UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMART APPROACHES TO MARIJUANA, et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services, et al.,

Defendants.

Civil Action No. 26-1081 (TNM)

**DEFENDANTS' MOTION TO DISMISS**

Defendants Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services ("HHS"), HHS, Dr. Mehmet Oz, in his official capacity as Administrator of the Centers for Medicare and Medicaid Services ("CMS"), and CMS respectfully move to dismiss this action pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure. The grounds for this motion are set forth in Defendants' Memorandum of Points and Authorities (1) In Opposition to Plaintiffs' Motion for Temporary Restraining Order, Preliminary Injunction, and Stay of Agency Action Pending Judicial Review and (2) In Support of Defendants' Motion to Dismiss. A proposed order is attached.

Dated: April 9, 2026

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**[PROPOSED] ORDER**

UPON CONSIDERATION of Defendants' Motion to Dismiss and Defendants' Memorandum of Points and Authorities (1) In Opposition to Plaintiffs' Motion for Temporary Restraining Order, Preliminary Injunction, and Stay of Agency Action Pending Judicial Review and (2) In Support of Defendants' Motion to Dismiss, it is hereby

ORDERED that Plaintiffs' motion for a preliminary injunction is DENIED; and it is

ORDERED that Defendants' motion to dismiss is GRANTED; and it is

FURTHER ORDERED that this action is dismissed with prejudice.

SO ORDERED, this _____ day of _____, 2026.

_____
TREVOR N. McFADDEN
United States District Judge

UNITED STATES DISTRICT COURT
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v.

ROBERT F. KENNEDY, JR., in his official capacity Secretary of Health and Human Services, et al.,

Defendants.

Civil Action No. 26-1081 (TNM)

**DEFENDANTS' MEMORANDUM OF POINTS AND AUTHORITIES (1) IN OPPOSITION TO PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, AND STAY OF AGENCY ACTION PENDING JUDICIAL REVIEW AND (2) IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS**

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## INTRODUCTION

This case begins and ends with *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024) (*AHM*). There, the Supreme Court confronted organizations and individuals who challenged FDA's regulatory actions concerning a product they neither prescribed nor used. The Court unanimously held:

> The plaintiffs have sincere legal, moral, ideological, and policy objections to elective abortion and to FDA's relaxed regulation of mifepristone. But under Article III of the Constitution, those kinds of objections alone do not establish a justiciable case or controversy in federal court.

*Id.* at 396.

Plaintiffs are anti-cannabis advocacy organizations and one Medicare beneficiary. None participates in any Centers for Medicare and Medicaid Services ("CMS") Innovation Center, also known as the Center for Medicare and Medicaid Innovation ("CMMI"), model. None administers the program they challenge. None faces any regulatory obligation from CMS. Their complaint is that CMS announced a voluntary component of existing models allowing willing providers to consult with consenting beneficiaries about eligible hemp products—and they object to it. Under *AHM*, objection is not injury.

The individual Plaintiff, David Evans, receives care from an ACO REACH participant. He opposes hemp products and says he would never use them. His claimed injury is that his provider might someday elect a voluntary program, might someday offer him a product, and he might be upset. That chain of contingencies is not Article III standing. It is speculation about the independent choices of third parties who are not before this Court.

Even if Plaintiffs could establish standing, their claims are barred. Section 1115A(d)(2) of the Social Security Act provides that there shall be "no administrative or judicial review" of "the elements, parameters, scope, and duration" of models tested under CMMI authority. 42 U.S.C.

§ 1315a(d)(2). The Substance Access Beneficiary Engagement Incentive ("Substance Access BEI" or "BEI") is an *element* of existing models. Plaintiffs challenge CMS's decision to include that element. That is exactly what Congress precluded.

On the merits, Plaintiffs' case rests on a fundamental conflation. Congress drew a bright statutory line between hemp and marijuana in the 2018 Farm Bill. Hemp is not a controlled substance. It is not illegal under federal law. The April 2025 CMS rule Plaintiffs invoke addressed "illegal substances under Federal law"—marijuana. *See* TRO Mem. (ECF No. 4) at 12 (citing 90 Fed. Reg. 15792, 15867 (Apr. 15, 2025)). The BEI addresses hemp. There is no inconsistency, no reversal, and no unexplained departure. There is a legal distinction that Congress enacted that Plaintiffs fail to acknowledge.

Plaintiffs cannot satisfy any *Winter* factor. *See Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The BEI is voluntary at every level—for model participants, for providers, and for beneficiaries. The organizational Plaintiffs face no regulatory obligation of any kind. Mr. Evans's provider has not elected the BEI, and even if he or she did, nobody is forcing Mr. Evans to use any product. The notice-and-comment claim flounders because the BEI is not a legislative rule but an optional component of voluntary participation agreements that has been implemented the same way CMMI has implemented every voluntary model for sixteen years. And, hypothetically, even if it were a rule, Section 553(a)(2) of the APA exempts matters relating to benefits from notice-and-comment requirements—and the D.C. Circuit has held that exemption applies to Medicare. *See Humana of S.C., Inc. v. Califano*, 590 F.2d 1070, 1082 (D.C. Cir. 1978).

Therefore, the Court should deny Plaintiffs' motion for preliminary injunctive relief and dismiss this action in its entirety.

## BACKGROUND

### A. The CMS Innovation Center and Section 1115A

In 2010, Congress enacted Section 1115A of the Social Security Act as part of the Affordable Care Act. *See* 42 U.S.C. § 1315a. Section 1115A established the CMMI within CMS. Its statutory purpose is to "test innovative payment and service delivery models" that are expected to "reduce program expenditures . . . while preserving or enhancing the quality of care" for Medicare and Medicaid beneficiaries. *Id.* § 1315a(a)(1).

Congress gave the Secretary of Health and Human Services (the "Secretary") broad authority to design and implement payment models. The Secretary selects models for testing, determines their elements and parameters, chooses participants, and sets the scope and duration of testing. *Id*. § 1315a(b). Congress required only that the Secretary consider certain statutory factors in selecting models and report periodically to Congress on model performance. *Id.* § 1315a(b)(2), (4). Congress also expressly precluded judicial review of the Secretary's decisions regarding "the selection of models for testing," "the selection of organizations, sites, or participants," and "the *elements*, parameters, scope, and duration of such models." *Id.* § 1315a(d)(2) (emphasis added).

Since its creation, CMMI has tested dozens of models. These include ACO REACH, the Enhancing Oncology Model ("EOM"), Bundled Payments for Care Improvement Advanced, Primary Care First, the Making Care Primary Model, and others.

CMS implements a voluntary model and model components through participation agreements between CMS and model participants. Participation agreements define model requirements including quality benchmarks, spending targets, reporting obligations, beneficiary engagement incentives, payment methodologies, and other conditions. CMS has added, modified, and removed model components throughout CMMI's sixteen-year history. It has never conducted

notice-and-comment rulemaking for any voluntary model component. Fishman Decl. ¶ 5 (copy attached as Ex. 1)

**B. Hemp and Marijuana Under Federal Law**

The Agriculture Improvement Act of 2018 (2018 Farm Bill) established a statutory line between hemp and marijuana. Congress defined "hemp" as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers," with "a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." 7 U.S.C. § 1639*o*(1) (italicization original). It simultaneously amended the Controlled Substances Act (CSA) to exclude hemp from the definition of "marihuana." *See* Agriculture Improvement Act of 2018, Pub. L. No. 115-334, § 12619, 132 Stat. 4490, 5018.

The legal consequence is that hemp is not a Schedule I controlled substance and is not illegal under federal law. Marijuana—cannabis above the 0.3% delta-9 THC threshold—remains a Schedule I substance. *See* 21 U.S.C. § 812 sched. I(c)(10).

**C. The Substance Access Beneficiary Engagement Incentive**

On March 20, 2026, CMS announced the Substance Access Beneficiary Engagement Incentive, an optional component available to participants in three existing Innovation Center models: ACO REACH, EOM, and (beginning January 1, 2027) the Long-term Enhanced ACO Design Model (LEAD). The BEI allows model participants that affirmatively elect it to consult with eligible beneficiaries about the possible use of eligible hemp products to improve symptom control and, if appropriate, to furnish such products up to $500 per year per eligible beneficiary. Fishman Decl. ¶ 8.

The BEI is voluntary at every level. Model participants are not required to elect it. Participants that do elect the BEI must submit an implementation plan for CMS approval. CMS retains authority to reject or suspend participation.

The BEI adopts the 2018 Farm Bill's definitional threshold: eligible products must contain no more than 0.3% delta-9 THC by weight. 7 U.S.C. § 1639*o*(1) (italicization original). Products above that threshold are marijuana and are ineligible. Physicians must determine beneficiary eligibility, including that the beneficiary is over 18 and does not have a disqualifying condition. Beneficiaries must consent through shared decision-making. Participants must report to CMS quarterly. No provider is compelled to offer hemp products. No beneficiary is compelled to accept them. Fishman Decl. ¶ 6.

CMS does not pay for hemp products under the BEI. The participating provider furnishes eligible products at its own cost, subject to the $500 annual cap per beneficiary. The BEI operates within the shared-savings framework that defines the underlying models. If a provider's investment in beneficiary engagement reduces the beneficiary's total cost of care, the provider and CMS share in the resulting savings. If it does not, the provider absorbs the loss. No new federal appropriation is involved. No new entitlement is created. The BEI is, at its core, a decision by willing providers that a particular intervention can reduce downstream claims. Fishman Decl. ¶ 4-6.

**D. Plaintiffs**

Plaintiffs are ten organizations and one individual. *See* Compl. (ECF No. 8) ¶¶ 8–18. The organizational Plaintiffs are advocacy organizations whose missions involve opposing the expansion of access to cannabis and hemp-derived products. *Id.* ¶¶ 8–17. None is a participant in ACO REACH, EOM, or LEAD. Fishman Decl. ¶ 10. None administers or is subject to the BEI. *Id.* None is regulated by CMS in any respect relevant to this case. *Id.*

The individual Plaintiff, David Evans, is a 78-year-old Medicare beneficiary who receives care from Hopscotch Primary Care, an ACO REACH participant. Evans Decl. (ECF No. 4-2) ¶¶ 4, 6. Mr. Evans alleges he is "opposed to expanded access to cannabis and hemp-derived products" and does "not want them provided by or through [his] Medicare provider." *Id.* ¶ 7. Plaintiffs make no allegation that Hopscotch Primary Care has elected the BEI, submitted an implementation plan, or offered Mr. Evans any hemp product.

**LEGAL STANDARD**

A preliminary injunction is an "extraordinary remed[ies] never awarded as of right." *Winter*, 555 U.S. at 24. A plaintiff seeking such relief "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 plaintiff bears the burden on each factor. *Id.* Where the government is a party, the balance of equities and public interest factors merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009).

Before the Supreme Court's decision in *Winter*, courts weighed these factors on a "sliding scale," allowing "an unusually strong showing on one of the factors" to overcome a weaker showing on another. *Damus v. Nielsen*, Civ. A. No. 18-0578 (JEB), 2018 WL 3232515, at *4 (D.D.C. July 2, 2018) (quoting *Davis v. Pension Ben. Guar. Corp.*, 571 F.3d 1288, 1291–92 (D.C. Cir. 2009)). The Supreme Court overruled the sliding scale approach, holding that "a plaintiff seeking a preliminary injunction must make a clear showing 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.'" *Starbucks Corp. v. McKinney*, 602 U.S. 339, 346 (2024) (quoting *Winter*, 555 U.S. at 20).

Before reaching these factors, however, the Court must satisfy itself that it has subject matter jurisdiction. A court may not "assume jurisdiction for the purpose of deciding the merits"

when Article III standing is in doubt. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998). And where Congress precludes judicial review, the Court lacks jurisdiction. *See Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 353 n.4 (1984) (preclusion is jurisdictional).[1]

## ARGUMENT

### I. Plaintiffs Lack Article III Standing.

A plaintiff must show "(i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief." *AHM*, 602 U.S. at 380 (citing *Summers v. Earth Island Institute*, 555 U.S. 488, 493 (2009); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992)). Where, as here, "a plaintiff challenges the government's 'unlawful regulation (or lack of regulation) of someone else,' 'standing is not precluded, but it is ordinarily substantially more difficult to establish.'" *Id.* at 382 (quoting *Lujan*, 504 U.S. at 562). That is because "unregulated parties may have more difficulty establishing causation—that is, linking their asserted injuries to the government's regulation (or lack of regulation) of someone else." *Id.* (citing *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 413-414 (2013); *Lujan*, 504 U.S. at 562; *Duke Power Co. v. Carolina Env't Study Grp, Inc.*, 438 U.S. 59, 74, 98 (1978); *Simon v. Eastern Ky. Welfare Rights Organization*, 426 U.S. 26, 41-46 (1976); *Warth v. Seldin*, 422 U.S. 490, 504-508 (1975)).

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[1] Local Civil Rule 7(n)(1) provides that "[i]n cases involving the judicial review of administrative agency action, unless otherwise ordered by the Court, the agency must file a certified list of the contents of the administrative record with the Court within 30 days following service of the answer to the complaint *or simultaneously with the filing of a dispositive motion, whichever occurs first*." (Emphasis added.) Consistent with paragraph 13(B) of the Court's Standing Order, ECF No. 6, the Secretary respectfully requests relief from the foregoing local rule in a separate motion contemporaneously with filing this dispositive motion. *See, e.g.*, *Varghese v. Blinken*, Civ. A. No. 21-2597 (CRC), 2022 WL 3016741, at *2 n.3 (D.D.C. July 29, 2022) (finding compliance with Local Civil Rule 7(n)(1) unnecessary where the "administrative record would not help resolve the government's motion [to dismiss]").

Plaintiffs are unregulated parties in every sense. CMS has not required them to do or refrain from doing anything. They do not participate in ACO REACH or EOM. They do not administer the Substance Access BEI. They seek to challenge CMS's regulation of others. None of their standing theories withstands scrutiny.[2]

**A. The Organizational Plaintiffs Lack Standing.**

The organizational Plaintiffs claim that the Substance Access BEI has "directly impaired" their "core programmatic activities" by "requiring" them to "divert staff and resources" to "monitor, analyze, and provide direct informational services" regarding the BEI. Compl. (ECF No. 8) ¶ 8. This is the same theory the Supreme Court unanimously rejected in *AHM*.

In *AHM*, the plaintiff medical associations argued that FDA had "'impaired' their 'ability to provide services and achieve their organizational missions'" and had "'forced' the associations to 'expend considerable time, energy, and resources' drafting citizen petitions to FDA, as well as engaging in public advocacy and public education." 602 U.S. at 369-370. The Court held that "an organization that has not suffered a concrete injury caused by a defendant's action cannot spend its way into standing simply by expending money to gather information and advocate against the defendant's action." *Id.* at 370. The Court further held that an "organization may not establish standing simply based on the intensity of the litigant's interest or because of strong opposition to the government's conduct." *Id*. at 394 (quotation omitted).

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[2] Plaintiffs have indicated an intent to add MMJ International Holdings and its subsidiaries as plaintiffs. Defendants note that this will not cure the standing deficiencies addressed herein. MMJ does not compete in the same market, its claimed injuries depend on a speculative chain of contingencies, and it does not appear to hold the regulatory authorizations its standing theories presuppose. The legal framework set forth in this opposition applies with equal force to MMJ. Defendants can address MMJ's specific deficiencies with more particularity in a supplemental filing, including under seal to the extent necessary.

Years earlier, the D.C. Circuit has applied the same principle in a cannabis case. In *Gettman v. DEA*, 290 F.3d 430 (D.C. Cir. 2002), the court dismissed a petition to reschedule marijuana for lack of standing where the petitioners—a cannabis policy advocate and High Times magazine—could show nothing more than a generalized interest in marijuana policy and speculation about downstream economic effects. The court held that "'[A] mere 'interest in a problem,' no matter how longstanding the interest and no matter how qualified the organization is in evaluating the problem, is not sufficient by itself[.]" *Id.* at 434 (quoting *Sierra Club v. Morton*, 405 U.S. 727, 739 (1972)). The petitioner's "desire to achieve vague objectives with relation to marijuana" did not "cross the Article III threshold." *Id*.

The organizational Plaintiffs' theory here is indistinguishable. If a longstanding interest in cannabis reform did not confer standing in *Gettman*, a longstanding interest in cannabis opposition does not confer standing here. For example, the mission of Smart Approaches to Marijuana, Inc. (SAM) "includes education and advocacy regarding the public health and safety impacts of marijuana and cannabis policy." Compl. (ECF No. 8) ¶ 8. The mission of Cannabis Industry Victims Educating Litigators (CIVEL) "includes educating legal professionals and the public about the harms caused by the cannabis industry." *Id*. ¶ 9. Every organizational Plaintiff exists to oppose cannabis access. The BEI did not divert these organizations from some unrelated core activity. It gave them exactly the kind of government action they exist to oppose. Their expenditure of resources to oppose it is the execution of their organizational missions, not a diversion from them. That is precisely the distinction the Supreme Court drew in *AHM* when it held that *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982), does not support "the expansive theory that standing exists when an organization diverts its resources in response to a defendant's actions." 602 U.S. at 370.

SAM's own filings confirm the point. SAM attaches as Exhibit A (ECF No. 4-1) to Plaintiffs' motion its participation in the ongoing DEA marijuana rescheduling proceedings and alleges in the Complaint that the BEI has "rendered essentially moot" its expenditure of resources opposing rescheduling because the BEI "provides marijuana products via a medical source." Compl. (ECF No. 8) ¶ 8. This argument fails twice. For starters, the BEI does not provide marijuana products but concerns hemp products. Hemp is not marijuana. Equally important, even accepting SAM's mischaracterization, its argument is that a separate government action under separate statutory authority has made SAM's advocacy in a different proceeding less effective. That is not Article III injury. It is a complaint that law and policy landscape has shifted in a direction SAM dislikes. The Supreme Court rejected precisely this theory in *AHM*: an organization's frustration that its advocacy efforts have been undermined by government action does not constitute standing.

*Havens* involved a housing counseling organization whose "core business activities" were "directly affected and interfered with" by the defendant's discriminatory conduct—specifically, the defendant gave the organization's employees false information about apartment availability, impairing the organization's ability to provide counseling and referral services. *AHM*, 602 U.S. at 395. Nothing analogous is present here. CMS's action does not interfere with any Plaintiff's ability to conduct its existing programs. Plaintiffs remain free to educate the public, train physicians, assist victims, and advocate for restrictions on cannabis access. The Substance Access BEI does not impede those activities in any way. Plaintiffs simply object to CMS's policy and have chosen to spend resources opposing it. Under *AHM* and *Gettman*, that is not enough.[3]

[3] Plaintiffs do not and could not assert associational standing on behalf of their members. *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977) (associational standing

The D.C. Circuit's most recent application of these principles confirms that *AHM* did not displace Circuit precedent but reinforced it. In *Center for Biological Diversity v. DOI*, 144 F.4th 296 (D.C. Cir. 2025), environmental organizations challenged over 4,000 Bureau of Land Management drilling permits, claiming organizational standing on the theory that BLM's failure to publicize information about the permits' climate impacts forced them to divert resources to their own informational and advocacy efforts. The court held that the organizations' alleged injuries were "limited to issue advocacy" and did not show "'a concrete and demonstrable injury to the organization's activities'" within the meaning of *Havens*. *Id.* at 314-315.

Critically, the court read *AHM* as clarifying rather than overruling D.C. Circuit organizational standing doctrine, noting that *AHM* "cautioned against extending [*Havens*] beyond circumstances in which the challenged action directly affected and interfered with a plaintiff's core business activities." *Id.* at 315 (quot. omitted). The court thus reaffirmed the distinction this Circuit has drawn for over three decades: an organization has standing when the defendant's conduct operationally impairs the organization's ability to deliver services to the people it serves; it does not have standing merely because it has chosen to spend money opposing a government policy it disfavors. *See also Fair Emp't Council of Greater Wash., Inc. v. BMC Mktg. Corp.*, 28 F.3d 1268, 1276–77 (D.C. Cir. 1994) (holding that an organization's "own budgetary choices" to investigate and oppose a defendant's conduct are "self-inflicted" and do not constitute injury in fact fairly traceable to the defendant).

The organizational Plaintiffs here are indistinguishable from the unsuccessful plaintiffs in *Center for Biological Diversity*. Their claimed injuries are not that the BEI has interfered with their

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requires at least one member has standing to sue in his own right). No individual member of these organizations has standing for the same reasons Mr. Evans does not.

ability to educate physicians, counsel patients, or deliver any service to any person. Their claimed injuries are that the BEI exists and they choose to spend money opposing it. That is issue advocacy, not operational impairment. And under Circuit law and *AHM*, it is not enough.

**B. David Evans Lacks Standing.**

Mr. Evans is a 78-year-old Medicare beneficiary who receives care from Hopscotch Primary Care, an ACO REACH participant. His claimed injury is that if his provider elects the BEI and offers him hemp products, he "would lose all faith in them and would be forced to seek out a different medical provider." TRO Mem. (ECF No. 10) at 19.

Starting with the obvious: Mr. Evans opposes hemp products and will not use them. He says so himself. Evans Decl. (ECF No. 4-2) ¶ 7. The Substance Access BEI is voluntary for beneficiaries. No one will force Mr. Evans to consume a hemp product. No one will force his provider to offer him one. His alleged injury is thus not that the BEI will cause him any physical, monetary, or regulatory harm. His alleged injury is that he might be offered a product he will decline. That is not an Article III injury. It is an offense to his sensibilities.

"[D]istress at or disagreement with the activities of others is not a basis under Article III for a plaintiff to bring a federal lawsuit challenging the legality of a government regulation allowing those activities." *AHM*, 602 U.S. at 390 n.3 (cite omitted). Mr. Evans is not distressed by something that has happened to him. He is distressed by the possibility that a program he opposes might exist in the vicinity of his medical care. That is a moral and ideological objection—sincere, perhaps—but not cognizable under Article III. *Id.* at 381 (the standing requirement "screens out plaintiffs who might have only a general legal, moral, ideological, or policy objection to a particular government action").

Even setting aside the nature of the claimed injury, the causal chain is wholly speculative. To connect the Substance Access BEI to any injury to Mr. Evans, Plaintiffs must establish that:

(1) Hopscotch Primary Care voluntarily elects the BEI; (2) Hopscotch submits an implementation plan and CMS approves it; (3) Hopscotch offers hemp products to Mr. Evans specifically; and (4) Mr. Evans suffers some concrete harm from that offer beyond being offended by it. No link in this chain is alleged to have occurred. No link is alleged to be imminent. Each depends on "unfettered choices made by independent actors not before the courts." *Clapper*, 568 U.S. at 414 n.5.

Mr. Evans's standing theory reduces to this: CMS created a voluntary program, and a provider he visits might someday elect it, and that provider might someday offer him a product, and he might be upset. This hypothetical in *AHM* is apt: If an emergency room doctor lacks standing to challenge increased speed limits because he might treat more car accident victims, 602 U.S. at 391, then a Medicare beneficiary surely lacks standing to challenge a voluntary model component because he might someday be offered a product he can freely refuse.

**C. Plaintiffs' Procedural Standing Theory Does Not Save Their Claims.**

Plaintiffs also assert procedural standing, arguing that CMS denied them the right to participate in notice-and-comment rulemaking under 5 U.S.C. § 553. This is Plaintiffs' only colorable standing theory. Still, it fails.

Even under the relaxed requirements for procedural standing, a plaintiff must show that the challenged action threatens a concrete, "particularized interest"—not merely a generalized ideological concern. *Summers*, 555 U.S. at 496–97. The relaxed standard relieves a procedural-rights plaintiff of the obligation to show that the agency might have reached a different result had it followed correct procedure. It does *not* relieve the plaintiff of the obligation to show that the plaintiff has a concrete stake in the outcome at all. *See id.* at 496 ("[D]eprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing." (emphasis original)). A procedural injury is

cognizable only when the procedure in question is "designed to protect some threatened concrete interest" of the plaintiff. *Lujan*, 504 U.S. at 573 n.8.

What concrete interests do Plaintiffs have? As they describe it, their interest is in opposing the expansion of access to hemp products and protecting the public from cannabis-related harms. But *AHM* held that opposition to a product being made available to others is a "moral, ideological, and policy objection" that "do[es] not establish a justiciable case or controversy in federal court." 602 U.S. at 396. Plaintiffs cannot transform that same insufficient interest into a sufficient one by repackaging it as a procedural gripe. Their interest in commenting on this policy is indistinguishable from their interest in opposing it.

The D.C. Circuit's decision in *American Institute of Certified Public Accountants v. IRS*, 804 F.3d 1193 (D.C. Cir. 2015) (*AICPA*), is instructive. There, a professional association challenged an IRS program for failure to conduct notice-and-comment rulemaking before implementing it. The court held that the right to participate in notice-and-comment rulemaking is not a generalized entitlement available to anyone who objects to a government action. Rather, it is a procedural mechanism that protects the concrete interests of parties with a stake in the regulatory outcome. *Id.* at 1198.

Plaintiffs here cannot satisfy that requirement. Their interest in commenting on the Substance Access BEI is indistinguishable from their interest in opposing it. They wish to participate in notice-and-comment proceedings for the purpose of urging CMS not to implement a policy they find objectionable—not because the BEI threatens any concrete interest of theirs that the rulemaking process is designed to protect. Under *AICPA* and *Summers*, the procedural right to comment does not exist in the abstract. It exists to safeguard concrete interests. Where, as here,

the only interest at stake is ideological opposition to the substance of the policy, the procedural claim adds nothing that *AHM* has not already held insufficient.

Mr. Evans is the plaintiff closest to having a concrete interest. He alleges that he receives care from an ACO REACH participant. But as discussed, his alleged injury is that he might someday be offered a product he can freely decline. He faces no regulatory obligation. He faces no economic injury. He faces no physical harm. His interest reduces to the desire not to be in the vicinity of a program he finds objectionable. That is not a concrete interest the notice-and-comment process is designed to protect.

Finally, as discussed below, there is another reason Plaintiffs' procedural theory fails. Even if the BEI were a rule, Section 553(a)(2) exempts matters relating to benefits from notice-and-comment requirements. Put simply, if Section 553 does not apply, there is no procedural right to invoke, and procedural standing collapses.

## II. Section 1115A Precludes Judicial Review.

Even if Plaintiffs could establish Article III standing, their claims are statutorily barred. Congress dictated that "[t]here shall be no administrative or judicial review of" specified actions under Section 1115A, including "the selection of models for testing or expansion under this section," "the selection of organizations, sites, or participants to test those models selected," and "the elements, parameters, scope, and duration of such models." 42 U.S.C. § 1315a(d)(2).

The Substance Access BEI falls squarely within the precluded categories. The BEI is an element of existing Innovation Center models. CMS did not create a new model. It added a beneficiary engagement incentive—a component—to ACO REACH, EOM, and (prospectively) LEAD. The participation agreements governing those models define their elements. CMS's decision to include a beneficiary engagement incentive involving eligible hemp products is a

decision about what elements those models contain and what parameters govern their operation. Section 1115A(d)(2) places those decisions beyond judicial review.

Plaintiffs attempt to evade the preclusion bar by recharacterizing their challenge as one to CMS's "procedures" rather than to model elements. They contend that they do not challenge what CMS did but how it did it—that is, without notice-and-comment rulemaking. This framing is more clever than persuasive. The substance of Plaintiffs' complaint is that CMS should not have added this element to these models, or at minimum that CMS should have used different procedures before doing so. But the decision to add a particular element to a model—including the process by which that element is added—is part and parcel of the "elements, parameters, scope, and duration" of the model. Congress did not preclude challenges to model elements while leaving open a backdoor challenge to the procedures by which those elements are adopted. The preclusion bar would be meaningless if any challenger could circumvent it simply by recasting a substantive objection as a procedural one.

This statutory structure confirms this reading. Section 1115A contains no requirement that CMS conduct notice-and-comment rulemaking before implementing model elements. It does not cross-reference the rulemaking requirements of 5 U.S.C. § 553. It does not require Federal Register publication of model components. Instead, it grants the Secretary broad discretion to "test" models, 42 U.S.C. § 1315a(b)(1), specifies factors the Secretary must consider in selecting models, *id.* § 1315a(b)(2), and requires periodic reports to Congress on model performance, *id.* § 1315a(b)(4).

The absence of any procedural rulemaking requirement in Section 1115A is not an oversight. It is a design choice. Congress built the CMMI for speed and flexibility. It shielded model-design decisions from judicial review to ensure that courts would not second-guess the agency's testing choices. Plaintiffs ask this Court to graft onto Section 1115A a procedural

requirement Congress omitted and then to adjudicate a claim that Congress precluded. The Court should decline.

Plaintiffs rely on *Regeneron Pharmaceuticals, Inc. v. HHS*, 510 F. Supp. 3d 29 (S.D.N.Y. 2020), which concluded that Section 1115A "does not bar review of the propriety of the procedures used" to establish models. *Id.* at 42. But *Regeneron* is distinguishable in a key respect. In *Regeneron*, CMS used its CMMI authority to impose a mandatory "Most Favored Nation" pricing model on drug manufacturers. The manufacturers had to accept reduced reimbursement rates or exit Medicare entirely. The district court held that a procedural challenge to a *mandatory* model, brought by parties subject to such a model, was not precluded.

The BEI is the opposite in every relevant respect. It is optional for model participants. Providers who do not wish to offer hemp products do not need to elect the BEI. Beneficiaries who do not wish to use hemp products may decline them. The Plaintiffs in this case are not model participants at all—they are unregulated third parties with no connection to any Innovation Center model. The mandatory dynamic that animated *Regeneron* is entirely absent.

The same is true of other Most Favored Nation model cases. *See, e.g.*, *Ass'n of Cmty. Cancer Ctrs. v. Azar*, 509 F. Supp. 3d 482 (D. Md. 2020). Those cases involved the same mandatory model that required participation by regulated entities. District courts outside this Circuit held that Congress did not intend Section 1115A's preclusion bar to shield mandatory programs—imposed on regulated parties with the force of law—from all judicial review. Whatever the merits of that holding, it has no application here because the Substance Access BEI is completely voluntary.

## III. Plaintiffs Cannot Satisfy the *Winter* Factors.

To obtain a temporary restraining order or preliminary injunction, Plaintiffs must show "(1) that [they are] likely to succeed on the merits, (2) that [they are] likely to suffer irreparable

harm in the absence of preliminary relief, (3) that the balance of equities tips in [their] favor, and (4) that an injunction is in the public interest." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Because the government is a party, the third and fourth factors merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009). The same standard applies to a request for interim relief under 5 U.S.C. § 705. *See Coal. for Humane Immigrant Rights v. DHS*, 780 F. Supp. 3d 79, 87 (D.D.C. 2025) (McFadden, J.). Plaintiffs cannot satisfy any of these elements.

**A. Plaintiffs Are Not Likely to Succeed on the Merits.**

Plaintiffs advance four merits theories: (1) the Substance Access BEI is a legislative rule that required notice-and-comment rulemaking; (2) the BEI is arbitrary and capricious; (3) the BEI exceeds CMS's statutory authority under the major questions doctrine; and (4) the BEI conflicts with federal law. None has merit.

1. The Substance Access BEI is not a legislative rule requiring notice and comment.

The APA's notice-and-comment requirements apply to legislative rules—agency statements that carry "the force and effect of law." *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 96 (2015). Whether an agency action constitutes a legislative rule depends on the substance of what the agency did, not the label it applied. *See Am. Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1109–12 (D.C. Cir. 1993). The Substance Access BEI is not a legislative rule.

The BEI is an optional component of existing voluntary Innovation Center models. It is implemented through amendments to participation agreements—the same mechanism CMS has used to administer every voluntary model tested under Section 1115A since 2010. It applies only to organizations that voluntarily enter model participation agreements and that affirmatively elect the component. It imposes no obligations on any person or entity that does not choose to

participate. It is not published in the Code of Federal Regulations. It does not amend any existing regulation. It does not bind the public at large.

These features distinguish the BEI from a legislative rule in every material respect. A legislative rule affects "individual rights and obligations." *Chrysler Corp. v. Brown*, 441 U.S. 281, 303 (1979). The BEI affects the rights and obligations of no one who does not voluntarily elect it. A legislative rule "has the force and effect of law." *Mortgage Bankers Ass'n*, 575 U.S. at 96. The BEI has force and effect only within the four corners of a participation agreement voluntarily entered by model participants—it has no effect in any broader sense.

CMS's sixteen-year practice confirms this conclusion. Since CMMI's creation, CMS has stood up dozens of models and added, modified, and removed model components through participation agreements. These components routinely include quality benchmarks, spending targets, reporting requirements, beneficiary engagement incentives, and payment methodologies—all of which impose binding conditions on participants who elect them. CMS has never conducted notice-and-comment rulemaking for any *voluntary* model component. No court has ever required it to do so. This consistent, longstanding practice reflects the statutory design: Congress created CMMI to test models with speed and flexibility and did not subject model implementation to Section 553's rulemaking requirements.

The BEI's economic structure confirms that it is a model component, not a regulation of general applicability. CMS does not pay for hemp products. The participating provider furnishes products at its own cost, bears the downside risk, and shares in any savings generated by reduced claims. This is an incentive mechanism embedded within a shared-savings payment model—the core of what CMMI models do. It is not a mandate. It is not an entitlement. It is a bet that a

particular intervention will reduce costs and improve care, with the provider putting its own money on the line. That is the definition of a model element, not a legislative rule.

Plaintiffs contend the BEI is a legislative rule because it imposes "binding obligations" on participating organizations—implementation plans, product specifications, dosing limits, reporting requirements. TRO Mem. at 13, ECF No. 10. That argument proves too much. Every participation agreement imposes binding obligations on participants. That is what a participation agreement does. If binding conditions in a voluntary participation agreement were sufficient to trigger Section 553, then every model component CMS has ever implemented—every quality benchmark, every spending target, every reporting requirement—would require notice-and-comment rulemaking. That has never been the law, and Plaintiffs cite no authority for such a sweeping proposition.

Plaintiffs' cannot rely on Most Favored Nation model cases. Those cases involved a mandatory model that required Medicare-participating drug manufacturers to accept reduced reimbursement rates. *See, e.g.*, *Ass'n of Cmty. Cancer Ctrs. v. Azar*, 509 F. Supp. 3d 482 (D. Md. 2020). The district courts held that a mandatory model—imposed through the force of law—was a legislative rule requiring notice and comment. The logic of those cases turned on the absence of voluntariness: manufacturers could not avoid the model's requirements without exiting Medicare entirely. The Substance Access BEI presents the opposite case. Model participants choose whether to enter ACO REACH or EOM. Having entered, they choose whether to elect the BEI. Having elected, they must submit an implementation plan for CMS approval. Participation is voluntary at every stage. The coercive features that made the Most Favored Nation model a legislative rule in the view of certain district courts are entirely absent.

Plaintiffs also invoke *American Hospital Ass'n v. Bowen*, 834 F.2d 1037 (D.C. Cir. 1987) (*AHA v. Bowen*), for the proposition that "contract provisions that are legislative [in character] are subject to § 553's notice and comment requirements." *Id.* at 1054. But *AHA v. Bowen* involved a *mandatory* Medicare condition of participation—the requirement that hospitals have an agreement with a peer review organization acting under contract with the Secretary—to participate in Medicare at all. The court held that the government could not use its contracts with peer review organizations to evade Section 553 when the substance of the requirements was mandatory and applied to all Medicare-participating hospitals. The Substance Access BEI is not a condition of participation in Medicare. It is not a condition of participation in ACO REACH or EOM. It is an optional add-on that model participants may elect or decline. *AHA v. Bowen* does not stand for the proposition that optional components of voluntary programs require notice-and-comment rulemaking.

2. Even if the BEI were a rule, the APA exempts it from notice-and-comment requirements.

Even assuming the BEI could be characterized as a rule, it would not be subject to Section 553's notice-and-comment procedures. Section 553(a)(2) exempts from rulemaking procedures any matter "relating to . . . benefits." 5 U.S.C. § 553(a)(2); *see also* Policy on Adhering to the Text of the Administrative Procedure Act, 90 Fed. Reg. 11,029, 11,029 (Mar. 3, 2025) (rescinding agency policy waiving benefits exception). The BEI is implemented through participation agreements between CMS and model participants related to Medicare benefits. Section 553(a)(2) exempts it from notice and comment by its plain text.

The D.C. Circuit has squarely held that the benefits exception applies to Medicare. In *Humana of South Carolina, Inc. v. Califano*, 590 F.2d 1070 (D.C. Cir. 1978), a hospital challenged a Medicare reimbursement regulation on the ground that HHS had failed to conduct notice-and-

comment rulemaking before adopting it. The hospital argued that providers were more like regulated entities than benefits recipients and therefore deserved the procedural protections of Section 553. The court rejected that argument. It held that even "construed narrowly, Section 553(a)(2) cuts a wide swath through the safeguards generally imposed on agency action," and that the exemption "prevails when 'grants,' 'benefits' or other named subjects are 'clearly and directly' implicated." *Id.* at 1082. The court applied the exemption to Medicare notwithstanding the public interest in participation and the impact of the rule on affected parties—holding that "in all cases in which the excepted subject matter is 'clearly and directly' involved, the congressional aim was to afford agencies procedural latitude regardless of the interest of affected parties and the public generally in contributing to formulation of the exempted rule." *Id.*

*Humana* has never been overruled or distinguished by the D.C. Circuit. It remains binding law in this Court. The BEI—a *voluntary* component of Medicare payment models—clearly and directly involves Medicare benefits. Under *Humana*, Section 553(a)(2) applies.

The exemption's original meaning confirms this reading. The Attorney General's Manual on the Administrative Procedure Act (1947)—the "most authoritative interpretation" of the APA, *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 218 (1988) (Scalia, J., concurring)—explains that the § 553(a)(2) exemption covers government "proprietary" as opposed to "regulatory" functions. The Manual identifies "benefits" as referring to "such programs as veterans' pensions and old-age insurance payments." Attorney General's Manual on the Administrative Procedure Act 27 (1947). Medicare is an old-age insurance program. A voluntary component of a Medicare payment model is, if anything, a clearer case than the examples the Manual provides, because it lacks the mandatory character of the programs the Manual describes.

Little case law beyond *Humana* interprets "benefits" under § 553(a)(2) in the Medicare context. The reason is historical, not doctrinal. In 1971, HHS adopted a policy known as the Richardson Waiver that voluntarily committed to follow notice-and-comment procedures even for matters the APA exempts, including those relating to benefits and contracts. 36 Fed. Reg. 2,532 (Feb. 5, 1971). *See also Stewart v. Smith*, 673 F.2d 485, 497 n.39 (D.C. Cir. 1982) (noting that many agencies voluntarily adopted notice and comment rulemaking procedures). Because HHS waived the exemption as a matter of policy for over fifty years, few occasions arose to litigate its scope. That policy was rescinded on March 3, 2025. See Policy on Adhering to the Text of the Administrative Procedure Act, 90 Fed. Reg. 11,029 (Mar. 3, 2025). The absence of case law reflects the exemption's dormancy, not its inapplicability.

Plaintiffs invoke *Azar v. Allina Health Services*, 587 U.S. 566 (2019) (*Allina*), which held that Section 1871(a)(2) of the Social Security Act independently requires notice-and-comment rulemaking for "substantive legal standards" governing Medicare. But *Allina* interpreted a different statute. Section 1871(a)(2) applies to rules that "establish[] or change[] a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter." 42 U.S.C. § 1395hh(a)(2). The BEI does not satisfy that standard. It does not change the scope of Medicare benefits—CMS does not pay for hemp products, no Medicare claim is submitted, and no entitlement is created. Nor does it change the payment for services—providers furnish products at their own cost within a shared-savings framework. And any conditions it establishes bind only participants who voluntarily elect it through a participation agreement, not the Medicare program at large. The BEI relates to Medicare benefits for purposes of Section 553(a)(2)'s exemption but

does not establish a substantive legal standard governing benefits "under this subchapter" for purposes of Section 1871(a)(2).

Nor could it. Section 1871 applies to rules adopted under Title XVIII of the Social Security Act. The BEI was adopted under Section 1115A, codified in Title XI of the Social Security Act, which is a separate statutory scheme with its own preclusion provision, its own grant of authority, and no cross-reference to Section 1871's rulemaking requirements. Congress did not incorporate Section 1871 into Section 1115A. It required only that the Secretary report to Congress on model performance. 42 U.S.C. § 1315a(b)(4). Applying Section 1871's rulemaking requirements to CMMI model components would nullify Section 1115A(d)(2)'s preclusion bar, because every model element could then be challenged in court for failure to comply with notice-and-comment procedures—the very result Congress precluded.

3. The BEI is not arbitrary and capricious.

Plaintiffs' centerpiece merits argument is that the BEI represents an unexplained reversal of CMS's April 2025 final rule, which stated that "medical marijuana or derivatives, such as cannabis oil, cannot be covered by [Medicare Advantage] organizations as they are illegal substances under Federal law." 90 Fed. Reg. 15,792, 15,867 (Apr. 15, 2025). This argument depends on a mischaracterization of the April 2025 rule that this Court should reject.

The April 2025 rule addresses marijuana. It says so. Its reasoning turns on a specific legal predicate: that the substances in question "are illegal substances under Federal law." *Id.* As to marijuana, that predicate is correct: it remains a Schedule I controlled substance under the CSA. 21 U.S.C. § 812 sched. I(c)(10). But it is inapplicable to hemp. The 2018 Farm Bill expressly removed hemp—defined as cannabis with a delta-9 THC concentration of not more than 0.3 percent on a dry weight basis—from the CSA's definition of marijuana. 7 U.S.C. § 1639*o*(1); *see*

*also* 2018 Farm Bill § 12619, 132 Stat. at 5018. Hemp is not a controlled substance. Hemp is not illegal under federal law. The April 2025 rule, by its own terms, does not address hemp.

The Substance Access BEI addresses hemp. Eligible products must contain no more than 0.3% delta-9 THC by weight—the 2018 Farm Bill's definitional threshold. Products above that threshold are marijuana and are not eligible. Plaintiffs assert that "hemp and marijuana are both forms of cannabis." Compl. (incorporating TRO Mem.). That is a botanically accurate statement. But Congress drew a bright line in the 2018 Farm Bill between hemp and marijuana. That line has legal consequences. One of those consequences is that a rule addressing "illegal substances under Federal law" does not apply to a substance that Congress removed from the schedules.

There is therefore no inconsistency between the April 2025 rule and the BEI. The April 2025 rule remains in effect. Medicare Advantage organizations (insurance companies offering health plans as an alternative to original Medicare) still cannot offer marijuana products as supplemental benefits. The BEI does not purport to change that. It creates a voluntary testing pathway for a legally distinct category of products—hemp—under a separate statutory authority. An agency does not act inconsistently when it treats legally distinct substances differently. It acts rationally. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016), requires a reasoned explanation when an agency "departs from a prior policy." CMS has not departed from its prior policy. Its prior policy addressed marijuana. The BEI addresses hemp. Hemp is not marijuana. There is nothing to explain.

Plaintiffs further contend that CMS failed to consider important aspects of the problem, including the health risks of hemp-derived products, the absence of FDA approval, and contamination concerns. *See Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). But the BEI is not a regulation of general applicability promulgated without

analysis. It is a limited, voluntary pilot program with multiple built-in safeguards: product eligibility requirements, THC limits, physician determination of beneficiary eligibility, disqualifying conditions (which CMS retains authority to specify), shared decision-making, a $500 annual cap, CMS approval of implementation plans, CMS authority to reject or suspend participation, and quarterly reporting. Plaintiffs may prefer different safeguards or no program at all. But the arbitrary-and-capricious standard does not require an agency to adopt the policy its critics prefer. It requires "reasoned decisionmaking." *State Farm*, 463 U.S. at 52. CMS's inclusion of multiple layers of safeguards in a voluntary, limited-scope testing program satisfies that standard.

4. The major questions doctrine does not apply.

The major questions doctrine applies when an agency claims authority to resolve a question of "vast economic and political significance" without clear congressional authorization. *West Virginia v. EPA*, 597 U.S. 697, 723 (2022). The doctrine is reserved for "extraordinary cases" in which the "history and the breadth of the authority that the agency has asserted" and the "economic and political significance of that assertion" provide "a reason to hesitate before concluding that Congress meant to confer such authority." *Id*. at 721 (quotation omitted).

A voluntary BEI capped at $500 per beneficiary attached to a CMMI model is not such a case. It does not mandate anything. It does not restructure an industry. It does not assert authority over a significant portion of the American economy. It is, by design, a limited pilot program—exactly the kind of incremental testing that Section 1115A authorizes.

Plaintiffs invoke the political attention the BEI has received as evidence of its significance. But the major questions doctrine does not turn on whether a policy is controversial. It turns on whether the agency has claimed authority of a scope and significance that Congress could not

plausibly have intended to delegate. *See West Virginia*, 597 U.S. at 725. Congress gave CMMI authority to test models. The BEI tests a model component.

5. The Substance Access BEI does not conflict with federal law.

Plaintiffs allege that the BEI conflicts with federal statutes. TRO Mem. at 17-18. None of these arguments has merit.

The 2018 Farm Bill removed hemp—defined as cannabis with a delta-9 THC concentration of not more than 0.3 percent on a dry weight basis—from the CSA's definition of marijuana. 7 U.S.C. § 1639*o*(1). Products meeting that definition are not Schedule I controlled substances. The BEI limits eligible cannabis products to those containing no more than 0.3% delta-9 THC by weight. Hemp is not marijuana. Plaintiffs' assertion that the BEI is "making Schedule I substances available" is a slogan, not a legal statement.

The Appropriations Act argument is no more serious. As Plaintiffs acknowledge (TRO Mem. at 7), the provision they cite does not take effect until November 2026—seven months after the BEI's April 1 effective date. There is no present conflict with a statute not yet in force.

**B. Plaintiffs Will Not Suffer Irreparable Harm.**

Irreparable harm must be "likely," not merely possible, and must be "actual and imminent, not conjectural or hypothetical." *Winter*, 555 U.S. at 22. Plaintiffs' claimed harms are speculative at every step.

The organizational Plaintiffs claim the BEI forces them to divert resources. But the Supreme Court held in *AHM* that spending money to oppose a government policy is not a cognizable injury for standing purposes. 602 U.S. at 393–94. What fails as standing cannot succeed as irreparable harm. Courts are loathsome to find irreparable harm based on financial injury; and it is well settled that economic loss does not, in and of itself, constitute irreparable harm." *John Doe Co. v. CFPB*, 849 F.3d 1129, 1134 (D.C. Cir. 2017) (citation modified). "The first hurdle

Plaintiffs face is that the harms they identify are economic in nature and therefore not generally irreparable." *Air Transp. Ass'n of Am. v. Exp.-Import Bank of the United States*, 840 F. Supp. 2d 327, 335 (D.D.C. 2012).

Mr. Evans claims that the BEI will alter his relationship with his healthcare provider. But his provider has not elected the BEI. Even if the provider were to elect it, Mr. Evans would not be required to accept any product. His feared injury depends on a chain of contingencies—provider election, implementation plan approval, an offer of products to Mr. Evans personally, and Mr. Evans's subjective reaction to that offer—none of which has occurred or is alleged to be imminent. Speculation about what might happen if multiple independent actors make choices they have not yet made is not the kind of "certainly impending" injury that justifies emergency relief. *Clapper*, 568 U.S. at 410.

Plaintiffs further assert procedural harm—that CMS denied them the right to participate in notice-and-comment rulemaking. But a procedural injury cannot independently establish irreparable harm when the underlying procedural claim fails on the merits. As explained above, the Substance Access BEI is not a legislative rule subject to Section 553. There is no procedural right to vindicate, and therefore no procedural injury to remedy. And even if the procedural claim had merit, procedural injury alone does not automatically establish irreparable harm. Courts routinely deny preliminary relief where the procedural defect can be cured on remand without the need for emergency intervention. *See, e.g.*, *Nat'l Venture Capital Ass'n v. Duke*, 291 F. Supp. 3d 5, 17 (D.D.C. 2017).

Finally, Plaintiffs invoke a "public health catastrophe." TRO Mem. (ECF No. 10) at 23. But hemp products are commercially available at a retail store, a pharmacy, or online—without a physician's involvement, without dosing limits, without product screening, and without any of the

safeguards the BEI provides. The BEI does not create access to hemp products. That access already exists, entirely outside the medical system. What the BEI does is allow participating providers to furnish up to $500 per year in eligible hemp products to consenting beneficiaries through a structured program that includes physician screening, product eligibility requirements, shared decision-making, disqualifying conditions, and quarterly reporting.

Plaintiffs' theory of irreparable harm is that seniors will be catastrophically harmed by receiving hemp products through a medical program that currently does not exist. That is not a theory of *harm*. It is a theory of *improvement*. Enjoining the BEI will not prevent a single Medicare beneficiary from purchasing hemp products. It only prevents them from doing so under medical supervision with safeguards CMS has built into the program.[4]

**C. The Balance of Equities and Public Interest Favor Defendants.**

The public interest weighs heavily against the requested relief. Congress created CMMI to test innovative payment and delivery models. Congress shielded model elements from judicial review. An injunction would override those legislative judgments. It would announce that advocacy organizations with mere opposition to a CMMI model can obtain emergency relief and halt model components they find objectionable. And it would establish a precedent requiring notice-and-comment rulemaking for optional model components—a requirement Congress deliberately omitted from Section 1115A and one that would undermine CMMI's core function.

The equities reinforce this conclusion. Model participants that wish to elect the Substance Access BEI—and the beneficiaries who might benefit from it—would be harmed by an injunction

[4] Plaintiffs have described hemp-derived products as a public health crisis precisely because of their widespread, unregulated commercial availability. *See, e.g.*, https://www.city-journal.org/article/hemp-thc-edibles-controlled-substances-act-loophole (op-ed from SAM CEO noting sale of hemp products at "convenience stores, gas stations, grocery stores, and other locations where families with children shop").

that prevents their voluntary participation in a program Congress authorized CMS to test. Those parties have concrete interests at stake. Meanwhile, Plaintiffs would suffer no cognizable injury from the denial of their motion. They face no regulatory obligation. They face no economic harm. They face no physical injury. They are not model participants. Their claimed injury is that a government program they oppose exists. That interest, however sincerely held, does not outweigh the interests of willing participants, CMMI's statutory mandate, and Congress's express judgment that model design decisions should not be subject to judicial review.

An injunction is an extraordinary remedy. It is not a tool for organizations with policy objections to halt government programs in which they do not participate. Plaintiffs ask this Court to enjoin a program that no provider has been forced to join, that no beneficiary has been forced to use, and that no Plaintiff has standing to challenge.

## IV. If Preliminary Injunctive Relief Is Granted, A Bond Should Be Required.

To the extent the Court orders any injunctive relief, Defendant respectfully requests that any such relief be accompanied by a bond. "The 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." Fed. R. Civ. P. 65(c). A bond is appropriate here given, among other things, the costs that would be associated with halting a program that already is underway.

## CONCLUSION

Plaintiffs are advocacy organizations and one Medicare beneficiary who object to a government policy. Those objections may be sincere. But sincerity is not standing. Even if Plaintiffs could cross the Article III threshold, Congress barred their claims. And were the Court to reach the merits, Plaintiffs have shown no likelihood of success and no irreparable harm with respect to a voluntary program in which they do not participate. Finally, the balance of equities favors CMS, because an injunction would override Congress's judgment that model design decisions belong to CMMI, not the courts. Therefore, the Court should deny Plaintiffs' motion and dismiss the Complaint.

Dated: April 9, 2026

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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| SMART APPROACHES TO MARIJUANA, et al.,<br><br>Plaintiffs,<br><br>v.<br><br>ROBERT F. KENNEDY, JR., Secretary of Health and Human Services, et al.,<br><br>Defendants. | Civil Action No. 26-1081 (TNM) |

**[PROPOSED] ORDER**

Upon consideration of Defendants' Memorandum of Points and Authorities (1) In Opposition to Plaintiffs' Motion for Temporary Restraining Order, Preliminary Injunction, and Stay of Agency Action Pending Judicial Review and (2) In Support of Defendants' Cross Motion to Dismiss, and for good cause shown, it is hereby

**ORDERED** that Plaintiffs' Motion for a Preliminary Injunction is **DENIED**. It is further

**ORDERED** that Plaintiffs' Complaint is dismissed with prejudice.

**SO ORDERED**, this ___ day of _____, 2026.

Trevor N. McFadden
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMART APPROACHES TO MARIJUANA, et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., Secretary of Health and Human Services, et al.,

Defendants.

Civil Action No. 26-1081 (TNM)

**DECLARATION OF ELIOT FISHMAN**

I, ELIOT FISHMAN, declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that my testimony below is true and correct:

1. I am the Director of the Policy and Programs Group at the Center for Medicare and Medicaid Innovation ("CMMI") within the Centers for Medicare & Medicaid Services ("CMS"), U.S. Department of Health and Human Services ("HHS"). I have served in this capacity since February 2023. In this role, I oversee multiple policy and technical support functions that cut across the various CMMI models.

2. The statements set forth in this declaration are based on my personal knowledge, information obtained in the course of performing my official duties, information provided to me by federal government employees acting within the scope of their employment, and my review of relevant government records maintained in the ordinary course of business.

3. I am providing this declaration in support of Defendants' Opposition to Plaintiffs' Motion for Temporary Restraining Order, Preliminary Injunction, and Stay of Agency Action Pending Judicial Review.

4. CMMI was established by Congress in 2010 with the express purpose of testing innovative payment and service delivery models that could reduce program expenditures while preserving or enhancing the quality of care for Medicare and Medicaid beneficiaries. *See* Social Security Act § 1115A(a)(1), 42 U.S.C. § 1315a(a)(1).

5. Since its creation, CMMI has fulfilled its mandate by testing dozens of models, such as ACO REACH, the Enhancing Oncology Model ("EOM"), and others. A voluntary CMMI model invites providers, payers, and accountable care organizations, to apply to participate. No accountable care organization, payer, or provider is required to participate in these models. These voluntary models and model components are implemented through participation agreements between CMS and model participants. CMS has added, modified, and removed voluntary models and model components since it was established in 2010. CMMI has never conducted notice-and-comment rulemaking for any voluntary model or model component.

6. On March 20, 2026, CMS announced the Substance Access Beneficiary Engagement Incentive ("Substance Access BEI"), an optional component available to voluntary participants in three existing CMMI models: ACO REACH, EOM, and (beginning January 1, 2027) the Long-term Enhanced ACO Design Model ("LEAD"). *See* CMS, Substance Access Beneficiary Engagement Incentive, https://www.cms.gov/priorities/innovation/substance-access-beneficiary-engagement-incentive (Mar. 20, 2026) ("March 2026 Announcement"). A beneficiary's participation is never required. Beneficiaries must elect to participate, and a physician must determine that use is appropriate and must document the required shared decision-making. A true and correct copy of the March 2026 Announcement is attached. CMS did not engage in notice-and-comment rulemaking before announcing the Substance Access BEI. Thus, the Substance Access BEI was

implemented in a manner similar to every voluntary model tested under Social Security Act § 1115A since 2010.

7. In my role as Director of the Policy and Programs Group at CMMI, I was involved in all major activities and decision-making regarding the policy and the implementation of the Substance Access BEI. In this role, I reviewed and edited drafts of all materials and made policy recommendations to CMS and HHS leadership.

8. The Substance Access BEI allows model participants that affirmatively elect it to consult with eligible beneficiaries about the possible use of eligible hemp products to improve symptom control and, if appropriate, to furnish such products up to $500 per year per eligible beneficiary. Medicare does not pay the participant for the products. If a provider's investment in beneficiary engagement reduces the beneficiary's total cost of care, the provider and CMS share in the resulting savings. If it does not, the provider absorbs the loss.

9. Model participants that elect the Substance Access BEI must submit an implementation plan for CMS approval and they must implement safeguards against abuse, including monitoring and oversight. CMS retains authority to reject or suspend participation.

10. None of the Plaintiffs in this case has submitted an implementation plan for CMS approval or has participated in any of the CMMI models that have the option of offering the Substance Access BEI.

11. Consistent with the voluntary nature of the component and the models involved, model participants are not required to elect Substance Access BEI. No model participant or provider is compelled to offer hemp products or to accept them.

12. To further inform model participants, providers, and the general public, the March 2026 Announcement includes answers to "Frequently Asked Questions" ("FAQs"). Among other

things, the FAQs explain that CMS's definition of "eligible hemp product" as used in the Substance Access BEI operates within the 2018 Farm Bill's hemp provisions, and neither overrides the Controlled Substances Act nor authorizes Schedule I substances (such as marijuana). The FAQs also emphasize that hemp products must comply with applicable state and local laws to be eligible, and model participants must meet certain quality and safety standards for the products, including third-party testing for potency, contaminants, and microbial hazards.

Executed on this 7th day of April, 2026.

Eliot Fishman

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# Substance Access Beneficiary Engagement Incentive

The Substance Access BEI is an optional Beneficiary Engagement Incentive that allows participants in certain CMS Innovation Center models to consult with eligible beneficiaries about the possible use of eligible hemp products to improve symptom control. Participants implementing this BEI may elect to furnish such hemp products up to $500 a year, per eligible beneficiary, subject to model requirements and safeguards.

*Note: Medicare does not pay the participant for the products, and beneficiaries should not be asked to submit a Medicare claim for the product.*

Model participants will have the option to offer this BEI in three Innovation Center models:

- ACO REACH Model
- Enhancing Oncology Model (EOM)
- Long-term Enhance ACO Design (LEAD) Model

Participants may begin offering the Substance Access BEI for both ACO REACH Model and EOM starting April 1, 2026. The BEI will become available to eligible LEAD participants on January 1, 2027.

Participants must submit required quarterly reports to CMS and provide supplemental information upon request, consistent with participation documentation.

For more information on the Innovation Center models that include the Substance Access BEI, visit the ACO REACH, EOM, and LEAD model webpages.

## Frequently Asked Questions

**Which organizations are eligible for the Substance Access BEI?**

Only participating organizations in ACO REACH, EOM and LEAD may offer the Substance Access BEI, and only if they:

- Elect the Substance Access BEI for the applicable performance period; AND
- Submit and maintain a CMS-required Implementation Plan describing, at minimum, the specific eligible hemp product(s) and dosing information, the amount/frequency of distribution, beneficiary eligibility criteria, safeguards/oversight, and other requirements outlined in participation agreements; AND
- Are approved by CMS (CMS may reject or suspend participation based on the Implementation Plan, compliance history, or other program integrity concerns).

**Which beneficiaries are eligible for the Substance Access BEI?**

Only beneficiaries currently aligned to participating organizations that have elected to offer the Substance ACCESS BEI in the REACH, EOM or LEAD models may receive the BEI. Additional beneficiary eligibility criteria are defined in each model's participation documentation and implementation plan, but generally includes:

- Being age 18 or older;
- Not meeting the model's frailty exclusion;
- Not having specified disqualifying conditions; and
- Not being pregnant or breastfeeding.

In addition, a physician must determine that use is appropriate and must document required shared decision-making (including medication review and follow-up planning). At a minimum, this includes a documented discussion of potential benefits and risks, the beneficiary's goals and preferences, and a review of current medications and potential interactions.

DISQUALIFYING CONDITIONS ARE SPECIFIED IN MODEL PARTICIPATION DOCUMENTATION AND ARE INTENDED TO REDUCE PATIENT SAFETY RISKS.

**What is an "'eligible hemp product" for purposes of this BEI?**

Eligible hemp products are limited to federally legal hemp-derived products containing no more than 0.3% delta-9 THC and expressly excludes inhalable products, any products containing more than 3 mg per serving of tetrohydrocannabinols (such as delta-8-tetrahyrdocannabinol, delta-10-tetrahyrdocannabinol, and tetrahydrocannabinolic acid) in an orally administered form, and any products containing cannabinoids not naturally produced or capable of being produced by or in the cannabis plant during its cultivation.

The definition operates within the 2018 Farm Bill's hemp provisions and does not override the Controlled Substances Act or authorize Schedule I substances. To be eligible, hemp products must also comply with applicable state and local laws.

If the legal limits on hemp-derived products changes, as with Section 781 of the FY2026 Agriculture Appropriations Act, CMS will adjust its definition in accordance with the law.

**How are eligible hemp products procured and furnished?**

Model participants are responsible for their own procurement and operational approach (including contracting, ordering, storage, inventory controls, and distribution workflows), consistent with model requirements and applicable law.

Eligible hemp products must be furnished and provided directly by a qualified physician affiliated with the participant organization, as specified by the model participation agreements.

*Note: Model participants cannot instruct beneficiaries to purchase retail products and submit receipts for reimbursement under the BEI.*

**What are the key program integrity and contracting requirements?**

Program integrity guardrails are described in model participation documentation and include:

- The BEI (and product availability) must not be marketed to induce beneficiaries to select or remain aligned to a participant organization; AND

- Participants may not enter into arrangements that provide remuneration to induce selection of a particular manufacturer or seller, and payments must be consistent with fair market value and not tied to the volume or value of referrals or other business; AND
- Participants must implement safeguards against abuse, including monitoring and oversight, and CMS may suspend or prohibit participation for integrity concerns.

**What quality and safety standards apply to products?**

Model participants are required to meet quality and safety standards requirements for products that at a minimum, must:

- Meet federal, state and local production, quality, and safety laws and other mandated standards; AND
- Come from a legally compliant source and high-quality farm, consistent with 2018 Farm Bill hemp requirements, AND
- Be tested by a third party for potency (including accurate cannabinoid measurement) and for contaminants and microbial hazards with negative results.

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