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.

* * *

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).

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

The Children's Hospital Association (CHA) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS's) proposed rule to prohibit federal financial participation (FFP) for gender-affirming care for youth[1] in Medicaid and the Children's Health Insurance Program (CHIP). **We respectfully urge CMS to withdraw the proposed rule, which we believe exceeds CMS's authority and encroaches on states' authority to determine the scope of coverage under their Medicaid state plans. With the proposed rule, CMS seeks to override clinical decision-making and informed consent conversations with patients and families by prohibiting funding for the entire class of services. In our view, the proposed rule, which attempts to limit coverage for 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. At a typical children's hospital, more than 50% of the patients are covered by Medicaid/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. That goal is best served when patients have robust health coverage for all medically necessary services recommended by their provider. However, CMS's proposed rule would force many states to choose between restricting access to gender-affirming care for low- and middle-income youth or making up the loss of federal dollars with state funds.

As described below, we believe the proposed rule has insufficient legal justification on two grounds. First, the statutes cited in the proposed rule do not authorize CMS to selectively bar FFP for disfavored treatments, either as to Medicaid (see Section I, below) or CHIP (Section II).

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 III). CMS's cited evidence emphasizes uncertainty 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.

[1] CMS's proposed rule uses the term "sex-rejecting procedures" to refer to gender-affirming medications and procedures.

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For these reasons, we respectfully urge CMS to withdraw the proposed rule.

I. In Medicaid, CMS Lacks Authority to Bar FFP for Specific Treatments Based on Ad Hoc Clinical Assessments

Congress has detailed baseline requirements for states' Medicaid plans, including the two statutes that CMS cites as the authority underlying the proposed rule: States must provide safeguards to ensure that eligibility decisions and services are administered "in a manner consistent with simplicity of administration and the best interests of" Medicaid enrollees (section 1902(a)(19) of the Social Security Act),[2] and must "assure that [provider] payments are consistent with efficiency, economy, and quality of care" (section 1902(a)(30)(A)).[3] As a matter of statutory interpretation and longstanding agency practice, these laws do not permit CMS to categorically ban FFP for specific types of treatment based on CMS's own ad hoc weighing of the clinical evidence.

Medicaid is a cooperative federal-state program. Congress defined a mix of mandatory and optional benefits, as well as express limitations on FFP for specific types of services in specific scenarios.[4] CMS must approve any state plan amendment that complies with these federal requirements.[5] In addition to defining the services for which FFP is available, Congress enacted various requirements for Medicaid program administration, such as quality oversight provisions.

Gender-affirming care is not a defined benefit under federal law; rather, relevant services fall within broad benefit categories such as hospital inpatient, hospital outpatient, physician, or clinic services. Within these broad benefit categories, **the Supreme Court has emphasized that states have "substantial discretion to choose the proper mix of amount, scope, and duration limitations on coverage,"** subject to compliance with federal requirements for minimum coverage and FFP limitations.[6] Congress expressly prohibited FFP for certain types of abortion services via the Hyde Amendment, for example. The Medicaid statutes enumerate other excluded services such as prosthetics and medications for "sexual or erectile disfunction," as well as state spending on "roads, bridges, [and] stadiums."[7]

Section 1902(a)(19) authorizes CMS to define procedural guardrails; it does <u>not</u> authorize CMS to exclude FFP for disfavored services. This section provides that a Medicaid state plan must "provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients."

By simultaneously addressing the "manner" for both making eligibility determinations and delivering services, and by directing states to balance the often-competing goals of "simplicity of administration" and "best interests of the recipients," this statute plainly contemplates <u>procedural</u> protections against inefficiency and error.

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[2] 42 U.S.C. § 1396a(a)(19); *see also id.* § 1302 (enabling CMS to publish rules for oversight of state Medicaid programs).
[3] *Id*. § 1396a(a)(30)(A); *see also* 42 U.S.C. § 1302 (enabling CMS to publish rules for oversight of state Medicaid programs).
[4] *See, e.g.*, *id.* §§ 1396a(a)(10) (identifying mandatory benefits), 1396b(i) (defining FFP exclusions), 1396d (defining various benefits under the state plan), 1396r-8(d) (defining permissible limits on coverage of prescription drugs).
[5] *Id*. § 1396n(f)(2); *see also id.* § 1316(a)(1).
[6] Pharm. Rsch. & Mfrs. of Am. v. Walsh, 538 U.S. 644, 665 (2003).
[7] 42 U.S.C. 1396b (i)(12), (17), (21).

We do not read this statute as authorizing CMS to define targeted coverage exclusions on an ad hoc basis. This plain reading is reinforced by the structure of the Medicaid statutes, which contain separate provisions expressly defining minimum coverage requirements, optional coverage extensions, and FFP exclusions, as noted above. Moreover, we are concerned that the precedent of reading this statute so broadly would allow for essentially unbounded discretion to terminate coverage for an array of treatments, as described below in Section III.

CMS has, moreover, historically interpreted section 1902(a)(19) consistent with this understanding, citing the "best interests" standard as a basis for defining procedural protections such as maximum timeframes and verification requirements for eligibility determinations.[8] Although courts will no longer defer to agency interpretations, the Supreme Court has advised that agency interpretations that "have remained consistent over time, may be especially useful in determining the statute's meaning."[9]

Section 1902(a)(30)(A) establishes limits on fee-for-service provider payment levels; it does <u>not</u> authorize CMS to exclude FFP for disfavored services. This section directs state plans to:

> "provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan … to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area."

On its face, this statute doesn't address the scope of Medicaid coverage at all. Rather, it regulates the maximum amount that states may pay their providers for furnishing covered services. Moreover, CMS has historically interpreted this statute as applying only to payments under the <u>fee-for-service</u> delivery system, and has relied on other authorities to regulate state directed payments under managed care—the dominant delivery system for Medicaid-covered children.[10] The "single, best meaning" of this statute[11] does not provide any authority for CMS to establish limits on FFP for coverage of specific services.

Two other statutes constrain CMS's ability to restrict Medicaid coverage on an ad hoc basis.

- ***Early and Periodic Screening, Diagnosis, and Treatment (EPSDT)***. To ensure that Medicaid offers comprehensive coverage for children and youth under the age of 21, Congress required

[8] *See, e.g.*, CMS, Medicaid Program; Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility Determination, Enrollment, and Renewal Processes, 89 Fed. Reg. 22780, 22792–93 (Apr. 2, 2024) (authorizing alignment of enrollment and renewal processes between individuals whose financial eligibility is based on MAGI and non-MAGI methodologies); CMS, Medicaid Program; Ensuring Access to Medicaid Services, 89 Fed. Reg. 40542, 40567, 40573, 40599, 40641–42 (May 10, 2024) (authorizing procedures for home and community-based services (HCBS) programs, such as annual reassessments of functional need and updates to person-centered services plans, grievance systems, incident management systems, and quality measure reporting).
[9] Loper Bright v. Raimondo, 603 U.S. 369, 394 (2024).
[10] *See, e.g.*, CMS, Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality, 89 Fed. Reg. 41002, 41069 n.114 (May 10, 2024).
[11] Loper Bright, 603 U.S. at 400 (reversing the *Chevron* doctrine of judicial deference to reasonable agency interpretations of ambiguous statutes, and instead directing courts to determine the statute's "single, best meaning").

states to cover all "necessary health care, diagnostic services, treatment, and other measures … to correct or ameliorate defects and physical and mental illnesses and conditions."[12]

- CMS has consistently maintained that states must cover all services deemed medically necessary for an individual child or youth, subject to the Medicaid program's overarching limitations on FFP for excluded services.[13] Historically, CMS has chosen not to establish a federal definition for "medical necessity" under EPSDT, instead directing each state to establish its own process for assessing medical necessity while emphasizing the breadth of the EPSDT requirement and the importance of individualized clinical assessments.[14]
- In the proposed rule, CMS seeks to add a new excluded service based on CMS's own weighing of the medical evidence. Effectively, CMS has declared that certain gender-affirming services are never medically necessary for any young person. This claim is not supported by CMS's own cited evidence, as discussed below in Section III. But it also encroaches on the EPSDT statute's requirement for individualized determinations of medical necessity.

- ***Covered Outpatient Drugs.*** Section 1927 of the Social Security Act requires state Medicaid programs to cover all "medically accepted indications" for covered outpatient drugs, subject to certain limited exceptions.[15]

  - Medically accepted indications include all drug uses listed on the drug label as approved by the Food and Drug Administration (FDA), as well as all off-label indications "supported by one or more citations included or approved for inclusion" in one of the following published compendia of evidence-based drug use: the American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, and the DrugDex Information System.[16]
  - In the proposed rule, CMS notes that "there is no pharmaceutical that is solely indicated" for gender-affirming care. But CMS fails to acknowledge that the statutorily enumerated compendia include certain evidence-based indications for hormone replacement therapy and puberty blockers. Thus, even if CMS had the authority to exclude FFP for certain services under sections 1902(a)(19) and (30)(A)—a claim we vigorously dispute—CMS would nonetheless lack authority to override section 1927's express requirement to cover "medically accepted indications" for covered outpatient drugs.

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[12] 42 U.S.C. §§ 1396a(a)(10), 1396d(a)(4)(B) & (r).
[13] *See generally* CMS, EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents (June 2014), https://www.medicaid.gov/medicaid/benefits/downloads/epsdt-coverage-guide.pdf [hereinafter "EPSDT Guide"]; CMS, State Health Official Letter: Best Practices for Adhering to EPSDT Requirements (2024), https://www.medicaid.gov/federal-policy-guidance/downloads/sho24005.pdf [hereinafter "EPSDT Best Practices"].
[14] EPSDT Guide at 23-24; EPSDT Best Practices at 7, 21, 26, 41.
[15] 42 U.S.C. 1396r-8(d)(1) & (4). This coverage requirement applies to states that have elected the optional benefit for covered outpatient drugs (as all have), and to drugs whose manufacturer has executed a Medicaid drug rebate agreement with CMS (as all relevant manufacturers have). Federal statute defines certain classes of drugs that states may exclude from coverage, such as drugs used for "cosmetic purposes or hair growth." *Id.* § 1927(d)(2). In addition, a state may exclude coverage for a medically accepted indication if the "excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for [a particular] population over other drugs included in the formulary." *Id.* § 1396r-8(d)(4)(C).
[16] *Id.* § 1395r-8(k)(6) (cross-referencing the compendia at *id.* § 1396r-8(g)(1)(B)).

By contrast, under the Medicare program, Congress has expressly authorized CMS to define targeted coverage exclusions after weighing the clinical evidence. When Congress passed the Medicare and Medicaid Act in 1965, Congress defined two very different structures for program administration. Whereas each state operates its own Medicaid program within broad federal constraints, Medicare is administered solely at the federal level. Congress consequently afforded CMS much greater authority to define and revise Medicare's precise coverage standards—an authority that, in Medicaid, largely falls to the states. Consider the following Medicare statutes:

- 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."[17] Congress further established requirements for transparency and public comment in the development of NCDs.[18]
- Congress also directed CMS to establish nuanced clinical coverage standards for specific types of services, such as durable medical equipment and screening mammography.[19]

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."[20] **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 Medicaid statutes weighs heavily against inferring that same authority under high-level standards related to efficient program administration and appropriate fee-for-service provider payment levels.[21]**

In light of the statutory text and statutory structure, it cannot be said that the "single, best meaning" of Medicaid's "best interests" and "quality of care" standards permits CMS to categorically ban entire classes of healthcare services that are permissible under state law and chosen with the full informed consent of patients and families. That remains so even if, in CMS's view, certain services offer an unfavorable risk/benefit profile.

It is noteworthy that **CMS has <u>never</u> previously asserted the authority to exclude FFP for specific services under these Medicaid statutes.** Congress can and has excluded FFP for certain services via statute, as described above. However, the sole example of a <u>regulatory</u> coverage exclusion is CMS's framework governing informed consent for sterilizations. Those regulations, however, were rooted in the statutory definition of covered "family planning services."[22] Based on that language—as interpreted in a court opinion—CMS defined a federal standard for informed consent for family planning services.[23] That

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[17] *Id.* § 1395y(a)(1).
[18] *Id.* § 1395y(l).
[19] *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.").
[20] Me. Cmty. Health Options v. United States, 140 S. Ct. 1308, 1323 (2020) (internal citations and quotation marks omitted).
[21] McGirt v. Oklahoma, 591 U.S. 894, 904 (2020).
[22] 42 U.S.C. § 1396d(a)(4)(C) (specifying that covered family planning services may be offered only to individuals "who desire such services").
[23] *See* Public Health Service, Provision of Sterilization in Federally Assisted Programs of the Public Health Service, 43 Fed. Reg. 52146, 52146–47 (Nov. 8, 1978) (incorporated by reference in CMS' regulations on Medicaid coverage for sterilization at Health Care Financing Administration [CMS' predecessor agency], Federal Financial Participation in State Claims for Sterilization, 43 Fed. Reg. 52171, 5271

statutory authority is inapplicable here, as no one contends that gender-affirming care is a form of "family planning." Nor has any court interpreted any Medicaid statute in a manner that would allow ad hoc service exclusions based on CMS's view of the clinical evidence.

Finally, **under the so-called "major questions" doctrine, courts "expect Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance."**[24] Although gender-affirming care represents only a fraction of a percent of overall Medicaid spending, the Medicaid program overall represents the single largest source of federal funding for states and covers almost 40% of all children and youth under the age of 19.[25] CMS's assertion of the authority to exclude coverage for disfavored medical services likely qualifies as a question of vast political significance. 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."[26]

For all these reasons—statutory text, statutory structure, and longstanding agency interpretation—the Medicaid statutes do not appear to have given CMS authority to categorically exclude FFP for specific types of services based on an ad hoc review of the clinical evidence.

II. In CHIP, CMS Similarly Lacks Authority to Bar FFP for Specific Treatments Based on Ad Hoc Clinical Assessments

Congress afforded states even greater flexibility in separate CHIPs than under Medicaid. Congress established CHIP in 1997 to support states in extending health coverage to uninsured children above the income threshold for Medicaid. States can choose between using CHIP funds to expand eligibility under Medicaid or designing a separate CHIP program that is subject to some, but not all, of the same federal requirements as Medicaid. "[S]tates with separate CHIP programs have greater flexibility around the design of their benefit packages … than is available for children in Medicaid," in the words of the Medicaid and CHIP Payment and Access Commission, a nonpartisan legislative branch agency.[27]

The Medicaid statute enumerates a finite list of mandatory and optional benefits, as described above. By contrast, **Congress expressly authorized separate CHIPs to cover "any other [medical services] recognized by State law,"** beyond those enumerated in the CHIP statute.[28] This provision prohibits CMS

(Nov. 8, 1978)); *see also* Relf v. Weinberger, 372 F. Supp. 1196, 1202 (D.D.C. 1974), vacated on other grounds, 565 F.2d 722 (D.C. Cir. 1977).

[24] Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs., 594 U.S. 758, 764 (2021) (internal quotation marks omitted).

[25] Elizabeth Williams et al., *Medicaid Financing: The Basics*, KFF (Jan. 29. 2025), https://www.kff.org/medicaid/medicaid-financing-the-basics/ (citing NAT'L ASS'N OF STATE BUDGET OFFICERS, STATE EXPENDITURE REPORT (2024), https://www.nasbo.org/reports-data/state-expenditure-report); KFF, *Health Insurance Coverage of Children 0-18*, 2024, https://www.kff.org/state-health-policy-data/state-indicator/children-0-18/ (last accessed Jan. 22, 2026).

[26] HHS OFF. OF POPULATION AFFS., TREATMENT FOR PEDIATRIC GENDER DYSPHORIA: REVIEW OF EVIDENCE AND BEST PRACTICES, at 10 (Nov. 19, 2025), https://opa.hhs.gov/sites/default/files/2025-11/gender-dysphoria-report.pdf [hereinafter "TREATMENT FOR PEDIATRIC GENDER DYSPHORIA"].

[27] Medicaid & CHIP Payment & Access Comm'n, *Overview of the State Children's Health Insurance Program*, in REPORT TO THE CONGRESS ON MEDICAID AND CHIP (Mar. 2011), https://www.macpac.gov/wp-content/uploads/2011/03/Overview-of-the-State-Childrens-Health-Insurance-Program.pdf.

[28] 42 U.S.C. § 1397jj(a)(24). To qualify under this provision, a service must be prescribed or supervised by a qualified health care practitioner or performed in a licensed health care facility.

from excluding FFP for any medical services "recognized by state law" unless CMS can point to a clear basis for exclusion elsewhere in the CHIP statutes. No such basis exists.

Neither of the statutes cited for CMS's Medicaid proposed rule apply to separate CHIPs. Section 2107(e) of the Social Security Act makes various Medicaid statutes applicable to separate CHIPs, but that list does not include sections 1902(a)(19) or (30)(A), the two statutes that underpin CMS's proposed FFP exclusion in Medicaid.[29] Thus, even if those statutes authorized Medicaid FFP exclusions—and they do not—CMS would still need to identify an independent source of authority to carry those exclusions into separate CHIPs.

No CHIP provision authorizes CMS to categorically bar FFP for disfavored services. In the proposed rule, CMS cites three potential legal bases, none of which provides the necessary authority, especially when analyzed through the lens of *Loper Bright*'s directive to identify the "single, best meaning" of any statute, as well as the major questions doctrine (as discussed above in Section I).

- CMS points to two phrases contained in the provision defining CHIP's statutory purpose: Funding state-administered health coverage "to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children."[30]
    - ***"Effective and efficient" program administration.*** This echoes the high-level standards discussed above for Medicaid, and in similar fashion, CMS has historically relied on this provision to define procedural safeguards for CHIP beneficiaries and for program integrity.[31] It should not be read as an implied exception to Congress's authorization for states to cover "any other" medical service recognized under state law.
    - ***"Coordinated with other sources of health benefits."*** This phrase, too, has historically been cited as a basis for procedural safeguards and accountability measures that align with Medicaid and other programs.[32] Moreover, the fact that CMS has sought to prohibit federal funding for gender-affirming care in Medicaid and in plans offered on the Marketplace does not justify extending a similar FFP exclusion to separate CHIPs because, unlike those programs, CHIP contains an express authorization for states to cover "any other" service recognized under state law, regardless of whether such service is covered under Medicaid or the Marketplace's Essential Health Benefits.

- ***"Secretary-approved coverage."*** In addition to enumerating objective benchmarks for defining the scope of coverage under a separate CHIP (such as the state's Medicaid program or the state employee health plan), Congress authorized CMS to approve state-developed coverage packages that "provides appropriate coverage for the population of targeted low-income

[29] *Id.* § 1397gg(e).
[30] *Id.* § 1397aa(a).
[31] For example, CMS has cited this provision to strengthen beneficiary protections with respect to eligibility and enrollment, and to heighten financial accountability for managed care organizations. CMS, Medicaid Program; Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility Determination, Enrollment, and Renewal Processes, 89 Fed. Reg. 22780 (Apr. 2, 2024); CMS, Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality, 89 Fed. Reg. 41002 (May 10, 2024).
[32] 89 Fed. Reg. 22780; CMS, Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers, 85 Fed. Reg. 25510 (May 1, 2020).

children."[33] In the proposed rule, CMS asserts its right to exercise "discretion" over the approval of such packages. However, that discretion does not include the authority to override Congress's authorization for states to cover "any other" medical service. And indeed, CMS's regulation implementing this provision lists examples of permissible benefit packages, all of which are at least as comprehensive as the other options for coverage benchmarks.[34]

As under Medicaid, when reading the statutory text in the context of the statutory structure, we do not believe any of CMS's cited authorities permit ad hoc FFP exclusions in separate CHIPs.

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

To the extent that CMS has the authority to limit coverage for specific procedures using high-level standards for program administration—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 a need to prohibit FFP for gender-affirming care for youth to protect Medicaid and CHIP beneficiaries, based on the findings of HHS's 2025 report weighing the clinical evidence. 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."[35] CMS's preamble echoes that "current evidence… does not conclusively support the use of sex-rejecting procedures to treat gender dysphoria in children."[36]

At face value, **this emphasis on uncertainty appears to undermine any claim that the proposed FFP exclusions are necessary to protect beneficiaries.**

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.[37]

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, pediatric trials" tend to be "rather small-scaled."[38] If CMS seeks to ban care based solely on inadequate

[33] 42 U.S.C. § 1397cc(a).
[34] *See, e.g.*, 42 C.F.R. § 457.450(d) (Secretary-approved coverage "may include … [c]overage that includes benchmark health benefits coverage, as specified in § 457.420, plus any additional coverage.").
[35] TREATMENT FOR PEDIATRIC GENDER DYSPHORIA at 15; CMS, Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children, 90 Fed. Reg. 59441, 59470 (Dec. 19, 2025) (weighing "known complications" against "weak and uncertain evidence of benefits").
[36] 90 Fed. Reg. at 59454.
[37] 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).
[38] 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,

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"outcomes data on safety and long-term effectiveness,"[39] 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 practice consistent with Congress's EPSDT mandate for Medicaid coverage. 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 by prohibiting funding for the entire class of services. In our view, the proposed rule, which attempts to limit coverage for disfavored services, is not supported by the statutory authorities.

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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 interfere with states' authority to determine the amount and scope of Medicaid and CHIP coverage 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

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.").

[39] 90 Fed. Reg. at 59470.