CHILDREN'S HOSPITAL ASSOCIATION

February 17, 2026

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-3481-P
P.O. Box 8016
Baltimore, MD 21244-8016

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

The Children's Hospital Association (CHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) proposal to amend the hospital Conditions of Participation (CoPs) for the Medicare and Medicaid programs to prohibit participation by hospitals that offer certain types of gender-affirming care to youth (referred to in the proposed rule as "sex-rejecting procedures"). **We respectfully urge CMS to withdraw the proposed rule, which we believe exceeds CMS's authority and encroaches on states' authority to regulate health care providers and the practice of medicine. With the proposed rule, CMS seeks to override clinical decision-making and informed consent conversations with patients and families, even for patients who aren't covered by federally funded health care programs. In our view, the proposed rule, which attempts to convert the CoPs into a nationwide ban on disfavored services, is not supported by the statutory authorities.**

CHA's more than 200 members are dedicated to the health and well-being of our nation's children. Virtually all children's hospitals participate in Medicaid and Medicare. Any change in the CoPs that jeopardizes participation presents an extraordinary threat to funding and, therefore, access to care. At a typical children's hospital, more than 50% of the patients are covered by Medicaid/Children's Health Insurance Program (CHIP); at some hospitals, the figure is closer to 75%. By the same token, children's hospitals are vital to ensuring access for low- and middle-income children: Though children's hospitals account for less than 5% of hospitals in the United States, they account for about 45% of all hospital days for children on Medicaid.

We believe that medical decisions should be left to patients, their parents and families, and their doctors. However, because of the vital role that Medicaid and Medicare play in the financial sustainability of children's hospitals, CMS's proposed rule would effectively ban children's hospitals from furnishing gender-affirming care to youth, even in states where state law authorizes—or requires—the provision of these services, and even for youth whose families are not beneficiaries of federal health care programs. Further, the proposed rule does not contain any provisions for transitions of care, meaning that some patients and families would face an immediate restriction of a current, ongoing treatment plan if the proposed rules are finalized.

As described below, we believe the proposed rule has insufficient legal justification on two grounds. First, CMS lacks the authority to enact a nationwide ban on specific treatments using the hospital CoPs (as described in Section I, below).

Second, even if CMS had this authority in certain circumstances, we do not believe the proposed rule offers sufficient justification to do so here (Section II). CMS's cited evidence emphasizes uncertainty

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concerning the long-term benefits of treatment—a description that applies to many commonly prescribed health care interventions, particularly with respect to children and other subpopulations that are underrepresented in large clinical trials. This fact exposes the absence of any limiting principle in CMS's assertion of authority other than CMS's own weighing of the clinical evidence.

For these reasons, we respectfully urge CMS to withdraw the proposed rule. If, however, CMS finalizes a treatment ban under the CoPs, we respectfully urge CMS to include accommodations for transitions of care, both for existing hospital patients as of the final rule's effective date and for continuity of care during an inpatient stay (Section III).

I. CMS Lacks the Authority to Ban Specific Treatments Using the Conditions of Participation

Congress established various conditions that hospitals must satisfy to participate in the Medicare and Medicaid programs, and further authorized CMS to define "such other requirements as [CMS] finds necessary in the interest of the health and safety of individuals who are furnished services in the institution."[1] Congress cautioned, however, that "[n]othing in [the Medicare statutes] shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided…."[2]

As a matter of statutory interpretation and longstanding agency practice, these twin statutes authorize CMS to define certain types of procedural requirements that safeguard patient health and safety as a general matter. They do not, however, appear to us to allow CMS to entirely ban hospitals from performing specific types of treatment under the record shown in the proposed rule.

The statutory authorization for CoPs is limited to broadly applicable procedural requirements. Congress did not authorize CMS to broadly define any CoPs that might promote "health and safety" in some way. Rather, Congress enumerated a specific list of procedural requirements for participating hospitals—such as maintaining clinical records, bylaws for medical staff, 24-hour nursing coverage, a utilization review plan, and a statutorily specified discharge planning process—and then authorized CMS to define "such other requirements as [CMS] finds necessary in the interest of the health and safety."[3]

Under the statutory interpretation canon of *ejusdem generis*, "a general or collective term at the end of a list of specific items is typically controlled and defined by reference to the specific classes that precede it."[4] Thus, the reference to "such other requirements" should be interpreted consistent with the facility-wide procedural requirements enumerated in the preceding paragraphs.[5]

This interpretation draws further strength from the specific examples Congress provides of the types of CoPs that CMS might establish to ensure health and safety. To the extent CMS defines "personnel requirements" under this statute, Congress advised, the agency must "take into account the availability of technical personnel and the educational opportunities for technical personnel in the area in

[1] 42 U.S.C. § 1395x(e).
[2] *Id.* § 1395.
[3] *Id.* § 1395x(e).
[4] Fischer v. United States, 603 U.S. 480, 487 (2024) (internal quotation marks and alterations omitted).
[5] Certain CoPs are targeted to specific hospital departments, but nonetheless consist of broadly applicable procedural requirements.

which such facility is located."[6] Similarly, if CMS defines "fire and safety requirements," the agency may waive those conditions under certain circumstances.[7]

Nowhere did Congress give any indication that CMS could leverage this same provision to enact a ban on specific types of disfavored medical services. Quite the contrary: **Congress expressly admonished that CMS cannot use the Medicare program to "exercise any supervision or control over the practice of medicine or the manner in which medical services are provided."[8]**

By contrast, in other areas, Congress has expressly authorized CMS to weigh the clinical evidence. Consider the statutes defining the scope of covered Medicare services. When it comes to conditions on federal payment for specific services rendered to program beneficiaries—as opposed to conditions of participation that apply facility-wide to all patients—Congress delegated authority for CMS to make certain clinical judgments:

- As a general matter, Congress empowered CMS to issue National Coverage Determinations (NCDs) excluding coverage for services that are "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[9] Congress further established requirements for transparency and public comment in the development of NCDs.[10]
- Congress also directed CMS to establish nuanced clinical coverage standards for specific types of services, such as durable medical equipment and screening mammography.[11]

The Supreme Court generally presumes that "when Congress includes particular language in one section of a statute but omits it in another, Congress intended a difference in meaning."[12] **The above examples demonstrate that "Congress knows how" to authorize or require CMS to make targeted clinical assessments in the context of Medicare coverage; the absence of any such authorization in the CoP statutes weighs heavily against inferring that same authority under the catch-all for CoPs necessary for health and safety.[13]**

In its 2024 decision in *Loper Bright Enterprises v. Raimondo*, the Supreme Court declared that courts should no longer defer to reasonable agency interpretations of statutes, and should instead decide on a "single, best meaning."[14] **In light of the statutory text and statutory structure, we do not believe that the "single, best meaning" of the Medicare statute permits CMS to categorically ban entire classes of health care services that are permissible under certain state laws and chosen with the full informed consent of patients and families,** even if, in CMS's view, certain services offer an unfavorable risk/benefit profile. CMS might seek to exclude Medicare coverage for such services by following the statutorily prescribed NCD process—an express delegation of authority for CMS to engage in ad hoc

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[6] 42 U.S.C. § 1395x(e)(B).
[7] *Id.* § 1395x(e)(C).
[8] *Id.* § 1395.
[9] *Id.* § 1395y(a)(1).
[10] *Id.* § 1395y(l).
[11] *Id.* § 1395m(a)(E)(i) (CMS "shall establish standards for clinical conditions for payment" for durable medical equipment.), (c)(2)(B) (CMS, "in consultation with the Director of the National Cancer Institute, shall review periodically the appropriate frequency for performing screening mammography, based on age and such other factors as the Secretary believes to be pertinent.").
[12] Me. Cmty. Health Options v. United States, 140 S. Ct. 1308, 1323 (2020) (internal citations and quotation marks omitted).
[13] McGirt v. Oklahoma, 591 U.S. 894, 904 (2020).
[14] 603 U.S. 369, 400 (2024).

reviews of the clinical evidence.[15] But the CoP statute's broad reference to "health and safety" does not authorize CMS to reach outside the Medicare program and prohibit hospitals from furnishing services to any patient at all.

Two additional principles of statutory construction weigh against CMS's interpretation, which seeks to read a broad grant of authority into high-level language in a "catch-all" provision at the end of an enumerated list.

First, **courts expect Congress to speak clearly when intruding on areas of state authority.** Under the so-called "federalism canon," when an agency asserts the authority to regulate an area of historical state responsibility, courts "have generally declined to read federal law as intruding on that responsibility, unless Congress has clearly indicated that the law should have such reach."[16]

As the Supreme Court itself has recognized, "States have traditionally exercised primary responsibility over … the regulation of the practice of medicine."[17] In this instance, Congress included a clear statement in the opposite direction, expressly declaring that "[n]othing in [the Medicare statutes] shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided."[18] Indeed, in recent years, most states have embraced their authority to actively regulate the specific services at issue in the proposed rule, with some imposing targeted limitations[19] and others seeking to bolster access through anti-discrimination requirements[20] and targeted protections for patient confidentiality and for providers acting in accordance with state law.[21]

A second key principle of statutory interpretation is **the so-called "major questions" doctrine, under which courts "expect Congress to speak clearly when authorizing an agency to exercise powers**

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[15] *See id.* at 404 (explaining that when Congress "confer[s] discretionary authority on agencies," courts must "police the outer statutory boundaries of those delegations"). CHA does not concede that CMS could successfully exclude Medicare coverage for any specific treatment through an NCD; we offer this comparison merely to illustrate that Congress has, in other instances, created a process for CMS to weigh the clinical evidence. Notably, no such process exists for Medicaid coverage, as detailed in our letter commenting on CMS's proposed rule to bar federal financial participation for youth gender-affirming care in Medicaid.

[16] Bond v. United States, 572 U.S. 844, 848 (2014).

[17] Medina v. Planned Parenthood S. Atl., 606 U.S. 357, 364 (2025) (internal quotation marks omitted).

[18] 42 U.S.C. § 1395.

[19] *See, e.g.*, Ala. S.B. 184 (2022); Ark. H.B. 1570 (2021); Ariz. S.B. 1138 (2022); Fla. S.B. 254 (2023); Ga. S.B. 140 (2023); Iowa S.F. 538 (2023); Idaho HB71 (2023); Ind. Act No. 480 (2023); Kan. S.B. 63 (2025); Ky. S.B. 150 (2023); La. H.B. 648 (2023); Miss. H.B. 1125 (2023); Mo. S.B. 49 (2023); Neb. L.B. 574 (2023); N.C. H.B. 808 (2023); N.D. H.B. 1254 (2023); Ohio H.B. 68 (2024); Okla. S.B. 613 (2023); S.C. B. 4624 (2024); S.D. H.B. 1080 (2023); Tenn. S.B. 001 (2023); Tex. S.B. 14 (2023); Utah S.B. 16 (2023); W. Va. H.B. 2007 (2023); Wyo. S.F. 0099 (2024).

[20] *See, e.g.*, N.Y. Comp. Civ. R. & Regs. tit. 10, § 405.7; Cal. Ins. Code § 10140; Conn. Gen. Stat. § 46a-64; D.C. Code §§ 2-1402.31(a)(1); Del. Code Ann. tit. 6, §§ 4501-4, 4601-5; Haw. Rev. Stat. § 432:1-607.3; N.M. Stat. Ann. § 24-34-3(A); 23 R.I. Gen. Laws § 23-17-19.1; 28 R.I. Gen. Laws § 28-5.1-12; 220 R.I. Code R. 80-05-1.

[21] *See, e.g.*, Cal. Civ. Code § 56.109(a); Colo. S.B. 23-188 (2023); Conn. H.B. 5506, §§ 503-07 (2022); D.C. Act. No. 24-738 (2023); Ill. H.B. 4664, art. 28 (2023); Me. Laws. Ch. 648 (2024); Md. S.B. 119 (2024); Mass. Acts Ch. 127 (2022); Minn. Laws Ch. 29 (2023); N.M. S.B. 13 (2023); N.Y. Laws Ch. 143 (2022); N.Y. Laws Ch. 101 (2024); Ore. H.B. 2002 (2023); R.I. H.B. 7577 (2024); Vt. Act No. 14 (2023); Vt. Act No. 15 (2023).

of vast economic and political significance."[22] Authorizing CMS to entirely prohibit disfavored medical services likely qualifies as a question of vast political significance, particularly in light of the states' historical primacy in regulating the practice of medicine.[23] Indeed, the Department of Health & Human Services (HHS) asserted that the current debate over access to gender-affirming care is "deeply cultural and political," noting further that the "public discourse is dominated by intensely polarizing narratives."[24]

The federalism canon and the major questions doctrine add yet more weight to the conclusion that, by authorizing CMS to establish CoPs "necessary in the interest of the health and safety" of hospital patients, Congress intended for CMS to establish facility-wide process requirements. Congress does not appear to have given CMS the authority to promulgate the proposed rule.

II. CMS's Proposed Rule Lacks Sufficient Justification and a Clear Limiting Principle

To the extent that CMS has the authority to ban specific procedures under this CoP standard—a claim we do not believe is supported by statutory authority, as noted above—a more articulated showing of the risks for the treatment should be developed. Failure to do so would allow for an unbounded precedent that could be used to place other restrictions on care.

In the proposed rule, CMS asserts that prohibiting specific types of care for specific populations is "necessary to protect the health and safety of children" based on "HHS' review of recent information on the safety and efficacy" of these procedures.[25] As justification, it is stated that these services present an unfavorable risk/benefit ratio because the "evidence for benefit of pediatric medical transition is very uncertain"—based in part on HHS's rejection of studies showing clinical benefit on the grounds that they were low quality—"while the evidence for harm is less uncertain."[26]

At face value, **this emphasis on uncertainty appears to undermine any claim that an outright ban on these procedures is necessary to protect the health and safety of young people.**

Clinical trials are more difficult to conduct for pediatric populations where blinding and randomized trials may not be feasible or ethical. As a result, **many commonly prescribed health care services lack robust evidence meeting the gold-star standard of large, double-blind, randomized controlled trials.** A 2020 review, for example, found that only one in ten medical treatments was supported by a high-quality evidence base.[27]

Moreover, even where robust studies exist, they typically focus on a carefully selected subpopulation to avoid confounding factors. **The evidence base is thus even less certain for groups that are commonly left out of the most robust clinical trials—including children.** One review article recently observed that "there are far too few clinical studies on children," and that "[c]ompared to trials in adults,

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[22] Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs., 594 US 758, 764 (2021) (internal quotation marks omitted).
[23] *See* W. Virginia v. Env't Prot. Agency, 597 U.S. 697, 744 (2022) (Gorsuch, J., concurring) ("Unsurprisingly, the major questions doctrine and the federalism canon often travel together" because overbroad assertions of executive authority "risk[] intruding on powers reserved to the States.")
[24] HHS OFF. OF POPULATION AFFS., TREATMENT FOR PEDIATRIC GENDER DYSPHORIA: REVIEW OF EVIDENCE AND BEST PRACTICES, at 10 (Nov. 19, 2025) [hereinafter "TREATMENT FOR PEDIATRIC GENDER DYSPHORIA"].
[25] 90 Fed. Reg. at 59463.
[26] TREATMENT FOR PEDIATRIC GENDER DYSPHORIA at 15; 90 Fed. Reg. at 59470 (weighing "known complications" against "weak and uncertain evidence of benefits").
[27] Jeremy Howick et al., *The Quality of Evidence for Medical Interventions Does Not Improve or Worsen: A Metaepidemiological Study of Cochrane Reviews*, 126 J. CLINICAL EPIDEMIOLOGY 154 (Oct. 2020).

pediatric trials" tend to be "rather small-scaled."[28] If CMS seeks to ban care based solely on inadequate "outcomes data on safety and long-term effectiveness,"[29] then many other well-established treatments could be vulnerable to similar targeted bans in the future.

Every day, clinicians exercise their medical judgment to make individualized recommendations based on the best evidence available combined with their clinical training, their experience treating prior patients, and conversations with colleagues. A treatment that works well for one patient may not work for another. Similarly, two patients with identical clinical profiles may make different informed choices about their care due to differences in their values, including how they and their families personally weigh the risks and potential benefits of each course of action.

With the proposed rule, CMS seeks to override clinical decision-making and informed consent conversations with patients and families, even for patients who aren't covered by federally funded health care programs. In our view, the proposed rule, which attempts to convert the CoPs into a nationwide ban on disfavored services, is not supported by the statutory authorities.

III. If CMS Finalizes a Ban on Specific Treatments, the Rule Should Allow for Transitions of Care to Protect Patient Wellbeing

Transitions of care are essential when a provider is no longer able to treat an existing patient. As a matter of medical ethics—and, in some cases, legal obligation—providers cannot abandon patients on short notice during an active course of treatment. If the provider is unable to continue an existing treatment plan, for whatever reason, the provider has a responsibility to reduce harm to the patient during the transition period. This responsibility applies with particular force to treatments—including chronic medications and surgeries requiring post-operative management—that present material health risks if a patient were to suddenly lose access to their regular provider.

A transition period of at least twelve months is necessary to protect health and safety. If CMS concludes that a ban on specific hospital treatments is necessary for health and safety—which we believe CMS lacks authority to implement, as described above—the final rule should consider the detrimental health and safety impacts for patients who are in active treatment at the time the rule is finalized. To that end, we urge CMS to allow continuation of care for existing patients or a grace period of at least twelve months following the rule's effective date, allowing hospitals to amend treatment plans and arrange referrals as needed to reduce harm to their existing patients. By way of example, in states that have established state-level restrictions on gender-affirming care as part of their regulation of the practice of medicine, newly enacted laws commonly allow existing patients to continue receiving services for a

[28] Veronika Bencheva et al., *Barriers and Facilitators to Enrollment in Pediatric Clinical Trials: An Overview of Systematic Reviews*, 13 SYSTEMATIC REVS. 283 (2024); *see also* Am. Soc'y of Hematology, *Adolescents and Minority Groups Underrepresented in Cancer Clinical Trials* (Oct. 2016), https://ashpublications.org/ashclinicalnews/news/2663/Adolescents-and-Minority-Groups-Underrepresented ("Adolescent and young adult (AYA) patients, defined as those between the ages of 15 and 29 years … are often under-represented in clinical trials of novel agents in hematologic malignancies.").

[29] 90 Fed. Reg. at 59470.

period of six to twelve months,[30] or as long as the treating physician determined was necessary in their professional judgment.[31]

Hospitals should also be permitted to maintain existing medication regimens for inpatients in active treatment. To ensure safety and promote whole-person care for inpatients, hospitals typically manage the patients' medications during their stay, including existing prescriptions that are not directly related to the reason for the patient's admission. Under the current proposed rule, patients would remain able to seek prohibited treatment from non-hospital providers; however, if a patient in active treatment were hospitalized, the hospital would be unable to take responsibility for managing all of the patient's medications, even if immediate cessation of certain medications would jeopardize the patient's health. Thus, if CMS finalizes the proposed rule, we urge CMS to create an exception allowing hospitals to manage existing prescriptions for admitted inpatients, even where the CoPs would not permit the hospital to initiate or maintain those medications on an outpatient basis.

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We appreciate the opportunity to provide comments on the proposed rule. For the reasons set forth above, we respectfully urge CMS to withdraw the rule. Children's hospitals cannot support policies that unduly encroach on states' authority to regulate the practice of medicine and patients' and their parents' and families' ability to determine with their clinicians the most appropriate treatment plans. Please contact Aimee Ossman at aimee.ossman@childrenshospitals.org or 202-753-5500 with any questions.

Sincerely,



Blake Schofield
General Counsel

[30] *See, e.g.*, Ind. Code § 25-1-22-13(d) (six months); Kan. Laws Ch. 1, § (3)(d) (ten months); La. Rev. Stat. § 40:1098.2(D) (one year); 63 Okla. Stat. Ann. § 2607.1(A)(2)(b)(7) (six months); S.C. Code § 44-42-320(D) (six months); S.D. Codified Laws § 34-24-38 (six months); Tenn. Stat. Ann. § 68-33-103(b)(1)(B) (nine months).

[31] *See, e.g.*, Ky. Rev. Stat. Ann. § 311.372(6) ("a period during which the minor's [treatment] is systematically reduced"); Tex. Health & Safety Code § 161.703(b)-(c) ("over a period of time and in a manner that is safe and medically appropriate and that minimizes the risk of complications"); Ohio Code Ann. § 3129.02(B) (no endpoint; exception available when "terminating the [treatment] would cause harm to the minor individual"); Mo. Rev. Stat. § 191.1720(4)(2) (no endpoint; exception available for any patient who was receiving treatment before enactment of the statute).