IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

GINA GOE, individually and as parent and next friend of GRACE GOE; KARLA KOE, individually and as parent and next friend of KYLIE KOE; LAURA LOE, individually and as parent and next friend of LOGAN LOE; and MELISSA MOE, individually and as parent and next friend of MAYA MOE,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services; CENTERS FOR MEDICARE & MEDICAID SERVICES; and MEHMET OZ, in his official capacity as Administrator of CMS,

Defendants.

No. 1:26-cv-803-SM-TSM

PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

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Defendants' Opposition fails to address the central question of this litigation: whether they may use general provisions governing a State's Medicaid plan administration and quality of care to impose a categorical federal funding exclusion that conflicts with Medicaid's specific treatment requirements for and with the agency's own longstanding rule against diagnosis-based denials. They may not. The relevant statutes' plain text does not authorize Defendants' efforts. The Rule withdraws federal funding from the treatment at issue and requires every State Medicaid agency to deny payment for it. Defendants' actions are politically-motivated and driven by disapproval of treatment for gender dysphoria; not because of a sincere engagement with the evidence and available alternatives.

As to the scope of any injunction, Defendants claim that under New Hampshire law, "it is not clear that New Hampshire's plan still covers these treatments." Defendants' Memorandum of Law Opposing Plaintiffs' Expedited Motion for Preliminary Injunction ("Opp.") at 28. But State law limitations, beneficiary-specific Medicaid coverage, and the availability of federal financial participation ("FFP") are distinct. The October 1 letter to which Defendants cite identifies no Plaintiff, denies no claim, and says nothing about ending the State's coverage of this treatment, which New Hampshire Medicaid has continued throughout 2026. ECF No. 27-1, Ex. A at 2; Loe Supp. Aff. ¶ 6.

Plaintiffs seek a narrow injunction against applying the Rule's pharmaceutical provisions to the adolescent Plaintiffs, to the extent their treatment is otherwise covered by New Hampshire Medicaid. They seek no relief concerning surgery and no universal injunction. Defendants do not contest any of the facts contained in Plaintiffs' declarations or the expert declaration of Kate Millington, M.D. The Court should grant that limited preliminary relief.

I. New Hampshire Law Does Not Prohibit Medicaid Coverage of Plaintiffs' Treatment

Plaintiffs need not show that their requested relief would eliminate every obstacle to care,

only that it is likely, rather than "merely speculative," to redress their injuries. *Dantzler, Inc. v. Empresas Berríos Inventory & Ops., Inc.*, 958 F.3d 38, 47 (1st Cir. 2020). New Hampshire Medicaid has covered each Plaintiff's treatment throughout 2026, including a change in Logan's course of treatment. Loe Supp. Aff. ¶ 6. Indeed, each adolescent was receiving clinical care for gender dysphoria prior to January 1, 2026. Goe Decl. ¶¶ 8, 11, 13; Koe Decl. ¶¶ 9, 11–15; Loe Decl. ¶ 11; Moe Decl. ¶¶ 9–11. The Rule ends that coverage by withdrawing FFP and requiring the State plan to provide that the agency "will not make payment under the plan" for Plaintiffs' medications. 42 C.F.R. § 441.802(a)–(b). Enjoining the Rule as to Plaintiffs would remove that obstacle, and no evidence in the record suggests New Hampshire Medicaid would discontinue their coverage but for the Rule.[1]

Defendants, who have no authority to interpret or enforce RSA 332-N, argue that New Hampshire law independently prohibits the care for which Plaintiffs seek Medicaid coverage. They read RSA 332-N:2, III to protect only medications prescribed before January 1, 2026. Opp. at 39. The Court need not definitively interpret that provision of New Hampshire law because Defendants' prediction of New Hampshire Medicaid's conduct rests entirely on their interpretation of a statute no New Hampshire court has addressed.

In any event, nothing in RSA 332-N:2, III limits "continued treatment" to continuing a single medication. The text and structure protect a course of treatment begun before January 1, 2026, including its later phases; Defendants' contrary reading produces results the legislature could not have intended. Even under their reading, the dispute concerns only the scope of relief, because Defendants concede that New Hampshire law permits at least Logan and Maya to continue

[1]The letter from the New Hampshire Department of Health and Human Services Defendants submitted as an exhibit to their Opposition says nothing to indicate any intent to change its practice of covering the treatments.

medications prescribed before January 1, 2026. Opp. at 38–39.

A. New Hampshire's Continuing Treatment Clause Protects the Course of Treatment That Began Before January 1, 2026

This Court "must predict how the [New Hampshire Supreme Court] would interpret the statute," *Garran v. SMS Fin. V, LLC (In re Garran)*, 338 F.3d 1, 6 (1st Cir. 2003), and that analysis begins—and, where the language is unambiguous, ends—with the statute's plain and ordinary meaning. *Petition of Carrier*, 165 N.H. 719, 721 (2013); *In re Town of Seabrook*, 163 N.H. 635, 644 (2012).

1. The text of the clause plainly protects continued treatment, not only continued medication

The continuing treatment clause provides: "Nothing in this chapter shall prohibit a health care provider from continuing the direction or administration of medication or treatment that began prior to January 1, 2026, and such continued treatment shall not be considered a violation of this chapter." RSA 332-N:2, III. Defendants read the clause to protect only the specific medications prescribed before January 1, 2026. Opp. at 39. But it protects "medication *or treatment*" and the continued "*direction* or administration" of treatment—not merely "a medication that was prescribed." Defendants thus add a limitation the legislature "did not see fit to include." *Carrier*, 165 N.H. at 721. Four textual features confirm that "treatment" means a course of care, not a particular drug.

First, the ordinary meaning of "treatment" is a course of care: the "management and care to prevent, cure, ameliorate, or slow progression of a medical condition."[2] "Management and care" occur and evolve over time, so "treatment," without qualification, denotes the course of care as a whole. The omission of "course of" from Paragraph III therefore implies no narrower meaning.

[2] Treatment, Merriam-Webster.com Dictionary, https://www.merriam-webster.com/dictionary/treatment (last visited Oct. 20, 2026).

New Hampshire statutes also use the terms interchangeably. *See* RSA 507-E:1, III (referring to "premature abandonment of a patient or of a course of treatment"). The technical meaning is the same: in medicine, "treatment" is a planned course of care that proceeds through clinically indicated phases. Millington Supp. Decl. ¶ 8. Thus, under either meaning, the "treatment that began prior to January 1, 2026" is the patient's course of care, which Paragraph III permits to continue.

Second, the clause lists "medication" and "treatment" as alternatives, and different words generally convey different meanings. *City of Concord v. State*, 164 N.H. 130, 141 (2012) (quotation omitted); *see John A. Cookson Co. v. N.H. Ball Bearings, Inc.*, 147 N.H. 352, 357 (2001). "Treatment" therefore means more than a particular medication. Nor does it merely mean a non-pharmaceutical "procedure": the legislature repeatedly used "procedure" in Paragraphs I and II but chose the broader term "treatment" in Paragraph III. Elsewhere, the chapter confirms that breadth by referring to "procedures, therapies, prescriptions, or other treatments." RSA 332-N:3, IV. The safe harbor thus protects continuing treatment generally, not merely a fixed list of interventions.

Third, after protecting "medication or treatment," the clause provides that "*such continued treatment* shall not be considered a violation." RSA 332-N:2, III (emphasis added). The legislature thus used "treatment" to encompass everything protected by the first half of the clause, including clinically indicated medication. A particular medication may be one component of the treatment that may continue.

Finally, the clause protects "continuing the direction" of treatment, not merely its "administration." Administration means giving medication[3]; direction means managing treatment over time, including monitoring the patient, adjusting dosages or formulations, and advancing to the next clinically indicated phase. Millington Supp. Decl. ¶¶ 8, 9. Limiting a provider to the

[3] Administration, Merriam-Webster.com Dictionary, https://www.merriam-webster.com/dictionary/administration (last visited Oct. 20, 2026).

medication prescribed before January 1 would reduce the provider's role to administration and render "continuing the direction" superfluous.

Nor does "that began prior to January 1, 2026" limit the clause to particular drugs. The phrase fixes when "medication or treatment" must have begun; it does not restrict later steps within that treatment. Defendants' reading would protect administration of the same drug but not direction of the next step in the same course of care—a distinction the text does not draw.

2. The use of "treatment" throughout the chapter confirms that "treatment" means course of care

Read as a whole, Chapter 332-N regulates care by purpose, not by a fixed list of drugs. Paragraph I prohibits a medical procedure, "including but not limited to" puberty-blocking or cross-sex hormone medication, when provided for specified purposes. RSA 332-N:2, I. Paragraph II likewise defines an exception by treatment purpose, and Paragraph III protects care begun before the cutoff date. *Id*. at II–III. The damages provision further lists "procedures, therapies, prescriptions, or other treatments," confirming that medications are components of broader treatment. *Id*. § 332-N:3, IV. The availability of the safe harbor therefore turns on when the course of care began, not on which medication was prescribed.

II. Plaintiffs Are Likely to Succeed on the Merits

A. CMS's General Plan-Administration Provisions Do Not Authorize a New Categorical Federal Exclusion

As they did in the Rule itself, Defendants invoke 42 U.S.C. §§ 1396a(a)(19), 1396a(a)(30)(A), 1397aa(a), 1397bb(a)(7)(A), and 1302(a), but those provisions authorize CMS to *oversee* State plans and enforce conditions; they do not authorize CMS to *create* a nationwide, diagnosis-specific funding condition that Congress did not enact. *See Moore v. Reese*, 637 F.3d 1220, 1238 (11th Cir. 2011). The cited provisions govern State-plan safeguards, administration, quality, CHIP standards, and rules consistent with the Social Security Act. 42 U.S.C. §§

1396a(a)(19), 1396a(a)(30)(A), 1397aa(a), 1397bb(a)(7)(A), 1302(a). These general oversight provisions do not authorize CMS to impose a new condition barring States from covering treatment for a particular condition.

Defendants' principal response is that §§ 1396a(a)(19) and 1396a(a)(30)(A) are "judgment-laden" standards that delegate discretion to the Secretary, so that the Court's only role under *Loper Bright* is to "fix[] the boundaries of the delegated authority" and ensure reasoned decision-making within them. Opp. at 14–17 (quoting *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 395 (2024)). But *Loper Bright* requires courts to "exercise their independent judgment in deciding whether an agency has acted within its statutory authority," 603 U.S. at 412, and to locate the boundaries of any delegation in the statute as a whole, not in the agency's own description of its powers. Here those boundaries are set by provisions Defendants barely mention: § 1396d(r)(5), which requires coverage of "necessary health care . . . to correct or ameliorate" a child's conditions "whether or not such services are covered under the State plan," and § 1396a(a)(10)(B), which requires that services be comparable among beneficiaries. A general instruction that State plans "safeguard against unnecessary utilization" cannot be read to authorize what those specific provisions forbid. *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) ("[T]he specific governs the general.").

Nor do the provisions Defendants cite delegate the power they claim. Sections 1396a(a)(19) and (a)(30)(A) are conditions on State plans. They describe what a State must do, and they authorize the Secretary to determine whether a State's plan does it. They do not say that the Secretary may himself prescribe, by nationwide rule, that a particular treatment for a particular diagnosis is never necessary for any beneficiary. *Armstrong* confirms as much. The Court there called § 1396a(a)(30)(A) a "judgment-laden standard" in explaining why its enforcement—against

a State's *payment rates* for habilitation services—was committed to the Secretary rather than to private suits. *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 323, 328–29 (2015). Nothing in *Armstrong* suggests that the provision empowers the Secretary to override the Act's specific coverage mandates. Section 1396c, finally, permits the Secretary to withhold funds when a State substantially fails to comply with the conditions *Congress* enacted; it does not authorize CMS to impose a new condition on an otherwise compliant State plan.

Defendants' fallback—that "necessary care . . . remains covered" because CMS has determined that this care is never necessary, Opp. at 23—is circular. If CMS can circumvent EPSDT by declaring a category of treatment categorically unnecessary, § 1396d(r)(5) imposes no independent limit on the agency. That reading also inverts *Loper Bright*, which assigns to the Court, not the agency, the task of fixing the boundaries of delegated authority. 603 U.S. at 395. Defendants cannot locate the boundary by assuming the conclusion that lies on the other side of it.

Defendants' reliance on Congress's express funding exclusions and the sterilization regulations does not supply the authority missing here. Opp. at 18–21. Congress's express exclusions reinforce that categorical exclusions require congressional direction. ECF No. 7 at 24–25. The sterilization regulations do not show otherwise. They govern a discrete procedure defined by its purpose—permanent infertility—not medications covered when prescribed for other diagnoses. CMS disclaimed those regulations as a "direct legal predicate" for the Rule, citing them only as "precedent illustrating" prior age-based limits. 91 Fed. Reg. 52,451. And any authority to adopt those regulations in 1978 does not establish authority for this Rule. An agency "literally has no power to act . . . unless and until Congress confers power upon it," *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986), and cannot bootstrap authority from its own prior, unchallenged action.

Finally, contrary to Defendants' assertion, Plaintiffs do not claim that States have "ultimate discretion to determine the best interests of recipients." Opp. at 21. Congress sets Medicaid's conditions and authorizes HHS to withhold funds for substantial noncompliance. 42 U.S.C. §§ 1396a(a), 1396c. That *enforcement* authority does not permit CMS to add a new coverage condition by rule. *See Medina v. Planned Parenthood S. Atl.*, 606 U.S. 357, 364 (2025).

B. The Rule Conflicts with EPSDT

Defendants invoke 1396(a)(30)(A) to support their interpretation of the statute. But Section 1396a(a)(30)(A) requires State plans to "provide . . . methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . as may be necessary to safeguard against unnecessary utilization of such care." States must also amend their plans "whenever necessary to reflect . . . [m]aterial changes in State law, organization, or policy, or in the State's operation of the Medicaid program," 42 C.F.R. § 430.12(c)(1), and CMS must review and "shall approve" a plan that satisfies the conditions Congress specified, 42 U.S.C. § 1396a(b). These provisions govern utilization, payment, and States' obligations to update their plans; none authorize CMS to declare an entire category of treatment medically unnecessary for certain beneficiaries regardless of their clinical circumstances or treating team's clinical judgment. Defendants' reading would convert general provisions governing State plan administration and utilization review into authority to override Congress's specific requirement that sets EPSDT as the coverage floor that both States and CMS must honor. *See Concord Hosp., Inc. v. N.H. Dep't of Health & Hum. Servs.*, 743 F. Supp. 3d 325, 336 (D.N.H. 2024).

Plaintiffs do not contend that a provider's label of a medical treatment as "necessary" automatically compels coverage or that CMS must "review and rebut the determination of treating physicians in each individual case." *See* Opp. at 22. CMS may not replace the medical necessity inquiry Congress granted to the States with a nationwide rule foreclosing any finding of necessity

for every treatment in a defined category when used for a particular diagnosis. By including the phrase "whether or not," Congress deliberately expanded coverage applicable to youth beyond services otherwise included in a State plan. *See* ECF No. 7 at 27. And because gender dysphoria is a recognized medical condition and the medications at issue fall within categories of medical assistance described in Section 1396d(a), coverage turns on whether a requested service is necessary to correct or ameliorate an individual adolescent's condition. The Rule answers that question with a categorical exclusion Congress did not authorize.

The cases Defendants cite do not save the Rule. They cite *Heckler v. Campbell*, 461 U.S. 458 (1983), which permits an agency to resolve by regulation issues that do not require case-by-case consideration, while preserving individualized fact-finding and an opportunity to show that a general guideline does not apply. *Id.* at 467–68; Opp. at 22. The Rule at issue here does the opposite: it declares the covered treatments medically unnecessary for every Medicaid-enrolled adolescent with gender dysphoria without exception based on the child's condition, treatment history, multidisciplinary assessment, or response to care. CMS therefore has not merely established criteria for assessing necessity but has eliminated the statutory inquiry altogether. That result conflicts with § 1396d(r)(5), which asks whether a service is necessary to correct or ameliorate the condition identified through screening.

And the Rule does more than withhold federal dollars. It requires every State plan to provide that the State Medicaid agency "will not make payment under the plan" for this treatment, 42 C.F.R. § 441.802(a), and it conditions approval of the State's plan on that assurance. Defendants emphasize that a State remains free to pay for this care "with State-only funds outside of the Federally-matched Medicaid program." Opp. at 18 (quoting 91 Fed. Reg. 52,407); *see id*. at 9–10, 31. But that is precisely the point: the only path the Rule leaves open is for a State to build and

fund a separate, non-Medicaid program for a single diagnosis. The Rule does not permit a State to continue covering these medications for adolescents through its Medicaid plan, as New Hampshire has done for these Plaintiffs throughout 2026, and nothing in the record suggests that New Hampshire has such a stand-alone program. EPSDT, by contrast, requires that necessary care be furnished *under the plan*, "whether or not such services are covered under the State plan." 42 U.S.C. § 1396d(r)(5).

Nor is *Skrmetti* in tension with Plaintiffs' EPSDT argument. *See United States v. Skrmetti*, 605 U.S. 495 (2025). It addressed whether a state restriction violated the Equal Protection Clause—not the Medicaid Act, the EPSDT requirements of Section 1396d(r)(5), or CMS's rulemaking authority. That the Constitution permits a State to enact a restriction does not mean CMS may impose the same restriction by regulation despite an affirmative statutory coverage mandate. *Skrmetti* did not speak to the operative question here.

Rush v. Parham likewise does not support the Rule. *Rush* held that a State may reasonably define medical necessity and limit physician discretion, including by excluding experimental or ineffective treatment. 625 F.2d 1150, 1154–58 (5th Cir. 1980). But *Rush* did not approve an irrebuttable exclusion imposed solely because of the diagnosis or treatment purpose. To the contrary, it preserved the treating physician's primary responsibility and contemplated individualized review of medical judgment. *Id.* at 1156 (noting that allowing states to establish standards for medical necessity "does not remove from the private physician the primary responsibility of determining what treatment should be made available to his patients."). *Flack* applied that very distinction, explaining that whatever *Rush* may have permitted on its 1980 record, a categorical exclusion was unreasonable where current authoritative evidence and professional consensus established that gender-confirming treatments can be safe, effective, and medically

necessary.[4] *Flack v. Wis. Dep't of Health Servs.*, 395 F. Supp. 3d. 1001, 1015–18 (W.D. Wis. 2019); *see also Miller by Miller v. Whitburn*, 10 F.3d 1315, 1320 (7th Cir. 1993) (finding "the best indicator that a procedure is experimental is its rejection by the professional medical community as an unproven treatment") (citations omitted). The Rule here forecloses coverage even when a treating clinician and multidisciplinary team determine that puberty-suppressing medication or hormone therapy is necessary for a particular adolescent, although the same medications remain eligible for FFP when used for other diagnoses. Reasonable utilization standards may shape a lawful definition of medical necessity; they may not predetermine the outcome for an entire class of patients and nullify EPSDT's command to cover necessary corrective or ameliorative services. Section 1302 authorizes only regulations "not inconsistent with" the Act, 42 U.S.C. § 1302(a), and the Rule crosses that line by making CMS's generalized assessment conclusive in every case.

C. The Rule Conflicts With Medicaid's Comparability Requirement and Prohibition Against Diagnosis-Based Denials

1. The Rule arbitrarily conditions FFP on the beneficiary's diagnosis

Defendants claim that because the Rule applies to every beneficiary under age 18 (or 19 for CHIP), it is treating every beneficiary alike. *See* Opp. at 26. This is nonsensical. The treatments at issue are only "sex-rejecting" when used to treat patients diagnosed with gender dysphoria; the identical medications are not "sex-rejecting" when used to treat other diagnoses. *See* 42 C.F.R. § 441.801. Claiming the Rule applies equally to all beneficiaries is akin to claiming that a ban on chemotherapy to treat abnormal cell growth is diagnosis neutral, when "abnormal cell growth" is a description of cancer. The Rule defines prohibited "sex-rejecting procedures" as those that

[4] Yesterday, the Supreme Court denied the government's motion to stay a preliminary injunction prohibiting the Bureau of Prisons from enforcing a policy that would prevent transgender inmates from receiving hormone therapy, among other treatment. The District Court entered the preliminary injunction after finding that "gender affirming care is the only effective treatment for gender dysphoria." *Kingdom v. Trump*, No. 1:25-cv-691-RCL, slip op. at 13 (D.D.C. June 17, 2026); *Kingdom v. Trump*, No. 26-5236, 2026 WL 2997915, at *1 (D.C. Cir. Sept. 18, 2026), *Trump v. Kingdom*, No. 26A416 (U.S. Oct. 21, 2026) (application for stay denied).

"attempt[] to align individual's physical appearance or body with an asserted identity that differs from the individual's sex." *Id.* That intended use is synonymous with use to treat gender dysphoria. *See* American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision* (defining "gender dysphoria" in children as "a marked incongruence between one's experienced/expressed gender and their assigned gender").

Section 440.230(d)'s "appropriate limits" cannot erase subsection (c)'s specific bar on denying a required service solely because of diagnosis, illness, or condition. Medical necessity may support individualized limits, not an irrebuttable rule that treatment is never necessary for one diagnosis. *See* 42 C.F.R. § 440.230(c)–(d); *White v. Beal*, 555 F.2d 1146, 1152 (3d Cir. 1977); *Flack*, 395 F. Supp. 3d at 1019.

2. The federal government cannot require a State to violate the comparability requirement

Defendants' contention that the comparability requirement binds only States is a red herring. The Secretary cannot evade Medicaid's comparability and coverage requirements by placing a diagnosis-based restriction in a federal regulation. The Rule does not merely apply to federal expenditures; it commands that each "State Medicaid plan must provide that the Medicaid agency will not make payment under the plan" for the disfavored uses. 91 Fed. Reg. 52,406 (Aug. 13, 2026); 42 C.F.R. § 441.802(a). The Rule thus compels State Medicaid agencies to implement the categorical diagnosis-based denial that § 440.230(c) forbids.

Nor does *Medina v. Planned Parenthood S. Atl.*, 606 U.S. at 379, hold otherwise. *Medina* addressed whether a Medicaid provision conferred an individually enforceable right under 42 U.S.C. § 1983; it did not authorize CMS to compel State plans to disregard § 440.230(c), much less shield that agency action from review under the APA.

Defendants' invocation of *Auer* deference fares no better because the regulations at issue

are not ambiguous. Section 440.230(c) expressly addresses denial or reduction "solely because of the diagnosis, type of illness, or condition," while subsection (d) permits only "appropriate" limits. No ambiguity permits CMS to redefine a diagnosis-specific categorical exclusion as diagnosis-neutral merely by labeling it evidence-based. *See Flack*, 395 F. Supp. 3d. at 1019 ("a state cannot say 'never' when it comes to medically necessary treatments, because there are no such reasons justifying categorical bans on medically necessary treatment.") (quotation omitted). And even if the regulations were ambiguous (they are not), deference to agency interpretation cannot validate an interpretation that conflicts with the regulation's text and structure.

Defendants focus on the word "arbitrarily" while largely reading out the remainder of subsection (c): "solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230(c); *see also infra* Section II.D. Their reading would permit a State to deny a required service solely by diagnosis whenever the State asserted some nonarbitrary reason for drawing that line. CMS cannot convert the prohibition on diagnosis distinctions into permissible utilization control by invoking generalized uncertainty about the benefit of treatment.

Flack held that criticism of the quality of scientific studies does not justify foreclosing individual review where the professional consensus is that the gender dysphoria treatments at issue are safe, effective, and medically necessary. *Id*. at 1013–18 (reviewing cases determining that "the medical consensus is that gender-confirming treatment . . . is accepted, safe, and effective in the treatment of gender dysphoria"); *see also Lankford v. Sherman*, 451 F.3d 496, 511 (8th Cir. 2006) ("[A] state's failure to provide Medicaid coverage for non-experimental, medically-necessary services within a covered Medicaid category is both per se unreasonable and inconsistent with the stated goals of Medicaid."); *Pinneke v. Preisser*, 623 F.2d 546, 548 n.2 (8th Cir. 1980).

White v. Beal is instructive because it considered "whether a state regulation that denies

benefits to some and grants them in full to others, based solely on the cause of the disability and not on medical necessity, is in keeping with the statutory plan." 555 F.2d at 1150. The *Beal* court held that it was not, explaining that Medicaid permits distinctions "based upon the degree of medical necessity but *not* upon the medical disorder from which the person suffers." *Id.* at 1152 (emphasis added). *Weaver v. Reagen* likewise held that a Medicaid program could not disregard individual medical need through a categorical drug restriction inconsistent with Medicaid's objectives. 886 F.2d 194, 199–200 (8th Cir. 1989) (finding such categorization constitutes an arbitrary denial based solely on diagnosis, illness, or condition). Even the *Rush* court held that "if defendants simply denied payment for the proposed surgery because it was transsexual surgery, [the state] should now be required to pay for the operation, since a 'state may not arbitrarily deny or reduce the amount, duration, or scope of a required service . . . solely because of the diagnosis, type of illness, or condition.'" 625 F.2d at 1156 n.12 (quoting 42 C.F.R. § 440.230(c)(1)). *Flack* synthesized these authorities and held that an exclusion denying medically necessary treatments for gender dysphoria, while covering the same treatments for other conditions, violated both Medicaid's availability and comparability requirements. 395 F. Supp. 3d 1001, 1018–19. Together, these cases foreclose Defendants' attempt to transform a categorical diagnosis-dependent denial into an "appropriate" limit based on medical necessity. That the command now comes from CMS rather than a State does not cure the violation, because the Rule expressly requires each State plan and Medicaid agency to implement the prohibited denial. The Rule therefore is a categorical, diagnosis-dependent denial that subsection (c) forbids.

D. The Rule Is Arbitrary and Capricious

CMS was required to examine the important aspects of the problem, confront significant contrary evidence, and explain its choice. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). It did not.

1. Defendants did not reasonably address reliance interests or obvious alternatives

Defendants' assertion that they "carefully considered" reliance interests does not address the reliance interest Plaintiffs identified: continued access to treatment already prescribed and covered after lengthy periods of individualized assessment. Opp. at 30–31. The Rule does not merely leave past treatment unpaid; it cuts off Medicaid coverage for adolescents mid-treatment, disrupting the care on which they and their families have relied.

The Rule's prospective application does not address that reliance because the injury is the loss of ongoing care. Nor does the six-month hormone taper address Plaintiffs' reliance interests: it imposes a phaseout to zero, applies only to hormone therapy and does not apply to puberty-suppressing medication. The Rule provides no transition for adolescents on these medications, even though stopping treatment will likely cause puberty to resume within months and produce permanent changes. *See* 42 C.F.R. § 441.802(c); 91 Fed. Reg. 52,416, 52,421–22; *see also* Loe Decl. ¶ 12; Koe Decl. ¶ 13; Goe Decl. ¶ 13.

CMS rejected continued coverage for beneficiaries already receiving treatment and dismissed individualized prior authorization and State or provider judgment as mere "administrative safeguards." Opp. at 30–31. *Regents* requires CMS to seriously consider reliance interests and alternatives within the scope of its policy. *DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 30–33 (2020). CMS's treatment of these alternatives does not meet that standard. The Rule names them and dismisses them with the assertion that CMS's concerns "cannot be rendered appropriate for Federal funding through administrative safeguards alone." 91 Fed. Reg. 52,473; Opp. at 31. *Regents* does not permit an agency to satisfy its obligation by naming an alternative and rejecting it; the agency must explain why the alternative would not address the problem it has identified. *See* 591 U.S. at 33. An exemption for adolescents already in treatment would not have

required CMS to fund a single new course of care. Defendants point to nothing in the Rule explaining why the agency's stated rationale—uncertainty about long-term benefit—justifies interrupting the treatment of patients whose clinicians have already assessed them, and who face documented and immediate harm from withdrawal.

The six-month taper period also does not address the medical risks of forced discontinuation of treatment. The record describes serious physical and psychological harms, including the possibility that withdrawal produces the very harms CMS says it seeks to prevent, such as decreased bone density. ECF No. 7 at 38–39, 41; Millington Decl. ¶ 25. CMS's discussion of State-only funding and prospective application does not explain how families unable to afford care can continue it, or how a State could realistically create and fund a separate, non-Medicaid program to pay for care that the Rule forbids its Medicaid agency to cover under the plan. 42 C.F.R. § 441.802(a); 91 Fed. Reg. 52,407, 52,434. Pointing to a hypothetical State-only program is not reasoned consideration of reliance when the Rule identifies no State that has one and offers no explanation of how one could be stood up before Plaintiffs' coverage ends. The agency's reliance analysis cannot be adequate when it treats the loss of treatment as a voluntary choice and leaves the practical consequences unaddressed.

2. CMS did not meaningfully engage with significant comments

Although the APA does not require an agency to answer every comment, it does require a reasoned response to significant objections. *See, e.g.*, *State Farm*, 463 U.S. at 43. The record shows that CMS did not meaningfully or genuinely engage with the significant comments it received. For example, the Endocrine Society explained that the standard methodology for assessing certainty in a body of evidence (called "GRADE") measures certainty, not whether treatment is clinically appropriate, and that guideline panels may make strong recommendations after considering patient

values and clinical judgment. CMS's response was to label the Endocrine Society's guidelines "of very low quality," citing a single systematic review of guideline methodology, and to declare that their recommendations "should not be implemented." 91 Fed. Reg. 52,411–12, 52,427; *see* Opp. at 33. That is not a response to the Society's point. The comment did not dispute that the underlying evidence is rated low-certainty under GRADE; it explained why a low-certainty rating does not mean treatment is clinically inappropriate and why guideline panels may still make strong recommendations. *Dekker v. Weida*, 679 F. Supp. 3d 1271, 1293–94 (N.D. Fla. 2023) *appeal docketed*, No. 23-12155 (11th Cir. June 27, 2023) (finding that "treatment should be banned based on the supporting research's GRADE score is a misuse of the GRADE system.") An agency that answers that argument by repeating the rating has not engaged with it. ECF No. 7 at 37–38. CMS similarly dismissed comments submitted by the American Academy of Pediatrics ("AAP") without addressing the AAP's emphasis on individualized assessment as being the clinical standard of care. 91 Fed. Reg. 52,427, 52,453–54.

3. CMS cherry-picked and misrepresented the evidence and imposed a categorical ban without explaining why contrary evidence and significant comments did not matter

Defendants defend CMS's reliance on the HHS umbrella review and assessments from the United Kingdom, Sweden, Finland, and Denmark while dismissing domestic clinical guidelines and evidence submitted by the Endocrine Society, the AAP, and other commenters. But as Dr. Millington describes, those health authorities did not reach the conclusion CMS attributes to them. Each continues to make puberty-suppressing medication or hormone therapy available to adolescents in specialized or research settings, each continues treatment for patients already receiving it, and none purported to find that this treatment can never be medically necessary for any adolescent. Millington Supp. Decl. ¶¶ 48–54. The HHS Review considered only 17 of the 286 systematic reviews it screened, acknowledged that evidence of harm was "sparse," and cautioned

that low-certainty evidence does not establish ineffectiveness. ECF No. 7 at 30, 37–39; Erchull Decl., Ex. H at 87–88, 230. The term "low-certainty" is a description of the *types* of available studies, not the quality of the evidence. And low-certainty evidence guides the majority of medical decisions. Millington Supp. Decl. ¶¶ 11–35. CMS did not have to accept Plaintiffs' preferred evidence, but it had to explain why its selected studies outweighed substantial contrary evidence and why uncertainty justified a categorical ban rather than individualized review. It did not.

The Rule followed an Executive Order directing HHS to end the treatment for gender dysphoria in children and agency statements announcing that result before rulemaking. ECF No. 7 at 4–9, 41; 90 Fed. Reg. 8,771; Erchull Decl., Ex. L. Plaintiffs do not claim policy motivation alone invalidates the Rule; however, the chronology of the Administration's pronouncements about treatment for adolescents with gender dysphoria underscores CMS's failure to engage contrary evidence and alternatives. *See also Kingdom v. Trump*, No. 1:25-cv-691-RCL, slip op. at 11-12 (D.D.C. June 17, 2026) (finding Bureau of Prisons policy against hormone therapy for transgender inmates "pretextual and reverse engineered to implement EO 14168").

4. The Rule's safety rationale is contradicted by its exceptions

CMS invokes risks such as decreased bone density and other physiological effects while preserving FFP for the same medications when used for other diagnoses. ECF No. 7 at 40; 91 Fed. Reg. 52,409. Defendants do not answer the objection, but instead explain that puberty blockers "have been primarily studied in children affected by precocious puberty" and are used there for a limited period to "temporarily halt an abnormal developmental process." Opp. at 35 (quoting 91 Fed. Reg. 52,416, 52,426, 52,431). The physiological risks CMS identifies, (e.g. suppressed bone-density accrual) are risks of the medication, not of the diagnosis. The drug acts on the body in the same way, no matter the diagnosis. If CMS's concern were the duration of suppression or the risk

to a particular patient, the agency could have adopted duration limits, monitoring requirements, or patient-specific criteria, and it was obligated to explain why it did not. *Regents*, 591 U.S. at 30–33. Defendants' framing confirms the problem. They defend the Rule as "[a] distinction based on the purpose for which a medication is used." Opp. at 35. But the only "purpose" that triggers the exclusion is treatment of gender dysphoria. Defendants chose a diagnosis-specific line and a taper that may produce the very harms the Rule says it seeks to prevent. That unexplained, and unacknowledged, contradiction is arbitrary and capricious.

E. The Remaining Factors Support Relief

1. The threatened harm is imminent and irreparable

Defendants' characterization of the Rule as affecting "only funding" ignores the critical fact that Plaintiffs cannot pay for the treatment without Medicaid coverage. The Rule therefore threatens the loss of care and is not merely an accounting matter. Logan's family cannot afford roughly $70,000 per year for blockers; Maya's implant costs more than her mother's annual income, in addition to the costs of estrogen and monitoring. Loe Decl. ¶ 16; Moe Decl. ¶ 14. Grace's and Kylie's clinicians identify imminent treatment windows. Goe Decl. ¶¶ 11, 13; Koe Decl. ¶¶ 9–11, 13–15. Maya's mother reports withdrawal, irritability, and depression when Maya's puberty suppressing medication wore off for only a short period. Moe Decl. ¶ 16. A later judgment cannot restore a lost treatment window or reverse permanent physical changes. These injuries fall squarely within the definition of irreparable harm. *See Rio Grande Cmty. Health Ctr., Inc. v. Rullan*, 397 F.3d 56, 76 (1st Cir. 2005).

2. The balance of hardships and public interest favor a narrow injunction

The requested injunction is limited to the named Plaintiffs, FFP for prescribed puberty-suppressing medication and hormone therapy for gender dysphoria, and the pendency of this case. It applies only to treatment that is otherwise lawful and covered by New Hampshire Medicaid. It

would not require New Hampshire to cover treatment, prevent CMS from enforcing the Rule against others, or reach surgical procedures. Instead, it would preserve the pre-Rule federal-funding status for the adolescents before the Court, in which New Hampshire Medicaid was providing coverage for these specific Plaintiffs. *See Braintree Lab'ys, Inc. v. Citigroup Glob. Mkts. Inc.*, 622 F.3d 36, 41 n.5 (1st Cir. 2010). The limited federal contribution for these named Plaintiffs is outweighed by the risk of permanent harm. The balance of hardships and public interest favor a preliminary injunction.[5]

CONCLUSION

For the foregoing reasons, as well as those set forth in Plaintiffs' opening brief, the Court should grant the relief requested in the motion and, under Federal Rule of Civil Procedure 65(a), preliminarily enjoin Defendants as described therein.

[5] The opposition also asks for security under Rule 65(c). The Court should set no bond. *See Int'l Ass'n of Machinists & Aerospace Workers v. E. Airlines, Inc.*, 925 F.2d 6, 9 (1st Cir. 1991) ("[T]here is ample authority . . . that the provisions of Rule 65(c) are not mandatory and that a district court retains substantial discretion to dictate the terms of an injunction bond.") (citations omitted).

Dated: October 22, 2026

Respectfully submitted,

/s/ Chris Erchull
Chris Erchull

/s/ Seth B. Orkand
Seth B. Orkand

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Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that, on this date, I electronically filed the foregoing document using the CM/ECF system, which will send notification of such filing to all those registered with the ECF system.

Date: October 22, 2026

/s/ Seth B. Orkand

Seth B. Orkand

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

GINA GOE, individually and as parent and next friend of GRACE GOE; KARLA KOE, individually and as parent and next friend of KYLIE KOE; LAURA LOE, individually and as parent and next friend of LOGAN LOE; and MELISSA MOE, individually and as parent and next friend of MAYA MOE,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services; CENTERS FOR MEDICARE & MEDICAID SERVICES; and MEHMET OZ, in his official capacity as Administrator of CMS,

Defendants.

Civil Action
No. 1:26-cv-00803-SM-TSM

SUPPLEMENTAL DECLARATION OF GINA GOE IN SUPPORT OF PLAINTIFFS' MOTION FOR STAY OR PRELIMINARY INJUNCTION AND PLAINTIFFS' MOTION TO PROCEED UNDER PSEUDONYM

I, Gina Goe,[1] hereby declare and state as follows:

1. I am over the age of 18, of sound mind, and in all respects competent to testify. I have personal knowledge of the information contained in this Declaration and would testify competently to those facts if called to do so.

2. I am a plaintiff in this Action and I am the parent and next friend of my minor child, Grace Goe.

[1] Contemporaneous with signing this declaration, I have signed with my legal name a separate copy of this declaration. My attorneys have a copy of that separate declaration.

3. In 2021, Grace was diagnosed with pediatric gender uncertainty by her pediatrician. Grace's first visit with a pediatric endocrinologist for gender dysphoria was in 2022.

4. Grace and I meet with her doctor roughly every six months to monitor Grace's hormone levels and discuss our care plan as she nears puberty. Grace, her doctor, and I have discussed puberty blockers in detail. In 2025, I signed consents for a treatment plan that includes puberty blockers.

5. Also in 2025, Grace's doctor prescribed her with medication to treat her worsening gender dysphoria. We discussed side effects of the medication with Grace's doctor. Medicaid has covered the cost of this prescription.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 22 day of October 2026.

Respectfully,

Gina Goe

Gina Goe

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

GINA GOE, individually and as parent and next friend of GRACE GOE; KARLA KOE, individually and as parent and next friend of KYLIE KOE; LAURA LOE, individually and as parent and next friend of LOGAN LOE; and MELISSA MOE, individually and as parent and next friend of MAYA MOE,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services; CENTERS FOR MEDICARE & MEDICAID SERVICES; and MEHMET OZ, in his official capacity as Administrator of CMS,

Defendants.

Civil Action
No. 1:26-cv-00803-SM-TSM

SUPPLEMENTAL DECLARATION OF KARLA KOE IN SUPPORT OF PLAINTIFFS' MOTION FOR STAY OR PRELIMINARY INJUNCTION AND PLAINTIFFS' MOTION TO PROCEED UNDER PSEUDONYM

I, Karla Koe,[1] hereby declare and state as follows:

1. I am over the age of 18, of sound mind, and in all respects competent to testify. I have personal knowledge of the information contained in this Declaration and would testify competently to those facts if called to do so.

2. I am a plaintiff in this Action and I am the parent and next friend of my minor child, Kylie Koe.

3. Kylie has been treated at a gender clinic in New Hampshire for several years.

[1] Contemporaneous with signing this declaration, I have signed with my legal name a separate copy of this declaration. My attorneys have a copy of that separate declaration.

4. Kylie and I have had multiple conversations with her treatment team about what Kylie's care options are, how to move forward, and what to expect. As we reach each new phase in Kylie's physical development, we talk with Kylie's care team about which next steps would best support Kylie's wellbeing.

5. In 2025, Kylie's endocrinologist prescribed medication to treat her gender dysphoria. Medicaid has covered the cost of this prescription.

6. On September 29, 2026, I was informed that Kylie is ready to begin puberty blockers. She was not able to start puberty blockers prior to October 13, 2026.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 21 day of October 2026.

Respectfully,

Karla Koe

Karla Koe

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

GINA GOE, individually and as parent and next friend of GRACE GOE; KARLA KOE, individually and as parent and next friend of KYLIE KOE; LAURA LOE, individually and as parent and next friend of LOGAN LOE; and MELISSA MOE, individually and as parent and next friend of MAYA MOE,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services; CENTERS FOR MEDICARE & MEDICAID SERVICES; and MEHMET OZ, in his official capacity as Administrator of CMS,

Defendants.

Civil Action
No. 1:26-cv-00803-SM-TSM

SUPPLEMENTAL DECLARATION OF LAURA LOE IN SUPPORT OF PLAINTIFFS' MOTION FOR STAY OR PRELIMINARY INJUNCTION AND PLAINTIFFS' MOTION TO PROCEED UNDER PSEUDONYM

I, Laura Loe,[1] hereby declare and state as follows:

1. I am over the age of 18, of sound mind, and in all respects competent to testify. I have personal knowledge of the information contained in this Declaration and would testify competently to those facts if called to do so.

2. I am a plaintiff in this Action and I am the parent and next friend of my minor child, Logan Loe.

3. Logan has been treated at a gender clinic in New Hampshire since 2022.

[1] Contemporaneous with signing this declaration, I have signed with my legal name a separate copy of this declaration. My attorneys have a copy of that separate declaration.

4. In 2024, Logan received her prescription for puberty suppressing medication to treat her gender dysphoria. Medicaid has covered the cost of this medication.

5. In 2025, we began to discuss starting hormone replacement therapy with Logan's doctor.

6. On October 9, 2026, Logan was prescribed estrogen. Medicaid covered the cost of filling the prescription.

7. We have been taking Logan's care on a step-by-step basis, and we continue to discuss the phases and timing of Logan's medical treatment with her care team.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 21st day of October 2026.

Respectfully,

Laura Loe

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

GINA GOE, individually and as parent and next friend of GRACE GOE; KARLA KOE, individually and as parent and next friend of KYLIE KOE; LAURA LOE, individually and as parent and next friend of LOGAN LOE; and MELISSA MOE, individually and as parent and next friend of MAYA MOE,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services; CENTERS FOR MEDICARE & MEDICAID SERVICES; and MEHMET OZ, in his official capacity as Administrator of CMS,

Defendants.

Civil Action
No. 1:26-cv-00803-SM-TSM

SUPPLEMENTAL DECLARATION OF MELISSA MOE IN SUPPORT OF PLAINTIFFS' MOTION FOR STAY OR PRELIMINARY INJUNCTION AND PLAINTIFFS' MOTION TO PROCEED UNDER PSEUDONYM

I, Melissa Moe,[1] hereby declare and state as follows:

1. I am over the age of 18, of sound mind, and in all respects competent to testify. I have personal knowledge of the information contained in this Declaration and would testify competently to those facts if called to do so.

2. I am a plaintiff in this Action and I am the parent and next friend of my minor child, Maya Moe.

[1] Contemporaneous with signing this declaration, I have signed with my legal name a separate copy of this declaration. My attorneys have a copy of that separate declaration.

3. Maya's first medical appointment to treat her gender dysphoria was in 2019. At that first appointment, Maya and I had a detailed discussion with her doctor about the plan for treating Maya's gender dysphoria. The plan was to monitor Maya for signs of puberty and begin puberty blockers at that stage, with hormone replacement therapy to follow to allow Maya experience female puberty at roughly the same time as other girls her age.

4. In 2022, Maya was prescribed puberty blockers to treat her gender dysphoria. In 2023, Maya was prescribed hormone replacement therapy. Medicaid has covered the cost of these prescriptions, as well as the costs of office visits and lab work.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 21 day of October 2026.

Respectfully,

Melissa Moe

Melissa Moe

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

GINA GOE, individually and as parent and next friend of GRACE GOE; KARLA KOE, individually and as parent and next friend of KYLIE KOE; LAURA LOE, individually and as parent and next friend of LOGAN LOE; and MELISSA MOE, individually and as parent and next friend of MAYA MOE,

Plaintiffs,
v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services; CENTERS FOR MEDICARE & MEDICAID SERVICES; and MEHMET OZ, in his official capacity as Administrator of CMS,

Defendants.

No. 1:26-cv-00803-SM-TSM

EXPERT REBUTTAL DECLARATION OF KATE MILLINGTON, MD IN FURTHER SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

I, Kate Millington, declare as follows:

1. I submit this expert declaration based on my personal knowledge.

2. If called to testify, I would testify truthfully based on my expert opinion.

3. In preparing this declaration, I reviewed the Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction, the Rule, and the HHS Review. As with my prior expert declaration, I relied on my scientific education and training, my research experience, and my knowledge of the scientific literature in the pertinent fields. The materials I have relied on in preparing this declaration are the same types of materials that experts in my field of study regularly rely on when forming opinions on these subjects. I may wish to supplement these opinions or the

bases for them based on new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

Medical Treatment for Gender Dysphoria in Minors

4. As discussed in my opening declaration, I have extensive clinical experience in caring for transgender patients and patients with disorders of sex development as well as a variety of endocrine conditions including disorders of growth and puberty, diabetes, and thyroid disease. The care of transgender youth is the major focus of my clinical practice, research, and teaching. I have been caring for transgender youth since 2018 and have personally cared for hundreds of transgender patients.

5. Medical interventions for the treatment of gender dysphoria in minors has broad support in the medical research for decades. The overwhelming conclusion from the available medical research, including systematic reviews, is that medical interventions for transgender youth improve gender dysphoria, anxiety, depression, and psychological well-being. In particular, puberty blocking medications have been consistently shown to achieve their intended purpose of preventing the worsening of gender dysphoria, and gender affirming hormones have similarly been shown to improve gender dysphoria in adolescents.

6. The course of puberty blocking medications is not indefinite but instead is tailored to the individual patient. Patients may continue puberty blocking medications until they are on an appropriate dose of gender affirming hormones (GAH), switch to another medicine to reduce the effect of their endogenous hormone, or have a surgical procedure. Rarely, patients may choose to stop puberty blocking medications and allow their endogenous puberty to progress. All of these options are discussed with patients and are part of gender affirming care.

7. The evidence used to guide decision making in the care of transgender youth is no different in terms of its quality than the evidence in other areas of pediatrics. Likewise, the medications used in the care of transgender youth are safe and routinely used in other pediatric endocrine conditions.

8. Throughout my clinical experience, I have understood that when clinicians discuss medical treatment or a course of treatment for gender dysphoria in minors, those terms mean a course of care that includes all anticipated phases of treatment. I would understand directing treatment for gender dysphoria to refer to managing treatment over time, including monitoring the patient, adjusting dosages and formulation, and moving to the next phase as clinically indicated.

9. In addition, when discussing medical treatment for gender dysphoria in minors, I have understood that this would include all medications that might be prescribed related to a gender dysphoria diagnosis. This would include both GnRHa and gender affirming hormones (GAH), which I described in my opening declaration, as well as medications to blunt the effect of male-type hormones for transgender women (e.g., the anti-androgens spironolactone and finasteride) and medications to reduce menses in transgender men (e.g., menstrual management). All these medications are used in other conditions and are considered safe. For example, spironolactone was originally developed and FDA treatment for high blood pressure, heart failure, and fluid retention. After its anti-androgen properties were recognized, it became routinely used off label for patients with acne and polyendocrine metabolic syndrome (PMOS) as well as in transgender care.

The HHS Review

10. Defendants discuss the HHS Review. As an initial matter, none of the authors of the HHS Review specializes in the medical treatment of gender dysphoria in minors. The opinions

discussed in the HHS Review are not consistent with current evidence-based standards of care or practice guidelines for the treatment of gender dysphoria in minors.

I. Medical Research Regarding the Treatment of Gender Dysphoria in Minors

11. The HHS Review states that the overall quality of research concerning the effects of hormonal interventions for minors is of a "very low certainty." As discussed in my opening report, this is false. Gender affirming medical treatment for minors has been shown to be effective at reducing gender dysphoria.

12. Medical knowledge is established through hypothesis-driven scientific studies. Medical research studies can include a few or many participants, can be prospective or retrospective, randomized or observational. Different medical questions are best answered by different types of research studies.

13. Research studies can be divided into observational and experimental studies. Observational studies include case series, cohort studies, case-control studies, and cross-sectional studies. Experimental studies include randomized and nonrandomized trials which can have either a parallel or crossover design. In an experimental study, the researcher is changing something about the participant's environment or exposures (e.g., giving a group of people a certain medicine), and in an observational study the researcher is simply observing what is already happening.

14. In a cohort study**,** a group of people (a *cohort*) who are exposed to something of interest (e.g., a lifestyle habit, environmental factor, etc.) are followed over time to see if they develop a disease or condition. The cohort that was exposed is then compared to a group that was not exposed. For example, a group of smokers and a group of nonsmokers may be followed for 10 years to see how many people in each group develop lung cancer. Cohort studies can suggest links

between exposures and outcomes but cannot directly prove cause and effect. They typically need to run for many years to decades to effectively capture the outcome of interest. Cohort studies are useful to study relatively common outcomes and to establish timelines between exposures and outcomes. They are also used to study exposures that you could not randomize people to. For example, you could not randomize some people to smoke and some to not smoke, but you can use an observational cohort study to study what happens to people who smoke. (Bosdriesz et al., 2020)

15. In a case control study researchers start by identifying people who have a disease or condition (*cases*) and those who don't have the disease or condition (*controls*). They then look back in time to see if they can identify exposures that are different between the *cases* and *controls*. A case control study may compare people who have lung cancer and those without it to see if rates of smoking are different between the two groups. Like cohort studies, case control studies can suggest associations between exposures and outcomes but cannot prove causality. Case control studies can be more efficient than cohort studies because you are selecting participants who already have the outcome you are interested in studying. They are useful for studying conditions that develop slowly.

16. Randomized control trials (RCTs) are experimental studies where participants are randomly assigned by the researcher to receive an intervention (e.g., a medication, educational initiative, etc.) or not (placebo group). Randomizing the assignment of participants to the intervention and placebo groups helps to reduce bias in who receives the intervention (e.g., only giving the medication to certain populations or to the healthiest patients). RCTs can establish causation. They are most useful for studying an intended outcome of an intervention that is relatively common and occurs in a reasonable time frame. Although they are the "gold standard" for establishing cause and effect between an exposure and an outcome, RCTs are not always

appropriate or possible and are not always necessary. If an observational study has established a clear benefit (e.g., insulin in diabetes, or antibiotics for certain infections) then an RCT would be inappropriate and unnecessary. RCTs are also not well suited for outcomes that are rare or take a long time to appear, or if participation in the treatment group rather than the placebo group would be obvious to the participants. The researchers also must be sure that there is no known difference between the placebo and the treatment groups, otherwise it would not be ethical to randomize people to receive either one.

17. Medical knowledge can also be gained from case reports or case series. A case report is a story about one or a few patients. A case series is a collection of several case reports. Because case reports only describe one or a few patients, they are considered the lowest level of evidence. They are not generalizable to larger populations, cannot establish cause and effect, and are subject to a lot of bias. These types of reports are useful for describing a rare condition, giving early evidence for a new therapy, identifying potentially new diseases, and generating hypotheses for future research. They document conditions of phenomena that should be furthered studied, but in the absence of additional studies almost never lead to a change in clinical practice. (Black, 1996; Bosdriesz et al., 2020)

18. Systematic reviews are careful summaries of research where authors clearly define inclusion criteria, gather all the studies that fit those criteria, and then rigorously analyze those studies using consistent criteria. (Brignardello-Petersen et al., 2024) The HHS Review is an overview of systematic reviews—also known as an “umbrella review.”

19. To guide their analysis, authors of systematic reviews use different frameworks, such as GRADE (Grading of Recommendations Assessment, Development and Evaluation) or the

Newcastle-Ottawa scale, to evaluate the certainty of the published evidence. (Berkman et al., 2015; Brignardello-Petersen et al., 2021)

20. The GRADE scale classifies evidence as high, moderate, low, or very low certainty. The initial rating is driven primarily by the type of studies included in the review—low certainty for observational studies and high for RCTs. Therefore, stating that a therapy has "low quality evidence" is not saying that the therapy is dangerous, has evidence of harm, or has no evidence. It is a statement in part about the types of studies examining the therapy available at the time the review was written.

21. Systematic reviews are important tools to understand the available evidence for a treatment outcome. However, the majority of medical decisions are made in settings with no or very low-quality evidence by the metrics used in systematic reviews. Studies examining the quality of evidence by the GRADE scale in a large database of systematic reviews across all of medicine, the Cochrane Database of Systematic Reviews, found that most reviews (55.7%) reported a low or very low level of evidence and only 4.1% to 5.6% of interventions had high-quality evidence. (Fleming et al., 2016; Howick et al., 2022) Medical interventions and decisions based on low-quality evidence are the rule, not the exception.

22. All types of research studies are commonly used in medicine. In my own field, there are several common clinical situations that are supported by limited low-quality evidence—stress dose steroids for minor illness in adrenal insufficiency, diagnosis of adrenal insufficiency, and the treatment of PMOS to name a few. (Bornstein et al., 2016; Teede et al., 2023) There are many common endocrine conditions that have never been tested with RCTs.

23. The use of levothyroxine in hypothyroidism is an illustrative example. Levothyroxine, or synthetic thyroid hormone, is routinely used in the treatment of hypothyroidism,

a condition where the thyroid stops producing enough thyroid hormone. In fact, levothyroxine is the second most prescribed medication in the United States. The use of levothyroxine was established by observational studies first of thyroid extracts in the 1890s and then synthetic thyroid hormone in the 1920s. (Kahaly, 2021) We use levothyroxine all the time, but it has never been tested via an RCT.

24. The use of growth hormone treatment in idiopathic short stature is another example. Growth hormone administered via daily injection over many years is given to children who are otherwise healthy in order to improve their adult height. On average, this produces an improvement in adult height of 1.5–2.5 inches, although there is a lot of variability in individual patient response. Growth hormone use has side effects (e.g., increased pressure around the brain, increased risk for diabetes, increased risk for certain types of bone fractures, etc.) and may carry an increased risk of cardiovascular events in adulthood. (Grimberg et al., 2017; Tidblad et al., 2021) There is no evidence that short stature in the range typically treated leads to disability, morbidity, or mortality which has led some to question if the risks are worth the benefit. (D. B. Allen, 2006; Cohen, 2014; Grimberg et al., 2017) However, because of a societal bias towards height especially in cisgender boys, growth hormone treatment is frequently requested by families and prescribed by pediatric endocrinologists. (Grimberg et al., 2015)

25. The treatment of idiopathic short stature is an example of a common clinical scenario encountered in pediatric endocrinology that requires the clinician to weigh the risks, benefits, patient characteristics, and patient goals. The consideration of the balance of evidence and treatment plan in the treatment of idiopathic short stature, like in gender affirming care, requires the expertise of a physician and should happen between the doctor, patient, and family.

26. To help clinicians make medical decisions, medical societies write clinical guidelines. Clinical guidelines are written by groups of experts after a careful review of the available literature. Such a review would include review of observational studies, case reports and series, RCTs, and expert opinion. The guidelines regarding the care of transgender youth were written in this fashion. (Coleman et al., 2022; Hembree et al., 2017)

27. The literature on outcomes of GnRHa and GAH in transgender youth has also been summarized in several systematic reviews. (Baker et al., 2021; Doyle et al., 2023; Thompson et al., 2023; Heathcote et al., 2024; Taylor, Hall, Heathcote, Hewitt et al., 2024b, 2024a; Taylor, Mitchell, Hall, Heathcote et al., 2024; Taylor, Mitchell, Hall, Langton et al., 2024; Miroshnychenko et al., 2025a; Miroshnychenko et al., 2025b) and reports. (Cass, 2024; Dopp et al., 2024; Strohecker et al., 2024)

28. These systematic reviews cover an overlapping body of evidence and have reached similar conclusions with regards to the outcomes associated with gender affirming medical care. A review completed by the RAND Corporation concluded that although the evidence was low or low certainty, “findings indicated low regret, low dissatisfaction levels, and low side effects and complications (all with very low certainty)” and “[s]ome studies found mental health improvements following hormones and surgeries, but others found no effects (very low certainty for all instances of the outcome, because of inconsistent study findings).” (Dopp et al., 2024)

29. The same review found that “gender identity and expression change efforts” (i.e., conversion therapy), which have been suggested as an alternative to medical treatment, were “associated with increases in suicidality (low certainty) and increases or no change in mental health symptoms (very low certainty).”

30. The Cass Report, commissioned by the National Health Service in England, itself commissioned several reviews that were conducted by a team at the University of York. Based on these reviews, the Cass Report noted that "[t]here is suggestive evidence from mainly pre-post studies that hormone treatment may improve psychological health, although robust research with long-term follow-up is needed." (Cass, 2024) The York reviews commissioned for the Cass Report found that 34 of the 53 reviewed studies assessing outcomes of youth with gender dysphoria treated with gender affirming hormones were of moderate or high (one study) quality evidence using the Newcastle-Ottawa Scale, and that there were 26 studies of moderate to high-quality assessing outcomes of youth with gender dysphoria treated with GnRHa medications. (Taylor et al., 2024a; Taylor et al., 2024b)

31. A report commissioned by the Utah Department of Health and Human Services as part of the moratorium on gender affirming care for youth passed by Utah legislators in January 2023 and completed by the University of Utah, which again reviewed the same body of literature, reached the following conclusion: "The conventional wisdom among non-experts has long been that there are limited data on the use of [gender affirming hormone therapy] in pediatric patients with [gender dysphoria]. However, results from our exhaustive literature searches have led us to the opposite conclusion." And "[t]he consensus of the evidence supports that the treatments are effective in terms of mental health, psychosocial outcomes, and the induction of body changes consistent with the affirmed gender in pediatric [gender dysphoria] patients. The evidence also supports that the treatments are safe in terms of changes to bone density, cardiovascular risk factors, metabolic changes, and cancer." (Strohecker et al., 2024)

32. The highest quality evidence by these grading systems is given by large RCTs. These types of trials are not feasible in many areas of pediatrics, including gender affirming care.

To conduct a RCT where participants are randomized to a treatment group or placebo group, you have to be certain that the placebo confers no added known risk over the treatment group at the start of the trial. (Emanuel et al., 2000)

33. In a RCT of gender affirmative treatment, transgender youth randomized to the placebo group would not receive GnRHa and would experience the body changes associated with a puberty not aligned to their gender identity or would not receive GAH and would continue to live in a body not aligned with their gender identity. This is not a neutral choice. Research tells us that untreated transgender youth have higher risks of poor mental health outcomes and suicidal thoughts. (Becerra-Culqui et al., 2018; Lucas et al., 2024; van der Miesen et al., 2020)

34. Furthermore, RCTs in children are held to a higher standard given the vulnerability of children. Studies in children must limit risk to no more than minimal risk, unless providing a direct benefit to children in the trial. (Field et al., 2004) Thus, an RCT of gender affirming medical treatment for youth that withheld treatment would not be ethical.

35. In the absence of RCTs in this population, cohort studies including pre-post studies where participants are compared to themselves before treatment are the highest quality studies available. These types of studies demonstrating the efficacy of gender affirming care are cited throughout my opening declaration.

II. Medical Treatments for Gender Dysphoria are Safe

A. Infertility

36. A discussion of fertility, the impact of medications on fertility, and fertility preservation options is part of the counseling before starting any gender affirming medications. The conversation starts at the initial medical visit and is revisited again at key junctions in the treatment journey. The guidelines include a recommendation that all transgender youth receiving

gender affirming medications receive fertility preservation and, if desired, be referred to a fertility specialist. (Coleman et al., 2022; Hembree et al., 2017)

37. GnRHa temporarily stop the development of eggs and sperm. If treatment is stopped—either before starting GAH or later in adulthood—fertility will resume normally. Long-term studies have shown that people who use GnRHa have the same rates of pregnancy and pregnancy outcomes as those who do not. (Lazar et al., 2014; Martinerie et al., 2021)

38. If GnRHa treatment is followed by GAH, eggs or sperm may never fully develop. In adulthood, individuals can choose to stop treatment to allow puberty and gamete development to resume, or explore other options for building a family—such as egg or sperm donation, embryo adoption, or adoption. (Cheng et al., 2019; De Roo et al., 2025) For transgender youth starting GAH without prior GnRHa, current guidelines recommend discussing fertility preservation, like banking eggs or sperm. (Coleman et al., 2022; Hembree et al., 2017) However, even if they are unable to preserve eggs or sperm, there is growing evidence that some transgender adults who have used GAH have had successful pregnancies and births. (Baram et al., 2019; De Roo et al., 2025; Light et al., 2014)

39. Gender affirming care is not the only area in pediatrics where fertility may be affected, and fertility preservation is recommended. For example, chemotherapy poses a high and well-known risk of infertility. Yet even in that setting, fertility preservation is not routinely done due to various barriers. (Johnson et al., 2017; Yang et al., 2024) For any treatment that may impact fertility, patients, families, and care teams should discuss the risks and benefits, including the consequences of delaying or avoiding treatment.

B. Bone Density Accrual

40. Puberty is a time of peak bone mass accrual, and estrogen and testosterone are important for the development of bone mass. The bone mass that is accumulated during puberty determines lifetime skeletal health, and impaired bone mass accrual during this time can increase the risk of osteoporosis in adulthood. There have been multiple studies of bone health in transgender individuals. (Guss et al., 2022; Joseph et al., 2019; Klink et al., 2015; Lee, 2023; Lee et al., 2020; Navabi et al., 2021; Schagen et al., 2020; Van Der Loos et al., 2023; Vlot et al., 2017) In general, these studies have found that GnRHa pause bone mass accrual and that once patients receive GAH their bone mass accrual resumes and they end up with normal bone mass.

41. Multiple studies have found that transgender youth have lower bone mineral density compared to their peers before receiving GnRHa. (Hodax et al., 2023; Klaver et al., 2020; Lee et al., 2020; Navabi et al., 2021; Schagen et al., 2020; Vlot et al., 2017) These studies also found that transgender youth have lower Vitamin D levels, report lower calcium intake, and lower physical activity levels than their cisgender peers. Vitamin D, calcium, and physical activity are factors that improve bone health. I recommend that all my patients take vitamin D supplements, get the recommended daily amount of calcium (1300 mg for adolescents), and engage in physical activity. I have never had a patient receiving gender affirming medical care sustain a broken bone without a clear mechanism (e.g., falling from a horse, sports injury, etc.).

42. Many of the older studies on bone health only included short term outcomes. One recent article by van der Loos et. al., looked at 75 individuals with over nine years of follow-up. This study found that during GnRHa treatment, bone mineral density decreased when compared to age and sex matched peers, however, after treatment with GAH bone density recovered to match

their peers with the exception of one site, the lumbar spine, in those DMAB. (Van Der Loos et al., 2023)

43. In summary, although bone mineral density does decrease compared to peers during GnRHa, it recovers after GAH treatment.

C. Sexual Dysfunction

44. Sexual functioning is influenced by multiple factors including biological (e.g., hormone treatments, surgical history, etc.), psychological factors, social and relationship factors, and cultural influences. Gender affirming care can impact any or all of these domains.

45. The effect of gender affirming medical care on sexual functioning differs by treatment modality. For transgender males, testosterone leads to increased libido, sexual arousal, and overall sexual satisfaction. Transgender females receiving estrogen, which leads to a decrease in testosterone levels, experience reduced sexual desire and fewer spontaneous erections.[1] However, many transgender females do not find the change in sexual functioning to be distressing.

46. There is no difference in sexual functioning between transgender individuals who received GnRHa in conjunction with GAH and those who received GAH alone.[2]

47. Gender affirming surgery is associated with an increase in sexual activity, orgasm quality, and sexual satisfaction in both transgender women and men.[3]

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[1] Kerckhof M.E., et. al, *Prevalence of Sexual Dysfunctions in Transgender Persons: Results from the ENIGI Follow-Up Study*, J Sex Med. (2019) Dec;16(12):2018-2029; Mattawanon N., et al., *Sexual Dysfunction in Transgender People: A Systematic Review*, Urol Clin North Am. 2021 Nov;48(4):437-460; Holmberg, M., et al., *Supporting Sexuality and Improving Sexual Function in Transgender Persons*, Nat Rev Urol. 16, 121–139 (2019).

[2] Van der Meulen I.S., et al., *Sexual Satisfaction and Dysfunction in Transgender Adults Following Puberty Suppression Treatment During Adolescence*, J Sex Med. 2025 Aug 4;22(8).

[3] Holmberg, M., et al., *Supporting Sexuality and Improving Sexual Function in Transgender Persons*, Nat Rev Urol 16, 121–139 (2019).

Treatment Protocols in Europe

48. Defendants reference the reports and decisions of certain European countries and agencies to purportedly demonstrate a lack of support for gender affirming medical treatment for transgender minors.

49. Most importantly, none of the countries Defendants discuss ban the medical treatment in its entirety nor do they ban federal funding for those treatments.[4]

50. In the United Kingdom, medical treatment for gender dysphoria for minors is available for existing patients who were already receiving treatment prior to restrictions or those in approved clinical trials.[5] As discussed above, the Cass Report, commissioned by the National Health Service in the United Kingdom noted that there is evidence that hormone treatment may improve psychological health.[6]

51. Although the Swedish National Board of Health and Welfare has stated, "Treatment with GnRH analogues, gender-affirming hormones, and mastectomy can be administered in

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[4] House of Lords Library Staff, *Hormone treatments and age consent: Government policy*, UK Parliament (October 15, 2026), https://lordslibrary.parliament.uk/hormone-treatments-and-age-consent-government-policy/#heading-1; Nat'l Board of Health and Welfare, *Care of children and adolescents with gender dysphoria Summary of national guidelines December 2022*, Socialstyrelsen (2023), https://www.socialstyrelsen.se/contentassets/444af6c0a5fb429c9b56fd51b931a816/2023-1-8330.pdf ; *Recommendation of the Council for Choices in Healthcare in Finland (PALCO/COHERE Finland)*, Society for Evidence-Based Gender Medicine (2020), https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation.pdf; Mette Vinther Hansen et al., *Health services for children and young people with gender discomfort*, Ugeskrift for Læger (July 3, 2023), https://ugeskriftet.dk/videnskab/sundhedsfaglige-tilbud-til-born-og-unge-med-konsubehag; Karena Phan, *Norway didn't ban gender-affirming care for minors, as headline falsely claims*, AP News (June 8, 2023), https://apnews.com/article/fact-check-norway-not-ban-gender-affirming-care-956221436313.

[5] House of Lords Library Staff, *Hormone treatments and age consent: Government policy*, UK Parliament (October 15, 2026), https://lordslibrary.parliament.uk/hormone-treatments-and-age-consent-government-policy/#heading-1.

[6] Cass, H. (2024), Independent review of gender identity services for children and young people: Final report, https://cass.independent-review.uk/home/publications/final-report/.

exceptional cases," it clarifies that by exceptional cases it means the criteria used by the "Dutch protocol" which is the basis for the clinical practice guidelines in the United States.[7]

52. Finland's policy states that in "clear cases of pre-pubertal onset of gender dysphoria that intensified during puberty" a minor can be assessed for the appropriateness of puberty suppression. Those who have already undergone puberty and "whose gender dysphoria occurs in the absence of co-occurring symptoms requiring psychiatric treatment, and whose experience of transgender identity failed to resolve following a period of reflection" can be assessed for the appropriateness of hormone therapy.[8]

53. Denmark has a centralized pediatric gender service, which encompasses intake, evaluation, consultation, and may provide referrals for puberty blockers and cross-sex hormones.[9]

54. Norway's guidelines require minors to undergo an assessment by a team of healthcare specialists and then those individuals who qualify can receive puberty-delaying treatment once puberty has started, and hormone therapy no earlier than age 16.[10]

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 21st day of October 2026.

Kate Millington, MD

[7] Nat'l Board of Health and Welfare, *supra* n. 4.
[8] *Recommendation of the Council for Choices in Healthcare in Finland (PALCO/COHERE Finland)*, *supra* n. 4.
[9] Mette Vinther Hansen et al., *supra* n. 4.
[10] Karena Phan, *supra* n. 4.