

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

COMMONWEALTH OF MASSACHUSETTS, et
al.

Plaintiffs,

v.

MEHMET OZ, M.D., et al.

Defendants.

Case No. 1:26-cv-12962

**LEAVE TO FILE GRANTED ON
JULY 9, 2026**

**PLAINTIFF STATES' REPLY IN SUPPORT OF THEIR MOTION FOR A
PRELIMINARY INJUNCTION**

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INTRODUCTION

CMS accuses Plaintiffs of “seek[ing] to bring a halt” to H.R. 1’s reforms. ECF 81 (“Opp.”) at 1. But it is CMS, not Plaintiffs, whose actions contradict Congress’s policy judgments by applying the work requirements to people Congress chose to exclude. And it is CMS, not Plaintiffs, who have ignored their legal obligations to consider problems engendered by their abrupt shift in policy, to address relevant data, and to provide at least a minimally reasoned explanation for their choice. Plaintiffs have been working tirelessly for the last year to implement H.R. 1 as written. In short, CMS has contravened Congress’s carefully-considered judgment and flouted its APA obligations. The Court should grant Plaintiffs’ motion.

ARGUMENT

I. Plaintiffs are likely to succeed on the merits.

A. The IFR is contrary to law in two respects.

When Congress delegates discretionary authority to an agency, courts must “fix[] the boundaries of the delegated authority” and ensure the agency acts “within those boundaries.” *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 395 (2024). CMS has twice violated those limits.

1. The Medically Frail Definition is contrary to law.

H.R. 1 does not permit CMS to condition the medical frailty exclusion for individuals with one of the enumerated conditions at 42 U.S.C. 1396a(xx)(9)(A)(ii)(V) on an additional showing that their condition “significantly impairs” their ability to comply with the Work Requirement. CMS leans on Congress’s limited grant of definitional authority, but the statute’s direction to “include” certain groups as medically frail, “sets a floor” that the Secretary’s definition cannot sink beneath. *Project Vote/Voting for America, Inc. v. Long*, 682 F.3d 331, 337 (4th Cir. 2012).

Interpretation of a statute begins with the “plain meaning” of its text. *United States v. Abbas*, 100 F.4th 267, 283 (1st Cir. 2024). H.R. 1 defines “medically frail or otherwise ha[ving]

special medical needs” as “including” five sub-categories of medically vulnerable individuals. 42 U.S.C. § 1396a(xx)(9)(A)(ii)(V). The participle “*including*” generally “indicates a partial list,” though “some drafters use phrases such as *including without limitation and including but not limited to*—which mean the same thing.” *Include*, BLACK’S LAW DICTIONARY (12th ed. 2024) (emphasis in original); *see also* ECF 3 (“Br.”) at 7 (“identifying” is a term of enlargement).¹ Put simply, “including” is “used to denote something that is within a larger whole.” *City of Philadelphia v. Attorney General*, 916 F.3d 276, 287 (3d Cir. 2019). Whatever the general term preceding “including” means, it must incorporate, at the very least, the items in the list that follows.

The statute’s grant of definitional authority to the Secretary does not permit CMS to ignore the plain meaning of “including.” When Congress gives an agency discretion to determine the meaning of a statutory phrase, “that discretion may only be exercised within the bounds of the statutory definition itself.” *Safer Chems., Healthy Families v. EPA*, 943 F.3d 397, 425 (9th Cir. 2019); *see also Loper Bright*, 603 U.S. at 395. *Safer Chemicals* is instructive. There, the Toxic Substances Control Act required that the EPA evaluate the risk posed by certain “chemical substances” based on those chemicals’ “conditions of use.” The statute defined the term “conditions of use” to mean “the circumstances, as determined by the [EPA] Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” *Safer Chems.*, 943 F.3d at 406–07. The EPA maintained that its definitional authority, provided in statute, permitted the agency to exclude from risk evaluations all chemical substances no longer being actively manufactured for associated

¹ Defendants agree that language like “shall include, at a minimum” would make clear Congress’s intent to set a statutory floor. Opp. at 17. But there is no daylight between “shall include at a minimum,” *id.*, and “including but not limited to,” which Black’s Law identifies as having the “same” meaning as “including,” *Include*, BLACK’S LAW DICTIONARY (12th ed. 2024). The difference in “shall” is not meaningful: a rule that Category A “includes” X & Y is no different than a rule that Category A “shall include” X & Y. And “at a minimum” and “including but not limited to” have no distinct definition for this purpose.

uses. But while the Ninth Circuit agreed that the statute provided EPA “discretion to determine the conditions of use for each chemical substance,” the agency exceeded such discretion by categorically excluding from its review chemical substances that the statute “clearly includes,” namely chemicals that are no longer manufactured. *Id.* at 425. So, too, here. The grant of some definitional authority does not allow the Secretary to omit from the “medically frail” definition individuals whom Congress expressly directed it to include.² Nor does CMS cite any authority to support such an omission. Rather, the sole authority CMS cites is inapposite, as it concerns an agency’s definition of a statutory term—“detailed”—which is not elucidated in the statute by a list “including” any specific definitions or examples. *See Seven Cnty. Infrastructure Coal. v. Eagle Cnty.*, 605 U.S. 168, 180-81 (2025) (cited at Opp. at 16); *see also* 42 U.S.C. § 4332(2)(C).

The structure of the statute confirms that CMS lacks authority to limit the medical frailty exclusion for the enumerated sub-categories by imposing a significant-impairment qualification. CMS asserts that, because “three of the five enumerated categories are explicitly functional,” the statute somehow grants the Secretary expanded authority to graft additional functional requirements onto all five categories. Opp. at 18. But this gets it entirely backwards: the fact that Congress already addressed the degree of functional limitation necessary to bring certain enumerated conditions within the “medically frail” definition confirms that CMS cannot layer on additional impairment-based limitations. “Where Congress has spoken with specificity, an agency may not promulgate regulations that are an attempted addition to the statute of something which is not there, even if the intent behind the attempted addition is consistent with the intent behind the

² CMS also invokes the Secretary’s authority to specify standards for the determination of “specified excluded individual[s]” to support their unlawful regulations. *See* Opp. at 20-22. But that provision grants the Secretary the authority to outline the processes by which States determine who is excluded, not to define terms. If the creation of “standards” included the power to define “medically frail,” then the later definitional grant would be “superfluous.” *Dep’t of Agric. Rural Dev. Rural Hous. Serv. v. Kirtz*, 601 U.S. 42, 53 (2024). And, in any case, that authority also does not allow CMS to exclude from medical frailty those whom the statute directs it to include.

authorizing statute.” *In re JPMorgan Chase Bank, N.A.*, 799 F.3d 36, 42 (1st Cir. 2015). And here, Congress has explicitly indicated whether and how a functional requirement defines whether an individual is entitled to the medical frailty exclusion. *See, e.g.*, 42 U.S.C. 1396a(xx)(9)(A)(ii)(V)(dd) (identifying individuals “with a physical, intellectual or developmental disability that significantly impairs their ability to perform 1 or more activities of daily living” as one of the medically frail sub-categories). The IFR’s addition of a separate functional limitation that applies to all of the sub-categories is precisely the type of “attempted addition” that is not allowed. *In re JPMorgan*, 799 F.3d at 42. And because Congress “knew how to impose a [significant impairment] restriction” as evidenced by 42 U.S.C. 1396a(xx)(9)(A)(ii)(V)(dd), this Court should read “the statute’s general provisions [without] such a limitation.” *Santana v. Holder*, 731 F.3d 50, 56 (1st Cir. 2013).

The history of the statutory definition also refutes CMS’s interpretation. As CMS notes, the longstanding ABP regulation identified the enumerated sub-groups as “medically frail” without qualification. Opp. at 6-10; *see also* Ex. 26,³ at 12-13. Congress then incorporated that regulation with minor alterations into H.R. 1. When “Congress chooses a term that has a well-established meaning as [an] administrative agency ... has previously defined it, the court should look to that agency ... definition in construing the meaning of the statute.” *Duckworth v. Pratt & Whitney, Inc.*, 152 F.3d 1, 6 n.6 (1st Cir. 1998); *see also Taggart v. Lorenzen*, 587 U.S. 554, 560 (2019) (“When a statutory term is obviously transplanted from another legal source, it brings the old soil with it.”).

With the text, structure, and history of the statute uniformly aligned against the IFR’s significant-impairment limit, the agency is left to make an argument that is contravened by the language of the IFR itself: that the limitation is an exercise of the Secretary’s discretion to place

³ References to “Ex.” herein refer to Exhibits to the Declaration of Nita K. Klunder, dated June 29, 2026, at ECF 6.

“individual limiting definitions” on each of the statutory sub-categories. Opp. at 18. In other words, CMS contends that the grant of definitional authority allows it to define the “broad and potentially ambiguous” list of conditions that the statute says must be included in the medical frailty definition—to specify what it means, for example, to have a “serious” or “complex” medical condition, a disabling “mental disorder,” or a “substance use disorder.” *Id.* at 16.

Even assuming that the statute granted such authority, that is not what CMS did in adding the significant-impairment limitation. That limitation applies to individuals who are already determined to have a condition that brings them within the statutorily mandated sub-categories. The IFR states that an “individual who is medically frail or otherwise has special medical needs is defined as an individual [1] whose ... health condition significantly impairs the individual’s ability to comply with the community engagement requirement ... **and** [2] is an individual [who meets one of the five sub-categories].” 42 C.F.R. § 435.554(c)(5)(i) (emphasis added). This plainly creates two separate and distinct preconditions for the medical frailty exclusion: (1) having one of the five medical conditions contemplated by the statute, and then (2) meeting the significant-impairment limitation. Under CMS’s implausible interpretation, an individual could have a “disabling mental disorder” within the meaning of the IFR at 42 C.F.R. § 435.554(c)(5)(i)(C), but if they fail to show that the disorder also significantly impairs their ability to comply with the Work Requirement, that same individual would not have a “disabling mental disorder” for purposes of the statutory exclusion, 42 U.S.C. § 1396a(xx)(9)(A)(ii)(V)(cc). That bizarre result contradicts the canon that “word[s] in an implementing regulation track[] the meaning of th[ose] same word[s] in the authorizing statute.” *Friends of Animals v. U.S. Fish & Wildlife Serv.*, 28 F.4th 19, 29 (9th Cir. 2022). In short, CMS did not offer individual interpretations of the sub-categories when it imposed

the significant-impairment limitation; it added a separate requirement that will deny the medical frailty exclusion to many people who fall within the statute’s enumerated sub-categories.⁴

2. The Declared Emergency Limitation is contrary to law.

As to the emergency declaration exception, the Secretary makes the surprising statement that the statute does not define “[w]hat it means for a ‘short-term’ emergency to ‘exist’ on a ‘county’ level.” Opp. at 20. That assertion ignores the plain text of the statute, which—under the heading “short-term hardship event defined”—details the kinds of Presidential declarations and economic conditions that constitute a short-term hardship under the statute. 42 U.S.C. § 1396a(xx)(3)(B)(ii). And because “Congress has spoken with specificity,” the Secretary’s “attempted addition to the statute of something which is not there” is impermissible. *In re JPMorgan*, 799 F.3d at 42. Even assuming that the Secretary has some authority to set the standards under which an emergency might be identified, nothing in the text equates emergencies with failure to follow the Work Requirement. CMS may believe that Congress’s national emergency exception is too broad. But while a “statute may be imperfect,” an agency “has no power to correct flaws that it perceives in the statute.” *Bd. of Governors of Fed. Rsrv. Sys. v. Dimension Fin. Corp.*, 474 U.S. 361, 374 (1986); *see also Central United Life Ins. Co. v. Burwell*, 827 F.3d 70, 73 (D.C. Cir 2016).

B. The promulgation of the Challenged Provisions was arbitrary and capricious.

Plaintiffs are also likely to prevail on the merits because CMS has flagrantly failed to meet its obligations under the APA. CMS has repeatedly failed to “consider an important aspect of the problem,” *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983), or provide an “adequate reason[] for its decisions.” *Encino Motorcars, LLC v.*

⁴ Even if CMS were actually defining the individual categories, those definitions would be arbitrary and capricious because at no point in the IFR was it “reasonably explained” why each of these five unique statutory exceptions are best read to require the imposition of a significant-impairment requirement. *Ohio v. EPA*, 603 U.S. 279, 292 (2024).

Navarro, 579 U.S. 211, 221 (2016).

1. Defendants have failed to consider the impacts of the Challenged Provisions on States and Medicaid members.

CMS did not acknowledge its departure from guidance it provided States less than a month before the IFR and failed to account for the nearly impossible burden the IFR’s modified Work Requirement has placed on States that relied on that earlier guidance. Plaintiff States, as they and CMS understood was necessary, began time-consuming and costly efforts to implement H.R. 1’s Work Requirement immediately after enactment. Ex. 12, ¶ 11. Both Plaintiffs and CMS were faced with the staggering challenge of implementing the Work Requirement by January 2027. As such, CMS provided detailed guidance, frequent meetings, and an exemplar in Nebraska’s early roll out.⁵ ECF 1-1 at 5 (CMS to release formal guidance “on a rolling basis in 2025-2026”), 25 (CMS acknowledges that full implementation of Work Requirement is a complex multi-variable process), 35 (CMS to resume weekly meetings with States). And just as CMS intended, the States relied on its guidance. Ex. 16, ¶ 41; Ex. 19, ¶ 43; Ex. 21, ¶ 41. Having engaged in this crucial partnership for at least seven months, CMS was not free to ignore the burden placed on Plaintiffs by changing key system and policy requirements a few months before a major implementation deadline. This is more than an “important aspect of the problem”: it is *the* key gating factor for launching the Work Requirement on time.⁶ *State Farm*, 463 U.S. at 43.

CMS suggests that because its prior guidance was subregulatory, it can simply ignore the extent to which States relied on the agency’s prior actions. *See* Opp. at 23-25. But even assuming *arguendo* that subregulatory guidance does not trigger the formal “change-of-position” doctrine—

⁵ Defendants attempt to disclaim approval of Nebraska’s early launch is belied by the fact that Defendant Oz appeared at the December 2025 press conference announcing Nebraska’s rollout. Ex. 29. Moreover, Nebraska’s early implementation is cited in the IFR. 91 Fed. Reg. 33459.

⁶ Defendants have also denied Plaintiffs’ request for a six-month extension to the implementation deadline, ECF 56 at 1, even though Congress has permitted such extensions to last up to two years. 42 U.S.C. § 1396a(xx)(11)(C)(i).

which requires a specific explanation about the change of position—prior guidance can create significant reliance interests and important aspects of the problem that the agency must consider. *FDA v. Wages & White Lion* is thus inapposite because it deals only with the formal “change-in-position” doctrine. 604 U.S. 542, 568 (2025). And in any event, the Supreme Court there assumed (without deciding) that the change-in-position doctrine *does* “appl[y] to an agency’s divergence from a position articulated in nonbinding guidance documents.” *Id.* at 569 n.5.

Here, that the States’ reliance interests were an “important factor” is clear from CMS’s own statements. The November 2025 slide deck presenting CMS’s pre-IFR guidance emphasized that “[S]tates ... are *strongly encouraged* to review this deck to inform planning.” ECF 1-1 at 5 (emphasis added). Even now, CMS concedes that it “began engaging with the States in November 2025—seven months before the rule was due—*so that States could begin planning* against an unusually short congressional clock.” Opp. at 25 (emphasis added). Having encouraged the States to rely on its pre-IFR statements, CMS cannot now ignore the impact of that contrary guidance.

CMS argues that “an agency need not weigh a reliance interest that is not legitimate, longstanding, and serious.” Opp. at 25. As an initial matter, there is little doubt that the reliance interests here are substantial. *See, e.g.,* Ex. 11, ¶ 53. But regardless of the agency’s *post hoc* view of the importance of the States’ reliance interests, this does not excuse its failure to contemporaneously “consider whether there [are] reliance interests, determine whether they [are] significant, and weigh any such interests against competing policy concerns.” *Doe v. Noem*, 152 F.4th 272, 290 (1st Cir. 2025); *Kisor v. Wilkie*, 588 U.S. 558, 579 (2019) (“[C]ourt should decline to defer to a merely ‘convenient litigating position’ or ‘*post hoc* rationalizatio[n] advanced’ to ‘defend past agency action against attack.’”). Indeed, *DHS v. Regents of the Univ. of Cal.* squarely rejects the argument CMS makes here—that it “did not need to” “consider[] potential reliance

interests” because of legal disclaimers noting that the agency’s views could change. 591 U.S. 1, 31 (2020). While “disclaimers are surely pertinent in considering the strength of any reliance interests, [] that consideration must be undertaken by the agency in the first instance.” *Id.* And because, like here, “[t]here was no such consideration” of those interests, the agency’s action was arbitrary and capricious. *Id.*

In addition to the nearly impossible runway CMS forced on Plaintiffs without consideration, it also failed to consider the operational burdens that implementing the IFR’s modified Work Requirement would place on States and the broad loss of health insurance coverage for members and enrollees. CMS attempts to elide this issue by conflating the impact of the IFR with the impact of the statute. Opp. at 21-23. But there is no dispute that the IFR adds provisions that do not exist in the statute and that will significantly increase disenrollments. So even if CMS had authority to add those provisions—which it did not, *see supra* at Part I.A—it was required to identify, address, and weigh the resulting burdens and impacts on the States and Medicaid enrollees. *Massachusetts v. Dep’t of Educ.*, 2026 WL 918941, at **2, 8–9 (D. Mass. Apr. 3, 2026) (agency must do more than address concerns in a “cursory fashion”). The Regulatory Impact Analysis (RIA) on which CMS relies only articulates costs and disenrollments arising from H.R. 1, not from the IFR. Most importantly, there are no references to additional costs or hours that will be spent (by members or agencies) or disenrollments that will occur as a result of the Medically Frail Definition. *See generally* 91 Fed. Reg. 33425–449. This is unsurprising because the significant-impairment limitation appears to have been a last-minute addition. At the time CMS submitted the IFR to OMB (March 31, 2026),⁷ the agency’s guidance to the States made no mention of such a limitation. In fact, a month later, on May 1, 2026, CMS was still discussing the

⁷ <https://perma.cc/XVZ5-CRCD>; Plaintiffs’ counsel requested a copy of the original IFR submitted to OIRA pursuant to Executive Order 12866 on July 20, 2026. Declaration of Nita K. Klunder, dated July 21, 2026, ¶ 4, Ex. 31.

medically frail exclusion without any reference to significant impairment. Ex. 5, ¶ 17.

CMS’s arbitrary and capricious failure to analyze the impact of the IFR’s new limitations is further illustrated by its failure to “examine relevant data” that it had available at the time it promulgated the IFR. *State Farm*, 463 U.S. at 43. First, CMS references—but then inexplicably excludes from the RIA—the most salient data available: earlier state-specific deployment of work requirements. 91 Fed. Reg. 33350, 33456. Ignoring inconvenient evidence and incorrectly asserting that “there is no direct historical experience from which to derive empirical estimates,” *id.*, is the height of arbitrariness. This is especially so where that evidence makes clear the harms of a more stringent work requirement. *See, e.g.*, Ex. 26 at 19 n.98. Second, CMS ignored disenrollment data provided by the Congressional Budget Office (CBO) in fall 2025 regarding H.R. 1. CBO, *Pub. L. No. 119-21* (Oct. 28, 2025), <https://perma.cc/6J7Y-8CG4>. While the CBO data was based on the less restrictive approach of H.R. 1, not the IFR, it calculated the number of disenrollments by 2034 as 5.3 million people, *id.* at 5-6, whereas the RIA, which should have yielded a higher number if it actually grappled with the consequences of the IFR and not just H.R. 1, put that number at 3.3 million people disenrolled, *see* 91 Fed. Reg. 33461.

The IFR similarly fails to consider the consequences of the Claims Period Limitation. 91 Fed. Reg. 33425–449. The Claims Period Limitation will lead to the disenrollment of otherwise eligible applicants and Medicaid members. CMS blithely says, “[t]he policy choice of how to balance such losses with rigorous enforcement ... was CMS’s to make, and it made that choice reasonably.” Opp. at 22. CMS certainly made a choice, but it did not do so reasonably (nor does simply calling it “reasonable” in litigation make it so). *See Kisor*, 588 U.S. at 579. To make a rational policy decision, an agency must, at a minimum, acknowledge what is at stake on each side of the scale. Defendants never considered how many people would lose, or never get, Medicaid

coverage as a result of limiting the review period to twelve months. While CMS may have the authority to weigh these competing factors and prioritize one over the other, it cannot ignore the analysis all together. *See California v. Dep't of Educ.*, 132 F. 4th 92, 98 (1st Cir. 2025).

2. The Medically Frail Definition and Claims Period Limitation are unsupported by any reasoned decisionmaking.

Even if CMS's definition of medical frailty were within Congress's delegation of authority, the agency has failed to provide any reasoned explanation for the significant-impairment limitation. CMS's explanation that it reflects the "best reading" of the statute fails for two reasons. First, in defending its authority to impose the significant-impairment limitation, CMS insists that the statute left the choice of such a limitation up to the agency. *Opp.* at 22. It cannot be both that the statute was agnostic as to the inclusion of a significant-impairment limitation *and* somehow directed the agency to include it. Second, CMS does not point to anything in the statute supporting its contention that the "best reading" compels a significant-impairment limitation. Although CMS claims that the phrase "medically frail or ... special medical needs" somehow "connotes diminished functional capacity," 91 Fed. Reg. 33373, it offers no evidence or even argument in support of this conclusory assertion. Indeed, the agency does not dispute that the medical frailty exclusion was likely designed to ensure continuity of care for medically vulnerable populations regardless of their ability to work.⁸ CMS is left to make the entirely circular argument that reading the statute without its regulation "risk[s] sweeping in" those who do not meet its regulatory definition.⁹ *Opp.* at 22. That is not reasoned decisionmaking.

Finally, Defendants' sole basis for the 12-month Claim Period Limitation is "older

⁸ CMS does not address why other categories of excluded individuals are clearly unrelated to ability-to-work, suggesting Congress sought to ensure uninterrupted care for vulnerable populations. 42 U.S.C. § 1396a(xx)(9)(a)(ii).

⁹ Defendants also apparently rely on this as their sole rationale for limiting States from relying solely on diagnosis or condition data in making medically frail determinations. This rationale is equally infirm as to the *ex parte* verification limitation as it is for the Medically Frail Definition.

information *may not* reflect the individual’s current condition.” 91 Fed. Reg. 33405 (emphasis added). But it *may* reflect an individual’s current condition, and CMS offers no explanation as to why State Medicaid agencies should be barred from determining whether older data bears on an individual’s current condition—as is the case for people with chronic or permanent conditions such as multiple sclerosis, spinal stenosis, or cerebral palsy. Defendants claim that States could simply look at other data, like an SSDI determination, Opp. at 27, but this only works where the individual has an SSDI determination. Indeed, CMS routinely uses longer lookback periods to assess chronic conditions.¹⁰ And a longer lookback period is also consistent with CMS regulations requiring States to make *ex parte* renewal determinations—that is, to rely on data already available to the state agency—where possible. *See* 42 C.F.R. §435.916(a)-(b), § 457.343. Moreover, CMS was well-aware that arbitrarily cutting off the lookback period would cause many otherwise-eligible members to lose coverage. Declaration of Nita K. Klunder, dated July 21, 2026, Ex. 32, ¶¶ 4-5. Against that context and given the absence of any stated need for a 12-month limit, the Claim Period Limitation is arbitrary and capricious.

II. The equities compel preliminary relief.

CMS dismisses Plaintiffs’ administrative burdens and costs as insufficiently “serious” to establish irreparable harm, Opp. at 29, but that argument fails both legally and factually. First, the relevant inquiry “focuses on irreparability, irrespective of the magnitude of the injury.” *Washington v. Trump*, 145 F.4th 1013, 1036 (9th Cir. 2025); *see also Rio Grande Community Health Center, Inc v. Rullan*, 397 F.3d 56, 76 (1st Cir. 2005) (“Irreparable harm” simply “means an injury that cannot adequately be compensated” by a later injunction or damages remedy). Second, as a factual matter, Plaintiffs’ harms would easily clear any “seriousness” standard. *See generally* Br. at 16-20.

¹⁰ CMS, *Chronic Conditions Data Warehouse: Chronic Conditions*, <https://perma.cc/UV3N-BG5V>.

Maryland, for example, estimates that compliance with the IFR’s modified Work Requirement will cost “at least an additional \$2 million in state funds alone.” Ex. 10, ¶ 62. Indeed, the States’ declarations provide detailed—and undisputed—explanations of the substantial overhaul States will need to undertake to comply with the IFR’s departure from the statute. *See, e.g.*, Ex. 2, ¶¶ 53-55; Ex. 3, ¶¶ 69-72; Ex. 4, ¶¶ 53-55; Ex. 5, ¶¶ 54-57. Such changes will be “very challenging and costly” to the States, beyond what they would otherwise incur to implement H.R. 1. Ex. 23, ¶ 20; *see also* Ex. 9, ¶ 20; Ex. 11, ¶ 24; Ex. 13, ¶ 18; Ex. 18, ¶ 19. And the fact that some federal support is available for implementation, *see* Opp. at 30, hardly refutes that State outlays are significant.

Courts routinely find States suffer irreparable harm when, as here, a federal policy imposes severe operational burdens on the administration of Medicaid or other benefits programs. *See, e.g.*, *Doe v. Trump*, 157 F.4th 36, 79 (1st Cir. 2025) (finding irreparable harms when States were forced to undertake “intensive alterations” to “eligibility verification systems for [] federal programs,” particularly where existence, as opposed to magnitude, of harms is undisputed); *New York v. DHS*, 969 F.3d 42, 86 (2d Cir. 2020) (finding irreparable harm where the States assert that federal action would require them “to undertake costly revisions to their [Medicaid] eligibility systems”); *California v. HHS*, 811 F. Supp. 3d 183, 210–11 (D. Mass. 2025) (“changes to existing procedures and systems” can “alone constitute an irreparable harm”); *New York v. DOJ*, 804 F. Supp. 3d 294, 331 (D.R.I. 2025) (“compliance costs really are irreparable”); *District of Columbia v. USDA*, 444 F. Supp. 3d 1, 39 (D.D.C. 2020) (burden of “training new and existing staff” and sending notices showed “irreparable injury in the form of significant regulatory and administrative burdens”).

Further, States will suffer another kind of irreparable harm: an increase in uncompensated care costs that state programs must cover due to the loss of health insurance for many medically vulnerable residents. Ex. 15, ¶¶ 57-58; Ex. 16, ¶¶ 57-58; Ex. 18, ¶¶ 57-58. Courts have repeatedly

found irreparable harm where a federal policy imposes such costs. *See, e.g., New York v. DHS*, 969 F.3d at 86 (strain on hospitals from more uninsured patients is irreparable); *Cook Cnty. v. Wolf*, 962 F.3d 208, 233 (7th Cir. 2020) (disenrollment from public health options led to “uncompensated emergency care from [publicly funded] hospital system” which led to “significant increase in costs [government] must bear”). Contrary to CMS’s suggestion, *Opp.* at 30, these costs will be incurred not only by private parties but also by the States’ public fiscs—through public hospitals and state uncompensated care programs. *Ex.* 19, ¶¶ 69-70; *Ex.* 20, ¶ 31. Moreover, “significant[] impediments to the delivery of basic health care services to vulnerable populations” itself supports a finding of irreparable injury to the States. *New York v. Trump*, 171 F.4th 1, 24–25 (1st Cir. 2026). Nor are the harms to public trust in state healthcare systems speculative; the record shows confusion over eligibility threatens damage to relationships that State agencies have spent years developing. *Ex.* 11, ¶ 63; *Ex.* 13, ¶ 52; *Ex.* 23, ¶ 49; *Ex.* 25, ¶ 55.¹¹

Finally, CMS’ suggestion that these costs are not irreparable because Plaintiffs can (1) ignore the IFR, (2) suffer untold millions in withheld Medicaid funds as a result, and (3) then reclaim those funds in an administrative proceeding after this case is closed is bizarre. *See Opp.* at 28-29. CMS cites no authority for this assertion, and courts considering recent challenges to burdensome Medicaid regulations have found that compliance costs constitute irreparable injury without suggesting that States could avoid that harm by violating federal law. *See, e.g., New York v. DHS*, 969 F.3d at 86; *California v. HHS*, 811 F. Supp. 3d at 210–11.

The other equities also favor Plaintiffs. While the government has an interest in “effectuat[ing] statutes enacted by representatives of the people,” *Opp.* at 31, that does not extend

¹¹ Defendants also suggest any penalties imposed by CMS could be recovered in the future. *See Opp.* at 28-29. But Plaintiffs’ irreparable harm is based primarily on compliance costs and other follow-on expenditures, which cannot be recouped. *See California v. Kennedy*, 802 F. Supp. 3d 273, 283 (D. Mass. 2025) (“Because plaintiffs are suing under the APA, they have no recourse to recover incurred costs if the challenged regulations are later found invalid.”).

to agency regulations that *contravene* duly-enacted statutes. *Cf. New York v. Kennedy*, 155 F.4th 67, 77 (1st Cir. 2025) (there is “no public interest in the perpetuation of unlawful agency action”).

III. The Court has broad equitable authority to order necessary relief and deny a bond.

CMS asks the Court to issue a “narrow” injunction because “the IFR is the only final agency action” in front of the Court. Opp. at 32. But when considering APA claims challenging discrete agency actions, courts have “broad [equitable] powers to order ‘mandatory affirmative relief.’” *NW Env’t. Def. Ctr. v. Bonneville Power Admin.*, 477 F.3d 668, 680–81 (9th Cir. 2007); *see also Doe v. Chao*, 540 U.S. 614, 619 n.1 (2004) (noting APA’s “general provisions for equitable relief”). And, “once invoked, the scope of a district court’s equitable powers ... is broad ... especially so where, as here, federal law is at issue and the public interest is involved.” *CREW v. DOJ*, 846 F.3d 1235, 1242 (D.C. Cir. 2017) (cleaned up); *see also Illinois v. FEMA*, 2025 WL 2908807 (D.R.I. Oct. 14, 2025) (granting relief in an APA case beyond vacatur, including prohibiting enforcement). Granting the relief Plaintiffs request—including enjoining enforcement of the August 31 notice deadline—is thus within this Court’s authority.

Finally, “no bond is required in suits to enforce important federal rights or ‘public interests,’” including those arising from “federal health and welfare statutes.” *Crowley v. Local No. 82*, 679 F.2d 978, 1000 (1st Cir. 1982), *rev’d on other grounds*, 467 U.S. 526 (1984). In a spate of recent cases, this Court has repeatedly applied that principle. *See, e.g., Öztürk v. Trump*, 819 F. Supp. 3d 45, 62 (D. Mass. 2025); *New York v. McMahon*, 784 F. Supp. 3d 311, 373 (D. Mass. 2025); *California v. Trump*, 786 F. Supp. 3d 359, 395 (D. Mass. 2025) (collecting other citations).

CONCLUSION

This Court should grant Plaintiffs’ Motion for a Preliminary Injunction.

Dated: July 21, 2026

Respectfully submitted,

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*pro hac vice granted

**pro hac vice forthcoming

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

COMMONWEALTH OF MASSACHUSETTS, et
al.,

Plaintiffs,

v.

MEHMET OZ, M.D., et al.,

Defendants.

CIVIL ACTION
NO. 26-12962

DECLARATION OF NITA K. KLUNDER

Pursuant to 28 U.S.C. § 1746, I, Nita K. Klunder, do hereby state:

1. I am an Assistant Attorney General in the Office of the Attorney General for the Commonwealth of Massachusetts. I am admitted to the U.S. District of Massachusetts and I appear on behalf of the Commonwealth of Massachusetts in this action.
2. I submit this declaration in support of Plaintiff States' Motion for a Preliminary Injunction, pursuant to Federal Rule of Civil Procedure 65.
3. I make the following statements of my own knowledge.
4. On July 20, 2026, pursuant to Sections 6(a)(3)(B), (C), and (E) of Executive Order 12866, I submitted a request via email to the Office of Management and Budget ("OMB") and to Dominic Mancini, Deputy Administrator, Office of Information and Regulatory Affairs ("OIRA"), OMB, at OIRA_submission@omb.eop.gov and dominic_mancini@omb.eop.gov, respectively. In that request, I sought the original version submitted to OIRA of RIN-00938-AV98, titled "Establishing Community Engagement Requirements for Certain Individuals Under Section 1902(xx) of the Social Security Act," along with "a redline between that version and the

final version with notation of any changes that were made at the request of OIRA.” A true and accurate copy of my July 20, 2026 request is attached to this declaration as **Exhibit 31**. I have not yet received a response to this request.

5. Attached to this declaration as **Exhibit 32** is a true and accurate copy of the Declaration of Hannah Katch, Founder and Principal, Katch Strategies, LLC.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this 21st day of July, 2026 in Denver, Colorado.

/s/ Nita K. Klunder

Nita K. Klunder

CERTIFICATE OF SERVICE

I certify that this document was filed through the CM/ECF system and will be sent electronically to the registered participants as identified in the Notice of Electronic Filing (NEF).

/s/ Nita K. Klunder

Nita K. Klunder

EXHIBIT 31

Kearns, Katherine (AGO)

From: Klunder, Nita (AGO)
Sent: Monday, July 20, 2026 1:25 PM
To: OIRA_submission@omb.eop.gov; dominic_mancini@omb.eop.gov
Subject: RE: RIN-00938-AV98 - request for original submission

All,

Forgive the serial emails, I think I have corrected all typos in the recipient email addresses. Please see below.

Nita

From: Klunder, Nita (AGO)
Sent: Thursday, July 16, 2026 4:53 PM
To: 'OIRA_submission@omb.eop.gov' <OIRA_submission@omb.eop.gov>
Cc: 'Dominic_J._Mancini@omb.eop.gov' <Dominic_J._Mancini@omb.eop.gov>
Subject: RIN-00938-AV98 - request for original submission

Hi there,

Pursuant to Executive Order 12866 Sections 6(a)(3)(B), (C), and (E) I'm requesting the original version first submitted to OIRA of RIN-00938-AV98, Establishing State Community Engagement Requirements for Certain Individuals Under Section 1902(xx) of the Social Security Act. I would also like a redline between that version and the final version with notation of any changes that were made at the request of OIRA.

Thanks very much, and please let me know if you need anything additional from me prior to fulfilling this request.

Nita

EXHIBIT 32

DECLARATION OF HANNAH KATCH

I, Hannah Katch, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the following is true and correct:

1. I am a resident of the District of Columbia. I am over the age of 18 and have personal knowledge of the matters set forth below. If called as a witness, I could and would testify competently to the matters set forth below.

2. I was previously a senior advisor in the Office of the Administrator at the Centers for Medicare & Medicaid Services (CMS) and worked closely with experts at the U.S. Department of Health and Human Services' Assistant Secretary for Planning and Evaluation (ASPE).

3. I am familiar with Drs. Benjamin Sommers, Ari Ne'eman, and Adrianna McIntyre. I have worked with Dr. Sommers in various capacities since 2020 and was familiar with his research for years prior to our working relationship.

4. On April 9, 2026, Drs. Sommers, Ne'eman, and McIntyre provided me with some research they had prepared relating to the new Medicaid work requirement. Among other findings, the research applied a claims-based frailty framework to evaluate approaches for using Medicaid data to automatically exclude individuals from work requirements when their diagnoses met the statutory definition of "medically frail." Their research found that a 24-month lookback period would automatically exclude 34.5% of Medicaid expansion enrollees subject to work requirements (7,260,275 people), compared with 26.9% (5,660,065) under a 1-year lookback — meaning shortening the lookback from two years to one could strip automatic exclusions from roughly 1.6 million medically frail enrollees. Their findings showed that excluded enrollees were substantially sicker than non-excluded enrollees, with markedly higher hospital, emergency department, HCBS, and nursing home use and a one-year mortality rate more than four times higher (0.9% vs. 0.2%,

p<0.001). These results indicate that a 1-year claims lookback period for medical frailty meaningfully narrows the excluded population relative to 2-years, and the excluded group's utilization and mortality profile confirms the framework captures genuinely high-need individuals.

5. I understand Drs. Sommers and Ne'eman shared this information with CMS on or about April 2 and in follow up communication on or about May 21, 2026.

I declare under penalty of perjury under the laws of the United States that, to the best of my knowledge, the foregoing is true and correct.

Executed this 20 day of July 2026.

/s/ *Hannah Katch*
Hannah Katch
Founder and Principal, Katch Strategies, LLC