical expertise in the treatment of gender dysphoria in minors.

Founded in 1977, Southern Legal Counsel is a Florida statewide not-for-profit public interest law firm committed to equal justice for all and the attainment of basic human and civil rights. Southern Legal Counsel assists individuals and groups with public interest issues who would not otherwise have access to the justice system. Southern Legal Counsel concentrates on people and issues in the most need of civil legal assistance, including LGBTQ+ individuals, individuals experiencing homelessness, individuals with disabilities, and other low income marginalized populations.

Since Southern Legal Counsel began its Transgender Rights Initiative in 2016, we have been a statewide leader in protecting the rights of transgender individuals in Florida, particularly those experiencing poverty. We have assisted thousands of transgender individuals in obtaining access to justice through: legal name and gender marker changes on government-issued identification documents; fighting for safe and affirming school environments; dismantling policies and practices that discriminate on the basis of sex; and accessing equal non-discriminatory health insurance benefits. Further, we have utilized federal impact litigation to challenge the state of Florida's discriminatory exclusion of gender-affirming care in state employee health plans (*Claire v. Fla. Dept. of Mgmt. Svcs.*, 4:20-cv-00020 (N.D. Fla., J. Walker, 2020) and the Florida Agency for Healthcare Administrations' discriminatory rule banning Medicaid coverage of gender-affirming care (*Dekker v. Marsteller*, 4:22-cv-00325 (N.D. Fla., J. Hinkle, 2022)). Due to Southern Legal Counsel's wealth of experience working with this community, we can speak directly to the significant harms the Proposed Rule will cause those it targets.

Florida Health Justice Project engages in comprehensive advocacy to expand health care access and promote health equity for marginalized and vulnerable Floridians.

BACKGROUND: THE DEVELOPMENT OF THE PROPOSED RULE

The text of the Proposed Rule, as published in the Florida Administrative Register on November 14, 2022, states:

64B15-14.014 Standards of Practice for the Treatment of Gender Dysphoria in Minors.

(1) The following therapies and procedures performed for the treatment of gender dysphoria in minors are prohibited.

(a) Sex reassignment surgeries, or any other surgical procedures, that alter primary or secondary sexual characteristics.

(b) Puberty blocking, hormone, and hormone antagonist therapies.

(2) Nonsurgical treatments for the treatment of gender dysphoria in minors may continue to be performed under the auspices of Institutional Review Board (IRB) approved, investigator-initiated clinical trials conducted at any of the Florida medical schools set forth in Section 458.3145(1)(i), Florida Statutes. Such clinical trials must include long term longitudinal assessments of the patients' physiologic and psychological outcomes.

(3) Minors being treated with puberty blocking, hormone, or hormone antagonist therapies prior to the effective date of this rule may continue with such therapies.

April: FDOH “Guidelines” and Secretary Marstiller Letter

The process leading up to the Board of Osteopathic Medicine publishing the Proposed Rule 64B15-14.014 began at the direction of the Florida Department of Health. On April 20, 2022 the Florida Department of Health (“FDOH”) released a misleading and factually inaccurate set of “guidelines” regarding the treatment of gender dysphoria for children and adolescents¹. These “guidelines” were released in direct response to the U.S. Office Department of Health and Human Services’ (HHS) Office of Population Affairs (OASH) fact sheet regarding the use of gender-affirming care as evidence-based treatment for gender dysphoria in young people.² The thoroughly debunked “guidelines” issued by FDOH made incorrect and scientifically unfounded recommendations against *all* evidence-based treatment for gender dysphoria for minors, including puberty blocking medications, hormones, and even “social gender transition” (which is not medical treatment nor within the purview of the FDOH). The FDOH “guidelines,” which are non-binding in nature, directly contradicted the guidelines from HHS, as well as the established medical guidelines supported by the country’s largest and leading medical organizations.

The FDOH “guidelines” were criticized by, among others, a group of more than 300 Florida health care professionals who care for transgender and gender diverse youth.³ This group denounced the FDOH Guidelines for citing “a selective and non-representative sample of small studies and reviews, editorials, opinion pieces and commentary to support several of their substantial claims” and misrepresenting “high-quality studies” by making “conclusions that are not supported by the authors of the articles.” The 300 Florida health care professionals further stated that the FDOH Guidelines “contradict[] existing guidelines from the American Academy of Pediatrics, the Endocrine Society, the American Academy of Child and Adolescent Psychiatry and the World Professional Association for Transgender Health,” and that “[t]hese national and international guidelines are the result of careful deliberation and examination of the evidence by experts including pediatricians, endocrinologists, psychologists and psychiatrists.”

¹ See *Treatment of Gender Dysphoria for Children and Adults*, FLORIDA DEP’T OF HEALTH (April 20, 2022), https://www.floridahealth.gov/_documents/newsroom/press-releases/2022/04/20220420-gender-dysphoria-guidance.pdf

² See *Gender-Affirming Care and Young People*, U.S. Dep’t of Health & Human Servs. (March 2022), <https://opa.hhs.gov/sites/default/files/2022-03/gender-affirming-care-young-people-march-2022.pdf>

³ Brittany S. Bruggeman, *et al.*, *Opinion: We 300 Florida health care professionals say the state gets transgender guidance wrong | Open letter*, TAMPA BAY TIMES (Apr. 27, 2022), <https://www.tampabay.com/opinion/2022/04/27/we-300-florida-health-care-professionals-say-the-state-gets-transgender-guidance-wrong-open-letter/>

On April 20, 2022, the Secretary of the Florida Agency for Healthcare Administration (AHCA), Simone Marstiller, sent a letter⁴ directing Deputy Secretary for Medicaid, Tom Wallace, to determine whether treatment of gender dysphoria for children and adolescents is “consistent with generally accepted professional medical standards and not experimental or investigational.” The request from Secretary Marstiller to Deputy Secretary Wallace was highly unusual, as AHCA does not generally draft a GAPMS report for services that it is already covering. (Note that prior to August 21, 2022, Florida Medicaid covered the full range of gender-affirming treatments, including puberty delaying medication, hormone therapy, and surgical care.)

June: GAPMS Memo and Surgeon General Ladapo Letter

On June 2, 2022, the Florida AHCA issued a purported “scientific report” concluding that treatment for gender dysphoria does not meet generally accepted medical standards and is experimental and investigational (hereinafter, “GAPMS Memo”).⁵ The publication of the GAPMS Memo was accompanied by the publication of a political webpage within AHCA’s website titled “Let Kids Be Kids” that included graphics, misleading “fact-checking” of HHS’s guidance, and false assertions about social media’s alleged influence on experiences of gender dysphoria.⁶ To support this conclusion, the GAPMS Memo cited to, and relied upon, five non-peer-reviewed, unpublished “assessments” that Defendants commissioned.

The selection of the individuals who were commissioned to provide the “assessments,” none of whom are Florida practitioners nor experts in the treatment of gender dysphoria in minors, demonstrates the pre-determined outcome of the process. For example: (1) Dr. Van Meter has been barred from providing expert testimony related to treatment of gender dysphoria in minors, and he is also a member of a non-professional association that holds openly anti-LGBTQ+ positions and promotes demonstrably harmful and damaging practices like conversion therapy; (2) Dr. Cantor has admitted in Court to having no experience in treating gender dysphoria in minors and (3) Dr. Brignardello-Petersen similarly lacks expertise regarding gender dysphoria; (4) Dr. Lappert’s “bias and reliability” to testify regarding gender dysphoria was called “into serious question” recently by a federal court, which went on to say Dr. Lappert “is not qualified to render opinions about the diagnosis of gender dysphoria, its possible causes, ... the efficacy of puberty blocking medication or hormone treatments, the appropriate standard of informed consent for mental health professionals or

⁴ *Letter from AHCA Secretary Marstiller to Deputy Secretary Wallace* (April 20, 2022), https://ahca.myflorida.com/LetKidsBeKids/docs/AHCA_GAPMS_June_2022_Attachment_A.pdf

⁵ Division of Florida Medicaid, Agency for Health Care Administration, Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria, June 2022, at https://www.ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Report.pdf

⁶ <https://ahca.myflorida.com/letkidsbekids/>

endocrinologists, or any opinion on [] non-surgical treatments,” and that his views “do not justify the exclusion” of gender-affirming medical care.⁷

The GAPMS Memo, and the evidence and data supporting its findings, was analyzed by various leading experts in the treatment of gender dysphoria, including doctors, scientists, and law professors from the Yale School of Medicine and Yale Pediatric Gender Program, the University of Alabama at Birmingham, and the University of Texas Southwestern.⁸ These experts conducted the first comprehensive examination of Florida’s GAPMS Memo, concluding that it was a misleading document intended to justify denying Florida Medicaid coverage for gender dysphoria treatment. (“The June 2 Report purports to be a review of the scientific and medical evidence but is, in fact, fundamentally unscientific. We are alarmed that Florida’s health care agency has adopted a purportedly scientific report that so blatantly violates the basic tenets of scientific inquiry. The report makes false statements and contains glaring errors regarding science, statistical methods, and medicine. Ignoring established science and longstanding, authoritative clinical guidance, the report instead relies on biased and discredited sources, including purported “expert” reports that carry no scientific weight due to lack of expertise and bias. So repeated and fundamental are the errors in the June 2 Report that it seems clear that the report is not a serious scientific analysis but, rather, a document crafted to serve a political agenda.”) The Yale School of Medicine’s Child Study Center and Departments of Psychiatry and Pediatrics, the Yale Law School, the University of Texas Southwestern, and University of Alabama at Birmingham also submitted a comment to AHCA in opposition to the Proposed Rule banning Medicaid coverage of gender affirming care which further refuted the unscientific claims behind the GAPMS Memo.⁹

On June 2, 2022, Surgeon General Joseph A. Ladapo sent a letter to the Florida Board of Medicine “encourag[ing] the Board to review the Agency’s findings and the Department’s guidance to establish a standard of care for these complex and irreversible procedures.”¹⁰ The “Agency’s findings” and the “Department’s guidance” that Surgeon General Ladapo references in the letter to the Board of Medicine are those references above, which were thoroughly debunked and discredited by the team of experts cited in footnotes 8 and 9, while ignoring the consensus among experts, including, among others:

⁷ *Kadel v. Folwell*, No. 1:19CV272, 2022 WL 3226731, at *12-13, 32 (M.D.N.C. Aug. 10, 2022).

⁸ Meredith McNamara, M.D., M.S, et al., A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria (July 8, 2022), at https://medicine.yale.edu/lgbtqi/research/gender-affirming-care/florida%20report%20final%20july%208%202022%20accessible_443048_284_55174_v3.pdf

⁹ Yale School of Medicine. (2022, August 29). Gender affirming care: Evidence-based reviews of legislative actions. Dean's Advisory Council on LGBTQI+ Affairs. Retrieved from <https://medicine.yale.edu/lgbtqi/research/gender-affirming-care>

¹⁰ *Letter from Surgeon General Ladapo to Florida Board of Medicine* (June 2, 2022), <https://www.losangelesblade.com/content/files/2022/06/board-letter.pdf>

- **The American Academy of Pediatrics**¹¹ (“[T]he mental and physical health and well-being of transgender children and adolescents often rely on their abilities to access much needed mental and physical health care— care that is in keeping with the widely recognized evidence-based standards of care for gender dysphoria. In proposing this rule, Florida ignores broad consensus among the medical community as to what those evidence-based standards of care are, and instead seeks, for its own discriminatory reasons, to impose alternate standards and an outright ban of specific treatments for transgender adolescents in the state’s Medicaid program.”);
- **The Endocrine Society**¹² (“The proposed rule would deny...access to medical interventions that alleviate suffering, are grounded in science, and are endorsed by the medical community. The medical treatments prohibited by the proposed rule can be a crucial part of treatment for people with gender dysphoria and necessary to preserve their health. ... [R]esearch shows that people with gender dysphoria who receive puberty blockers and/or hormone therapy experience less depression, anxiety, and suicidal ideation.”)
- **Researchers whose studies were cited within the FDOH Guidelines and GAPMS Memo who say FDOH misinterpreted and misrepresented their studies**¹³ (for example, Dr. Ken Pang, who said “One of the first principles [in the medical field] is to do no harm. So to be seeing the research we’ve done being utilized in this way—I was just dismayed by that.”)

In the June 2, 2022 letter asking the Board of Medicine to “establish a standard of care,” Surgeon General Ladapo acknowledges that standards of care already exist, and that they are set by and followed by our country’s professional medical organizations. *Supra*, FN 10. (“While some *professional organizations*, such as the American Academy of Pediatrics and the Endocrine Society, *recommend these treatments for “gender affirming” care...*” and “[t]he *current standards set by numerous professional organizations* appear to follow a preferred political ideology instead of the highest level of generally accepted medical science.”) (emphasis added).

July-August: FDOH Petition to Initiate Rulemaking

On July 28, 2022, the FDOH sent the Florida Board of Medicine a “Petition to Initiate Rulemaking,” asking the Board to, among other things, adopt a categorical ban on the

¹¹ *Letter from the American Academy of Pediatrics and the Florida Chapter of the AAP to AHCA Deputy Secretary Tom Wallace* (July 7, 2022), <https://perma.cc/ND5M-TGYJ>

¹² *Letter from the Endocrine Society to AHCA* (July 8, 2022), <https://perma.cc/F5TX-J3JY>

¹³ Sam Greenspan, *How Florida Twisted Science to Deny Healthcare to Trans Kids*, VICE NEWS (Aug. 3, 2022), <https://www.vice.com/en/article/m7gg54/florida-transgender-healthcare-minors>

provision of gender-affirming medical care to people under 18 years of age and, with respect to adults, to adopt a 24-hour waiting period.¹⁴

On August 5, 2022, the Florida Board of Medicine¹⁵ discussed the June 2, 2022 Letter from Surgeon General Ladapo and the July 28, 2022 Petition to Initiate Rulemaking from the FDOH. See *Meeting Minutes from August 5, 2022 Meeting, VI. Discussion*, at page 18-19.¹⁶ The Board voted to accept the Petition to initiate the rulemaking process. The FDOH Petition to Initiate Rulemaking was sent to the Board of Medicine pursuant to Florida Statute 120.54(7), which states that the agency to whom the Petition is directed has the option to “**deny the petition** with a written statement of its reasons for the denial.” Fla. Stat. 120.54(7)(a). The Boards of Medicine and Osteopathic Medicine decided to move forward, even after hearing from Florida-based physicians with extensive clinical experience in the treatment of gender dysphoria in minors, including Dr. Michael Haller, who provided the following testimony directly to the Board during the August 5, 2022 Florida Board of Medicine meeting:

“I am a graduate of the University of Florida College of Medicine, the University of Florida Pediatric Residency, and the University of Florida Pediatric Endocrinology Fellowship. I hold a Master’s Degree in Clinical Investigation, and I currently serve as the Professor and Chief of Pediatric Endocrinology at the University [of Florida].

I have trained thousands of medical providers, participated in the development of national and international guidelines, and have treated tens of thousands of children. I have numerous NIH grants and have published more than 200 peer-reviewed papers. I provide this background with full humility but also to establish myself as an expert, both in pediatric endocrinology and in the review and analysis of scientific literature.

Respectfully, the Department of Health’s Petition for Rulemaking and the proposed prohibition of pubertal blockers, hormone therapy, and surgery for gender dysphoric patients under 18 is in direct conflict with the guidelines from the American Academy of Pediatrics, the Endocrine

¹⁴ *Petition to Initiate Rulemaking Setting the Standard of Care for Treatment of Gender Dysphoria* (July 28, 2022), https://www.lambdalegal.org/sites/default/files/legal-docs/downloads/doh_petition_proposed_standard_of_banned_care.pdf

¹⁵ The Florida Board of Osteopathic Medicine consists of six members appointed by the Governor. The current makeup of the Florida Board of Medicine does not contain any individuals with expertise in the subject matter area being regulated: treatment of gender dysphoria in minors. Dr. Sandra Schwemmer, Chair of the Board, specializes in emergency medicine; Dr. Jorge Gadea is an internal medicine specialist; Dr. Tiffany Sizemore Di Pietro is a cardiologist; Dr. Michelle Mendez practices family medicine; Valerie Jackson is a healthcare consultant; and Dr. William Kirsh is a family medicine doctor.

¹⁶ https://www10.doh.state.fl.us/pub/medicine/Agenda_Info/Public_Information/Public_Minutes/2022/August/08052022_FB_Minutes.pdf

Society, the American Psychological Association, and the World Professional Association for Transgender Health. The Association's guidelines have established gender-affirming care as the standard of care. Importantly, the quality of evidence used to establish the standards of care for other less politicized diagnoses is far weaker than the data supporting gender-affirming care. As such, the assertion that gender-affirming care is not adequately data driven is at best a double standard, and at worst discriminatory political theatre. [...]

While you as the Board thankfully are apolitical, each of you are appointed by, and serve at the pleasure of, the Governor. As such, in order to have meaningful conversations regarding gender care in Florida, we must acknowledge the highly unusual political nature of the State's Petition. We must admit that the State's recent actions to remove Medicaid coverage for both adolescents and adults with gender dysphoria are indeed politically motivated. We must recognize that the State-supported AHCA report on transgender medicine makes numerous false claims, uses a highly biased review of the literature, and relies on discredited pseudo-experts. While there are numerous flaws with the AHCA or GAPMS report, and the State's proposed rule, the following issues deserve specific commentary:

- (1) First, the State's primary assertion that gender-affirming therapy has not demonstrated efficacy and safety is patently false. Nearly every major medical organization that provides care for children is supportive of gender-affirming care and the State is either unaware of or willfully chooses to ignore the totality of the evidence in support of gender-affirming care.
- (2) Second, the State's use of anti-trans pseudo-experts as external advisors seeking to discredit the standard of care is frankly absurd. [...]
- (3) Third, the State's ongoing implication that the overwhelming majority of children resolve their gender dysphoria is a gross misrepresentation of the data. [...]

With all that as background, I'd like to remind the Board what the *actual* established standard of care actually recommends. First of all, evaluation by multi-disciplinary groups of providers with expertise in psychology, pediatrics, and endocrinology is recommended. Second, adolescents who present to gender care clinics must have co-morbid mental health issues diagnosed and treated before confirming their gender dysphoria or identity. Third, when gender dysphoria persists, and when the patient starts puberty, endocrinologists can then offer pubertal blockers. This is never done in pre-pubertal children. In addition, the overwhelming majority of side effects associated with the use of pubertal blockers are in fact reversible. Fourth, only when gender identity continues to be well-established are patients offered gender-affirming hormones. Fifth, mastectomy is considered only after the age of 16 in trans men and most

often occurs after age 18. And sixth, genital surgeries are considered only after age 18. That is the standard of care. [...]

Not a single patient followed by any of our centers [three largest youth gender clinics in Florida where over 1,000 children are followed], has been referred for genital surgery before the age of 18. So while the state has used exceptional cases of poor care from outside the state of Florida to support their positions, I am not aware of a single complaint made to this Board of Medicine by a patient in Florida regarding their gender-affirming care. [...]

In closing, I ask you to uphold the sanctity of the doctor-patient relationship. I ask each of you to vote against the State's petition and to let doctors and patients continue to have the freedom to assess the care they need. Thank you very much."

Florida Board of Medicine, August 4, 2022, Full Board Meeting, Meeting Audio: https://ww10.doh.state.fl.us/pub/medicine/MQA_Audio/2022/August/Friday,%20August%205,%202022/TAB%2026%20and%2039%20Gender%20Dysphoria%20Discussion%20and%20Petition%20to%20Initiate%20Rulemaking%20-%20Part%20I.MP3, "TAB 26 and 39 Gender" at 23:00 to 30:36.

October: Rule Development Workshop

The Florida Boards of Medicine and Osteopathic Medicine Joint Rules/Legislative Committee published a Notice of Meeting/Workshop¹⁷ for Rule No. 64B8-9.019, *Practice Standards for the Treatment of Gender Dysphoria*" which was set to occur on Friday, October 28, 2022. ("The Florida Boards of Medicine and Osteopathic Medicine Joint Rules/Legislative Committee will conduct a rule workshop and meeting to receive and consider presentations from subject matter experts and comments from the public, and to discuss and develop draft rule language related to practice standards for the treatment of gender dysphoria.") The Board heard from six individuals who the Board determined were subject matter experts¹⁸ on this topic, including: Mr. Michael Biggs, Dr. Kristin Dayton, Dr. Aron Janssen, Dr. Riittakerttu Kaltiala, Dr. Michael Laidlaw, and Dr. Meredith McNamara. Of those testifying experts, three were in support of the development of a proposed rule banning access to gender-affirming care for minors, and three were opposed to the development of such a proposed rule that would contravene the authoritative, evidence-based standards of care for the treatment of gender dysphoria.

The three individuals who supported the State's position seeking to prohibit the treatment of gender dysphoria in minors in Florida were: **Michael Biggs**, a Professor of

¹⁷https://ww10.doh.state.fl.us/pub/medicine/Agenda_Info/Public_Information/Notices/2022/October/10282022_RL_Notice.pdf

¹⁸https://ww10.doh.state.fl.us/pub/medicine/Agenda_Info/Public_Information/Public_Minutes/2022/October/10282022_RL_Minutes.pdf

Sociology in Oxford England who has no experience in providing medical care; **Dr. Riittakerttu Kaltiala**, a psychiatrist in Finland, and **Dr. Michael Laidlaw**, an endocrinologist in California who has never provided treatment for a transgender patient nor a transgender minor.

The three individuals who opposed the State's position to ban gender-affirming care in direct conflict with the authoritative, evidence-based medical standards were: **Dr. Kristin Dayton**, a board-certified pediatrician and pediatric endocrinologist at the University of Florida, the Director of the UF Health Youth Gender Program, and the only individual selected by the Board who actually practices medicine in Florida; **Dr. Meredith McNamara**, an adolescent medicine specialist and Assistant Professor of Pediatrics at the Yale School of Medicine; and **Dr. Aron Janssen**, Board Certified in Child Adolescent Psychiatry, and Vice Chair of Clinical Affairs at the Pritzker Department of Psychiatry and Behavioral Health and Associate Professor of Psychiatry and Behavioral Sciences, Northwestern University Feinberg School of Medicine.

At the conclusion of the subject matter expert portion of the meeting and the public comment portion of the meeting, a Motion was made which was summarized in the October 28, 2022 Meeting Minutes as follows:

"A Motion was made, seconded, and approved with two votes in opposition to prohibit such therapies as puberty blockers, cross hormonal therapies, and surgeries to treat gender affirming care for gender dysphoria to anyone under the chronological age of eighteen. These are prohibited unless being done within the auspices of an Institutional Review Board (IRB) approved university-affiliated clinical trial. The rule will be a prospective rule. The rule will apply exclusively to minors with gender dysphoria. Board counsel will prepare draft language for consideration to be presented at the Joint Boards of Medicine and Osteopathic Medicine Meeting scheduled to be held on November 4, 2022."

November: Drafting of the Proposed Rule

The Proposed Draft Rule was developed and voted upon during the October 28, 2022 Public Workshop and subsequently drafted by General Counsel of the Boards of Medicine (Rule 64B8-9.019, F.A.C.) and Osteopathic Medicine (Rule 64B15-14.014, F.A.C.) and published in the Public Book for the Nov. 4, 2022 meeting.

On November 14, 2022, the Florida Board of Osteopathic Medicine published the Notice of Proposed Rule in the Florida Administrative Register.¹⁹ The full text of the proposed rule as published in the F.A.R. is as follows:

64B15-14.014 Standards of Practice for the Treatment of Gender Dysphoria in Minors.

¹⁹ Notice No. 26536986, Notice of Proposed Rule 64B15-14.014, Standards of Practice for the Treatment of Gender Dysphoria in Minors, at https://www.flrules.org/Gateway/View_notice.asp?id=26536986

(1) The following therapies and procedures performed for the treatment of gender dysphoria in minors are prohibited.

(a) Sex reassignment surgeries, or any other surgical procedures, that alter primary or secondary sexual characteristics.

(b) Puberty blocking, hormone, and hormone antagonist therapies.

(2) Nonsurgical treatments for the treatment of gender dysphoria in minors may continue to be performed under the auspices of Institutional Review Board (IRB) approved, investigator-initiated clinical trials conducted at any of the Florida medical schools set forth in Section 458.3145(1)(i), Florida Statutes. Such clinical trials must include long term longitudinal assessments of the patients' physiologic and psychologic outcomes.

(3) Minors being treated with puberty blocking, hormone, or hormone antagonist therapies prior to the effective date of this rule may continue with such therapies.

Rulemaking Authority 459.015(1)(z) FS. Law Implemented 459.015(1)(z) FS. History-New

The Proposed Rule promulgated by the Board of Osteopathic Medicine, 64B15-14.014, goes further than any area that the Board has previously regulated, upon information and belief. The Proposed Rule represents the first time that the Board has declared an entire area of practice to be forbidden. The Proposed Rule prohibits medical providers from providing evidence-based, medically necessary care to their transgender minor patients in contravention of the authoritative Standards of Care governing the treatment of gender dysphoria. Further, the Proposed Rule interferes with the constitutional rights of parents of transgender youth in the state of Florida to direct the medical care for their children, inserts the government between the doctor-patient relationship, and strips physicians of their ability to make independent decisions about what care is in the best interests of their patients, mandating that they violate the authoritative standards of care governing their area of practice. See Florida Statutes 1014.02 (which provides that "it is a fundamental right of parents to direct the upbringing, education, and care of their minor children."); Florida Statutes 1014.03 ("The state, any of its political subdivisions, any other governmental entity, or any other institution **may not infringe on the fundamental rights of a parent to direct** the upbringing, education, **health care**, and mental health of his or her minor child[.]") (emphasis added).

FLORIDA BOARD OF OSTEOPATHIC MEDICINE'S PROPOSED RULE 64B15-14.014 SHOULD NOT BE ADOPTED

Southern Legal Counsel and Florida Health Justice Project urge the Florida Board of Osteopathic Medicine not to adopt Rule 64B15-14.014 because prohibiting medical providers from providing the appropriate, medically necessary treatment for gender dysphoria to their minor patients: **(1) directly contravenes** the widely accepted, authoritative standards of care and the consensus of every major medical and mental health association; **(2) will cause significant harm** to the individuals we serve by depriving them of critical medical care; **(3) interferes with, and substitutes the state's judgment in place of** the doctor/patient relationship, the rights of the individual, and the fundamental rights of a parent to determine appropriate medical treatment for their child;

and **(4) is a shameful waste of resources**, as similar exclusions have been enjoined and/or struck down by courts across the country, and the litigation that the state will certainly find itself embroiled in will waste valuable state resources that could be better utilized enhancing the lives of Floridians rather than attacking them.

Through a Medical Legal Partnership (MLP) with a pediatric endocrinology clinic that specializes in transgender care, Southern Legal Counsel has had the opportunity to work with over 100 transgender children and families. Over the years spent engaging in this work, we have witnessed the profound and unmistakable benefits that access to gender-affirming care can have on individuals who experience gender dysphoria. At the same time, we have witnessed first-hand the detrimental impact that lack of access to such care can have on many individuals with gender dysphoria, particularly transgender adolescents who have entered puberty.

“Gender dysphoria” is a formal diagnosis under the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) in which there is a pronounced incongruence between someone’s gender identity or expression and sex assigned at birth. While not all transgender individuals experience gender dysphoria, for those who do, the clinically significant distress resulting from gender dysphoria is serious and requires treatment. Left untreated, gender dysphoria can result in serious mental distress, depression, anxiety, self-harm, and suicidality. We have seen first-hand how gender dysphoria negatively impacts our clients in myriad facets of their lives, including mental health and wellbeing, academic achievement, social and emotional growth, access to employment and housing, and more. However, we have also witnessed first-hand how access to gender-affirming care has ameliorated and mitigated the negative impacts of gender dysphoria on the clients we serve.

Gender-affirming care is medical care provided to transgender people to treat gender dysphoria, and can include psychotherapy, social transition, puberty blockers, hormone therapy, and various surgeries. Gender-affirming care is the widely accepted standard of care for treating transgender individuals with gender dysphoria, and is endorsed and recommended by the American Academy of Pediatrics, the Florida Chapter of the American Academy of Pediatrics, the American Medical Association, the Endocrine Society, the Pediatric Endocrine Society, the American Psychological Association, the American Academy of Child and Adolescent Psychiatry, the American College of Obstetricians and Gynecologists, the American College of Physicians, the American Psychiatric Association, the American Academy of Family Physicians, the Society for Adolescent Health and Medicine, the World Professional Association for Transgender Health (WPATH), and additional major medical organizations. Gender-affirming care is not, experimental; it is the prevailing standard of care accepted by medical experts and healthcare providers.

The World Professional Association for Transgender Health (WPATH) is “an international, multidisciplinary, professional association whose mission is to promote evidence-based care, education, research, advocacy, public policy, and respect for transgender health.” WPATH Standards of Care are clinical guidelines to treat gender

dysphoria accepted by major medical and mental health associations and have been accepted as authoritative by federal courts in this state and many others.

In addition to the overwhelming consensus of the medical experts and scientific community, our clients' lived experiences have made clear that access to gender-affirming care can be life saving. Access to puberty blocking hormones like Lupron, for example, have resulted in profound transformations in transgender youth we serve, including marked decreases in depression, anxiety, suicidal ideation, and psychological distress, and significant improvements in academic achievement and positive school experience. For countless youth we have represented, being able to live authentically as themselves at school, including accessing the bathroom aligned with their gender identity and having their affirmed names and pronouns respected by teachers and peers, has had a truly life-changing impact on their educational experience and wellbeing. Living authentically as oneself becomes increasingly difficult as one begins to develop secondary sex characteristics, and without access to medically necessary gender-affirming healthcare, these changes can have a devastating impact on the individual's ability to navigate life in accordance with their gender identity.

Ultimately, like with all medical care, these healthcare decisions should be made between the individual and their doctor and should be based on individual needs, not blanket prohibitions.

Other states' implementation of regulations that deny medically necessary gender affirming care similar to the Board of Osteopathic Medicine's Proposed Rule have led to litigation. These cases have raised challenges under the Equal Protection Clause of the Fourteenth Amendment, the Due Process Clause of the Fourteenth Amendment, Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116, and the First Amendment to the U.S. Constitution. These cases have resulted in preliminary or permanent injunctions enjoining the state from enforcing similar bans on the treatment of gender dysphoria in minors. *See Eknes-Tucker v. Marshall*, 2022 WL 1521889 (M.D. Ala. May 13, 2022) ("Because the Supreme Court and the Court of Appeals for the Eleventh Circuit have made clear that: (1) parents have a fundamental right to direct the medical care of their children subject to accepted medical standards; and (2) discrimination based on gender-nonconformity equates to sex discrimination, the Court finds that there is a substantial likelihood that Section 4(a)(1)–(3) of the Act is unconstitutional and, thus, enjoins Defendants from enforcing that portion of the Act pending trial."); *see also Brandt v. Rutledge*, 551 F.Supp.3d 382 (E.D. Ark. 2021), *aff'd sub nom. Brandt by & through Brandt v. Rutledge*, 47 F.4th 661 (8th Cir. 2022) (finding state law banning gender-affirming care for minors discriminates on the basis of sex).

The evidence makes clear that denial of medically necessary care, as would occur under the Proposed Rule, constitutes irreparable harm for which there is no other adequate legal remedy. *See Brandt*, 2022 WL 3652745, at *4 (affirming conclusion that "Plaintiffs will suffer irreparable harm" by being "denied access to hormone treatment"); *Eknes-Tucker v. Marshall*, 2022 WL 1521889, at *12 (concluding "Plaintiffs will suffer irreparable harm absent injunctive relief" because "without transitioning medications, []

Plaintiffs will suffer severe medical harm, including anxiety, depression, eating disorders, substance abuse, self-harm, and suicidality”).

There is no important rational or reasonable basis upon which to deny the same care to transgender minors that is regularly provided to, and will continue to be regularly provided to, cisgender minors. Under this Rule, physicians are permitted to provide the same prescriptions and medical care that is prohibited for the treatment of gender dysphoria to any other minor for any other medically necessary reason. For example, puberty blocking medications have been used for decades to treat precocious puberty and other conditions, yet the Board is deeming them harmful *only when used* for the treatment of gender dysphoria. Minors in need of puberty blocking medications can obtain them, and physicians can prescribe them, without the burdensome requirements imposed by the requirements of an IRB-approved clinical trial, as this obstacle exists only for minors with gender dysphoria (i.e. transgender minors). Similarly, the same hormone therapy that is prohibited under the Proposed Rule is regularly prescribed to adolescents, and will continue to be regularly prescribed to adolescents, for myriad other conditions and diagnoses, it is only prohibited for transgender minors. There is no justification as to why these treatments are experimental and unsafe when used for the treatment of gender dysphoria, but not experimental and unsafe when used for the treatment of any other condition? The Proposed Rule discriminatorily carves out one condition – gender dysphoria – which is a condition experienced solely by one class of minors – transgender minors – for unequal access to medical care in the state of Florida.

In addition to the arguments posed above, the reality is that this care *is simply not experimental*. Opinion and Order Granting Preliminary Injunction, *Ecknes-Tucker v. Marshall*, No. 22 Civ. 184, Docket No. 107, at 17-18 (N.D. Ala. May 13, 2022) (the Court found that Alabama officials “**produce[d] no credible evidence to show that transitioning medications are ‘experimental’**” and continued on to say “the uncontradicted record evidence is that at least twenty-two major medical associations in the United States endorse transitioning medications as well-established, evidence-based treatments for gender dysphoria in minors...” and “the record shows that medical providers have used transitioning medications for decades to treat medical conditions other than gender dysphoria.”)

The Proposed Rule is a cruel and discriminatory measure that is inconsistent with the rights guaranteed to minors, parents of minors, and medical providers under the Equal Protection Clause and Due Process Clause of the Fourteenth Amendment, the Affordable Care Act, and the First Amendment. It is a shameful waste of resources that will likely embroil the state in protracted litigation. Implementation of this Rule will leave transgender individuals in limbo while its constitutionality is litigated, depriving an already marginalized population of medically necessary—and often life-saving—healthcare.

The Florida Board of Osteopathic Medicine has a duty to ensure that the doctors licensed to practice osteopathic medicine in the state of Florida are providing high quality, evidence-based care to patients. By adopting and enacting the Proposed Rule,

the Florida Board of Osteopathic Medicine would be denying Florida medical providers the right to utilize their own judgment and expertise and mandating that they violate the evidence-based treatment guidelines for gender dysphoria. Further, utilizing this process to categorically exclude the provision of medical care to an entire group of people (transgender minors) will set a dangerous precedent whereby standards of care in the state of Florida can change based on the whim of the Governor and political motivations.

Thank you for the opportunity to submit this comment. Please do not hesitate to contact the undersigned with any questions or for further information.

Respectfully submitted,

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