

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

COMMONWEALTH OF
MASSACHUSETTS, *et al.*,

Plaintiffs,

v.

No. 1:26-cv-12962

MEHMET OZ, M.D., in his official capacity as
Director of the Centers for Medicare and
Medicaid Services, *et al.*,

Defendants.

**DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION
FOR A PRELIMINARY INJUNCTION**

TABLE OF CONTENTS

INTRODUCTION	1
BACKGROUND	3
I. The Medicaid Program	3
II. The Community Engagement Requirement For Medicaid Eligibility.....	4
A. The Community Engagement Requirement Does Not Apply To Individuals Who Are “Medically Frail”	4
B. Residence-Based Exceptions For “Short-Term Hardship Events”	5
III. The Interim Final Rule.....	6
A. Definition of “Medically Frail”	6
B. Definition of “Short-Term Hardship Event” Respecting Emergency Declarations.....	10
C. Verification Procedures For Community Engagement	11
IV. Plaintiffs’ Complaint And The Present Motion.....	13
STANDARD OF REVIEW	14
ARGUMENT	14
I. Plaintiffs Are Unlikely To Succeed On The Merits	14
A. The IFR Is Not Contrary To Law	14
B. The IFR Satisfies The APA’s Requirement Of Reasoned Decision-Making	21
II. Plaintiffs Fail To Establish Irreparable Harm	27
A. Plaintiffs Have Not Shown Their Legal Remedies Are Inadequate.....	28
B. Plaintiffs’ Allegations Of Irreparable Harm Are Not Sufficient	29
III. The Balance of Equities and the Public Interest Favor the Government.....	31
IV. If An Injunction Issues, It Should Be Narrowly Tailored And Accompanied By An Injunction Bond	32
CONCLUSION.....	33

TABLE OF AUTHORITIES

Cases

<i>A.L. Pharma, Inc. v. Shalala</i> , 62 F.3d 1484 (D.C. Cir. 1995)	32
<i>Am. Hosp. Ass’n v. Kennedy</i> , 164 F.4th 28 (1st Cir. 2026)	25
<i>Arkansas Dep’t of Health & Human Servs. v. Ahlborn</i> , 547 U.S. 268 (2006)	3
<i>Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.</i> , 591 U.S. 1, 33 (2020).....	23
<i>FCC v. Fox TV Stations, Inc.</i> , 556 U.S. 502 (2009)	25
<i>FCC v. Prometheus Radio Project</i> , 592 U.S. 414 (2021).	21
<i>FDA v. Wages & White Lion Invests., LLC</i> , 604 U.S. 542 (2025)	24, 25
<i>Feliciano v. Dep’t of Transp.</i> , 605 U.S. 38 (2025)	17
<i>Immigr. & Naturalization Serv. v. Legalization Assistance Project of the L.A. Cty. Fed’n of Labor</i> , 510 U.S. 1301 (1993)	31
<i>K-Mart Corp. v. Oriental Plaza, Inc.</i> , 875 F.2d 907 (1st Cir. 1989)	28
<i>Loper Bright Enters. v. Raimondo</i> , 603 U.S. 369 (2024)	15
<i>Maryland v. King</i> , 567 U.S. 1301 (2012)	31
<i>Mass. Ass’n of Older Ams. v. Sharp</i> , 700 F.2d 749 (1st Cir. 1983)	30, 31
<i>Mass. Coal. of Citizens with Disabilities v. Civ. Def. Agency</i> , 649 F.2d 71 (1st Cir. 1981)	27-28, 29, 31
<i>Massachusetts v. Mellon</i> , 262 U.S. 447 (1923)	30
<i>Murthy v. Missouri</i> , 603 U.S. 43 (2024)	30

<i>Nieves-Marquez v. Puerto Rico</i> , 353 F.3d 108 (1st Cir. 2003)	14
<i>Nken v. Holder</i> , 556 U.S. 418 (2009)	14, 31
<i>Pharm. Coal. for Patient Access v. United States</i> , 126 F.4th 947 (4th Cir. 2025)	16
<i>Pub. Int. Legal Found. v. Bellows</i> , 92 F.4th 36 (1st Cir. 2024)	16
<i>Puerto Rico v. United States</i> , 490 F.3d 50 (1st Cir. 2007)	32
<i>Sampson v. Murray</i> , 415 U.S. 61 (1974)	27
<i>Sedima, S.P.R.L. v. Imrex Co.</i> , 473 U.S. 479 (1985)	19
<i>Seven Cnty. Infrastructure Coal. v. Eagle Cnty.</i> , 605 U.S. 168 (2025)	16
<i>Shenzen Youme Info. Tech. Co., Ltd. v. FDA</i> , 147 F.4th 502 (5th Cir. 2025)	25
<i>Sindicato Puertorriqueño de Trabajadores v. Fortuño</i> , 699 F.3d 1 (1st Cir. 2012) (per curiam)	14
<i>Somerville Public Schools v. McMahon</i> , 139 F.4th 63 (1st Cir. 2025)	31
<i>Trump v. CASA, Inc.</i> , 606 U.S. 831 (2025)	32
<i>U.S. D.I.D. Corp. v. Windstream Commc'ns, Inc.</i> , 775 F.3d 128 (2d Cir. 2014)	33
<i>Univ. of Tex. v. Camenisch</i> , 451 U.S. 390 (1981)	27
<i>VanDerStock v. Garland</i> , 633 F. Supp. 3d 847 (N.D. Tex. 2022)	30
<i>Washington v. U.S. Dep't of Hous. & Urban Dev.</i> , 171 F.4th 473 (1st Cir. 2026)	14, 17
<i>Winter v. Nat. Res. Def. Council, Inc.</i> , 555 U.S. 7 (2008)	14, 31

Statutes

5 U.S.C. § 704	32
5 U.S.C. § 706	14, 21
42 U.S.C. § 1315	4
42 U.S.C. § 1320b-2	28
42 U.S.C. § 1382c	18, 19
42 U.S.C. § 1396	3
42 U.S.C. § 1396a	<i>passim</i>
42 U.S.C. § 1396b	3, 28
42 U.S.C. § 1396c	4, 28
42 U.S.C. § 1396u-7	6, 7
42 U.S.C. § 5121	6
50 U.S.C. § 160	6

Regulations

42 C.F.R. § 95.19	28
42 C.F.R. § 430.42	28
42 C.F.R. § 435.554	8, 10, 15
42 C.F.R. § 435.555	10, 11, 20
42 C.F.R. § 435.557	<i>passim</i>
42 C.F.R. § 435.557 –(viii)	12
42 C.F.R. § 440.315	7, 23, 24
42 CFR 440.315 to 42	7
Declaring a National Emergency at the Southern Border of the United States, 90 Fed. Reg. 8,327 (January 29, 2025)	11
Declaring a National Energy Emergency, 90 Fed. Reg. 8,433 (January 29, 2025)	10
Imposing Duties to Address the Flow of Illicit Drugs Across Our Northern Border, 90 Fed. Reg. 9,113 (February 7, 2025)	11
Community Engagement Requirement for Certain Individuals, 91 Fed. Reg. 33,348 (June 3, 2026) (June 3, 2026)	<i>passim</i>

Other Sources

Fed. R. Civ. P. 65	30, 32
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INTRODUCTION

In July 2025, Congress enacted, and the President signed into law, historic reforms to the Medicaid program. The centerpiece of those reforms is the community engagement requirement. It requires those who became eligible for Medicaid under the Affordable Care Act—generally speaking, nonpregnant adults ages 19 to 64 with incomes under 138 percent of the federal poverty line—to work, train, volunteer, or study to obtain coverage. *See* 42 U.S.C. § 1396a(xx). Congress directed the Secretary of Health and Human Services (“HHS”) to specify how the statute would be implemented and to define some of its key terms. And Congress directed that this take place swiftly. It set January 1, 2027, as the target date for implementation, and to pave the way, directed the Secretary to issue an interim final rule by June 1, 2026. Acting through the Centers for Medicare & Medicaid Services (“CMS”), he did so. Community Engagement Requirement for Certain Individuals, 91 Fed. Reg. 33,348 (June 3, 2026) (“IFR”).

Plaintiffs, a consortium of State governments, seek to bring a halt to these reforms. They sued CMS and HHS under the Administrative Procedure Act (“APA”) to challenge certain aspects of the Secretary’s implementation of § 1396a(xx). Their preliminary injunction motion, ECF No. 2, seeks to enjoin three key provisions of the IFR: its definition of the exclusion of individuals who are “medically frail or otherwise ha[ve] special medical needs,” 42 U.S.C. § 1396a(xx)(9)(ii)(V), as contrary to law and arbitrary and capricious; its definition of what constitutes a “short-term hardship event” when an individual “resides in a county . . . in which there exists an emergency or disaster declared by the President,” 42 U.S.C. § 1396a(xx)(3)(B)(ii)(II)(aa), as contrary to law and arbitrary and capricious; and its restriction on the use of claims data older than one year for use by state agencies to verify an individual’s “medically frail” status, 42 C.F.R. § 435.557(f)(1), as arbitrary and capricious.

For a preliminary injunction to issue, Plaintiffs carry the burden of making strong merits claims that are likely to succeed at final judgment; showing a serious, actual threat of irreparable harm; and demonstrating equities that weigh sharply in their favor. That burden is especially demanding here because Plaintiffs seek to enjoin implementation of a critical legislative reform

that Congress directed HHS to implement on an expedited basis. Plaintiffs fall short of making the necessary showing on any of the relevant preliminary injunction factors.

Plaintiffs' contrary-to-law claims lack merit across the board. Congress explicitly delegated to the Secretary the authority to "define[]" what individuals are "medically frail," and the IFR exercises that authority by, among other things, requiring that "medically frail" individuals show their condition "impairs [their] ability to engage in community engagement activities (including but not limited to work) or otherwise comply with the statutory requirements." 91 Fed. Reg. at 33,373. Plaintiffs would instead pose arbitrary limits on his authority to define what it means to be "medically frail." Under their rubric, "medically frail" is a one-way ratchet: the Secretary could create more categories of "medically frail" individuals, but would have to excuse from the community engagement requirement anyone with, for example, a substance use disorder that has no bearing on their ability to meet the requirement, such as a tobacco use disorder. Plaintiffs' reading distorts both the statutory text and Congress's intent and should be rejected. Plaintiffs' other contrary to law argument similarly ignores Congress's instructions to the Secretary to specify standards by which States can grant short-term hardship exemptions due to Presidentially declared emergencies. The IFR's explanation that the exemption applies when an emergency "affects the ability of applicable individuals to demonstrate community engagement in a particular county" falls well within this grant of authority.

CMS adequately explained its reasons for issuing the IFR, as well. Even though CMS followed Congress's direction to issue the IFR on an expedited schedule, without the benefit of a comment period before its issuance, CMS appropriately considered the burdens and challenges attendant to the requirements it is imposing on Plaintiffs and reasonably explained why it chose to proceed with those requirements. Plaintiffs also advocate for enjoining the IFR's "medically frail" provisions because the impairment requirement that the Secretary ultimately settled on was not previewed in phone calls and presentations given by CMS in the run-up to issuance of the IFR, but there is no basis in law for crediting supposed reliance interests in such presentations. Plaintiffs

may not agree with the policy Congress directed, or with CMS's approach to implementing that policy, but there is no doubt that CMS provided a reasonable explanation for the choices it made.

The remaining injunction factors support denial of Plaintiffs' motion. Plaintiffs' alleged irreparable injuries are simply the incidents of an agency being asked to implement a new policy with rapidity, and are not sufficiently serious to preliminarily enjoin key aspects of this important legislative reform. Moreover, since requirements of the Medicaid program are ultimately enforced through the withdrawal of money, there is not even a basis for Plaintiffs to say their legal remedies are inadequate. The balance of equities also tips sharply in CMS's favor, as the congressional policy of swiftly implementing the community engagement requirement far outweighs Plaintiffs' assignments of error, particularly their arbitrary and capricious claims, which are more appropriately addressed through participating in public comment on the IFR than emergency motion practice. Finally, the Court should narrow Plaintiffs' overbroad proposed injunction and require an injunction bond if it is inclined to issue an injunction. But for all of the reasons stated above, an injunction is not appropriate in this case.

For these reasons, the Court should deny Plaintiffs' motion.

BACKGROUND

I. The Medicaid Program

Enacted in 1965, Medicaid is a cooperative federal-state program in which the Federal Government supplies funding to States to assist them in providing medical assistance to specified categories of low-income individuals. 42 U.S.C. § 1396 *et seq.* Each state that elects to participate must submit a plan to the Secretary of Health and Human Services ("HHS"), who has delegated his authority under the Medicaid statute to the Administrator of the Centers for Medicare & Medicaid Services ("CMS"), for approval. *Id.* §§ 1396, 1396a; *Arkansas Dep't of Health & Human Servs. v. Ahlborn*, 547 U.S. 268, 275 (2006). If the plan is approved, the state receives Medicaid funds from the Federal Government for a percentage of the money spent by the state in providing covered medical care to eligible individuals. 42 U.S.C. § 1396b(a)(1). If state programs do not comply with the requirements of sections 1396 and 1396a, the Secretary can initiate proceedings

to deny federal financial participation (FFP) in whole or in part “until the Secretary is satisfied that there will no longer be any such failure to comply.” 42 U.S.C. § 1396c.

II. The Community Engagement Requirement For Medicaid Eligibility

On July 4, 2025, President Trump signed into law H.R. 1, known colloquially as the One Big Beautiful Bill Act, which CMS often refers to as the Working Families Tax Cut (“WFTC”) legislation. Pub. L. No. 119-21, 139 Stat. 72. As relevant here, the WFTC legislation contains a “community engagement requirement for certain individuals” in order to be eligible for Medicaid. *Id.* at 306 (section 71119). Paragraph (1) of the statute, encoded at 42 U.S.C. § 1396a(xx), requires the States to “provide, as a condition of eligibility for medical assistance for an applicable individual, that such individual is required to demonstrate community engagement.” 42 U.S.C. § 1396a(xx)(1). “Applicable individuals” are those made eligible for Medicaid by the Affordable Care Act—generally speaking, nonpregnant adults ages 19–64 with income under 138 percent of the federal poverty level, a group often referred to as the Medicaid “expansion population.”¹ Paragraph (2) defines the community engagement requirement that must be met for at least one month in a review period. The requirement can be met in many different ways, including part-time work, community service, or participation in a work or educational program. *Id.* § 1396a(xx)(2).

A. The Community Engagement Requirement Does Not Apply To Individuals Who Are “Medically Frail”

Paragraph (9) of § 1396a(xx) includes definitions used throughout the community engagement statute. The statute defines “applicable individuals,” as used in paragraph (1) and throughout the statute, both in terms of affirmative requirements and by carving out “specified excluded individuals” to whom the community engagement requirements do not apply. *Id.* § 1396a(xx)(9)(A)(i). “Specified excluded individual” means “an individual, as determined by the State (in accordance with standards specified by the Secretary),” who falls in certain categories,

¹ “Applicable individuals” also includes those eligible for or enrolled in a demonstration project under 42 U.S.C. § 1315 that provides coverage that meets minimum essential coverage requirements and who are ages 19–64, not pregnant, and not entitled to or enrolled in Medicare Part A or B, and who are not otherwise eligible to enroll in Medicaid under the state plan.

including pregnant and postpartum women, inmates at public institutions, participants in certain treatment programs for drug addiction or alcoholism, disabled veterans, certain caregivers, and members of Indian tribes. *Id.* § 1396a(xx)(9)(A)(ii)(II), (III), (IV), (VII), (VIII), (IX).

“Specified excluded individual” also includes someone “who is medically frail or otherwise has special medical needs (as defined by the Secretary), including an individual—

- (aa) who is blind or disabled (as defined in [42 U.S.C. §] 1382c)
- (bb) with a substance use disorder;
- (cc) with a disabling mental disorder;
- (dd) with a physical, intellectual or developmental disability that significantly impairs their ability to perform 1 or more activities of daily living; or
- (ee) with a serious or complex medical condition.”

Id. § 1396a(xx)(9)(A)(ii)(V). No other category of “specified excluded individual” contains the parenthetical “as defined by the Secretary” that modifies the phrase “medically frail or otherwise has special medical needs” in subclause (V). The only reference to any of these criteria elsewhere in the statute arises in the exceptions to community engagement due to “short-term hardship events” (to be discussed as a more general matter *infra*). In states that elect it, an exception to the community engagement rule may be granted to an individual if “such individual or their dependent must travel outside of their community for an extended period of time to receive medical services necessary to treat a serious or complex medical condition (as described in item (9)(A)(ii)(V)(ee)) that are not available within their community of residence.” *Id.* § 1396a(xx)(3)(B)(ii)(III).

B. Residence-Based Exceptions For “Short-Term Hardship Events”

Paragraph (3) of the community engagement requirement statute lists “exceptions” to the requirement. 42 U.S.C. § 1396a(xx)(3). In addition to mandatory exceptions for certain individuals which are not at issue here, the statute permits an “optional exception for short-term hardship events.” *Id.* § 1396a(xx)(3)(B). The statute provides that “in the case of an applicable individual who experiences a short-term hardship event during a month,” the States that have elected the short-term hardship exception “shall, under procedures established by the State (in accordance

with standards specified by the Secretary), in the case of a short-term hardship event described in clause (ii)(II) . . . deem such individual to have demonstrated community engagement under paragraph (2) for such month.” Clause (ii)(II)(aa) defines, in turn, counties (or equivalent local governments) experiencing emergency or disaster conditions. Individuals can be deemed in compliance with community engagement requirements if they live in a county where there is either an “emergency or disaster declared by the President” under the National Emergencies Act, 50 U.S.C. § 160 *et seq.*, or the Stafford Act, 42 U.S.C. § 5121 *et seq.*; or that meets certain unemployment benchmarks. *Id.* § 1396a(xx)(3)(B)(ii)(II)(aa)–(bb).

III. The Interim Final Rule

Congress directed CMS and the States to implement the community engagement requirement no later than January 1, 2027, and to begin providing notice no later than August 31, 2026, to beneficiaries of the need to comply. *See* 42 U.S.C. § 1396a(xx)(1), (8). To facilitate this rapid implementation, Congress directed CMS to “promulgate an interim final rule for purposes of implementing the provisions of, and the amendments made by,” the WFTC legislation by June 1, 2026. 139 Stat. at 314, § 71119(d). CMS did so, making an interim final rule available for inspection on June 1 that appeared in the Federal Register on June 3..

A. Definition of “Medically Frail”

CMS’s review of the “medically frail” exclusion, 91 Fed. Reg. at 33,372– 77, begins with a discussion of the term’s origins before proceeding to an explanation of how the term should be understood in the new context of community engagement. Although the phrase is not a new one to the Medicaid expansion population, the term is not used in precisely the same way in § 1396a(xx) as it has been used in the past, and takes on new resonance in the context of community engagement.

Prior to the WFTC legislation, 42 U.S.C. § 1396u-7 authorized States to offer so-called “alternative benefit plans,” or ABPs. As relevant here, States are required to provide coverage to a significant subset of individuals subject to the community engagement requirement (*i.e.*, individuals eligible for or enrolled in the adult expansion population at 42 U.S.C.

§ 1396a(a)(10)(A)(i)(VIII)) through an ABP. *See generally* 42 U.S.C. §§ 1396a(k)(1), 1396b(i)(26), 1396d(y). The ABP statute and implementing regulations provide protections related to enrollment in ABPs for those who are “medically frail or otherwise an individual with special medical needs (as identified in accordance with regulations of the Secretary).” *Id.* § 1396u-7(a)(2)(B)(vi). The broad grant of authority to the Secretary to “identify” these individuals in accordance with “regulations” mirrors § 1396a(xx)(9)(A)(ii)(V)’s grant of authority to the Secretary to “define” the meaning of that phrase for community engagement purposes.

The relevant regulation created to implement § 1396u-7(a)(2)(B)(vi), 42 C.F.R. § 440.315, limits a state’s ability to define “medically frail or an individual with special needs” as follows:

For these purposes, the State's definition of individuals who are medically frail or otherwise have special medical needs must at least include [certain individuals under the age of 19], individuals with disabling mental disorders (including children with serious emotional disturbances and adults with serious mental illness), individuals with chronic substance use disorders, individuals with serious and complex medical conditions, individuals with a physical, intellectual or developmental disability that significantly impairs their ability to perform 1 or more activities of daily living, or individuals with a disability determination based on Social Security criteria or in States that apply more restrictive criteria than the Supplemental Security Income program, the State plan criteria.

42 C.F.R. § 440.315(f).

Although the language of this regulation has surface similarities to § 1396a(xx)(9)(A)(ii)(V), there are no explicit references to § 1396u-7(a)(2)(B)(vi) or to its corresponding regulation in the text of the statute itself. While § 440.315(f) authorizes States to add categories of “medically frail” persons, subclause (V) empowers the Secretary to “define” the phrase. The text of the subclause deviates from § 440.315(f) in numerous ways:

Table 1: Differences Between “Medically Frail” Definition In ABP Regulation And Community Engagement Statute

Item	Redline of 42 CFR § 440.315(f) to 42 U.S.C. § 1396a(xx)(9)(A)(ii)(V)
(aa)	<u>who is blind or disabled (as defined in section 1382c of this title)</u> individuals with a disability determination based on Social Security criteria or in States that apply more restrictive criteria than the Supplemental Security Income program [“disability” under § 1382(c) is substantively the same as “a disability determination based on Social Security criteria”]

(bb)	individuals with chronic substance use disorders
(cc)	individuals with <u>a</u> disabling mental disorders (including children with serious emotional disturbances and adults with serious mental illness)
(dd)	with a physical, intellectual or developmental disability that significantly impairs their ability to perform 1 or more activities of daily living
(ee)	individuals with <u>a</u> serious and <u>or</u> complex medical conditions

As such, despite acknowledging “similarities” between these definitions, CMS exercised its authority to define “medically frail or otherwise has special medical needs” to create “a separate but similar definition of medically frail for community engagement purposes.” 91 Fed. Reg. at 33,373. At the same time, CMS did “not identif[y] any other populations that we believe could reasonably be considered medically frail outside of the five categories identified” in the statute. *Id.* It also expressed concern “that there may be more of an incentive for some States to include individuals who would not reasonably be considered medically frail.” *Id.* As such, the new “community engagement” rules define “medically frail or otherwise has special needs” to reflect the “distinct[ions]” between the community engagement requirements and the restrictions on ABPs, in two ways. *Id.* at 33,372.

First, the IFR limits the exclusion to individuals whose “physical, mental, or other behavioral health condition significantly impairs the individual’s ability to comply with the community engagement requirement,” regardless of which subpart the individual falls under. 42 C.F.R. § 435.554(c)(5)(i). That is because “[t]he best reading of the statutory phrase ‘medically frail or otherwise has special medical needs’ is one that considers not only the presence of a particular diagnosis or condition, but also the extent to which the condition impairs an individual’s ability to engage in community engagement activities (including but not limited to work).” 91 Fed. Reg. at 33,373. Congress authorized CMS to exercise reasoned discretion in defining “medically frail or otherwise has special medical needs” two times over: in § 1396a(xx)(9)(A)(ii) by authorizing the Secretary to set “standards” by which States determine which individuals are excluded, and in subclause (V) by reinforcing the Secretary’s ability to “define[]” “who is medically frail or otherwise has special medical needs” for purposes of the exclusion. And for all of the reasons set out in the IFR, it was reasonable for the Secretary to clarify that individuals who,

despite their condition, can meet the community engagement requirement should not be excluded from compliance with this requirement.

Second, the IFR refines the statutory definitions of the five categories of “medically frail or otherwise has special medical needs” in the following ways:

Table 2: Refinements To “Medically Frail” Definition In The IFR

Item	Redline of 42 U.S.C. § 1396a(xx)(9)(A)(ii)(V) to 42 C.F.R. § 435.554(c)(5)
(aa)	who is blind or disabled (as defined in section 1382e of this title <u>1614 of the Social Security Act</u>) [these are references to the same statute]
(bb)	with a substance use disorder, <u>excluding an individual in stable recovery (which means, an individual who is in recovery for 5 or more years)</u>
(cc)	with a disabling mental disorder
(dd)	with a physical, intellectual or developmental disability that significantly impairs their ability to perform 1 or more activities of daily living; or
(ee)	With a serious or complex medical condition <u>which is a medical condition that is life threatening, seriously disabling without necessarily being life threatening, causing significant pain or discomfort that can cause serious interruptions to life activities, requiring a major time or effort commitment from caregivers for a substantial period of time, requiring frequent monitoring, associated with severe consequences or negative consequences for someone else, affecting multiple organ systems, requiring management to tight physiological parameters, requiring coordination of multiple specialties, requiring treatment that carries a risk of serious complications, or requiring adjustment in non-medical environments.</u>

As Table 2 demonstrates, three of the five items are unchanged or have only cosmetic changes. With respect to item (bb), CMS excluded individuals in stable recovery “since their SUDs are unlikely to significantly impair their ability to comply with the community engagement requirement.” 91 Fed. Reg. at 33,374. With respect to item (ee), CMS relied upon a report the Institute of Medicine (now the National Academy of Medicine) prepared in a response to a request from the Health Care Financing Administration (now CMS) that developed a more nuanced definition of what it means for a medical condition to be “serious and complex,” and acknowledged that this determination is dynamic, as “conditions may be serious and complex at some points during [a patient’s] disease or disability,” but may not be “serious and complex for all patients at all times.” *Id.* at 33,375–76 & n.74. The IFR provides a list of conditions that the agency “believe[d] it would be reasonable for States to consider . . . serious or complex, when such

conditions significantly impair an individual’s ability to comply with the community engagement requirement,” as well as conditions that would typically not qualify. *Id.* at 33,376. Nonetheless, CMS did not provide an “exhaustive list” of conditions, giving room for the States to implement the exclusion with fidelity to the regulation. *Id.* at 33,376.

The IFR charges the States with developing “a list of diseases, diagnoses, disorders, or other health conditions to identify individuals” who meet the definition of “medically frail or otherwise has special medical needs.” 42 C.F.R. § 435.554(c)(5)(ii). It also mandates that States create “reasonable processes and criteria” for individuals “to request consideration for the exclusion” if they believe they qualify but do not meet the standard criteria. *Id.* § 435.554(c)(5)(ii)(C).

B. Definition of “Short-Term Hardship Event” Respecting Emergency Declarations

42 C.F.R. § 435.555(d)(2) implements the exception in § 1396a(xx)(3)(B) for individuals who “experience[] a short-term hardship event” arising from a Presidentially declared disaster or national emergency. In preparing the implementing regulations, CMS considered several complicating factors. First, “[u]nlike declared disasters, national emergencies are generally not declared for discrete areas of the country and are at times declared for situations that, while affecting the United States, are external to its borders” or applicable to a region. 91 Fed. Reg. at 33,384. But section 1396a(xx)(3)(B)(ii) looks to whether an emergency exists in a “county (or equivalent unit of local government).” Second, many national emergencies lack a clear end date and can be reauthorized on an annual basis. *Id.* To give a few examples, a “national energy emergency” was declared by the President in 2025² which identified “our Nation’s Northeast and West Coast” as areas with serious energy infrastructure problems, but in theory, the declaration applies nationally, as the energy “capacity of the United States . . . is inadequate to meet our Nation’s needs.” *Id.* at 33,385. There are also declared national emergencies at the “southern

² See Declaring a National Energy Emergency, 90 Fed. Reg. 8,433 (January 29, 2025).

border” and “northern border” of the United States³ that do not identify particular state or local government units impacted by the emergency. 91 Fed. Reg. at 33,384 & n.91.

CMS concluded that allowing an exception from the community engagement requirement to arise from any declared national emergency would “in effect nullify the community engagement requirement for an indefinite period of time . . . and would be inconsistent with the concept of a *short-term* hardship,” a term Congress used in the statute no less than six times. 91 Fed. Reg. at 33,385. It would also be discordant with the statute’s other explicit short-term hardship exceptions that prevent beneficiaries from meeting the community engagement requirement, including inpatient care, comparatively high unemployment, or a “serious or complex medical condition” that requires extended travel for treatment (as to both patients and caregivers). 42 U.S.C. § 1396a(xx)(3)(B)(ii)(I), (II)(bb), (III). Accordingly, the agency exercised the Secretary’s authority to “specif[y]” the “standards” by which States can grant “short-term hardship exceptions,” 42 C.F.R. § 435.555(d)(2), to provide that an “emergency exists when the emergency affects the ability of applicable individuals to demonstrate community engagement in a particular county or other equivalent unit of local government, or multiple counties, or statewide.” This articulation is more consistent with the text and purpose of the statute by limiting the circumstances in which the exception applies to cases of true “short-term hardship” similar to the other events described in 42 U.S.C. § 1396a(xx)(3)(B).

C. Verification Procedures For Community Engagement

The final provision relevant to the parties’ dispute concerns information States may use to verify an individual’s compliance with, or exception or exclusion from, the community engagement requirement. Section 1396a(xx)(5) creates a norm of “*ex parte* verifications”—*i.e.*, verifications that do not “require[e] . . . the applicable individual to submit additional information”—in order to reduce burdens on individuals. It instructs States, “in accordance with

³ See Declaring a National Emergency at the Southern Border of the United States, 90 Fed. Reg. 8,327 (January 29, 2025); Imposing Duties to Address the Flow of Illicit Drugs Across Our Northern Border, 90 Fed. Reg. 9,113 (February 7, 2025).

standards established by the Secretary,” to “establish processes and use reliable information available to the State . . . without requiring, where possible, the applicable individual to submit additional information.” 42 U.S.C. § 1396a(xx)(5).

The IFR provides an extensive definition of what sort of information is “reliable” for *ex parte* verification purposes, with eight illustrative examples of “reliable” sources.. 42 C.F.R. § 435.557(a)(i)–(viii). Two of those sources, “claim(s) relevant to the individual . . . including those that have been paid, pending, or denied,” and “encounter data,” are limited to information from “the preceding 12 months.” *Id.*

With respect to the “medical frailty” exclusion, the IFR provides further direction. States are to “attempt to verify that an individual is a specified excluded individual” on medical frailty grounds by “using reliable information available to the State, including claim(s) relevant to the individual that have been adjudicated in the preceding 12 months.” *Id.* § 435.557(f)(1). Although this definition is intended to be inclusive, the IFR explains elsewhere that claims data older than a year should be excluded when verifying “medical frailty” “because older information may not reflect the individual’s current condition.” 91 Fed. Reg. at 33,405. But the regulation does not limit States from looking to other forms of reliable information in adjudicating “medically frail” status.

Moreover, the absence of data appropriate for *ex parte* verification does not mean an individual will not be classified as “medically frail.” States are directed to establish procedures to gather additional information from the individual for purposes of determining whether or not they are “medically frail,” with the goal of eventually developing reliable claims that can be used to verify their condition once they are able to obtain treatment to address their condition. *Id.* § 435.557(f)(1); 91 Fed. Reg. at 33,406. These procedures allow States to determine someone is excluded from the community engagement requirement through self-attestation or other documentation provided to the State, with the goal of eventually transitioning to *ex parte* verification through claims data once the individual begins to receive Medicaid-covered services. 91 Fed. Reg. at 33,406. Beginning in 2028, States may accept these alternate forms of proof only

once during a period of enrollment when there is otherwise no reliable data for States to rely upon as to an enrollee's condition. 42 C.F.R. § 435.557(f)(1)(ii).

IV. Plaintiffs' Complaint And The Present Motion

Plaintiffs filed the operative complaint on June 29, 2026, along with a motion for a preliminary injunction. ECF No. 2 ("PI Mot."). The preliminary injunction raises two types of challenges to the IFR that arise under the APA: contrary to law claims and arbitrary and capricious claims. (The complaint raises other legal issues with the IFR, including a constitutional challenge to it under the Spending Clause, that are not advanced in the motion for a preliminary injunction.)

As to the first type of challenge, Plaintiffs raise two claims. First, they allege that the IFR improperly limited the medical frailty exclusion, 42 U.S.C. § 1396a(xx)(9)(A)(ii)(V), to include only individuals whose condition "significantly impairs the[ir] . . . ability to comply with the community engagement requirement." PI Mot. 6-8. Second, they allege the IFR improperly narrowed the category of Presidentially declared national emergencies that constitute a "short-term hardship event," 42 U.S.C. § 1396a(xx)(3)(B)(ii). PI Mot. 9.

Plaintiffs make three types of challenges to the reasoning of the IFR under the APA's provisions for review of "arbitrary and capricious" agency action. First, they allege that the "medically frail" definition, "short-term hardship event" definition, and the one-year limitation on claims data discussed above are all arbitrary and capricious because CMS failed to consider "the administrative burdens" they create "and the resulting impacts on health coverage" they impose on individuals who receive coverage as a result of the reforms of the Affordable Care Act (ACA) to expand Medicaid coverage. PI Mot. 10-12. Second, Plaintiffs advance a host of other reasons for deeming the "medical frailty" exclusion arbitrary and capricious, including failure to consider the States' reliance on discussions with CMS in advance of the IFR's release, failure to consider alternatives to the IFR's approach to the "medical frailty" issue, lack of a reasoned explanation for requiring impairment of the ability to meet the community engagement requirement, and failure to consider how States would verify the requirement on an *ex parte* basis. PI Mot. 13-16. Third, Plaintiffs allege that the one-year limitation on claims data is arbitrary and capricious for failing

to account for cases where individuals are likely “medically frail” but cannot demonstrate existence of a claim within the past year that would constitute “reliable evidence” of such a condition. PI Mot. 16.

STANDARD OF REVIEW

A preliminary injunction is “an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). A “plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.” *Id.* at 20. The third and fourth factors “merge when the Government is the opposing party.” *Nken v. Holder*, 556 U.S. 418, 435 (2009). The plaintiff bears the burden of demonstrating those requirements. *Nieves-Marquez v. Puerto Rico*, 353 F.3d 108, 120 (1st Cir. 2003).

“To demonstrate likelihood of success on the merits, plaintiffs must show ‘more than mere possibility’ of success—rather, they must establish a ‘strong likelihood’ that they will ultimately prevail.” *Sindicato Puertorriqueño de Trabajadores v. Fortuño*, 699 F.3d 1, 10 (1st Cir. 2012) (per curiam). The Supreme Court has also instructed that a preliminary injunction cannot issue on the basis of speculative or possible injury. Rather, the moving party must establish that irreparable harm is “*likely* in the absence of an injunction.” *Winter*, 555 U.S. at 22.

ARGUMENT

I. Plaintiffs Are Unlikely To Succeed On The Merits

A. The IFR Is Not Contrary To Law

Plaintiffs seek to enjoin CMS from applying and enforcing two provisions of the IFR on the grounds that they are “contrary to law.” *See* 5 U.S.C. § 706(2)(C). Both of Plaintiffs’ contentions present straightforward questions of statutory interpretation. “As usual, when tasked with interpreting a statute, we ‘must start with the text of the statute itself,’ aiming as best we can ‘to effectuate congressional intent.’” *Washington v. U.S. Dep’t of Hous. & Urban Dev.*, 171 F.4th 473, 490 (1st Cir. 2026) (quoting *Teles de Menezes v. Rubio*, 156 F.4th 1, 12 (1st Cir. 2025)). “In

a case involving an agency, of course, the statute’s meaning may well be that the agency is authorized to exercise a degree of discretion” in implementing the statute. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394 (2024). “When the best reading of a statute is that it delegates discretionary authority to an agency, the role of the reviewing court” in evaluating a contrary to law claim is to “recognize” the delegation and affirm the agency if the action falls within the bounds of the delegation. *Id.* at 394–95. The task of “ensuring the agency has engaged in ‘reasoned decisionmaking’ within those boundaries” is reserved for “arbitrary and capricious” review under §706(a)(A) of the APA. *Id.* (quoting *Michigan v. EPA*, 576 U.S. 743, 750 (2015)). Because the best reading of § 1396a(xx) authorizes CMS to define or specify (1) what individuals fall within the “medically frail” exclusion and (2) what national emergencies constitute a “short-term hardship event,” both of Plaintiffs’ challenges fail.

1. The Secretary Properly Exercised His Statutory Authority To Define The “Medically Frail” Exclusion

Section 1396a(xx)(9)(A)(ii) gives CMS authority to “specif[y]” the “standards” by which States “determine[]” whether an individual is a “specified excluded individual” for purposes of the community engagement requirement. And with respect to the exclusion for an individual who is “medically frail or otherwise has special medical needs,” Congress re-emphasized that this term of art is to be “defined by the Secretary.” 42 U.S.C. § 1396a(xx)(9)(A)(ii)(V). Under *Loper Bright*, courts presented with delegations of interpretive authority must “recognize” the delegation and permit reasonable exercises of that delegated authority. *Loper Bright*, 603 U.S. at 394–95. Here, the Secretary exercised this authority by defining what it means to have a “substance use disorder” or a “serious or complex medical condition,” and by requiring beneficiaries to show their ability to meet the community engagement requirement is “significantly impair[ed].” 42 C.F.R. § 435.554(b)(V)(i). The Court should reject Plaintiffs’ contrary reading of the statutory language.

Plaintiffs’ interpretation of § 1396a(xx)(9)(A)(ii) effectively reads the delegation to the Secretary out of the statute. They understand the phrase “including an individual” to excuse from the community engagement requirement anyone who could be said to meet their generous

understanding of items (aa) through (ee), “without any qualification,” such as individuals with any sort of substance use disorder. PI Mot. 7. On this reading, “Congress set the floor for the definition of medical frailty and permitted the agency to expand, but not contract, the definition beyond the enumerated categories.” *Id.* The Court should reject this reading of the statute.

First, Plaintiffs’ argument puts more weight on the term “including” than it can bear, and in so doing distorts the statute’s delegation to the Secretary. Plaintiffs contend that “include” is a term of enlargement rather than limitation. *See* PI Mot. 7 (citing *Pub. Int. Legal Found. v. Bellows*, 92 F.4th 36, 48 (1st Cir. 2024) (concluding phrase “shall include” indicated list was not limited to categories that followed it and was “further evidence” statute extended to other kinds of information); *Pharm. Coal. for Patient Access v. United States*, 126 F.4th 947, 960 (4th Cir. 2025) (interpreting phrase “any remuneration (including any kickback, bribe or rebate)” as precluding a limited reading of the term “remuneration”). But neither case cited by Plaintiffs involved a statute that paired “including” with an express grant of definitional authority to an agency, much less suggests that the agency may not supply content to the categories set out in the statute.

Plaintiffs’ understanding that the word “includes” rigidly fixes a term’s definition, rather than allowing discretion to ensure the definition is complete and consistent with the statute, is particularly inapt here. Many of the categories in the exclusion are broad and potentially ambiguous. *Seven Cnty. Infrastructure Coal. v. Eagle Cnty.*, 605 U.S. 168, 180–81 (2025) (concluding that whether an environmental impact statement is “detailed,” as required by statute, “requires the exercise of agency discretion—which should not be excessively second-guessed by a court,” even if the “the meaning of ‘detailed’ is a question of law to be decided by a court”). Section 1396a(xx) does not say what it means for someone to have a “substance use disorder”; what makes a “mental disorder” “disabling” or not; how much impairment of an activity of daily living is “significant”; or what a “serious or complex medical condition” is. Congress could have aligned subclause (V) more closely with the definition of the term used in the implementing regulations for ABP, which expressly delegates standard setting authority to the States. But the absence of an express reference to § 1396u-7 in subclause (V), as well as Congress’s numerous

changes to the language of the regulation, demonstrate this was not the aim. Instead, Congress tasked the Secretary with defining these terms, and the Secretary concluded that a functional limitation requirement marked the best interpretation of Congress's statutory language.

Second, Plaintiffs overlook that the definitional grant (“as defined by the Secretary”) of § 1396a(xx)(9)(A)(ii)(V) modifies “medically frail or otherwise has special medical needs.” The items that follow illustrate the term the Secretary was asked to define; they do not circumscribe his ability to promulgate a definition. As CMS explained, “[t]he best reading of the statutory phrase ‘medically frail or otherwise has special medical needs’ is one that considers not only the presence of a particular diagnosis or condition, but also the extent to which the condition impairs an individual’s ability to engage in community engagement activities.” 91 Fed. Reg. at 33,373. Congress could easily have written a floor such as “shall include, at a minimum,” or “and such other individuals as the Secretary may identify,” if it shared Plaintiffs’ understanding of the intention of this exclusion. Congress did not do so.

Third, Plaintiffs’ reading is problematic with respect to the text of § 1396a(xx)(9) as a whole. The goal of statutory interpretation is to effectuate Congress’s intent, with the statutory text as the starting point for that inquiry. *Washington*, 171 F.4th at 190. Paragraph (9)(A)(ii) already authorizes the Secretary to “specify” “standards” regarding all of the exclusions. Congress then accorded the Secretary a further grant of authority, under paragraph (9)(A)(ii)(V), to “define” the meaning of “medically frail or otherwise has special medical needs.” But Plaintiffs’ theory of paragraph (9)(A)(ii)(V) transforms this definitional power into a mere authority to add categories. This is hardly a power at all, as item (ee) provides a “serious . . . medical condition” as one of the categories. Plaintiffs’ reading would accord the Secretary *less* discretion over subclause (V) than he would have over any other category of excluded individual. The Court should assume Congress was not “wasting its breath” when it enacted § 1396a(xx) and give meaning to its delegations to the Secretary to define “medically frail.” *Feliciano v. Dep’t of Transp.*, 605 U.S. 38, 53 (2025).

Fourth, Plaintiffs’ reading yields consequences Congress cannot have intended. Plaintiffs advocate that the Secretary’s definition “must ‘includ[e],’ at a minimum, individuals who have one

of the five enumerated conditions—without *any* qualification.” PI Mot. 7 (emphasis added). But as noted above, many of the exclusions are broad and ambiguous. For example, does a person with a tobacco use disorder qualify as “medically frail” because he has a “substance use disorder,” even if he has no functional limitations whatsoever? Do asthmatics and diabetics have a “serious” or “complex” disorder if they are not functionally limited? Congress directed the Secretary to answer these questions, and nothing in the statute prevented him from answering them from a functional perspective. Not even Plaintiffs fully embrace the logic of their “without any qualification” position. They do not quarrel with the Secretary’s decision to limit the “substance use disorder” exclusion of item (bb) to those who are in “stable” recovery, and to incorporate the National Academy of Medicine’s definition of “complex or serious” for purposes of item (ee). Both interpretations “qualify” the exclusion’s scope. Whether the Secretary chooses to refine the categories provided by Congress through individual limiting definitions, or through an overall limitation on who is “medically frail,” he is properly exercising his power to define what “medically frail” means.

Fifth, Plaintiffs assert that Congress “did not want to tether the medical frailty exclusions overall to an individual’s ability to work,” and instead sought “continuity of care for individuals with especially significant health care needs.” PI Mot. 8. They first argue that because certain of the five exclusions contain some type of functional requirement, the Secretary lacked authority to impose a different functional requirement on the other exclusions. PI Mem. at 7-8 (citing (aa) (individuals who satisfy 42 U.S.C. § 1382c(a)(3)’s definition of disability) and (dd) (individuals “with a physical, intellectual or developmental disability that significantly impairs their ability to perform 1 or more activities of daily living”)). In fact, *three* of the five enumerated categories are explicitly functional, as item (cc) requires that a mental disorder be “disabling.” The presence of multiple functional categories in subclause (V) suggests a functional reading of the subclause is well within the Secretary’s statutory authority. Again, Plaintiffs do not follow through on the logic of their stance, as they did not challenge the Secretary’s decision to define “serious or complex

medical conditions” in item (ee) to include conditions that are “seriously disabling” or create “serious interruptions to life activities.”

Plaintiffs place special focus on item (aa) to make this argument, but again, it merely demonstrates the merits of the Secretary’s interpretation. PI Mem. 7 n.7. Item (aa) covers people the Social Security Administration (SSA) has already found “unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment.” 42 U.S.C. § 1382c(a)(3)(A). Someone who has been found unable to work in that sense will almost always meet the “significantly impairs” standard in the context of assessing community engagement, and Plaintiffs do not suggest otherwise. Thus, Congress’s leading example of a “medically frail” person is someone defined by functional incapacity, which hardly suggests Congress did not intend that the Secretary consider it.

Moving outside of paragraph (9)(A)(ii)(V), Plaintiffs assert that the other exclusions from who qualifies as an “applicable individual” speak to Congress’s intent not to tie the exclusions to functional qualifications. But they only cite to one such exclusion, for pregnant or postpartum women, *see* 42 U.S.C. § 1396a(xx)(9)(A)(ii)(IX), as “consistent” with the desire “to ensure continuity of care.” PI Mot. 8. Congress did not say why it created this exclusion, or why it excluded members of Indian tribes, caregivers, disabled veterans, participants in drug rehabilitation programs, and prisoners, as well. *Id.* § 1396a(xx)(9)(A)(ii)(II), (III), (IV), (VI), (VIII). A functional limitation cannot be inferred from these exclusions.

Finally, Plaintiffs invoke a “liberal construction” requirement for the Social Security Act that supposedly requires rejection of the Secretary’s interpretation. PI Mot. 8. No such rule of construction exists in the text of the community engagement statute, or, indeed, in the text of the Social Security Act as a whole. And even if such a principle exists, it “only serves as an aid for resolving an ambiguity; it is not to be used to beget one.” *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 492 n.10 (1985). Section 1396a(xx)(9)(A)(ii)(V) unambiguously accords the Secretary the power to define “medically frail or otherwise has special medical needs,” as explained above.

For these reasons, the best reading of § 1396a(xx)(9)(A)(ii)(V) gives the Secretary the authority to define what it means to be “medically frail,” and the Secretary acted within the boundaries the statute sets to connect the medical frailty determination with the ability to carry out the community engagement requirement. Plaintiffs’ contention that this choice was contrary to law should be rejected.

2. The Secretary Reasonably Exercised His Statutory Authority To Define What National Emergencies Constitute A “Short-Term Hardship Event”

Plaintiffs briefly address the “short-term hardship exception” in their motion for a preliminary injunction, arguing that Congress “deliberately chose to except those residing in areas in which there exists a declared emergency” from the community engagement requirement, and that CMS impermissibly narrowed the exception to emergencies that affect the ability of individuals to demonstrate community engagement. PI Mot. 9. But Plaintiffs’ argument starts from an oversimplification of the statutory text and falters from there. CMS has the authority to “specify” the “standards” by which a state can find that an individual sustained a “short-term hardship event” because that individual “resides *in a county* (or equivalent unit of local government) *in which there exists* an emergency or disaster” declared by the President. 42 U.S.C. §1396a(xx)(3)(B)(ii)(II) (emphasis added).

The President’s power to declare a national emergency is wide-ranging. Such declarations often lack geographic specificity, a clear end date, or a connection to conditions that would impede someone from complying with the community engagement requirement. What it means for a “short-term” emergency to “exist” on a “county” level is not a question the statute answers, and again, Congress directed the Secretary to specify an answer. He specified that the “short-term hardship exemption” arises when an “emergency affects the ability of applicable individuals to demonstrate community engagement in a particular county or other equivalent unit of local government, or multiple counties, or statewide.” 42 C.F.R. § 435.555(d)(2)(i). That specification faithfully implements the statutory exception for “short-term hardship” by limiting it to situations where a national emergency “exists” in a particular locality, or localities, such that the ability to

comply with § 1396a(xx) is affected. It also brings the exception in line with the other “short-term hardship” exceptions for counties with high levels of unemployment, individuals seeking inpatient treatment, and individuals engaged in extended travel for treatment of serious or complex medical conditions. Far from being contrary to law, the regulation falls squarely within the bounds of the Secretary’s statutory authority, and the Court should decline Plaintiffs’ invitation to enjoin it.

B. The IFR Satisfies The APA’s Requirement Of Reasoned Decision-Making

Plaintiffs’ arbitrary and capricious claims pursuant to 5 U.S.C. § 706(2)(A) are also unlikely to succeed on the merits. “[R]eview under [this] standard is deferential,” requiring a “court simply [to] ensure[] that the agency has acted within a zone of reasonableness and ... reasonably considered the relevant issues and reasonably explained the decision.” *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). Such deference is especially apt here. When Congress enacted the WFTC legislation, it directed CMS to issue an interim final rule no later than June 1, 2026, in light of the August 31, 2026 notice deadline for beneficiaries and a January 1, 2027 implementation date for the requirements. CMS met its June 1 deadline to issue an interim final rule soliciting comments. As such, so long as its “path may reasonably be discerned” from the record before the Court, deference to CMS should be given when reviewing the choices and trade-offs made in the IFR. *Encino Motorcars*, 579 U.S. at 221.

1. CMS Appropriately Considered Hardships Arising From Congress’s Eligibility Requirements

Plaintiffs begin with the administrative burdens the IFR places on themselves and their beneficiaries. They argue CMS did not consider the administrative burdens the IFR imposes on States and individuals seeking coverage, thus overlooking an important aspect of the problems arising from implementation of the community engagement requirement. PI Mot. 10–12. But CMS was, in fact, acutely aware of these burdens. The agency conducted a thorough review of the information collection and verification requirements of the IFR, as well as a complete estimate of total costs associated with the implementation of the requirement. 91 Fed. Reg. at 33,425–33,449. It considered alternative procedures for compliance and verification of eligibility and, “where

permitted . . . allow[ed] States to implement these requirements in a manner tailored to their specific needs.” *Id.* at 33,465–66. And when it could do so, it “aligned definitions of compliance activities as closely as possible with existing statutory and regulatory requirements across Medicaid and/or other Federal benefit programs to minimize disruption of States’ existing eligibility systems and operational capacities.” 91 Fed. Reg. at 33,465.

Plaintiffs may have preferred CMS to strike the balance between administrative simplicity and rigorous enforcement of the community engagement requirement differently. But CMS explained why it chose the policies challenged here. It defined “medical frailty” to avoid the risk of “sweeping in individuals whose conditions do not significantly impair their functional capacity” into the exception. 91 Fed. Reg. at 33,373. It defined the “short-term hardship” exception for a “national emergency” to avoid “nullify[ing] the community engagement requirement for an indefinite period of time.” *Id.* at 33,385. And it imposed a one-year lookback period on claims data because “older information may not reflect the individual’s current condition.” 91 Fed. Reg. at 33,405. Having acknowledged the potential costs of its implementation strategy—costs which are, to a significant degree, inherent in the policy Congress asked CMS to implement—CMS chose to proceed, and the reasons it gave for doing so satisfied the APA’s deferential review standard.

Plaintiffs proceed to argue that the IFR’s verification requirements are not well reasoned because they “will undoubtedly lead to a greater loss in coverage for Medicaid members” who fail to obtain coverage “because of the increased difficulty of showing eligibility.” PI Mot. 11. But as Plaintiffs must concede, CMS recognized that implementation of § 1396a(xx) would lead to eligible individuals losing coverage for administrative or procedural reasons, as well as individuals losing coverage due to being ineligible. 91 Fed. Reg. at 33,459–60. Such coverage losses are, to some degree, inherent in the administration of any eligibility. The policy choice of how to balance such losses with rigorous enforcement of Congress’s policy directives was CMS’s to make, and it made that choice reasonably.

Plaintiffs also articulate concerns about “the burdens on States of having to assess an individual’s ability to work.” PI Mot. 12. Again, CMS specifically considered the burden on

current enrollees, new applicants and enrollees, and the States that would arise from the verification requirements. 91 Fed. Reg. at 33,435 (Table 17, “Total Beneficiary Application Burden”). CMS understood the burdens the rule would impose but nonetheless chose to avoid categorizing individuals under the “medically frail” exclusion who are, in fact, capable of satisfying the community engagement requirements of the statute.

Plaintiffs may disagree with the policy trade-offs CMS made in the IFR, but CMS reasonably considered the burdens of implementation on States, applicants, and beneficiaries in conjunction with how it chose to implement the statute. That choice was not arbitrary and capricious.

2. CMS Appropriately Explained The Grounds For Its Definition Of The “Medically Frail” Standard

Plaintiffs raise at least four other bases for concluding the “medically frail” definition is arbitrary and capricious. PI Mot. 13–16. None has merit.

First, Plaintiffs argue that CMS failed to appropriately consider that the “impairment” standard found in the IFR was not previewed with the States prior to its issuance in the IFR, constituting a breach of the agency’s duty to consider reliance interests, as in *Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 33 (2020), or a failure to consider an important aspect of the problem, PI Mem. 13 n.10 (citing *Am. Hosp. Ass’n v. Kennedy*, 164 F.4th 28, 31 (1st Cir. 2026)). Plaintiffs allege that they began to build out systems to verify “medical frailty” based on expectations developed during calls between CMS and the States that the “medical frailty” framework would be “similar to that described in regulations at 42 C.F.R. §440.315(f), which closely resembles the language of [the WFTC legislation],” and that they could “verify the exclusion through medical claims data review or provider documentation, or completion of a screening tool.” PI Mot. 4 (cleaned up). According to Plaintiffs, they were never apprised of the possibility that the version of the “medically frail” exclusion that appears in the IFR was under consideration. They also allege that CMS approved of the State of Nebraska implementing the

community engagement requirement early, which further reinforced their view that the “medically frail” exception would be interpreted similarly to § 440.315(f). PI Mot. 14.

The Court should reject this argument. The change-in-position doctrine assumes a “changed *existing* policy,” *FDA v. Wages & White Lion Invests., LLC*, 604 U.S. 542, 569 (2025) (emphasis added). *Regents*, which Plaintiffs rely upon, presupposes not only a settled policy but one that regulated parties could reasonably treat as fixed and order their affairs around. No such policy exists here. Congress told CMS and the States, in the statute, that the operative policy would be set by an IFR at a date certain in the future. And although that fact alone would usually be enough to settle the legal question, the preliminary injunction record reflects that CMS was appropriately circumspect in its informal technical assistance presentations with Plaintiffs. CMS repeatedly stated that comments at these meetings constituted “CMS’ preliminary policy, systems, and operational considerations”; that “all information described here is preliminary and subject to change”; and that information was “intended only to be a general informal summary of technical legal standards.” CMS, *Implementing Section 71119 of the Working Families Tax Cut Legislation*, ECF No. 1-1 at 5 (Nov. 19, 2025). Each substantive slide, including the slide about the “medically frail” standard, restates that CMS’s engagement with stakeholders prior to the IFR’s issuance was “[p]re-decisional and iterative,” with “[a]ll policies and requirements are subject to change.” *Id.* at 11. As to medical frailty specifically, CMS stated only that its “intention” was to use a definition “similar to” that at 42 C.F.R. § 440.315(f), not an identical one. *Id.* Nebraska’s decision to implement the verification requirements ahead of an IFR was done without CMS’s formal approval, and therefore does not represent a fixed prior policy, either. Plaintiffs are sophisticated entities who routinely deal with CMS; they cannot claim reliance interests arising from pre-decisional slide decks in the face of both explicit statutory guidance as to how the relevant legal standard would be defined and CMS’s numerous disclaimers.

To get around the lack of an “existing” policy that CMS could plausibly be said to change, Plaintiffs argue that informal guidance documents can give rise to legally cognizable reliance interests. But as the Supreme Court has cautioned, “[w]e have traditionally applied the change-in-

position doctrine” only “when an agency shifts from a position expressed in a more formal setting,” *FDA v. Wages & White Lion Invs.*, 604 U.S. at 569 n.5 (2025)—for example, by “rescind[ing] a prior regulation,” *id.* at 570; *See also, e.g., Fox TV Stations, Inc.*, 556 U.S. 502. The doctrine simply has no application here, where no policy existed here until issuance of the IFR. But even if the Court were to hold that such informal conversations could give rise to reliance interests, the argument fails. “A legitimate reliance interest is a high bar,” on a par with ““decades of industry reliance.”” *Shenzhen Youme Info. Tech. Co., Ltd. v. FDA*, 147 F.4th 502, 513 (5th Cir. 2025) (quoting *Wages & White Lion*, 604 U.S. at 570). Seven months of cautious pre-decisional technical assistance and one state proceeding without formal CMS approval, when an IFR was to be issued imminently, does not meet this high bar.

That conclusion disposes of Plaintiffs’ fallback argument as well. Plaintiffs suggest that even if the change-in-position doctrine is not triggered, their reliance remains an “important aspect of the problem” that CMS was independently obliged to weigh. PI Mem. 13 n.10 (citing *Am. Hosp. Ass’n v. Kennedy*, 164 F.4th 28, 31 (1st Cir. 2026)). But an agency need not weigh a reliance interest that is not legitimate, longstanding, and serious. In *American Hospital Association*, the relevant reliance interest was based “on more than thirty years of established practice.” *Id.* at 32. No such interest exists here.

The practical implications of Plaintiffs’ reliance arguments are also significant. CMS began engaging the States in November 2025—seven months before the rule was due—so that States could begin planning against an unusually short congressional clock. If pre-decisional technical assistance of that kind generates binding reliance interests enforceable under the APA, even in the face of clear disclaimers about the nature of the advice, agencies operating under compressed statutory deadlines will simply stop providing it. The States would be the losers if CMS becomes more circumspect about engaging in such consultations if they create the potential for cognizable reliance interests.

Second, Plaintiffs fault CMS for overlooking less restrictive ways of implementing the “medically frail” exclusion. PI Mot. 14. They also argue it was arbitrary and capricious for CMS

to take an approach to the “medically frail” exclusion that does not rely solely on records that can be verified *ex parte* by the States. PI Mot. 15-16. But CMS explicitly considered, and rejected, the less restrictive proposal that Plaintiffs prefer:

Reading the statute to require automatic classification as medically frail or otherwise having special medical needs based solely on diagnosis or condition would risk sweeping in individuals whose conditions do not significantly impair their functional capacity, meaning that they are able to perform 80 hours per month of qualifying activities, and thus would fail to give full meaning to the term “medically frail or who otherwise has special medical needs.”

91 Fed. Reg. at 33,373. Plaintiffs may not agree with that explanation for rejecting their preferred approach, but they cannot claim that CMS failed to consider that approach. Moreover, it does not follow that this approach will always require soliciting input from beneficiaries, as Plaintiffs suggest. States “should have access” to, among other things, other forms of relevant information from federal, State, or local agencies; the State’s eligibility system; the individual’s case record; payroll data; and encounter data, from which a finding of impairment could be made. 42 C.F.R. § 435.557(a). Ultimately, it is CMS’s responsibility to make the policy choice as to when it is “possible” to verify eligibility without relying on information provided by the beneficiary, and when it is not. CMS’s explanation of its choice easily satisfies the APA’s standards.

Third, Plaintiffs assert that CMS did not explain why it was reasonable to exercise its authority to define “medically frail” in the manner it did, rather than attempting to expand the categories of who qualifies. PI Mot. 14-15. Again, the IFR says otherwise. CMS considered, but declined, adding new categories of “medically frail” individuals because “we have not identified any other populations that we believe could reasonably be considered medically frail.” 91 Fed. Reg. at 33,373. CMS also explained that its definition of the “medically frail” standard represented the “best reading” of the statute by aligning the requirement with the statute’s purpose: “an individual’s ability to engage in community engagement activities.” *Id.* As explained above, there is ample statutory evidence supporting that conclusion, and it was not arbitrary and capricious for CMS to adopt that conclusion in the IFR.

3. CMS Appropriately Explained Its Use Of A One-Year Claim Lookback Period For Determining Applicability Of The Medical Frailty Exclusion

According to Plaintiffs, the one-year limitation on claims data is arbitrary and capricious because certain conditions “do not require regular treatment but impact someone’s ability to work (such as quadriplegia).” PI Mot. 10, 16. Generally speaking, the IFR only permits use of data from claims adjudicated in the last year for purposes of verifying “medical frailty” because “older information may not reflect the individual’s current condition.” 91 Fed. Reg. at 33,405. But “claims data” is not the only form of “reliable information available to the State” that may be used to verify “medical frailty.” The illustrative definition of this term in 42 C.F.R. § 435.557 encompasses eight different forms of data. For instance, if a quadriplegic receives SSDI and seeks exclusion under item (aa), they have already demonstrated in an administrative setting that they are unable to engage in “substantial gainful activity.” That would constitute a form of “reliable information” as explained in § 435.557(a). So even if there is no data on claims processed within the last twelve months for a particular individual, it is not necessarily the case that a State would not be able to verify the beneficiary’s status *ex parte*. Second, if a State cannot verify an applicant or beneficiary’s information through these *ex parte* data sources, the regulations require the State to seek further documentation or, under certain circumstances, attestation or other information from the beneficiary in order to verify their exclusion from the community engagement requirement. 42 C.F.R. § 435.557(f). These provisions satisfy CMS’s obligation to implement verification requirements in a reasonable way.

II. Plaintiffs Fail To Establish Irreparable Harm

A preliminary injunction is an extraordinary tool that should only be used “to preserve the relative positions of the parties until a trial on the merits can be held.” *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981). As such, a plaintiff must demonstrate “irreparable harm and inadequacy of legal remedies” in order to obtain one. *Sampson v. Murray*, 415 U.S. 61, 88 (1974). Not just any type of harm will do; “[o]nly a viable threat of serious harm which cannot be undone authorizes exercise of a court’s equitable power to enjoin before the merits are fully determined.” *Mass. Coal.*

of *Citizens with Disabilities v. Civ. Def. Agency*, 649 F.2d 71, 74 (1st Cir. 1981). Here, the ultimate consequences of State non-compliance with the community engagement requirement are fiscal ones, and Plaintiffs have not demonstrated that their legal remedies are inadequate to address those concerns. And even if this were not the case, the demanding standard for issuance of a preliminary injunction is not met by the daily challenges inherent in operating a state Medicaid program, as Plaintiffs contend. As such, Plaintiffs' motion should be denied for a failure to show irreparable harm.

A. Plaintiffs Have Not Shown Their Legal Remedies Are Inadequate

State compliance with federal Medicaid program requirements is primarily enforced through financial incentives. *See* 42 U.S.C. § 1396b(d)(2)(A). If CMS believes “there is a failure to comply substantially with any such provision” of the statutes governing Medicaid, FFP can be denied or limited on a prospective basis after the state agency has “reasonable notice and opportunity for hearing.” 42 U.S.C. § 1396c Regulations set forth the procedures by which CMS would seek to recover an excess payment, which a State may challenge through an administrative process in which it may seek reversal of the disallowance and ultimately recoup any disallowed amounts. *See* 42 C.F.R. § 430.42.

But if financial compensation will “fully alleviate harm” to Plaintiffs, “then the harm cannot be said to be irreparable,” and injunctive relief is inappropriate. *K-Mart Corp. v. Oriental Plaza, Inc.*, 875 F.2d 907, 914 (1st Cir. 1989) (addressing money damages). If CMS were to ultimately impose financial penalties one or more of Plaintiffs for failure to implement the community engagement requirement with fidelity to the IFR, and CMS was ultimately found to have acted contrary to law, CMS has ample statutory authority to make up for the discrepancy and ensure Plaintiffs receive matching funds. *See* 42 U.S.C. § 1320b-2(a) (States may claim federal financial participation for Medicaid within two years of the date of the expenditure); 42 C.F.R. § 95.19 (noting exceptions to time limits, including “[a]ny claim resulting from a court-ordered retroactive payment”). Plaintiffs have not demonstrated these avenues for relief are inadequate to

redress whatever consequences would befall them for failure to comply with § 1396a(xx), and as such, a preliminary injunction must be denied.

B. Plaintiffs’ Allegations Of Irreparable Harm Are Not Sufficient

The States allege they will suffer irreparable harm “if forced to communicate [the] unlawful conditions to their members.” PI Mot. 16. The gravamen of their concern is the ability to make necessary changes to implement the requirement and notify beneficiaries in a timely manner. *See* Gregosky Decl. ¶ 40, ECF No. 6-18 (describing Congress’s deadlines as “extraordinarily challenging”); Stinchcombe Decl. ¶ 17, ECF No. 6-22 (changes “increase” the “operational complexity” of Medicaid); Ford Decl. ¶¶ 50–51, ECF No. 6-23 (noting challenges in standing up relevant systems in Virginia); *see also* PI Mot. 17–18 (relying on these declarations). It was Congress that dictated the community engagement requirement and the timing demands for both the IFR and final implementation. 139 Stat. at 314, § 71119(d); 42 U.S.C. § 1396a(xx)(1). CMS was under no legal obligation to definitively share the IFR with Plaintiffs until Congress’s ordered release date of June 1. Plaintiffs thus are in no better or worse a position than they would have been had CMS simply not engaged with them at all in the run-up to issuing the IFR.

Even if these timing concerns were weightier, Plaintiffs’ claim injuries that arise from standard concerns about implementing a new regulation, educating the public about that change, and responding to public questions and concerns. For example, the declarants from Maine and Massachusetts explain that the state is harmed by “analyzing, developing, and implementing” the regulation; “integrat[ing] new data sources to evaluate eligibility”; fielding increased calls from beneficiaries due to the regulation’s impact; and the need to “educat[e] . . . members, staff, and other stakeholders.” Yaffe Decl. ¶ 57, ECF No. 6-9; Schwartz Decl. ¶ 65, ECF No. 6-11 (similar); Hertel Decl. ¶ 24, ECF No. 6-12 (similar); Weiner Decl. ¶¶ 54–55, ECF No. 6-13 (similar); *see* PI Mot 17 & 18 (relying on these declarations)). But these problems could describe practically any situation in which an agency must make regulatory changes in the face of some degree of uncertainty. They hardly rise to the level of “serious harm” needed to enjoin a major federal regulatory initiative in a preliminary injunction posture. *Mass. Coal.*, 649 F.2d at 74. Plaintiffs also

assert a loss of goodwill from beneficiaries frustrated by the new eligibility requirements. Huang Decl. ¶ 52, ECF No. 6-2; Wilson Decl. ¶ 53, ECF No. 6-5; *see* PI Mot. 18 (relying on these declarations). But it is pure speculation that beneficiaries would impute such frustration to Plaintiffs, or that the frustration would arise from the implementation of the IFR by Plaintiffs as opposed to the IFR itself.

CMS is also easing the States' compliance challenges by funding much of the cost. CMS pays: 90% of the states' costs of designing, developing and installing state eligibility systems to implement the rule, 75% of the states' costs of operating those systems, 75% of the states' costs of compensating and training skilled professional medical personnel and staff supporting such personnel (e.g., if states opt to hire skilled medical professionals to assess supporting documentation for medical frailty), and 50% of other costs the states expend on administration of the requirement. *See* 42 U.S.C. §§ 1396b(a)(2)(A), (a)(3)(A)(i), (a)(3)(B), and (a)(7). Moreover Congress required the Secretary to issue grants to States to enable them to “establish systems necessary to carry out” the community engagement requirement and other sections of the WFTC that pertain to eligibility determinations and redeterminations. 139 Stat. at 314, § 71119(e).

Finally, Plaintiffs argue that the loss of health coverage by beneficiaries, and corresponding potential costs for caring for the uninsured, give rise to irreparable injury. PI Opp. 18–19. But preliminary injunctions may only issue to prevent serious, imminent injury to the moving party, and “alleged irreparable harm to non-parties is not a basis for a preliminary injunction.” *VanDerStock v. Garland*, 633 F. Supp. 3d 847, 862 (N.D. Tex. 2022); *cf.* Fed. R. Civ. P. 65(d)(2) (preliminary injunctions only bind “the parties” to a dispute). In the case they rely upon to support this view, *Mass. Ass’n of Older Ams. v. Sharp*, 700 F.2d 749 (1st Cir. 1983), the plaintiffs were “a subclass consisting of approximately 4,400 families with stepchildren” who had benefits terminated by a state agency. 700 F.2d at 750. Plaintiffs do not represent such interests here, as they lack standing to advance *parens patriae*-type interests on behalf of citizens against Defendants. *Murthy v. Missouri*, 603 U.S. 43, 76 (2024); *Massachusetts v. Mellon*, 262 U.S. 447, 486 (1923). Moreover, in *Sharp*, the state had already begun sending out termination notices to

members when suit was filed. *Sharp*, 700 F.2d 751. Plaintiffs cannot adduce evidence of a similar “presently existing, actual threat,” *Mass. Coal.*, 649 F.2d at 74, in this case.

Preliminary injunctions are the exception, not the rule, and Plaintiffs’ evidence fails to meet the high standard necessary for one to issue. The Court should deny the motion on this basis.

III. The Balance of Equities and the Public Interest Favor the Government.

Plaintiffs’ proposed injunction threatens significant and irreparable harm to the Government and public, *see Nken*, 556 U.S. at 435, which greatly outweighs any claimed injury to Plaintiffs. As the First Circuit has recognized, the “government’s inability to ‘effectuate statutes enacted by representatives of the people’” is irreparable injury to the Government and the people who elected those representatives. *Somerville Public Schools v. McMahon*, 139 F.4th 63, 74 (1st Cir. 2025) (quoting *Int’l Ass’n of Machinists Loc. Lodge 207 v. Raimondo*, 18 F.4th 38, 47 (1st Cir. 2021)); *see also Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers). Enjoining CMS’s efforts to implement WFTC legislation through issuance of an IFR, as directed by Congress, is “an improper intrusion by a federal court into the workings” of both the Executive and Legislative Branches that is highly inequitable to Defendants and the public. *Immigr. & Naturalization Serv. v. Legalization Assistance Project of the L.A. Cty. Fed’n of Labor*, 510 U.S. 1301, 1305–06 (1993) (O’Connor, J., in chambers).

The balance of equities is especially lopsided with respect to Plaintiffs’ arbitrary and capricious claims. The Supreme Court’s analysis in *Winter* is instructive on this point. In that case, the Supreme Court reversed a preliminary injunction prohibiting the Navy from using sonar technology in training exercises at sea, where plaintiffs claimed the sonar would injure them because they “observ[ed]” and “photograph[ed]” marine mammals in the area and “conduct[ed] scientific research.” 555 U.S. at 13–14, 25–26. The Court explained that “the District Court and the Ninth Circuit significantly understated the burden the preliminary injunction would impose on the Navy’s ability to conduct realistic training exercises, and the injunction’s consequent adverse impact on the public interest in national defense,” which “plainly outweighed” the harms asserted by the plaintiffs. *Id.* at 24, 33. Here, Congress directed CMS to issue the implementing regulations

for the community engagement requirement as an IFR on an expedited timetable. 139 Stat. at 314. CMS solicited comments in conjunction with the IFR, which CMS will review and integrate into a final version of the rule. 91 Fed. Reg. at 33,351 (describing decision to solicit comments). Plaintiffs could also avail themselves of the opportunity to comment on the IFR, which has thus far received thousands of comments that CMS will address in a final rule. The Court should not enjoin the challenged provisions of the IFR if it merely finds the supporting explanation for those provisions inadequate. *Cf. A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1492 (D.C. Cir. 1995) (noting courts have discretion to remand a case to agency for further explanation, without vacatur, if enjoining agency action would be inequitable).

For these reasons, the balance of equities tips sharply in CMS's favor, and a preliminary injunction should be denied.

IV. If An Injunction Issues, It Should Be Narrowly Tailored And Accompanied By An Injunction Bond

As explained above, the Court should not issue a preliminary injunction in this case at all because Plaintiffs have not demonstrated a likelihood of success on the merits, irreparable harm, or that the balance of the equities tips in their favor. But if the Court concludes otherwise, it should issue a more narrow injunction than the one Plaintiffs propose. Proposed Judgment, ECF No. 2-1. To be sure, the proposed injunction only covers Plaintiffs, and CMS agrees a nationwide injunction should not issue. *See Trump v. CASA, Inc.*, 606 U.S. 831, 847 (2025). But the proposed order purports remains overbroad because it purports to enjoin not just the IFR, but “any substantially identical provision, legal interpretation, or other agency action, as against the Plaintiff States.” *Id.* at 1. It also enjoins CMS “from penalizing States for any delays in sending the notices.” *Id.* at 2. At this time, the IFR is the only final agency action properly before the Court, 5 U.S.C. § 704, and Plaintiffs lack jurisdiction to enjoin agency actions that have not taken place. *Puerto Rico v. United States*, 490 F.3d 50, 70 (1st Cir. 2007).

Finally, the Government respectfully requests that any injunctive relief be accompanied by a bond under Fed. R. Civ. P. 65(c), which provides that “[t]he court may issue a preliminary

injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained.” *See also U.S. D.I.D. Corp. v. Windstream Commc’ns, Inc.*, 775 F.3d 128, 135 (2d Cir. 2014) (explaining that the bond’s purpose is to protect defendants who “may have already suffered harm while the TRO was in effect even if the TRO is subsequently dissolved”). “[I]njunction bonds are generally required.” *Nat’l Treasury Emps. Union v. Trump*, No. 25-5157, 2025 WL 1441563, at *3 n.4 (D.C. Cir. May 16, 2025) (per curiam). If the Court were to enter an injunction, the Government asks that the bond amount reflect the amount of funding affected by Plaintiffs’ requested relief—that is, the costs and damages that would be sustained by the Government. To effectuate the purposes behind Rule 65(c), the Court should determine how much security is necessary based on Plaintiffs’ estimates of the amount of Medicaid reimbursements its members receive each month.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs’ motion.

Dated: July 15, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 15, 2025, the foregoing pleading was filed electronically through the CM/ECF system, which causes all parties or counsel to be served by electronic means as more fully reflected on the Notice of Electronic Filing.

/s/ Michael J. Gerardi

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