ENDOCRINE SOCIETY
Hormone Science to Health

February 17, 2026

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicaid Program: Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children (CMS-2451-P)

Dear Administrator Oz,

The Endocrine Society writes in opposition to the proposed rule, which would deny Medicaid and CHIP funding for certain types of care for patients under age 18 who have been diagnosed with gender dysphoria.[1] The Endocrine Society believes that health care decisions should be made by qualified medical professionals in partnership with patients and their families, based on scientific evidence and the individualized needs and values of the patient and their family. We oppose the proposed rule because it overrides this approach for patients under age 18 who depend on Medicaid and CHIP for their care. We also oppose the proposed rule because it misstates our clinical practice guidelines and the consensus among the medical professional community regarding options for the treatment of gender dysphoria.

Founded in 1916, The Endocrine Society is a 501(c) (3) charitable, non-profit organization dedicated to accelerating scientific breakthroughs and improving human health. The Endocrine Society has more than 18,000 members including scientists, physicians, educators, and nurses in 122 countries. It is the largest and most active organization devoted to hormone research and clinical practice in endocrinology. Endocrinology is a broad field including prevalent health concerns such as diabetes, obesity, fertility, bone health, and hormone-related cancers in addition to many rare conditions. Endocrine Society members provide endocrine treatment across this spectrum, and the goal of the Endocrine Society is to advance endocrine science and education and ensure access to evidence-based endocrine care for all who seek it.

To achieve this, the Endocrine Society publishes multiple highly ranked peer-reviewed journals and publications; hosts the premier global meeting on endocrinology research and clinical care; and, among other things, develops and disseminates educational resources on a wide range of

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clinical endocrine issues. These educational resources include clinical guidelines that reflect scientific research and evidence-based options for care.

The Endocrine Society's guidelines are made publicly available as a resource that medical providers may use to facilitate conversations with patients and their families about options for treatment. They do not dictate the treatment of a particular patient or any specific course of treatment more generally. Instead, the guidelines may help medical providers support patients and families in making informed health care choices that align with a patient's individual health circumstances as well as their (and, for patients under age 18, their parents') values and preferences. The Endocrine Society's 2017 clinical practice guideline titled *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline* (the "2017 Guidelines")[2] is one of the many such guidelines published by the Endocrine Society.

Endocrine Society Guidelines

The Endocrine Society's guidelines are developed by guideline writing panels, which consist of individuals chosen for their clinical or other expertise.[3] To ensure that its guidelines reflect existing clinical science and meet the needs of practicing physicians, guideline writing panels employ a rigorous methodology to craft guidelines using the Grading of Recommendations, Assessment, Development, and Evaluation ("GRADE") system.[4] The GRADE system captures a key principle of evidence-based medicine, namely that "evidence alone is never sufficient to make clinical decisions" and "optimal treatment decisions require integration of clinical knowledge and research evidence with patient circumstances, including their values and preferences."[5] Through the GRADE system, key clinical questions are identified, existing scientific evidence is collected and summarized, and criteria for going from evidence to the healthcare decision (the "Evidence-to-Decision" framework) are considered.[6]

The GRADE system classifies evidence into one of four categories (high, moderate, low, or very low) based on the type of study design. Randomized controlled trials begin with a "high" quality rating while observational studies (e.g., cohort studies, unsystematic clinical observations, case reports) start with a "low" or "very low" rating. Randomized trials receive this higher rating because they eliminate some potential flaws of observational studies (e.g., errors in patient recall, non-representative sample groups or data) but require that the treatment or non- treatment of each participant must be made at random—based on chance rather than the need of the participant— which raises ethical concerns not present with observational studies. The GRADE system further recognizes that the strength of a recommendation (identified numerically as “1” if recommended and “2” if suggested) requires the consideration of evidence along with other criteria, including values and preferences; as a result, sometimes guideline panels “can make strong recommendations based on low to very low quality evidence.”[7]

The Endocrine Society’s draft guidelines undergo a rigorous review and approval period prior to publication. This includes review by Endocrine Society members as well as cosponsoring organizations identified by the guideline writing panel based on the clinical topic, desired expertise, and intended audience of the guidelines. Published guidelines provide recommendations for care that reflect the strength of each recommendation along with summaries of evidence, an explanation of the criteria employed, and justification for the recommendation. This ensures that the Endocrine Society’s process is transparent and allows those who elect to use the guidelines to understand and assess the evidence and criteria used in making these judgments.

To further ensure transparency, objectivity, and trustworthiness, the guideline development process protects against conflicts of interest in several ways. Funding for the development of clinical practice guidelines is provided by the Endocrine Society; no other entities provide financial support. Its guideline writing panels must disclose conflicts of interest and adhere to the Endocrine Society’s conflict of interest policy.[8]

The 2017 Guidelines

The Endocrine Society’s 2017 Guidelines followed the same levels of process and rigor required of all its guidelines. The experts serving on the guideline writing panel used the GRADE system to draft recommendations that were subject to review, including by Endocrine Society Members and cosponsoring organizations. The published guidelines cite more than 260 research studies, which represent the best available data found during a thorough review of the research at the time. In determining the strength of its recommendations, the guideline writing panel considered the quality of the supporting evidence and applicable criteria—including values and preferences for consideration by a patient and their family. These guidelines reflect and are based on the best available medical literature and clinical experience, set forth a conservative approach to care centered on the need for individualized assessments by qualified health care providers in partnership with patients and their families, and serve as a resource that medical providers may use to help these patients and their families make informed choices about the treatment of gender dysphoria.

The 2017 Guidelines recognize that "gender affirmation is a multidisciplinary treatment in which endocrinologists play an important role."[9] They emphasize the importance of shared decision-making, including a robust diagnostic assessment by a highly qualified mental health professional working with a pediatric endocrinologist or experienced clinician and suggest proceeding as conservatively as possible, in consultation with and consent from the patient and family and to give youth with gender dysphoria and their parents time to consider their options.[10]

Before the onset of puberty, the guidelines provide for mental health care and support but recommend against puberty blocking and gender-affirming hormone treatment.[11] Where gender dysphoria continues into adolescence—after the onset of puberty—the 2017 Guidelines provide for consideration of puberty blockers and gender-affirming hormone therapy in addition to mental health care and support.[12]

Puberty-Delaying Medication

The 2017 Guidelines suggest the use of medication to delay puberty where a qualified mental health professional has determined that certain diagnostic and treatment criteria are met, including a demonstrated, long-lasting, and intense pattern of gender dysphoria that has worsened with the onset of puberty and the patient (and, for minors, their parent or guardian) is requesting this treatment.[13] An adolescent requesting puberty-blocking medication also must be capable of giving informed consent and the patient and their family must be informed of the effects and possible side effects of treatment, as well as options to preserve fertility.[14] The patient's parents or other guardians must also consent to the treatment and be involved in supporting the adolescent through the treatment process.[15] A pediatric endocrinologist or other clinician experienced in pubertal assessment must agree with the indication for puberty blockers, confirm that puberty has started, and confirm that there are no contraindications to this treatment.[16]

If these criteria are met, and the patient and family are requesting treatment, the 2017 Guidelines recommend use of gonadotropin-releasing hormone (GnRH) analogs as the most effective method of delaying puberty.[17] The use of this medication is a generally reversible and conservative approach that expands the diagnostic phase and gives patients more time to live in the experienced gender before making any decision about whether to proceed with additional gender-affirming care, some of which is irreversible. For some patients, prescribing GnRH analogs early in puberty can relieve psychological distress of gender incongruence.[18] This treatment also can help patients avoid physical changes that are irreversible and may then require surgery in the future, such as the development of the Adam's apple.[19]

In the "values and preferences" explanation, the Guidelines state that the "suggestion" of using puberty blockers places a "high value" on avoiding the development of undesirable secondary sex characteristics, which are not reversible, a "higher value" on psychological well-being, and a "lower value" on avoiding potential harm from early pubertal suppression.[20]

GnRH analogs have been used for more than 40 years to treat central precocious puberty, a disorder where puberty begins in children younger than eight. The purpose behind the use for treatment of individuals with gender dysphoria is the same as the medication's use in patients with early puberty—to delay the progression of puberty until a later time. Medical experts have determined that the benefits of delaying puberty generally outweigh its risks, with the risk of any serious adverse effects from these treatments exceedingly rare when provided under clinical supervision.[21]

Gender-Affirming Hormone Therapy

For older adolescents who meet specific diagnostic, consent, and treatment requirements, and who are requesting this treatment (with, for patients under age 18, consent of their parent or guardian), the 2017 Guidelines also contemplate hormone therapy to allow the development of secondary sex characteristics consistent with a patient's gender identity. The 2017 Guidelines recommend gender-affirming hormone therapy only when a qualified mental health professional has confirmed the persistence of gender dysphoria, the patient and their family have been informed of the effects (some irreversible) and side effects of treatment, the patient has the mental capacity to consent to this treatment (usually considered to occur around age 16), and any coexisting problems, including mental health concerns, have been addressed.[22] As the 2017 Guidelines explain: "The MHP [mental health professional] who has followed the adolescent during GnRH analog treatment plays an essential role in assessing whether the adolescent is eligible to start sex hormone therapy and capable of consenting to this treatment. Support of the family/environment is essential."[23] Again, the patient's parents or guardians also must request and consent to this treatment and be involved in supporting the older adolescent throughout the treatment process. The 2017 Guidelines are transparent in cautioning to proceed with hormone therapy "only when the individual has sufficient mental capacity" and the consent and support of their parents or guardians, factors that must be determined on an individualized basis.

Where the criteria for hormone therapy are met, the 2017 Guidelines recommend pretreatment screening and regular medical monitoring to assess physical changes and prevent potential adverse outcomes.[24]

The 2017 Guidelines recommend proceeding with treatment as conservatively as possible to give transgender and gender-diverse youth and their parents time to consider their options. While societal change has encouraged more people to live openly, the number of transgender and gender-diverse youth taking medications remains small. The reality of treatment for gender dysphoric adolescents matches the conservative approach in the Guidelines. Around 85% of adolescents diagnosed with gender dysphoria are prescribed <u>no</u> gender-affirming medication at all.[25]

The 2017 Guidelines are respected, influential, and trusted around the world. They are supported by more than 20 highly-regarded medical societies, including the American Medical Association, American College of Physicians, American Psychiatric Association, and other pediatric and specialty medical professional societies.[26] While individual health care providers must tailor care plans to fit the individualized needs of a patient, these organizations agree that gender-affirming care is appropriate and necessary for some patients and should remain available for the small percentage of people who need it.

Observations on the Cass Report

The proposed rule cites the Cass Review Final Report ("Cass Report"), published by a working group created by the United Kingdom's National Health Service (NHS) to assess and provide recommendations regarding its system of care for young people with gender dysphoria and those questioning their gender identity. Notably, the Cass Review recognizes and endorses that "the care of this population needs to be holistic and personal. It may comprise a wide range of interventions and services,"[27] which is also a key tenet of the 2017 Guidelines. Contrary to some reporting, *the Cass Report does not recommend or support a ban on gender-affirming medical care*. In fact, it recognizes that "[f]or some, the best outcome will be transition," and calls on NHS to provide for this: "[a]mong those being referred to [NHS], some may benefit from medical intervention and some may not. *The clinical approach must reflect this*."[28] The 2017 Guidelines reflect this approach. As the Cass Report recognizes:

> A compassionate and kind society remembers that there are real children, young people, families, carers and clinicians behind the headlines. The Review believes that each individual child and young person seeking help from the NHS should receive the support they need to thrive.[29]

The Endocrine Society's guidelines seek to ensure this. While the Cass Report critiques existing guidelines, the Endocrine Society stands by the rigor used to develop its 2017 Guidelines and the resulting recommendations. Notably, the Cass Report does not contain any new research that would contradict the recommendations made in the 2017 Guidelines. We also note that the Cass Report itself has come under considerable criticism for its methodology and lack of transparency, with the British Medical Association announcing an evidence-based review of the Cass Report and raising concerns about "weaknesses in the methodologies used in the Review and problems arising from the implementation of some of the recommendations."[30]

Conclusions

Decisions about medical care should be based on individualized assessments by qualified professionals in consultation with the patient and their parents and guided by medical evidence. The 2017 Guidelines serve as a resource for providers, setting forth evidence-based information about treatment options. They are made publicly available and medical providers may elect to use them to facilitate conversations with patients and their families about the relative risks, benefits, and patient values and preferences implicated by any given treatment choice. The proposed rule discredits and overrides this approach, which is embraced by the established medical community, supported by science, and reflects a guiding principle underpinning all of health care; namely, allowing qualified medical providers to support patients and their families in making informed decisions that are supported by science and align with their medical needs, health goals, and personal values. The proposed rule would eliminate this approach to care for patients under age 18 diagnosed with gender dysphoria who are enrolled in Medicaid and CHIP and we therefore oppose it.

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[1] As explained by the American Psychiatric Association, gender dysphoria is a condition characterized by clinically significant distress resulting from an incongruence between one's sex assigned at birth and one's gender identity (i.e., one's innate sense of their gender). *See* THE DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (American Psychiatric Association 5th ed. 2018); *see also What is Gender Dysphoria?,* AMERICAN PSYCHIATRIC ASSOCIATION (Aug. 2022), https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria.

[2] Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline,* 102 J. CLIN. ENDOCRINOL. & METAB. 3869 (2017) (HEREINAFTER "2017 Guidelines").

[3] *See Clinical Practice Guidelines,* ENDOCRINE SOCIETY, https://www.endocrine.org/clinical-practice-guidelines.

[4] *Id*.

[5] *See* Brian A. Swiglo et al., *A Case for Clarity, Consistency, and Helpfulness: State-Of-The-Art Clinical Practice Guidelines in Endocrinology Using the Grading of Recommendations, Assessment, Development, and Evaluation System*, 93 J. CLIN. ENDOCRINOL. METAB., 666, 667 (2008).

[6] *Id*.

[7] *Id*.

[8] *See* Conflict of Interest Policy and Procedures for Endocrine Society Clinical Practice Guidelines, ENDOCRINE SOCIETY (2019), https://www.endocrine.org/-/media/endocrine/files/cpg/methodology-page-refresh/conflict_of_interest_cpg_final.pdf;

[9] 2017 Guidelines, at 3873.

[10] *Id.* at 3876-79.

[11] *Id.* at 3879.

[12] *Id.* at 3871.

[13] *Id.* at 3878 (Table 5), 3880-81.

[14] *Id.* at 3878 (Table 5).

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id*.

[19] *Id.* at 3880-81.

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[20] *Id.* at 3881.

[21] *Id.* at 3883 (noting that "[t]hese compounds are usually safe, but some side effects have been reported" and, "[d]uring treatment, adolescents should be monitored for negative effects of delaying puberty"); *see also* Annemieke S. Staphorsius et al., *Puberty Suppression and Executive Functioning: An fMRI-Study in Adolescents With Gender Dysphoria,* 56 PSYCHONEUROENDONCRINOLOGY 190 (2015), https://pubmed.ncbi.nlm.nih.gov/25837854/.

[22] 2017 Guidelines, *supra* note 2 at 3878 (Table 5), 3883-3885.

[23] *Id.* at 3885.

[24] *Id.* at 3883, 3885.

[25] *See* Komodo Health Inc. analysis for Reuters on how many youths have sought and received care, https://www.reuters.com/investigates/special-report/usa-transyouth-data/.

[26] *See* Brief of *Amici Curiae* American Academy of Pediatrics and Additional National and State Medical and Mental Health Organizations in Support of Petitioner and Respondents in Support of Petitioner, United States v. Skrmetti et al., (No. 23-477), https://www.supremecourt.gov/DocketPDF/23/23- 477/323964/20240903155151548_23-477%20tsac%20Brief%20of%20Amici%20Curiae%20AAP%20et%20al..pdf

[27] *Independent Review of Gender Identity Services for Children and Young People: Final Report*, THE CASS REVIEW (2024) at 21.

[28] *Id*. at 21, 27 (emphasis added).

[29] *Id.* at 22.

[30] BMA Media Team, *BMA to Undertake an Evaluation of the Cass Review on Gender Identity Services for Children and Young People*, BRITISH MEDICAL ASSOCIATION (July 31, 2024), https://www.bma.org.uk/bma-media- centre/bma-to-undertake-an-evaluation-of-the-cass-review-on-gender-identity-services-for-children-and-young- people; *see also* Meredithe McNamara et al., *An Evidence-Based Critique of "The Cass Review" on Gender- Affirming Care for Adolescent Gender Dysphoria*, THE INTEGRITY PROJECT AT YALE LAW SCHOOL (July 1, 2024), https://law.yale.edu/sites/default/files/documents/integrity-project_cass-response.pdf.