American Hospital Association™
Advancing Health in America

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February 17, 2026

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

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

Dear Administrator Oz:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinical partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on this proposed rule.

The AHA is the national organization that represents and serves all types of hospitals, as well as their patients and communities. Through its representation and advocacy activities, the AHA ensures that its members' perspectives and needs are heard and addressed in national health policy development, legislative and regulatory debates, and judicial matters. The AHA does not provide clinical guidance, and so the AHA does not produce treatment guidelines, medical studies, or other materials on what the proposed rule calls "sex-rejecting procedures" for minors. This letter therefore does not address those procedures, and the AHA takes no position on their "safety, efficacy, and propriety." *United States v. Skrmetti*, 605 U.S. 495, 525 (2025).

Instead, the AHA writes to offer a general word of caution about expanding the Medicare Conditions of Participation (CoP) to forbid (or, for that matter, require) particular treatments for particular diagnoses. To the best of our knowledge, the Centers for Medicare & Medicaid Services (CMS) has never promulgated a CoP like that. The AHA has done its best to review the entire history of the CoPs — from their statutory enactment in the Social Security Amendments of 1965 through the present day — and we have not identified a prior CoP that barred (or mandated) a particular treatment for a particular diagnosis.

The AHA has long raised concerns about expanding the CoPs to bar or mandate particular treatments. In 2011, for example, CMS proposed a CoP that would have required hospitals to provide all patients an annual influenza vaccination, unless medically contraindicated or unless the patient or patient's representative or surrogate declined vaccination. *See* Medicare & Medicaid Programs; Influenza Vaccination Standard for Certain Participating Providers and Suppliers, 76 Fed. Reg. 25460 (May 4, 2011). CMS never finalized the rule — itself a telling data point. And that is exactly what the AHA recommended. We explained in our comment letter:

> We believe that it is inappropriate to use the Medicare and Medicaid conditions of participation (CoPs) for these purposes. According to CMS, the CoPs are "minimum standards for patient health and safety, and CoPs focus on creating a foundation to ensure quality and safe care for beneficiaries throughout a given facility." In other words, the CoPs are supposed to articulate the processes and structures hospitals should have in place to ensure safe and effective delivery of the services they have chosen to provide, not introduce requirements for expanded services.

American Hospital Association, Comment Letter on Influenza Vaccination Standard for Certain Medicare Participating Providers and Suppliers at 2 (CMS-3213-P) (July 1, 2011); *see id*. at 3 (distinguishing the proposed influenza vaccine CoP from a "fire safety" CoP).

The AHA's concerns today are the same as they were 15 years ago: There are serious questions *whenever* CMS proposes to expand the scope of CoPs to address particular treatments. So, just like then, we encourage CMS to be mindful that finalizing the proposed rule could be the first step down a slippery slope. One can imagine a host of other particular treatments for particular diagnoses that could be banned (or mandated) in the future via CoPs. And if this rule is finalized, there may be nothing to stop future administrations from turning around and mandating the same procedures that this Administration would bar. That has never been — and never should be — the role of CoPs, especially if it leads to a continual back-and-forth across administrations over what specific medical procedures hospitals can, cannot or must provide. Relatedly, the specific medical treatments or diagnoses most likely to draw CMS' attention would be those, like this one, that are most caught up in political crosscurrents. But political considerations should never dictate the practice of medicine, as CMS appears to agree. After all, the proposed rule itself recognizes the dangers of allowing "political pressures" to affect medical judgments. 90 Fed. Reg. 59,471; *see also* U.S. Department of Health and Human Services, *Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices* at 14, 181-85 (Nov. 19, 2025), *at* https://opa.hhs.gov/gender-dysphoria-report.

For all these reasons, the AHA asks CMS to carefully weigh the precedent it will set when it decides whether to finalize this novel CoP.[1]

A. The Proposed Condition of Participation Appears To Be Unprecedented

Since 1965, CMS has used its CoP-setting authority to impose certain minimum process, structure and standards requirements to ensure the health and safety of patients and the quality of care in the nation's hospitals. To the best of our knowledge, it has not used those CoPs to regulate particular treatments for particular diagnoses. To do so in *any* context would be a departure from CMS' longstanding practice, including how CMS has viewed the scope of CoPs since they underwent a major revision in 1986.

The CoPs that were in place from 1965 through 1986 were largely "measures of organizational and clinical capacity, such as staff qualifications, written policies and procedures, and committee structure. These were usually specified at the standard level." Inst. of Med. (US) Comm. to Design a Strategy for Quality Rev. & Assurance in Medicare, MEDICARE: A STRATEGY FOR QUALITY ASSURANCE, VOLUME 1: HOSPITAL CONDITIONS OF PARTICIPATION IN MEDICARE, *at* https://www.ncbi.nlm.nih.gov/books/NBK235451//. Those early CoPs did not address particular medical treatments for particular medical diagnoses.

Under the 1965 legislation, moreover, hospitals that were accredited by the Joint Commission on the Accreditation of Healthcare Organizations were automatically "deemed" to meet all the health and safety requirements for participation; in fact, the 1965 Act affirmatively prohibited the federal government from imposing any requirements on such hospitals that were stricter than the Joint Commission's. *See* Social Security Amendments of 1965, Pub. L. No. 89-97, § 102(a), § 1865, 79 Stat. 286, 326-27. The AHA has reviewed the Joint Commission's 1964 and 1965 "Standards for Hospital Accreditation," and *none* addressed particular medical treatments for particular medical diagnoses. That, too, offers compelling evidence of Congress' understanding, at the time of enactment, of the permissible scope of the CoPs and HHS' authority

[1] The AHA does not intend to separately comment on CMS' other proposed rule addressing "sex-rejecting procedures." *See* Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children, 90 Fed. Reg. 59,441 (Dec. 19, 2025). We note here, however, that this other proposed rule raises several of the same slippery slope risks as this one. For example, the AHA is concerned about the precedent CMS would set by limiting states' longstanding flexibility to develop state-specific processes for determining when a service is medically necessary under Medicaid's Early and Periodic Screening, Diagnostic and Treatment (EPSDT) requirements.

under 42 U.S.C. § 1395x(e)(9) to impose requirements "necessary in the interest of the health and safety of individuals."[2]

The 1986 regulations were a watershed moment for the CoPs. By the mid-1980s, the early CoPs were viewed as overly complicated and outdated. CMS recognized that revisions were needed to, among other things, "provide for sufficient flexibility in the requirements to allow their application to both the smallest rural facility and to the most complex urban hospital centers." Medicare and Medicaid Programs; Conditions of Participation for Hospitals, 51 Fed. Reg. 22010, 22010 (Jun. 17, 1986). After a lengthy, two-round rulemaking process in which tens of thousands of comments were submitted, CMS articulated several principles that have continued to guide how CMS approaches CoPs:

- Conditions should only be required if they are necessary to protect the health and safety of patients.
- Conditions should only contain requirements that are clearly authorized by statute.
- Conditions should not overlap with similar requirements enforced by other Federal, State, or local government rules.
- Conditions also must be consistent with CMS' objective of permitting maximum flexibility to allow providers to administer their facilities without unnecessary and undue interference in their operations.

Id. Consistent with these principles, CMS explained that its 1986 final rules were designed "to eliminate unnecessary provisions, delete overly prescriptive requirements, and revise requirements to reflect changes in the state of the art." *Id*. at 22011.

The AHA need not recount all of the CoPs that were finalized in the 1986 rule. Taken together, however, some important themes emerge. Those CoPs: 1) set forth processes and standards for protecting the health and safety of patients; 2) were explicitly aimed at preserving hospital flexibility; 3) were intentionally aimed at avoiding overlap with other Federal, State or local regulations; and 4) did not dictate to hospitals what specific services hospitals must or must not provide.

In fact, the 1986 final rule affirmatively rejected proposals to dictate particular services. For example, CMS declined to require hospitals to perform routine urinalysis and

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[2] In 1972, Congress eliminated the original statutory prohibition on imposing CoPs with requirements "higher than the comparable requirements prescribed for the accreditation of hospitals by the Joint Commission on Accreditation of Hospitals." *See* Social Security Amendments of 1972, Pub. L. No. 92-603, § 244(c), 86 Stat. 1329, 1422 (1972). But even with that enhanced authority, CMS has never imposed a CoP that regulates particular treatments for particular diagnoses.

hemoglobin/hematocrit tests for surgical patients, explaining "[w]e believe that it would be inappropriate for the federal government to require hospitals to provide specific services to patients. The ordering of specific services or routine tests should be the responsibility of the practitioner responsible for the patient's care." *Id*. at 22024. Likewise, CMS addressed a requirement for psychiatric hospitals to provide certain therapeutic activities, reasoning that the "requirements concerning therapeutic activities were overly and unnecessarily prescriptive. We believe that the hospital should have the flexibility to determine which activities are most appropriate to its patient population and to determine the criteria to be met by employees providing these services." *Id*. at 22032.

This approach continued for the next 40 years. For example, in a 2024 proposed rule, CMS sought information about a potential CoP related to obstetrical services. *See* Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long-Term Care Hospitals; Quality Program Requirements; and Other Policy Changes, 89 Fed. Reg. 35934, 36500 (May 2, 2024). The agency sought to "develop *a standard* by which obstetrics care delivery is performed." *Id*. (emphasis added). It did *not* seek to impose any requirements for particular obstetric services. In fact, CMS recognized that any such CoP would conflict with a separate provision of law (discussed below in Section B), which "prohibits federal interference in the practice of medicine." *Id*. Accordingly, CMS expressly stated that it was "seeking comment on interventions that do not interfere in medical practice." *Id*.[3]

Unsurprisingly, the current CoPs also reflect this approach. They contain general standards for hospital operations, governance, and safety — not specific prescriptions

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[3] Although CMS did not propose any CoPs regarding particular obstetric services, the AHA nonetheless urged caution. It explained: "CoPs are important regulatory tools establishing baseline standards for quality and safety. However, the AHA believes CoPs are ill-suited to address the complex factors contributing to poor maternal outcomes, most of which occur outside of hospital walls. American Hospital Association, Comment Letter on CMS-1808-P, Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes (May 2, 2024) 63, *at* https://www.aha.org/system/files/media/file/2024/06/aha-comments-on-cms-inpatient-payment-proposal-for-fy-2025-letter-6-5-24.pdf. The same proposed rule also would have used the CoPs to impose certain reporting requirements for respiratory illnesses, and the AHA again urged caution about the overuse of CoPs. *See id*. at 52-53 ("[T]his proposed permanent CoP appears part of a troubling trend of CMS using CoPs to achieve policy goals that do not always have a direct and clear link to health and safety standards in hospitals.… To be clear, we understand fully the potential value of hospitalization data on acute respiratory illnesses to inform broader public health preparedness efforts. However, we do not believe that CoPs are either the appropriate or optimal way to achieve this goal."). In these respects, the AHA's position regarding CoPs has remained consistent: CoPs are blunt instruments that CMS must cautiously wield in *all* situations, but *especially* when seeking to regulate particular treatments for particular diagnoses.

for particular treatments. For example, they require hospitals to "develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program." 42 C.F.R. § 482.21. They require hospitals to "periodically conduct appraisals" of its medical staff, *id*. § 482.21(a)(1), and that hospital nursing services "have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed," *id*. § 482.23(b). They provide general requirements for medical record-keeping, *id*. at 482.24, the condition of the hospital's physical plant, *id*. at 482.41(a), and fire safety, 482.41(b). They require hospitals to have "antibiotic stewardship programs," *id.* at 482.42, but they do not require hospitals to provide particular antibiotics in response to any particular infections (nor do they constrain hospitals from administering particular antibiotics).[4] They require reporting of data on "acute respiratory illnesses, including influenza, SARS-CoV-2/COVID-19, and RSV," *id.* at 482.42(e), but they do not require or forbid any particular treatments for those conditions. And in many instances, the CoPs are written in the conditional tense — "if the hospital provides surgical services," *id.* at 482.51, "if the hospital provides respiratory care service," *id.* at 482.57, "[i]f the hospital offers obstetrical services," *id*. at 482.59, and so on. They do not, however, require hospitals to have any of these optional services; the CoPs come into place only *if* hospitals choose to offer those services. There are many more CoPs currently on the books, but they all follow this general standard-setting approach.

In short, none of the current CoPs dictates particular treatments for particular diagnoses. Nor have they ever. The CoPs have remained this way since 1965, through the 1986 revisions, and across major changes in the practice of medicine, hospital operations, American politics, and party leadership. Given that consistency, any CoP that bars or mandates a particular treatment for a particular diagnosis would be novel. That alone should give CMS pause about the precedent it will set if it finalizes the proposed CoP.

The novelty of the proposed CoP also raises questions about the agency's authority to promulgate it. *E.g., NFIB v. OSHA*, 595 U.S. 109, 119 (2022) ("This 'lack of historical precedent,' coupled with the breadth of authority that the Secretary now claims, is a

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[4] *See* Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care, 84 Fed. Reg. 51732 (Sep. 30, 2019) ("*Comment*: A few commenters were concerned that the proposed requirements for antibiotic stewardship programs would dictate the treatment options for patients with conditions such as Lyme disease.… *Response*: We proposed to intentionally build flexibility into the regulation by proposing language that requires hospitals to demonstrate adherence to nationally recognized guidance and guidelines, rather than any specific guidance, guideline, or set of guidelines, for best practices in infection prevention and control and for implementing antibiotic stewardship programs.").

'telling indication' that the mandate extends beyond the agency's legitimate reach." (quoting *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd*., 561 U.S. 477, 505 (2010))). The AHA agrees, of course, that "CMS has broad statutory authority under the Social Security Act … to establish health and safety regulations, which includes the authority to establish requirements that protect the health and safety of children." 90 Fed. Reg. 59,464. As the proposed rule recognizes, the Secretary may promulgate conditions that are "necessary in the interest of the health and safety of individuals who are furnished services in the institution." 42 U.S.C. § 1395x(e)(9). But as capacious as that text is, it is not limitless. In the only Supreme Court case to have ever addressed Section 1395x(e)(9), *Biden v. Missouri*, 595 U.S. 87 (2022), both the majority and dissenting opinions illustrate why.

Start with Justice Thomas' dissent. That opinion concluded that "this kind of catchall provision [Section 1395x(e)(9)] does not authorize every regulation related to 'health and safety.'" *Id*. at 102 (Thomas, dissenting). Instead, Justice Thomas looked to statutory context to interpret the scope of Section 1395x(e)(9). His opinion explained that "none of the myriad subsections preceding the 'health and safety' subsection suggests that the Government can order hospitals to require virtually all hospital personnel to be vaccinated." *Id*. By contrast, he explained:

> these subsections show that HHS' residual authority embraces only administrative requirements like those that precede it—including "provid[ing] 24-hour nursing service," "maintain[ing] clinical records on all patients," or having "bylaws in effect." §§ 1395x(e)(2), (3), (5). A requirement that all healthcare workers be vaccinated is plainly different in kind.

Id.

To be sure, Justice Thomas wrote a *dissenting* opinion, meaning his view did not carry the day. But the majority opinion's reasoning raises similar questions about the scope of CMS discretion under Section 1395x(e)(9). In that opinion, the *per curiam* majority relied heavily on "the longstanding practice of Health and Human Services in implementing the relevant statutory authorities." *Id*. at 94. And when reviewing that "longstanding practice," the Court explained that the agency's CoP

> requirements govern in detail, for instance, the amount of time after admission or surgery within which a hospital patient must be examined and by whom, 42 CFR § 482.22(c)(5), the procurement, transportation, and transplantation of human kidneys, livers, hearts, lungs, and pancreases, § 482.45, the tasks that may be delegated by a physician to a physician assistant or nurse practitioner, § 483.30(e), and, most pertinent here, the programs that hospitals must implement to govern the "surveillance, prevention, and control of ... infectious diseases," § 482.42.

> Moreover, the Secretary routinely imposes conditions of participation that relate to the qualifications and duties of healthcare workers themselves. *See, e.g.*, §§ 482.42(c) (2)(iv) (requiring training of "hospital personnel and staff" on "infection prevention and control guidelines"), 483.60(a)(1)(ii) (qualified dieticians must have completed at least 900 hours of supervised practice), 482.26(b)–(c) (specifying personnel authorized to use radiologic equipment). And the Secretary has always justified these sorts of requirements by citing his authorities to protect patient health and safety. *See, e.g.*, §§ 482.1(a).

Id. The majority opinion said nothing about CoPs that address particular treatments for particular diagnoses. Nor could it. There is no "longstanding practice" of doing so.

Both opinions therefore offer cautionary signals. The four-Justice-dissent (Thomas, Alito, Gorsuch, Barrett, JJ.) strongly suggests that, based on its statutory context, Section 1395x(e)(9) does not authorize a CoP that bars or mandates particular medical treatment for a particular medical diagnosis. In their view, such a CoP would be "plainly different in kind" from the "administrative requirements" elsewhere in Section 1395x(e). *Id*. at 102 (Thomas, dissenting). The dissenters also likely would require CMS to justify such a CoP under the "major questions doctrine." In their view, this particular proposed CoP could very well: a) raise a question of vast political significance, and b) significantly alter the balance between state and federal power, thereby requiring a clearer statement from Congress authorizing it. *See id.* at 104.

Similarly, the majority's reliance on CMS' "longstanding practice" indicates that a genuinely novel CoP prohibiting (or requiring) a specific treatment for a particular diagnosis might not withstand scrutiny. Relatedly, it is far more difficult to situate the proposed CoP in any past or present CoP than it was for the vaccine mandate in *Missouri*. For example, CMS "routinely imposes conditions of participation that relate to the qualifications and duties of healthcare workers themselves," *Missouri*, 595 U.S. at 94, which is exactly what the vaccination CoP in *Missouri* did. By contrast, the proposed CoP does not operate on hospital staff, and there is no "routine" practice of CoPs regulating the specific treatments that hospital staff could perform on their patients. Likewise, the CoPs have "long included" general requirements related to infection control, *id*. at 90, which (again) is exactly what the vaccine mandate in *Missouri* addressed. By contrast, there is no history at all of CoPs regulating "sex-rejecting procedures" or anything comparable. Separately, the *per curiam* majority observed that, under existing state law, "[v]accination requirements are a common feature of the provision of healthcare in America." *Id*. at 95. By contrast, the proposed CoP is far from "common." Indeed, the states are at odds over the treatments and diagnoses it would regulate. *See* 90 Fed. Reg. at 59,469-59,470. Finally, both CMS itself and the *per curiam* majority expressly relied on the unique nature of what gave rise to the

vaccination CoP in the first place —the COVID-19 pandemic.[5] Taken together, these factors show that unlike the CoP upheld in *Biden v. Missouri*, the proposed CoP is not "a straightforward and predictable example of the 'health and safety' regulations that Congress has authorized the Secretary to impose." *Id.*

The AHA does not know how the courts would evaluate these legal questions. We can say with confidence, however, that this novel CoP raises novel (and challenging) legal questions. We ask CMS to bear in mind this legal uncertainty as it considers whether to finalize this precedent-setting CoP.

B. The Proposed Condition of Participation Appears To Regulate The Practice of Medicine

The proposed rule also discusses 42 U.S.C. § 1395, the statutory ban on federal interference with the practice of medicine. 90 Fed. Reg. 59,471. Rightly so. The same 1965 statute that authorized the Secretary to establish CoPs also enacted that provision, making it highly relevant to CMS' analysis here.

Section 1395 provides that "[f]ederal officer[s]" may not ''exercise any supervision or control over the practice of medicine or the manner in which medical services are provided." Courts have held that the federal government violates this provision if it "actually direct[s] or prohibit[s] any kind of treatment or diagnosis;" if it "favor[s] one procedure over another;" or "influence[s] the judgment of medical professionals." *Goodman v. Sullivan*, 891 F.2d 449, 451 (2d Cir. 1989) (per curiam); *see Texas v. Becerra*, 89 F.4th 529, 542 (5th Cir. 2024) ("Section 1395 underscores the 'congressional policy against the involvement of federal personnel in medical treatment decisions.'" (quoting *United States v. Univ. Hosp., State Univ. of N.Y. at Stony Brook*, 729 F.2d 144, 160 (2d Cir. 1984)); *Florida v. Dep't of Health & Hum. Servs*., 19 F.4th 1271, 1315 (11th Cir. 2021) (upholding a federal vaccine mandate for all covered health care workers because it did not regulate "the practice of medicine, the manner in which medical services are provided, or the operation an institution"). The proposed rule's prohibition on "sex-rejecting procedures" seems to run afoul of Section 1395, at least under existing precedent, especially because that provision must be read alongside the CoP-authorizing provisions that were enacted in the same 1965 legislation. *See Gustafson v. Alloyd Co.*, 513 U.S. 561, 570 (1995) ("The 1933 Act, like every Act of Congress, should not be read as a series of unrelated and isolated provisions."); *see*

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[5] *See* Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555, 61,568 (Nov. 5, 2021) ("We acknowledge that we have not previously imposed such requirements, but, as discussed throughout section I of this rule, this is a unique pandemic scenario with unique access to effective vaccines."); *Missouri*, 595 U.S. at 95 ("Of course the vaccine mandate goes further than what the Secretary has done in the past to implement infection control. But he has never had to address an infection problem of this scale and scope before.").

generally A. Scalia & B. Garner, READING LAW 167 (2012) (explaining that "the whole-text canon" requires consideration of "the entire text, in view of its structure" and "logical relation of its many parts").

The proposed rule nevertheless contends "that providing the SRPs for children is not healthcare and hence are not subsumed under the term of 'the practice of medicine.'" Therefore, the proposed rule would not regulate the practice of medicine." 90 Fed. Reg. 59,471. The proposed rule goes on to state that "the intentional destruction of healthy biological functions … is not health care and hence imposing restrictions as this rule proposes does not limit the practice of medicine." *Id*.

Respectfully, this reasoning is logically circular. As we read it, CMS is arguing that Section 1395's ban on federal interference with the "practice of medicine" does not apply because CMS does not regard the procedures it seeks to prohibit as "medicine." That, however, is self-justifying. If adopted, CMS' approach would allow the agency to define away any procedure it wishes to ban simply by saying, as it does here, that the procedure is not "medicine" or "healthcare." This approach runs the risk of giving CMS impermissible discretion to oversee the practice of medical decision-making. *See Coll. of Am. Pathologists v. Heckler*, 734 F.2d 859 (D.C. Cir. 1984) ("The Secretary's authority, however broad, is not boundless. Congress explicitly prohibits federal actions that interfere with the practice of medicine.").

CMS' circular approach also appears to contradict certain facts that the agency recognizes in the proposed rule. For example, the proposed rule acknowledges that 14 states and the District of Columbia have shield laws protecting "sex-rejecting procedures," and three other states have executive orders protecting these procedures. *See* 90 Fed. Reg. at 59,469-59,470. Presumably, those jurisdictions recognize these procedures as "medicine." *See, e.g., Pa. Med. Soc. v. Marconis*, 942 F.2d 842, 846 n.4 (3d Cir. 1991) ("We regard [Section 1395] as recognizing that the practice of medicine is, in general, a subject of state regulation."); N.Y. State Soc'y *of Orthopaedic Surgeons v. Gould*, 796 F. Supp. 67, 73 (E.D.N.Y. 1992) (describing Section 1395 as reserving "power … for the states"); *see also Moyle v. United States*, 603 U.S. 324, 357-58 (2024) (Alito, J., dissenting) ("The Medicare Act … disclaims any construction that would 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 in a particular State. 42 U.S.C. § 1395. This disclaimer evidences a desire to minimize federal intrusion' into state healthcare regulation." (cleaned up)). Similarly, the proposed rule includes exceptions that would allow for the use of these procedures in certain circumstances (*e.g.*, treating complications). Presumably, the procedures would qualify as "medicine" or "healthcare" in those excepted circumstances.

In pointing out these facts, the AHA is not disputing or endorsing the proposed rule's position that "these procedures lack strong evidentiary foundations, and our understanding of long-term health impacts is limited and needs to be better

understood." 90 Fed. Reg. at 59,471-59,472. Again, the AHA does not weigh in on medical or scientific disputes over particular medical procedures or diagnoses. Nor are we taking sides among the states. The AHA recognizes the divide across the United States about whether to ban or protect "sex-rejecting procedures." As a national organization, the AHA does not weigh in on those state-level debates.

The AHA is merely pointing out that the proposed rule comes as close to regulating "any kind of treatment or diagnosis" as anything CMS has ever done with a CoP. *Goodman*, 891 F.2d at 451. And in so doing, CMS appears to be engaging in the very kind of federal management of medical decisions that Congress sought to preclude when it enacted the Social Security Amendments of 1965. Before taking so consequential a step, CMS should be certain that it possesses the legal authority to do so by addressing the legal issues discussed above. Importantly, that would ensure consistency with one of CMS' well-established guiding principles for the development of CoPs: "Conditions should only contain requirements that are *clearly authorized* by statute." 51 Fed. Reg. at 22010 (emphasis added).

We appreciate your careful consideration of these issues. Please contact me if you have any questions.

Sincerely,

/s/

Chad Golder
General Counsel & Secretary