

February 17, 2026

*Submitted electronically via regulations.gov*

The Honorable Robert F. Kennedy Jr.  
Health and Human Services Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

The Honorable Dr. Mehmet Oz  
Administrator of the Center for Medicare & Medicaid Services  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Re: APHA and Public Health Deans and Scholars' Comments on the Centers for Medicare and Medicaid Services' "Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children" (CMS-3481-P; RIN 0938-AV73)

Dear Secretary Kennedy and Administrator Oz:

The American Public Health Association (APHA), along with 122 public health and health policy deans, chairs, and scholars (in their individual capacities), file this comment on the Centers for Medicare & Medicaid Services' (CMS) December 2025 Notice of Proposed Rulemaking (NPRM), which would bar any hospital from participating in Medicare and Medicaid if it provides puberty-pausing medications, hormone therapy, or surgery for transgender youth under the age of 18. CMS proposes this rule in violation of the Constitution, Medicare and Medicaid statutes, and the Administrative Procedure Act, infringing on certain powers reserved to Congress and the States. CMS proposes this rule without sufficient evaluation of the significant negative impact that restricting access to this necessary, life-saving healthcare will have on individual health, community health, and state economies. For these reasons, we urge CMS to withdraw the proposed rule.

The individual signatories are distinguished deans, chairs, and scholars at the nation's leading academic institutions and research universities. They are experts in the fields of health law, public health, healthcare policy and research, and national health reform. They include individuals known for their expertise in access to healthcare, including Medicaid as the leading insurer for low-income people and other populations that face systemic barriers to essential healthcare services, and Medicare. The individual signatories join this comment in their individual capacities and not as representatives of their respective institutions. The complete list of individual signatories is included at the end of this letter.

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## I. CMS Lacks the Authority to Ban Hospitals from Providing Gender Affirming Care to Transgender Youth Under Age 18, and Its Proposal To Do So is Contrary to Law

*CMS' proposal unlawfully interferes with the practice of medicine and provision of medical services in violation of the Constitution and the Medicare & Medicaid Statutes.*

CMS' proposal flouts the basic premise of the entire Medicare statute and its express prohibition in section 1801—the very first section of the Medicare Act—against “any” federal interference in the supervision or control over the practice of medicine and provision of medical services.<sup>1</sup> Medicare's anti-interference provision “underscores the ‘congressional policy against the involvement of federal personnel in medical treatment decisions.’”<sup>2</sup> Congress has unambiguously prohibited the government from “direct[ing] or *prohibit[ing]* any [particular] kind of treatment or diagnosis” in administering Medicare,<sup>3</sup> and it has further conditioned hospitals' Medicare participation on “assur[ing] that personnel are licensed or meet other applicable standards that are required by State or local laws.”<sup>4</sup> CMS' proposal, if finalized, would have the exact effect of prohibiting hospitals from providing particular treatments for children with gender dysphoria, gender identity disorder, and gender incongruence<sup>5</sup> that are regulated and, in some states, explicitly protected<sup>6</sup> under State law. As discussed more fully below, CMS cannot use Conditions of Participation and general rulemaking provisions to attempt to affect a categorical, nationwide ban for hospitals that directly conflicts with Medicare's non-interference requirements.

In two short paragraphs at the end of the preamble of the proposed regulations, CMS attempts to argue that gender affirming care is not healthcare and thus does not fall under the practice of medicine.<sup>7</sup> CMS acknowledges it included this argument, which is notably brief, conclusory, and fails to grapple with significant bodies of medical evidence about the safety and effectiveness of transition-related healthcare for transgender young people as discussed in detail in Section III,

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<sup>1</sup> 42 U.S.C. § 1395. This provision explicitly states Congress's intent “to minimize federal intrusion” into state healthcare regulation. *Mass. Med. Soc. v. Dukakis*, 815 F.2d 790, 791 (1st Cir. 1987) (opinion of Breyer, J.).

<sup>2</sup> *Texas v. Becerra*, 89 F.4th 529, 542 (5th Cir. 2024) (quoting *United States v. Univ. Hosp., State Univ. of N.Y. at Stony Brook*, 729 F.2d 144, 160 (2d Cir. 1984)).

<sup>3</sup> *Goodman v. Sullivan*, 891 F.2d 449, 451 (2d Cir. 1989) (per curiam) (emphasis added).

<sup>4</sup> See 42 C.F.R. § 482.11(c).

<sup>5</sup> Regulations that “may have the effect of directly influencing a doctor's decision on what type of medical treatment will be provided, [] directly interfere[] with the practice of medicine. *Am. Med. Assn. v. Weinberger*, 522 F.2d 921, 925 (7th Cir. 1975).

<sup>6</sup> KFF, State Shield Laws: Protections for Abortion and Gender Affirming Care Providers, Jul. 2025, <https://www.kff.org/state-health-policy-data/state-indicator/shield-laws/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>.

<sup>7</sup> 90 *Fed. Reg.* 59463, 59471–72 (“Under Section 1801 of the Act, CMS may not “exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, (42 U.S.C. 1395). However, we believe 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.”).

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because of Congress' insistence that the Medicare statute "shall [not] be construed" to interfere with "the practice of medicine or the manner in which medical services are provided."<sup>8</sup>

Without clear Congressional authorization, which it does not have here, CMS lacks the authority to define what healthcare is (or what it is not) or to specify the scope of what constitutes the practice of medicine, particularly for purposes of prohibiting state-licensed, evidence-based treatments. And CMS certainly cannot take this unauthorized action to circumvent the prohibition against "any" federal interference in the supervision or control over the practice of medicine and provision of medical services.<sup>9</sup>

CMS does not have the authority to make such extraordinary pronouncements about healthcare and medical practice because that authority belongs to the states. States, not the federal government, are authorized to license and regulate medical providers "under their police powers" for "the protection of the lives, limbs, health, comfort, and quiet of all persons" (i.e., health and safety).<sup>10</sup> States also retain the authority to protect the integrity and ethics of the medical profession,<sup>11</sup> a reserved power inherent in "the structure and limitations of federalism."<sup>12</sup> This is particularly true "in areas where there is medical and scientific uncertainty."<sup>13</sup> No authority available to CMS—a federal administrative agency—including section 1861(e)(9) of the Social Security Act (the Act)<sup>14</sup> (i.e., a definitional provision) and Medicare's general rulemaking authority at section 1871 of the Act,<sup>15</sup> grants the agency the power to define, or in this case, redefine, healthcare. As discussed below, this fact is especially true with respect to healthcare that has been the subject of such politically contentious debate "about the safety, efficacy, and propriety of medical treatments."<sup>16</sup> For these reasons, CMS' unprecedented statements that gender affirming care is not "healthcare" are made without legal authority.

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<sup>8</sup> 42 U.S.C. § 1395.

<sup>9</sup> *Id.* (emphasis added).

<sup>10</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (citation omitted). *See also Hillsborough Cnty., Fla. v. Auto. Med. Labs., Inc.*, 471 U.S. 707, 719 (1985) (citing *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218 (1947) ("[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern.")).

<sup>11</sup> *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997); *Pa. Med. Soc. v. Marconis*, 942 F.2d 842, 847 (3d Cir. 1991) ("The licensing and regulation of physicians is a state function."). *See also Dent v. West Virginia*, 129 U.S. 114, 122 (1889) (recognizing the state's powers to regulate medical professions from "time immemorial").

<sup>12</sup> *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006). Indeed, the Constitution provides that all powers not specifically granted to the Federal Government are reserved to the States or citizens. This "allocation of powers in our federal system preserves the integrity, dignity, and residual sovereignty of the States." *Bond v. United States*, 564 U.S. 211, 221, 131 S. Ct. 2355, 180 L. Ed. 2d 269, 279-280 (2011).

<sup>13</sup> *United States v. Skrmetti*, 605 U.S. 495, 524 (2025) (quoting *Gonzales v. Carhart*, 550 U.S. 124, 163 (2007) ("We afford States "wide discretion to pass legislation in areas where there is medical and scientific uncertainty").

<sup>14</sup> 42 U.S.C. § 1395x.

<sup>15</sup> 42 U.S.C. § 1395hh.

<sup>16</sup> *United States v. Skrmetti*, 605 U.S. 495, 498 (2025).

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CMS attempts to rely on some of the most general provisions in the Medicare statute<sup>17</sup> to prevent hospitals nationwide from providing gender affirming care to transgender youth under age 18.<sup>18</sup> Neither of the two general authorities on which CMS relies suggest that Congress intended for the federal government to define lawful medical care or regulate in an area historically reserved for states, and they certainly do not permit CMS to reclassify state-licensed, evidence-based treatments as being outside the scope of "healthcare" in an effort to categorically prohibit such treatment under the Conditions of Participation for hospitals.

First, the agency attempts to rely on a general catch-all provision related to hospitals in section 1861(e)(9) of the Act, which appears at the end of the *definition* of the term "hospital" in the Medicare statute and provides that a hospital must "meet[] such other requirements as [CMS] finds necessary in the interest of the health and safety of individuals who are furnished services in the institution." This 'health and safety' language permits process-oriented standards that promote patient safety. CMS' existing regulations implementing section 1861(e)(9) of the Act demonstrate that the agency understands this limitation. For example, these regulations are clear that hospitals must "meet other applicable standards that are required by State or local laws."<sup>19</sup> As CMS' own implementing regulations acknowledge, section 1861(e) of the Act does not give CMS authority to displace state laws allowing for and, in some cases, protecting gender affirming care, by effectively prohibiting hospitals from providing state-licensed treatments for a targeted subset of the population.<sup>20</sup>

Second, CMS cites its general rulemaking authority under section 1871 of the Act. This provision allows CMS to regulate "as may be necessary to carry out the administration of the insurance programs under [the Medicare program]."<sup>21</sup> This general Medicare rulemaking authority allows CMS broad authority to regulate the administrative (i.e., ministerial) aspects of its national health insurance program for seniors and certain people with disabilities. It does not, however, grant CMS the authority to displace states' traditional role as the regulating authority

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<sup>17</sup> 90 *Fed. Reg* at 59464. CMS' full discussion of its statutory authority is as follows:

CMS has broad statutory authority under the Social Security Act (the Act) to establish health and safety regulations, which includes the authority to establish requirements that protect the health and safety of children. Section 1861(e)(9) of the Act, applicable to hospitals that participate in the Medicare program, explicitly gives CMS the authority to enact regulations that the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in a hospital, while section 1871 of the Act gives CMS the authority to prescribe regulations as necessary to carry out the administration of the program.

<sup>18</sup> In addition to the legal problems with CMS' reliance on broad authorities in the Medicare statute to effectively ban hospitals from providing gender affirming care to transgender youth, this proposal, if finalized, would create especially problematic precedent by opening the door to administrative agencies unilaterally prohibiting other kinds of politically disfavored care and actions.

<sup>19</sup> 42 C.F.R. § 482.11.

<sup>20</sup> *Id.*

<sup>21</sup> 42 U.S.C. § 1395hh.

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over the practice of medicine and determine whether certain care can be lawfully provided to specific populations in any hospital in the state.<sup>22</sup>

When Congress wants to use its limited constitutional powers to regulate or prohibit medical care, it does so very clearly,<sup>23</sup> and unsurprisingly, the instances of such authorized Congressional action are limited.<sup>24</sup> Under the Emergency Medical Treatment and Active Labor Act (EMTALA), for example, Congress unambiguously and proscriptively requires screening and stabilization services for anyone presenting with an emergency medical condition at a hospital's emergency department.<sup>25</sup> The statute goes as far as to define "emergency medical condition" and "to stabilize."<sup>26</sup> Similarly, with the Partial-Birth Abortion Ban Act,<sup>27</sup> Congress expressly prohibits physicians from knowingly and intentionally performing "partial-birth abortions," and includes a two-prong definition of the prohibited conduct in the statute. In contrast, Sections 1861(e)(9) and 1871 of the Act—the general authorities on which CMS purports to rely here—make no mention of gender affirming care or suggest in any way that any kind of medical care may be prohibited or considered not to be healthcare. Neither these authorities nor any other authorities available to CMS give it the authority to determine and pronounce that gender affirming care for transgender youth under age 18 is not healthcare.

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<sup>22</sup> The federal government cannot override the laws of nonconsenting states. The government's extraordinary view of its power under the Spending Clause here would vastly "undermine the status of the States as independent sovereigns in our federal system." *NFIB v. Sebelius*, 567 U.S. 519, 577 (2012) (opinion of Roberts, C.J.). Under the Supremacy Clause there is a presumption against preemption in areas of traditional state police powers; state and local regulation of health and safety is not invalidated absent a "clear and manifest purpose of Congress (or equivalent agency intent) to preempt." See *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715, 105 S. Ct. 2371, 2376 (1985). To rebut this presumption it "must be show[n] that Congress intended to displace the state's police power function." *Pa. Med. Soc'y v. Marconis*, 942 F.2d 842, 847 (3d Cir. 1991).

<sup>23</sup> Indeed, Congress's clarity about when it is regulating or prohibiting medical is also required under the Spending Clause of the Constitution. Under the Spending Clause, "if Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981) (holding that funding conditions under the Spending Clause must provide "clear notice" to the funds recipient of what actions are required in exchange for the funds and the consequences of noncompliance).

<sup>24</sup> Courts have a long-standing practice of "assum[ing] that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). "That assumption applies with particular force when Congress has legislated in a field traditionally occupied by the States." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008). See, e.g., *Gonzales v. Oregon*, 546 U.S. 243 (2006) (holding that the Attorney General's rulemaking power under the Controlled Substances Act did not include the power to declare illegitimate a medical standard for care and treatment of patients that was specifically authorized under state law and declaring invalid the rulemaking that determined that using controlled substances to assist suicide was not a legitimate medical practice and that dispensing or prescribing drugs for that purpose was unlawful); *NFIB v. DOL, OSHA*, 595 U.S. 109, 123–24 (2022) ("The agency seeks to . . . induce individuals to undertake a medical procedure that affects their lives outside the workplace. Historically, such matters have been regulated at the state level by authorities who enjoy broader and more general governmental powers").

<sup>25</sup> 42 U.S.C. § 1395dd.

<sup>26</sup> *Id.*

<sup>27</sup> 18 U.S.C. § 1531.

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In light of these considerations, CMS' cursory claim that gender affirming care is not "healthcare" is wholly insufficient and without legal authority, and it cannot be made to overcome Congress's very clear pronouncement against any federal interference in the practice of medicine in section 1801 of the Act.

To be clear, CMS has long regulated hospitals through Conditions of Participation regarding, for example, patient rights, infection control, and quality assessment. While conditions governing patient safety may have some indirect influence on clinical practice, patient-safety processes and quality standards are distinguishable from CMS' proposed categorical ban on specific, state-authorized treatments for a specific population. The latter crosses the line from quality oversight into prohibiting medical treatment in violation of the Constitution and the Medicare statute.

Finally, CMS' proposal is also in conflict with the Medicaid statute. Section 1902(a)(23) of the Act<sup>28</sup> provides that Medicaid beneficiaries may choose any provider "*qualified* to perform the service or services required . . . who undertakes to perform such services." The term "qualified" is not defined by Congress, and instead, the states, in their proper exercise of regulating health and safety, determine provider qualifications. Under the Medicaid statute, it is up to the states, not the federal government, to determine which providers are qualified to participate in the Medicaid program.<sup>29</sup>

*CMS' proposed rule attempts to resolve a politically contentious policy debate that is the responsibility of state legislatures in violation of the Major Questions Doctrine.*

The proposal is also unauthorized under the Major Questions Doctrine because CMS, a federal administrative agency, may not rely on general terms and definitional provisions in the Medicare statute to make politically significant decisions, like whether hospitals nationwide should be permitted to provide gender affirming care to certain minors, particularly when doing so would displace states' traditional role as the regulating authority over the practice of medicine. Congress does not "alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not [. . .] hide elephants in mouseholes,"<sup>30</sup> and refrains from settling important political issues using "cryptic" language.<sup>31</sup> Indeed, CMS needs more than a mere

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<sup>28</sup> 42 U.S.C. § 1396a(a)(23).

<sup>29</sup> See *Medina v. Planned Parenthood South Atlantic*, 606 U.S. 357, 364 (2025).

<sup>30</sup> *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001).

<sup>31</sup> *West Virginia v. E.P.A.*, 597 U.S. 697, 721 (2022). "[E]xtraordinary grants of regulatory authority are rarely accomplished through 'modest words,' 'vague terms,' or 'subtle device[s].' Nor does Congress typically use oblique or elliptical language to empower an agency to make a 'radical or fundamental change' to a statutory scheme. Agencies have only those powers given to them by Congress, and 'enabling legislation' is generally not an 'open book to which the agency [may] add pages and change the plot line.'" *Id.* at 723 (2022) (citations omitted).

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“plausible textual basis” to support its agency action here;<sup>32</sup> under Major Questions principles, such transformative changes require clear congressional authorization.<sup>33</sup>

The Major Questions Doctrine is implicated when an agency claims the power to resolve matters of vast economic and political significance or to effect a transformative expansion of its authority without clear congressional authorization.<sup>34</sup> Courts have established that evidence of a matter's political significance may include: “earnest and profound debate across the country,” not “confined to the halls of Congress,” or topics “that are personal and emotionally charged.”<sup>35</sup> In addition, a major question may arise if a Federal agency “intrudes into an area that is the particular domain of state law.”<sup>36</sup>

There is no question that CMS' proposal would regulate a matter of great political significance. Just last term, Chief Justice Roberts, in the majority opinion in *United States v. Skrmetti*,<sup>37</sup> described the debate around gender affirming care for minors as a “fierce scientific and policy debate” with profound implications.<sup>38</sup> Justice Thomas's concurring opinion similarly described the debate as “politically contentious.”<sup>39</sup>

In this same case, the highest Court in the United States further recognized that states are the sovereign bodies with authority to regulate gender affirming care for transgender youth.<sup>40</sup> While some states have sought to restrict this care with the Court's approval,<sup>41</sup> other states allow and, in some cases, explicitly protect this care.<sup>42</sup> Consistent with the discussion above, states, not the federal government, hold the power to regulate the practice of medicine, and under the Major

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<sup>32</sup> *Id.* at 723.

<sup>33</sup> If administrative agencies seek to regulate the daily lives and liberties Americans, under the Major Questions Doctrine, the agency must at least be able to trace that power to a clear grant of authority from Congress. *NFIB v. DOL, OSHA*, 595 U.S. 109, 124 (2022).

<sup>34</sup> *West Virginia v. EPA*, 597 U.S. 697 (2022). “Congress is more likely to have focused upon, and answered, major questions, while leaving interstitial matters [for agencies] to answer themselves in the course of a statute's daily administration.” *Biden v. Nebraska*, 600 U.S. 477, 514-15 (2023) (Barrett, J. concurring) (quoting S. Breyer, *Judicial Review of Questions of Law and Policy*, 38 *Admin. L. Rev.* 363, 370 (1986)).

<sup>35</sup> *Purl v. United States HHS*, 787 F. Supp. 3d 284, 322 (N.D. Tex. 2025) (quoting *Biden v. Nebraska*, 600 U.S. at 503, 504 (2023)).

<sup>36</sup> *Id.*

<sup>37</sup> *United States v. Skrmetti*, 605 U.S. 495 (2025)

<sup>38</sup> *Id.* at 498. (“This case carries with it the weight of fierce scientific and policy debates about the safety, efficacy, and propriety of medical treatments in an evolving field. The voices in these debates raise sincere concerns; the implications for all are profound.”)

<sup>39</sup> *Id.* at 547 (Thomas, J. concurring).

<sup>40</sup> *Id.* at 532, 540.

<sup>41</sup> *Id.*

<sup>42</sup> KFF, *State Shield Laws: Protections for Abortion and Gender Affirming Care Providers*, Jul. 2025,

<https://www.kff.org/state-health-policy-data/state-indicator/shield-laws/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>.

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Questions Doctrine, a federal administrative agency cannot rely on general provisions in the Medicare statute to usurp that state authority.<sup>43</sup>

As discussed previously, CMS inappropriately attempts in its proposed rule to rely on some of the most general provisions in the Medicare statute,<sup>44</sup> which Congress enacted to allow CMS to administer the Medicare program, not to regulate conduct that falls squarely under the state's authority. Unlike the very clear and limited instances in which Congress has used its constitutional powers to define lawful medical care, there is no such clear Congressional authorization in section 1861(e)(9) or 1871 of the Act to allow CMS to regulate medical care or an area of great political contention. CMS' effort to resolve the political and policy debates around gender affirming care for transgender youth by attempting to prohibit such care by regulation when CMS cannot point to any Congressional language in the Medicare statute or elsewhere in federal statute about the care at issue or authority to prohibit medical care that is lawful under state law anywhere unquestionably violates the Major Questions Doctrine. Courts are likely to meet with a considerable "measure of skepticism" the administration's claim that Congress somehow prohibited gender affirming care for transgender youth without even mentioning that care in the statute.<sup>45</sup>

CMS' proposal is additionally questionable under the Major Questions Doctrine because of its vast economic significance. If the proposal is finalized, hospitals would face the (politically significant) choice of ceasing to provide gender affirming care or no longer participating in Medicare and Medicaid. The choice to forgo Medicare and Medicaid payment would have substantial economic consequences. Nationally, nearly half (44%) of all spending on hospital care comes from Medicare and Medicaid payments.<sup>46</sup> Reductions in federal spending would be nearly impossible to make up through other revenue sources and could be especially challenging for hospitals that are financially vulnerable, such as rural and safety-net hospitals.<sup>47</sup> But the significant economic effects will not end with the hospitals; they will be felt widely across the healthcare system. Assuming hospitals could survive the federal payment reductions and avoid closure, they would likely shift costs onto patients and offer fewer services, which could mean patients will not be able to get needed care, or they could receive lower quality of care.<sup>48</sup> The more likely outcome, however, is hospital closures. Hospitals are essential to the economic

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<sup>43</sup> Furthermore, this federal-state balance "is not just an end in itself: Rather, federalism secures to citizens the liberties that derive from the diffusion of sovereign power." *Shelby Cty. v. Holder*, 570 U.S. 529, 543 (2013).

<sup>44</sup> 90 *Fed. Reg.* at 59464.

<sup>45</sup> *Util. Air Regul. Grp. v. E.P.A.*, 573 U.S. 302, 324 (2014).

<sup>46</sup> Dawson, L., Hulver, S., New Trump Administration Proposals Would Further Limit Gender Affirming Care for Young People by Restricting Providers and Reducing Coverage, KFF, Dec. 22, 2025, <https://www.kff.org/lgbtq/new-trump-administration-proposals-would-further-limit-gender-affirming-care-for-young-people-by-restricting-providers-and-reducing-coverage/>.

<sup>47</sup> Levinson, Z., Hulver, S., Godwin, J., Neuman, T., Key Facts about Hospitals, KFF, Feb. 19, 2025, <https://www.kff.org/health-costs/key-facts-about-hospitals/>.

<sup>48</sup> *Id.*

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stability of the communities where they operate and closures would be disruptive to the economies of those communities.<sup>49</sup>

Considering the significant constitutional, federalism, and statutory authority concerns, we respectfully request that CMS withdraw its proposal. The proposal is ripe with constitutional problems, and the proposal is entirely without statutory authority. Moreover, it directly violates the Medicare statute and its implementing regulations.

## **II. The Proposed Rule, if finalized as proposed, is Arbitrary and Capricious and will Violate the Administrative Procedure Act**

The Administrative Procedure Act requires courts to “hold unlawful and set aside agency actions, findings, and conclusions found to be . . . arbitrary, capricious, [or] an abuse of discretion.”<sup>50</sup> An agency action that “entirely fail[s] to consider an important aspect of the problem, offer[s] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise” is arbitrary and capricious.<sup>51</sup> CMS’ proposal, if finalized, is arbitrary and capricious for several reasons.

First, CMS has entirely failed to consider an important aspect of the problem the rule creates, including the importance of gender affirming care for transgender youth and the harms to patients and providers that would be caused should this rule be implemented. CMS wrongly claims that there is an “absence of rigorous scientific data demonstrating the safety and effectiveness of [transition-related care].”<sup>52</sup> As discussed below in Section III, decades of peer-reviewed research and clinical data show that transition-related healthcare for transgender young people is safe and effective. The agency also failed to adequately consider alternative policies and instead took the most drastic course of action to cut off all federal funding.<sup>53</sup>

Second, CMS’ explanation for its decision runs counter to the evidence. CMS cherry-picked the evidence it relied on while failing to contend with the evidence that runs counter to its position. The agency must examine the relevant data and articulate a satisfactory explanation for its

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<sup>49</sup> Shachar, C., Huberfeld, N., Proposed HHS rule on gender-affirming care radically expands use of Medicare, Medicaid as policy weapons, Dec. 24, 2025, <https://www.statnews.com/2025/12/24/gender-affirming-care-hhs-rule-medicare-medicaid-weapons/>.

<sup>50</sup> 5 U.S.C. § 706(2)(A).

<sup>51</sup> *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

<sup>52</sup> 90 *Fed. Reg.* at 59470.

<sup>53</sup> *Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 29 (2020) (finding that the Secretary’s failure to consider an obvious alternative— retaining DACA’s deferred-action component while terminating the associated benefits—rendered the agency’s action arbitrary and capricious).

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action,<sup>54</sup> including a "rational connection between the facts found and the choice made."<sup>55</sup> If CMS continues to fail to give meaningful consideration to the body of evidence supporting gender affirming care for transgender young people in formulating its final policy and does not make a rational connection between that evidence and its final policy, the final rule will be arbitrary and capricious.

CMS relies on two main documents to support its proposed rule. Notably, the two documents – HHS Report and Cass Review – have both been widely criticized by medical experts for misrepresenting data and scientific evidence.<sup>56</sup> The HHS Report, initially released in May 2025, claims to be a review of evidence and best practices for treating pediatric gender dysphoria.<sup>57</sup> Yet, the initial report omitted author names and did not go through a peer review process.<sup>58</sup> In November 2025, after widespread criticism, HHS released an updated report revealing the authors names and adding a "peer review supplement."<sup>59</sup> One review of the HHS Report, published by medical experts in the *Journal of Adolescent Health*, details the violations of scientific norms, misrepresentation of scientific evidence, and mischaracterization of gender

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<sup>54</sup> "The task of a court reviewing agency action under the APA's arbitrary and capricious standard is to determine whether the agency has examined the pertinent evidence, considered the relevant factors, and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983).

<sup>55</sup> *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 43 (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)).

<sup>56</sup> AAP Statement on HHS Report Treatment for Pediatric Gender Dysphoria. (2025, May 1). *American Academy of Pediatrics*. Retrieved February 3, 2026, from <https://www.aap.org/en/news-room/news-releases/aap/2025/aap-statement-on-hhs-report-treatment-for-pediatric-gender-dysphoria/>; Jacobs, P. (2025, May 2). *Researchers slam HHS report on gender-affirming care for youth*. *Science*. <https://www.science.org/content/article/researchers-slam-hhs-report-gender-affirming-care-youth>; Moore, J. K., Rayner, C., Skinner, S. R., Wynne, K., Cavve, B. S., Fraser, B., Ganti, U., McAllister, C., Meyerowitz-Katz, G., Nguyen, T., Ravine, A., Ross, B., Russell, D. B., Saunders, L. A., Siafarikas, A., & Pang, K. C. (2025). Cass Review does not guide care for Trans Young People. *Medical Journal of Australia*, 223(7), 331–337. <https://doi.org/10.5694/mja2.70035>; Dowshen, N., Baker, K., Garofalo, R., Chen, D., Inwards-Breland, D. J., Sequeira, G., Mehringer, J. E., & McNamara, M. (2025). A critical scientific appraisal of the Health and Human Services Report on Pediatric Gender Dysphoria. *Journal of Adolescent Health*, 77(3), 342–345. <https://doi.org/10.1016/j.jadohealth.2025.06.002>; McNamara, M., Baker, K., Connelly, K., Janssen, A., Olson-Kennedy, J., Pang, K. C., Scheim, A., Turban, J., & Alstott, A. (2024). An Evidence-Based Critique of "The Cass Review" on Gender-affirming Care for Adolescent Gender Dysphoria. Retrieved February 3, 2026, from [https://law.yale.edu/sites/default/files/documents/integrity-project\\_cass-response.pdf](https://law.yale.edu/sites/default/files/documents/integrity-project_cass-response.pdf).

<sup>57</sup> U.S. Department of Health and Human Services. (2025, November 19). *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices*. HHS Office of Population Affairs. <https://opa.hhs.gov/gender-dysphoria-report>.

<sup>58</sup> Jacobs, P. (2025, May 2). *Researchers slam HHS report on gender-affirming care for youth*. *Science*. <https://www.science.org/content/article/researchers-slam-hhs-report-gender-affirming-care-youth>; Dowshen, N., Baker, K., Garofalo, R., Chen, D., Inwards-Breland, D. J., Sequeira, G., Mehringer, J. E., & McNamara, M. (2025). A critical scientific appraisal of the Health and Human Services Report on Pediatric Gender Dysphoria. *Journal of Adolescent Health*, 77(3), 342–345. <https://doi.org/10.1016/j.jadohealth.2025.06.002>.

<sup>59</sup> See U.S. Department of Health and Human Services. (2025, November). *Gender dysphoria report peer reviews and Responses*. HHS Office of Population Affairs. Retrieved February 3, 2026, from <https://opa.hhs.gov/gender-dysphoria-report-peer-reviews>.

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identity in young people and the standard of care.<sup>60</sup> For example, the authors state that the HHS Report "misrepresents and improperly appraises studies, often ignoring their primary conclusion" and "provides no evidence for its assertion that puberty-pausing medications and hormone therapy are harmful to TGD youth, and it even states that evidence of harms is 'sparse'."<sup>61</sup>

The Cass Review, published in 2024, purports to provide recommendations regarding transition-related care for young people in England; but, notably none of the contributors have research or clinical experience in transgender healthcare.<sup>62</sup> Similar to the HHS Report, a group of medical experts published an article critiquing the Cass Review and "identified a high risk of bias in each of the systematic reviews driven by unexplained protocol deviations, ambiguous eligibility criteria, inadequate study identification."<sup>63</sup> The authors also "identified methodological flaws and unsubstantiated claims in the primary research."<sup>64</sup>

Third, CMS argues that these transition-related services are harmful or unsafe for transgender youth, yet continues to allow them for cisgender youth with precocious puberty or for intersex youth.<sup>65</sup> Allowing the use of federal funding for the same services, just for people with a different diagnosis, is inconsistent with CMS' claim that these services are harmful or unsafe. CMS' distinction for coverage of care based on diagnostic criteria, with no scientific or medical supporting evidence, is on its face arbitrary and capricious. If these services are truly categorically unsafe, as CMS wrongly claims, it could not plausibly permit their use for other pediatric populations. Allowing federal funding for identical hormone therapies or puberty-pausing medications, differing only in the diagnosis or patient population, contradicts CMS' claim that safety concerns motivate the proposed policy change and acts as a subterfuge for discrimination against transgender people. Moreover, the agency's diagnosis-based distinction risks substituting categorical exclusions for individualized medical judgment. Rather than deferring to the child's treating physician to determine whether a particular treatment is necessary for a particular patient, CMS imposes a blanket funding restriction unconnected to

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<sup>60</sup> Dowshen, N., Baker, K., Garofalo, R., Chen, D., Inwards-Breland, D. J., Sequeira, G., Mehringer, J. E., & McNamara, M. (2025). A critical scientific appraisal of the Health and Human Services Report on Pediatric Gender Dysphoria. *Journal of Adolescent Health*, 77(3), 342–345. <https://doi.org/10.1016/j.jadohealth.2025.06.002>

<sup>61</sup> *Id.*

<sup>62</sup> McNamara, M., Baker, K., Connelly, K., Janssen, A., Olson-Kennedy, J., Pang, K. C., Scheim, A., Turban, J., & Alstott, A. (2024). An Evidence-Based Critique of "The Cass Review" on Gender-affirming Care for Adolescent Gender Dysphoria. Retrieved February 3, 2026, from [https://law.yale.edu/sites/default/files/documents/integrity-project\\_cass-response.pdf](https://law.yale.edu/sites/default/files/documents/integrity-project_cass-response.pdf).

<sup>63</sup> Noone, C., Southgate, A., Ashman, A., Quinn, É., Comer, D., Shrewsbury, D., Ashley, F., Hartland, J., Paschedag, J., Gilmore, J., Kennedy, N., Woolley, T. E., Heath, R., Biskupovic Goulding, R., Simpson, V., Kiely, E., Coll, S., White, M., Grijseels, D. M., ... McLamore, Q. (2025). Critically appraising the cass report: Methodological flaws and unsupported claims. *BMC Medical Research Methodology*, 25(1). <https://doi.org/10.1186/s12874-025-02581-7>.

<sup>64</sup> *Id.*

<sup>65</sup> 90 *Fed. Reg.* at 59471.

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clinical standards. This approach not only contradicts CMS' stated concern for patient safety but also further underscores the arbitrary and capricious nature of the proposed rule.

Lastly, CMS has proposed these changes to longstanding policy without adequate consideration of reliance interests. When an agency changes a policy or position, it is required to acknowledge the change and provide a "reasoned explanation" in support of the reversal that addresses the interests of those who significantly relied on the prior policy.<sup>66</sup> CMS has failed to acknowledge or seek comments on the serious reliance interests that its current policy has created across the healthcare system, including for patients who receive this care.

Hospitals structure their staffing, training, resources, and more around the availability of federal funding for these services. By abruptly restricting federal funding for transition-related care, CMS threatens to destabilize existing care and force hospitals and providers to stop providing services they have long offered in good faith reliance on prior agency policy and their own state's laws. Instead of meaningfully engaging with hospitals' concerns about the potential financial harm and reliance interest, CMS provides a conclusory statement in the collection for information requirements section that states, "primary care providers and endocrinologists outside of hospitals, who would not be affected by these requirements, can also prescribe these treatments."<sup>67</sup> This not only downplays the impact this rule will have on access to care, but it also insinuates that these providers will have other avenues to continue to receive compensation for providing medical care" with no further explanation or discussion. CMS completely ignores the reliance interest of transgender young people and their families. There is no discussion in the NPRM regarding their reliance on access to this care that hospitals have long provided. By failing to grapple with these reliance interests, CMS has not provided a reasonable explanation that is required when making changes to longstanding policy.

### **III. The proposed rule will have serious negative health impacts on transgender and gender diverse young people.**

Peer-reviewed research and clinical data show that transition-related healthcare for transgender young people is safe and effective. CMS incorrectly claims that there is an "absence of rigorous scientific data" showing the safety and effectiveness of transition-related care in youth,<sup>68</sup> and that there is "weak and uncertain evidence of benefits."<sup>69</sup> As discussed above, CMS relies on documents, including the HHS Report and Cass Review, that are rife with misrepresented data interpretations and methodological errors, to conclude that "the risk-benefit profile of these procedures for children is extremely poor."<sup>70</sup> Further, CMS fails to consider and downplays the

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<sup>66</sup> *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211 (2016).

<sup>67</sup> 90 *Fed. Reg.* at 59472.

<sup>68</sup> *Id.* at 59470.

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* at 59471.

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harm and lack of alternatives for transgender young people and families when access to this necessary healthcare is restricted.

These proposed restrictions on access to transition-related healthcare for transgender young people will deprive them of necessary healthcare services proven to be safe and beneficial. The harmful effects of the current political climate and other restrictive policies on transgender and gender diverse individuals are well documented.<sup>71</sup> State-level anti-transgender laws have been associated with significant increases in suicide attempts among transgender and nonbinary youth.<sup>72</sup> Additionally, studies show that exposure to news about proposed bills restricting access to transition-related care contributes to worsening mental and physical health outcomes for transgender youth and young adults.<sup>73</sup>

A 2022 survey reported that 98% of respondents ages 18 or older who received gender-affirming hormone therapy, and 97% who received gender-affirming surgery, reported being happier and more satisfied with their lives.<sup>74</sup> Transgender individuals who transition report better health outcomes compared to those who do not.<sup>75</sup> These survey findings are supported by multiple comprehensive systematic literature reviews. A 2018 review conducted by researchers at Cornell University reviewed all peer-reviewed articles on transgender healthcare published between 1991 and mid-2017 and found that gender transition — including access to transition-related care — improves overall well-being.<sup>76</sup> Notably, no study over this twenty-six-year period concluded that

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<sup>71</sup> Dhanani, L. Y., & Totton, R. R. (2023). Have you heard the news? The effects of exposure to news about recent transgender legislation on transgender youth and young adults. *Sexuality Research and Social Policy*, 20(4), 1345–1359. <https://doi.org/10.1007/s13178-023-00810-6>; Horne, S. G., McGinley, M., Yel, N., & Maroney, M. R. (2022). The stench of bathroom bills and anti-transgender legislation: Anxiety and depression among transgender, nonbinary, and cisgender LGBQ people during a state referendum. *Journal of Counseling Psychology*, 69(1), 1–13. <https://doi.org/10.1037/cou0000558>; Lee, W. Y., Hobbs, J. N., Hobaica, S., DeChants, J. P., Price, M. N., & Nath, R. (2024). State-level anti-transgender laws increase past-year suicide attempts among transgender and non-binary young people in the USA. *Nature Human Behaviour*, 8(11), 2096–2106. <https://doi.org/10.1038/s41562-024-01979-5>

<sup>72</sup> Lee, W. Y., Hobbs, J. N., Hobaica, S., DeChants, J. P., Price, M. N., & Nath, R. (2024). State-level anti-transgender laws increase past-year suicide attempts among transgender and non-binary young people in the USA. *Nature Human Behaviour*, 8(11), 2096–2106. <https://doi.org/10.1038/s41562-024-01979-5>

<sup>73</sup> Dhanani, L. Y., & Totton, R. R. (2023). Have you heard the news? The effects of exposure to news about recent transgender legislation on transgender youth and young adults. *Sexuality Research and Social Policy*, 20(4), 1345–1359. <https://doi.org/10.1007/s13178-023-00810-6>; Horne, S. G., McGinley, M., Yel, N., & Maroney, M. R. (2022). The stench of bathroom bills and anti-transgender legislation: Anxiety and depression among transgender, nonbinary, and cisgender LGBQ people during a state referendum. *Journal of Counseling Psychology*, 69(1), 1–13. <https://doi.org/10.1037/cou0000558>

<sup>74</sup> Rastogi, A., Menard, L., Miller, G. H., Cole, W., Laurison, D., Caballero, J. R., Murano-Kinney, S., & Heng-Lehtinen, R. (2025, June). Health and wellbeing: A report of the 2022 U.S. Transgender Survey (pp. 10–11). *Advocates for Transgender Equality*. <https://ustranssurvey.org/download-reports/>

<sup>75</sup> *Id.* at 24.

<sup>76</sup> What We Know Project, Cornell University. (2018). *What does the scholarly research say about the effect of gender transition on transgender well-being?* <https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-the-scholarly-research-say-about-the-well-being-of-transgender-people/>

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gender transition causes overall harm.<sup>77</sup> Reported positive health outcomes include “improved quality of life, greater relationship satisfaction, higher self-esteem and confidence, and reductions in anxiety, depression, suicidality, and substance use.”<sup>78</sup> A more recent 2024 comprehensive systematic review conducted by researchers at the University of Utah affirmed these findings, concluding that hormone therapy is safe and effective for transgender youth.<sup>79</sup> Many of the studies examined in these comprehensive reviews are discussed in more depth below.

Numerous studies report that hormone therapy and puberty-pausing medications in young people do not negatively impact other aspects of their physical health, or that any potential risks can be mitigated. Research has shown that girls who receive hormone therapy in childhood report normal bone density and ovarian function in early adulthood, with no notable impact on their final height.<sup>80</sup> The same study also reported no proven predisposition for polycystic ovary syndrome or menstrual irregularities connected with hormone therapy in young girls.<sup>81</sup> Additional studies show no negative impacts on liver enzymes or creatinine levels in transgender young people using puberty-pausing medications.<sup>82</sup> Further, a study found no adverse effects on cognitive functioning, behavioral, or social problems among young girls receiving puberty-pausing medications compared to their peers who do not receive this treatment.<sup>83</sup>

Transgender youth face a higher risk for lifetime substance use, depression, anxiety, and suicidality than their cisgender counterparts.<sup>84</sup> Transition-related care has been shown to improve mental health outcomes for transgender individuals, particularly youth, including reductions in

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<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> LaFleur, J., Heath, L., Gonzalez, V., et al. (2024). *Gender-affirming medical treatments for pediatric patients with gender dysphoria: A report of the University of Utah College of Pharmacy Drug Regimen Review Center (DRRC)*. University of Utah. <https://le.utah.gov/AgencyRP/reportingDetail.jsp?rid=636>

<sup>80</sup> Magiakou, M. A., Manousaki, D., Papadaki, M., et al. (2010). The efficacy and safety of gonadotropin-releasing hormone analog treatment in childhood and adolescence: A single center, long-term follow-up study. *The Journal of Clinical Endocrinology & Metabolism*, 95(1), 109–117. <https://doi.org/10.1210/jc.2009-0793>

<sup>81</sup> *Id.*

<sup>82</sup> Schagen, S. E. E., Cohen-Kettenis, P. T., Delemarre-van de Waal, H. A., & Hannema, S. E. (2016). Efficacy and safety of gonadotropin-releasing hormone agonist treatment to suppress puberty in gender dysphoric adolescents. *The Journal of Sexual Medicine*, 13(7), 1125–1132. <https://doi.org/10.1016/j.jsxm.2016.05.004>

<sup>83</sup> Wojniusz, S., Callens, N., Sütterlin, S., Andersson, S., De Schepper, J., Gies, I., Vanbesien, J., De Waele, K., Van Aken, S., Craen, M., Vögele, C., Cools, M., & Haraldsen, I. R. (2016). Cognitive, emotional, and psychosocial functioning of girls treated with pharmacological puberty blockage for idiopathic central precocious puberty. *Frontiers in Psychology*, 7, 1053. <https://doi.org/10.3389/fpsyg.2016.01053>

<sup>84</sup> Coulter, R. W. S., Egan, J. E., Kinsky, S., et al. (2019). Mental health, drug, and violence interventions for sexual/gender minorities: A systematic review. *Pediatrics*, 144(3), e20183367. <https://doi.org/10.1542/peds.2018-3367>; McKenna, J. L., Anglemeyer, E. T., & McGregor, K. (2024). Gender-affirming mental health care for transgender and gender diverse youth on pediatric inpatient psychiatry units. *Journal of the American Academy of Child & Adolescent Psychiatry*, 63(6), 576–580. <https://doi.org/10.1016/j.jaac.2023.05.021>

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suicidal ideation.<sup>85</sup> Compared to their cisgender peers, transgender youth are more likely to experience emotional distress, internalize and externalize problems, have high rates of suicidality, and psychiatric inpatient hospitalization.<sup>86</sup> Multiple studies report that young people who wanted, but did not receive, transition-related hormone therapy had higher chances of seriously considering suicide or attempting it as opposed to those who accessed the care they needed.<sup>87</sup> Importantly, even when controlling for psychiatric medication use and counseling, hormone therapy is independently associated with reductions in depression and suicidal ideation.<sup>88</sup> Multiple studies confirm that transgender and gender diverse youth who received puberty-pausing medications present lower instances of internalizing their problems and are less likely to have suicidal thoughts.<sup>89</sup> Relatedly, evidence consistently shows that when young

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<sup>85</sup> Rew, L., Young, C. C., Monge, M., & Bogucka, R. (2020). Puberty blockers for transgender and gender diverse youth—a critical review of the literature. *Child and Adolescent Mental Health*, 26(1), 3–14. <https://doi.org/10.1111/camh.12437>; Guss, C., & Gordon, C. M. (2022). Pubertal blockade and subsequent gender-affirming therapy. *JAMA Network Open*, 5(11), e2239763. <https://doi.org/10.1001/jamanetworkopen.2022.39763>; Rastogi, A., Menard, L., Miller, G. H., Cole, W., Laurison, D., Caballero, J. R., Murano-Kinney, S., & Heng-Lehtinen, R. (2025, June). *Health and wellbeing: A report of the 2022 U.S. Transgender Survey*. Advocates for Transgender Equality. <https://ustransurvey.org/download-reports/>; Turban, J. L., King, D., Carswell, J. M., & Keuroghlian, A. S. (2020). Pubertal suppression for transgender youth and risk of suicidal ideation. *Pediatrics*, 145(2), e20191725. <https://doi.org/10.1542/peds.2019-1725>

<sup>86</sup> McKenna, J. L., Anglemyer, E. T., & McGregor, K. (2024). Gender-affirming mental health care for transgender and gender diverse youth on pediatric inpatient psychiatry units. *Journal of the American Academy of Child & Adolescent Psychiatry*, 63(6), 576–580. <https://doi.org/10.1016/j.jaac.2023.05.021>; van der Miesen, A. I. R., Steensma, T. D., de Vries, A. L. C., Bos, H., & Popma, A. (2020). Psychological functioning in transgender adolescents before and after gender-affirmative care compared with cisgender general population peers. *Journal of Adolescent Health*, 66(6), 699–704. <https://doi.org/10.1016/j.jadohealth.2019.12.018>

<sup>87</sup> Green, A. E., DeChants, J. P., Price, M. N., & Davis, C. K. (2022). Association of gender-affirming hormone therapy with depression, thoughts of suicide, and attempted suicide among transgender and nonbinary youth. *Journal of Adolescent Health*, 70(4), 643–649. <https://doi.org/10.1016/j.jadohealth.2021.10.036>; Turban, J. L., King, D., Carswell, J. M., & Keuroghlian, A. S. (2020). Pubertal suppression for transgender youth and risk of suicidal ideation. *Pediatrics*, 145(2), e20191725. <https://doi.org/10.1542/peds.2019-1725>

<sup>88</sup> Achille, C., Taggart, T., Eaton, N. R., Osipoff, J., Tafuri, K., Lane, A., & Wilson, T. A. (2020). Longitudinal impact of gender-affirming endocrine intervention on the mental health and well-being of transgender youths: Preliminary results. *International Journal of Pediatric Endocrinology*, 2020, 8. <https://doi.org/10.1186/s13633-020-00078-2>

<sup>89</sup> McGregor, K., McKenna, J. L., Williams, C. R., Barrera, E. P., & Boskey, E. R. (2024). Association of pubertal blockade at Tanner 2/3 with psychosocial benefits in transgender and gender diverse youth at hormone readiness assessment. *Journal of Adolescent Health*, 74(4), 801–807. <https://doi.org/10.1016/j.jadohealth.2023.10.028>; Allen, L. R., Watson, L. B., Egan, A. M., & Moser, C. N. (2019). Well-being and suicidality among transgender youth after gender-affirming hormones. *Clinical Practice in Pediatric Psychology*, 7(3), 302–311. <https://doi.org/10.1037/cpp0000288>; Croteau, T. A., Gelech, J., Morrison, M. A., & Morrison, T. G. (2025). Psychological and physical health outcomes associated with gender-affirming medical care for transgender and gender-diverse youth: A critical review. *Healthcare*, 13(14), 1659. <https://doi.org/10.3390/healthcare13141659>; Turban, J. L., King, D., Carswell, J. M., & Keuroghlian, A. S. (2020). Pubertal suppression for transgender youth and risk of suicidal ideation. *Pediatrics*, 145(2), e20191725. <https://doi.org/10.1542/peds.2019-1725>;

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people receive transition-related care, including hormones, puberty-pausing medications, or surgery, there are notable reductions in rates of depression as well.<sup>90</sup> One study in particular found that among youth aged 13 to 20, receiving gender affirming care, including puberty-pausing medications and hormone therapy, was "associated with 60% lower odds of moderate or severe depression and 73% lower odds of suicidality."<sup>91</sup>

Eating disorders are also a significant concern for transgender and gender-diverse youth. A study found that nearly one in four gender diverse young people reported various eating disorder symptoms, including those of anorexia and bulimia.<sup>92</sup> Research further indicates that improvements in body image in transgender young people following hormone therapy result in better mental health outcomes and enhanced overall well-being.<sup>93</sup>

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(2021). Association between gender-affirming surgeries and mental health outcomes. *JAMA Surgery*, 156(7), 611–618. <https://doi.org/10.1001/jamasurg.2021.0952>

<sup>90</sup> Tordoff, D. M., Wanta, J. W., Collin, A., Stepney, C., Inwards-Breland, D. J., & Ahrens, K. (2022). Mental health outcomes in transgender and nonbinary youths receiving gender-affirming care. *JAMA Network Open*, 5(2), e220978. <https://doi.org/10.1001/jamanetworkopen.2022.0978>; McGregor, K., McKenna, J. L., Williams, C. R., Barrera, E. P., & Boskey, E. R. (2024). Association of pubertal blockade at Tanner 2/3 with psychosocial benefits in transgender and gender diverse youth at hormone readiness assessment. *Journal of Adolescent Health*, 74(4), 801–807. <https://doi.org/10.1016/j.jadohealth.2023.10.028>; Croteau, T. A., Gelech, J., Morrison, M. A., & Morrison, T. G. (2025). Psychological and physical health outcomes associated with gender-affirming medical care for transgender and gender-diverse youth: A critical review. *Healthcare*, 13(14), 1659. <https://doi.org/10.3390/healthcare13141659>; de Vries, A. L., McGuire, J. K., Steensma, T. D., Wagenaar, E. C., Doreleijers, T. A., & Cohen-Kettenis, P. T. (2014). Young adult psychological outcome after puberty suppression and gender reassignment. *Pediatrics*, 134(4), 696–704. <https://doi.org/10.1542/peds.2013-2958>; Achille, C., Taggart, T., Eaton, N. R., Osipoff, J., Tafuri, K., Lane, A., & Wilson, T. A. (2020). Longitudinal impact of gender-affirming endocrine intervention on the mental health and well-being of transgender youths: Preliminary results. *International Journal of Pediatric Endocrinology*, 2020, 8. <https://doi.org/10.1186/s13633-020-00078-2>; Fisher, A. D., Ristori, J., Romani, A., Cassioli, E., Mazzoli, F., Cocchetti, C., Pierdominici, M., Marconi, M., Ricca, V., Maggi, M., Vignozzi, L., & Castellini, G. (2024). Back to the future: Is GnRHa treatment in transgender and gender diverse adolescents only an extended evaluation phase? *The Journal of Clinical Endocrinology & Metabolism*, 109(6), 1565–1579. <https://doi.org/10.1210/clinem/dgad729>; Chelliah, P., Lau, M., & Kuper, L. E. (2024). Changes in gender dysphoria, interpersonal minority stress, and mental health among transgender youth after one year of hormone therapy. *Journal of Adolescent Health*, 74(6), 1106–1111. <https://doi.org/10.1016/j.jadohealth.2023.12.024>

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The benefits of receiving transition-related care extend into adulthood as well. A 2022 study found that 98% of people who began gender-affirming medical treatment in adolescence continued treatment in adulthood.<sup>94</sup> Adults who accessed transition-related hormone therapy in their youth report lower odds of severe psychological distress, suicidal ideation, binge drinking, and lifetime illicit drug use when compared to those who desired such treatment but were unable to access it.<sup>95</sup> More broadly, evidence strongly shows that receiving gender-affirming hormone treatment in youth is associated with better mental health outcomes into adulthood.<sup>96</sup> Satisfaction rates for transition-related care are high, and rates of regret are notably low compared to many other medical and life decisions.<sup>97</sup> A systematic review found that regret following gender affirming surgery was less than 1%, which is significantly lower than regret rates reported for procedures such as plastic surgery (5.1–9.1 % for breast augmentation and 10.82–33.3 % for body contouring), having children (7%), and getting a tattoo (16.2%).<sup>98</sup> Among the very few people who do choose to de-transition, most cite external factors that caused the decision, such as pressure from the community or societal stigma, rather than dissatisfaction with the medical care itself.<sup>99</sup>

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Restricting access to necessary, transition-related care through this proposed rule will have devastating consequences on health outcomes for transgender young people. As detailed above, the peer-reviewed and scientifically backed evidence base for the positive impacts of access to transition-related care, specifically hormone-related treatments, is well documented and supported by extensive research. Any assertion to the contrary by CMS blatantly ignores the findings and reports from scholars and medical experts detailing the safety and efficacy of transition-related care for young people.

### **Conclusion**

For all the foregoing reasons, APHA and the individual public health deans and scholars listed below urge CMS to withdraw the NPRM. CMS lacks the legal authority to issue this rule to regulate the practice of medicine by prohibiting healthcare that states have deemed appropriate. If finalized, the proposed rule will lead to significant individual health, community health, and economic harms, will be arbitrary and capricious, and violate the law. Lastly, CMS exceeds its authority, infringing on certain powers reserved to Congress and the States.

We also respectfully request that the full text of our comments, as well as the full text of each of the individual studies, reports, and other supporting materials that we have cited and made available through active links in our comments, be considered part of the formal administrative record on this NPRM for purposes of the Administrative Procedure Act. Please let us know if CMS is unable for any reason to include our linked materials, so we will have the chance to otherwise submit copies of the supporting documents into the administrative record.

Thank you for your consideration of our comments. If you need any additional information, please contact Allyson Crays at [a.crays@gwu.edu](mailto:a.crays@gwu.edu).

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1. American Public Health Association

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