Florida Medicaid

Comment Summary for Rule 59G-1.050, F.A.C. and Responses Regarding the Generally Accepted Professional Medical Standards Determination on Treatment for Gender Dysphoria

Pl. Trial Ex. 326

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Introduction and General Comment Summary

Comments Submitted In-Person by Hearing Attendees

On July 8, 2022, the Florida Agency for Health Care Administration (Agency) held a hearing to receive public comments on the proposed changes to Rule 59G-1.050, Florida Administrative Code (F.A.C.).[1] Attendees included physicians, attorneys, individuals who had detransitioned, and other interested parties. Of those physically present, an overwhelming majority spoke in favor of the changes that will prohibit Medicaid coverage of puberty blockers, cross-sex hormones, and sex reassignment surgery when used to treat gender dysphoria.

Among the first speakers were two former trans-males who had transitioned while teenagers. The first was Chloe Cole, a 17-year-old from California, who explained how she had taken puberty blockers and cross-sex hormones before undergoing a double mastectomy. Cole asserted that she was not capable of making those decisions when she decided to take treatments that permanently altered her body and expressed regret at having done so. She further explained how she will be unable to breastfeed a child in the future, or even be able to carry one to full term, and that she continued to experience side effects from the drugs. Her statements about how she and her parents were misled by medical professionals are quoted below:

> *"My parents took me to a therapist to affirm my male identity. The therapist did not care about causality or encourage me to learn to be comfortable in my body because of -- partially due to California's conversion therapy bans. He brushed off my parents' concerns about that because he had hormones, puberty blockers, and surgeries. My parents were given a suicide threat as a reason to move me forward in my transition.*
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> *I was unknowingly physically cutting off my true self from my body, irreversibly and painfully. Our transidentities were not questioned. I went through with the surgery. Despite having therapists and attending the top surgery class, I really didn't understand all of the ramifications of any of the medical decisions I was making. I wasn't capable of understanding it, and it was downplayed consistently. My parents, on the other hand, were pressured to continue my so-called gender journey with the suicide threat."*

The second detransitioner, Sophia Galvin, explained how she had decided to become a trans-male at the age of 17 and began taking cross-sex hormones at 18. Her comments included how she had had a history of trauma and mental illness and that her gender dysphoria originated more out of fear of becoming a woman. Galvin further discussed how she received no support from both her physician and therapist when she decided to detransition. She concluded how she had been "harmed by this" and that medical treatment for gender dysphoria "is not good for children" and "should not be covered under Medicaid." Examples of her specific statements are quoted below:

> *"I had a history of mental illness. I had suicidal ideation and I would self-harm. And my wanting to transition was all in an effort to escape the fear of being a woman in this society and because of traumas that I had been through in my life. So I continued down the process, and then I ended*

[1] See Attachment A for the complete transcript of the July 8, 2022 hearing.

> *up removing my breasts at 19 years old because I was trapped, afraid to go back to my original ideo- -- to my original sex, and basically look crazy to the people around me."*

Another speaker, Katie Caterbury, explained how her 14-year-old daughter had decided to become a trans-male and began receiving testosterone injections without parental consent prior to undergoing a double mastectomy, hysterectomy, and phalloplasty while still a minor. The speaker also stated that her state's Medicaid program reimbursed for these services despite private insurance being available. She further discussed how changing biological sex is impossible and what kind of rational physician could administer such treatments. To close, Caterbury stated that "amputating the healthy body parts of a child whose brain has not reached full decision-making maturity is simply criminal."

Jeanetter Cooper, one of the founders of Parents for Ethical Care, spoke about how many mental health therapists have become "cheerleader(s) for gender identity affirmation" and that children and their families dealing with gender dysphoria "are being met with a medical treatment for a psychological condition." Cooper further asserted that "the state has no business using taxpayer funding to turn children into permanent medical patients."

In addition to parents, detransitioners, and stakeholders, a Florida pediatric endocrinologist, Dr. Matthew Benson, spoke in support of the proposed rule changes. He explained how studies completed in Sweden and Denmark indicated that treatment for gender dysphoria increased the risk of suicide and that long-term data is insufficient to support their use. His exact statements are quoted below:

> *"The National Board of Health and Welfare of Sweden has recently enacted in that country pretty significant restrictions. And if we're going to do this type of care, it needs to be under an IRB-approved protocol and it needs to be based on the best data. I'm used to prescribing these medications in the sense of puberty blockers.*
>
> *And one of the largest studies that came from Sweden was published around 2016, and basically what they showed is that in those individuals who are transgender and receive these types of procedures, the rates of overall mortality compared to the general population was three times that of the general population; completed suicide, 19 times that of the general population; five times suicide attempts of the general population. Similarly, in Denmark, out of a 20-year period, by the time a similar study was done, 10 percent of the population had died. We need better data. We need long-term perspective trials where we can look at adverse effects. We need much more robust data to justify these kinds of very aggressive therapies."*

Other speakers in support of the proposed changes to Rule 59G-1.050, F.A.C. repeatedly commented on how the Agency's actions will "protect Florida residents, especially minors" and how "children are being pressured and socialized at a very young age to identify as transgender."

Attendees commenting in opposition to the proposed rule changes included Dr. Michael Haller, a pediatric endocrinologist at the University of Florida, who asserted that the Florida Medicaid Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria (GAPMS report) made "numerous false claims, use(d) a biased review of the literature, and relies on more so-called experts who actually lack actual expertise in the care of children with dysphoria." He further went on to explain that "nearly every major medical organization that provides care for children, as you heard

previously, have provided well-evidenced guidelines supporting gender-affirming care as the standard of care." His comments elicited a response from panelist Dr. Quentin Van Meter who responded by saying:

> *"These are not standards of care. Standards of care by definition are an arduous process of listening to all input from every side, every aspect, of a medical condition, and these individuals get together and they agree on someplace in the middle that they can all live with as a then standard of care. These are merely guidelines. The guidelines from the Endocrine Society specifically state they are not standards of care. They're just guidelines. They are the opinions of the individuals who wrote the guidelines. The Endocrine Society guidelines were written by nine people in the first go-round and ten in the second go-round, all of which were ideologues from the World Professional Association of Transgender Health."*

Another attendee whose comments opposed the proposed rule changes was Nathan Bruemmer, who was appointed by Nikki Fried as Florida's LGBTQ consumer advocate. He argued that "documented, well-researched standards of care have been established, are based on a wide range of evidence, and conclude gender-affirming medical care is medically necessary and safe and effective. In other words, gender-affirming care is the standard of care." In addition, Bruemmer asserted how "the proposed rule as it stands would deny health care consumers in the state of Florida access to the standard of care."

Speakers who also commented against the rule's proposed changes included representatives from Equality Florida and Lambda Legal. Both of whom referred to the Agency's actions respectively as "discriminatory" and how they "will cause serious, immediate and irreparable harm to transgender Medicaid participants in Florida." In response to some of the comments advocating opposition, panelist Dr. Andre Van Mol responded with the following:

> *"The histories in the United Kingdom, Sweden, Finland, France, four nations that were leading this from quite some time, they did national-level reviews involving scientific organizations, divisions of governments, medical professionals. And mind you, these are nations that were leading it. And after review, they all came to the same conclusion, this should not be going on in minors at all under 16, and only between 16 and 18 under tightly-regulated studies, the kind of which we really don't see happening."*

In summary, comments presented in-person at the hearing overwhelmingly supported the proposed changes to Rule 59G-1.050, F.A.C. The majority of individuals who submitted comments in opposition primarily did so via email, which are addressed in the following.

Written Comments Submitted during the Comment Period

During the comment period for the proposed changes to Rule 59G-1.050, F.A.C., the Agency received multiple submissions from the below stakeholder and advocacy groups:

American Academy of Pediatrics
Endocrine Society
Planned Parenthood
The Trevor Project
Southern Legal Counsel
University of California at Los Angeles
Equality Florida
Yale University
American Civil Liberties Union
National Health Law Program
Legal Services of Great Miami
Lambda Legal
Fenway Health
Human Rights Campaign

Transgender Legal Defense and Education Fund
American Atheists

Parris Law

The majority of the comments object to the proposed rule changes and provide similar arguments regarding why the Agency should not move forward with adoption. These range from stating that treatment for gender dysphoria is medically necessary and lifesaving to arguing that Florida Medicaid denying coverage of these services is discriminatory and illegal under the equal protection clause of the 14th Amendment and Section 1557 of the Affordable Care Act. In addition, some submissions listed clinical organizations that endorsed the use of puberty blockers, cross-sex hormones, and sex reassignment surgery to treat gender dysphoria. Such organizations consist of the American Medical Association, American Psychiatric Association, and the American College of Obstetricians and Gynecologists. Furthermore, comments submitted by Yale University, the American Academy of Pediatrics (AAP), and the Endocrine Society include critiques of Florida Medicaid's Generally Accepted Professional Medical Standards Determination on the Treatment for Gender Dysphoria (GAPMS report).

To support their arguments, these stakeholder and advocacy groups referenced studies and statistics. Most of which the GAPMS report deemed as low or very low quality and insufficient to meet medical necessity criteria. In addition, multiple comments listed recent court cases such as *Bostock v. Clayton County* (2020) and *Eknes-Tucker et al v. Marshall* (2022) where judges struck down prohibitions on treatment for gender dysphoria.

From the groups listed above, one (Parris Law) offered comments supporting the proposed changes, arguing evidence supporting the treatment is insufficient, an absence of a standard of care prevents malpractice lawsuits, and informed consent cannot be given by minors for these services.

Because Yale University, the AAP, and the Endocrine Society provided detailed critiques of the GAPMS report, the following sections analyze their statements and provide responses.

Agency Response to Yale University's Rule Comments and GAPMS Rebuttal

Introduction and Overview

On July 8, 2022, faculty from Yale University[2] submitted comments regarding the proposed changes to Rule 59G-1.050, F.A.C. and a rebuttal (referred to as the Yale rebuttal and titled as "A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria) to the GAPMS report. These comments protest the proposed rule changes and charge the Agency with justifying them based on a "shoddy quality" report. In addition, Yale's faculty provide a detailed critique of the GAPMS report in an effort to discredit the final determination. Despite composing 47 pages of content, the Yale professors do not provide sufficient evidence to support overturning Florida Medicaid's final determination and halting changes to Rule 59G-1.050, F.A.C.

Instead of providing a well-researched document that demonstrates how evidence supporting treatment of gender dysphoria is based on robust methodologies and lacks bias, Yale's faculty submitted content that is rife with ad hominem attacks, exaggerations, misrepresentations, and patently false statements. Rather than attempt to counter the GAPMS report's primary argument that the treatments lack sufficient proof to meet medical necessity criteria, the Yale rebuttal does little more than launch insults against Florida Medicaid's experts, engage in logical fallacies, and make no effort to argue that "supporting" research adequately answers any outstanding questions. Because of these flaws, the Yale professors' comments and rebuttal are biased, misleading, and even unbecoming. Based on their statements, these academics appear to be relying not on the strength of their analyses but on the eminence of Yale University as the foundation for their credibility.

Comprehensive Problems in the Yale Rebuttal

The comments and rebuttal address multiple aspects of the GAPMS report, including the report itself and the experts' contributions, particularly the literature assessment by Romina Brignardello-Petersen and Wojtek Wiercioch. When evaluating Florida Medicaid's expert content, the Yale professors engage very little with the research and analyses, choosing instead to attack credentials and professional affiliations. The only exception is Brignardello-Petersen and Wiercioch's assessment, which the Yale rebuttal offers a detailed critique. The fact that these faculty members refuse to engage with the experts' content and conclusions indicates a likely inability to do so. If Florida Medicaid's experts were truly mistaken, would not Yale's professors point to such errors rather than attempt to dismiss entire documents based on qualifications? Additionally, the Yale rebuttal errs in assuming that only those with narrow credentials are suited for critical analysis. This is illogical and overlooks the notion that the ability to critically read, analyze, and evaluate can transcend throughout similar academic disciplines. Attempting to dismiss Florida Medicaid's expert reports by denigrating credentials is a thinly veiled method to avoid engaging with the actual content.

[2] Eight authors contributed to the Yale rebuttal. Six of whom are faculty at Yale University. The two remaining authors are professors at the University of Alabama at Birmingham and University of Texas Southwestern. Because the lead author, Meredithe McNamara, is faculty at the Yale School of Medicine and the report being released by the Yale Law School, this response collectively refers to the authors as the Yale faculty or Yale professors.

Another aspect of the Yale rebuttal is its over-reliance on adjectives and other descriptors. Throughout the content, its authors depend heavily on hyperbole and terms such as "shoddy," "unscientific," and "pseudo-science." Using this language is sensationalist and also a cover for weak analyses. The GAPMS report does not utilize such rhetoric because it demonstrates that treatment for gender dysphoria is experimental and investigational through careful evaluation and critical thought. In addition, adjectives and hyperbole serve only to mislead and confuse an audience while using affiliation with Yale University as cover for a paucity of reason and evidence.

A core component the Yale rebuttal lacks is making a case arguing that existing studies supporting treatment for gender dysphoria are sufficient. By not doing so, its authors fail to engage with the GAPMS report's main argument, resulting in the rebuttal's inability to demonstrate any significant flaws. What the Yale faculty needed to do was demonstrate that the methods used to prove the treatment's effectiveness were sufficient to meet medical necessity criteria. They could have accomplished this by explaining how bias was not an issue, that sample selection was robust, that participants' longitudinal histories were detailed, and that follow-up periods were lengthy. The Yale professors do none of this and repeatedly note that their evidence is "solid" and "authoritative" without providing a basis for why it is. In addition, the Yale rebuttal offers detailed critiques of Lisa Littman's work and devotes substantial content to criticizing her methods, sampling, and conclusions. This indicates a strong bias against any opposing evidence and unwillingness to consider any hypothesis going against their opinions. The authors' use of such rigorous critiques begs the question whether their "solid" studies, which they treat as irrefutable fact, would still be solid after going through the same review process.

In addition to not engaging with the GAPMS report's main argument, the Yale rebuttal uses a multitude of analogies that have no relevance to the subject at hand. In particular, the authors elaborate substantially on the Agency misusing the term "low quality" regarding evidence and go so far as to state that Florida Medicaid should not cover statins because low quality evidence also supports their use. Such language is misleading and false. For starters, multiple moderate and high-quality studies demonstrate the effectiveness of statins. Second, the benefits from this class of drugs far outweigh any potential risks. The GAPMS report sufficiently argues the risks posed by gender dysphoria treatment are too dangerous to long-term physical and mental health and that inadequate evidence is available to prove the benefits. Using such analogies deflects from the GAPMS report's main points and serves to confuse readers about the consequences of basing the use of medications and surgical procedures that pose irreversible effects on low and very low-quality evidence.

Another problem with the Yale rebuttal is its misrepresentation of evidence supporting the use of puberty blockers. In the text, the authors state that 16 studies demonstrate that cross-sex hormones and puberty blockers are effective. However, they do not list these in the citations and reference their response to Alabama and Texas' actions[3], stating the bibliographic information can be found there. What those cited pages list is low quality studies that suffer from poor sampling methods, high risks of bias, and subjective self-reports. In addition, the Alabama and Texas response, written by the exact same Yale faculty, also misrepresents evidence asserting that puberty blockers are safe. All studies cited focus on children diagnosed with central precocious puberty. Children with this condition take the

[3] For the complete response to Alabama and Texas, refer to "Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims." Yale University. 28 April 2022. Access at the following link.

medication at much younger ages (e.g., 8-9 years) as opposed to those with gender dysphoria (e.g., 12-13 years). This difference in ages does not account for the rapid changes in child development that could affect the physiological effects of puberty blockers.

Agency Responses to the Yale Rebuttal's Individual Comments

Because the Yale rebuttal provides a list of criticisms regarding the GAPMS report, the following will address each individually to demonstrate that not only do the Yale professors engage in poor reasoning but how they make false claims indicating that they failed to read the entire document.

Yale Rebuttal Point 1: *The GAPMS report[4] repeatedly and erroneously dismisses solid studies as "low quality." If Florida's Medicaid program applied the GAPMS report's approach to all medical procedures equally, it would have to deny coverage for widely-used medications like statins and common medical procedures like mammograms and routine surgeries.*

> **Agency Response:** The above statement as previously discussed is based on analogies that do not relate to the subject. Not only does the Yale rebuttal provide false information regarding statins (e.g., referencing one study) but it fails to account for weighing the benefits of a medication against the risks. The GAPMS report conclusively finds that treatment for gender dysphoria poses high risks to physical and mental health while offering questionable benefits.
>
> In addition, the GAPMS report and its attachments, Attachment C in particular, identify numerous issues with studies supporting gender "affirming" care. These problems include small sample sizes, absence of participants' longitudinal histories, and inadequate follow-up periods. Such problems leave unanswered questions such as whether mental health co-morbidities were caused by trauma rather than gender dysphoria and whether the participants still felt relief five or even ten years after transitioning. Because the available literature does not sufficiently answer those, it cannot prove if treatment for gender dysphoria is medically necessary.

Yale Rebuttal Point 2: *The GAPMS report disregards robust clinical research studies and instead relies on letters to the editor and opinion pieces. The GAPMS report's analysis fails to satisfy Florida's own regulatory standards for Medicaid coverage decisions and does not undermine the scientific research that supports medical treatment for gender dysphoria.*

> **Agency Response:** This statement is patently false. The GAPMS report relies solely on peer-reviewed studies to support its determination and provides critiques to demonstrate how the evidence is insufficient to support treatment of gender dysphoria. In addition, the Agency followed the process as specified in Florida Rule (Rule 59G-1.035, F.A.C.) to evaluate puberty blockers, cross-sex hormones, and sex reassignment surgery.
>
> One such example of how the Yale rebuttal's authors attempt to mislead readers is their critique of how the GAPMS report treated Chen et al's 2020 study, "Consensus Parameter: Research Methodologies to Evaluate Neurodevelopmental Effects of Pubertal Suppression in Transgender Youth." By stating that the article is a "consensus parameter" and accusing the Agency of "cherry-picking" quotes, the Yale faculty attempt to misrepresent how the GAPMS report

[4] The Yale rebuttal refers to the GAPMS report as the "June 2 Report." For the purposes of clarity, this analysis replaces the term "June 2 Report" with "GAPMS report" when reproducing the Yale rebuttal's comments.

contextualizes the study. When citing Chen et al, the Agency did so to highlight how questions concerning the effect of puberty blockers on neurodevelopment remain unanswered. This is a critical point regarding whether off-label use of those drugs is safe for adolescents because if puberty blockers halt neurodevelopmental milestones they could pose significant physical costs to achieve a mental health benefit.

Furthermore, the Yale rebuttal dismisses the GAPMS report's explanations regarding how several Western European countries, including Sweden, are updating their guidelines on treatment for gender dysphoria because the evidence does not support its use in children and adolescents. These international determinations are based on robust research and careful consideration of the risks and benefits, which the Yale faculty ignore completely.

Also, the authors of the Yale rebuttal insinuate that the Agency determined that treatment for gender dysphoria is experimental and investigational based on a "student blog." This is also extremely misleading. The GAPMS report contained one citation to reference the difference between eminence-based versus evidence-based medicine. The source in no way contributed to the research used to demonstrate how the evidence supporting treatment for gender dysphoria is insufficient.

Yale Rebuttal Point 3: *The GAPMS report mistakenly claims that puberty blockers and hormones are experimental because they are used "off-label" and not approved by the FDA. In fact, off-label use, when supported by scientific evidence, as is the case here, is extremely common in medical practice and especially in pediatrics.*

Agency Response: This criticism is misleading. The GAPMS report does not assert puberty blockers and cross-sex hormones are experimental solely because the FDA has not approved them to treat gender dysphoria. Highlighting the drugs' off-label use serves as one example among myriad examples to explain that the evidence fails to prove these medications are safe for that clinical indication. If they were, the FDA would likely have approved them for treating gender dysphoria.

Another problem with the Yale rebuttal's criticism is that using drugs off-label is normally done to achieve a physiological effect that is documented in the research. In addition, the risks of using a drug off-label when medically necessary do not outweigh the benefits. The low-quality evidence supporting gender dysphoria treatment does not demonstrate that causing infertility, disfigurement, and mutilation is worth the supposed mental health benefits. To compare such use with drugs like statins and Gabapentin misses the point while confusing the reader. Also, the Yale faculty fail to mention any drugs created specifically for physical conditions being used off-label to address mental illness.

Yale Rebuttal Point 4: *The GAPMS report falsely claims that medical care for gender dysphoria is provided to a large percentage of children who will come to regret their treatment. In fact, patients with gender dysphoria have vanishingly low rates of regret regarding their medical treatment.*

The GAPMS report attempts to cast doubt on medical treatment for gender dysphoria by repeating the debunked claim that most transgender teens ultimately reject their transgender identity.

Agency Response: This is another false statement. Research does reveal that a high percentage of transgender youth will desist following puberty. Furthermore, the studies that the Yale professors rely on to make this claim are low quality and lack long-term follow-up. Additionally, the Yale rebuttal makes an erroneous statement by claiming that the GAPMS report "ignores a recent study, Olson et al. (2022), who find that after an average of 5 years of social transition, only 2.5% of youth identified as cisgender."

The above quote is highly concerning. Not only is it false because the GAPMS report actually provides a detailed analysis of Olson et al's article, but it also indicates that the Yale professors did not even read the entire GAPMS report, opting instead to read only the sections on cross-sex hormones and puberty blockers. If they had read the document in its entirety, they would have discovered the Agency addressed that research and provided an analysis.

Yale Rebuttal Point 5: *The GAPMS report repeats discredited claims that "social contagion" is leading teens to become transgender. The issue, although sensationalized in the GAPMS report, is ultimately irrelevant to medical treatment, which is provided only after a multidisciplinary assessment and after a finding that gender dysphoria is persistent and medical treatment is warranted.*

Agency Response: When referring to discredited claims, the Yale rebuttal is referencing a study by Lisa Littman that introduces the concept of rapid-onset gender dysphoria (ROGD). In their criticism, the authors quote their prior response to Alabama and Texas' actions, stating that Littman's study required "extensive correction" due to its "misstatements." This is also misleading. Following what was most likely significant political backlash, the journal (*PLOS One*) republished the article to clarify that the results were based on parental observations. These clarifications had no impact on the results.[5]

Additionally, the GAPMS report refers to the Littman study in its discussion of the etiology of gender dysphoria to emphasize that the causes of the condition are unknown. Furthermore, insinuating that the GAPMS report uses ROGD as a rationale for determining that treatment for gender dysphoria is experimental and investigational is unfounded. The Agency based its conclusion primarily on the paucity of quality evidence demonstrating that the treatment can alleviate the condition.

Yale Rebuttal Point 6: *The GAPMS report claims that inappropriate medical care is provided to adolescents with gender dysphoria who also have anxiety, depression, and other mental health conditions. These assertions are unsupported by scientific evidence and disregard evidence-based clinical practice guidelines that provide sound guidance for treating complex cases.*

Agency Response: This is also a false statement. The research explicitly states that high percentages of youths diagnosed with gender dysphoria have other mental health co-morbidities (e.g., anxiety and depression). In addition, the GAPMS report highlights research revealing that these youths also have experienced elevated rates of trauma, abandonment, and other circumstances that contribute to mental illness.

[5] For additional information on the revisions to Lisa Littman's 2018 article, "Rapid-Onset Gender Dysphoria in Adolescents and Young Adults: A Study of Parental Reports," refer to the following link.

Furthermore, the Yale rebuttal fails to mention that the "evidence-based clinical practice guidelines" originate from the World Professional Association for Transgender Health (WPATH) and the Endocrine Society. The former does not qualify as a clinical organization and serves as an advocacy group, which is highly biased; and the latter notes that its guidance is based on low and very low-quality evidence. In addition, the Endocrine Society clearly states that its guidance does not constitute a standard of care.

Yale Rebuttal Point 7: *The GAPMS report speculates, without evidence, that psychotherapy alone is as effective as medical treatment for gender dysphoria. This claim contradicts the findings of solid scientific studies, which show that medical care is more effective than psychotherapy alone.*

Agency Response: This criticism is extremely misleading. The GAPMS report is not about psychotherapy's effectiveness when used to treat gender dysphoria, nor does it speculate that idea. The GAPMS report is strictly about evaluating whether puberty blockers, cross-sex hormones, and sex reassignment surgery have sufficient evidence to meet medical necessity criteria. In addition, the "solid scientific studies" that the authors refer to are low quality and based on flawed methods.

Conclusion

The Yale rebuttal to Florida Medicaid's GAPMS report makes an insufficient and problematic case for overturning the determination and halting the proposed rule changes. Due to myriad flaws including ad hominem attacks, hyperbolic language, and illogical statements, the Yale rebuttal fails to demonstrate that the conclusions drawn by the GAPMS report are incorrect. Instead of presenting a logical and well-reasoned case, as the authors' years of professional experience and training suggest they are capable of, they provide 47 pages of content that ignore the GAPMS report's main argument, disseminate misinformation, and make false claims, all while doing so under the eminence of Yale University. Creating such a document demonstrates that the Yale professors are intellectually dishonest and biased to the point where they will consider no evidence that challenges their beliefs. Because of the aforementioned issues, the Yale rebuttal is not a persuasive counterargument to the GAPMS report.

Agency Response to the Endocrine Society's Comments on the GAPMS Report

On July 7, 2022, the Endocrine Society submitted comments opposing the Agency's proposed changes to Rule 59G-1.050, F.A.C. These consisted of a narrative description of how the organization develops clinical guidelines and evaluates studies in addition to multiple criticisms of the GAPMS report. After careful consideration, the Agency does not find the Endocrine Society's comments sufficiently persuasive to warrant overturning the determination and proposed rule changes based on the following reasons:

- The Endocrine Society asserts that the Agency "did not include endocrinologists with expertise in transgender medicine."
    - In response, the Agency consulted a pediatric endocrinologist when making its determination in addition to experts across other fields and specialties to provide a comprehensive analysis of the problems concerning evidence supporting treatment for gender dysphoria. Also, the Endocrine Society's comment insinuates that the Agency's expert, Quentin Van Meter, lacks the appropriate credentials to comment on areas for which he is fully qualified.
- Another criticism claims that the Agency "does not acknowledge the data showing harm reduction and improvements in behavioral health issues, such as depression and anxiety, with gender affirming care."
    - This statement is not true. The Agency reviewed numerous studies supporting the use of gender "affirming" care and found that the methods used to obtain those results were poor and biased, consisting of self-report surveys, lack of participant histories, small sample sizes, and insufficient follow-up periods. This led to the conclusion that the available evidence was insufficient to meet medical necessity criteria.
- The Endocrine Society further argues that the GAPMS report is flawed because it "suggests that because puberty blockers are used off-label they are experimental and investigational."
    - This criticism is misleading. The GAPMS report does not assert that puberty blockers and cross-sex hormones are experimental solely because the FDA has not approved them to treat gender dysphoria. Highlighting the drugs' off-label use serves as one example among myriad examples to explain that the evidence fails to prove these medications are safe for that clinical indication. If they were, the FDA would likely have approved them for treating gender dysphoria.

      Another problem with the Endocrine Society's criticism is that using drugs off-label is normally done to achieve a physiological effect that is documented in the research. In addition, the risks of using a drug off-label when medically necessary do not outweigh the benefits. The low-quality evidence supporting gender dysphoria treatment does not demonstrate that causing infertility, disfigurement, and mutilation is worth the supposed mental health benefits.

Following its criticisms, the Endocrine Society points to multiple studies, including ones by Green et al and Turban et al, claiming that puberty blockers and cross-sex hormones can alleviate gender dysphoria. However, Attachment C of the GAPMS report composed by Romina Brignadello-Petersen determined

these two studies present confounding evidence and suffer from critical risks of bias. These findings reinforce the notion that evidence supporting treatment for gender dysphoria is insufficient to demonstrate mental health benefits.

Based on the above evaluation of the Endocrine Society's comments, the Agency stands by the determination of the GAPMS report and the proposed changes to Rule 59G-1.050, F.A.C.

Agency Response to the AAP's Comments on the GAPMS Report

On July 7, 2022, the American Academy of Pediatrics (AAP) submitted comments to the Agency's opposing proposed changes to Rule 59G-1.050, F.A.C. The organization argues that Florida Medicaid should not deny coverage of gender "affirming" treatments because they are the "standard of care." In addition, the AAP promotes erroneous and flawed arguments while asserting that the GAPMS report misrepresents the science. Due to these deficiencies, the Agency does not find the AAP's comments compelling enough to consider overturning the determination and proposed rule changes.

Among the numerous issues, the most glaring problem with the AAP's comments is its consistent reference to puberty blockers and cross-sex hormones acting as the "standard of care" for gender dysphoria. This representation is patently false. Currently, no standard of care exists for the condition that endorses such treatments, just clinical guidelines. By deliberately confusing the two categories, the AAP is misleading its audience to believe that no debate surrounds using puberty blockers and cross-sex hormones to address gender dysphoria. The term "standard of care" has specific legal ramifications. For example, physicians who practice outside of a given standard can be found liable for medical malpractice. What this means is that a "standard of care" is the minimum level of competency a practitioner must exercise when treating a patient.[6] Treatment for gender dysphoria has yet to reach this level. However, the AAP appears to want to obfuscate that fact.

Instead of a "standard of care," what is available supporting the use of puberty blockers and cross-sex hormones for this condition is clinical guidelines based on low-quality evidence. In its guidance, the Endocrine Society acknowledges that its recommendations are not a "standard of care" and that they are based on weak evidence. The other set of widely cited clinical guidelines is from the World Professional Association for Transgender Health (WPATH). While WPATH has clinicians serving as members, it is an advocacy group and not a professional organization. Furthermore, WPATH also bases its guidance on the same low-quality evidence as the Endocrine Society.[7]

Aside from misrepresenting the meaning of "standard of care," the AAP's comments have numerous other issues and errors, consisting of logical fallacies, false statements, and reliance on biased research. These consist of the following:

AAP Comments Problem 1: The AAP attempts to argue that because puberty blockers and cross-sex hormones are medically necessary for conditions such as endometriosis, polycystic ovarian syndrome, and acne that they are also appropriate for gender dysphoria.

> **Agency Response:** This is a logical fallacy and blatant misrepresentation. Taking drugs to correct hormonal imbalances is medically necessary and supported by quality science. However, just because certain medications are beneficial for some conditions does not mean that using them to obtain the secondary sexual characteristics of the opposite sex is justifiable to treat a mental health issue.

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[6] Moffett P and Moore G. The Standard of Care: Legal History and Definitions: The Bad and Good News. *West J Emerg Med*. 2011. 12:1. 109-112.

[7] For additional information regarding clinical guidelines offered by WPATH and the Endocrine Society, please refer to the Florida Medicaid Generally Accepted Professional Medical Standards Determination on the Treatment for Gender Dysphoria.

AAP Comments Problem 2: Throughout the document, the AAP attributes almost 20% of its citations to its own statement promoting gender "affirmative" care and a flawed report from Yale University composed in response to Texas and Alabama's actions regarding treating minors for gender dysphoria.[8]

> **Agency Response:** The over-reliance on flawed statements and research compromises the credibility of not only the AAP's comments but any document that utilizes such a practice. The strength of any scientific analysis is based only on the quality of evidence used to support the findings. By using discredited and biased work, the AAP further undermines its own credibility.

AAP Comments Problem 3: The AAP asserts that "gender-affirming medical care is a highly individualized model of care."

> **Agency Response:** This is a false statement. The AAP's method of gender "affirming" care is not individualized but a one-sized-fits-all model. According to the AAP, WPATH, and similar organizations, children and adolescents diagnosed with gender dysphoria first receive counseling followed by puberty blockers and then cross-sex hormones before undergoing sex reassignment surgery.

AAP Comments Issue 4: When addressing the GAPMS report's analyses on puberty blockers, cross-sex hormones, and desistance, the AAP attempts to argue that puberty blockers provide additional time for adolescents to "explore their gender identity" and are safe when used to treat gender dysphoria. In addition, the AAP assertions that the GAPMS report's highlighting that puberty blockers and cross-sex hormones are not FDA-approved for gender dysphoria "lack any basis."

> **Agency Response:** The AAP misses the point when it asserts that puberty blockers allow additional time for an adolescent to explore his or her gender identity. By halting pubertal development, these physicians are prohibiting children from fully realizing their natal sex before beginning cross-sex hormones. How can the AAP argue that children and adolescents should be able to "explore" while simultaneously denying them the experience of being a physically mature male or female?
>
> Additionally, the AAP does not acknowledge that puberty blockers do not allow for natural desistance to occur. At least five studies assert that approximately 96% of adolescents who start the drugs go on to take cross-sex hormones. Research cited in the GAPMS report, however, indicates that these youths would desist during or following puberty without medical intervention. This reinforces the notion that puberty blockers do act as a "gateway" drug for cross-sex hormones.
>
> Regarding the AAP's comments about the drugs' lacking FDA approval for gender dysphoria and being used off-label, this criticism is misleading. The GAPMS report does not assert puberty blockers and cross-sex hormones are experimental solely because the FDA has not approved them to treat gender dysphoria. Highlighting the drugs' off-label use serves as one example among myriad examples to explain that the evidence fails to prove these medications are safe

[8] Please refer to "Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims." Yale University. 28 April 2022. Access at the following link. For the Agency's critique of this report, please see Attachment A.

for that clinical indication. If they were, the FDA would likely have approved them for treating gender dysphoria.

Another problem with the AAP's comments is that using drugs off-label is normally done to achieve a physiological effect that is documented in the research. In addition, the risks of using a drug off-label when medically necessary do not outweigh the benefits. The low-quality evidence supporting gender dysphoria treatment does not demonstrate that causing infertility, disfigurement, and mutilation is worth the supposed mental health benefits.

AAP Comments Issue 5: The AAP refers to multiple studies in an attempt to bolster its argument that Florida Medicaid's GAPMS report is flawed and draws the wrong conclusions. The organization states that "research shows that hormone therapy, as a component of gender-affirming care, is beneficial to caring for adolescents with gender dysphoria" and then cites two studies, one by Green et al and another by Tordoff et al.

Agency Response: The Agency worked with Romina Brignardello-Petersen and Wojtek Wiercioch to evaluate and grade available research on treatment for gender dysphoria during the GAPMS review process. Their analysis reviewed both studies cited by the AAP and concluded that they each suffered from moderate and critical risks of bias. Furthermore, the AAP refers to an additional study by Turban et al, which Brignardello-Petersen and Wiercioch also appraised as having a critical risk of bias.

Considering the myriad issues with the AAP's comments, the Agency has determined they lack any sufficient standing to overturn the GAPMS report's determination or proposed changes to Rule 59G-1.050, F.A.C. Instead of composing a well-reasoned counterargument that demonstrates the evidence supporting treatment for gender dysphoria is robust and high quality, the AAP created a document rife with errors, misrepresentations, and non-applicable analogies. Attempting to veil such comments under the eminence of the AAP serves only to mislead its audience into accepting mistruths as fact. The GAPMS report thoroughly demonstrated that the evidence supporting treatment for gender dysphoria is insufficient to meet medical necessity criteria.

Analysis of Yale University's April 2022 Report

Overview of the Yale's April 2022 Report Responding to Alabama and Texas

On April 28, 2022, six faculty members of Yale University and one from the University of Texas Southwestern released a report (Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims) in response to the Texas Attorney General's (AG) opinion and Alabama law that restricts youth access to treatments for gender dysphoria. The report addresses multiple themes including sex-reassignment surgery for minors, effectiveness of puberty blockers and cross-sex hormones, and using drugs for off-label purposes. Currently, advocacy organizations such as Lambda Legal are citing this report as one that sufficiently debunks the research used in Florida's June 2022 GAPMS report. However, the report has significant flaws related to bias, omissions, and misrepresentations of evidence as presented in the following:

Critique of the Report's Content at Large

- This report provides a highly biased critique of the Texas AG's opinion and the Alabama law. This bias is evident in the heavy criticism leveled at studies that do not support the effectiveness of treatments for gender dysphoria and the omission of highly significant facts (e.g., permanent effects of cross-sex hormones). Further proof of bias is present in the failure to subject supporting studies to the same level of academic rigor applied to the opposing research.
- Due to the bias and omissions, the conclusions of this report are misleading and provide insufficient information to its audience. Individuals that reference this report prior to receiving treatments for gender dysphoria are only getting a fraction of the information and thus cannot provide fully informed consent.
- The authors also fail to provide an understanding that demonstrating the safety and effectiveness of any given treatment requires robust, high-quality evidence. When making that case, researchers need to put forward such evidence. The report's authors do not do that. Instead, they wrongfully assume that criticizing opposing evidence while ignoring the flaws in their own sufficiently proves their case. It does not. The authors appear oblivious that the burden of proof is on them, and they provide little evidence, which is low quality, to overcome that burden.

Content on WPATH, SEGM, and the Endocrine Society

- The report misrepresents WPATH and cites it as a clinical organization, when in reality it is an advocacy group that anyone can join.
- The authors attempt to discredit the Society for Evidence-Based Gender Medicine (SEGM) by arguing that it is biased against gender "affirming" care. However, the authors do not level such criticisms toward WPATH.
- The report fails to mention that the Endocrine Society gives low grades to treatments for gender dysphoria and that the organization's guidance does not constitute a standard of care.

Content on Puberty Blockers

- The report asserts that puberty blockers are safe and do not pose any irreversible effects when research has not fully answered the questions about prohibiting neurodevelopmental milestones, reducing bone mineral density accumulation, and potentially causing long-term problems with fertility and sexual functions.
- All research used to substantiate the authors' claims consists of studies regarding puberty blockers when used to treat central precocious puberty, which is a separate condition requiring the drugs to be used at younger ages (e.g., 8-10 years) as opposed to when puberty begins. This is a direct misrepresentation of scientific evidence.
- The report also attempts to downplay the off-label use of puberty blockers, which the FDA has not approved to treat gender dysphoria. It does this by arguing that drugs approved for adults are used off-label for children on a frequent basis. However, these analogies are flawed for the following reasons:
    - The report provides no examples of drugs only approved for adults that are used off-label for children, which makes it impossible to determine whether the medications apply to the same conditions as clinically indicated by their FDA-approved labels.
    - Examples cited of drugs being prescribed for off-label purposes are for the treatment of physical conditions such as acne. Even propranolol (beta blocker), which is used off-label to treat performance anxiety, is administered to address the accompanying physical effect of elevated blood pressure.

Content on Cross-Sex Hormones

- The report understates how cross-sex hormones can reduce fertility in trans-females (men who transition into women) by stating that fertility quickly returns after the estrogen and anti-androgen treatments stop. This conflicts directly with the University of California at San Francisco's guidance to patients that advises them to have sperm frozen prior to treatment because fertility will not likely return.
- The authors emphasize that estrogen treatments improve long-term cardiovascular health in trans-females. However, they make no mention of how testosterone negatively affects trans-males (women who transition into men). Effects such as hypertension and cardiovascular damage receive no mention whatsoever.
- The report also fails to mention other permanent effects caused by cross-sex hormones such as enlarged breasts in trans-females and facial hair in trans-males, while downplaying the effects on fertility.

Content on Quality of the Evidence Supporting the Effectiveness of Treatment for Gender Dysphoria

- The authors fail to elaborate on the evidence supporting treatment for gender dysphoria, citing only a handful of studies and not providing any critique or analysis of the research methods used.
    - Attachment C in the AHCA reported assessed that the study by Tordoff et al published in 2022 (cited in the Yale report) had a moderate risk of bias and small sample size.

- The authors falsely refer to research supporting treatment for gender dysphoria as the "best scientific evidence." When in reality, all published studies with supporting conclusions are low or very low quality.

Criticism of Studies That Do Not Support Treatments for Gender Dysphoria

- The report devotes significant content to critiquing Littman's study on rapid-onset gender dysphoria (ROGD) and Dhejne et al's study on transexuals in Sweden.
    - The authors state that the Dhejne study is "badly out of date," which is a very hypocritical criticism. They provide no explanation for why the study's publication date (2011) makes it invalid while citing evidence going back to 1988 on the effectiveness of puberty blockers.
    - For Littman's study, the authors criticize the survey methodology used to obtain the findings and assert repeatedly that the findings were discredited. Although the authors are correct that the research methods were not robust enough to provide moderate or high-quality results, they ignore the fact that the studies supporting the treatments also use the same methods (e.g., surveys and biased sampling selection). In addition, their analysis provides no information that debunks the ROGD phenomenon. The authors just say that the study's results have been "debunked" without substantiating their argument.