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Submitted via www.regulations.gov

Secretary Robert F. Kennedy, Jr.
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Administrator Mehmet Oz
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Comment Regarding “Medicaid Programs: Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children” Proposed Rule, Docket No. CMS-3481-P, 90 FR 59463 (Dec. 19, 2025)

Dear Secretary Kennedy and Administrator Oz:

Governing for Impact (“GFI”) submits this comment on a proposed rule, “Medicare and Medicaid Programs; Hospital Condition of Participation Prohibiting Sex-Rejecting Procedures for Children” (“the Proposed Rule”), issued by the Centers for Medicare and Medicaid Services (“CMS”) within the Department of Health and Human Services (“HHS”).¹ GFI is a regulatory policy organization dedicated to ensuring that the federal government operates more effectively for everyday working Americans.²

The Proposed Rule would prohibit hospitals from providing certain treatments for gender dysphoria³ to minors as a Condition of Participation (“CoP”) in Medicare and Medicaid, with limited exceptions.⁴ We oppose the Proposed Rule because it exceeds CMS’s authority to promulgate CoPs and impermissibly seeks to regulate the practice of medicine. Additionally, the Proposed Rule, if finalized, would likely violate the Administrative Procedure Act’s (“APA”) reasoned-decisionmaking requirement, rendering the rule arbitrary and capricious. We urge CMS to withdraw the Proposed Rule.

¹ See Medicare and Medicaid Programs; Hospital Conditions of Participation Prohibiting Sex-Rejecting Procedures for Children, 90 Fed. Reg. 59463 (Dec. 19, 2025).

² Governing for Impact, <https://governingforimpact.org/>.

³ CMS refers to these forms of care as “sex-rejecting procedures.” We instead use “treatment for gender dysphoria” or “gender affirming care,” the more widely accepted medical terminology for such interventions.

⁴ 90 Fed. Reg. 59463.

I. The Proposed Rule exceeds CMS’s authority to promulgate Conditions of Participation.

CMS principally relies upon Section 1861(e)(9) of the Social Security Act, which grants authority to the Secretary to impose upon hospitals “such other requirements” that the Secretary “finds necessary in the interest of the health and safety of individuals who are furnished services in the institution” as a condition of receiving Medicare⁵ (and Medicaid⁶) payments. From that language, CMS extracts a sweepingly broad authority to prohibit hospitals from providing certain services to a specific patient population based on CMS’s disagreements with the decisions of doctors, families, and patients.⁷

CMS’s interpretation cannot be squared with the text or history of Section 1861(e)(9). Start with the text: by referencing “the health and safety of individuals who are furnished services in the institution,”⁸ the statute is most naturally read to refer to measures needed to prevent system-wide health and safety concerns, like disease prevention and staffing standards. The statute permits CMS to regulate the setting in which services are provided, not to prohibit certain services from being offered at all. As the House Report indicates, Congress enacted Section 1861(e)(9) “because it would be inappropriate and unnecessary to include in the legislation all the precautions against fire hazards, contagion, etc., which should be required of institutions to make them safe.”⁹

In the decades since the enactment of CMS’s CoP authority, CMS has, as far as we are aware, never used it to prohibit a particular form of care. CMS first promulgated CoP regulations in 1966 that were largely focused on “structural . . . measures of organizational and clinical capacity,” including staff qualifications, hospital-wide policies, and administrative organization.¹⁰ Beginning in the 1980s, CoPs shifted focus to “quality assurance standards,” including hospital-wide policies to evaluate patient services.¹¹ More recent CoPs have identified health and safety risks and sought to improve patient care through minimum staffing and service availability. For example, CoPs have addressed new technological advances like telehealth, new organizational models like multi-hospital systems, and subjects like a broader recognition of patient rights and the need to modernize definitions of

⁵ 42 U.S.C. § 1395x(e)(9); *see also* 42 C.F.R. § 482.1(a)(1)(ii) (“The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals.”).

⁶ 42 U.S.C. § 1396d; 42 C.F.R. § 440.10(a)(3)(iii) (requiring an institution to “meet[] the requirements for participation in Medicare as a hospital”).

⁷ CMS also relies upon its general authority to promulgate rules necessary to administer Medicare and Medicaid. *See* 90 Fed. Reg. 59464 (citing 42 U.S.C. § 1395hh; 42 U.S.C. § 1302(a)). But it would be counterintuitive to suggest that that sort of housekeeping provision grants authority to issue CoPs beyond that conferred by the CoP provision itself, and CMS presents no argument to the contrary. Indeed, CMS has previously disclaimed reliance upon Section 1302(a) in issuing other CoPs. *See, e.g.*, Reply of Applicants at 5, *Biden v. Missouri*, Nos. 21A240 & 21A241 (Jan. 2, 2022), https://www.supremecourt.gov/DocketPDF/21/21A240/207150/20220103092323377_21A240%2021A241%20-%20Government%20Combined%20Reply%20final.pdf.

⁸ 42 U.S.C. § 1395x(e)(9).

⁹ H.R. Rep. No. 213, 89th Cong., 1st Sess. 25–26 (1965) (House Report).

¹⁰ Kathleen N. Lohr, Committee to Design a Strategy for Quality Review and Assurance in Medicare, Institute of Medicine, Medicare: A Strategy for Quality Assurance, Vol. 1: Hospital Conditions of Participation 119–34, 121 (1990), <https://www.nationalacademies.org/publications/1547>.

¹¹ *Id.* at 125; HHS, Health Care Financing Administration, Medicare and Medicaid Programs; Conditions of Participation for Hospitals, 51 Fed. Reg. 2201 (June 17, 1986).

family.¹² And across all of these CoPs, CMS has generally maintained broad flexibility for hospitals to meet the applicable standards. This consistent regulatory history provides all the more reason to doubt CMS’s assertion that Section 1861(e)(9) gives it the authority to prohibit specific medical treatments.

Indeed, CMS’s interpretation raises serious questions under the major questions doctrine. Although the jurisprudential foundation for that doctrine is disputed, the Supreme Court has suggested that a major question exists when an agency (a) claims “to discover in a long-extant statute an unheralded power” that (b) represents “a transformative expansion in its regulatory authority.”¹³ Such an assertion of power must be supported by “clear congressional authorization,” not just “a merely plausible textual basis.”¹⁴

The Proposed Rule, if finalized, would be an unprecedented and sweeping expansion of the agency’s authority to regulate covered providers through CoPs. In contrast to prior CoPs, which have generally set baseline standards that hospitals must meet to address system-wide health and safety concerns,¹⁵ the Proposed Rule would prohibit hospitals from offering a specific set of medical services when needed by a specific patient population. Much like HHS’s 2019 “conscience rule,” which was vacated by a district court, it is “not sustainable to conclude that Congress would cede such broad and unusual authority through an implicit delegation” to CMS.¹⁶ While CMS may have a capacious mandate to regulate in the interest of patient “health and safety,” nowhere in the statute’s text does Congress grant CMS the ability to regulate the practice of medicine, let alone ban medically appropriate care.

Comparing the new proposed CoP to the policy upheld in *Biden v. Missouri*—a seminal major-questions case—is instructive. In *Missouri*, the Supreme Court upheld a CoP that required certain hospital staff to be vaccinated against COVID-19.¹⁷ The Court reasoned that the CoP was within the agency’s authority in part because the Secretary determined that COVID-19 “is a highly contagious, dangerous, and—especially for Medicare and Medicaid patients—deadly disease,” and the vaccine mandate would substantially reduce the spread of the disease.¹⁸ In contrast, in the Proposed Rule CMS has not provided adequate evidence to support the assertion that treatment for gender dysphoria is “dangerous” for minors (which we address below), much less that it poses a systemic risk to the health and safety of hospital patients.

Moreover, courts, including in *Biden v. Missouri*, have treated a proposed CoP’s benefits for Medicare beneficiaries to be persuasive in determining whether the agency has authority to issue the CoP

¹² See, e.g., 76 Fed. Reg. 25550–65 (May 5, 2011) (telemedicine); 79 Fed. Reg. 27106, 27112–17 (May 12, 2014) (multi-hospital systems); 71 Fed. Reg. 71378–428 (Dec. 8, 2006) (patients’ rights); 75 Fed. Reg. 70831–44 (Nov. 19, 2010) (visitation rights).

¹³ *W. Virginia v. Env’t Prot. Agency*, 597 U.S. 697, 724 (2022) (internal citations omitted).

¹⁴ *Id.* at 723 (internal citations omitted).

¹⁵ See, e.g., 42 C.F.R. 482.23; 42 C.F.R. 482.42.

¹⁶ *New York v. U.S. Dep’t of Health & Hum. Servs.*, 414 F. Supp. 3d 475, 531 (S.D.N.Y. 2019) (internal quotations omitted).

¹⁷ *Biden v. Missouri*, 595 U.S. 87, 91 (2022).

¹⁸ *Id.* at 93.

under its general rulemaking and CoP authorities.¹⁹ The Proposed Rule provides no explanation of how the CoP would benefit or safeguard Medicare beneficiaries, and it is difficult to imagine how it could.²⁰ In fact, with respect to the population affected by the Proposed Rule, Medicare only covers dependent children with end-stage renal disease,²¹ and so only one other CoP, which regulates organ donation services in pediatric facilities, explicitly conditions pediatric services.²² The weak connection between Medicare and the provision of gender dysphoria treatment to transgender minors only underscores CMS's usurpation of power.

II. The Proposed Rule impermissibly regulates the practice of medicine.

Even if CMS possessed the authority to issue the Proposed Rule, the rule purports to prohibit doctors from offering certain forms of lawful medical care to their patients and is therefore contrary to law. Section 1801 of the Social Security Act prohibits CMS from “exercis[ing] any supervision or control over the practice of medicine or the manner in which medical services are provided.”²³ The statute further prohibits CMS from controlling the “administration or operation” of any covered entity.²⁴ Section 1861 defines “medical and other health services” to include “physicians’ services,” which encompasses “professional services” offered by a doctor “legally authorized to practice medicine and surgery by the state in which [they] perform[] such function or action.”²⁵ Put simply, Section 1801 generally allows states to regulate how doctors may practice medicine, not the federal government.

Unlike the Proposed Rule, existing CoPs respect this prohibition on interfering with the doctor-patient relationship. While current hospital CoPs dictate the type of medical professional that can administer certain services, no CoPs unilaterally restrict specific services unless required by relevant state law.²⁶ In the Proposed Rule, however, CMS impermissibly regulates the practice of medicine by prohibiting doctors in covered facilities from providing certain services to a certain population of patients. There would be no question that a CoP prohibiting doctors from offering heart transplants, vasectomies, or hip replacements would violate Section 1801, and there should similarly be no question here.

CMS attempts to sidestep this obvious flaw in the Proposed Rule by declaring that treatment for gender dysphoria is “not healthcare” and so does not fall within CMS’s self-selected definition of

¹⁹ See, e.g., *Merck & Co. v. HHS*, 962 F.3d 531, 538–39 (D.C. Cir. 2020) (finding that HHS could rely on its general rulemaking authority if there was an “actual and discernable nexus between the rule and the conduct or management of Medicare and Medicaid programs”)

²⁰ Instead, the Proposed Rule asserts that the statute grants the agency broad authority to enact regulations which “protect the health and safety of children,” 90 Fed. Reg. at 59464—a sharp contrast to the government’s argument in defense of the vaccine mandate in *Biden v. Missouri*, where the government maintained that Medicare and Medicaid beneficiaries were “disproportionally vulnerable to severe negative outcomes from COVID-19.” Reply of Applicants at 7, *supra*; see also *Missouri*, 595 U.S. at 93 (recognizing that COVID-19 was “especially” deadly for Medicare and Medicaid patients).

²¹ 42 U.S.C. 426-1.

²² 42 C.F.R. 482.76.

²³ 42 U.S.C. 1395.

²⁴ *Id.*

²⁵ 42 U.S.C. § 1395x(q), (r), (s).

²⁶ 42 C.F.R. Part 482.

the practice of medicine under Section 1801.²⁷ But that makes matters *worse*, not better; it would confer a sweeping power upon CMS to regulate medical care through wordplay by simply writing entire types of care—potentially including mental health care or habilitative services—out of the statute’s definition as CMS sees fit. Nor does the statute give CMS any authority to define the bounds of permissible medical care. Instead, the agency’s primary function is to provide *coverage* for medically appropriate care and ensure proper management of that care, as determined by medical professionals.

Nor is it tenable to argue that treatment for gender dysphoria does not constitute the practice of medicine.²⁸ The treatments singled out by CMS involve widely available pharmaceutical and surgical interventions practiced by doctors to remedy medical conditions—i.e., the practice of medicine. Even the Supreme Court’s recent decision in *United States v. Skermetti*, which permitted states to limit access to certain forms of gender affirming care, described those treatments as “medical care.”²⁹ And as the Proposed Rule notes, major medical organizations, including the American Medical Association, the American Academy of Pediatrics, and the American Psychological Association, agree that treatment for gender dysphoria is medically necessary care.³⁰ The Proposed Rule also notes that 17 states and D.C. currently have protections or other requirements related to the provision of this care.³¹ Indeed, CMS’s *own review* of the medical literature reflects the fact that treatment for gender dysphoria is considered medical care.³²

Finally, CMS’s flawed interpretation of Section 1801 also raises profound major-questions and federalism problems. The Proposed Rule twists a prohibition on regulating the practice of medicine into an affirmative power for CMS to police the bounds of permissible medical interventions—an interpretation that would seem to be a perfect example of discovering “hid[den] elephants in mouseholes.”³³ And it does so in a way that would make procedures expressly permitted in many states far more difficult to access, even if it would not prohibit them entirely. That kind of “federal intrusion” into state healthcare regulation is precisely what Congress sought to foreclose.³⁴

²⁷ 90 Fed. Reg. 59471.

²⁸ *Id.*

²⁹ 605 U.S. 495, 500 (2025).

³⁰ 90 Fed. Reg. 59467–69 (citing Clarification of Evidence-Based Gender-Affirming Care H-185.927, American Medical Association Policy Finder, American Medical Association, 2024, <https://policysearch.ama-assn.org/policyfinder/detail/%22Clarification%20of%20Evidence-Based%20Gender-Affirming%20Care%22?uri=%2FAMADoc%2FHOD-185.927.xml>; Alyson Sulaski Wyckoff, *AAP Continues to Support Care of Transgender Youths as More States Push Restrictions*, AAP News (Jan. 6, 2022), <https://publications.aap.org/aapnews/news/19021/AAP-continues-to-support-care-of-transgender>; *APA Adopts Groundbreaking Policy Supporting Transgender, Gender Diverse, Nonbinary Individuals*, Am. Psychological Ass’n (Feb. 28, 2024), <https://www.apa.org/news/press/releases/2024/02/policy-supporting-transgender-nonbinary>.)

³¹ 90 Fed. Reg. 59469–70.

³² *See, e.g.* HHS Office of Population Affairs, Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices 20–21 (Nov. 19, 2025), <https://opa.hhs.gov/gender-dysphoria-report> [hereinafter “OPA Report”] (noting the rate of “pediatric medical transition” in U.S. institutions and the “gender-affirming care” model endorsed by the World Professional Association for Transgender Health (WPATH) and the Endocrine Society (ES)).

³³ *Whitman v. Am. Trucking Associations*, 531 U.S. 457, 468 (2001).

³⁴ *Moyle v. United States*, 603 U.S. 324, 357 (2024) (Barrett, J., dissenting) (citing *Mass. Med. Soc. v. Dukakis*, 815 F.2d 790, 791 (1st Cir. 1987) (opinion of Breyer, J.)).

Moreover, even if CMS could usurp the authority to redefine the practice of medicine, the views of the medical community notwithstanding, CMS's rationales are incoherent and unsupported.

First, CMS asserts that the supposedly poor “risk-benefit profile” of gender affirming care means that clinicians cannot provide it.³⁵ But redefining medical care to exclude treatments CMS (wrongly) believes are unjustified is simply regulation of the practice of medicine by another name. In addition, treatment for gender dysphoria includes a host of possible medical interventions, all of which require individual consideration as to benefits and risks, given the particular patient and their circumstances. Medical professionals, acting consistent with the standard of care, are best positioned to assess these possible risks and potential benefits based on an individual's needs, obtain parental informed consent, and deliver high-quality care. CMS's conclusory statement that treatments for gender dysphoria fall below some risk-benefit threshold does not take that required medical expertise or parental involvement into consideration and notably does not account for other factors, like mental health distress, that may contribute to a clinician's recommendation of gender affirming care.

Second, CMS argues that healthcare cannot include interventions that remove or hinder the functioning of “healthy” body parts or processes that are “operating according to their biological functions.”³⁶ Leaving aside the lack of any support for that narrow definition, it would necessarily exclude several medical interventions that impair or disable otherwise “healthy” organs, like vasectomies or gastric bypass surgery, to improve the health of the body overall. CMS also discounts the possibility that a patient “may experience psychological distress relating to his or her sexed body,”³⁷ but provides no justification for its decision to overlook mental health as an important aspect of health overall.

Third, CMS claims that treatment for gender dysphoria “lack[s] [a] strong evidentiary foundation.”³⁸ That is incorrect, and regardless, doctors determine whether the evidence supports a certain intervention for their patients, not CMS. Moreover, by conditioning payment on withholding treatment for gender dysphoria entirely, rather than considering reasonable alternative policies to monitor the provision of this care, CMS weakens the ability of clinicians to generate more robust evidence over time.

III. The Proposed Rule is arbitrary and capricious.

Even if CMS had the authority to promulgate the Proposed Rule, if finalized as proposed, it would fail the APA's reasoned-decisionmaking requirement. The APA requires courts to set aside agency action that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”³⁹ This standard requires an agency to “examine[] ‘the relevant data’” and “articulat[e] ‘a satisfactory explanation’” for its decision.⁴⁰

³⁵ 90 Fed. Reg. 59471.

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ 5 U.S.C. § 706(2)(A).

⁴⁰ *See Id.*; *Dept. of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019) (citing *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983)).

The Proposed Rule is deficient in several respects. Most importantly, CMS failed to reasonably explain why it rejected the literature supporting treatment for gender dysphoria. Among other things, it fails to consider the robust data showing that gender affirming care for youth has been proven to improve mental health outcomes.⁴¹ And restricting access to medically necessary care to this vulnerable group is especially harmful because transgender and nonbinary youth have higher rates of depression, anxiety, and suicidal ideation than their cisgender peers.⁴²

The studies on which CMS instead relies also have significant flaws. In the Proposed Rule, CMS states that gender affirming surgical and pharmaceutical interventions “are not consistent with the health and safety of children, given the risk of significant (long-term) harms, known complications, and weak and uncertain evidence of benefits” to justify its rulemaking.⁴³ However, neither the Proposed Rule nor the underlying report by the Office of Population Affairs (“OPA”)—which has been widely criticized⁴⁴—shows any clear evidence of purported harms. In fact, the OPA report concludes that for both pharmaceutical and surgical interventions, “there is considerable uncertainty regarding their psychological and long-term health outcomes.”⁴⁵ CMS claims that a variety of *possible* harms justify the Proposed Rule’s prohibition on providing certain treatments for gender dysphoria.⁴⁶ However, neither the OPA report nor the Proposed Rule presents any data supporting these purported harms, let alone explains why these harms will outweigh the proven benefits of gender affirming care in all or even a majority of cases.

Finally, even if the studies CMS relies on were persuasive, they do not support the Proposed Rule’s broad prohibition on certain forms of treatment for gender dysphoria. Although the Proposed Rule cites studies from several countries, it glosses over the fact that none of the countries described at length—Norway, Finland, Sweden, Denmark, and the United Kingdom—have adopted blanket prohibitions on medical treatment for gender dysphoria.⁴⁷ There is also no indication in the Proposed Rule that CMS reasonably considered the policies of these countries, or any other less restrictive alternatives, in deciding to impose a categorical prohibition on this care for providers that accept Medicare and Medicaid funding.

⁴¹ For example, in a 2022 study of 104 transgender and nonbinary youths, researchers found that gender-affirming medical interventions, including ones prohibited by the Proposed Rule, were associated with lower rates of depression and suicidality over 12 months. Diana M. Tordoff et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care*, *JAMA Netw. Open* 2022 Feb 1; 5(2):e220978, doi: 10.1001/jamanetworkopen.2022.0978. A longitudinal study also found that hormonal interventions have improved youth’s gender dysphoria and psychological functioning. Annelou L.C. de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, *Pediatrics* (2014) 134(4): 696–704, doi.org/10.1542/peds.2013-2958.

⁴² Wittlin, N. M., Kuper, L. E., & Olson, K. R., *Mental Health of Transgender and Gender Diverse Youth*, *Annual Review of Clinical Psychology* 19, 207 (2023), <https://doi.org/10.1146/annurev-clinpsy-072220-020326>.

⁴³ 90 Fed. Reg. 59470.

⁴⁴ See Phie Jacobs, *Researchers Slam HHS Report on Gender-Affirming Care for Youth*, *Science* (May 2, 2025), <https://www.science.org/content/article/researchers-slam-hhs-report-gender-affirming-care-youth>.

⁴⁵ OPA Report, *supra*, at 100.

⁴⁶ 90 Fed. Reg. at 59471 (citing OPA Report, *supra*, at 227–28).

⁴⁷ 90 Fed. Reg. 59466–67.

Instead, CMS simply dismisses less restrictive options, like requiring states to have more restrictive prior authority or other requirements, or even allowing those already receiving gender affirming care services to continue receiving them, to “maximize health and safety for all children.”⁴⁸ And there are a host of other alternative policies that CMS failed to consider, including, for example, provider requirements. While we do not purport to have expertise in which guardrails, if any, are supported by available evidence, and may object to such policies as unnecessary and potentially inconsistent with the statute depending on their scope, it is CMS’s total failure to consider such alternatives that is arbitrary and capricious. Without any data to support the conclusion that more restrictive regulations will ultimately benefit transgender minors who need this care and, in fact, with plenty of evidence that restricted access will harm transgender minors, CMS has not provided a reasoned justification for the Proposed Rule.

IV. Any use of artificial intelligence in this rulemaking must be disclosed.

Finally, CMS must disclose information related to any use of artificial intelligence as part of this rulemaking and, to the extent such use is significant, provide an additional opportunity for public comment.⁴⁹ Under the APA’s reasoned-decisionmaking requirement, “[w]hen an agency uses a computer model, it must explain the assumptions and methodology used in preparing the model.”⁵⁰ Moreover, the public must have notice of, and an opportunity to comment on, agencies’ uses of models and data, AI-enhanced and otherwise, to regulate.⁵¹ Such disclosures are “[t]he safety valves in the use of . . . sophisticated methodology.”⁵²

Beyond being legally required, disclosure of AI usage is prudent policy. Administrative agencies should uphold the values of transparency and public participation.⁵³ In particular, the Administrative Conference of the United States has recognized that “[a]gencies’ efforts to ensure transparency in connection with their AI systems can serve many valuable goals,” and it therefore recommends that “agencies might prioritize transparency in the service of legitimizing its AI systems, facilitating internal or external review of its AI-based decision making, or coordinating its AI-based activities.”⁵⁴ Among other things, disclosure of AI usage allows the public to confirm that agencies are adhering to relevant laws, apply technical expertise to improve agencies’ use of technology, assess the risk that federal policies might be influenced by biased or otherwise faulty methods or products, and learn about an emerging and important field of technology. Indeed, the Office of Management and

⁴⁸ 90 Fed. Reg. 59476.

⁴⁹ We adopt the definition of artificial intelligence at Pub. L. 115-232 § 238(g), 132 Stat. 1697–98.

⁵⁰ *Owner-Operator Ind. Drivers Ass’n, Inc. v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 204 (D.C. Cir. 2007) (quotation omitted).

⁵¹ See *Am. Radio Relay League v. FCC*, 524 F.3d 227, 236 (D.C. Cir. 2008); *Air Transp. Ass’n v. FAA*, 169 F.3d 1, 7 (D.C. Cir. 1999).

⁵² *Sierra Club v. Costle*, 657 F.2d 298, 334 (D.C. Cir. 1981).

⁵³ See Attorney General’s Manual on the Administrative Procedure Act 9 (1947) (describing the APA’s purposes to include “requir[ing] agencies to keep the public currently informed of their organization, procedures, and rules” and “provid[ing] for public participation in the rule making process”).

⁵⁴ Admin. Conf. of the U.S., Statement #20, Agency Use of Artificial Intelligence, 86 FR 6612, 6616 (Jan. 22, 2021).

Budget has recognized that the government, in using AI, must “provide improved services to the public, while maintaining strong safeguards for civil rights, civil liberties, and privacy.”⁵⁵

Consistent with these requirements and principles, CMS must disclose, first, whether it has used or plans to use AI as part of this rulemaking, including to develop substantive policy, produce supporting analysis, or respond to public comments. If so, CMS must disclose the particular AI product it has used and why it was selected, how that product was procured, whether the product was fine tuned, what prompts or inputs the agency used to elicit responses from the product, and the responses the product produced. CMS must also disclose how agency staff used AI-produced information, including any quality control, peer review, or other validation performed. And CMS must disclose what measures it took to ensure that its use of AI complied with applicable data security and privacy requirements. To that end, it must disclose whether and to what extent any persons and entities not employed by the agency developed, modified, provided access to, or used AI in the course of the agency’s decisionmaking process. To the extent the disclosed use of AI is significant, CMS must provide an additional opportunity for public comment.

V. Conclusion

As we have detailed above, CMS does not have the authority to promulgate the Proposed Rule, and the Proposed Rule is contrary to law. Additionally, if finalized, the Proposed Rule would violate the APA’s reasoned-decisionmaking requirement by failing to consider the substantial research supporting gender affirming care, relying upon deficient studies, and failing to consider alternative policies. Given these serious deficiencies, GFI opposes the Proposed Rule and urges the agency to withdraw it.

Sincerely,

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⁵⁵ Memorandum for the Heads of Executive Departments and Agencies from Russell T. Vought, Director, Office of Management & Budget 1, M-25-21 (Apr. 3, 2025), *available at* <https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-21-Accelerating-Federal-Use-of-AI-through-Innovation-Governance-and-Public-Trust.pdf>.