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HCFA Health Care For All MASSACHUSETTS

February 17, 2026

Submitted electronically via regulations.gov

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

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

Re: "Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children" CMS-3481-P (RIN 0938-AV73)

Dear Secretary Kennedy and Administrator Oz:

Health Law Advocates, Inc. (HLA) and Health Care For All (HCFA) submit this comment in opposition to the Centers for Medicare & Medicaid Services' (CMS) December 2025 Notice of Proposed Rulemaking (NPRM) entitled "Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children." The proposed rule, if finalized, would bar any hospital from participating in Medicare and Medicaid if it provides puberty-pausing medications, hormone therapy, or surgery for transgender or gender expansive youth under age 18.

This proposal is unauthorized by law, unsupported by the evidence, and will cause substantial harm. CMS lacks statutory authority to prohibit hospitals from providing state-licensed medical care. The agency's purported evidentiary basis is fatally flawed. The rule, if finalized, will inflict serious harm on trans and gender expansive youth—vulnerable populations whose health outcomes depend on access to evidence-based care. For these reasons, which are discussed more fully in this comment letter, CMS must not finalize the NPRM and we urge CMS to withdraw its proposal in its entirety.

HLA is a non-profit, public interest law firm headquartered in Boston that represents individuals with low incomes who face barriers to accessing health care and coverage. For the past 30 years, HLA has represented thousands of Massachusetts residents in cases involving access to necessary medical services, including those covered through private insurance and our state Medicaid system, as well as medical debt collections. While Massachusetts has made great progress toward improving access to health care and has achieved the highest rate of insurance coverage in the nation, HLA's work illustrates how gaps remain, especially among our most vulnerable residents.

HCFA is Massachusetts' leading 501(c)(3) health care consumer advocacy organization. HCFA serves everyone in the Commonwealth, with a particular focus on those at the greatest risk of falling through the cracks of the current health care system including the uninsured, children, the elderly, immigrants, racial and ethnic minorities, and persons with disabilities. We provide direct service through our multilingual HelpLine, partner with community-based organizations on outreach and education campaigns, and advocate for systemic policy change.

This comment addresses the following issues:

1. CMS lacks statutory authority to prohibit hospitals from providing gender-affirming care;

2. The Proposed Rule, if finalized, will be arbitrary and capricious in violation of the Administrative Procedure Act;

3. The Proposed Rule, if finalized, will cause serious harm.

I. CMS Lacks Statutory Authority to Prohibit Hospitals from Providing Gender-Affirming Care

A. The Proposed Rule Violates Medicare's Prohibition on Federal Interference with Medical Practice

The very first section of the Medicare Act expressly prohibits the federal government from interfering with the practice of medicine. Section 1801 of the Social Security Act (the Act) provides that nothing in the Medicare statute "shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided."[1] This provision was included by Congress when it created the Medicare and Medicaid programs,[2] "underscores the 'congressional policy against the involvement of federal personnel in medical treatment decisions'"[3] and unambiguously prohibits the government from "direct[ing] or *prohibit[ing]* any [particular] kind of treatment or diagnosis."[4]

CMS's proposal, if finalized, will do exactly what Congress unambiguously forbids. CMS's proposal will have the effect of prohibiting hospitals nationwide from providing specific medical

[1] 42 U.S.C. § 1395.

[2] "It is said that this program will somehow interfere with the freedom of doctors to practice medicine. Mr. President, I can only submit that this program can only enhance the freedom of doctors in the care of their patients. Nothing in this bill relates in any way to what a doctor should or should not do for his patient. In fact in this bill there is specific prohibition against any kind of interference with medical practice. I say that the bill will enhance the freedom of doctors to practice medicine." 111 Cong. Rec. Part 12, S.16069, 16154 (July 9, 1965) (statement of Senator Moss).

[3] *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)).

[4] *Goodman v. Sullivan*, 891 F.2d 449, 451 (2d Cir. 1989) (per curiam) (emphasis added).

treatments (i.e., puberty-pausing medications, hormone therapy, and surgery-for patients with a specific diagnosis) to a subset of vulnerable (and politically disfavored) patients. The categorial ban on providing such care is the exact type of federal interference that Congress prohibits under the Act.[5]

CMS attempts to circumvent the prohibition in section 1801 of the Act by declaring, in two conclusory paragraphs, that gender-affirming care "is not healthcare" and, therefore, it falls outside "the practice of medicine."[6] This assertion is legally and factually indefensible. CMS has no statutory authority to redefine what constitutes "healthcare" or the "practice of medicine." Those determinations belong to the states, which "under their police powers" have historically regulated the medical profession "for the protection of the lives, limbs, health, comfort, and quiet of all persons."[7] States retain authority to "protect the integrity and ethics of the medical profession"[8]—a power "inherent in the structure and limitations of federalism."[9]

CMS cannot unilaterally declare that treatments licensed by state medical boards and provided by state-licensed physicians are "not healthcare" merely to evade a statutory prohibition that Congress enacted specifically to prevent federal agencies from making such determinations.

B. CMS's Cited Authorities Do Not Support This Action

CMS relies on two general statutory provisions as its legal basis for issuing this rule: Section 1861(e)(9) and Section 1871 of the Act.[10] Neither provides the necessary authority for this rule.

Section 1861(e)(9) of the Act is a definitional provision permitting CMS to establish requirements "in the interest of the health and safety of individuals who are furnished services in the institution."[11] This language authorizes process-oriented patient-safety standards, not categorical bans on state-licensed medical treatments for disfavored patient populations. CMS's own implementing regulations recognize this limitation: they require hospitals to "meet other applicable standards that are required by State or local laws."[12] Instead, the proposed rule would override state laws that permit, and in some cases affirmatively protect, gender-affirming care.[13]

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[5] *See Am. Med. Ass'n v. Weinberger*, 522 F.2d 921, 925 (7th Cir. 1975) (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").

[6] 90 Fed. Reg. 59,463, 59,471-72.

[7] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996).

[8] *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997).

[9] *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006).

[10] 90 Fed. Reg. at 59,464.

[11] 42 U.S.C. § 1395x(e)(9).

[12] 42 C.F.R. § 482.11(c).

[13] *See* KFF, *State Shield Laws: Protections for Abortion and Gender Affirming Care Providers* (July 2025).

Section 1871 of the Act grants CMS authority to issue regulations "as may be necessary to carry out the administration of the insurance programs [under the Medicare program]."[14] This general rulemaking authority does not authorize CMS to displace states' traditional regulatory authority over medical practice or to decide which treatments hospitals may or may not provide.

When Congress intends to regulate or prohibit specific medical treatments, it does so with unmistakable clarity. The Emergency Medical Treatment and Active Labor Act (EMTALA) explicitly requires screening and stabilization services, defining the key terms with precision.[15] The Partial-Birth Abortion Ban Act expressly prohibits specified procedures through detailed statutory definitions.[16] In stark contrast, nothing in sections 1861(e)(9) or 1871 of the Act mentions gender-affirming care or in any way suggests that CMS may prohibit a category of medical treatment.

C. The Major Questions Doctrine Forecloses CMS's Claimed Authority

Even if CMS's cited statutory provisions provided the necessary authority to support this proposal, the Major Questions Doctrine would preclude the agency's ability to rely on this authority.

Under the Major Questions Doctrine, consistent with the principle that Congress does not "hide elephants in mouseholes,"[17] an agency cannot rely on "vague terms or ancillary provisions" to resolve matters of "vast *economic* and *political* significance" without "clear congressional authorization."[18] When a federal agency "intrudes into an area that is the particular domain of state law," courts will apply "a considerable measure of skepticism" to the agency's claim of authority.[19]

The Supreme Court has squarely recognized that gender-affirming care for minors is a matter of profound political significance. In *United States v. Skrmetti*, the Court described the issue as a "fierce scientific and policy debate" with "profound" implications,[20] while Justice Thomas's concurrence characterized it as "politically contentious."[21] The Court further

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[14] 42 U.S.C. § 1395hh.

[15] 42 U.S.C. § 1395dd.

[16] 18 U.S.C. § 1531.

[17] *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001).

[18] *West Virginia v. EPA*, 597 U.S. 697, 721-23 (2022) (emphasis added).

[19] *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014); *Purl v. United States HHS*, 787 F. Supp. 3d 284, 322 (N.D. Tex. 2025).

[20] *United States v. Skrmetti*, 605 U.S. 495, 498 (2025).

[21] *Id.* at 547 (Thomas, J., concurring).

recognized that states are the sovereign bodies with authority to regulate this care,[22] with some restricting it and others protecting it.

CMS's proposal would override that state-by-state determination through a nationwide categorical ban premised on some of the most general provisions in the Medicare statute.[23] This is precisely the type of "transformative expansion" of agency authority that the Major Questions Doctrine prohibits.[24] No provision of the Medicare statute clearly authorizes CMS to resolve a politically contentious national debate by prohibiting medical treatments that are lawful in numerous states.

The Major Questions Doctrine is also implicated by the rule's vast economic significance. Under CMS's proposal, hospitals that provide gender-affirming care would face a forced choice: cease providing state-licensed medical treatments or forfeit Medicare and Medicaid participation. The latter option is financially catastrophic—nationally, Medicare and Medicaid account for 44% of all spending on care provided by hospitals.[25]

Most hospitals could not continue operating without federal reimbursement. Many would be forced to close, with devastating consequences for the communities they serve.[26] Rural and safety-net hospitals, already financially vulnerable, would be especially at risk.[27] Congress did not silently authorize CMS to leverage federal healthcare funding to coerce hospitals into abandoning lawful medical treatments authorized under state laws and regulations.

II. The Proposed Rule Is Arbitrary and Capricious

A. CMS Has Misrepresented the Evidence

The Administrative Procedure Act (APA) requires courts to set aside agency action that is "arbitrary, capricious, [or] an abuse of discretion."[28] An agency acts arbitrarily when it "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."[29] CMS's proposal, if finalized, would encounter all of these APA problems.

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[22] *Id.* at 532, 540.

[23] 90 Fed. Reg. at 59,464.

[24] *West Virginia v. EPA*, 597 U.S. at 723.

[25] KFF, *New Trump Administration Proposals Would Further Limit Gender Affirming Care for Young People* (Dec. 22, 2025).

[26] Shachar & Huberfeld, *Proposed HHS rule on gender-affirming care radically expands use of Medicare, Medicaid as policy weapons*, STAT News (Dec. 24, 2025).

[27] KFF, *Key Facts about Hospitals* (Feb. 19, 2025).

[28] 5 U.S.C. § 706(2)(A).

[29] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

CMS claims there is an "absence of rigorous scientific data demonstrating the safety and effectiveness" of gender-affirming care.[30] This assertion is flatly contradicted by decades of peer-reviewed research. The agency has cherry-picked evidence to support a predetermined conclusion while ignoring the substantial body of evidence demonstrating that gender-affirming care is safe and effective for transgender youth.

CMS relies primarily on two documents: the HHS Report issued under the current Administration and the Cass Review from the United Kingdom. Both have been widely criticized by medical experts for misrepresenting data and scientific evidence.[31]

The HHS Report, initially released in May 2025, omitted author names and bypassed peer review.[32] After widespread criticism, HHS released an updated version, but the added "peer review supplement" revealed that reviewers found the report misrepresented evidence.[33] Medical experts publishing in the *Journal of Adolescent Health* identified violations of scientific norms, including that the 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."[34]

The Cass Review, conducted in the United Kingdom, has been subject to similar criticism. Medical experts identified "a high risk of bias in each of the systematic reviews driven by unexplained protocol deviations, ambiguous eligibility criteria, [and] inadequate study identification," as well as "methodological flaws and unsubstantiated claims."[35] Notably, none of the report's contributors have research or clinical experience in transgender healthcare.[36]

B. Scientific Evidence Demonstrates That Gender-Affirming Care Is Safe and Effective

In contrast to CMS's selectively cited sources, peer-reviewed medical studies consistently demonstrate the safety and effectiveness of gender-affirming care for transgender youth.

Comprehensive systematic reviews confirm positive outcomes. A 2018 Cornell University review of all peer-reviewed articles on transgender healthcare published between 1991 and 2017 found that gender transition, including access to transition-related care, improves

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[30] 90 Fed. Reg. at 59,470.

[31] *See* AAP Statement on HHS Report Treatment for Pediatric Gender Dysphoria (May 1, 2025); Jacobs, *Researchers slam HHS report on gender-affirming care for youth*, Science (May 2, 2025).

[32] U.S. Dep't of Health & Human Servs., *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* (May 1, 2025).

[33] *See* HHS Office of Population Affairs, *Gender Dysphoria Report Peer Reviews and Responses* (Nov. 2025).

[34] Dowshen et al., *A critical scientific appraisal of the Health and Human Services Report on Pediatric Gender Dysphoria*, 77 J. Adolescent Health 342 (2025).

[35] Noone et al., *Critically appraising the Cass report: Methodological flaws and unsupported claims*, 25 BMC Med. Rsch. Methodology 1 (2025).

[36] McNamara et al., *An Evidence-Based Critique of "The Cass Review"*, Yale Law School (2024).

overall well-being.[37] Not a single study over this 26-year period concluded that gender transition causes overall harm.[38] A 2024 University of Utah systematic review reaffirmed these findings, concluding that hormone therapy is safe and effective for transgender youth.[39]

Transition-related care reduces depression, suicidality, and psychological distress. Multiple studies report that gender-affirming care, including hormone therapy and puberty-pausing medications, significantly reduces depression and suicidal ideation in transgender youth.[40] One study found that receiving gender-affirming care was "associated with 60% lower odds of moderate or severe depression and 73% lower odds of suicidality."[41] Young people who wanted but could not access hormone therapy had substantially higher rates of suicidal ideation and attempts of self harm.[42]

Physical health outcomes are favorable. Research demonstrates that hormone therapy in young people does not negatively impact bone density, ovarian function, liver enzymes, creatinine levels, or cognitive functioning.[43]

Benefits persist into adulthood. A 2022 study found that 98% of people who began gender-affirming medical treatment in adolescence continued treatment in adulthood.[44] Adults who accessed hormone therapy in their youth report lower odds of severe psychological distress, suicidal ideation, binge drinking, and illicit drug use compared to those who desired but could not access such treatment.[45]

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[37] What We Know Project, Cornell University, *What does the scholarly research say about the effect of gender transition on transgender well-being?* (2018).

[38] *Id.*

[39] LaFleur et al., *Gender-affirming medical treatments for pediatric patients with gender dysphoria*, University of Utah College of Pharmacy (2024).

[40] Turban et al., *Pubertal suppression for transgender youth and risk of suicidal ideation*, 145 Pediatrics e20191725 (2020); Green et al., *Association of gender-affirming hormone therapy with depression, thoughts of suicide, and attempted suicide*, 70 J. Adolescent Health 643 (2022).

[41] Tordoff et al., *Mental health outcomes in transgender and nonbinary youths receiving gender-affirming care*, 5 JAMA Network Open e220978 (2022).

[42] Green et al., *supra* note 39; Turban et al., *supra* note 39.

[43] Magiakou et al., *The efficacy and safety of gonadotropin-releasing hormone analog treatment in childhood and adolescence*, 95 J. Clinical Endocrinology & Metabolism 109 (2010); Schagen et al., *Efficacy and safety of gonadotropin-releasing hormone agonist treatment*, 13 J. Sexual Medicine 1125 (2016); Wojniusz et al., *Cognitive, emotional, and psychosocial functioning of girls treated with pharmacological puberty blockage*, 7 Frontiers in Psychology 1053 (2016).

[44] van der Loos et al., *Continuation of gender-affirming hormones in transgender people starting puberty suppression in adolescence*, 6 Lancet Child & Adolescent Health 869 (2022).

[45] Turban et al., *Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults*, 17 PLOS ONE e0261039 (2022).

Regret rates are extremely low. A systematic review found that regret following gender-affirming surgery was less than 1%, which is significantly lower than regret rates for breast augmentation (5.1-9.1%), body contouring (10.8-33.3%), having children (7%), or getting a tattoo (16.2%).[46]

C. The Diagnostic-Based Distinction Is Irrational

CMS proposes to permit the identical medications (i.e., puberty blockers and hormones) for cisgender youth with precocious puberty and for intersex youth, while prohibiting their use for transgender youth.[47] If these medications were truly "unsafe," as CMS contends, the agency could not plausibly permit their use for other pediatric populations.

This diagnosis-based distinction reveals that CMS's stated patient safety rationale is pretextual. The rule substitutes categorical exclusions for individualized medical judgment, imposing blanket restrictions unconnected to clinical evidence or standards. This irrationality further underscores the proposal's arbitrary and capricious nature.

D. CMS Failed to Consider Reliance Interests

When an agency changes longstanding policy, it must acknowledge the change and provide a "reasoned explanation" that addresses the interests of those who relied on the prior policy.[48] CMS has failed to do so.

Hospitals have structured staffing, training, and resources around the delivery of these services. Transgender youth and their families have relied on access to care that hospitals have long provided. Rather than meaningfully engaging with these reliance interests, CMS offers only a conclusory assertion that "primary care providers and endocrinologists outside of hospitals . . . can also prescribe these treatments."[49] CMS provides no explanation, analysis, or evidence that such alternatives exist or are accessible.

III. The Proposed Rule Will Cause Serious Harm

A. Restricting Care Harms Transgender Youth

The proposed restrictions will deprive transgender and gender expansive youth of health care services that have proven to be safe and beneficial and consequences will be devastating for many individuals and their families. The evidence of harm from restricting access to transition-related care is unambiguous:

[46] Thornton et al., *A systematic review of patient regret after surgery*, 234 Am. J. Surgery 68 (2024).

[47] 90 Fed. Reg. at 59,471.

[48] *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211 (2016); *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 29 (2020).

[49] *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 29 (2020).

State-level anti-transgender laws have been associated with significant increases in suicide attempts among transgender and nonbinary youth.[50] Exposure to news about proposed restrictive legislation contributes to worsening mental and physical health outcomes for transgender youth.[51] These harms are not speculative-they are documented in peer-reviewed research.

By contrast, transgender individuals who access transition-related care report substantially better health outcomes than those who do not.[52] A 2022 survey found that 98% of respondents who received hormone therapy and 97% who received surgery reported being happier and more satisfied with their lives.[53]

All of HLA's minor clients who have sought gender-affirming care have experienced debilitating psychological anguish due to gender dysphoria. One HLA client had identified as the opposite gender since they were four-years-old, and made a full social transition, supported by their parents, during elementary school. In their late teens, they experienced barriers to getting gender-affirming care and wrote the following reflections:

> "While I feel that I have made great progress in managing my gender dysphoria, I fear that the stress and anxiety I am currently experiencing will cause me to get worse. The ongoing delay and uncertainty around receiving necessary medical services are triggering my feelings of loss of control, anxiety, depression and disillusionment. While I have strong support from my family and my therapist, I want to do whatever I can to limit my risk of having to endure this additional stress for an extended period of time. Also, with every passing day, I continue to suffer from gender dysphoria. My need to have my body align with my gender identity is real and intense…any delay in care is harmful for me."

This young person's experience is emblematic of the stories HLA has heard from our minor clients: inability to access gender-affirming care prescribed by their medical team and supported by their parents caused substantial psychological harm. Every single one of HLA's clients who have been able to receive gender-affirming care have reported improved psychological well-being and other positive differences in their lives. For example, one young client who HLA helped to access needed care, wrote:

> "At the time I first contacted HLA about my case, I could not have imagined how much my life would change for the better…the difference of where I am now and where I might be is vast, and owes much to the advocacy and conviction of folks like yourselves. From the bottom of my heart, thank you!"

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[50] Lee et al., *State-level anti-transgender laws increase past-year suicide attempts among transgender and non-binary young people in the USA*, 8 Nature Human Behaviour 2096 (2024).

[51] Dhanani & Totton, *Have you heard the news? The effects of exposure to news about recent transgender legislation*, 20 Sexuality Rsch. & Soc. Pol'y 1345 (2023).

[52] Rastogi et al., *Health and Wellbeing: A Report of the 2022 U.S. Transgender Survey*, Advocates for Transgender Equality (June 2025).

[53] *Id.* at 10-11.

In HLA's experience, access to needed gender-affirming care – helping people become who they know themselves to be – is crucial to ensuring people can fully participate in their communities and broader society. We have even seen access to gender-affirming care as a life-or-death proposition for some clients who have engaged in self-harm or attempted suicide when they were unable to live as the person they knew themselves to be. Access to gender-affirming care for young people can literally save lives.

B. The Economic Consequences Are Severe

CMS's own economic analysis is inadequate but nevertheless shows that the rule's economic impact would be substantial. Hospitals nationwide would face the impossible choice between abandoning lawful medical care they customarily provide and forfeiting 44% of their revenue. Hospital closures would be disruptive to communities across the country.[54] Even hospitals that survive would likely shift costs onto patients and reduce services, harming patients who need care for conditions entirely unrelated to gender dysphoria.[55] Where hospitals are forced to abandon providing these crucial services for youth, we expect to see significant harms among individuals who can no longer access this medically necessary care.

Conclusion

HLA and HCFA vigorously oppose the Proposed Rule because it lacks statutory authority, is without evidentiary support, and will be harmful to vulnerable patients. The agency is explicitly prohibited from interfering with the practice of medicine and lacks the authority to circumvent this statutory prohibition. The declaration that state-licensed medical treatments are "not healthcare" is conclusory and factually incorrect. The evidentiary foundation for the rule is fatally compromised. Also, the rule will cause serious harm to transgender and gender expansive youth, a population that already faces elevated risks of depression, anxiety, and suicidality. HLA and HCFA urge CMS to withdraw the proposed rule in its entirety.

Please do not hesitate to contact us regarding any of the matters discussed above.

Respectfully submitted,

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[54] Shachar & Huberfeld, *supra* note 25.

[55] KFF, *Key Facts about Hospitals*, *supra* note 26.

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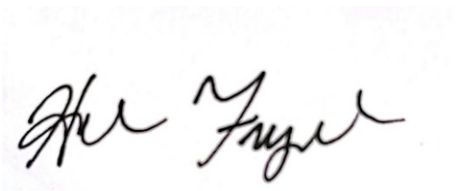

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