From: FL-Rules@dos.state.fl.us
Sent: Thursday, July 7, 2022 1:43 PM EDT
To: Cole.Giering@ahca.myflorida.com
Subject: One-time User Comment From FLRules.com

FLRules.com one-time comment:

Name: Scott VanDeman
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Title: Comments from American Academy of Pediatrics and Florida Chapter, American Academy of Pediatrics
Comment: July 7, 2022

Tom Wallace
Deputy Secretary for Medicaid
Florida Agency for Health Care Administration
2727 Mahan Drive
Mail Stop #8
Tallahassee, FL 32308

Dear Director Wallace,

The American Academy of Pediatrics (AAP), a nonprofit organization representing 67,000 pediatricians dedicated to the health, safety and well-being of all children and the Florida Chapter of American Academy of Pediatrics, Inc (FCAAP), a nonprofit organization representing more than 2,600 pediatricians committed to serving all children across the state, thank you for the opportunity to provide comments on the Florida Agency for Health Care Administration's proposed rule to prohibit gender-affirming care in the state's Medicaid program.

We write to express our grave concerns with the proposed rule. Denying evidence-based, medically necessary standards of care to transgender adolescents constitutes a broad and sweeping discriminatory action by the State of Florida and its Medicaid program.

Gender-affirming care is the widely accepted standard of care for treating transgender adolescents with gender dysphoria. Gender-affirming care is endorsed and recommended by the American Academy of Pediatrics; the Florida Chapter of the American Academy of Pediatrics, Inc; the American Medical Association; the American College of Obstetricians and Gynecologists; the American College of Physicians; the American Psychiatric Association; the American Psychological Association; the American Academy of Family Physicians; the American Academy of Child and Adolescent Psychiatry; the Endocrine Society; the Society for Adolescent Health and Medicine; the Pediatric Endocrine Society; the World Professional Association for Transgender Health (WPATH); and many more members of the medical community.

Gender-Affirming Care is the Standard of Care
Gender-affirming care is developmentally appropriate care that seeks to understand and appreciate a child's or adolescent's gender identity and experience through a safe and nonjudgmental partnership that includes general pediatricians, pediatric specialists, mental health providers, children and adolescents and their families. While gender-affirming care is irrefutably the standard of care, it must, like all other areas of medicine, be individualized to meet the needs of each and every unique patient.

WPATH and the Endocrine Society have developed well-researched and evidence-based standards of care and clinical guidelines for the care of children and adolescents with gender dysphoria. WPATH's Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7 and the Endocrine Society's Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline (both are herein referenced as "standards of care") are in fact the gold standard, contrary to the State of

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Florida's assertion, among the medical community for caring for children and adolescents with gender dysphoria.

For a model of care to be considered the standard of care for a specific diagnosis, the care must be "treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals." The State of Florida's attempt to argue that gender-affirming care is not the standard of care, as referenced in its Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria report and its "Florida Fact-Checked" version of the HHS Office of Population Affairs Guidance on gender-affirming care, is entirely inconsistent with the well-recognized and established definition of standard of care, and represents a purposeful mischaracterization of available evidence as well as the position of the medical community.

Instead of supporting the standard of care for transgender adolescents, the state is seeking to rely only on "watchful waiting." This outdated model is based on long-refuted binary notions of gender and assumes without evidence that gender identity becomes fixed at a certain age and will result in direct harm to gender dysphoric children and adolescents who are denied access to well-evidenced multidisciplinary care. Notably, "watchful waiting" is based on studies with flawed methodology, validity concerns, and limited follow-up of transgender adolescents. Thus, "watchful waiting" is not recommended by any major medical association in the United States.

Gender Dysphoria
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. For the diagnosis, the patient must exhibit 2 of the following for at least 6 months:
? A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
? A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
? A strong desire for the primary and/or secondary sex characteristics of the other gender
? A strong desire to be of the other gender (or some alternative gender different from one's assigned gender)
? A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender)
? A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender)
In an apparent attempt to undermine the validity of the diagnosis of gender dysphoria, the state, under "Etiology of Gender Dysphoria," implies that mental and physical health conditions are the primary cause of gender dysphoria and that psychological support is all that is needed to provide care for gender dysphoric youth. However, the preponderance of the evidence indicates that gender dysphoria is indeed a primary diagnosis in which mental health issues are often exacerbated by lack of access to appropriate gender affirming care. The state disqualifies its own arguments by stating: "At the moment, none of these studies provides a definitive cause and offer only correlations and weakly supported hypotheses. In addition, evidence favoring a biological explanation is highly speculative." To be clear, there is no evidence that mental or physical health conditions cause gender dysphoria. As such, mischaracterizing the diagnosis in an effort to prohibit gender-affirming care is disingenuous at best and would result in direct harm to transgender children and adolescents.

Included in the state's document is the suggestion that mental health care should be the first line of care for youth diagnosed with gender dysphoria. On this, we agree. In fact, the evidence-based standards of care for gender-dysphoria, as referenced above, recommend mental health evaluation and care as the first step for affected children and adolescents. Indeed, research demonstrates that transgender children and adolescents experience stigma and discrimination, which adversely affects their mental health. Children and adolescents diagnosed with gender dysphoria often have to hide their gender identities to avoid bullying and harassment and face greater risks of homelessness, physical violence in the home and in the community, and substance use. However, the state conflates the association of mental health diagnoses, trauma, and attachment issues with causality for gender dysphoria in an effort to discredit the primary diagnosis. In reality, the mental health issues faced by those with gender dysphoria are often the direct result of a lack of access to care or not being supported in their gender identity.

In further attempting to undermine the well-established diagnosis of gender dysphoria, the state seeks to incorporate

the concept of "rapid onset gender dysphoria." The manuscript from which the term "rapid onset gender dysphoria" originates has been widely criticized. An expert review emphasized the following issues:

? "This study of parent observations and interpretations serves to develop the hypotheses that rapid-onset gender dysphoria is a phenomenon and that social influences, parent-child conflict, and maladaptive coping mechanisms may be contributing factors for some individuals. Rapid-onset gender dysphoria (ROGD) is not a formal mental health diagnosis at this time. This report did not collect data from the adolescents and young adults (AYAs) or clinicians and therefore does not validate the phenomenon. Additional research that includes AYAs, along with consensus among experts in the field, will be needed to determine if what is described here as rapid-onset gender dysphoria (ROGD) will become a formal diagnosis. Furthermore, the use of the term, rapid-onset gender dysphoria should be used cautiously by clinicians and parents to describe youth who appear to fall into this category. The term should not be used in a way to imply that it explains the experiences of all gender dysphoric youth nor should it be used to stigmatize vulnerable individuals."
? "…the study design of this research falls under descriptive research: as such, it did not assign an exposure, there were no comparison groups, and the study's output was hypothesis-generating rather than hypothesis-testing."

The Coalition for the Advancement & Application of Psychological Science, which includes the American Psychiatric Association, the American Psychological Association, the Society for a Science of Clinical Psychology, the Society of Clinical Child and Adolescent Psychology, the Society of Pediatric Psychology, and many more international, national, and state psychological and psychiatric associations, published a position statement on the concept of rapid onset gender dysphoria, stating:

? …it has not been subjected to rigorous peer-review processes that are standard for clinical science. Further, there is no evidence that ROGD aligns with the lived experiences of transgender children and adolescents.
? Research on gender identity development in children and adolescents continues to evolve and these advances will likely influence diagnosis and empirically-based standards of care, as well as the legislative landscape impacting trans people's access to care and legal protections. The available research is clear that transgender people are subjected to marginalization, stigmatization, and minority stress, which have significant detrimental effects on health and well-being. Terms, such as ROGD, that further stigmatize and limit access to gender-affirming and evidence-based care violate the principles upon which CAAPS was founded and public trust in clinical science.

Mental Health Care
Under the evidence-based standards of care, mental health care is indeed the first step in the care of children and adolescents diagnosed with gender dysphoria. The evidence-based standards of care recommend that a child or adolescent diagnosed with gender dysphoria be seen and evaluated by a qualified mental health professional trained in child and adolescent developmental psychopathology, competent in diagnosing and treating the ordinary problems of children and adolescents and meeting the same competency requirements as mental health professionals working with adults. Under the evidence-based standards of care, a qualified mental health professional has a responsibility to:

? Directly assess gender dysphoria in children and adolescents (see general guidelines for assessment, below).
? Provide family counseling and supportive psychotherapy to assist children and adolescents with exploring their gender identity, alleviating distress related to their gender dysphoria, and ameliorating any other psychosocial difficulties.
? Assess and treat any coexisting mental health concerns of children or adolescents (or refer to another mental health professional for treatment). Such concerns should be addressed as part of the overall treatment plan.
? Refer adolescents for additional physical interventions (such as puberty-suppressing hormones) to alleviate gender dysphoria. The referral should include documentation of an assessment of gender dysphoria and mental health, the adolescent's eligibility for physical interventions (outlined below), the mental health professional's relevant expertise, and any other information pertinent to the youth's health and referral for specific treatments.
? Educate and advocate on behalf of gender dysphoric children, adolescents, and their families in their community (e.g., day care centers, schools, camps, other organizations). This is particularly important in light of evidence that children and adolescents who do not conform to socially prescribed gender norms may experience harassment in school (Grossman, D'Augelli, & Salter, 2006 Grossman, D'Augelli, Howell, & Hubbard, 2006); Sausa, 2005), putting them at risk for social isolation, depression, and other negative sequelae (Nuttbrock et al., 2010).

? Provide children, youth, and their families with information and referral for peer support such as support groups for parents of gender-nonconforming and transgender children (Gold & MacNish, 2011; Pleak, 1999; Rosenberg, 2002).

The evidence-based standards of care clearly recommend that mental health providers who care for children and adolescents with gender dysphoria diagnose and treat any other mental health conditions the child or adolescent is experiencing. Thus, the state's implication that mental health providers are not addressing existing mental health concerns prior to beginning gender-affirming medical care is wholly inaccurate. Prior to puberty, mental health professionals, pediatricians, and other health care providers "work together to destigmatize gender variance, promote the child's self-worth, facilitate access to care, educate families, and advocate for safer community spaces where children are free to develop and explore their gender" without medical interventions.

Medical Care
The state begins its literature review on gender dysphoria and puberty suppression by attempting to argue that a majority of children and adolescents will cease showing signs of gender dysphoria and conform to their sex assigned at birth. Herein lies a distinction between prepubertal children and adolescents that the state fails to consider, or outright ignores.

In its "Florida Fact-Checked" version of the HHS Gender Affirming Care document, the state notes that "most children identifying as transgender will detransition following the onset of puberty." Additionally, in the ACHA GAPMS report, the state makes a similar argument, including "neither organization explains that a majority of young adolescents who exhibit signs of gender dysphoria eventually desist and conform to their natal sex and that puberty suppression can have side effects." By definition, a child is defined as "a young person especially between infancy and puberty," while adolescence is defined as "the period of life when a child develops into an adult: the period from puberty to maturity terminating legally at the age of majority." The key difference between children and adolescents being the onset of puberty. By referencing "children" it is "Florida Fact- Checked" document and "young adolescents" in the ACHA GAPMS report, the state erroneously conflates the 2 terms. However, the definitions of these terms are different and cannot be used interchangeably.

Furthermore, the state relies on a study that "offers data on the percentage of children who opt not to transition after experiencing gender dysphoria." Similar claims made in other states that have attempted to ban gender-affirming care have been thoroughly debunked by a recent expert review from faculty from Yale University and the University of Texas Southwestern. The report from Yale examined in detail the misrepresentation of the Steensma et al study, explaining that:

? "...the Steensma study was not designed to (and the lead author has acknowledged) does not provide a basis for calculating what percentage of prepubertal children diagnosed with gender dysphoria persist with that diagnosis into adolescence. Rather, the Steensma study was designed only to study the characteristics of those who persisted.60 Among other limitations, in Steensma (2013), former patients who opted to not participate in the study (either refused to participate or did not respond to an offer to participate) were categorized as "desisters," i.e., patients whose gender dysphoria resolved without transition or treatment. Patients can fail to respond to a study request for many reasons, including having moved away, receiving treatment elsewhere, or being uninterested in participating in a study. Thus, SEGM misuses the Steensma data by counting nonresponding patients as having "desisted" in experiencing gender dysphoria.61 Indeed, in published correspondence, Steensma emphasizes that the 2013 study should not be used to calculate the percentages of "persisters" and "desisters."62 The misrepresentation of Steensma on the SEGM website constitutes a major violation of the scientific method and the accepted conventions of research."

Some prepubertal children's diagnosis of gender dysphoria will indeed not continue in adolescence, and as such, there are no recommended medical interventions for prepubertal children. For prepubertal children, gender exploration is a natural part of child development. However, for children diagnosed with gender dysphoria persisting at the onset of puberty (adolescence), research demonstrates that gender dysphoria will continue. ; Under gender-affirming care, adolescents diagnosed with gender dysphoria, after careful and exhaustive mental health evaluation and care , may progress to gender-affirming medical care under the evidence-based standards of care.

Pubertal Blockers

Under the evidence-based standards of care, gender-affirming medical care is a highly individualized model of care. Prior to beginning gonadotrophin-releasing hormone agonists (GnRH, herein referred to as puberty blockers) as a component of a multidisciplinary approach to caring for adolescents diagnosed with gender dysphoria, adolescents must meet stringent criteria under the evidence-based standards of care from WPATH, including:

? The adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed);
? Gender dysphoria emerged or worsened with the onset of puberty;
? Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment.
? The adolescent has given informed consent and, particularly when the adolescent has not reached the age of medical consent, the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process. Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment."

The Endocrine Society lays out additional criteria that must be met prior to undergoing puberty blockers as a component of gender-affirming medical care:

? (the adolescent) has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility,
? (the adolescent) has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
? And a pediatric endocrinologist or other clinician experienced in pubertal assessment
o agrees with the indication for GnRH agonist treatment,
o has confirmed that puberty has started in the adolescent (Tanner stage =G2/B2),
o has confirmed that there are no medical contraindications to GnRH agonist treatment.

In the ACHA GAPMS report and the "Florida Fact- Checked" document, the state asserts that there is no credible evidence demonstrating puberty blockers benefit adolescents diagnosed with gender dysphoria. However, the state either unknowingly or willingly ignores the body of evidence that supports this practice. Medication to suppress puberty has been used to treat precocious puberty for decades. The identical therapeutics are also used in adolescents diagnosed with gender-dysphoria and perhaps more importantly represent a very reasonable balance of risk and benefit when considering the totality of the available data and clinical experience. The pubertal blocker phase of gender-affirming care importantly allows the patient to delay the development of secondary sex characteristics. By pausing the progression of secondary sex characteristics, adolescents are provided time to explore their gender identity, access and/or continue mental health support, and assess and define their treatment goals, in conjunction with their families.

Contrary to the state's assertion that the evidence supporting use of puberty blockers is "weak," a large body of evidence supports their use in adolescents diagnosed with gender dysphoria. For example, recent research examined 272 adolescents who were referred to a gender clinic, but had not yet began undergoing gender-affirming medical care, including puberty blockers, and 178 adolescents who had already began receiving gender-affirming care using puberty blockers with 651 cisgender adolescents. The researchers found that adolescents with gender dysphoria had worse psychological health compared with their cisgender adolescent peers and that after receiving puberty blockers as part of gender-affirming care, the adolescents with gender dysphoria had similar or better psychological health than their cisgender peers. Another recent study found that transgender adults who wanted and were able to access puberty blockers as adolescents were less likely to have lifetime suicidal ideation compared to transgender adults who were not able to access puberty suppression medication as adolescents. In a 2-year follow-up study, researchers found that the use of puberty blockers led to improvements in overall functioning and decreased instances of depression.

The state further asserts that "puberty suppression causes side effects, some of which have the potential to be permanent." However, experts point out that "recent studies suggest that puberty-blocking medication has

negligible or small effects on bone development in adolescents, and any negative effects are temporary and reversible. The most recent studies show that puberty-blocking drug therapy either has no effect on bone mineral density (BMD), a proxy measure of bone strength, or is associated with a very small decrease." Overall, the studies that have examined the use of puberty blockers, as a component of gender-affirming care, demonstrate that the use of these medications is evidence-based and provides for an appropriate risk/benefit ratio for adolescents diagnosed with gender dysphoria.

In addition, the state fixates on the argument that puberty blockers are used off-label, not approved by the Federal Drug Administration (FDA), and that no randomized clinical trials (RCT) have been completed on the use of puberty blockers to treat gender dysphoria. These arguments lack any basis. First, in pediatric medicine, "the purpose of off-label use is to benefit the individual patient. Practitioners use their professional judgment to determine these uses. As such, the term "off-label" does not imply an improper, illegal, contraindicated, or investigational use. Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient." The use of off-label medication in pediatric medicine is supported by clinical evidence and data. In suggesting that puberty blockers cannot be used to treat gender dysphoria simply because they have not been approved by the FDA for such purposes, the state fails to understand the relationship between the FDA and the practice of medicine:

? Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of a marketed product in this manner when the intent is the "practice of medicine" does not require the submission of an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB). However, the institution at which the product will be used may, under its own authority, require IRB review or other institutional oversight.

The use of off-label medication in pediatric medicine is not experimental, nor does it constitute anything other than the practice of evidence-based medicine. Off-label medication use for pediatric patients is commonplace and there is no basis to prohibit puberty blockers because of their off-label use in pediatrics.

The state's argument that puberty blockers have not undergone RCTs and therefore should be disqualified for use treating adolescents diagnosed with gender dysphoria is also severely flawed. As explained by Armand H. Antommaria, MD, PhD, FAAP, HEC-C, Director of the Ethics Center, the Lee Ault Carter Chair of Pediatric Ethics, and an Attending Physician in the Division of Hospital Medicine at Cincinnati Children's Hospital Medical Center:

? …it may, at times, be unethical to conduct randomized trials. For randomized trials to be ethical, clinical equipoise must exist; there must be uncertainty about whether the efficacy of the intervention or the control is greater. Otherwise, it would be unethical to knowingly expose trial participants to an inferior intervention or control. Trials must also be feasible; it would also be unethical to expose individuals to the risks of trial participation without the benefit of the trial generating generalizable knowledge. A randomized trial that is unlikely to find enough people to participate because they believe they might be randomized to an inferior intervention would be unethical because it could not produce generalizable knowledge due to an inadequate sample size.

Furthermore, a group of leading bioethicists echo Dr Antommaria's explanation: "Randomized control trials also are only ethical when there is clinical "equipoise," which means they are only appropriate when there is genuine uncertainty about whether the intervention will be more effective than the control." There is no uncertainty about the use of puberty blockers to treat adolescents diagnosed with gender dysphoria -- the evidence fully supports this intervention as a component of gender-affirming care. Studies other than RCTs are, in fact, utilized regularly in the practice of medicine and are preferable in some instances.

Gender-Affirming Hormone Therapy
As a component of gender-affirming care, adolescents who have received extensive mental health care and puberty blockers may progress to hormone therapy. As with every component of gender-affirming care, the use of hormone therapy is a highly individualized decision, and any decisions are made in concert with the adolescent, their family, and mental health and medical care providers. Under the evidence-based standards of care for receiving hormone

therapy, the following criteria must be met:

? A qualified MHP (mental health professional) has confirmed:
o the persistence of gender dysphoria,
o any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start sex hormone treatment,
o the adolescent has sufficient mental capacity (which most adolescents have by age 16 years) to estimate the consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent to this (partly) irreversible treatment,
? And the adolescent:
o has been informed of the (irreversible) effects and side effects of treatment (including potential loss of fertility and options to preserve fertility),
o has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
? And a pediatric endocrinologist or other clinician experienced in pubertal induction:
o agrees with the indication for sex hormone treatment,
o has confirmed that there are no medical contraindications to sex hormone treatment.

The state remarks in its Fact-Checked document that it is "misleading" to state that hormone therapy is partially reversible. This is purposefully misleading. The evidence-based standards of care acknowledge that some forms of hormone therapy are reversible and that some are not reversible. Initiating hormone therapy is not a decision that is made lightly and there are stringent criteria that must be met, as referenced above. Furthermore, experts at Yale University explain that hormone therapy has a wide range of uses in adolescents:

? Estrogen and testosterone are often used off-label to treat adolescents with intersex conditions. Common hormonal medications used off-label include norethindrone, a progesterone analogue used off-label for the treatment of heavy menstrual bleeding in those with polycystic ovarian syndrome, bleeding disorder, and anovulatory bleeding of early puberty. It is also used to treat endometriosis, which is a painful inflammatory condition. Many forms of combined hormonal contraception, as well as a testosterone-blocking medication (spironolactone), are used off-label to treat acne. Other examples include clonidine, a blood pressure medication used off-label for the treatment of ADHD, migraine headaches, disorders of behavioral regulation, and insomnia; and propranolol, a blood pressure medication used off-label for the treatment of performance anxiety.

As referenced in the preceding paragraph, the off-label use of hormone therapy for adolescents diagnosed with gender dysphoria "does not imply an improper, illegal, contraindicated, or investigational use. Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient." Decision-making to initiate this form of gender-affirming care takes place at the clinical level, using the evidence-based standards of care and the best available evidence. By attempting to argue that hormone therapy is somehow more dangerous to adolescents with gender dysphoria than to cisgender adolescents undergoing to same treatment for a different medical condition, the state makes it abundantly clear that this is not about the health and well-being of adolescents; it is rather a misguided attempt to discriminate against adolescents with gender dysphoria.

In the GAPMS report, the state cites a study by Dutra et al that "examined the results of over 50 studies evaluating the effects of cross-sex hormones on not only transgender individuals but those with menopause and other endocrine disorders, all of which indicate that the use of estrogen or testosterone can increase risks for cardiovascular disease." To use this as a basis for the state's argument to prohibit gender-affirming care for adolescents diagnosed with gender dysphoria would mean that the state would need to prohibit the use of hormone therapy in Florida's population at large. Additionally, in making this argument the state fails to consider the intent of hormone therapy -- to align one's body with one's gender identity. The experts at Yale University also clarify this misrepresentation or misunderstanding:

? The medical result is that transgender individuals move toward the typical medical profile of their identified gender. And so transgender women, like cisgender women, have lower risks of cardiovascular disease than

cisgender men.111 Transgender women, like cisgender women, have a slightly higher risk of venous thromboembolism than cisgender men. In fact, transgender women have a lower risk of venous thromboembolism than cisgender women, and the overall risk is extremely low (less than 1%) for all transgender individuals, both women and men.112 The risk of venous thromboembolism in transgender women and non-pregnant cisgender women is less than the risk in pregnancy, which is the highest estrogenic physiologic state known.
? It is also critical to note that the medical impact of gender-affirming treatment is generally the same in transgender people as in cisgender people who take the same hormone medications. For example, physicians commonly prescribe hormonal contraceptives containing ethinyl estradiol (a synthetic estrogen) to adolescents for reasons including birth control, management of irregular or painful menstrual periods, and acne. In other words, similar doses of exogenous sex hormones are commonly administered to cisgender individuals for a host of reasons and are well tolerated.

Research shows that hormone therapy, as a component of gender-affirming care, is beneficial to caring for adolescents diagnosed with gender dysphoria. A recent study in the Journal of Adolescent Health examined data from transgender or nonbinary adolescents and young adults between 13-24 and found that the provision of hormone therapy in those under 18 resulted in lower levels of depression and suicide attempts compared to adolescents who were unable to access hormone therapy. Another recent study demonstrated that the provision of puberty blockers and hormone therapy reduced depression and suicidality over the course of 1 year.

Additionally, the evidence cited in the evidence-based standards of care reinforces the sound basis for the provision of hormone therapy in adolescents diagnosed with gender dysphoria. Under the evidence-based standards of care, there are specific criteria for gender-affirming surgical interventions. The state's focus on gender-affirming surgery and its attempt to classify it as common is a blatant misrepresentation intended to politicize the issue and cast doubt on the evidence-based standards of care.

Risks
Unlike the state's assertion on its "Florida Fact-Checked" document that "no reliable evidence shows that gender dysphoria significantly increases the risk of suicide," there is in fact evidence to support this. In a study of more than 1,000 transgender adolescents, transgender adolescents had higher odds of all suicide outcomes compared to cisgender adolescents, and were at greater risk for suicidal ideations and attempts compared to their cisgender peers. Additionally, in the first large scale (N = 120,670) study examining the relationship between transgender adolescents and suicide, the authors found that between 30-51% of transgender adolescents reported engaging in suicidal behavior, compared to between 10-18% of their cisgender peers.

As noted in the earlier section on mental health, adolescents with gender dysphoria face increased bullying, discrimination, harassment, and a lack of social acceptance. To add to these daily, ongoing issues, adolescents with gender dysphoria are at greater risk for suicide and other mental health conditions. Curiously, the State of Florida appears to agree that transgender adolescents (and other LGBTQ adolescents) face more serious mental health concerns than their cisgender peers, as it maintains a web site, Youth Suicide Prevention under the FL Department of Health, explaining the protective factors and risks associated with suicide in adolescents (the state refers to this population as teens). In identifying these protective factors and risks associated with suicide in adolescents, the state readily admits that "It is important to know that some youths experience an increased amount of risk. Youths are those who identify as LGBTQ, American Indian/Alaska Native, youth in the child welfare and juvenile justice systems or military service members can have higher incidence of suicidal behavior." The state cannot have it both ways; it cannot argue that gender dysphoria doesn't increase the risk of suicide, as noted it its "Florida Fact-Checked" document (ignoring the evidence that patently refutes this argument), and then readily acknowledge via its youth suicide prevention web site that transgender adolescents are at increased risk of suicide.

As referenced in an earlier section of this comment letter, access to and the provision of puberty blockers and hormone therapy as part of gender-affirming care works and is the gold standard according to the medical community to alleviate mental health conditions and risks associated with gender dysphoria in adolescents.

Medicaid is a Critical Source of Health Care for Children, including Transgender Adolescents
Medicaid is a vital source of health insurance for children (for data reporting purposes below, the term "children" is inclusive of "adolescents") in Florida and across the United States. Nationally, children make up the single largest group of enrollees in Medicaid and the Children's Health Insurance Program (CHIP); more than 40 million—or 53%

of all US children—rely on Medicaid and CHIP coverage, including with special health care needs and those from low-income families. In Florida, over 2.8 million children were enrolled in Medicaid or CHIP as of February 2022. Medicaid also provides comprehensive prenatal care, enabling millions of healthy pregnancies and births, thereby helping millions of children obtain a healthy start. In states that have expanded Medicaid coverage to low-income adults, this coverage not only provides many documented benefits to those adults, but also has added benefits for children and adolescents, including an increased likelihood that they are covered, improved access to needed care, improved financial security for the family, higher preventive care use, and other benefits. ;

The direct benefits of Medicaid coverage for children and adolescents are many. In addition to improved access to care and health outcomes, those with Medicaid coverage miss less school, do better in school, are more likely to graduate and attend college, become healthier adults, earn higher wages, and pay more in taxes. Together with CHIP, Medicaid has been instrumental in driving down the rate of uninsurance among children, which stands at 5.7% nationally and 7.6% in Florida (2019).
Medicaid is not a benefit exclusive to cisgendered individuals. Indeed, Medicaid is of vital importance to transgender individuals, as it is estimated that almost 1/3 of all transgender persons will fall below the poverty line, more than twice the rate of the general population. Both cisgender and transgender individuals enrolled in Medicaid rely on the program to cover their necessary medical care. However, the State of Florida, in promulgating this rule, is discriminating against Medicaid's transgender enrollees by seeking to arbitrarily ban a whole category of treatments which is exclusively utilized by transgender individuals.

Unlike many private health insurance plans, Medicaid guarantees that benefits for children are designed specifically for them. The Early and Periodic Screening, Diagnosis and Treatment (EPSDT) provision of federal Medicaid law is a cornerstone Medicaid protection and the definitive gold standard of pediatric health care benefits. EPSDT guarantees that all Medicaid-eligible children are screened to assess and identify health issues early and ensures the provision of medically necessary health services to address those identified health conditions. EPSDT is designed to attend to a broad range of child health needs, including preventive care; physical and mental health; oral, hearing and vision care; habilitative care; and social and emotional development. EPSDT ensures that the medically necessary health care needs of the individual child determine what services and treatments Medicaid ultimately covers for that child. Such decisions of medical necessity are based on the expertise of the pediatrician or other treating clinician, who, through years of education, clinical training, and practice, takes into consideration the widely accepted evidence-based standards of care for the condition being treated.

This regulation as proposed would usurp this process of expert clinical decision-making made in the context of the physician-patient relationship; instead, it seeks to codify a discriminatory ban on widely accepted evidence-based standards of care for transgender adolescents and other individuals. As described in detail above, these standards of care are evidence-based and recommended by the medical community. Presented under the guise of an alternative care standard, this proposed prohibition on specific treatments for gender dysphoria not only ignores the prevailing consensus of numerous medical organizations, but also seeks to jettison the role of the treating clinician in determining medically necessary care for an individual. In every way, this proposed ban is a discriminatory gutting of the practice of medicine for transgender adolescents and other individuals, seeking to stifle the physician-patient relationship and replace it with the state's entirely ideological interest in ending gender affirming care in Florida's Medicaid program. In so doing, this proposed rule ignores the health and well-being of children, adolescents, and other individuals in Florida, both now and in the future, who could benefit from these treatments, and places their health interests as secondary to that of the state. This proposed rule counters medical consensus, discriminates against transgender adolescents, obstructs the physician-patient relationship, subverts Medicaid's EPSDT protection that places medical judgment central to coverage determinations, and, if finalized as proposed, would leave transgender adolescents and other individuals enrolled in Florida Medicaid with nowhere to turn for their much-needed health care.

The consequences of such actions are likely to be many. As detailed throughout this letter, the 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. As pediatricians who care for the health and well-being of all children in Florida and across the United

States, we call for the Florida Medicaid program to return to the evidence-based standards of care widely accepted among the medical community, and for this discriminatory ban to be rescinded. Only by doing so will the health and well-being of transgender children and adolescents in Florida be preserved.

Sincerely,

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**Please note: A sourced version of this letter containing footnotes is being provided in PDF format via email.