February 5, 2026

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

Submitted electronically via regulations.gov

RE: Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children (CMS-3481-P)

Dear Dr. Oz,

On behalf of the American Academy of Family Physicians (AAFP), which represents 128,300 family physicians and medical students across the country, we appreciate the opportunity to comment on the proposed rule published in the Federal Register on December 19, 2025, regarding Hospital Conditions of Participation (CoPs) for Medicare and Medicaid.

CMS is proposing to update hospital CoPs participating in Medicare and Medicaid to include a prohibition on the provision of "sex-rejecting procedures," or SRPs, for children under 18. CMS is defining "sex-rejecting procedure" as any pharmaceutical or surgical intervention that attempts to align an individual's physical appearance or body with an asserted identity. The proposed rule defines "sex-rejecting procedures" as pharmaceutical or surgical interventions intended to align a minor's physical development or appearance with an asserted identity different from the minor's sex, which CMS defines based on reproductive function. The definition excludes treatment for medically verifiable disorders of sexual development, interventions performed for unrelated medical reasons, and treatment of complications arising from prior procedures. If finalized, this rule would apply to hospitals participating in Medicare and Medicaid, including most provider-based facilities, depending on their degree of hospital integration.

The AAFP urges CMS to withdraw the proposed CoP which prohibits hospitals and many provider-based facilities from participating in Medicare and Medicaid based on the services they provide. CMS cites sections 1861(e)(9), 1871, and 1905(a) of the Social Security Act as authority for establishing hospital Conditions of Participation (CoPs) and acknowledges that section 1801 prohibits the agency from exercising supervision or control

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over the practice of medicine. CMS then asserts that SRPs for children do not constitute "healthcare," and therefore fall outside the scope of section 1801. **This interpretation raises significant legal and policy concerns.** Historically, CoPs are designed to set baseline institutional standards, including hospital operational requirements for staffing, quality assurance, patient safety, documentation, and infection control. They have not been used to categorically prohibit specific clinical interventions or to determine which treatment modalities fall within accepted medical practice. Determinations of clinical appropriateness have long rested with state oversight boards and the professional judgment of individual physicians. If finalized, this rule would depart from this established framework by defining certain clinical services as outside the practice of medicine.

The Social Security Act does not grant CMS explicit authority to reclassify clinical services in this manner, and the statutory text does not suggest that Congress enabled CMS to define what services constitute "healthcare". Adopting this interpretation would extend the CoPs beyond their traditional institutional role and create uncertainty about the limits of CMS's regulatory authority. Section 1801's prohibition on federal control over the practice of medicine reflects Congress's intent to preserve the longstanding distinction between federal oversight of institutional standards and state and physician authority over clinical practice. **We encourage CMS to reconsider this interpretation and ensure that CoPs remain focused on institutional standards**, while determinations of clinical appropriateness and scope of practice continue to reside with state oversight bodies and licensed medical professionals.

CMS cites the 2025 HHS Review on Gender Dysphoria as the scientific basis for the proposed prohibition. While the Review identifies evidence gaps and critiques aspects of existing clinical guidelines, it does not employ the level of methodological rigor or standardized evidence-grading typical of clinical evidence syntheses used to justify major clinical or regulatory changes. The limitations in the HHS Review reinforce the need for continued, individualized clinical decision-making, improved data collection, and ongoing evaluation—not a categorical prohibition. A federal prohibition without robust scientific consensus risks undermining patient-centered care and sets a concerning regulatory precedent.

Further, we are concerned that the scope of the proposed CoP exceeds the intended procedural focus. Although characterized as a child safety measure, its operational impact would reverberate across the entire care continuum. Pediatric care is routinely managed across hospital and community settings. A blanket prohibition within hospital CoPs would fragment established care plans, disrupt coordination, and risk disengagement from trusted clinical environments, particularly for medically complex children.

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Findings from the 2025 KFF Tracking Poll reinforce that individual physicians remain the most trusted source of health information, surpassing federal agencies and public health officials. At a time when trust in healthcare officials is already low, this proposed rule risks further eroding this critical source of trust.[i]

These concerns are amplified when the proposed CoP is considered alongside the proposed Medicaid and CHIP prohibition on coverage for SRPs. Together, the rules would restrict services across both hospital settings *and* independent practices. By eliminating reimbursement pathways and layering new restrictions, the rules effectively block access to these services and place hospital- and community-based physicians in the untenable position of balancing regulatory compliance with their duty to provide the best available, evidence-based, and patient-centered care.

Additionally, the proposed rule's impact analysis shows that hospitals will face substantial administrative and operational costs if finalized. CMS estimates roughly $7 million in nationwide upfront costs for patient notifications and policy updates, and this figure does not account for reduced referrals, shifts in patient volume, or the burden on affiliated outpatient settings that must assess their CoP status. CMS also acknowledges that the proposed rule likely underestimates the full scope of transition-related costs. We agree. Beyond these initial burdens, the prohibition may disrupt multidisciplinary programs, research infrastructure, and integrated models of care. These effects may precipitate, impacting workforce recruitment, training pathways, and continuity of comprehensive services. Most critically, noncompliance with CoPs can result in termination from Medicare and Medicaid. Because these programs make up a substantial share of hospital revenue, no hospital can realistically withstand the loss of federal participation. Such a consequence would reverberate far beyond SRPs by destabilizing local care networks, reducing access across service lines, and straining the broader healthcare system. In effect, the rule leaves hospitals with no viable choice but to comply.

Thus, we respectfully urge CMS to withdraw this proposed rule. If CMS proceeds, the agency should at minimum allow patients already receiving SRPs to complete their current course of treatment, consistent with the option CMS noted it considered. Disruptions to longitudinal care delivery have been well-documented in driving poor health outcomes and higher downstream costs, including increased emergency department utilization, greater incidence of behavioral health crises, and heightened long-term care needs.[ii, iii] Instead, we encourage CMS to advance patient safety by collaborating with physicians and families to design care continuity pathways that preserve shared decision-making, respect state authority within statutory parameters, and ensure beneficiaries retain access to patient centered care.

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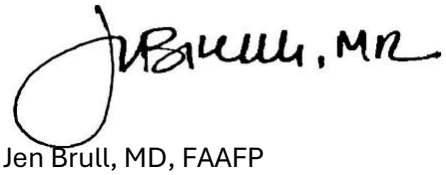
For additional questions, please contact David Tully, Vice President, Government Relations, AAFP at dtully@aafp.org.

Sincerely,



Jen Brull, MD, FAAFP
American Academy of Family Physicians, Board Chair

[i] Kearney, A., Sparks, G., Hamel, L., Montalvo III, J., Valdes, I., & Kirzinger, A. (2025, January 28). *KFF tracking poll on health information and trust: January 2025*. KFF. https://www.kff.org/health-information-trust/kff-tracking-poll-on-health-information-and-trust-january-2025/

[ii] Burch, P., Walter, A., Stewart, S. *et al.* Patient reported measures of continuity of care and health outcomes: a systematic review. *BMC Prim. Care* **25**, 309 (2024). https://doi.org/10.1186/s12875-024-02545-8

[iii] Goodwin JS. Continuity of Care Matters in All Health Care Settings. *JAMA Netw Open.* 2021;4(3):e213842. https://doi:10.1001/jamanetworkopen.2021.3842

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