UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

STATE OF CALIFORNIA, COMMONWEALTH OF MASSACHUSETTS, STATE OF NEW JERSEY, STATE OF ARIZONA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, STATE OF ILLINOIS, STATE OF MAINE, STATE OF MARYLAND, PEOPLE OF THE STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEW MEXICO, STATE OF NEVADA, STATE OF NEW YORK, STATE OF OREGON, JOSH SHAPIRO, *in his official capacity as Governor of the Commonwealth of Pennsylvania*, STATE OF RHODE ISLAND, STATE OF VERMONT, STATE OF WASHINGTON, STATE OF WISCONSIN,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of Health and Human Services*, MEHMET OZ, *in his official capacity as Administrator for the Centers for Medicare and Medicaid Services*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants.

No. 1:25-cv-12019

PLAINTIFF STATES' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR A PRELIMINARY INJUNCTION AND STAY

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INTRODUCTION

Congress enacted the Patient Protection and Affordable Care Act (ACA) in 2010 to increase health insurance coverage and decrease the cost of healthcare. Fifteen years later, the ACA continues to meet its twin goals. Annual enrollment on the ACA marketplaces doubled over the past five years, resulting in over 24 million people—7 million in Plaintiff States alone—selecting a health insurance plan for 2025 on the ACA exchanges, ninety percent of whom receive subsidies to make coverage affordable.[1] Now, with less than four months until open enrollment for 2026 begins, the U.S. Department of Health and Human Services (HHS) and Centers for Medicare & Medicaid Services (CMS) have issued a Final Rule that will reverse that trend. The Rule makes comprehensive and, in several instances, unprecedented changes that will impose arbitrary and unlawful costs, increase paperwork burdens, and erode the value of insurance.

Defendants admit the Rule's new barriers to enrollment will end coverage for up to 1.8 million people, reduce States' revenue, impose substantial compliance costs, and drive up the costs Plaintiff States will incur backstopping healthcare for our uninsured residents. It imposes illegal junk charges, unlawfully allows denial of coverage in violation of the ACA's "guaranteed issue" requirement, and excludes as an essential health benefit any "sex-trait modification procedure,"[2] a novel and nebulous term that encompasses treatments across multiple mandated benefit categories. Moreover, the decision to modify EHBs in this manner did not consider state-by-state

[1] Centers for Medicare & Medicaid Services, Health Insurance Exchange 2025 Open Enrollment Report, pp. 5-6, 16, https://www.cms.gov/files/document/health-insurance-exchanges-2025-open-enrollment-report.pdf

[2] As in the accompanying Complaint, *see* Compl. at 3, n.2, Plaintiff States adopt the term "sex-trait modification" to refer to the ambiguous and arbitrary set of services HHS attempts to exclude as EHB. Where appropriate, Plaintiff States may employ different terminology that best reflects the context, including "gender-affirming care," "treatment for gender dysphoria," and "medically necessary care for gender and sexual minorities."

differences in typical employer plan coverage, as required by law.

The loss of enrollees will worsen the risk pool in health insurance markets and harm overall public health. These harms are not theoretical: they are already occurring and will accelerate if the Rule's provisions become operational on the Rule's effective date, August 25, 2025. In Defendants' view, these harsh measures are urgently necessary to combat fraud. But, as countless commenters pointed out during rulemaking, the evidence shows the Rule's most harmful provisions will do little, if anything, to address that concern. Nor did Defendants consider reasonable alternatives or significant downsides, including the profound impact on the millions who will lose coverage. What's more, several of the provisions go into effect for only one year. Defendants provided no notice of that possibility during rulemaking and have not reckoned with the doubling of compliance costs states and consumers will face as a result of the sunset provision.

These changes violate the Administrative Procedure Act (APA) and are contrary to law, arbitrary and capricious, and profoundly harmful to Plaintiff States. The States bring this suit to have the challenged provisions of this unlawful and unjustified HHS regulation stayed, or preliminarily enjoined, and ultimately vacated—protecting access to affordable healthcare for millions of our residents.

BACKGROUND

I. ACA HEALTH INSURANCE MARKETPLACES

The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (as amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010)) is a landmark law designed to "increase the number of Americans covered by health insurance and decrease the cost of health care." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 538 (2012). To achieve these goals, the ACA created health insurance markets, or exchanges, in each State, allowing people to compare and purchase insurance plans. 42 U.S.C.

§ 18031; *King v. Burwell*, 576 U.S. 473, 479 (2015). Congress authorized exchanges to be operated by either a State (state-based exchanges, or SBEs), or, if a State opted not to establish an exchange, by the federal government (federally facilitated exchanges, or FFEs). 42 U.S.C. § 18041(c).

The ACA's purpose is to protect consumers' access to health insurance. The "guaranteed issue" requirement forbids insurers' pre-ACA practice of denying coverage to those with preexisting conditions, and the "guaranteed renewability" requirement ensures people remain covered after getting sick. *See* 42 U.S.C. § 300gg-1(a) (guaranteed issue); *id.* § 300gg-2(a) (guaranteed renewability). Notably, renewability is not guaranteed to those who owe past-due premiums, *id.* § 300gg-2(b)(1), but the guaranteed issue provision contains no such exception, *see id.* § 300gg-1(b).

Several provisions of the ACA operate to ensure that the risk pool is broad, with as many healthy enrollees as possible. *See* 42 U.S.C. § 18091(2)(I) (a "risk pool [with] healthy individuals . . . will lower health insurance premiums"). To promote enrollment by people who could otherwise not afford coverage, Congress appropriated billions of dollars to fund advance premium tax credits (APTCs) that reduce monthly premiums for individuals with household incomes between 100% and 400% of the federal poverty level (FPL). 26 U.S.C. § 36B(b)(3).

To qualify for sale through the Exchanges, health plans must cover a list of ten "essential health benefits" for several categories of care that were previously excludable, such as maternity care, mental health treatment, or prescription drugs. The EHBs are minimum standards for these plans, but the States are free to add "additional benefits." 42 U.S.C. § 18031(d)(3)(B). Several key ACA financial protections—including provisions that cap annual out-of-pocket costs and prohibit annual or lifetime dollar limits on care—apply only to the coverage of EHBs. As a result, insurers can cap coverage, and consumers can face unlimited out-of-pocket costs, for non-EHB items and

services. These critical financial protections apply to most private health plans, including those in individual and small group markets as well as many employer-sponsored health plans.

II. THE FINAL RULE

For the stated purpose of combating fraud and improper enrollments, on March 19, 2025, HHS proposed a series of sweeping changes to ACA eligibility and enrollment. Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability, 90 Fed. Reg. 12,942 (Mar. 19, 2025) (Proposed Rule). HHS proposed wide-ranging changes to both the federal exchange and the SBEs, which, according to HHS' own estimates, would cause "750,000 to 2,000,000 individuals to lose coverage." Proposed Rule at 13,025. In the 23-day period after publication during which HHS allowed public comment, 26,396 individuals and organizations submitted feedback. Several commenters, including many of the undersigned States,[3] pointed out that the Proposed Rule did little to strike at the root of the problem of fraudulent enrollments—which occur primarily on the federal government's own healthcare platform, healthcare.gov, not on the SBEs.

HHS published its Final Rule just over three months later. *See* Patient Protection and Affordable Care Act; Marketplace Integrity & Affordability, 90 Fed. Reg. 27,074 (June 25, 2025) (Final Rule).[4] For the most part, HHS pressed forward with its original proposal. The Final Rule makes substantial changes to the rules governing ACA exchanges—many of which go into effect almost immediately. These changes place new hurdles in front of individuals who need health insurance. *See* Rule at 27,200 (HHS acknowledging that just one of the fifteen changes will cause nearly half a million people to lose subsidies). These changes narrow opportunities for enrollment,

[3] *See* State of California, Commonwealth of Massachusetts, State of New Jersey, et al., Comment Letter on Proposed Rule (Apr. 11, 2025), at 35, available at https://www.regulations.gov/comment/CMS-2025-0020-23836 (attachments) (California et al. Comment Letter).

[4] Citations to the Final Rule will take the form "Rule at ____."

hamper access to affordable plans, and impose new bureaucratic barriers, such as new eligibility verification requirements for FFEs before individuals experiencing events such as a job loss, move, or birth of a child can obtain coverage or change plans. Rule at 27,148. New barriers to coverage also include refusing to accept individuals' self-attestation of projected household income, which the Final Rule predicts will cause 488,000 people to lose subsidies. Rule at 27,200. Still other changes permit insurers to deny coverage to individuals with past-due premiums, including for previous policies, Rule at 27,084, in violation of the ACA's "guaranteed issue" requirement, 42 U.S.C. § 300gg-1(a). And the Final Rule makes methodological changes to the APTC calculation formula, Rule at 27,102 (a formula set by statute, 26 U.S.C. § 36B(b)); premium adjustments, Rule at 27,166; and actuarial value ranges for health plans, Rule at 27,174, which diminish the value of health coverage and make it less affordable. It also bars "sex-trait modification procedures" from being covered as an EHB. Rule at 27,154. Many of these changes, which are outlined in more detail below, will begin to become effective on August 25, 2025.

LEGAL STANDARD

The APA permits courts to stay "agency action" to "prevent irreparable injury" and "may issue all necessary and appropriate process to . . . preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705. "When assessing a request for a preliminary injunction, a district court must consider '(1) the movant's likelihood of success on the merits; (2) the likelihood of the movant suffering irreparable harm; (3) the balance of equities; and (4) whether granting the injunction is in the public interest.'" *Norris ex rel. A.M. v. Cape Elizabeth Sch. Dist.*, 969 F.3d 12, 22 (1st Cir. 2020) (quoting *Shurtleff v. City of Bos.*, 928 F.3d 166, 171 (1st Cir. 2019)). "[T]he same standard governs both forms of relief." *Mass. Fair Hous. Ctr. v. U.S. Dep't of Hous. and Urb. Dev.*, 496 F.Supp.3d 600, 609 (D. Mass. 2020). All four factors support Plaintiff

States.

ARGUMENT

I. PLAINTIFF STATES ARE LIKELY TO SUCCEED ON THE MERITS.

A. HHS's 23-Day Period for Notice and Comment Was Legally Insufficient.

By allowing only twenty-three days of public comment on a Rule that made substantial changes to complex regulatory policies and abruptly reversed prior agency decisions, HHS failed to provide a meaningful "opportunity to participate in the rulemaking through submission of written data, views, or arguments," as required by the APA. 5 U.S.C. § 553(b)-(c). Where, as here, a rule proposes substantial changes, a 30-day comment period is generally the shortest period sufficient for interested persons to meaningfully review and provide informed comment. *See Prometheus Radio Project v. FCC*, 652 F.3d 431, 453 (3d Cir. 2011) (holding 28-day comment period insufficient); *Azar v. Allina Health Servs*., 587 U.S. 566, 570 (2019) (referring to the "APA minimum of 30 days"). And even a 30-day period is atypical, and highly disfavored, especially for such substantial changes. *See Petry v. Block*, 737 F.2d 1193, 1202 (D.C. Cir. 1984) (observing that 30 days for comment "cut[s] the comment period to the bone" and 60 days is "a more reasonable *minimum* time for comment" for complex rules (quotation omitted)); *Nat'l Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1117-18 (D.C. Cir. 2019) (citing *Petry*, 737 F.2d at 1201) ("When substantial rule changes are proposed, a 30-day comment period is generally the shortest time period sufficient for interested persons to meaningfully review a proposed rule and provide informed comment.").

Here, the Proposed Rule was published in the Federal Register on March 19, 2025, and comments were accepted through April 11, 2025. HHS therefore provided only 23 days to review a complicated, multifaceted rule spanning 90 pages in the Federal Register. As Plaintiff States explained to HHS when the rule was pending, the shortened comment period prejudiced Plaintiff States' ability to address certain highly technical matters; for example, SBEs could not perform a

complete analysis of the expected enrollment losses, premium impacts, and risk pool changes associated with this rule because of the truncated comment period.[5] As such, the 23-day comment period afforded by HHS is legally deficient, not only because it is less than the bare legal minimum of 30 days, *Petry*, 737 F.2d at 1202, but also because a rule of such complexity and magnitude, involving various technical issues under the ACA, requires a significantly longer comment period to ensure technical comments. *See* Parts I.B-C, *infra* (discussing substantive provisions of the Final Rule). Indeed, multiple recent prior rulemakings under the ACA typically afforded a comment period well over 30 days. *See, e.g.*, Extension of Comment Period for Rule Regarding ACA Interoperability, 84 Fed. Reg. 16,834 (Apr. 23, 2019) (extending existing comment period from 60 days to 90 days in response to public feedback); Patient Protection and Affordable Care Act; Increasing Consumer Choice Through the Sale of Individual Health Insurance Coverage Across State Lines Through Health Care Choice Compacts, 84 Fed. Reg. 8,657 (Mar. 11, 2019) (56-day comment period). As such, the Final Rule is procedurally invalid—a sufficient basis for the Final Rule to be stayed or enjoined (and ultimately vacated).[6]

[5] *E.g.*, California Department of Managed Health Care, Comment Letter on Proposed Rule (Apr. 11, 2025), at 1-2, available at https://www.regulations.gov/comment/CMS-2025-0020-23127 (attachments); Washington Health Benefit Exchange, Comment Letter on Proposed Rule (Apr. 11, 2025), at 2-3, available at https://www.regulations.gov/comment/CMS-2025-0020-24557 (attachments) (Washington HBE Comment Letter).

[6] Nor does the Final Rule include a finding of "good cause" justifying such a truncated comment period, as required by 5 U.S.C. § 553(b)(B). A rule with a comment period of less than 30 days is "generally characterized by the presence of exigent circumstances in which agency action was required in a mere matter of days." *N.C. Growers' Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 770 (4th Cir. 2012). The Final Rule makes no such showing, instead arguing that the Proposed Rule was "displayed for public inspection" for 30 days. Rule at 27,180. But only official publication in the Federal Register is sufficient to provide legal notice of a proposed rule to the public. *See* 44 U.S.C. § 1507 (documents are "not valid" until "filed" and "made available for public inspection as provided by section 1503," which describes the publication process).

Finally, even if HHS had allowed for a legally sufficient comment period, the notice-and-comment process was still inadequate because the agency failed to notify the public that many of the Final Rule's most burdensome provisions could be adopted for 2026 only. Had HHS disclosed this possibility in the Proposed Rule, commenters could have pointed out the fundamental illogic of the agency's approach. CMS's failure to make this disclosure renders the notice-and-comment process inadequate. *See Chocolate Mfrs. Ass'n of U.S. v. Block*, 755 F.2d 1098, 1105 (4th Cir. 1985) (reversing denial of vacatur where rulemaking provided no notice of the action taken).

B. The Final Rule's Marketplace Integrity Changes Are Unlawful.

Agency actions are arbitrary and capricious if they are not "reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). An explanation is only reasonable if it is consistent with the evidence before the agency, and the agency must additionally provide "a satisfactory explanation for its action" and demonstrate "a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.* (*State Farm*), 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. U.S.*, 371 U.S. 156, 168 (1962)). The Court may vacate an agency action where "[s]everal points, considered together, reveal a significant mismatch between the decision . . . made and the rationale [] provided," even where "no particular step in the process stands out as inappropriate or defective." *Dep't of Com. v. New York*, 588 U.S. 752, 783 (2019).

The challenged provisions of the Final Rule do little to accomplish HHS's stated goal of combating "fraudulent and improper enrollments at scale." Rule at 27,074. As its primary evidence of such fraud, HHS points to a report finding potential indicia of improper enrollment that occurs at "far higher" rates in non-Medicaid expansion states—in particular "nine States where erroneous and improper enrollment is most noticeable (that is, Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, Tennessee, Texas, and Utah)"—and that is "highly concentrated in

Exchanges on the Federal platform." Rule at 27,106, 27,122, 27,213. Notwithstanding this limited evidence and while acknowledging that SBEs do not have the same levels of fraudulent activity, Rule at 27,108, the Final Rule implements sweeping changes that directly impact Plaintiff States, all of which have expanded Medicaid (with one exception), none of which are among the nine States supposedly experiencing significant problems with improper enrollment, and most of which operate through SBEs. Further, HHS acknowledges that the expiration of enhanced premium tax credits at the end of 2025 "will substantially mitigate the threat of future improper enrollments," Rule at 27,075, but goes on to impose these sweeping changes in 2026 anyway—with no explanation.

Without any rational basis grounded in fraud prevention, let alone the actual fraud concern HHS has identified, the challenged provisions of the Final Rule amount to little more than unjustified administrative barriers to coverage that will swiftly throw millions of people off of the health insurance exchanges, impose substantial new administrative barriers, wrongfully deny coverage to eligible consumers, increase costs for all enrollees, and decrease the quality and availability of coverage. All of the challenged provisions are arbitrary and capricious, and many are contrary to law too.

Mandating a $5 minimum premium for auto-reenrollments is unlawful and arbitrary.[7] The Rule mandates that insurance exchanges must charge $5 monthly premiums to re-enrollees who are by law entitled to pay $0 until those enrollees confirm their re-enrollment. Rule at 27,102. This provision contravenes the plain text of the ACA and is not justified.

[7] This provision of the Final Rule applies to States utilizing the Federal Exchange; among Plaintiff States, those states are Arizona, Delaware, Michigan, Oregon, and Wisconsin.

The ACA sets forth the method for calculating the amount of APTC that an enrollee receives using a formula that considers household size, household income as a percentage of the FPL, the rate of inflation, and the "second lowest cost silver plan" available to the applicant in the applicant's geographic area. 26 U.S.C. § 36B(b). It further requires that APTC amounts "shall" be paid as directed by 26 U.S.C. § 36B. 42 U.S.C. § 18082(c)(2)(A). The use of "shall" indicates that the amount calculated under 26 U.S.C. § 36B is not discretionary. Yet the Rule commands a reduction in the amount of APTC credited to enrollees by $5, without lawful authority to do so.

HHS did not meaningfully respond to commenters who pointed out the illegality of this provision, offering only its unsupported "belie[f]" that the ACA allows the Secretary to "establish procedures" for redetermining "eligibility on a periodic basis in appropriate circumstances." Rule at 27,109; *See Mass. v. NIH*, 770 F. Supp. 3d 227, 306 (D. Mass. 2025) ("conclusory statements" do not satisfy the APA).

In addition to being unlawful, this provision of the Final Rule is arbitrary and capricious. HHS has provided no evidence to support its claim that the $5 charge would reduce improper enrollments, and no justification for choosing $5 as the amount automatic re-enrollees should owe. Nor does the Final Rule address the risk of substantial consumer confusion and harm—including the potential for disenrollment or of consumers being locked out of coverage for the remainder of the year—that is likely to result from the federal exchange imposing $5 charges on people who are by law entitled to pay $0 premiums.[8] *See* Rule at 27,103 (acknowledging but not addressing the possibility of "consumer confusion").

[8] Covered California, Comment Letter on Proposed Rule (Apr. 11, 2025), at 7, available at https://www.regulations.gov/comment/CMS-2025-0020-25629 (attachments) ($5 charge "complicates a previously clear procedure, risking lower enrollment, market destabilization, decreased long-term affordability and added administrative hurdles.").

Requiring 75% verification for triggering-event SEPs is arbitrary.[9] Consumers and small businesses seeking health coverage typically sign up during annual open enrollment periods (OEPs). But consumers who experience certain life events may be eligible for special enrollment periods (SEPs)—including events such as the loss of minimum coverage, the loss of a job, a move to a new area, or the birth of a child. The Final Rule now requires the federal platform to verify 75% of SEPs for all triggering events before a consumer's new coverage can take effect. Compl. ¶¶ 105-109.

That change is arbitrary and capricious. The Final Rule claims this requirement protects the risk pool by deterring adverse selection, Rule at 27,148, but the evidence before the agency shows the reverse: verification "may deter healthier, less motivated individuals from enrolling," Rule at 27,148. HHS estimates this change will generate 293,073 SEP verification issues that consumers will need to rectify before enrolling in coverage. Rule at 27,186. Those motivated to overcome that barrier will be those who are older and sicker—meaning younger, healthier enrollees are likely to be discouraged from maintaining coverage because of this change, harming the risk pool, a downside Defendants readily acknowledge. Rule at 27,148. Their own data, presented during rulemaking, showed that many enrollees struggle to submit documents and verify their eligibility. Compl. ¶ 115 (citing Proposed Rule at 12,983).

Moreover, HHS offers no data showing that SEP enrollees are more expensive to insure compared to non-SEP enrollees, meaning there is no justification for this change. In fact, during rulemaking, several commenters provided data showing that the aggregate risk score for SEP enrollees was the same as, or lower than, that of non-SEP enrollees. Compl. ¶ 105 (citing Covered

[9] This provision of the Final Rule applies to States utilizing the Federal Exchange; among Plaintiff States, those states are Arizona, Delaware, Michigan, Oregon, and Wisconsin.

California Comment Letter and Washington HBE Comment Letter). And Defendants sunset this provision after just one year, undermining their assertion that it is necessary to prevent adverse selection. Rule at 27,151.

Ending acceptance of self-attested projected household income is arbitrary. The Final Rule makes two arbitrary changes pertaining to income verification. First, it forbids the self-attestation of an enrollee who claims eligibility for APTC by projecting annual household income at or above 100% of the FPL if existing tax data shows a lower income. In such cases, a "data matching issue" (DMI) will be generated (the "contradictory-data DMI"). Rule at 27,121. Second, whenever there is no IRS data available, a DMI will be generated if other trusted data sources cannot corroborate the consumer's income (the "missing-data DMI"). *Id*. In either case, consumers must submit additional paperwork before they may obtain health insurance. *Id*.

HHS's rationale for these changes is to crack down on enrollees wrongly claiming APTC eligibility. *Id.* at 27,126. But nearly every Plaintiff State has expanded Medicaid, meaning adults with incomes up to 138% FPL qualify—so there is no incentive to inflate incomes. *See* Compl. ¶¶ 132-34. Rather than tailoring these new verification requirements to only those States that have not expanded Medicaid, HHS imposes these requirements on all States, effective immediately.

These changes will impose enormous financial and administrative burdens on SBEs and on low-income consumers. They will generate an estimated 2.7 million new DMIs—meaning that nearly 3 million people will need to track down and submit additional paperwork to purchase health insurance. Moreover, the vast majority of these DMIs—2.1 million—will be generated

because of *missing* IRS data (not contradictory IRS data), which may be no fault of the consumer.[10]

HHS estimates that implementing the contradictory-data DMI will cause the SBEs to spend $12.4 million to receive, review, and verify documents and to conduct outreach and communication with consumers, on top of another $14.7 million in one-time system update costs. Rule at 27,199. But thanks to the sunset provision, HHS projects that Exchanges will have to spend *another* $14.7 million to undo this change. *Id*. As for consumers, the Final Rule further acknowledges that this DMI will cost them over $13 million, and 81,000 will lose access to APTC (50,000 on the FFE and 31,000 on the SBEs). *Id*.

The Rule estimates that the missing-data DMI will cost the SBEs $62.8 million in verification costs on top of $16.6 million in one-time system update costs. *Id.* at 27,200. Again, SBEs would incur another $16.6 million cost to undo the change at the end of 2026. *Id*. HHS estimates that this DMI will revoke APTC from 252,000 enrollees on the FFE and 155,000 enrollees on the SBEs. *Id*. In total, HHS projects that 488,000 people may lose APTC on account of these new requirements. But HHS's justifications for imposing these acknowledged harms are meritless, rendering these changes arbitrary and capricious.

First, the Final Rule "acknowledge[s] that income verification can be more challenging for lower-income tax filers due to less consistent employment," *id*., which is consistent with the evidence before the agency.[11] Despite this evidence, the Final Rule states only that "the [income verification] process does not impose a substantial burden," *id*., but that evidence-free conclusion

[10]Jason Levitis et al., Comment Letter on Proposed Rule (Apr. 11, 2025), at 20, available at https://www.regulations.gov/comment/CMS-2025-0020-25047 (attachments) (Levitis et al. Comment Letter).

[11] *Id*. at 19.

"runs counter to the evidence before the agency," *State Farm*, 463 U.S. at 43, and contradicts HHS's own conclusion that consumers and exchanges will spend hundreds of millions of dollars and hundreds of thousands of hours trying to meet these new requirements, and that almost half a million people will fail to do so. Rule at 27,199.

Second, the Final Rule claims that enough consumers "are intentionally inflating their incomes" to justify these new burdens, *id*. at 27,121, but the limited evidence cited justifies, at most, a far narrower policy change. The Government Accountability Office (GAO) recommended that HHS verify household incomes only "when attested income amounts significantly exceed income amounts reported by IRS or other third-party sources." Proposed Rule at 12,964. That recommendation at most justifies only the first DMI—based on an actual *contradiction* between self-reported income and IRS-reported income. It would not justify the missing-data DMI (which would generate more than 75% of new DMIs under this policy change). Moreover, the GAO report shows that HHS' action is grossly disproportionate to the problem it purports to solve. Every instance that the GAO identified of a mismatch between self-reported income and IRS data occurred "for individuals residing in States that did not expand Medicaid." *Id*. Again, none are Plaintiffs here (save Wisconsin), and there is no incentive to inflate incomes for APTC purposes in those States. In addition, many Medicaid-expansion States have mechanisms to ensure that Medicaid-eligible clients do not receive APTC. Defendants fail to consider an "obvious alternative"—imposing these two verification requirements only in non-expansion States—so this change is "arbitrary or capricious." *California v. EPA*, 72 F.4th 308, 317 (D.C. Cir. 2023) (citing *State Farm*, 463 U.S. at 43) (failure to rationally connect evidence to agency action is arbitrary).

Transitioning to a one-year FTR eligibility window is arbitrary. The ACA awards APTCs to enrollees based on their projected future income. 26 U.S.C. § 36B; 42 U.S.C. § 18082.

When the enrollee files income taxes with the Internal Revenue Service the following year, the amount of the APTC award that was claimed is reconciled against eligibility as shown by the tax data. Importantly, HHS does not have access to such data—only the IRS does. *See* Rule at 27,116 ("privacy concerns" prevent HHS from knowing whether an individual has failed to file and reconcile). Under existing law, an enrollee who fails to file taxes and reconcile their claimed award against their actual eligibility—known as failure to file and reconcile, or FTR—for two consecutive years loses eligibility for future APTCs. The Rule temporarily ends this policy, imposing a one-year FTR window.[12]

Reverting to a one-year FTR grace period rather than a two-year grace period is unlikely to accomplish HHS' stated goal of reducing fraud on the Exchanges, as demonstrated by the fact that many more people receive one-year FTR codes than two-year FTR codes.[13] HHS acknowledges that the availability of enhanced APTCs drove fraudulent enrollment in the first place, and further acknowledges that the eAPTCs are expiring at the end of *2025*—yet imposes this change for 2026 anyway, before reverting to a two-year window once again for 2027. Rule at 27,091-103.

Not only is this change ineffective, it is also harmful. A one-year FTR window risks eligible individuals losing access to APTCs due to administrative error or paperwork delays. HHS acknowledged during rulemaking that the FTR eligibility check needed to be suspended during

[12] Underscoring the absurdity, the recently enacted budget reconciliation bill then *re-imposes* this sunsetted FTR provision for plan years 2028 and beyond. *See* One Big Beautiful Bill Act, Pub. L. 119-21 §§ 71303(a)-(c), 139 Stat. 72, 324 (July 4, 2025) (implementing this provision of the Rule with an effective date of January 1, 2028). Thus, over the next few years, Exchanges must change to a one-year FTR window for 2026 (due to the Rule), revert to a two-year window for 2027 (due to the Rule's sunset provision), and then change *again* to a one-year window for 2028 (due to the legislation).

[13] California et al. Comment Letter, *supra* note 3, at 9.

the Covid-19 emergency "due to concerns that consumers who had filed and reconciled would lose APTC due to IRS processing delays resulting from IRS processing facility closures and a corresponding backlog of paper filings." Proposed Rule at 12,958. Far from theoretical, HHS acknowledged that the IRS backlog during the pandemic "severely impacted the IRS's ability to process tax returns for the 2019, 2020, and 2021 tax years." Rule at 27,114. That concern is especially relevant today, when the Administration may be planning to cut the IRS in half.[14] Plaintiff States pointed this out during rulemaking,[15] and HHS did not specifically respond to the concern regarding the looming cuts to IRS staffing.

Moreover, the compliance costs of this change are significant. HHS estimates one-time costs of $19.4 million borne by the SBEs to update their systems, and then another $19.4 million to revert to the two-year window that will once again be in effect for 2027. Additionally, some states, like Washington, will struggle severely to create a new one-year FTR window from scratch in a matter of months.[16] HHS is unmoved. Remarkably, HHS seems not to care that the "majority of State Exchanges expressed in comments that they *could not make the technological changes* to revert back to a 1-year FTR policy in time for OEP 2026," requiring "all Exchanges" to "impose a 1-year FTR requirement beginning for PY 2026" regardless of the Exchanges' warnings that compliance on this timeline is impossible. Rule at 27,199 (emphasis added).

HHS's changes to the premium adjustment percentage methodology are arbitrary. The Final Rule changes the premium adjustment methodology—beginning in plan year 2026—to

[14] Fatima Hussein, The IRS is drafting plans to cut as much as half of its 90,000-person workforce, AP sources say, Associated Press (Mar. 4, 2025), https://apnews.com/article/irs-doge-layoffs-tax-season-0659e4b439400bf66023273f6a532fa0 (last accessed July 16, 2025).

[15] California et al. Comment Letter, *supra* note 3, at 9.

[16] Urley Declaration (Exhibit 24), ¶¶ 24-25.

include consideration of premium changes in the individual market (in addition to premium changes in the employer market). *Id*. at 27,166-73. Including the more price-volatile individual market premiums in the measure of inflation significantly increases out-of-pocket premiums for consumers receiving APTCs. *Id*. at 27,168. As a result, the consumer's share of premiums for the APTC benchmark silver plan in 2026 will be about 4.5% higher than it would have been under the prior methodology. *Id*. This translates to an additional $313 in premiums for a family of four making $85,000.[17] These increases will cause enrollment to decline, shrinking the risk pool and likely increasing premiums further for the less-healthy enrollees who remain. *Id*. These changes to the premium adjustment percentage methodology are arbitrary and capricious for three reasons.

First, HHS improperly factored in individual market premiums from 2013. Rule at 27,166-73. Unlike group market premiums, individual market premiums were highly volatile just before the ACA went into effect in 2013, and as such, are statistical outliers that do not represent underlying trends in health coverage costs, which the premium adjustment measures.[18] Commenters noted that considering these highly volatile, pre-ACA individual market premiums artificially inflates premium growth over time. *See* Compl. ¶¶ 150-55 (discussing comments). Group market premiums, by contrast, are more stable and accurate metrics of healthcare spending trends. *Id*. That is why HHS previously considered only group market premiums when calculating the annual premium adjustment percentage. *See* Patient Protection and Affordable Care Act; HHS

[17] Gideon Lukens and Elizabeth Zhang, Proposed AZA Marketplace Rule Would Raise Health Care Costs for Millions of Families, Center on Budget and Policy Priorities (Apr. 1, 2025), https://www.cbpp.org/research/health/proposed-aca-marketplace-rule-would-raise-health-care-costs-for-millions-of (last accessed July 16, 2025).

[18] *See* Levitis et al. Comment Letter, *supra* note 10, at 3 ("Individual market premiums experienced a discrete period of volatility. . . ."); *see also* 42 U.S.C. § 18022(c)(4) (setting comparator year).

Notice of Benefit and Payment Parameters for 2015, 79 Fed. Reg. 13,744, 13,801-04 (Mar. 11, 2014) (explaining the decision to exclude individual-market premiums from the calculation).

Second, the changes to the premium adjustment percentage methodology squarely undermine Congress' twin goals of expanding access to healthcare and making it more affordable. *See Sebelius*, 567 U.S. at 538 (Congress enacted the ACA to "increase the number of Americans covered by health insurance and decrease the cost of health care."). Although this change knowingly reduces enrollment and sharply increases premiums and cost-sharing, HHS claims—remarkably—that "making coverage more accessible and affordable" is an improper "policy objective[]." Proposed Rule at 12,990. But HHS "is not free to substitute new goals in place of the statutory objectives" set by Congress without "link[ing]" those goals with the law's stated objectives. *Indep. U.S. Tanker Owners Comm. v. Dole*, 809 F.2d 847, 854 (D.C. Cir. 1987).

Third, HHS failed to "be cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account.'" *DHS v. Regents of Univ. of Cal.*, 591 U.S. 1, 30 (2020) (quoting *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016)). The 24 million healthcare consumers who obtained health coverage through the exchanges this year rely on HHS to keep healthcare premiums and out-of-pocket costs from rising too quickly. This change disregards those reliance interests by imposing huge increases in premiums and cost-sharing limits.

Expanding the acceptable actuarial value ranges for health plans is arbitrary. The Final Rule widens the accepted ranges for the actuarial value (AV) of health plans, expanding the de minimis AV range for expanded bronze plans to +5/-4 percentage points and +2/-4 percentage points for standard bronze, silver, gold, and platinum. Rule at 27,175-76. Prior to the Final Rule, HHS set narrower AV ranges of +2/-2 or +2/-0 for most plans to balance transparency and affordability for consumers against flexibility for issuers. Patient Protection and Affordable Care

Act; HHS Notice of Benefit and Payment Parameters for 2023, 87 Fed. Reg. 27,208, 27,306 (May 6, 2022). By allowing less-generous plans within each metal tier, the Final Rule's expanded AV ranges undermine consumer choice, by decreasing the differences between metal tiers, and reduce affordability, by increasing out-of-pocket costs and net premiums. As a result, these expanded *de minimis* ranges will lead to higher out-of-pocket costs and less comprehensive coverage for most individuals enrolled on the exchanges. This change is arbitrary and capricious for two reasons.

First, HHS' primary justifications are conclusory and contradict the evidence before the agency. HHS claimed that the prior ranges "substantially reduce[d] issuer flexibility" and that issuers "voiced concern about their ability to continue to participate in the market generally." Rule at 27,175. But the Final Rule offers no empirical support for these assertions, and by contrast, a commenter pointed to increased issuer participation since the prior *de minimis* ranges were put into place. *See* Compl. ¶ 169 (discussing Levitis et al. Comment Letter showing an increased number of participating issuers and the expansion of service areas by existing issuers). HHS also asserts that the changes will improve the risk pool by promoting unsubsidized (and healthier) enrollee participation through lowered premiums, Rule at 27,175, but as commenters noted, lower premiums come at the expense of less-generous coverage. *See* Compl. ¶ 170. The Final Rule does not explain why less-generous plans with lower premiums will attract unsubsidized consumers, given that lower metal tier plans *already* offer these choices. HHS's justifications lack support and "run[] counter to the evidence before the agency." *State Farm,* 463 U.S. at 43.

Second, the Final Rule fails to consider that wider AV ranges may in fact increase gross premiums for unsubsidized enrollees as well, reducing unsubsidized enrollment and harming risk pools. The Final Rule acknowledges that wider AV ranges will decrease APTCs by $1.22 billion in 2026 (and more in each subsequent year) by allowing the APTC benchmark plan to undershoot

the 70% AV requirement by an additional 4 percentage points. Rule at 27,208. Because decreased APTCs lead to higher net premiums for subsidized enrollees, commenters pointed out these ranges will likely harm risk pools as healthier individuals are more likely to drop coverage, leading to an increase in gross premiums for unsubsidized enrollees as well. *See* Compl. ¶ 171 (discussing comments). HHS accepted commenters' prediction of "an initial weakening of the risk pool," caused by healthier subsidized enrollees "drop[ping] coverage when net premiums rise," Rule at 27,177, yet failed to account for the likely increase in unsubsidized enrollees' gross premiums as a result. *Id*. As such, the Final Rule arbitrarily overlooked "an important aspect of the problem," *Ohio v. EPA*, 603 U.S. 279, 294 (2024).

Allowing plans to deny coverage to those who owe past-due premiums from previous policies is unlawful and arbitrary. Enrollees who do not pay their premiums typically fall into a grace period of between one and three months, during which coverage is still available if the enrollee brings their account current. Premiums remain due during the grace period even if the consumer makes no claim and the insurer thus incurs no cost. Failure to pay outstanding premiums by the end of the grace period can result in termination of coverage. Insurers can take steps to recoup any past-due premiums, such as placing the debt into collections. But insurers may not deny coverage to new enrollees who owe past-due premiums from prior coverage, so long as the enrollee pays the new premium. This longstanding policy is commanded by the ACA's "guaranteed issue" provision, which requires that participating insurers "must accept every employer and individual in the State that applies for such coverage." 42 U.S.C. § 300gg-1(a).

HHS tries to supplant that statutory command with rulemaking, allowing insurers to deny coverage to enrollees with past-due premiums from prior coverage. This is contrary to law. The statute requires insurers to cover "every" eligible individual. *Id.* Notably, the guaranteed-

renewability provision does allow nonrenewal for past-due premiums, *see id.* § 300gg-2(b)(1); the absence of that exception from the guaranteed-issue provision makes Congress's intent clear. HHS is not free to rewrite statutes that do not align with its policy preferences.

Moreover, despite HHS's assertions that the point of this policy is to help consumers avoid "premium debt," Rule at 27,089, the Rule does not even require insurers to notify consumers of the reason for their denial—meaning a person who is denied coverage on this basis might not know *why* she was denied coverage or that the debt even exists. Nor is this change necessary: HHS found during previous rulemaking that existing debt-collection practices are sufficient to protect insurers. Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review, 78 Fed. Reg. 13,406, 13,416-17 (Feb. 27, 2013). The Rule's only explanation for the change in position is that HHS now believes "other forms of debt collection, such as placing the debt into collections, can be costly and time-consuming." Rule at 27,089. But surely debt-collection was just as costly and time-consuming in 2013 as in 2025.

HHS arbitrarily failed to consider reasonable alternatives. Only one of HHS's changes to the ACA rules—making it easier to remove brokers for cause—effectively addresses the issue of fraudulent broker enrollments. Plaintiff States supported,[19] and continue to support, that proposal. But it is not enough. If HHS had been serious about combating fraud, it would have seriously considered adopting the several changes Plaintiff States proposed during the comment period, such as multi-factor authentication.[20] Defendants' only response is that they "are continuing to explore additional operational solutions to further curb improper enrollments,

[19] California et al. Comment Letter, *supra* note 3, at 15.

[20] *Id.* at 16; *see also* Justin Giovannelli & Stacey Pogue, Policymakers Can Protect Against Fraud in the ACA Marketplaces Without Hiking Premiums, The Commonwealth Fund (Mar. 5, 2025), https://www.commonwealthfund.org/blog/2025/policymakers-can-protect-against-fraud-aca-marketplaces-without-hiking-premiums (last accessed July 16, 2025).

including two-factor verification." Rule at 27,147. Nowhere do Defendants acknowledge Plaintiff States' suggested solutions that would have effectively blocked improper enrollments by unscrupulous brokers without burdening innocent consumers. The Rule is arbitrary and capricious due to its failure to consider these "obvious alternative[s]." *California*, 72 F.4th at 317.

C. The Final Rule's Elimination Of "Sex-Trait Modification" As An Essential Health Benefit Is Unlawful.

1. The Final Rule Is Contrary to Law

The HHS Secretary must ensure that the scope of EHBs "is equal to the scope of benefits provided under a typical employer plan." 42 U.S.C. § 18022(b)(2)(A). To determine typicality, the ACA requires the Labor Secretary to conduct a survey of employer-sponsored coverage "to determine the benefits typically covered by employers." *Id*. This approach is well settled. In December 2011, in anticipation of the ACA's EHB provisions becoming effective in 2014, HHS determined for the first time what benefits are typically covered by employers by considering the Department of Labor (DOL) survey,[21] recommendations from the Institute of Medicine (IOM), plus public input, before issuing agency guidance.[22] Despite this well-established practice, HHS failed to conduct such a study before drafting the Final Rule that changed the scope of EHBs, violating its statutory mandate.

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[21] The Department of Labor released that survey of employer-sponsored plans, which included those of large and small employers, on April 15, 2011. *See* Selected Medical Benefits: A Report from the Department of Labor to the Department of Health and Human Services, Department of Labor (Apr. 15, 2011), https://www.bls.gov/ebs/additional-resources/selected-medical-benefits-a-report-from-dol-to-hhs.pdf (DOL Report). The survey used 2008 and 2009 National Compensation Survey data. Essential Health Benefits Bulletin, Centers for Medicare & Medicaid Services: Center for Consumer Information and Insurance Oversight, 2 (Dec. 16, 2011), https://www.cms.gov/cciio/resources/files/downloads/essential_health_benefits_bulletin. (2011 CMS Bulletin). This 2011 Department of Labor survey was the first and last completed in accordance with 42 U.S.C. §18022(b)(2).

[22] *See* 2011 CMS Bulletin.

Moreover, the ACA mandates that in "revising [EHB] the Secretary shall submit a report to the appropriate committees of Congress," presumably premised on renewed reports by DOL based on "a survey of employer-sponsored coverage." 42 U.S.C. § 18022(a)(2). Because this procedure is mandated by statute and is a well-established process, the failure of HHS to conduct a new DOL report and submit a report to Congress is contrary to law. *Perales v. Sullivan*, 948 F.2d 1348, 1354 (2d Cir. 1991); *see also New Mexico Farm & Livestock Bureau v. U.S. Dep't of Interior*, 952 F.3d 1216, 1231 (10th Cir. 2020) (holding that agency's failure to follow own regulations or offer reasoned explanation for its failure to do so is arbitrary and capricious). While CMS adhered to this rigorous and evidence-based process in first promulgating the benchmark plan process, it failed to do so in excluding "sex-trait modification" as EHB. The consideration of new DOL reports is not only statutorily required but also would provide a more accurate snapshot of the increasing coverage for services falling within the umbrella of gender-affirming care than the limited data upon which the Rule currently relies.

2. HHS's Exclusion of "Sex-Trait Modification Procedures" is Arbitrary and Capricious

The Final Rule's exclusion of any "sex-trait modification procedure" from EHBs and its finding that such care "is not typically included in employer-sponsored plans," Rule at 27,152, are also arbitrary and capricious. *First*, HHS diverges without good reason, *see FCC v. Fox*, 556 U.S. 502, 515 (2009), from its settled policy of determining on a flexible state-by-state basis what benefits are provided under a "typical" employer plan. And HHS does so without even considering and addressing the significant reliance interests of states. *See Regents of the Univ. of Cal.*, 591 U.S. at 33. *Second*, even taken on its own terms, HHS's explanation of what benefits are covered under a "typical" employer plan inexplicably "runs counter to the evidence before the agency."

State Farm, 463 U.S. at 43. *Third*, HHS departed from its past practice and statutorily required procedures in redefining EHBs, relying instead on a limited data set.

The Final Rule bars any "sex-trait modification procedure" from being treated as an EHB, defining the term as "any pharmaceutical or surgical intervention that is provided for the purpose of attempting to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex either by: (1) intentionally disrupting or suppressing the normal development of natural biological functions, including primary or secondary sex-based traits; or (2) intentionally altering an individual's physical appearance or body, including amputating, minimizing or destroying primary or secondary sex-based traits such as the sexual and reproductive organs." Rule at 27,154.[23]

In excluding this care from EHBs, the Final Rule arbitrarily diverges from the longstanding approach of determining a "typical" employer plan on a state-by-state basis, instead dictating to all States a brand-new exclusion with little to no explanation for the change. Considering the established state-by-state approach to EHBs, the "typical" employer plan in Plaintiff States provides coverage for medically necessary treatment of gender dysphoria, services likely falling within the definition of "sex-trait modification".[24] The process by which each state fills in the

[23] The Final Rule adopts a novel definition of "sex-trait modification procedure," a term that does not exist in medicine or law and that HHS did not include in the Proposed Rule. HHS thus deprived Plaintiff States and other commenters, such as medical professionals and insurers, of the opportunity to comment on a definition that HHS did not propose during this rulemaking process *and* that has never before been used or defined by the federal government. By adopting an entirely new term and associated definition in the Final Rule, HHS "substantially depart[ed] from the terms or substance of the proposed rule," rendering the notice-and-comment process "inadequate." *Chocolate Mfrs. Ass'n*, 755 F.2d at 1105.

[24] Small Business Health Option Plans (SHOP) are one of the types of plans pointed to by HHS as "typical." Rule at 27,155. However, SHOP plans are fully insured, which means that they cover services treating gender dysphoria under anti-discrimination laws. Notably, the Final Rule does not even evaluate SHOP plans; rather, it uses enrollment and claims data from a variety of plans to make an assertion about SHOP plans specifically.

details of the ten statutory EHB categories has always been in the form of a benchmark plan "reflecting both the scope of services and any limits offered by a 'typical employer plan' *in that State* as required by section 1302(b)(2)(A) of the [ACA]."[25] The 2011 CMS Bulletin announced the agency's commitment to "State flexibility" and clarified that assessing the contents of a "typical employer plan" is a state-specific inquiry.[26] Consequently, HHS confirmed in its 2013 rule on EHBs that "typical employer plans differ by state." Patient Protection and Affordable Care Act; Standards Related to EHBs, Actuarial Value, and Accreditation, 78 Fed. Reg. 12,834, 12,843 (Feb. 25, 2013) (emphasis added).

The Final Rule effects this drastic change while failing to consider or address the significant reliance interests of States. *See Regents of the Univ. of Cal.*, 591 U.S. at 33. As contemplated by the ACA and HHS's regulations, states have selected their EHB benchmark plans to best reflect the coverage and benefits typical to each state's insurance market, including coverage that complies with state-based legal requirements, including nondiscrimination protections, and state-specific conditions. *See* Patient Protection and Affordable Care Act; Standards Related to EHBs, Actuarial Value, and Accreditation, 78 Fed. Reg. 12,834, 12,841 (Feb. 25, 2013) ("The benchmark plan options for each state reflect the scope of benefits and services typically offered in the employer market *in that state*." (emphasis added)). HHS's abrupt decision to exclude "sex-trait modification" from EHBs nationwide is highly disruptive and will force states to re-evaluate their benchmark plans. Five states explicitly include certain gender-affirming care in their benchmark plans. *See* Rule at 27,154 n.196 ("The EHB-benchmark plans for California, Colorado, New Mexico, Vermont, and Washington specifically include coverage of some sex-trait

[25] 2011 CMS Bulletin, *supra* note 22, at 8 (emphasis added).

[26] *Id.* at 8-9.

modification."). For those states that do not explicitly include medically necessary treatment for gender dysphoria in their benchmark plans, but that otherwise require coverage of this care through state law, they will be subject to defrayal costs pursuant to 45 C.F.R. § 155.170. Rule at 27,161 (states with coverage mandates are subject to defrayal costs). States could not have reasonably anticipated such a restriction in part because medically necessary treatment for gender dysphoria is not a stand-alone category of health care and rather spans more than one of the 10 mandatory categories of EHBs, including prescription drugs. Because the Rule applies the exclusion to PY 2026, states must finalize these changes in under two months. HHS was required to at least consider the states' significant reliance interests when imposing such a profound change in approach, and HHS's failure to do so is arbitrary and capricious. *Regents of the Univ. of Cal.*, 591 U.S. at 33 (where agency is "'not writing on a blank slate,' it [i]s required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns" (citation omitted)).

HHS's purported finding that a typical employer plan does not cover "sex-trait modification" is contradicted by the very evidence before the agency, rendering it arbitrary. *State Farm*, 463 U.S. at 43. In its Final Rule, HHS relied on Movement Advancement Project (MAP) data, which shows that 24 states explicitly require coverage of services falling within the umbrella of gender-affirming care in their state employee health benefit plans, which would include "sex trait modification" by insurers, as compared to 14 states that exclude coverage from such plans. In other words, of those states' plans that mention these services, 63 percent explicitly require coverage. Twelve states "do not mention or ha[ve] no clear policy" regarding coverage of gender-affirming care. Rule at 27,153. When compared to other EHBs determined by HHS, the level of coverage for these services is sufficiently "typical" to qualify as EHB even on a nationwide basis.

By way of comparison, HHS's 2011 determination of EHBs was informed by the Department of Labor's dataset, which revealed that only 27 percent of plans surveyed explicitly offered coverage for infertility treatments.[27] Yet HHS did not exclude coverage for infertility treatment services, nor did the agency suggest that these services were not part of a typical employer plan under 42 U.S.C. § 18022(b)(2)(A).

Further evidencing its untenable rationale, HHS's Final Rule disregards without meaningful explanation the evidence that undercuts its premise for the regulatory action. *See* Compl. ¶ 213 (72 percent of Fortune 500 companies cover gender-affirming care according to Corporate Equality Index); *see also* Compl. ¶ 214 (significant numbers of companies of all sizes cover gender-affirming care according to Kaiser Family Foundation's survey). The Final Rule rejects data proving that the vast majority of Fortune 500 companies, and a substantial number of companies of all sizes, cover treatment for gender dysphoria on the basis that the typicality analysis should focus solely on small employers, not large employer plans, even though the latter plans cover more Americans.[28] *See* Rule at 27,154-55.

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[27] *See* DOL Report, *supra* note 22. In order to assess employer-sponsored coverage for the report, DOL drew on data from the Bureau of Labor Statistics (BLS). *Id.* DOL not only reviewed the BLS National Compensation Survey, which captured data from approximately 36,000 employers, but also a BLS analysis of 3,900 private sector plans to assess "detailed provisions of employment-based health care benefits." *Id.* BLS analyzed plan documents requested from those 3,900 private sector plans to evaluate existing coverage for treatments for conditions like infertility; BLS found that, of all of the private sector plans, only 27 percent covered infertility treatments (meaning, covered diagnosis *and* treatment). Overall, 47 percent of assessed plan documents mentioned infertility treatments, and 60 percent of those that mentioned infertility treatments covered more than a diagnosis. *Id.*

[28] HHS tries to dismiss this data by suggesting, without evidence, that "very large employers also receive more pressure from advocacy organizations to cover sex-trait modification procedures and, therefore, likely do not represent the typical employer to the degree a portion respond to this pressure." Rule at 27,155. HHS suggests that the "voluntary participation" of employers in that survey "suggests these employers do not represent the typical employer and, instead, align with the advocacy organization's views." *Id*. HHS could have commissioned its own survey or

Once again, this approach is a sharp divergence from how HHS has approached these issues until now. HHS's 2011 analysis of Department of Labor survey data, for example, examined benefits offered by plans of all sizes,[29] and CMS's December 2011 Essential Health Benefits Bulletin explained that, in trying to define "typical," HHS "gathered benefit information on large employer plans (which account for the majority of employer plan enrollees)" as well as "small employer products (which account for the majority of employer plans), and plans offered to public employees."[30] While the Bulletin expressed that HHS's "intended approach to EHB incorporates plans typically offered by small employers," it clarified that the approach also "incorporates . . . benefits that are covered *across the current employer marketplace*" – those covered by plans of all sizes.[31] This underscores the importance of the state-by-state approach—disregarded here by HHS—which provides the most accurate picture of the benefits covered in the employer marketplace in each state.

The Final Rule also capriciously misinterprets a "limited data set" that describes levels of enrollment in certain plans and the frequency of types of claims submitted, the External Data Gathering Environment (EDGE) data, to make conclusive assertions about nationwide coverage.[32]

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analysis—as it did through an extensive process before issuing guidance in 2011. But the agency cannot use its own failure to thoroughly investigate this issue to dismiss evidence submitted by commenters that its policies are capricious.

[29] *See* DOL Report, *supra* note 22. Notably, this was the first and last DOL report on the contents of typical employer plans.

[30] 2011 CMS Bulletin at 3-4.

[31] 2011 CMS Bulletin at 8 (emphasis added).

[32] Rule at 27,153 ("The EDGE limited data set contains certain masked enrollment and claims data for on- and off- Exchange enrollees in risk adjustment covered plans in the individual and small group (including merged) markets, in States where HHS operated the risk adjustment program required by section 1343 of the ACA, and is derived from the data collected and used for the HHS-operated risk adjustment program.")

Because the number of claims for "sex-trait modification" is purportedly low,[33] the Final Rule leaps to the conclusion that gender-affirming care is infrequently utilized and therefore not typically covered by small business plans.[34] Rule at 27,155-56. But utilization rates are not a substitute for coverage rates; indeed, the fact that there were claims at all undercuts the argument that this care is not covered. Further, public and commercial insurers regularly cover healthcare services that are infrequently used. For example, heart and lung transplants are exceptionally rare,[35] but the vast majority of public and private insurance plans cover them, and transplants themselves are not excluded from EHBs.[36] Likewise, HHS has never before cited utilization as grounds for exclusion from EHB coverage, 78 Fed. Reg. at 12,844-45 (excluding as EHBs limited category of services "because they are not typically included in medical plans offered by a typical employer"). Indeed, even within the Final Rule itself, low utilization is not consistently grounds for exclusion from EHB coverage. For example, the Final Rule permits hormone therapy for the treatment of precocious puberty to be included as an EHB, even though it is less frequently utilized than hormone therapy to delay puberty to affirm an individual's gender identity.[37] It is

[33] The Final Rule does not define what claims it considered in making this assessment.

[34] As explained above, the Final Rule uses the EDGE data to make claims about SHOP coverage, specifically that "sex-trait modification" is not covered by the typical small business plan, even though EDGE data includes enrollment and claim information from plans of various sizes and SHOP plans in all Plaintiff States cover gender-affirming care.

[35] Detailed Description of Data, Health Res. and Servs. Admin., https://www.organdonor.gov/learn/organ-donation-statistics/detailed-description (last accessed July 16, 2025).

[36] Lindsey Dawson, Kaye Pestaina, & Matthew Rae, New Rule Proposes Changes to ACA Coverage of Gender-Affirming Care, Potentially Increasing Costs for Consumers, Kaiser Family Found. (Mar. 24, 2025), https://www.kff.org/private-insurance/issue-brief/new-rule-proposes-changes-to-aca-coverage-of-gender-affirming-care-potentially-increasing-costs-for-consumers/ (last accessed July 17, 2025).

[37] Precocious puberty affects 1 in 5-10,000 children, predominantly girls, whereas 1.4 percent of adolescents identify as transgender. Precocious Puberty, Rare Diseases, available at

unreasonable for HHS to maintain that services must be excluded from EHBs due to data that purportedly show infrequent utilization of "sex-trait modification" procedures.

Ultimately, because HHS failed to consider evidence and incorrectly dismissed what it dubs "sex-trait modification," as not being typically covered, the decision to exclude the services theoretically falling within this ambit from EHBs is arbitrary and capricious.

II. THE EQUITIES COMPEL PRELIMINARY RELIEF.

A. Preliminary Relief Is Needed To Avert Irreparable Harm.

Plaintiff States are "likely to suffer irreparable harm in the absence of preliminary relief." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The Final Rule results in imminent irreparable harm to Plaintiff States through: (1) costs that SBE States are incurring and will continue to incur to comply with the Final Rule by the effective date and in advance of the start of open enrollment in less than four months on November 1, 2025; (2) lost revenue derived from fees for each insurance premium sold on the SBEs that will no longer be collected; (3) increased expenses to provide medical care and other health-related services to individuals who will lose insurance coverage, and who are unable to enroll in alternative health insurance coverage after the end of the open enrollment period; and (4) increased costs resulting from adverse health outcomes that follow predictably from newly-uninsured individuals foregoing preventive or emergency health care in the absence of affordable health insurance coverage.[38]

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https://rarediseases.org/rare-diseases/precocious-puberty (last accessed July 17, 2025); Many Adults and Youth Identify as Transgender in the United States?, UCLA School of Law Williams Institute (June 2022), available at https://williamsinstitute.law.ucla.edu/publications/trans-adults-united-states/ (last accessed July 17, 2025).

[38] For the same reasons that Plaintiffs have demonstrated that they will be irreparably harmed absent an injunction, Plaintiffs have Article III standing to sue because they will suffer an "injury in fact" that is "fairly traceable" to the Final Rule and "may be redressed by" a court order enjoining its implementation. *McBreairty v. Miller*, 93 F.4th 513, 518 (1st Cir. 2024). States satisfy the Article III injury when they establish a "substantial risk" that the action will impose a "fiscal

First, the Final Rule correctly acknowledges that it will "result in costs to State Exchanges and the Federal Government to update eligibility systems in accordance with this policy." Rule at 27,193. As open enrollment for benefit year 2026 begins in less than four months, Plaintiff States that operate their own ACA exchange would immediately incur compliance costs. The changes made by the Final Rule require such States to implement changes to technology platforms, retrain their staff, update websites and publications, conduct advertising and outreach, and send notices to affected individuals.[39] The Final Rule's exclusion of treatment for gender dysphoria from essential health benefits further requires SBEs to work with carriers to review revised health plans and develop cost-defrayal mechanisms on an expedited basis.[40] Even a temporary disruption will cause irreparable harm.[41]

Second, the Final Rule will also reduce the specific revenue streams from the user fees levied on plans sold on the SBEs. As the Final Rule acknowledges, up to 1.8 million people, many of whom reside in Plaintiff States, may lose access to health insurance coverage. Rule at 27,213. Plaintiff States with SBEs and State exchanges on the federal platform receive millions of dollars in fees tied directly to insurance premiums paid by individuals who access insurance through ACA

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injury" on them. *Mass. v. HHS*, 923 F.3d 209, 222 (1st Cir. 2019); *In re Fin. Oversight & Mgmt. Bd. for P.R.*, 110 F.4th 295, 308 (1st Cir. 2024) (agreeing financial losses are "a quintessential injury in fact"). The compliance costs, lost tax revenue, and increased expenditures all qualify.

[39] *See*, *e.g.*, Altman Decl. (Exhibit 3) ¶11 (detailing over $1.5 million in compliance costs that will be incurred as a result of the Final Rule); Holahan Decl. (Exhibit 20) ¶20 (anticipating $10 million spent on staff time); Humphreys Decl. (Exhibit 21) ¶28 (projecting roughly $5.5 million in compliance costs); Michel Decl. (Exhibit 5) ¶17 (compliance requiring over 1,000 hours of staff time); Schneider Decl. (Exhibit 10) ¶18 (estimating compliance costs of more than $2 million); Woltmann Decl. (Exhibit 11) ¶8 (compliance requiring 1,500 hours of staff and vendor time).

[40] *E.g.*, Beyer Decl. (Exhibit 23) ¶¶7-8; Lang Decl. (Exhibit 22) ¶21; Zimmerman Decl. (Exhibit 18) ¶26.

[41] Huck Decl. (Exhibit 17) ¶14.

exchanges.[42] As one example, New Jersey's state-run exchange, GetCoveredNJ, generates revenue because insurance carriers pay a 3.5% fee on the total monthly premium collected for each health benefits plan sold in the individual market.[43] The Final Rule will deprive the States of the revenues generated by these premiums. Plaintiff States need relief before this extensive revenue loss occurs.

Third, the Final Rule imposes on Plaintiff States increased expenses for providing medical care to individuals who lose insurance due to these changes. State expenditures will balloon as people who lose subsidized marketplace coverage turn to publicly funded healthcare as a backstop. And for those individuals who become uninsured, Plaintiff States will incur substantial costs for their care, including millions annually in unreimbursed costs for the care of uninsured residents at public hospitals,[44] and hundreds of millions in annual subsidies to defray the cost of health care services that are provided to uninsured residents.[45] These costs include subsidies for preventive or emergency care services for uninsured residents. One example is New Jersey's Uncompensated Care Fund, which subsidizes preventive health services for uninsured residents by paying a flat rate from State funds per visit ($114 per visit for primary and dental care, and $74 per visit for mental health services).[46] For this program, and similar programs across Plaintiff States, the greater the number of uninsured residents, the more the State spends on healthcare for uninsured individuals.[47] Moreover, because these state-operated programs do not defray all costs of uncompensated care, state-owned hospitals also incur significant costs in providing services to

[42] Altman Decl. (Exhibit 3) ¶8; Eberle Decl. (Exhibit 12) ¶13; Humphreys Decl. (Exhibit 21) ¶24; Lang Decl. (Exhibit 22) ¶14; Winters Decl. (Exhibit 9) ¶10.

[43] Zimmerman Decl. (Exhibit 18) ¶18.

[44] *See* Huck Decl. (Exhibit 17) ¶12.

[45] Beyer Decl. ¶17; Holahan Decl. ¶32; Huck Decl. ¶¶12-13; Humphreys ¶31.

[46] Brown Decl. ¶24.

[47] *E.g.*, Smith Decl. ¶ 15, Altman Decl. ¶ 24.

uninsured patients.[48]

Finally, Plaintiff States face increased costs resulting from the adverse health outcomes that predictably follow from newly uninsured individuals foregoing preventive or emergency health care because they lack affordable insurance. The Rule acknowledges these harms. *See* Rule at 27,213 (acknowledging "strain on emergency departments" and a "reduction in labor productivity," among other harms); 27,171 (Rule "may increase the number of uninsured"); 27,192 (enrollees "may . . . become uninsured" and "may face higher costs for care and medical debt if care is needed."). Just a year ago, HHS acknowledged that "[i]ndividuals without health insurance are less likely to receive preventive or routine health screenings and may delay necessary medical care, incurring high costs and debts," and that such "[d]elays in care can lead to negative health outcomes including longer hospital stays and increased mortality." Rule Regarding ACA Exchanges And Basic Health Program, 89 Fed. Reg. 39,392, 39,396 (May 8, 2024). Loss of insurance can also result in increased medical debt, reduced spending power, lost work productivity, and absenteeism—as uninsured individuals, less likely to seek preventive care, are more likely to get sick and miss work. *Id*. Moreover, individuals who have recently initiated a time-sensitive course of treatment may have to decide whether to continue such treatment and pay out-of-pocket, or to interrupt treatment and risk significant adverse health consequences.[49]

B. The Balance Of Equities And Public Interest Favor Preliminary Relief

The balance of equities and public interest cut the same way. *Winter*, 555 U.S. at 20; *Does 1-6 v. Mills*, 16 F.4th 20, 37 (1st Cir. 2021) (noting these prongs "merge when the [g]overnment is the opposing party"). Plaintiff States will suffer the immediate and irreparable harms discussed

[48] Huck Decl. (Exhibit 17) ¶10 (University Hospital incurred roughly $58 million in uncompensated care costs in fiscal year 2023).

[49] *E.g.*, Holahan Decl. (Exhibit 20) ¶33.

above. And beyond these harms, the Final Rule acknowledges some of its changes "may deter enrollments among younger people at higher rates, which could worsen the risk pool and increase premiums." Rule at 27,203. For another, the Final Rule will cause up to 1.8 million people to lose insurance coverage and will increase the risk and magnitude of disease outbreaks and thus place a greater strain on hospitals due to the nature of communicable diseases.[50] And because uninsured individuals are less likely to have access to regular outpatient care—leading to greater rates of hospitalization for longer periods, *see* 89 Fed. Reg. at 39,396—smaller communities with fewer resources to address higher hospitalization rates will feel the strain most acutely.[51] In light of these imminent injuries, which cannot be cured after the Final Rule becomes effective or after the close of open enrollment, Plaintiff States will suffer irreparable harm absent a preliminary injunction.

On the other hand, Defendants suffer no harm by maintaining the status quo while this litigation proceeds. Defendants will be able to obtain complete relief at the conclusion of the litigation. Given the imminence of open enrollment for the 2026 benefit year, allowing the pre-Final Rule status quo to remain in place will avert significant disruption to the reliance interests of Plaintiff States, state-based exchanges, and our residents seeking healthcare.

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[50] *E.g.*, Travis Campbell et al., Exacerbation of COVID-19 Mortality by the Fragmented United States Healthcare System, The Lancet Regional Health (May 12, 2022), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC9098098/ (last accessed July 17, 2025) (finding that "insurance gaps exacerbated local COVID-19 outbreaks and resulted in more cases, hospitalization, and death than experienced by jurisdictions with better coverage.")

[51] Jennifer Tolbert et al., Key Facts About the Uninsured Population, Kaiser Family Foundation (Dec. 18, 2023) , available at https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population (last accessed July 16, 2025) ("[h]igh uninsured rates contribute to rural hospital closures and greater financial challenges for rural hospitals, leaving individuals living in rural areas at an even greater disadvantage to accessing care.")

III. THE COURT SHOULD NOT REQUIRE A BOND.

The Federal Rules of Civil Procedure ordinarily require "security in an amount the court considers proper" before a preliminary injunction may issue. Fed. R. Civ. P. 65(c). "However, the First Circuit has recognized an exception to the bond requirement in suits to enforce important federal rights or public interests, as is precisely the case here." *New York v. McMahon*, --- F.Supp.3d ---, 2025 WL 1463009, at *39 (D. Mass. May 22, 2025) (Joun, J.) (quoting *Westfield High Sch. L.I.F.E. Club v. City of Westfield*, 249 F.Supp.2d 98, 129 (D. Mass. 2003)). The Court should not require a bond.

CONCLUSION

This Court should grant the motion for a stay under Section 705 and a preliminary injunction, and stay/enjoin the challenged components of the Final Rule from taking effect in Plaintiff States.

July 17, 2025

Respectfully submitted,

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**Application for pro hac vice admission forthcoming*

LOCAL RULE 7.1 CERTIFICATE

I certify that on July 17, 2025, at 11:46 a.m., I contacted Diane Kelleher, Director, Federal Programs Branch, U.S. Department of Justice (diane.kelleher@usdoj.gov), Rayford Farquhar, Chief, Defensive Litigation, Civil Division, U.S. Attorney's Office for the District of Massachusetts (rayford.farquhar@usdoj.gov), Abraham George (abraham.george@usdoj.gov), and Brad Rosenberg (brad.rosenberg@usdoj.gov) by email in an attempt to meet and confer regarding the foregoing request for relief. Eric Beckenhauer (Eric.Beckenhauer@usdoj.gov) responded on behalf of Defendants. Plaintiffs and Defendants have met and conferred in good faith and have been unable to resolve or narrow the subject of this Motion.

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CERTIFICATE OF SERVICE

I, Allyson Slater, certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants.

_/s/_____
Allyson Slater