

**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
AUGUST 5, 2026**

**PLAINTIFF STATES' REPLY IN SUPPORT OF THEIR
MOTION FOR PARTIAL SUMMARY JUDGMENT AND OPPOSITION TO
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

The Challenged Provisions will result in millions of people losing their health coverage—particularly medically vulnerable Medicaid members whom Congress explicitly protected from potential interruptions in much-needed medical care. CMS stripped these medically precarious Americans of that statutory protection, and it did so without any reasoned explanation. It also unreasonably denied States important tools that would allow them to more easily and accurately verify whether an individual is entitled to a medical frailty exemption. Moreover, CMS did all this without considering the effects of its policy choices: lost medical coverage for millions of vulnerable Americans, and significant burdens on State Medicaid agencies and providers. The Challenged Provisions contravene the statute and are arbitrary and capricious in violation of the Administrative Procedure Act (APA).

ARGUMENT

I. The Court should vacate and enjoin the Significant Impairment Provision.

CMS does not meaningfully dispute that its definition of “medically frail or otherwise has special medical needs” would exclude individuals whom Congress instructed the agency to include. Instead, CMS argues that it is free to decide whether to define them as “medically frail” based on any other requirements it chooses. But that implausible interpretation would effectively re-write the statute, impermissibly overriding Congressional will. Moreover, even if CMS had the discretion to exclude these individuals, it was still bound by the constraints of the APA—requiring, at a minimum, that CMS engage in reasoned decisionmaking. It failed to do so. This Court should therefore vacate and enjoin the Significant Impairment Provision.

A. The Significant Impairment Provision is contrary to law.

CMS relies on an implausible interpretation of H.R. 1 that would allow it to exclude from its medical frailty definition individuals whom the statute expressly directed it to “includ[e].” 42 U.S.C. § 1396a(xx)(9)(A)(ii)(V). But Congress did not allow CMS to decide whether such individuals are medically frail based on whether they meet other requirements CMS chooses to

impose. The Court must therefore reject the Significant Impairment Provision as contrary to law.

As an initial matter, CMS makes much of its statutory authority to define “medically frail or other special needs,” *id.*, but Congress placed an important limit on this authority: the definition must include individuals with one of five enumerated types of conditions. *See id.* And this Court’s role is to ensure that CMS did not exceed this limit. Congress may authorize agencies “to exercise a *degree* of discretion” in defining a statutory term. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394 (2024) (emphasis added). But to ensure that agencies exercise only the “degree of discretion” delegated by Congress—and no more—courts must independently “fix[] the boundaries” of the agency’s delegated authority based on the “best reading of the statute.” *Id.* at 394–95, 400. Here, CMS concedes that Congress “circumscribe[d] CMS’s definitional authority to a degree” by requiring inclusion of certain kinds of conditions. ECF 138-1 (“Opp.”) at 10. Applying, as it must, “the traditional tools of statutory construction” to resolve “the scope of an agency’s own power,” this Court should find that the Significant Impairment Provision exceeded that carefully-circumscribed limit. *Loper Bright*, 603 U.S. at 401.

Every tool of statutory construction—from plain meaning to interpretive canons to statutory and legislative history—confirms the “best reading” of the statute: it set a definitional floor, requiring the agency to include as “medically frail” any individual with one of five kinds of conditions listed in the statute. *See* ECF 104 (“Br.”) at 9-15. The Court must enforce that statutory floor, regardless of whatever discretion CMS has to broaden the definition of medical frailty. The Ninth Circuit’s ruling in *Safer Chemicals, Healthy Families v. EPA* illustrates the point. There, the Toxic Substances Control Act required EPA to evaluate certain substances’ “conditions of use,” meaning “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.” 943 F.3d 397, 407 (9th Cir. 2019). EPA, invoking its delegated authority, excluded from evaluation chemicals which were no longer commercially produced or sold. *See id.* at 408. But this interpretation left out certain chemical substances—like asbestos—which were clearly “intended, known, or reasonably foreseen to be ... used[] or disposed of.” *Id.*

at 407. So, while the statute granted the agency a degree of “discretion to determine” the meaning of the term “conditions of use,” that “discretion may only be exercised within the bounds of the statutory definition itself.” *Id.* at 425. And because EPA’s interpretation excluded certain substances that the statute required it to include, the Ninth Circuit struck down the rule as unlawful. *See id.* at 425–26.¹ In short, as here, the statute set a definitional floor that limited the agency’s discretion, and the agency breached that limit.²

CMS responds by advancing a tortured interpretation of “include”—one that does not actually require inclusion. The agency does not dispute that “Congress’s instructions to ‘include’ five discrete categories of individuals within the definition of this term circumscribes CMS’s definitional authority to a degree.” *Opp.* 10. Instead, asserting that the statute allows it to “set[] limits on these categories,” *id.* at 11, CMS contends that the Significant Impairment Provision’s *possible* inclusion of individuals falling within the statutory categories complies with Congress’s instructions. That argument defies reason and the clear meaning of the word “include.”

By CMS’s logic, as long as individuals with the conditions listed in the statute *may or may not* be considered medically frail—depending on whether they satisfy a separate and independent requirement—then CMS has complied with the mandate to include such individuals as medically frail. Tellingly, CMS offers absolutely no authority for this odd definition of “including,” likely because that reading is supported neither by courts nor dictionaries nor common use. *See Br.* 9-15

¹ CMS attempts to distinguish *Safer Chemicals* by asserting that here, Congress delegated authority to define a “term of art ... without limitation.” *Opp.* 14. But elsewhere, CMS admits Congress *did* impose a “limitation” on its authority, conceding that the statutory inclusion of the five sub-categories “circumscribes CMS’s definitional authority.” *Id.* at 10. Nor is there any basis for CMS’s “term of art” distinction. In both cases, (1) Congress identified a general term, (2) granted the agency some authority to define that term, and (3) partially defined the term in statute, then (4) the agency exceeded its authority by defining the general term to exclude categories Congress had included.

² CMS suggests that the explicit delegation of authority to define medical frailty reinforces CMS’s power to set “standards” for determining who is a “specified excluded individual,” 42 U.S.C. § 1396a(xx)(9)(A)(ii). To the extent CMS is attempting to rely separately on this standard-setting authority, this argument fails. That authority only permits CMS to outline the administrative processes by which the States identify exclusions, not to define terms. Further, the canon against surplusage counsels that the delegation of authority to define medically frail must be independent from the standard-setting power; otherwise, the explicit delegation of definitional authority is a “meaningless” restatement of an existing provision. *City of Providence v. Barr*, 954 F.3d 23, 37 (1st Cir. 2020). Because the IFR rests exclusively on CMS’s power to define medically frail, *infra* at n.3, the Provision is not, and cannot be, an expression of CMS’s ability to set standards. Finally, even if the standard-setting authority applied here, it would also be bound by Congress’s instruction to include the statutory conditions without imposing a functional limitation.

(canvassing sources which define the term “including”). Imagine that a principal instructs a teacher to “throw a party for all of the high-performing classes, including Ms. Smith’s class.” That teacher would not “include” Ms. Smith’s class in any sense of the word if he invited only the students in that class who received an A on their last math test. So too here, where a failure to categorically include the statutory conditions forecloses any argument that they have been “included.”

The logical implications of CMS’s argument reveal its obvious flaws. Under CMS’s interpretation, the statute only requires it to consider the presence of a statutory condition as one factor—among any number of others that CMS may elect to consider—in determining whether someone is “medically frail.” That means CMS could add countless other requirements before considering someone with a statutory condition to be medically frail. Perhaps CMS thinks someone must be over the age of 40 to be medically frail. Or unable to sit at a desk. Or to lack access to physical therapy. In CMS’s telling, it could impose an endless series of criteria that someone with a statutory condition would have to satisfy before being considered medically frail. Indeed, it could do so without regard to whether *any* individuals in the statutory sub-categories can even meet those criteria. That turns Congress’s direction to include the statutory categories into a nullity that does not “circumscribe[] CMS’s definitional authority” at all. Opp. 10.

CMS’s assertion of sweeping authority to exclude—based on whatever criteria it wishes—the very individuals whom Congress directed the agency to “include” would require this Court to re-write the statutory text. Had Congress wanted to limit or qualify “including,” it could have “written the law differently,” *Bostock v. Clayton County*, 590 U.S. 644, 658 (2020), qualifying “including” with language like “to the extent compatible with the definition of medical frailty promulgated by the Secretary” or “but with such exemptions as the Secretary may allow” or simply “some, but not all.” But “that is not the law we have.” *Id.* at 659. Congress chose the more definitive and categorical term, and CMS is obligated to respect that policy judgment.

CMS’s half-hearted efforts to refute the plain meaning of “include” fall flat. The agency faults Plaintiffs for not offering a case pairing “including” with a delegation of definitional authority. Opp. 12. But that is beside the point. The statute does not delegate to CMS authority to

interpret the meaning of “including,” much less to interpret it in a way that allows it to *exclude* the categories that follow. CMS also observes that, in some cases, the words after “including” need to be construed narrowly so they are not “broader than the general category” they follow. *See* Opp.12 (citing *Hincapie-Zapata v. Attorney General*, 977 F.3d 1197, 1202 (11th Cir. 2020)). But that obviously does not apply here: each of the five statutory conditions can easily describe a person who is “medically frail or has a serious medical condition.” *Cf. id.* (noting the phrase “any American automobile, including any truck or minivan” cannot plausibly include foreign-made trucks or minivans). As in *Hincapie-Zapata*, “[t]he rule, not the exception, applies here.” *Id.* CMS also argues Plaintiffs’ “crabbed reading of the statute” would leave it without any definitional discretion at all, but this is untrue: Plaintiffs agree that the statute gives CMS discretion to include “other categories beyond those specifically listed” as “part of the definition” of medically frail. Opp. 12. And as CMS acknowledges, it exercised this discretion by deciding not to include any other types of medical conditions in its definition. *Id.* at 5.

Unable to refute the plain meaning of “include,” CMS quibbles with the other interpretive points that Plaintiffs make. None of these arguments can overcome the plain meaning of the word “include,” but they also fail on their own terms. The agency rejects Plaintiffs’ “old soil” argument because Congress did not “expressly incorporate the ABP standards by reference,” Opp. 13, but that is not a requirement for invoking the old soil doctrine under First Circuit precedent. *See Doe v. Trump*, 157 F.4th 36, 59 (1st Cir. 2025). CMS also contends that the *expresio unius* canon does not apply because none of the sub-categories includes the precise kind of functional limitation that CMS has added here. Opp. 13. That is factually wrong: to be “disabled” under sub-clause V(aa), one must be unable to engage in “substantial gainful work.” 42 U.S.C. § 1382c(a)(3)(B); *see also* 42 U.S.C. § 1396a(xx)(9)(A)(ii)(V)(aa) (defining “disabled” according to § 1382c). And regardless, CMS cites no authority for its odd reading of the canon, which, if adopted, would allow an agency to evade Congress’s implicit exclusions simply by employing regulatory terms that are textually distinct from, but substantively identical to, the language Congress rejected. Finally, First Circuit precedent supports a substantive canon of liberal interpretation of the Medicaid Act in favor

of beneficiaries, even if such an instruction is not in the particular statutory text. *See Paiva v. Kijakazi*, 704 F. Supp. 3d 268, 276 (D. Mass. 2023) (citing *McCuin v. Sec’y of Health & Hum. Servs.*, 817 F.2d 161, 174 (1st Cir. 1987)).

CMS also attempts, but fails, to indirectly support its position by noting that the statute separately authorizes the agency to define the meaning of the statutory conditions listed at subclause (V). Opp. 11. To be clear, the Significant Impairment Provision does not itself define the meaning of any of those conditions. Rather, it imposes a separate and independent requirement that applies to individuals who are *already* defined to have one of the conditions set forth in the statute. *See* 42 C.F.R. 435.554(c)(5)(i).³ CMS does not appear to dispute this. Instead, it contends there is no “principled difference” between claiming authority to (i) define the statutory conditions and (ii) place further limits on medical frailty for individuals who are already defined to have a statutory condition. Opp. 11. This argument fails twice over. To begin with, there is clearly a meaningful difference between whether someone has a particular medical condition and whether that condition prevents them from working. And it is entirely sensible that Congress would have found that distinction important in determining whom to exempt from the Work Requirement: even if a condition does not prevent someone from working, it may subject them to catastrophic medical consequences if they lose access to medical care because they cannot prove their inability to work or are prevented from working in a given month by some other life circumstance. *See, e.g.*, RSMF

³ The IFR’s preamble and recent CMS guidance confirm that the Significant Impairment Provision does not define the meaning of the medical conditions listed in the statute but imposes a separate requirement on individuals who undisputedly have one of those conditions. *See, e.g.*, 91 Fed. Reg. at 33,373 (medical frailty definition “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.)” (emphasis added)); CMS, *Implementing Medical Frailty Under Community Engagement*, at 4, 6 (September 2026) <https://perma.cc/Y8HD-YU47> (“an individual in one of the five categories”—in other words, someone already falling within those categories—“is considered medically frail *only if* the individual’s ... condition significantly impairs the individual’s ability to comply with the [Work Requirement]” and acknowledging that the IFR “did not further define” several statutory conditions beyond their statutory text (emphasis added)). And even if CMS had tried to define each condition based on significant impairment, that would be contrary to the statute—for example, many individuals are indisputably blind even if their blindness does not prevent them from working.

This is one reason CMS’s tortured response to Plaintiffs’ grocery store analogy fails. Opp. 11. CMS is not simply clarifying the meaning of items in the list (like the kind of milk or eggs to get) but deciding not to include those items *at all* unless they meet a separate criterion (like refusing to get milk or eggs unless they come in a blue carton).

¶¶151, 174–76. The statute protects these individuals from that risk. But regardless, whether CMS thinks the distinction is “principled” is irrelevant. Opp. 11. Congress made the distinction by mandating that any individual with one of the statutory conditions *must* be considered medically frail, and that constrains CMS’s discretion as a matter of law.

Ultimately, CMS’s brief makes plain its true goal: to advance a policy view that is divorced from the statute. The agency argues they must “consider functional impairment” so individuals with conditions “such as asthma or diabetes” are not “excused from the community engagement requirement.” Opp. 10. But the text of the statute shows this is exactly what Congress intended—to protect medically vulnerable populations from a loss of coverage regardless of their ability to prove compliance with the Work Requirement. There is nothing “counterintuitive” about ensuring that individuals with diabetes do not lose access to life-saving insulin under any circumstances. *Id.* Regardless, “[p]urposive argument[s] simply cannot overcome the force of the plain text.” *Bowe v. United States*, 607 U.S. 13, 41 (2026). And CMS cannot, as it has done here, issue an “interpretation contradicting what Congress has said” simply because it disagrees with the underlying policy. *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 218 n.4 (2009).

The Significant Impairment Provision is contrary to Congressional will and to law. It must be enjoined and vacated.

B. CMS’s promulgation of the Significant Impairment Provision was arbitrary and capricious.

Defendants paint an incomplete picture of what the APA demands of agencies, and in turn, of courts when reviewing agency action. Though arbitrary and capricious review under the APA may be narrow, there is a bounty of well-developed caselaw cited in Plaintiffs’ brief, which Defendants ignore, about *how* a court is to ensure an “agency has acted within a zone of reasonableness.” *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). Defendants fail to acknowledge the well-developed framework that courts, beginning with the Supreme Court, have established for arbitrary and capricious review. *See* Br. 17-28. Plaintiffs have identified meaningful tools to test the reasonableness of (1) the Challenged Provisions, and (2) CMS’s contemporaneous

explanation for the Challenged Provisions. Agency action is arbitrary and capricious if the agency “has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem,” *Motor Vehicle Mfrs. Ass’n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983), or failed to “consider and explain its rejection of... significant and viable and obvious alternatives,” *Nat’l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 215 (D.C. Cir. 2013). As to CMS’s explanation, this court’s review is limited to “the grounds that the agency invoked when it took the action.” *Dep’t of Homeland Sec. v. Regents of Univ. of Cal.*, 591 U.S. 1, 20 (2020). Neither litigation counsel’s *post hoc* explanations nor uncited documents in the administrative record can cure defects in an agency explanation. *Ohio v. EPA*, 603 U.S. 279, 293–94 (2024) (explanations that do not appear in the rule cannot be relied upon by the agency as a basis for their decision). Finally, CMS’s purported contemporaneous explanations must “includ[e] a rational connection between the facts found and the choice made.” *Ohio*, 603 U.S. at 292. CMS has failed at every step of even the “narrow” arbitrary and capricious review, and the Challenged Provisions should therefore be vacated and enjoined.

Defendants’ principal “explanation” for the Significant Impairment Provision is that it is the best reading of the statute. Opp. 15-17; 91 Fed. Reg. 33,373. It defies credulity that the *best* reading of the statute is one that occurred to CMS after nearly a year of its expert staff working to implement H.R. 1 without that extra-statutory criterion, and months of providing contrary direction to the States. Moreover, if the only explanation is one of statutory interpretation, the court should determine the best reading of the statute, which, as stated above, does not impose a functional limitation requirement on the medically frail exclusion. *See supra* Section I.A.

CMS seeks to buttress this inadequate justification by noting the statement, “we believe... participating in community engagement activities... could potentially help them escape isolation and dependency, build confidence, achieve self-sufficiency and prosperity, and improve health.” Opp. 16; 91 Fed. Reg. 33,376. First, CMS simply asserts without support that medically frail people suffer from these maladies in the first place. *New York v. HHS*, 414 F. Supp. 3d 475, 546 (S.D.N.Y. 2019) (a “solution in search of a problem” is arbitrary and capricious). Second, this

belief that the Significant Impairment Provision *could potentially* help medically frail people, “an indisputably worthy goal,” lacks “a reasoned explanation as to how the agency determined that [the Significant Impairment Provision] would advance that goal.” *President & Fellows of Harvard Coll. v. U.S. Dep’t of Health & Hum. Servs.*, 798 F. Supp. 3d 77, 129 (D. Mass. 2025) (citing *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016)) (finding funding termination did not serve stated goal of fighting antisemitism). CMS provided no such explanation, and accordingly this bald assertion does not aid in their arbitrary and capricious defense. *Ohio*, 603 U.S. at 293–94. Moreover, the notion that a policy choice that causes millions of medically vulnerable people to lose health coverage would result in increased “confidence,” “self-sufficiency and prosperity, and improve health” is arbitrary and capricious on its face. *Dep’t of Commerce v. New York*, 588 U.S. 752, 785 (2019) (courts “cannot ignore the disconnect between the decision made and the explanation given”).

CMS’s decision to impose a hurdle to health care coverage not found in H.R. 1 is no less arbitrary because it was “consistent with feedback that CMS received while it was developing the IFR.” Opp. 16. It was also inconsistent with other feedback. *E.g.*, ECF 138-3 (“RSMF”) at ¶¶98, 110, 118, 175–77.⁴ The mandate of the APA is that an agency with expertise considers feedback it receives and resolves conflicting feedback based on that expertise and provides an *explanation* as to why it chose a particular path so that courts can determine whether that choice was arbitrary and capricious. The administrative record citations in CMS’s brief were not cited in the IFR; in fact,

⁴ CMS improperly raises legal arguments couched as “general objections” in its Responses to Plaintiff States’ Statement of Material Facts (“RSMF”). These arguments should be ignored because they “are not properly part of a party’s statement of material facts or a nonmoving party’s response thereto.” *In re Intuniv Antitr. Litig.*, Nos. 1:16-cv-12653-ADB, 1:16-cv-12396-ADB, 2020 WL 5045148, at *2 (D. Mass. Aug. 26, 2020). But they are also without merit. *See supra* p. 11; L.R. 56.1 (noting that failure to include a statement of undisputed material facts constitutes grounds for denial of a motion for summary judgment and noting no exception for APA cases); *see also Greater Bos. Legal Servs. v. DHS*, No. 2025 WL 1725826, at *1 n.1 (D. Mass. June 25, 2025) (considering “all facts proffered by the parties which are neither inconsistent with the facts proffered by the other party nor inconsistent with the administrative record”). Having relied exclusively on their general objections without reference to any record evidence with which to contest Plaintiffs’ facts, those facts are now “deemed for purposes of the motion to be admitted.” L.R. 56.1; *Quincy Mut. Fire Ins. Co. v. Atlantic Specialty Ins. Co.*, No. 18-cv-11868-ADB, 2019 WL 3409980, at *3 n.3 (D. Mass. July 29, 2019)

the IFR never invokes stakeholder feedback as a basis for the provision, and accordingly, do not constitute “grounds that the agency invoked when it took the action.” *Regents*, 591 U.S. at 20; *Ohio*, 603 U.S. at 293–94 (court will not consider explanations outside of the agency’s rule).

Perhaps more troubling is CMS’s inaccurate characterization of feedback as “consistent” with its position. Opp. 16-17. CMS has cherry-picked quotes from submissions it received (which it claims to have considered) that completely mischaracterize the point of the submission. For example, CMS claims a 2017 letter “advocat[ed] for ‘a functional analysis’ rather than ‘rely[ing] on a simple list of conditions to determine medically frail status.” Opp. 16. In fact, this letter did the opposite, encouraging use of expansive means of determining medical frailty, including, at a minimum, functional analysis *and* condition. Pls’ Resp. to Stmt. Mat. Facts (“Pls’ Resp.”) ¶20. Likewise, CMS argued that a December 2025 letter from disability advocates argued for a limited medically frail definition. Opp. 16. Quite the opposite. This letter argued against deeming someone ineligible for the medical frailty exclusion because they can work. Pls’ Resp. ¶25.

As to CMS’s response about the millions of people losing health coverage because of the Significant Impairment Provision (and the Claims Period Limitation and Self-Attestation Limitation), its careful word choice belies the truth—CMS did not evaluate the costs of the Challenged Provisions, it only evaluated the costs of H.R. 1’s Work Requirement overall. Opp. 18. The APA requires an agency to measure the impact of *its* choices, not those of Congress. *Ohio*, 603 U.S. at 292. CMS protests that it should not have to “separately analyz[e] the impact of the ‘substantial impairment’ test,” but this is precisely the agency action at issue. Having failed to “analyze the impact” of that choice, CMS utterly fails to explain its choice, particularly where experts show that this choice will lead to nearly 1.8 million more people losing health coverage by 2034. Opp. 18; RSMF ¶¶250-51. Having failed to find *any* facts about the disenrollment consequences of its choice, it has failed to provide a satisfactory explanation.⁵

⁵ CMS’s bizarre reference to 5 U.S.C. § 553 in no way relieves CMS of its burden to consider this important aspect of the problem or to tie its choice to the facts it found. CMS seems to suggest that they need not consider “every scrap of evidence” because notice and comment was not required. This strawman is easily dismissed. The administrative

CMS incorrectly argues that “extra-record” evidence has no role in this court’s analysis. Opp. 19-22. In fact, such evidence is permitted precisely where, as here, it is relevant to “determine[ing] whether the agency considered all relevant factors in making its decision.” *Housatonic River Initiative v. EPA*, 75 F.4th 248, 278–79 (1st Cir. 2023). For example, while CMS acknowledges that losing health coverage was “the central issue” in promulgating the IFR, Opp. 20, it admittedly closed its eyes to contemporaneously available evidence showing millions more people will be harmed, Opp. 19. CMS claims it was not “obliged to explicitly differentiate these studies.” *Id.* But CMS did not even *consider* these other numbers. *See* Br. 19, n.8. This head-in-the-sand approach ignored “an important aspect of the problem,” *State Farm*, 463 U.S. at 43: millions of Americans losing their badly-needed health coverage. An actual analysis of the IFR inclusive of the Challenged Provisions revealed disenrollment by 2034 at 8.2 million people, nearly 5 million more people than CMS calculated. RSMF ¶¶224, 251. This significant deviation, 150% more people identified as disenrolled based on the IFR, underscores the seriousness of CMS’s failure to consider a critically important issue.

CMS also claims it need not have considered predictable, foreseeable, and knowable consequences of stripping people of their health insurance such as “harms to the entire healthcare system,” Opp. 19-20. What CMS calls “downstream” consequences, *id.*, are no less consequences of the rulemaking because they are intermediated by the dramatic disenrollment caused by the IFR. *Regents*, 591 U.S. at 31 (evaluating downstream consequences of DACA rescission that “radiate outward,” including impacts on recipients’ families, schools, and employers). These consequences both speak to reliance interests and are an important aspect of the problem, and CMS’s admitted

record CMS is referring to includes information from members of Congress; patient advocates and organizations; physician groups; public health and health policy experts; state Medicaid agencies; health systems; other health industry groups and representatives; and CMS itself. *See, e.g.*, RSMF ¶¶ 94, 98, 107, 115, 117, 119, 125, 127, 128, 129, 133, 137, 138, 150, 174. These so-called “scraps” matter because they show key facts that run counter to CMS’s conclusions supporting the Challenged Provisions and identify important aspects of the problem that the agency failed to consider. *State Farm*, 463 U.S. at 43.

failure to consider them is fatal to its APA defense. *Id.* at 32.⁶

CMS’s excuses for failing to consider the burden the Significant Impairment Provision places on States fare no better. Opp. 20-22. In fact, in its brief, it only responds to a small portion of the burden—that associated with changing systems from the one CMS has told states to create pre-IFR, to the one it told them to create in the IFR. *Id.* But the States will be saddled with the burdens of much more time-consuming and costly verification processes extending indefinitely into the future if any of the Challenged Provisions are allowed to remain in effect. Br. 20-21. And they will also be burdened with significantly more uncompensated care costs, which CMS admittedly ignored, again calling the costs “downstream.” Opp. 19.

Contrary to the only evidence cited in the record, CMS claims it was not “changing the definition of ‘medical frailty’” in the IFR. Opp. 21. Through hearsay, CMS ironically claims that removing the Significant Impairment Provision at this juncture would cause states to face “severe whiplash and wasted resources.” ECF 138-4 at ¶12. That the change between the pre-IFR definition and the IFR definition would cause “whiplash” is proof that CMS changed the definition. As the States have shown, CMS’s departure from the original definition caused “whiplash and wasted resources.” *See* Br. 20-23 (CMS had worked with states from November 2025 through May 2026 on a definition of medical frailty that *did not* include a functional limitation, and its failure to consider the limited runway left for States ahead of the Congressionally imposed implementation deadline was arbitrary and capricious). CMS’s repeated refrain that it was not conducting notice-and-comment rulemaking is likewise not a reason to ignore important factors, like those raised by the States in the days before the IFR was issued. That they were sent to, and received by, CMS so late, is simply because of CMS’s eleventh hour about face. Br. 22-23.

CMS provides no satisfactory explanation now, or critically, in the IFR for the limitation on *ex parte* verification. Opp. 22-23; RSMF ¶215. Highlighting the lack of reasoned explanation,

⁶ CMS provides no rebuttal regarding its admission that the Work Requirement was “an entirely new factor of eligibility,” RSMF ¶212, which would require it to consider reliance interests. *Regents*, 591 U.S. at 30 (“When an agency changes course... it must be cognizant that longstanding policies have ‘engendered serious reliance interests that must be taken into account.’”).

CMS says “states ‘should have access’ to, among other things, other forms of relevant information.” Opp. 23. Among the “relevant information” identified is “payroll data.” 42 C.F.R. § 435.557(a)(vi). But CMS never explained how payroll data could support a determination of medical frailty. CMS’s sole explanation for this limitation is that relying on claims data alone would risk “sweeping” into the exclusion the people Congress meant to be captured by the exclusion. 91 Fed. Reg. 33,373. This explanation is at odds with the statute and is arbitrary and capricious.

II. CMS’s promulgation of the Claims Period Limitation was arbitrary and capricious.

As to the Claims Period Limitation, CMS fails to provide a “reasoned explanation” as required by the APA. *Harvard*, 798 F. Supp. 3d at 129. CMS’s sole explanation for the Claims Period Limitation is that “older information may not reflect the individual’s current condition.” Opp. 23. CMS does not dispute that such information *may* reflect an individual’s current condition, like in the case of permanent or chronic conditions, and CMS has identified *no* downside to allowing State Medicaid agencies *access* to that information. CMS itself uses up to two years of claims data in its own chronic conditions algorithms. RSMF ¶134. Merely having the information would not force States to find someone medically frail based on older claims data, but it would allow them to more accurately assess medical frailty and avoid liability for noncompliance with the IFR based on collection or consideration of that data.⁷ See 91 Fed. Reg. 33,377 (States would not be in compliance with the IFR if they “approv[ed] individuals as medically frail with little to no support”). CMS arbitrarily *prevents* States from considering information it admits has probative value. Opp. 24 (“Of course, expanding the time window increases the likelihood of finding a diagnostic code consistent with medical frailty.”). Where CMS has failed to identify a downside of a longer lookback period which would allow more medically frail people to be *ex parte* verified, the speculative explanation provided is neither “sufficient,” *State Farm*, 463 U.S. at 52, nor “reasonable,” *Prometheus Radio Project*, 592 U.S. at 423. CMS states it has “balance[d] competing

⁷ As described in Section IV, *infra*, the potential financial risks to States for noncompliance with the IFR are severe.

interests,” Opp. 24, but neither the IFR nor the brief evidence such balancing.

CMS inaccurately characterizes Plaintiffs’ argument regarding the “reasonable alternative” that CMS ignored. Opp. 25. CMS’s failure to “consider and explain its rejection of... significant and viable and obvious alternatives,” provides independent grounds for finding the Claims Period Limitation arbitrary and capricious. *Nat’l Shooting*, 716 F.3d at 215. Plaintiffs need not, and do not, “advocat[e]”, Opp. 25, for a two-year lookback period or otherwise concede that a time limitation is necessary. They simply note that CMS failed to consider this alternative that was specifically presented to it, along with evidence that at least two million more people would maintain their coverage with the additional year lookback. RSMF ¶¶131-32.⁸ As noted above, mere access to information does not require States to act on information that is not relevant to an individual’s current condition, and CMS has tools in place (audits) that would prevent States from granting medically frail exclusions without adequate support. As Plaintiffs demonstrated, and CMS again ignores, a longer lookback is consistent with the goals of H.R. 1 and the IFR; allowing states to *view* more claims data would allow for more accurate, efficient, and less costly verification. Br. 24-26; RSMF ¶256.

III. CMS’s promulgation of the Self-Attestation Limitation was arbitrary and capricious.

CMS’s lone explanation for the Self-Attestation Limitation is an arbitrary and capricious “solution in search of a problem,” *New York*, 414 F. Supp. 3d at 546, namely that it would cause people to seek needed medical care. CMS argues that it need not “produce empirical evidence” that people in need of care fail to seek it out, Opp. 28, but CMS was required to “offer a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made.” *Ohio*, 603 U.S. at 292. Because no facts support this choice, it is unreasonable. *Id.* That CMS received mixed feedback regarding limits on self-attestation, RSMF ¶¶98-101, 124, 262-63, does not excuse CMS’s failure to engage in “reasoned decisionmaking,” *Regents*, 591 U.S. at 16.

CMS also failed to consider the burdens placed on providers and members. Opp. 29. As to

⁸ Defendants were not required to adopt the two-year lookback, they did have to “consider and explain its rejection.” *Nat’l Shooting*, 716 F.3d at 215; *see also Dubois v. U.S. Dep’t of Agric.*, 102 F.3d 1273, 1289 (1st Cir. 1996).

providers, CMS misconstrues Plaintiffs’ argument. CMS agrees that members should have access to “care they do need,” Opp. 29, but fails to grapple with the fact that this care may not relate to an individual’s medical frailty, and available claims data often do not reference primary underlying conditions. Br. 24, 27 (a visit for an ear infection likely would not yield claims data evidencing cerebral palsy); *see also* Pls’ Resp. ¶31 (“people with serious health conditions... may not have information on these health conditions in their claims”); ¶35 (“many individuals with brain injury... may have claims that do not fully capture the extent of their impairments.”). Thus, the Self-Attestation Limitation does burden providers by requiring additional paperwork not associated with the provision of necessary care. RSMF ¶144; ECF 119 at 14–17.

CMS’s response to evidence of members’ difficulty historically in obtaining provider documentation is equally unreasoned (and missing from the IFR). Opp. 29. Defense counsel’s post-hoc reasoning is that CMS “*allowed* for self-attestations; it just does not allow for them at all times and under all circumstances.” *Id.* This fails to speak to the challenge *every* member will face starting in 2028. CMS does not counter with data showing the ease of obtaining provider documentation; it simply says members can avoid that issue once before they are confronted with a reality the agency did not consider or address. Opp. 29. This is arbitrary and capricious.

IV. The IFR violates the Spending Clause.

Defendants request summary adjudication of Plaintiffs’ Spending Clause claim, but do not come close to meeting their burden to show that the law or undisputed facts justify such a ruling.⁹

First, Defendants assert, without citation, that the Spending Clause “does not limit the authority of the Executive Branch.” Opp. 30. But the “Spending Clause constrains not only Congress but federal agencies to which responsibility has been placed in implementing authorized spending[.]” *San Francisco Unified Sch. Dist. v. AmeriCorps*, 789 F. Supp. 3d 716, 737–38 (N.D. Cal. 2025). Courts in this circuit have consistently applied the Spending Clause to Executive Branch actions. *See, e.g., Massachusetts v. U.S. Dep’t of Agric.*, No. 26-cv-11396-MJJ, 2026 WL 1815807, at *15–17 (D. Mass. June 24, 2026); *New Jersey v. U. S. Office of Mgmt. and Budget*,

⁹ Plaintiffs moved for summary adjudication on only their APA claims in order to allow the Court’s expedited review.

837 F. Supp. 3d 258, 282–83 (D. Mass. July 17, 2026); *California v. U.S. Dep’t of Transp.*, 808 F. Supp. 3d 291, 311 (D.R.I. 2025). And for good reason: to the extent Congress has authorized an agency to impose conditions that would violate the Spending Clause if imposed directly by Congress, that is no less a breach of Constitutional limits.

The parties agree that the Constitution generally allows Congress to place conditions on federal grants (and to authorize the Executive Branch to do the same), and specifically to condition receipt of federal Medicaid funds on states’ administration of those programs according to federal rules. *See Landor v. La. Dep’t of Corr. & Pub. Safety*, 609 U.S. 59, 63 (2026) (citing *Medina v. Planned Parenthood S. Atlantic*, 606 U.S. 357, 362–64 (2025)). But the power of the purse comes with limits. When the federal government attaches conditions to states’ acceptance of federal funds, they “must be set out ‘unambiguously,’” because States “cannot knowingly accept conditions [...] which they are ‘unable to ascertain.’” *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006), (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981)). The Supreme Court also considers whether federal conditions are so coercive that they constitute a “gun to the head” to sovereign states. *Nat’l Fed’n of Indep. Bus. (NFIB) v. Sebelius*, 567 U.S. 519, 581 (2012).

In requesting summary judgment on the Spending Clause claim, Defendants again argue that issuance of the IFR’s Significant Impairment Provision was within CMS’s “discretionary” authority, *see* Opp. 30, which Plaintiffs vigorously dispute. Even assuming *arguendo* that CMS had that authority, however, the statute does not provide States with clear notice of the IFR’s Significant Impairment Provision, in violation of the Spending Clause. Evidence in the record, including State Medicaid agencies’ reliance on the statute and CMS’s earlier subregulatory statements, bears this out. RSMF ¶¶67–88, 155, 157, 160–61, 167, 233–35. And the States remain unable to ascertain exactly how to implement the Significant Impairment Provision given the conflict between laws requiring *ex parte* eligibility determinations and Defendants’ unclear direction that determinations cannot rest “solely” on “the presence of a particular diagnosis or condition.” Br. at 23–24. These unclear expectations, combined with state Medicaid agencies’ and

clinicians’ lack of experience and capacity for determining ability to work, RSMF ¶¶11, 113, 142, 172, raise factual questions of whether the Significant Impairment Provision is an impermissible “shift in kind,” *see NFIB*, 567 U.S. at 583, rather than analogous to past changes in Medicaid eligibility. For all these reasons, Defendants have fallen short of their constitutional obligation to “clearly and unambiguously alert” the States of a new condition. *Landor*, 609 U.S. at 69. At a minimum, factual questions remain as to whether the new condition is sufficiently clear.

Defendants also assert that the costs to States of compliance are not large enough to render the Significant Impairment Provision unconstitutionally coercive, but they ignore evidence in the IFR, Medicaid rules, and the record of the true financial stakes for States. Defendants’ own declarant acknowledges that if States’ “systems and processes for making medical frailty determinations are not built around the legally effective definition of medical frailty and the applicable evidentiary standards contained in the IFR, they would effectively be unable to make medical frailty determinations.” ECF 138-4 at ¶10. And the IFR warns States that non-compliance with the requirements of the IFR, including the Significant Impairment Provision, would expose States to severe risks of corrective action from CMS under Payment Error Rate Management (PERM) regulations,¹⁰ *see generally* 42 C.F.R. § 431.958-431.1010, and a finding that States were “not [] in compliance with the regulation.” 91 Fed. Reg. 33377. Noncompliance in turn can allow CMS to withhold *all* federal funding for the States’ well-established expansion Medicaid programs. *See* Pls’ Resp. ¶4 (Medicaid program noncompliance can cause CMS to deny federal funds “in whole”); 42 U.S.C. § 1396c, 42 C.F.R. § 430.35 (allowing CMS to withhold federal payments “in whole or in part” for noncompliance). This would cripple the States’ Medicaid programs and is the kind of “economic dragooning” that leaves States with “no real option.” *NFIB*, 587 U.S. at 581–82. Defendants’ motion for summary judgment on this claim should be denied.

V. Plaintiffs are entitled to the relief they seek.

¹⁰ Section 71106 of H.R. 1 further ups the ante for States by widening the definition of erroneous Medicaid payments and eliminating CMS’s authority to waive penalties for States undertaking “good faith” efforts despite error rates of more than 3%. *See* Pub. L. No. 119-21, 139 Stat. 172 (2025).

A. The Court should vacate the Challenged Provisions.

As CMS concedes, the APA authorizes “vacatur as an available remedy for a successful APA challenge.” Opp. 31.¹¹ And as the First Circuit has held, an “excess-of-statutory-authority APA claim, if sound, in and of itself fully supports” vacatur. *California v. Mullin*, 183 F.4th 42, 48 (1st Cir. 2026); *see also Washington v. FEMA*, 818 F. Supp. 3d 195, 204–05 (D. Mass. 2025) (vacating agency actions which contradicted FEMA’s statutory obligations).¹² And that makes sense: if a regulation violates a statute, that defect cannot be cured by remanding to the agency. Thus, if Plaintiff States succeed on their contrary to law claim, they are *per se* entitled to vacatur.

Vacatur is also appropriate where an agency action is arbitrary and capricious. *See, e.g., Am. Fed’n of Gov’t Emps. v. FLRA*, 26-cv-11747-DJC, 2026 WL 1870987, at *14 (D. Mass. June 29, 2026) (“Having determined that the IFR’s delegation revocation provisions are arbitrary and capricious, the Court concludes that they must be set aside[.]”); *New York v. Trump*, 811 F. Supp. 3d 215, 244 (D. Mass. 2025) (vacating agency action on the grounds that it was arbitrary and capricious). Whether vacatur is appropriate in such cases depends on “[1] the severity of the errors, [2] the likelihood that they can be mended without altering the order, and [3] on the balance of equities and public interest considerations.” *Cent. Me. Power Co. v. FERC*, 252 F.3d 34, 48 (1st Cir. 2001). These factors all favor vacatur here. The consequence of CMS’s errors is severe: millions of Americans will face a loss of health insurance if the IFR takes effect. *See supra*, at I.B. And, given the scope of information CMS would need to review on remand and the number of policies that review may impact, it is likely that “correcting the error” may “alter [the agency’s] final decision,” an argument the First Circuit has found “persuasive.” *Town of Weymouth v. Mass. Dep’t of Env’tl. Prot.*, 961 F.3d 34, 58 (1st Cir. 2020), *on reh’g*, 973 F.3d 143 (1st Cir. 2020).

The balance of equities and public interest likewise support vacating the Challenged

¹¹ CMS cites a concurring opinion by Justice Gorsuch suggesting that vacatur is unavailable under the APA. *See* Opp. 31-32. But a non-binding concurrence cannot overcome extant First Circuit precedent.

¹² Indeed, “remand-without-vacatur” makes little sense when a court finds agency action exceeds statutory authority, because “an agency can’t ‘cure’ the fact that it lacks authority to take a certain action.” *Bridgeport Hospital v. Becerra*, 108 F.4th 882, 890 (D.C. Cir. 2024). And the equities will always support vacatur in this context, because there is “no public interest in the perpetuation of unlawful agency action.” *Rhode Island v. Trump*, 155 F.4th 35, 50 (1st Cir. 2025).

Provisions if they are found arbitrary and capricious. CMS points to the cost of complying with another change in policy, but it is far easier for Plaintiff States to implement the Work Requirement on an ongoing basis without the Challenged Provisions. RSMF ¶¶242-45; *see also* RSMF 251-63. And to the extent any non-Plaintiff State has short-term difficulty complying with the IFR after the Challenged Provisions are vacated, the solution is not to plow ahead with an unlawful rule, but for CMS to use its statutory authority to afford that State a good faith extension of the compliance deadline. *See infra* at V.C. Of course, CMS could later promulgate a lawful rule that modifies the medical frailty definition, and if that happens, States will adjust their systems as necessary. But the possibility of some new rule in the future provides no reason to maintain an unlawful one now, particularly given the operational burdens it imposes on the States. *See Rhode Island*, 155 F.4th at 50 (“[T]here is generally no public interest in the perpetuation of unlawful agency action.”).

B. The Court should permanently enjoin the Challenged Provisions.

As for a permanent injunction, CMS ignores entirely—and thus concedes—Plaintiffs’ argument that the Challenged Provisions will impose irreparable harms on the States by requiring burdensome medical frailty assessment. *See* Br. 28-29.¹³ Instead, CMS jumps to arguing that the public interest precludes injunctive relief, “regardless of whether Plaintiffs succeed on the merits of their claim or face irreparable harm.” Opp. 33. But again, binding First Circuit precedent holds there is “no public interest in the perpetuation of unlawful agency action.” *Rhode Island*, 155 F.4th at 50. And even if there were, it would not outweigh the concrete harms to Plaintiffs and the public interest from a rule that would impose substantial long-term operational burdens, while depriving millions of Americans of health insurance coverage.

C. A six-month enforcement stay is appropriate.

CMS’s assertion that retaining the authority to take punitive measures against States is “the only way the IFR may be effectively enforced” only highlights the threat of sanctions and the need for a stay of enforcement. Opp. 35. Plaintiffs merely request what Congress has already

¹³ This is analytically distinct from the “irreparable harm” argument that Plaintiffs advanced in seeking a preliminary injunction pending resolution of this action on the merits. That argument turned on the short-term challenges of complying with the Challenged Provisions rather than the long-term burdens. *See* ECF 3 at 16-19.

allowed—a period of six months during which Plaintiffs will not be sanctioned for errors made as they implement the Work Requirement in good faith. *See* 42 U.S.C. § 1396a(xx)(11) (authorizing deadline waiver through Dec. 31, 2028). There is good cause for such relief. CMS’s unlawful IFR derailed Plaintiff States’ implementation efforts and deprived them of roughly six months of time to create and vet compliance systems under a lawful regulatory regime. *See* RSMF ¶¶227-45. Indeed, to the extent CMS asserts that vacating the Challenged Provisions would cause compliance challenges for both Plaintiff and non-Plaintiff States, ECF 138-4 at ¶11, that is not a reason to keep unlawful provision, as CMS contends. It is a reason to grant Plaintiffs’ requested relief and extend the time period for compliance once the IFR is vacated—an option Congress expressly authorized.

To be clear, States “are working diligently” to implement the Work Requirement by January 1st. ECF 106-66 at 1. But the delays caused by the States having to divert resources to comply with the Challenged Provisions “heighten the risk of systems error, improper terminations, and administrative failures affecting eligible individuals,” RSMF ¶161. States have lost time to stress-test their medical frailty verification systems and cannot be certain those systems will be error-free. And because the medical frailty verification process necessarily occurs before assessing whether someone has met the Work Requirement, errors and uncertainty in the assessment of medical frailty are likely to lead to additional downstream errors. Thus, there is a significant likelihood that system errors and design flaws come to light after systems go live on January 1st. *See id.* The solution is for this Court to exercise its equitable authority and restore the parties to the status quo—that is, “the last uncontested status which preceded the pending controversy,” *Braintree Labs., Inc. v. Citigroup Glob. Mkts.*, 622 F.3d 36, 41 n.5 (1st Cir. 2010)—which was the time immediately prior to issuance of the IFR, when Plaintiff States had six months to develop and test systems to implement the medical frailty exclusion.¹⁴

CONCLUSION

The Court should grant Plaintiffs’ motion and deny Defendants’ cross-motion.

¹⁴ CMS expresses concern that such action will give Plaintiff States special treatment, *see* Opp. 35, but Plaintiff States do not object to CMS extending the grace period to all States.

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Respectfully submitted,

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

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