UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

GINA GOE, et al.,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

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

DEFENDANTS' MEMORANDUM OF LAW OPPOSING PLAINTIFFS' EXPEDITED MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Few questions in American medicine are more contested than whether children should receive puberty blockers, cross-sex hormones, or surgery to align their bodies with an identity that differs from their sex. The Supreme Court has described "fierce scientific and policy debates about the safety, efficacy, and propriety of medical treatments in an evolving field." *United States v. Skrmetti*, 605 U.S. 495, 525 (2025). States have answered that question differently.

But this case does not ask that question or ask the Court to settle that debate. The only question this Court must answer is whether the federal government may choose to not fund these sex-rejecting procedures using federal Medicaid dollars while allowing States the option to continue funding them. The Rule[1] at issue bans no procedures, regulates no physicians, and does not impose any requirements on any beneficiary. Instead, the Rule simply prohibits federal Medicaid funds from being used to pay for these interventions because "the evidence for benefit of pediatric medical transition is very uncertain, while the evidence for harm is less uncertain." U.S. Dep't of Health & Human Servs., *Treatment for Pediatric Gender Dysphoria* 15 (Nov. 19, 2025) ("HHS Review"), available at https://opa.hhs.gov/sites/default/files/2026-06/gender-dysphoria-report.pdf. The HHS Review, conducted by a committee that included medical professors from distinguished universities, involved a thorough examination of the relevant literature and determined that the evidence of long-term benefit is very low while the significant risks posed by those procedures—including infertility, bone density accrual, and sexual dysfunction—make those procedures uniquely risky.

[1] The Rule at issue is a final rule published by the Centers for Medicare & Medicaid Services ("CMS") entitled "Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children," 91 Fed. Reg. 52406 (Aug. 13, 2026) (to be codified at 42 C.F.R. § 441.800, § 441.801, § 441.802, and § 457.476) (the "Rule").

Plaintiffs make several arguments for why the Court should enjoin application of the Rule as to them. None have merit. CMS acted within its authority under 42 U.S.C. §§ 1396a (a)(19) and 1396a(a)(30)(A) of the Social Security Act (the "Act") to ensure that there is no unnecessary utilization of care and that all care and services under State Medicaid plans are consistent with the best interests of recipients and within its authority of 42 U.S.C. § 1397aa(a) and 42 U.S.C. § 1397bb(a)(7)(A) to ensure that Children's Health Insurance Program ("CHIP") plans effectively and efficiently administer CHIP funds and provide appropriate care. And it did so in a manner consistent with both Early and Periodic Screening, Diagnostic, and Treatment ("EPSDT") and comparability provisions in the Act. Likewise, CMS reasonably explained its decision and stated what data it relied on to make its decision and why it chose to follow certain guidance rather than what Plaintiffs highlight in their Motion. Plaintiffs have a different view of the evidence, but the judgment call ultimately lies with CMS, not Plaintiffs. The Court should not accept Plaintiffs' invitation to second-guess CMS's judgment.

Plaintiffs emphasize the Rule's political context. But the underlying evidentiary concerns are not unique to this Administration. Independent reviews commissioned by health authorities in Sweden, Finland, and the United Kingdom likewise identified substantial uncertainty, which led those countries to restrict these interventions for children. Further complicating this case for Plaintiffs is the fact that they all live in New Hampshire, a State that has determined that sex-rejecting procedures—*i.e.*, cross-sex hormone therapy, puberty blockers, and surgical or other medical procedures—cannot be used on children if the performance or administration of the procedure or medication is for the purpose of altering or attempting to alter the appearance of or affirm the minor's perception of his or her gender or sex. N.H. Rev. Stat. § 332-N:2, I. The statute allows providers to "continu[e] the direction or administration of medication or treatment that

began prior to January 1, 2026," *id.* 332-N:2, III, but none of the Plaintiffs have established that New Hampshire will even make state funding available for those procedures in light of the passage of Section 332-N:2. At the very least, a plain reading of Section 332-N:2 makes clear that the two child Plaintiffs who hope to receive puberty blockers and hormonal therapy in the future, Grace Goe and Kylie Koe, are not entitled to any relief and that the child Plaintiff who currently receive puberty blockers but not hormonal therapy, Logan Loe, is not entitled to any injunction permitting hormonal therapy because New Hampshire law does not allow them to be prescribed new treatments after January 1, 2026.

The Motion for Preliminary Injunction should be denied.

BACKGROUND

I. Federal Law Requires Medicaid and the Children's Health Insurance Program to Ensure the Integrity of Federal Spending and the Protection of Beneficiaries.

1. Medicaid is a cooperative federal-state program. Title XIX of the Act authorizes federal financial assistance to States to provide medical assistance to persons with limited income. Participation by the States is voluntary, "but once a State elects to join the program, it must administer a state plan that meets federal requirements." *Frew ex rel. Frew v. Hawkins*, 540 U.S. 431, 433 (2004).

A participating State runs its program under a plan approved by the Secretary. 42 U.S.C. § 1396a(b). The federal government then pays a share of the State's costs: the Secretary pays each State with an approved plan the federal medical assistance percentage of "the total amount expended . . . as medical assistance under the State plan." *Id.* § 1396b(a)(1).

42 U.S.C. § 1396a(a) sets out the conditions that federal law requires for every State Medicaid plan. There are dozens of conditions, including some that define who must be covered and what must be provided. *See, e.g.*, 42 U.S.C. § 1396a(a)(43) (requiring participating States to

have an EPSDT program). And Congress has made the Secretary responsible for ensuring that the States' plans meet all the conditions and approving such plans. *See* 42 U.S.C. § 1396a(b) ("The Secretary shall approve any plan which fulfills the conditions specified in subsection (a) . . . .").

Among those conditions are ones that protect beneficiaries and the integrity of federal spending. Every plan must "provide such 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 and services and to assure that payments are consistent with efficiency, economy, and quality of care." *Id.* § 1396a(a)(30)(A). And every plan must provide "such safeguards as may be necessary to assure that . . . such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients." *Id.* § 1396a(a)(19).

CMS has long carried out those protections by regulation. Its utilization-control rules require each State to run a program that "[s]afeguards against unnecessary or inappropriate use of Medicaid services." 42 C.F.R. § 456.3(a); *see id.* § 456.1(b)(1) ("[42 U.S.C. § 1396a(a)(30)] requires that the State plan provide methods and procedures to safeguard against unnecessary utilization of care and services."). Other regulations require each service to be "sufficient in amount, duration, and scope to reasonably achieve its purpose." *Id.* § 440.230(b). And although a state Medicaid agency may not "arbitrarily" deny a required service "solely because of the diagnosis, type of illness, or condition," *id.* § 440.230(c), it may "place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures." *Id.* § 440.230(d). CMS has also previously prohibited Federal financial participation ("FFP") from being used for sterilization services furnished to individuals under age 21. *See* Rule at 52432; 42 C.F.R. § 441.253.

Congress also charged the Secretary with ensuring that States comply with 42 U.S.C. § 1396a. Congress provided that, if "in the administration of the plan there is a failure to comply substantially with any such provision [of § 1396a]," then the Secretary must, after notice and an opportunity for a hearing, stop or limit payments to the State. 42 U.S.C.§ 1396c(2). Congress also provided the procedure for disallowing Medicaid claims: when the Secretary determines that "any item or class of items on account of which [FFP] is claimed under subchapter XIX shall be disallowed," the State may seek reconsideration and then review by the Departmental Appeals Board. *Id.* § 1316(e). And the Secretary must "make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which [he] is charged." *Id.* § 1302(a).

2. Congress also established that States could have a separate State Children's Health Insurance Program ("CHIP") through Title XXI, which funds health coverage for uninsured, low-income children. Under 42 U.S.C. § 1397aa, a CHIP plan must provide "child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children." 42 U.S.C. § 1397aa(a). A State may provide that coverage through a separate CHIP plan, through its Medicaid plan, or both. *Id.* And under 42 U.S.C. § 1397bb, a CHIP plan must describe the methods used "to assure the quality and appropriateness of care." *Id.* § 1397bb(a)(7)(A). New Hampshire covers CHIP-eligible children through its Medicaid program. *See* Mem. in Supp. of Pls' Expedited Mot. for Prelim. Inj. (ECF No. 7) at 14 n.9 (the "PI Motion").

II. The President Orders an Evaluation of Sex-Rejecting Procedures on Children, and HHS Publishes a Thorough Review and this Rule.

1. In January 2025, the President directed HHS to publish a review of the existing literature on best practices in the field of treatment for pediatric gender dysphoria. Exec. Order No. 14187,

Protecting Children from Chemical & Surgical Mutilation, 90 Fed. Reg. 8771 (Jan. 28, 2025). HHS published that review, *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices*, on May 1, 2025, and later released a revised version after peer review. *See* HHS Review 1. The Review's nine authors brought expertise spanning internal medicine, endocrinology, psychiatry, bioethics, and research. They include Farr A. Curlin, an internist and professor at Duke University School of Medicine; Michael K. Laidlaw, an endocrinologist; and Kristopher Kaliebe and Kathleen McDeavitt, both psychiatrists at prominent universities. *Id.* at 17-18. In a jointly authored op-ed, the authors stated that they had spent years studying gender medicine, described their group as politically diverse, and said that they conducted the review independently of the Administration. *See* Evgenia Abbruzzese et al., *We Wrote the HHS Review on Treatment for Minors with Gender Dysphoria. We Hope Our Critics Actually Read Our Report*, STAT (Dec. 8, 2025) (stating "We did not expect HHS to entrust this sensitive task to us; it could have chosen a team that was ideologically aligned with the current administration. We are grateful that the administration set aside coalition politics and chose us instead.").

The HHS Review was an overview of systematic reviews—*i.e.*, an "umbrella review"—"to evaluate the direct evidence regarding the benefits and harms of treatment for children and adolescents with gender dysphoria." HHS Review at 13. Several of the systematic reviews were written by informed health authorities in Europe. *Id.* The HHS Review assessed the evidence of "existing systematic reviews to evaluate the evidence regarding the benefits and harms of hormonal and surgical interventions for children and adolescents diagnosed with gender dysphoria" and "found that the overall quality of evidence" concerning the effects of these procedures demonstrated a "very low certainty" of successful outcomes while demonstrating "risk of significant harms" that were "comparatively less uncertain." Rule at 52452-53 (discussing the

HHS Review).[2] The HHS Review also identified irreversible harms that could be caused by these interventions, including infertility, bone density accrual, and sexual dysfunction. *See, e.g.*, Rule at 52455.

2. After the HHS Review was conducted, CMS proposed the Rule on December 19, 2025. *Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children*, 90 Fed. Reg. 59441 (Dec. 19, 2025) (Docket No. CMS-2025-1823). The comment period ran through February 17, 2026. CMS received more than 11,000 timely comments. Rule at 52421.

CMS published the final Rule on August 13, 2026, and it went into effect on October 13, 2026. Rule at 52406. The preamble responds to the comments over more than fifty pages. *Id.* at 52421-73. The Rule requires each State Medicaid plan to provide that the state Medicaid agency "will not make payment under the plan" for "sex-rejecting procedures" furnished to beneficiaries under 18, and it makes FFP unavailable for those procedures. Rule at 52474 [codified as 42 C.F.R. §§ 441.800-441.802]. A "[s]ex-rejecting procedure" is defined as "any pharmaceutical or surgical intervention that attempts to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex" that either: (1) "[i]ntentionally disrupt[s] or suppress[es] the normal development of natural biological functions, including primary or secondary sex-based traits," or (2) "[i]ntentionally alter[s] an individual's physical appearance or body, including amputating, minimizing or destroying primary or secondary sex-based traits such

[2] Plaintiffs say the Review included "only 17 out of 286 systematic reviews that were considered for inclusion," and that "[t]he remaining 269 reviews, representing a combined several thousand studies, were discarded." PI Motion at 7. Of the 286 articles the Review assessed in full, 48 were not systematic reviews at all, 129 did not focus on the pediatric population the Review addressed, 87 did not address the treatments at issue, and five duplicated other reports. HHS Review, App. 4, at 11. Those articles were not discarded. Rather, they did not answer the question the Review asked.

as the sexual and reproductive organs." 42 C.F.R. § 441.801. Sex-rejecting procedures do not include procedures that (1) "treat an individual with a medically verifiable disorder of sexual development," (2) are completed "[f]or purposes other than attempting to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex," or (3) "treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s)." *Id.* The Rule also establishes a parallel requirement for CHIP plans for beneficiaries under 19. Rule at 52406 [codified as 42 C.F.R. § 457.476].

The Rule relies on CMS's requirement to oversee Medicaid State programs and ensure that there is no unnecessary utilization of care and that all care and services under State Medicaid plans are consistent with the best interests of recipients for Medicaid funds under 42 U.S.C. §§ 1396a (a)(19) and 1396a(a)(30)(A) of the Act. *See, e.g.*, Rule at 52406, 52420, 52422. For CHIP, the Rule relies on CMS's authority to effectively and efficiently administer CHIP and assure the quality and appropriateness of care under 42 U.S.C. § 1397aa(a) and 42 U.S.C. § 1397bb(a)(7)(A) of the Act. *See, e.g.*, *id.* at 52407-08, 52415. The Rule also notes that 42 U.S.C. § 1302 requires the Secretary to make and publish rules and regulations, "not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which each is charged under this chapter." 42 U.S.C. § 1302(a); *see* Rule at 52407. The Rule found the regulated uses lack a sufficient evidentiary basis to support individualized medical-necessity determinations and are not consistent with quality of care, and that administrative safeguards could not cure those concerns. Rule at 52414-19, 52473.

When promulgating the Rule, CMS did not rely solely on the HHS Review. It also considered several studies evaluating the long-term effects of sex-rejecting procedures from

Europe. Those include the United Kingdom's Cass Review—a 4-year independent evaluation of pediatric gender medicine that was published in April 2024 and commissioned by the UK's National Health Service—which resulted in the UK largely banning puberty blockers and restricting cross-sex hormones; Sweden's National Board of Health and Welfare's determination that the risks of puberty suppressing and hormonal treatments likely outweigh the possible benefits; and evaluations by Finland, Denmark, and Norway to favor psychosocial interventions before resorting into any hormonal or surgical interventions, among others. *Id.* at 52410-11, 52453-56. The Rule noted that "there has been growing international concern about the use of hormonal and surgical interventions for pediatric gender dysphoria." *Id.* at 52411. It also considered evidence commenters submitted in contradiction to the Rule, including professional-society guidelines and studies reporting benefits, and explained why that evidence did not change its assessment. *Id.* at 52411-12, 52427, 52453-56. The Rule noted that there was evidence that those advocating for sex-rejecting procedures—primarily, some U.S. medical associations—were suppressing dissent and stifling debate about the issue and were instead relying on a small number of specialized committees for their recommendations, making it far from clear that their views were shared by the wider medical community." *Id.* at 52411 & n.66 (quoting the HHS Review at 15). And the Rule noted that there continued to be "evolving professional consensus in this area," which further demonstrated "genuine uncertainty regarding the risk-benefit profile of these procedures for children—an uncertainty that is central to our determination that Federal funds should not support them under Medicaid and CHIP." *Id.* at 52455.

3. The Rule does not, however, govern providers' medical practice or prevent States from covering sex-rejecting procedures with State-only funds; it covers only federal payments within federally matched programs. Rule at 52428. The Rule does not regulate providers at all or direct

them regarding how to conduct clinical assessments or what advice to give patients. *Id.* at 52432. States instead have "the authority [and] ability . . . to regulate the practice of medicine within their borders, to establish their own coverage requirements for private insurance, and to fund sex-rejecting procedures for Medicaid and CHIP beneficiaries using non-Federal dollars outside the Federally matched programs." *Id.* at 52434; *see also id.* at 52436 ("The rule does not affect States' authority to regulate the practice of medicine within their borders, to license providers, and to set standards of care.").

The Rule also does not affect mental-health services; instead, it agrees that "mental health care, psychotherapy, and psychosocial support are critical components of care for children with gender dysphoria, and this rule does not limit Federal payment of those services." *See* Rule at 52428. In addition, the final Rule includes a provision allowing FFP to "remain available for cross-sex hormone therapy for a tapering period of up to 6 months from October 13, 2026, for beneficiaries who were receiving such therapy as of October 13, 2026." 42 C.F.R § 441.802(c). This six-month tapering period is meant "to provide beneficiaries and their treating providers a reasonable opportunity to phase off these medications in a manner that allows for clinical discretion, if desired." Rule at 52416; *see id.* at 52421-22.

Finally, the Rule is severable. "[I]f any provision in this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be severable from this final rule and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances." Rule at 52421.

III. New Hampshire Bans the Same Sex-Rejecting Procedures Covered by the Rule with a Limited Exception for Treatments that Have Already Started.

Before the final Rule was published, New Hampshire enacted a law that generally prohibits providers from performing the sex-rejecting procedures covered by the final Rule as of January 1, 2026. *See generally* N.H. Rev. Stat. § 331-N:2. Specifically, Section 331-N:2 prohibits knowingly performing, administering, or offering to perform or administer medical procedures to a minor—including puberty-blocking or cross-sex hormone medications—"if the performance or administration of the procedure or medication is for the purpose of altering or attempting to alter the appearance of or affirm the minor's perception of his or her gender or sex" when it will "enabl[e] a minor to identify with, or live as, a purported identity inconsistent with the minor's biological sex" or "treat[] purported discomfort or distress from a discordance between the minor's biological sex and asserted identity." *Id.* § 331-N:2, I. Persons who violate this statute can be subjected to administrative disciplinary actions, *id.* § 331-N:2, IV; private suits for damages and injunctive relief, *id.* 332-N:3; and enforcement suits by the Attorney General, *id.* 332-N:3, VI(a). Section 331-N:2 carves out two exceptions: (1) there is no prohibition on "a procedure undertaken to treat a minor born with a medically verifiable disorder of sex development as defined in [N.H. Rev. Stat. §] 332-M:2, II," and (2) the statute does not "prohibit a health care provider from continuing the direction or administration of medication or treatment that began prior to January 1, 2026." *Id.* § 331-N:2, II-III.

On October 1, 2026—the same day this lawsuit was filed—New Hampshire sent CMS Administrator Oz a letter stating that it "does not anticipate any changes to the State Plan . . . in response to [the Rule]" and that "[s]ignificant operational or administrative changes are also not expected beyond the changes being implemented to comply with New Hampshire law that preceded the federal rule." *See* Ex. A (Oct. 1, 2026 Letter).

IV. Plaintiffs File This Lawsuit and Seek Preliminary Relief to Enjoin the Rule as to Them.

Plaintiffs are four New Hampshire children and their parents, who sue individually and as next friends. Compl. (ECF No. 1) ¶¶ 10-17. Each adolescent is enrolled in New Hampshire Medicaid, and Plaintiffs allege that all of them reside and receive medical care in New Hampshire. *Id.* ¶¶ 8, 14-17. They sued HHS, the Secretary, CMS, and the Administrator. *Id.* ¶¶ 18-21. They pleaded five counts: (1) that the Rule is arbitrary and capricious and thus violates the Administrative Procedure Act ("APA"), *id.* ¶¶ 71-76; (2) that the Rule violates a CMS' regulation, 42 C.F.R. § 440.230(c), by arbitrarily denying Medicaid coverage based on a patient's diagnosis of gender dysphoria, *id.* ¶¶ 77-81; (3) that the Rule exceeds CMS's statutory authority and conflicts with the EPSDT mandate, *id.* ¶¶ 82-87; (4) that the Rule procedurally violates the APA by not considering all comments submitted, *id.* ¶¶ 88-94; and (5) that the Rule violates the equal-protection component of the Fifth Amendment. *Id.* ¶¶ 95-99.

Plaintiffs simultaneously filed the PI Motion on their APA claims only. Plaintiffs ask the Court to bar Defendants from applying 42 C.F.R. §§ 441.800-441.802 "insofar as those provisions prohibit FFP for puberty-suppressing medications and hormone therapy prescribed for gender dysphoria to Plaintiffs, pending final judgment." PI Motion at 45-46.

Plaintiffs do not seek to enjoin any aspect of CMS's prohibition of using FFP for surgical interventions. *See id.* at 1 n.1. Plaintiffs argue only that the child Plaintiffs either currently receive puberty blockers or hormonal therapy or seek to receive them. Specifically, Plaintiffs state that Logan Loe receives puberty-blocking injections "every three months" and seeks to "begin estrogen therapy," PI Motion at 18 (citing Decl. of Laura Loe (ECF No. 7-3) ¶ 11, 13); that Maya Moe has an implanted puberty-suppressing medication and receives estrogen therapy, *id.* at 20 (citing Decl. of Melissa Moe (ECF No. 7-4) ¶¶ 9-11); and that Grace Goe and Kylie Koe do not currently receive

puberty blockers or hormonal therapy of any kind but seek to have them in the future. *See id.* at 15, 16.

LEGAL STANDARD

A preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). It is "never awarded as of right." *Id.* at 24. The movant must show "(1) a substantial likelihood of success on the merits, (2) a significant risk of irreparable harm if the injunction is withheld, (3) a favorable balance of hardships, and (4) a fit (or lack of friction) between the injunction and the public interest." *NuVasive, Inc. v. Day*, 954 F.3d 439, 443 (1st Cir. 2020) (quoting *Nieves-Márquez v. Puerto Rico*, 353 F.3d 108, 120 (1st Cir. 2003)). While all four factors are relevant, likelihood of success is the "main bearing wall" of the preliminary injunction framework. *Corp. Techs., Inc. v. Harnett*, 731 F.3d 6, 10 (1st Cir. 2013) (citation omitted); *see also New Comm Wireless Servs., Inc. v. SprintCom, Inc.*, 287 F.3d 1, 9 (1st Cir. 2002) (stating likelihood of success is "the sine qua non" of the inquiry). And the third and fourth factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009).

ARGUMENT

I. Plaintiffs Do Not Have a Substantial Likelihood of Succeeding on the Merits of Any APA Claim.

Plaintiffs argue that the Rule violates the APA in several ways. *First*, they argue that the Rule goes beyond CMS's statutory authority and violates two discrete provisions of the Act—the EPSDT and comparability requirements. Those arguments fail because CMS acted within the authority cited in the Rule, which gives the Secretary discretion to make determinations about whether a State Medicaid plan complies with the statute, and neither the EPSDT or comparability provision are implicated as sex-rejecting procedures are not necessary care and were not arbitrarily

excluded. *Second*, Plaintiffs raise several arbitrary and capricious arguments, but all boil down to requests for the Court to second-guess CMS's sound judgment and thus lack merit.[3]

A. The Rule Is Within CMS's Statutory Authority and Contradicts No Statute.

1. CMS Acted Within Its Statutory Authority When Promulgating the Rule.

Plaintiffs argue that the Rule exceeds the authority that Congress provided to CMS. *See* PI Motion at 24-26. They are incorrect. The statutory authority cited in the Rule allows CMS to prevent the use of federal funding for procedures that have limited benefits to beneficiaries and possibly severe, irreversible consequences.

The APA provides that a reviewing court "shall . . . hold unlawful and set aside agency action" that is "found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A). When reviewing a contrary-to-law claim, "courts must exercise independent judgment in determining the meaning of statutory provisions" and "set aside" any action that is "inconsistent with the law as they interpret it." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 392, 394 (2024). But "[w]hen the best reading of a statute is that it delegates discretionary authority to an agency," then the Court's role is to "recogniz[e] constitutional delegations, fix[] the boundaries of the delegated authority, and ensur[e] the agency has engaged in reasoned decisionmaking within those boundaries." *Id.* at 395 (citation modified). Here, CMS's interpretation is "within the statutory goalposts," *Rutherford v. United States*, 146 S. Ct. 1320, 1334 (2026) (an agency's "interpretation must land within the statutory goalposts"), and Plaintiffs are unlikely to succeed on the merits.

[3] Plaintiffs do not rely on their Equal Protection Clause claim for this Motion. *See* Compl. ¶¶ 95-99.

1. The best reading of 42 U.S.C. §§ 1396a(a)(19), 1396a(a)(30)(A), 42 U.S.C. § 1397aa(a), and 42 U.S.C. § 1397bb(a)(7)(A) of the Act—the statutory provisions relevant here—is that the Secretary is required to ensure the integrity of federal spending and protect the best interests of recipients.

Starting with the statute's structure, Congress enacted a system where federal money is sent to State-provided plans when the plan meets the conditions required by Congress. But the States are not the arbiters of their own compliance—the Secretary is. Congress directed the Secretary to approve only plans that fulfill the statutory conditions, 42 U.S.C. § 1396a(b); to stop or limit payments when a State fails "to comply substantially" with them, *id.* § 1396c; and to make the rules "necessary to the efficient administration of the functions with which [he] is charged," *id.* § 1302(a). It also provided the procedure by which Medicaid claims are disallowed. *Id.* § 1316(e). The Secretary thus pays the federal share of amounts spent "as medical assistance under the State plan," 42 U.S.C. § 1396b(a)(1), after determining that every plan satisfies 42 U.S.C. § 1396a(a).

Two of 42 U.S.C. § 1396a(a)'s several statutory conditions are relevant here, and both are substantive requirements. *First*, Congress created a condition addressing the use of services, tying payment to the quality of care provided and requiring every State plan to employ the methods and procedures necessary "to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care." 42 U.S.C. § 1396a(a)(30)(A). *Second*, Congress said that any plan must have safeguards to ensure that care is provided "in a manner consistent with . . . the best interests of the recipients." *Id.* § 1396a(a)(19). When a State fails to comply substantially with these conditions, "the Secretary . . . can withhold

some or all of its federal Medicaid funding." *Medina v. Planned Parenthood S. Atl.*, 606 U.S. 357, 363 (2025).

Supreme Court precedent confirms that these provisions are substantive standards that provide the Secretary discretion to review whether the State Medicaid plan accomplishes the statutory criteria. In *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320 (2015), the Court held that the Act precluded private enforcement against the States in courts, in part because 42 U.S.C. § 1396a(a)(30)(A)'s text was "judicially unadministrable" and provided the Secretary with significant discretion by "[e]xplicitly conferring enforcement of [the statute's] judgment-laden standard upon the Secretary alone." *Id.* at 328-29. Indeed, the Court said "[i]t is difficult to imagine a requirement broader and less specific than" 42 U.S.C. § 1396a(a)(30)(A)'s mandate, demonstrating that the statute was meant to "achiev[e] the expertise, uniformity, widespread consultation, and resulting administrative guidance that can accompany agency decisionmaking," *Id.* 42 U.S.C. § 1396a(a)(19) is similarly broad: it specifically allows the Secretary to ensure, through his authority to approve State plans, *see* 42 U.S.C. § 1396a(b), that there are "safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients." 42 U.S.C. § 1396a(a)(19). The term "best interests" itself requires that certain discretionary judgments will be made, and the Secretary is the one who has discretion to determine whether State plans satisfy all 42 U.S.C. § 1396a(a) requirements. Indeed, that language is comparable to other statutes that the Supreme Court and First Circuit found delegated authority. *See id.* at 395 n.6 (noting as examples a statute allowing the EPA to regulate power plants "if the Administrator finds such regulation is appropriate and necessary" and a statute that allowed the EPA Administrator to establish effluent limitations when

in his judgment, those would "assure" various outcomes, such as the "protection of public health" and "public water supplies" (citing and quoting 33 U.S.C. § 1312(a); 42 U.S.C. § 7412(n)(1)(A)); *Sutherland v. Peterson's Oil Serv., Inc.*, 126 F.4th 728, 739 (1st Cir. 2025) (stating that Congress's granting the EEOC "the authority to issue regulations implementing the definitions of disability" in a statute was "a quintessential example of Congress expressly delegat[ing] to an agency the authority to give meaning to a particular statutory term" (citation modified) (citing and quoting 42 U.S.C. § 12205a; *Loper Bright*, 603 U.S. at 394). Accordingly, with respect to both statutory provisions, the Court's only responsibilities are to "fix[] the boundaries of the delegated authority" and "ensur[e] the agency has engaged in reasoned decisionmaking within those boundaries." *Loper Bright*, 603 U.S. at 395.

Likewise, CHIP programs, which are also approved by the Secretary, must also comply with certain substantive requirements. Two of those are relevant here. *First*, 42 U.S.C. § 1397aa (a) of the Act imposes a substantive requirement on CHIP's administration, by establishing that CHIP funds are provided to enable States "to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children." 42 U.S.C. § 1397aa(a). *Second*, 42 U.S.C. § 1397bb(a)(7)(A) requires that any State CHIP plan must describe how the plan will "assure the quality and appropriateness of care, particularly with respect to . . . well-child care." 42 U.S.C. § 1397bb(a)(7)(A). Like 42 U.S.C. §§ 1396a(a)(19) and 1396a(a)(30)(A), these provisions require the Secretary to exercise his discretion to assure that the care provided to children is appropriate and of high quality and is provided in an effective and efficient manner.

Here, the Secretary appropriately exercised discretion within the boundaries of his delegated authority and "engaged in 'reasoned decisionmaking' within those boundaries." *Loper*

Bright, 603 U.S. at 394-95. The Rule thoroughly explains why sex-rejecting procedures "lack medical necessity and may pose a risk of harm to children" based on review of the evidence. Rule at 52419; *see id.* at 52408-12, 52453-56. Subject to limited exceptions, the Rule found that those procedures "lack a sufficient evidentiary basis to support individualized medical necessity determinations." *Id.* at 52419. It concluded that federal payment for them "would not be consistent with the statutory standards in [42 U.S.C. §§ 1396a(a)(19), 1396a(a)(30)(A), and 42 U.S.C. § 1397aa(a)] of the Act," *id.*, and it explained why payment for them is not consistent with quality of care. *Id.* at 52414-17.

Those findings track the statutes' requirements. Paying for procedures that lack evidentiary basis to support individualized medical necessity is paying for unnecessary utilization. *See* 42 U.S.C. § 1396a(a)(30)(A). Paying for procedures—when any benefits remain very uncertain and significant risks include potentially irreversible harm—is not consistent with quality of care or in the best interests of beneficiaries. *See id.* § 1396a(a)(19). And paying for inappropriate care that is ineffective, inefficient, and not of high quality violates CHIP's requirements. *See id.* §§ 1397aa(a), 1397bb(a)(7)(A). The Rule thus implements Congress's requirements within the bounds of the Secretary's discretion. *See Loper Bright*, 603 U.S. at 394-95. And it addresses only payment, not medical practice, as it allows States to continue paying for any services "with State-only funds outside of the Federally-matched Medicaid program or CHIP." Rule at 52407. The Rule reaches only uses that CMS evaluated and found to be of high risk with very low evidence of any benefit. *Id.* at 52433, 52474. The same medications remain eligible for federal funding for purposes of "interven[ing] in an abnormal" developmental process, such as treating precocious puberty or a disorder of sex development. *Id.* at 52431, 52474. And the Rule applies only to children, leaves

mental-health care untouched, *id.* at 52414, and provides a tapering period for current recipients of cross-sex hormones. *Id.* at 52416.

2. Plaintiffs primarily make two related arguments: (1) Medicaid requires payments to be made unless Congress specifically forecloses funding for a procedure; and (2) States, not CMS, have the authority to dictate what is in the best interest of recipients by directing where federal funds are spent. *See* PI Motion at 24-26. Both are incorrect.

Plaintiffs argue that because Congress has excluded some services by statute, through the Hyde Amendment, 42 U.S.C. § 1396b(i), and 42 U.S.C. § 1396d(a), it forbade any other limits. PI Motion at 24-25. That is wrong, as it ignores the import of the statutory provisions cited in the Rule. 42 U.S.C. § 1396b(i), and 42 U.S.C. § 1396d(a) withhold payment by legislative command no matter what the evidence is or what a State's plan provides. The statutory provisions cited in the Rule, by contrast, operate through specific agency findings about utilization and quality, *see* 42 U.S.C. § 1396a(a)(30)(A); about whether the proposed care and services are in the best interests of recipients, *see id.* § 1396a(a)(19); and about whether the health assistance is provided in an effective and efficient manner while assuring the quality and appropriateness of the care. *See id.* §§ 1397aa(a), 1397bb(a)(7)(A). Those provisions thus operate differently. Plaintiffs' suggested inference—that Congress's express exclusion of some services otherwise ties the hands of the Secretary, no matter the evidence of supporting a lack of medical necessity—is not a sensible one. *See NLRB v. SW Gen., Inc.*, 580 U.S. 288, 302 (2017) ("The *expressio unius* canon applies only when circumstances support a sensible inference that the term left out must have been meant to be excluded." (citation modified)). And CMS has used the authority provided by similar provisions to restrict federal funding of certain services. For nearly fifty years, regulations have barred federal funds for sterilizing anyone under 21 and for hysterectomies performed for the purpose of

sterilization, although no statute specifically identifies either limit. 42 C.F.R. §§ 441.253(a), 441.255; 43 Health Care Financing Administration, Federal Financial Participation in State Claims for Sterilizations, Fed. Reg. 52171 (Nov. 8, 1978).

The cases cited by Plaintiffs are not to the contrary. *Brito v. Garland*, 22 F.4th 240 (1st Cir. 2021), stands for the unremarkable proposition that "Congress meant only what it said," *id.* at 252, and Defendants explicitly rely on what Congress said here. *Russello v. United States*, 464 U.S. 16 (1983), merely states that when Congress includes "particular language"—*i.e.*, a particular phrase—"in one section of a statute but omits it in another section of the same Act," then it can be presumed that Congress acted intentionally. *Id.* at 23 (citation omitted). For example, the question presented in *Russello* was whether Congress intended the application of one subsection of a statute to be limited to "an interest in an enterprise" rather than any interest at all when Congress excluded the phrase "in an enterprise" from one subsection but included it "in the immediately following subsection." *Id.* That question is not presented here, as Plaintiffs do not identify "particular language" that Congress disparately included or excluded. And *City of Providence v. Barr*, 954 F.3d 23 (1st Cir. 2020), said only that the government could not condition grants on "unrelated law enforcement priorities" that differed from the grant statute's requirements containing a specific statutory formula. *See id.* at 34-35, 38. Here, by contrast, the Rule is based on specific requirements found in the statutes governing the Medicaid or CHIP programs.

Although, in some places, Plaintiffs criticize reading limitations into Congressional silence, *see* PI Motion at 25 (arguing that "the absence of any express delegation to CMS [] forecloses any inference that [Congress] silently delegated to CMS the power" to exclude funds in certain circumstances), Plaintiffs argue that Congress's failure to enact legislation specifically prohibiting federal funding for sex-rejecting procedures for children is evidence that CMS lacks

authority to do so. PI Motion at 24. To start, the most recent bill covered a broader array of topics than the sex-rejecting procedures that CMS chose not to fund here, including "placement[s] of chest implants to create feminine breasts" and "placement[s] of fat or artificial implants in the gluteal region." *See* PROTECTS Act of 2025, H.R. 742, 119th Cong. (2025). Regardless, the Supreme Court has repeatedly cautioned against reading into Congressional inaction when interpreting statutes "because several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change." *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 187 (1994) (quoting *Pension Benefit Guaranty Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990)). So the Court should not give Congressional silence any weight, especially in light of Defendants' reliance on the current statutory language as the basis for the Rule.

Plaintiffs are also incorrect to assert that States are the ones who retain ultimate discretion to determine the best interests of recipients. As discussed above, the Secretary is the ultimate arbiter over whether a State Medicaid or CHIP plan complies with the organic statute, not the individual States. In any event, Plaintiffs have not established that New Hampshire will continue covering sex-rejecting procedures in its State Medicaid and CHIP plans in light of the passage of Section 332-N:2. Although Section 331-N:2 does not "prohibit a health care provider from continuing the direction or administration of medication or treatment that began prior to January 1, 2026," N.H. Rev. Stat. § 331-N:2, III, it does not demonstrate that New Hampshire will continue to cover (and thus pay for) such medication or treatment in its State plans. A decision not to prohibit providers from prescribing or administering treatment in limited circumstances is a far different question than whether the State agrees that it should continue covering and paying for sex-rejecting procedures.

2. The Rule Complies with the EPSDT Mandate.

Plaintiffs also argue that the Rule conflicts with the Medicaid Act's EPSDT mandate. *See* PI Motion at 27-30. That too is incorrect.

Every State participating in Medicaid must have an EPSDT program. *See* 42 U.S.C. §§ 1396a(a)(43), 1396d(r). The statute defines EPSDT as (1) screening services with specific requirements to check for conditions, *id.* § 1396d(r)(1); (2) vision services, *id.* § 1396d(r)(2); (3) dental services, *id.* § 1396d(r)(3); (4) hearing services, *id.* § 1396d(r)(4); and "[s]uch other necessary health care, diagnostic services, treatment, and other measures described in subsection (a) to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State plan." *Id.* § 1396d(r)(5). The goal of EPSDT programs is to "provide health care services to children to reduce lifelong vulnerability to illness or disease." *Frew*, 540 U.S. at 433-34; *see also* CMS State Medicaid Manual § 5010.B (noting that a principal goal of the program is to "[a]ssure that health problems found are diagnosed and treated early, before they become more complex and their treatment more costly" while ensuring "unnecessary services are avoided").

Plaintiffs are incorrect that the EPSDT mandate requires coverage whenever a provider labels a sex-rejecting procedure as "necessary." *See* PI Motion at 28 (stating that the Rule violates Section 1396d(r)(5) by "appl[ying] even when the treating clinician and a multidisciplinary team determine that a service is necessary to correct or ameliorate the young person's condition"). CMS is not obligated to review and rebut the determination of treating physicians in each individual case, and instead may "rely on [its] rulemaking authority" to set a more general standard. *Heckler v. Campbell*, 461 U.S. 458, 467 (1983). And the Rule correctly explained that "EPSDT's medical necessity requirement does not unconditionally defer to individual provider judgment; it reflects a standard that must be assessed against the available evidence and our responsibility to ensure

quality of care and services provided in the best interest of beneficiaries." Rule at 52443. Services such as robust psychotherapy, in contrast, may be medically necessary and are covered for most children by Medicaid. *Id.* at 52415.

Plaintiffs' reasoning likewise does not align with the full scope of the Medicaid Act's text. The text of the Medicaid Act must be read in its entirety to not make any subparagraph meaningless. *See In re Fin. Oversight & Mgmt. Bd. for Puerto Rico*, 7 F.4th 31, 38 (1st Cir. 2021). So Section 1396d(r)(5) must be read in congruence with 42 U.S.C. § 1396a(a)(30)(A)'s requirement to safeguard against "unnecessary utilization" as well as the other provisions relied upon by CMS. And the limit CMS applied is medical necessity—CMS did not exclude any necessary care but found that the sex-rejecting procedures lacked evidence to support individualized medical necessity. Rule at 52419. It found that, for this use, the evidence does not support such determinations at all: the regulated uses "lack a sufficient evidentiary basis to support individualized medical necessity determinations." *Id.* Plaintiffs are thus wrong to argue (at 28-29) that Defendants' reading renders Section 1396d(r)(5) superfluous. *See* PI Motion at 28-29. Congress's mandate stands, as necessary care—the only care that the "Act requires the State to provide and requires the Secretary to fund," *id.* at 29—remains covered.

Plaintiffs' argument also is in tension with the Supreme Court's decision in *Skrmetti*, which held that States may, consistent with the Equal Protection Clause of the Fourteenth Amendment to the Constitution, categorically ban providers from prescribing puberty blockers, hormonal treatments, and surgical procedures for the purpose of treating gender dysphoria, gender identity disorder, and gender incongruence, even if it is based on a so-called diagnosis-based classification. *See* 605 U.S. at 523-24. Plaintiffs appear to suggest that a State that has made such a categorical ban may still have to pay for such coverage through the EPSDT if a provider labels the care as

"necessary." *See* PI Motion at 27-28 (arguing that EPSDT's text prevents "categorical exclusions that override individualized EPSDT medical necessity determinations"). Given New Hampshire's decision to generally prohibit these interventions for children, *see* N.H. Rev. Stat. § 332-N:2, I, Plaintiffs' argument fails. A provider's decision to label a treatment as medically necessary cannot override CMS's decision to not fund the treatment based on CMS's evidence-based assessment of its high risk and limited benefit, and that does not violate EPSDT.

And CMS's basis for the Rule is reasonable. CMS has "consistently described medical necessity in the EPSDT context as requiring consideration of the child's long-term needs, all aspects of the child's health, and the full range of interventions available, not simply deference to whatever intervention a provider may recommend in a given case." Rule at 52443. For these procedures prohibited under the final rule, "the evidence identifies plausible and, in some cases, established risks of significant and irreversible or potentially irreversible harms," so they "do not constitute medically necessary services eligible for FFP under EPSDT." *Id.*

Further, Plaintiffs insinuate that CMS can never have criteria of general application and instead must have an "individualized medical necessity determination" under Section 1396d(r)(5). *See* PI Motion at 28. But that's incorrect. Generally speaking, CMS has the authority to implement the medical necessity requirement through a rule, rather than on a case-by-case basis by evaluating individual medical frailty determinations. *Heckler*, 461 U.S. at 467; *see also SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947) ("[T]he choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency."). States apply utilization limits through criteria of general application as well as case by case. 42 C.F.R. § 440.230(d); *see* Rule at 52418. And CMS has generally prohibited certain sterilization procedures. 42 C.F.R. §§ 441.253(a), 441.255. Moreover, at least one circuit

court has squarely held that a State program is not required to pay for all services—including sex-rejecting procedures—that a physician determines to be medically necessary. *See Rush v. Parham*, 625 F.2d 1150, 1154 (5th Cir. 1980) (reversing a district court's holding that "a state program is required to pay for any services a physician determines to be medically necessary for the patient," which was a "transsexual surgery" in that proceeding). Instead, a State "may adopt a definition of medical necessity that places reasonable limits on a physician's discretion" and reasonable, evidence-based limits are permissible. *See id.* at 1154, 1158.

Plaintiffs also argue that these medications are "not experimental in any accepted sense." PI Motion at 30.[4] But the Rule does not depend on whether these uses are labeled experimental. CMS weighed the evidence of benefit and risk, describing the evidence of benefit as uncertain and identifying serious risks, some plausible and some established. Rule at 52414-19. It did not find these interventions ineffective, and the HHS Review's statement that low-certainty evidence "does not prove that the interventions are ineffective," PI Motion at 30, is consistent with what CMS did find: that the evidence does not establish medical necessity for this use. The Rule, quoting the HHS Review, stated the balance directly: "[t]he evidence for benefit of pediatric medical transition is very uncertain, while the evidence for harm is less uncertain." Rule at 52409. When the available data does not settle that balance, an agency "must then exercise its judgment in moving from the facts and probabilities on the record to a policy conclusion." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52 (1983).

[4] As noted by the Rule, some other countries have decided these treatments are experimental or reduced them to clinical trials and research settings because of the significant uncertainty of their benefit. *See* Rule at 52410-11.

3. The Rule Complies with the Comparability Requirement.

Plaintiffs also argue that the Rule conflicts with the Medicaid Act's comparability requirement. *See* PI Motion at 30-34. Plaintiffs once again are incorrect.

Medicaid's requirement mandates that, with certain exceptions, the Medicaid services available to any individual in the categorically needy groups and within any covered medically needy group must be equal in amount, duration, and scope for all beneficiaries within a group. *See* 42 U.S.C. § 1396a(a)(10)(B). Additionally, 42 C.F.R. § 440.230(c) prohibits States from "arbitrarily" denying or reducing the amount, duration, or scope of a required service solely because of the diagnosis, type of illness, or condition. These requirements establish that "similarly situated individuals, whether they be categorically needy . . . or medically needy, must receive comparable services," *Rolland v. Cellucci*, 52 F. Supp. 2d 231, 238 (D. Mass. 1999), even though 42 U.S.C. § 1396a(a)(10)(B) does "not require that the medically needy be treated comparably to the categorically needy in all respects." *Schweiker v. Hogan*, 457 U.S. 569, 587 (1982).

The Rule does not violate either provision. It does not violate 42 U.S.C. § 1396a(a)(10)(B) because the Rule treats every beneficiary alike—for all beneficiaries under the age of 18 for Medicaid and under the age of 19 for CHIP, federal funding is not available for sex-rejecting procedures and, for all beneficiaries, these procedures remain eligible for federal funding for other purposes. As noted by the Rule, the sterilization regulations previously promulgated illustrate that there are appropriate age-based limits on FFP when a treatment can cause potentially irreversible consequences. *See* Rule at 52421 ("We referenced the sterilization regulations in the proposed rule not as a direct legal predicate but as a precedent illustrating that we have previously recognized, in a different context, that age-based limits on FFP for procedures with potentially irreversible consequences are an appropriate exercise of our rulemaking authority where concerns about the

capacity of the affected population to meaningfully consent to or appreciate those consequences are well-founded."). All beneficiaries are thus treated equally.

The Rule also does not violate 42 C.F.R. § 440.230(c). To start, 42 C.F.R. § 440.230(c) does not apply to the federal government—it applies to States. Specifically, 42 C.F.R. § 440.230(c) applies to "Medicaid agenc[ies]." That phrase is ordinarily used in the Act and in regulations to refer to the State agencies that administer State Medicaid plans. *See, e.g.*, 42 U.S.C. § 1396a(a)(13)(F)(v)(IV) (defining, for purposes of the statute's paragraph, the term "State Medicaid agency" as "the State agency responsible for administering the State Medicaid plan"); 42 C.F.R. § 431.10(a)(2) (noting that for purposes of this regulation, a "Medicaid agency is the single State agency for the Medicaid program"). Thus, the statute "speaks only to a State's duties to the federal government." *Medina*, 606 U.S. at 379.

In any event, as discussed by the Rule, the operative word of that regulation is "arbitrarily." *See* Rule at 52441. The Rule did not establish an arbitrary restriction. Instead, CMS "conducted a thorough review of the available evidence . . . and [it] concluded that the risk/benefit profile of sex-rejecting procedures when used to align a child's physical appearance or body with an asserted identity that differs from the child's sex does not support [FFP] for those procedures." *Id.* at 52441-42. CMS also noted that the Rule was "grounded in a substantive, evidence-based analysis of risk and benefit" and "based on a carefully developed evidentiary record." *Id.* at 52442. Indeed, as acknowledged by Plaintiffs, 42 C.F.R. § 440.230(d) permits "limits based on medical necessity or utilization control." *See* PI Motion at 32. The Rule is such a limit, so it cannot be an "arbitrary denial" as it was not imposed "solely because of" a diagnosis. *See* Rule at 52441 (42 C.F.R. § 440.230(c)). And CMS's reading of its own regulations—sometimes described as *Auer* deference—is still owed deference after *Loper Bright*. *See, e.g.*, *Campaign Legal Ctr. v. Fed.*

Election Comm'n, No. CV 24-2585 (SLS), 2025 WL 1768099, at *7 (D.D.C. June 26, 2025) ("[T]his sort of deference survives *Loper Bright* . . . since it concerns an agency's interpretation of its own regulations rather than that of a statute." (citation omitted)); *see also Battineni v. Mayorkas*, 752 F. Supp. 3d 195, 207 n.3 (D.D.C. 2024) ("While the D.C. Circuit does not appear to have addressed this question, other circuits have concluded that *Loper Bright*'s concern with statutory interpretation does not impact the deference afforded to agencies interpreting their own regulations." (collecting cases)).

Plaintiffs also argue that all their current and sought-after treatments are medically necessary under New Hampshire's Medicaid State Plan. PI Motion at 31-32. But it is not clear why this argument relates to the comparability requirement rather than the EPSDT provision since Plaintiffs' argument appears to be about medical necessity. In any event, it is far from clear that these treatments are medically necessary under New Hampshire's Medicaid State Plan for two reasons. *First*, by Plaintiffs' own attestations, two child Plaintiffs do not take puberty blockers or hormone therapy at all, *see id.* at 13-16 (noting Grace Goe and Kylie Koe seek to have these treatments in the future), and one who takes puberty blockers seeks to "begin estrogen therapy." *Id.* at 18 (Logan Loe). None of those sought-after treatments are permitted under New Hampshire law, which allows only the continuation of "medication or treatment that began prior to January 1, 2026." N.H. Rev. Stat. § 332-N:2, III. *Second*, it is not clear that New Hampshire's plan still covers these treatments. While Section 332-N:2 does not prohibit health care providers from continuing administration of these sex-rejecting procedures for certain persons who began treatment before January 1, 2026, that is an entirely separate question from whether the State still determines that these treatments are medically necessary. If anything, the natural inference drawn from Section

332-N:2 is the opposite as the State has clearly demonstrated that these procedures are not medically necessary given its decision to ban them.

Plaintiffs further argue that 42 C.F.R. § 440.230 forbids State Medicaid agencies from "singl[ing] out a diagnosis and exclud[ing] treatment of it outright." PI Motion at 33. Plaintiffs fail to acknowledge *Rush*, which allowed such a limitation on performance of a "prescribed transsexual surgery." 625 F.2d at 1154-55.

Moreover, the case law Plaintiffs cite does not support their conclusion. The court in *White v. Beal*, 555 F.2d 1146 (3d Cir. 1977), invalidated a diagnosis-based distinction that the record did not connect to medical need: Pennsylvania furnished eyeglasses for "visual impairment caused by eye disease" when the uncontroverted record showed that "persons with refractive error . . . may be far more visually handicapped." *Id.* at 1150, 1152. The record here is quite different. The Rule explains why the procedures covered by the Rule are treated differently when used to intentionally disrupt normal biological development or to intentionally alter a person's appearance. And the court in *Weaver v. Reagen*, 886 F.2d 194 (8th Cir. 1989), rejected Missouri's restriction of a certain drug because there was "widespread recognition by the medical community and the scientific and medical literature that [the drug] [wa]s the only available treatment for most persons with AIDS." *Id.* at 200. No such widespread recognition exists here—instead, the growing international consensus is that psychotherapy is the "first line of treatment" for children, and that treatment remains available under the Rule. *See* Rule at 52415.

B. Plaintiffs' Arbitrary and Capricious Claim Fails Because CMS Had a Rational Basis for Its Determination and Considered All Relevant Factors.

Plaintiffs also argue that the Rule is arbitrary and capricious for several reasons. *See* PI Motion at 37-42. All fail.

Under the APA, a district court will uphold an agency's decision unless it was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). When determining whether an agency decision was arbitrary or capricious, a court must leave the decision undisturbed "unless 'the agency lacks a rational basis for making the determination or if the decision was not based on consideration of the relevant factors.'" *P.R. Tel. Co. v. Telecomms. Regul. Bd. of P.R.*, 665 F.3d 309, 319 (1st Cir. 2011) (citation omitted). A court cannot "second-guess[] [an agency's] weighing of risks and benefits" or "substitute [its] judgment for that of the agency." *Dep't of Com. v. New York*, 588 U.S. 752, 777 (2019). Review under the arbitrary-and-capricious standard is thus "highly deferential," and a court cannot set aside an agency's decision "even if it disagrees with the agency's conclusions." *Atieh v. Riordan*, 797 F.3d 135, 138 (1st Cir. 2015). Agency decisions are instead "presumed to be valid," *P.R. Tel. Co.*, 665 F.3d at 319, and if a decision "is supported by any rational view of the record," a court "must uphold it," *Atieh*, 797 F.3d at 138. Agencies are also "free to change their existing policies as long as they provide a reasoned explanation for the change." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016).

CMS Adequately Considered Reliance Interests. Plaintiffs first argue that the Rule did not "adequately consider" reliance interests of those who "have relied on Medicaid and CHIP coverage for transgender health care." PI Motion at 35-36. But that's wrong. The Rule explicitly states that CMS has "carefully considered th[e] reliance interests in this rule" of "States, providers, and beneficiaries." Rule at 52448. The Rule went on to state that CMS "carefully considered those reliance interests but concluded they are outweighed by the potential for significant and irreversible harm to children in circumstances where the evidentiary basis for benefit is very uncertain," so CMS made a "reasoned weighing of competing considerations, not a failure to

consider an important aspect of the problem." *Id.* An agency that has considered reliance interests "may determine, in the particular context before it, that other interests and policy concerns outweigh" them. *DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 32 (2020).

The Rule also noted that any reliance interests were mitigated by (1) States' ability to continue covering sex-rejecting procedures with State-only funds; (2) the prospective application of the Rule; and (3) the six-month tapering period for cross-sex hormone therapy medications. Rule at 52448-49. And the Rule explained why a tapering-period was being implemented for cross-sex hormones and not puberty blockers. For cross-sex hormones, CMS decided to implement "a reasonable opportunity to phase off these medications in a manner that allows for clinical discretion" to address "the most acute continuity-of-care concerns." *Id.* at 52416, 52421-22. But puberty blockers are different: "upon stopping puberty blockers, pubertal manifestations generally reappear within months." *Id.* at 52416.

Plaintiffs disagree with CMS's decision and argue that alternatives exist. *See* PI Motion at 36. But the Rule addressed the alternatives proposed—exempting children already in treatment, requiring individualized prior authorization or multidisciplinary assessment, and leaving any decisions to States and treating providers, Rule at 52412-13, 52421— and those do not address the problems identified by the Rule equally well, as they do not protect the best interests of child beneficiaries, protect against unnecessary utilization of federal funds, and ensure that care is appropriate and provided in an effective and efficient manner. And these proposed alternatives are mostly mere administrative safeguards, and CMS explained why its concerns "cannot be rendered appropriate for Federal funding through administrative safeguards alone." Rule at 52473.

CMS Reasonably Engaged with All Significant Comments. Plaintiffs next argue that CMS did not "genuinely" consider and respond to all comments. PI Motion at 37-40. Plaintiffs'

argument is nothing more than an invitation for the Court to second-guess CMS's decision and to substitute Plaintiffs' evaluation of the evidence for CMS's.

To start, legally, all that is required is for agencies to respond to *significant* comments. *See, e.g.*, *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015) (an agency "must consider and respond to *significant* comments received during the period for public comment." (emphasis added)); *Nat'l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 215 (D.C. Cir. 2013) (same). That is so because "[t]he failure to respond to comments is significant only insofar as it demonstrates that the agency's decision was not based on a consideration of the relevant factors." *Covad Commc'ns Co. v. FCC*, 450 F.3d 528, 550 (D.C. Cir. 2006); *id.* (the agency "need not address every comment, but it must respond in a reasoned manner to those that raise significant problems." (quoting *Reytblatt v. Nuclear Regul. Comm'n,* 105 F.3d 715, 722 (D.C. Cir. 1997))). Here, there is no question that the Rule responded to all significant comments.

And factually, CMS did all that was required because every objection raised by Plaintiffs was addressed by CMS. CMS received more than 11,000 comments, Rule at 52421, and the Rule's preamble contains more than 50 pages responding to those comments. *See id.* 52421-73. Plaintiffs argue that CMS did not "genuinely" consider all comments and respond to all objections or "meaningfully engage several specific objections." PI Motion at 37. But that's wrong; each of Plaintiffs' noted objections were addressed.

- *First*, Plaintiffs point to the Endocrine Society's comment relating to the Endocrine Society's clinical practice guidelines and the Grading of Recommendations Assessment, Development, and Evaluation ("GRADE") framework, explaining that some studies have "very low" ratings and guideline panels may make strong recommendations anyway. *See* PI Motion at 37-38. But CMS did address the Endocrine

Society's comment, the Endocrine Society's clinical practice guidelines, and the GRADE framework; CMS explained that there was significant criticism of these guidelines in light of the weak evidence base and the very low quality of evidence explaining the benefits of sex-rejecting procedures for children. *See, e.g.*, Rule at 52411-12, 52453-55.

- *Second*, Plaintiffs point to the American Academy of Pediatrics' comment relating to its guidance document that a "very low" GRADE rating reflects limited and uncertain evidence, and all evaluations should be "individualized and multidisciplinary" rather than categorically prohibiting payment for sex-rejecting procedures. PI Motion at 38. But CMS addressed this comment and concluded, based on "a recent systematic review of international guideline quality," that this document (as well as the Endocrine Society clinical practice guidelines) was "of very low quality" and contained recommendations that "should not be implemented." *See, e.g.*, Rule at 52411-12, 52427.
- *Third*, Plaintiffs point to a comment by the American Public Health Association and others criticizing the HHS review and arguing that "no professionally recognized standards . . . exist for tapering these treatments." PI Motion at 38-39. CMS also addressed these comments, explaining why it relied on the HHS review—along with several other studies by European nations—and decided to allow tapering for cross-sex hormonal therapy. *See, e.g.*, Rule at 52416, 52421-23, 52426, 52428.

Plaintiffs also cite no case law to support their view that CMS needed to do more to satisfy the APA's "highly deferential" standard. *See Atieh*, 797 F.3d at 138. All that is required is that CMS "acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 592

U.S. 414, 423 (2021). And CMS made the decision to rely on the reasonable opinions of its own qualified experts. *See Marsh v. Oregon Nat. Res. Council*, 490 U.S. 360, 378 (1989).

CMS Thoroughly Explained Why Sex-Rejecting Procedures Cannot Be Covered Under Medicaid. Plaintiffs next argue that CMS did not explain its "unprecedented departure" from not taking a position on whether specific treatments are medically necessary. PI Motion at 40. Specifically, Plaintiffs criticize CMS's acknowledgment that it has "not historically taken a position at the Federal level that particular services when provided to particular individuals for a particular purpose are inherently not medically necessary" but did so here because of "the prevailing evidentiary landscape." *Id.* at 38 (quoting Rule at 52,443).

This argument ignores the 23-page Notice of Proposed Rulemaking and 69-page final rule, where CMS fully explained its reasoning. Among other things, the preamble explains that sex-rejecting procedures are particularly unusual because "the current evidence is uncertain on whether these procedures are effective in improving long-term mental health outcomes, reducing gender dysphoria symptoms, or producing other meaningful benefits for children with gender dysphoria" while the evidence also "identifies plausible and, in some cases, established risks of significant and irreversible or potentially irreversible harms." Rule at 52443. The Rule also describes the reviews and guidance issued by or for health authorities in the United Kingdom, Sweden, Finland, and Norway, and HHS's own review, *id.* at 52409-11, and its evidentiary findings. *Id.* at 52414-19.

Plaintiffs also argue that a more detailed justification is required under *Fox*, which applies when a new policy "rests upon factual findings that contradict those which underlay [an agency's] prior policy." *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). *Fox* does not apply here because CMS's prior practice did not rest on any contrary factual findings. In any event,

the Rule adequately explains the reasons CMS took the steps it did to address a uniquely threatening practice. All the APA requires is a "good reason[] for the new policy" even if it is not "better than [the] reasons for the old one." *Id.* (emphasis omitted).

CMS Adequately Explained the Rule's Exceptions. Plaintiffs also argue that the Rule is unreasonable because it permits federal funding for the same medications and procedures for some purposes but not others. PI Motion at 41-42. The Rule allows the covered medications to be used (1) "[t]o treat an individual with a medically verifiable disorder of sexual development," (2) "[f]or purposes other than attempting to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex," or (3) "[t]o treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedures." 42 C.F.R. § 441.801.

CMS explained why the Rule restricts funding when these medications and procedures are provided for some purposes but not others. For example, federal funding remains available to treat precocious puberty because "[p]uberty blockers have been primarily studied in children affected by precocious puberty," and they are ordinarily used for a limited period of time to "temporarily halt an abnormal developmental process." Rule at 52416, 52426, 52431. In contrast, the sex-rejecting procedures addressed in the Rule have had limited studies regarding long-term benefits, so CMS's decision was reasonable. A distinction based on the purpose for which a medication is used is not conceptually unusual, and *Skrmetti* rejected the argument that a materially similar purpose-based distinction necessarily constituted impermissible sex discrimination. 605 U.S. at 521-25.

CMS Made a Reasonable Decision Based on the Evidence Before It. Plaintiffs finally argue that CMS "reached its conclusion before it began" and accuse CMS of not relying on the

evidence before it. PI Motion at 41-42. But that characterization is wrong factually. It is also insufficient, as a matter of law, to set aside an agency action.

Factually, as discussed extensively in the Rule and in this brief, CMS made a reasoned decision to prohibit federal Medicaid and CHIP funding for sex-rejecting procedures for children because there is limited evidence of long-term benefits and significant risk of irreversible harm. New Hampshire has apparently come to the same conclusion, as have other States and other countries. Rule at 52410-11.

Legally, there is no "open-mindedness test" under the APA. *See Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657, 685 (2020). "It is hardly improper for an agency head to come into office with policy preferences and ideas, discuss them with affected parties, sound out other agencies for support, and work with staff attorneys to substantiate the legal basis for a preferred policy." *Dep't of Com.*, 588 U.S. at 783. Nor is the Rule arbitrary and capricious merely because Plaintiffs disagree with it.

II. The Remaining Injunction Factors Favor Denying an Injunction

The remaining preliminary injunction factors further favor denying Plaintiffs' requested injunction.

First, Plaintiffs have failed to establish that a preliminary injunction is necessary to prevent imminent irreparable harm. It is not clear that New Hampshire's plan continues to cover any of the child Plaintiffs' sex-rejecting procedures, as New Hampshire stated that it did not anticipate "[s]ignificant further operational or administrative changes . . . beyond the changes being implemented to comply with New Hampshire law that preceded the federal rule." *See* Ex. A at 2. In any event, Plaintiffs cannot demonstrate irreparable harm because the Rule merely prevents Federal payment for sex-rejecting procedures, which carry significant risks with very low quality evidence of any benefit. Even if the Rule rather than New Hampshire law were the reason that

Plaintiffs did not receive the sex-rejecting procedures, Plaintiffs will not be irreparably harmed by the Rule because they will be protected against significant irreversible and harmful side effects, decisions more appropriate for the child Plaintiffs to make when they are adults. And Plaintiffs additionally have not demonstrated irreparable harm because it is not at all clear that the sex-rejecting procedures the child Plaintiffs currently receive or those sought are covered by New Hampshire's State Medicaid plan.

Second, the public interest and balance of the equities factors—which merge where the government is the opposing party, *Nken*, 556 U.S. at 435—likewise weigh against preliminary relief. The Government "suffers a form of irreparable injury" when it is enjoined from carrying out a policy adopted under statutory authority. *See Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers), *cited by Trump v. CASA, Inc.*, 606 U.S. 831, 861 (2025); *see also Trump v. Orr*, 146 S. Ct. 44, 46 (2025) (noting the Government suffers a form of irreparable injury when a district court enjoins enforcement of an Executive Branch policy); *Trump v. California*, No. 26A124, 2026 WL 2473573, at *4 (U.S. Aug. 24, 2026) (finding irreparable harm when a "District Court's errors deal[t] 'a serious setback' to the Executive's 'goals' while [a] litigation unfold[ed]." (quoting *Coleman v. Paccar Inc.*, 424 U.S. 1301, 1307 (1976) (Rehnquist, J., in chambers)).

Plaintiffs argue primarily that the equities favor Plaintiffs because there would be "irreversible pubertal changes for Grace, Kylie, and Logan" and "worsening withdrawal, irritability, and depression when [Maya Moe's] puberty blocker wore off." PI Motion at 44-45. But as discussed, most of these alleged harms may be due to the effect of a recently enacted New Hampshire law, not the Rule, as that is the primary reason for the "interruption of treatment" complained of by Plaintiffs. *See id.* at 45. And in any event, HHS has made the determination,

after considering all the best evidence available, that preventing irreversible consequences such as infertility and decreased bone density is in the best interest of those who receive Medicaid funding.

The remainder of Plaintiffs' arguments depend on their likelihood of success on the merits. They argue that government agencies must "follow the law" and that "preserv[ing] [] longstanding federal policy that preceded the Rule" is in the public interest, *see id.* at 44-45, but Plaintiffs are not likely to succeed on the merits, as discussed above, and there is no question that a federal policy is valid if the Rule complies with the APA. The public interest favors allowing the Secretary to perform his obligations to administer rules that ensure the integrity of federal funds and protect beneficiaries and to do so in a uniform manner nationwide.

III.. Any Injunctive Relief Should Be Narrowly Tailored and Limited to Logan Loe and Maya Moe's Medications that Began Prior to January 1, 2026.

If the Court were to provide preliminary relief (which it should not), the injunction should be narrowly tailored to provide only what "will offer complete relief to the plaintiffs before the court." *CASA*, 606 U.S. at 852. In line with this principle, the only equitable relief that can be ordered that also complies with New Hampshire law is to require federal funding for Logan Loe to continue receiving puberty blockers and Maya Moe to continue receiving puberty blockers and hormones because, according to the PI Motion, those individuals were receiving those treatments prior to January 1, 2026—the relevant period under New Hampshire law. *See* PI Motion at 18 (arguing that Logan Loe "receive[s] injections every three months" (citing Decl. of Laura Loe ¶ 11)); Decl. of Melissa Moe ¶¶ 9-10 (noting that Maya Moe receives an implanted version of puberty blockers); PI Motion at 20 (noting Maya Moe receives "estrogen therapy" that "began in 2023" (citing Decl. of Melissa Moe ¶ 11)).

In contrast, Grace Goe and Kylie Koe have never taken puberty blockers and Logan Loe has never taken hormones; Plaintiffs argue that Grace Goe will "soon need" puberty blockers, PI

Motion at 14, that Kylie Koe "will need puberty blockers imminently," *id.* at 16, and that Logan Loe "strongly desires" to "begin estrogen therapy, PI Motion at 18 (citing Decl. of Laura Loe ¶ 13). But Section 332-N:2 does not allow the administration of new treatments that did not begin before January 1, 2026; instead, the exception to the law's prohibition merely allows health care providers to "continu[e] the direction or administration of medication or treatment that began prior to January 1, 2026." N.H. Rev. Stat. § 332-N:2, III. Because Grace Goe and Kylie Koe did not start taking puberty blockers or hormonal therapy before that date, no health care provider in New Hampshire is allowed to prescribe those medications to them. Nor can a provider begin estrogen therapy for Logan Loe because that treatment did not begin before January 1, 2026. And to the extent that the Court thinks a tapering period is necessary for puberty blockers as well, any scope of relief should be limited to ordering that Logan Loe and Maya Moe can taper off their puberty blockers over the next six months.[5]

CONCLUSION

The Court should deny Plaintiffs' Motion for a Preliminary Injunction.

Dated: October 15, 2026

Respectfully submitted,

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/s/ J. Stephen Tagert
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[5] Defendants ask the Court to enter a bond in an appropriate amount in the event it enters an injunction against them in this case, as the Federal Rules of Civil Procedure require that a "court may issue a preliminary injunction . . . only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." Fed. R. Civ. P. 65(c).

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CERTIFICATE OF SERVICE

I certify that on October 15, 2026, I filed this document through the Court's CM/ECF system, which will send notice of the filing to all counsel of record.

/s/ J. Stephen Tagert
J. STEPHEN TAGERT