SUBJECT
Safeguarding Kids from Gender Surgeries & Drugs

SUMMARY ANALYSIS

In April 2022, the Florida Department of Health issued guidance regarding treatments for gender dysphoria. Immediately thereafter, the Florida Agency for Health Care Administration ("Agency") entered into a formal process to determine whether to cover under the Florida Medicaid program sex reassignment treatments for gender dysphoria. At that time, the Agency had not yet determined whether to cover such treatments under the Florida Medicaid program. The treatments at issue included (1) puberty blockers, (2) hormone therapy, and (3) sex reassignment surgery.

In June 2022, the Agency issued a report based on its research and analysis as well as five written assessments provided by subject-matter experts that the Agency retained for this purpose. The report recommended against covering sex reassignment treatments as reimbursable health services because they are not consistent with generally accepted professional medical standards and are experimentational and investigational.

In August 2022, the Agency promulgated a rule based on its report. The rule, codified in Rule 59G-1.050(7)(a), states that "Florida Medicaid does not cover," as "treatment of gender dysphoria," the use of (1) "puberty blockers," (2) "hormones or hormone antagonists," (3) "sex reassignment surgeries," or (4) "other procedures that alter primary or secondary sexual characteristics."

In September 2022, four Medicaid recipients sued the Agency in federal court seeking to enjoin the rule. To date, the plaintiffs' motion for a preliminary injunction is fully briefed. An evidentiary hearing is scheduled for Wednesday, October 12.

Gapms process

Generally Accepted Professional Medical Standards ("GAPMS") is a formal rule-based process that allows the Florida Medicaid program to determine whether health services will be covered. See generally Rule 59G-1.035, Florida Administrative Code. Anyone, including a member of the public, can request a review of a health service for coverage. In practice, the most common requestors tend to be pharmaceutical and other health care companies seeking coverage of their services and Florida Medicaid managed care plans seeking to pay or deny claims.

To quality for coverage, a health service must be "consistent with generally accepted professional medical standards and not experimental or investigational." The determination process requires the Deputy Secretary for Medicaid to make the final determination in a written report. The rule enumerates several factors that must be considered in making that determination. Those factors include consideration of evidence-based clinical guidelines, published medical and scientific literature, and effectiveness of the health service. The rule also contemplates the use of "recommendations or assessments by clinical or technical experts on the subject of field." In practice, experts tend not to be consulted during the GAPMS process, often because the inquiry is straightforward or under a tight deadline.

The Bureau of Medicaid Policy is responsible for drafting the GAPMS report. When a report is completed, it is routed for approval through the Bureau Chief, then to the Assistant Deputy Secretary for Medical Policy and Quality, and finally to the Deputy Secretary for Medicaid, who either concurs with the recommendation or does not concur. Once the Deputy Secretary signs the GAPMS report, a copy is delivered to the requestor. GAPMS reports generally are not considered confidential and do not fall under an exemption to public records laws. Still, they tend not to be made public to anyone other than the requestor, largely due to a lack of public interest.

Subject-matter experts

As contemplated by the GAPMS rule, the Agency retained seven subject-matter experts, including five experts that provided written assessments based on their respective expertise. While retaining experts is uncommon in the GAPMS process, doing so was necessary in this circumstance because of the politicization and ideological indoctrination of professional medical associations that have endorsed "gender affirming" treatment despite weak supporting evidence. A summary of the opinions of the five experts who submitted reports is below.

- **Dr. Romina Brignardello-Petersen**, together with a post-doctoral fellow, conducted a systematic review of medical studies published between 2020 and April 2022. They concluded that the evidence simply does not support the use of puberty blockers, cross-sex hormones, and reassignment surgeries as treatments for gender dysphoria. As they put it, there is "low and very low certainty evidence" to support these excluded treatments.

- **Dr. James Cantor**, editor-in-chief of the peer-reviewed journal Sexual Abuse, a professor, and a clinician, also looked at the medical literature and drew on his own experience. He found every one of the "11 outcome studies" that tracked pre-pubescent children showed that "the majority of children" "cease to feel dysphoric by puberty," thereby making the use of puberty blockers, cross-sex hormones, and surgeries inappropriate in this population. For adolescents, the medical literature showed some improvement with medical intervention and psychotherapy but could not show whether it was the medical intervention or psychotherapy that helped. For those with gender dysphoria, regardless of age, there was a greater likelihood of comorbidities—some other affliction—being the root cause of distress and even suicide. And Dr. Cantor concluded that the perspective of the leadership of medical trade groups in the United States was increasingly at odds with the current positions of European countries with formerly permissive regimes for the treatment of gender dysphoria.

- **Dr. Quentin Van Meter**, a pediatric endocrinologist who trained at Johns Hopkins, and is currently on the clinical faculties of Emory University and Morehouse College, discussed the effects of the excluded treatments on children. He cautioned against the "interruption of natural puberty," because it is puberty that "prepare[s] the body for reproduction and affects the bones, gonads, and brain." He further explained that "blocking puberty at the age of normal puberty prevents the needed accretion of calcium into the skeleton and prevents the maturation of the gonads." This contrasts with treatments for precocious puberty—the early onset of puberty—where puberty blockers are carefully used and the "end of treatment is carefully timed" so that natural puberty resumes at the appropriate age. He also rebutted the notion that the use of puberty-blockers and cross-sex hormones is reversible, noting, for example, that there can be "permanent infertility." And, recognizing that most of those with gender dysphoria later identify with their biological sex, he recommended against the very "permanent" surgical treatments.

- **Dr. Patrick Lappert,** a plastic surgeon with decades of experience, focused on the appropriateness of sex reassignment surgeries on a person's chest. He criticized the methods of those who have performed "breast removal surgery" on patients as young as thirteen, and distinguished sex reassignment surgeries from procedures like gynecomastia (an "objectively abnormal condition" that "makes males develop female-type breast gland tissue") and breast reduction (done when women suffer from "debilitating orthopedic" pain in their neck, back, or shoulders). He concluded that "the

> medical necessity of transgender chest surgery is not supported by scientific evidence and appears to be firmly in the category of cosmetic surgery." Worse yet, this type of procedure poses ethical concerns for surgeons because "[n]o other cosmetic procedure is expected to produce major functional loss."

Dr. G. Kevin Donovan, formerly the Director for the Center for Clinical Bioethics at Georgetown University School of Medicine, discussed ethical concerns associated with the excluded treatments. He found that "[v]ulnerable subjects such as children cannot legally or ethically participate in the consent process" needed for the excluded treatment "due to their age and maturity level." More broadly, he criticized the terminological wordplay used in recent years; he noted that the 2013 adoption of the phrase "gender dysphoria" to replace "gender identity disorder" in the DSM-V shifted the focus away from "correcting the underlying cause of the dysphoria" towards "transitioning to the preferred gender."

Gapms Report Summary

The June 2022 GAPMS Report summarized the findings of the consulting experts and concluded as follows: "the evidence shows that the [excluded] treatments pose irreversible consequences, exacerbate or fail to alleviate existing mental health conditions, and cause infertility or sterility," and, as such, the "treatments do not
conform to GAPMS and are experimental and investigational."

Specifically, the evidence relied upon by proponents of "gender affirming" treatment, including evidence of suicidality in the absence of such care, is either low or very low quality:

• Puberty Blockers: Evidence does not prove that puberty blockers are safe for treatment of gender dysphoria. Evidence that they improve mental health and reduce suicidality is low or very low quality.

• Cross-Sex Hormone Therapy: Evidence suggesting that hormone therapy provides benefits to mental health and prevents suicidality are low or very low quality. Rather, evidence shows that hormone therapy causes multiple irreversible consequences as well as infertility.

• Sex Reassignment Surgeries: Evidence of improvements in mental health and reductions in suicidality following sex reassignment surgery is low or very low quality. Sex reassignment surgeries result in irreversible physical changes, including sterility.

While professional medical associations like the American Academy of Pediatrics, the American Psychological Association, and the American Medical Association endorse the above treatments, none of those organizations relies on critically appraised evidence. Their prominence in the medical community alone does not validate their views in the absence of quality, supporting evidence. To the contrary, the evidence shows that the above treatments pose irreversible consequences, exacerbate existing mental health conditions, and cause infertility or sterility.

The Rulemaking

Following the report, the Agency entered into rulemaking. The text of the proposed rule, which was later finalized without modification, states that "Florida Medicaid does not cover," as "treatment of gender dysphoria," the use of (1) "puberty blockers," (2) "hormones or hormone antagonists," (3) "sex reassignment surgeries," or (4) "other procedures that alter primary or secondary sexual characteristics." Rule 59G-1.050(7)(a), Florida Administrative Code.

In July 2022, the Agency held a hearing on the proposed rule. During the hearing, the Agency took public comments concerning the GAPMS Report and Rule 59G-1.050(7)(a). Among those providing oral comments were two detransitioners—those who stopped and sought to reverse the effects of the excluded medical treatments. The comments received during the hearing were overwhelmingly supportive of the proposed rule. The Agency also accepted public comments in writing both before and after the hearing.

Florida finalized Rule 5G-1.050(7)(a), which became effective August 21, 2022. Even after the rule became final, the Agency continues to reimburse a long list of gender dysphoria treatments provided by clinical psychologists, child psychotherapists, psychiatrists, family therapists, and social workers. The rule only prohibits reimbursements for certain treatments specified in the text of the rule itself.

The Lawsuit

In September 2022, four Medicaid recipients sued the Agency and its Secretary in federal court in Tallahassee. While not representatives for a putative class, the four plaintiffs with gender dysphoria seek "preliminary and permanent injunctions prohibiting" the state from implementing Rule 59G-1.050(7)(a).

A separate motion for preliminary injunction also seeks relief beyond that necessary for the named plaintiffs. The only two bases for this broad, class-like request are the Equal Protection Clause, and the Affordable Care Act's non-discrimination provision. 42 U.S.C. § 18116(a).

At this time, the plaintiffs' motion for a preliminary injunction is fully briefed. An evidentiary hearing is scheduled for Wednesday, October 12, in Tallahassee.

SAFEGUARDED KIDS

FROM GENDER SURGERIES & DRUGS

LET KIDS BE KIDS

FLORIDA LEADS THE NATION AS THE FIRST STATE TO RELEASE EVIDENCE-BASED GUIDANCE RECOMMENDING AGAINST "GENDER AFFIRMING CARE" FOR CHILDREN EXPERIENCING GENDER DYSPHORIA

THIS RECOMMENDS AGAINST SURGERY, HORMONE THERAPY, AND THE USE OF PUBERTY BLOCKERS BEFORE THE AGE OF 18

THE AGENCY FOR HEALTH CARE ADMINISTRATION RELEASED A REPORT THAT FOUND GENDER DYSPHORIA TREATMENTS PROMOTED BY THE FEDERAL GOVERNMENT ARE NOT CONSISTENT WITH WIDELY ACCEPTED PROFESSIONAL MEDICAL STANDARDS AND ARE EXPERIMENTAL AND INVESTIGATIONAL WITH THE POTENTIAL FOR HARMFUL LONG-TERM EFFECTS

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Key Points

- In June 2022, the Agency for Health Care Administration (AHCA) released a report recommending against covering sex reassignment treatments as reimbursable health services because they are not consistent with generally accepted professional medical standards and are experimentational and investigational.
- Following the report, the agency released a rule stating that "Florida Medicaid does not cover," as "treatment of gender dysphoria," the use of "puberty blockers," "hormones or hormone antagonists," "sex reassignment surgeries," or "other procedures that alter primary or secondary sexual characteristics."

Guidance Regarding Gender Dysphoria

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