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)

DEFENDANTS' MEMORANDUM OF POINTS AND AUTHORITIES (1) IN OPPOSITION TO PLAINTIFFS' MOTION FOR 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, a pharmaceutical company with no approved product, a physician who does not participate in any CMS model, and one Medicare beneficiary. None participates in any CMS Innovation Center (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.

Plaintiffs have now had the full benefit of Defendants' original opposition. The gaps in their renewed motion are telling. Plaintiffs do not address *Center for Biological Diversity v. DOI*, 144 F.4th 296 (D.C. Cir. 2025), the D.C. Circuit's most recent organizational standing decision. They do not address *Gettman v. DEA*, 290 F.3d 430 (D.C. Cir. 2002), which denied standing to cannabis-policy advocates in this Circuit. They do not engage with Defendants' argument that their resource diversion is the execution of their organizational missions, not a diversion from them. They do not address *Humana of South Carolina, Inc. v. Califano*, 590 F.2d 1070 (D.C. Cir. 1978), binding D.C. Circuit authority holding that Section 553(a)(2)'s benefits exception applies to

Medicare. They do not address the distinction between voluntary and mandatory models that separates this case from every Most Favored Nation case they cite. And they do not address Defendants' argument that Section 1115A(d)(2)'s preclusion bar cannot be circumvented by recasting a substantive challenge as a procedural one.

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 exercise 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. Tetrahydrocannabinols in hemp are not controlled substances. The April 2025 CMS rule Plaintiffs invoke addressed "illegal substances under Federal law"—marijuana. *See* PI Memo. (ECF No. 28) at 28 (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 refuse 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*, 590 F.2d at 1082.

The Court should deny Plaintiffs' second 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 Center for Medicare and Medicaid Innovation ("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 voluntary models 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. A).

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). 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 dry weight. 7 U.S.C. § 1639*o*(1). Products above the threshold are marijuana and 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.

D. Plaintiffs

Plaintiffs are eleven organizations, a pharmaceutical company and its subsidiaries, a physician, and one individual. Am. Compl. (ECF No. 25) ¶¶ 6-21. The organizational Plaintiffs are advocacy organizations whose missions involve opposing the expansion of access to cannabis and hemp-derived products. *Id.* ¶¶ 6-16. 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.*

MMJ International Holdings, Inc. (MMJ) and its subsidiaries claim to be developing cannabinoid therapeutics through the FDA's botanical drug pathway. Am. Compl. (ECF No. 25) ¶¶ 19-21. MMJ has no FDA-approved product. It has publicly claimed to be "positioned to commence clinical trials" since at least 2019. Seven years later, its Investigational New Drug (IND) application is on Full Clinical Hold, and so it cannot have conducted the required clinical trials for FDA approval to market and earn revenue from its product. Boise Decl. (ECF No. 28-8) ¶25.

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. 28-6) ¶¶ 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.

Dr. Kenneth Finn is a physician who practices pain medicine in Prescott, Arizona. Dr. Finn Decl. (ECF No. 28-7) ¶ 3. He does not state that he participates in any ACO REACH, EOM, or any CMMI model. *See id.* ¶ 16 (testifying that his practice would lose Medicare patients who wish to access substances under the BEI).

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 *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).

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)).

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.

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. Am. Compl. ¶¶ 6-16. 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).

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.

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.

Defendant Smart Approaches to Marijuana, Inc.'s (SAM) own filings confirm the point. SAM attaches as Exhibit A (ECF No. 28) to Plaintiffs' motion its participation in the ongoing Drug Enforcement Administration (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." Am. Compl. ¶ 6. 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.[1]

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

[1] SAM's declarant also states under penalty of perjury that the BEI "provides marijuana products via a medical source." Niforatos Decl. (ECF No. 28-1) ¶ 11. It does not. The BEI provides hemp products. Hemp is not marijuana. Congress drew that line. If Plaintiffs' lead organizational declarant cannot accurately characterize the program they challenge, the Court should question whether their standing theories rest on any firmer foundation.

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.

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.[2]

Plaintiffs submit seven organizational declarations in support of standing. Each follows an identical template. Each asserts, in nearly identical language, that the organization "operates concrete programmatic activities that go beyond general issue advocacy"; that the BEI has "directly affected and interfered with" the organization's "core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources"; and that the organization's "injury is not abstract policy disagreement but concrete impairment of specific programmatic activities with a consequent drain on organizational resources." *See* Niforatos Decl. (ECF No. 28-1) ¶¶ 6, 9–10 (on behalf of SAM); Ronshausen Decl. (ECF No. 28-2) ¶¶ 5, 7, 9 (on behalf of Defendant Drug Free America Foundation); Coleman Decl. (ECF No. 28-3) ¶¶ 5, 7, 9 (on behalf of Defendant

[2] 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 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.

Drug Watch International); Snelling Decl. (ECF No. 28-4) ¶¶ 5, 7, 9 (on behalf of Defendant Hillsborough County Anti-Drug Alliance); Valente Decl. (ECF No. 28-5) ¶¶ 4, 6–7 (on behalf of Defendant Illinois Family Institute). These are not descriptions of concrete injury. They are conclusory assertions based on the *Havens* standard.

Conclusory legal assertions do not create standing. The Court examines the facts a declarant alleges, not legal labels Plaintiffs attach to them. And the facts in each declaration are essentially the same: the organization opposes cannabis policy; the BEI is a cannabis-related policy; the organization chose to spend resources opposing it. None of these declarations identify a single client who could not be served, a single programmatic output that was cancelled, or a single person who received worse service because of the BEI. Not one describes any operational interference beyond a decision to oppose a government action the organization exists to oppose. That is what advocacy organizations do when a policy they disfavor is announced. It is the execution of their missions, not a diversion from them. Under *AHM* and *Center for Biological Diversity*, it is not standing.

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 organizations' description of their activities establishes that they fall within the latter category. Take the Illinois Family Institute. It "educate[s] Christians and the general public on matters of moral concern" and to "safeguard and advance public morality consistent with Biblical Christianity." Valente Decl. (ECF No. 28-5) ¶ 4. Its claimed injury is that it had to divert resources from Christian moral education to oppose a Medicare payment model feature about hemp product dosing limits for elderly beneficiaries. Drug Watch International promotes "'healthy drug-free cultures' globally" and advocates for "the prohibition of and abstinence from all drugs, including alcohol and tobacco." Coleman Decl. (ECF No. 28-3) ¶ 4. Its declarant states that DWI would have commented to CMS that "the growing power of the Executive Branch to make laws through rulemaking is considered by some to be both unconstitutional and anti-democratic." *Id*. ¶ 12. That is a political philosophy grievance about the administrative state, not a concrete interest in the regulatory outcome of a CMMI model component. The Hillsborough County Anti-Drug Alliance runs tobacco prevention clubs for middle and high school students, supports "safe rides" programs, and provides volunteers for DEA Drug Take Back Days. Snelling Decl. (ECF No. 28-4) ¶ 5. What connection do these activities have to Medicare, CMMI models, or the regulation of hemp products in a shared-savings payment framework? These organizations are not operationally impaired by the BEI. They encountered a government action they oppose and choose to oppose it. That choice is the execution of their missions, not cognizable Article III injury.

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 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. MMJ Lacks Standing.

MMJ asserts competitor standing, claiming the BEI creates a federally supported pathway for non-FDA-approved cannabinoid products to reach Medicare beneficiaries, undercutting companies like MMJ that have invested in the FDA approval process. For multiple independent reasons, this theory fails.

First, MMJ has no approved product. Indeed, it is not even close to having one. MMJ has publicly claimed to be "positioned to commence clinical trials" since at least 2019. *See, e.g., MMJ International Holdings Files FDA Orphan Drug Application for Huntington's Disease*, MMJ, https://mmjih.com/mmj-international-holdings-files-fda-orphan-drug-application-for-huntingtons-disease/ (last visited Apr. 19, 2026). Seven years later, it has disclosed no completed clinical trial, no New Drug Application (NDA) for approval to market its product, and no revenue from an FDA-approved product. MMJ's own CEO confirms that its Investigational New Drugs (IND) have been on Full Clinical Hold since February 2025—meaning FDA has ordered a delay or suspension of clinical investigation. Boise Decl. (ECF No. 28-8) ¶ 25; 21 C.F.R. § 312.42. MMJ's bulk manufacturing registration has been the subject of contested administrative proceedings before a DEA Administrative Law Judge for years. *Id*. ¶ 19. The National Institute on Drug Abuse (NIDA) eliminated MMJ's research proposal because MMJ could not prove it held a finalized DEA registration. *Id*. ¶ 18. MMJ describes its INDs as "accepted" in its PI brief. PI Memo. (ECF No. 28) at 2. But its own declaration tells a different story. Competitor standing requires a "direct and current competitor" whose "bottom line may be adversely affected by the challenged government action." *Air Excursions LLC v. Yellen*, 66 F.4th 272, 278 (D.C. Cir. 2023). MMJ is neither a current competitor nor a competitor in the foreseeable future.

Second, MMJ does not compete in the same market as the products available under the BEI. *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 90–91 (2013) (competitor must show "an injury in fact caused by the [challenged action]—i.e., an injury to a legitimate commercial interest"). MMJ claims to be developing prescription biopharmaceutical drug candidates for Huntington's disease and multiple sclerosis—serious, progressive neurological diseases with no cure. The BEI permits voluntary CMMI model participants to furnish up to $500 per year in over-the-counter hemp products to consenting Medicare beneficiaries for general symptom management. These are different products, targeting different conditions, for different patient populations, through different delivery mechanisms.

Put another way, no Medicare beneficiary with a Huntington's disease diagnosis is choosing between enrolling in a clinical trial for a novel pharmaceutical therapy targeted specifically at improving the symptoms of their disease and obtaining a CBD gummy through a shared-savings incentive. To state the proposition is to show its absurdity.

Further, even if MMJ were able to obtain FDA-approval, an FDA-approved drug showing safety and efficacy in treating Huntington's disease or multiple sclerosis would very likely be covered by Medicare for these indications and would not be offered only through a limited shared-savings incentive. Again, no Medicare beneficiary would forgo coverage for an FDA-approved treatment for their disease to enroll in an incentive program for an over-the-counter hemp product aimed at general symptom management.

The D.C. Circuit rejected a similar standing theory in *Hemp Industries Ass'n v. DEA*, 36 F.4th 269 (D.C. Cir. 2022). In that case, hemp industry members challenged DEA action benefiting a competing cannabis product. The court dismissed for lack of standing because petitioners did not produce a competing product. If active hemp market participants could not establish competitive

standing from the descheduling of a rival CBD product, a company with no approved drug and no market presence cannot establish competitive standing from a voluntary CMMI model component.

Third, even if the markets overlapped—and they do not—MMJ's claimed injuries depend on a speculative chain of contingencies that *Clapper* forecloses. For the BEI to cause MMJ any harm, the following must all occur: (1) MMJ must resolve outstanding regulatory issues; (2) MMJ must successfully cultivate or acquire and process pharmaceutical-grade cannabis; (3) MMJ must complete multiple clinical trials that will take years; (4) the clinical trials must show favorable results; (5) FDA must approve at least one MMJ drug candidate; (6) MMJ must bring an approved product to market; (7) that product must compete for the same patients who receive hemp products through the BEI—and for the many of the BEI beneficiaries (*i.e.*, oncology patients in the EOM model), it would not; and (8) the BEI must cause those patients to choose over-the-counter hemp supplements over MMJ's FDA-approved prescription drugs for serious neurological diseases. Every link depends on events that have not occurred and may never occur. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 (2013); *see also AHM*, 602 U.S. at 382 (standing requires a "predictable chain of events," not speculation about "unfettered choices made by independent actors not before the courts"). The Federal Circuit recently rejected an analogous theory in *Incyte Corp. v. Sun Pharmaceutical Industries, Inc.*, No. 2023-1300 (Fed. Cir. May 7, 2025), holding that a pharmaceutical company's development plans were "too speculative to show concrete plans" and constituted "at best, a wish to enter a market with no concrete plan how to do so." MMJ's position is weaker.

Fourth, MMJ's own public statements contradict its claimed injury. On April 6, 2026, MMJ's CEO stated publicly that the BEI "confirms what we have said for years" and that MMJ is "already there" in terms of strategic positioning. MMJ's investor communications describe the BEI

as strengthening its competitive position, not harming it. *See* *https://finance.yahoo.com/sectors/healthcare/articles/trumps-fda-cbd-enforcement-shift-100000534.html#:~:text=%22The%20FDA's%20decision%20to%20allow,CA%20Privacy%20Notice* (last visited Apr. 20, 2026). A party cannot tell investors that a government program validates its business strategy and strengthens its market position while simultaneously telling this Court that the same program causes it competitive injury. Courts have consistently held that speculative impacts on development incentives and investment value do not constitute injury in fact. *See AstraZeneca Pharms. LP v. HHS*, 137 F.4th 116, 123 (3d Cir. 2025) (rejecting standing where pharmaceutical company "did not identify any actual decision about drug development or marketing" made in response to challenged agency action). If a company with AstraZeneca's market presence cannot establish standing from speculative effects on development decisions, MMJ cannot.

The contradiction runs deeper. MMJ's PI brief describes its INDs as "accepted." PI Memo. (ECF No. 28) at 2. Its own declaration reveals they have been on Full Clinical Hold since February 2025. Boise Decl. (ECF No. 28-8) ¶ 25. MMJ's brief describes a "federally authorized Huntington's disease program." Its declaration reveals that NIDA eliminated MMJ's research proposal because MMJ could not prove it held a finalized DEA registration. *Id.* ¶ 18. And its bulk manufacturing application has been mired in contested DEA administrative proceedings for years. *Id.* ¶ 19. The Court should evaluate MMJ's standing claims in light of its actual regulatory status, not the aspirational characterizations in its counsel's brief.

Fifth, MMJ's theory is indistinguishable from the theory rejected in *AHM*. Stripped down, MMJ believes cannabinoid access should proceed exclusively through the FDA approval process. The BEI, it claims, creates an alternative pathway. MMJ objects. That is a "legal, moral,

ideological, and policy objection" of the kind the Supreme Court unanimously held does not "establish a justiciable case or controversy in federal court." *AHM*, 602 U.S. at 396. MMJ may dress this objection in the language of competitive injury, but the substance is the same. MMJ's grievance is not that the BEI has taken customers from it—it has no customers—but that the federal government has endorsed a pathway for cannabinoid access that MMJ finds scientifically and regulatorily illegitimate.

C. David Evans and Dr. Finn Lack 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 Memo. (ECF No. 10) at 19.

Start with the obvious: Mr. Evans opposes hemp products and will not use them. He says so himself. Evans Decl. (ECF No. 28-6) ¶ 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).

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.

Dr. Kenneth Finn is a physician who practices pain medicine in Prescott, Arizona. He does not participate in ACO REACH, EOM, or any CMMI model. No patient has asked him to prescribe anything under the BEI. His declaration is the most detailed of any Plaintiff's, reflecting genuine expertise in cannabis pharmacology. But expertise in the subject matter of a government policy does not confer standing to challenge it. *See AHM*, 602 U.S. at 396. Dr. Finn claims injuries of malpractice liability from products he has not prescribed, loss of patients who have not left, emergency room visits that have not occurred, and retroactive legal exposure from a statutory change seven months away. These are projections about what might happen to physicians generally if the BEI operates as he fears. That is an expert opinion about policy consequences, not a particularized injury to Dr. Finn personally. The Supreme Court confronted this exact dynamic in *AHM*, where individual physicians with genuine medical expertise and sincere professional objections to FDA's regulation of mifepristone were held to lack standing because their injuries

depended on a "speculative chain of possibilities." *Id.* at 391. A physician who has not been asked to do anything under a program that does not apply to him has not suffered injury-in-fact.

D. 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 procedural. 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.

The plaintiffs 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, even if the BEI were a rule, Section 553(a)(2) exempts matters relating to benefits from notice-and-comment requirements. If Section 553 does not apply, there is no procedural right to invoke, and procedural standing collapses.

II. Plaintiffs Lack a Cause of Action Under Any Relevant Statute.

Independent of Article III standing, there is another threshold question: does any Plaintiff have a cause of action to bring the procedural claims asserted here? The answer is no. The cause analysis begins with the text of the APA, through the Supreme Court's framework in *Lexmark International, Inc. v. Static Control Components, Inc.*, 572 U.S. 118 (2014), and ends with the identification of the relevant statute whose zone-of-interests governs this case.

A. Section 702 and the Zone-of-Interests Framework.

Section 702 of the APA provides a cause of action only to "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute." 5 U.S.C. § 702. The phrase "within the meaning of a relevant statute" is the textual foundation of the zone-of-interests test. The Supreme Court held in *Lexmark* that this inquiry is not jurisdictional but goes to "whether a legislatively conferred cause of action encompasses a particular plaintiff's claim." 572 U.S. at 128 n.4. A plaintiff may satisfy Article III—injury, causation, redressability—and still lack a cause of action if the plaintiff's interests fall outside the zone of interests of the relevant statute.

The "relevant statute" for zone-of-interests purposes is not the APA itself but the substantive statute the agency allegedly violated. *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 224–25 (2012). Plaintiffs' PI brief asserts that MMJ's interests "fall within the zone of interests protected by the APA's procedural requirements." PI Memo. (ECF No. 28) at 19. But that framing is wrong. Under *Lexmark* and *Patchak*, the relevant

statute is not "the APA's procedural requirements." Section 553 is a general procedural provision that tells agencies how to make rules. It does not define whose interests are protected. The relevant statute is the substantive statute that governs the agency's conduct—here, either Section 1115A of the Social Security Act or Section 1871(a)(2), 42 U.S.C. § 1395hh(a)(2).

B. Section 553 Does Not Apply.

Section 553(a)(2) of the APA exempts from notice-and-comment rulemaking any matter "relating to . . . benefits." 5 U.S.C. § 553(a)(2). The D.C. Circuit has squarely held that this exemption applies to Medicare. *Humana of S.C., Inc. v. Califano*, 590 F.2d 1070, 1082 (D.C. Cir. 1978). The BEI is a voluntary component of Medicare payment models. It clearly and directly relates to Medicare benefits. Section 553(a)(2) exempts it from notice-and-comment requirements by its plain text. Plaintiffs' brief devotes half a page to the benefits exception but does not cite or address *Humana*. *Humana* is binding D.C. Circuit authority. Plaintiffs' failure to engage with it speaks for itself. If Section 553 does not apply, it provides no procedural right for anyone to invoke.

C. Section 1871(a)(2) Does Not Apply, and These Plaintiffs Are Outside Its Zone of Interests.

The only remaining potential source of a notice-and-comment obligation applicable to CMS action relating to Medicare is Section 1871(a)(2) of the Social Security Act, 42 U.S.C. § 1395hh(a)(2), which the Supreme Court held in *Azar v. Allina Health Services*, 587 U.S. 566 (2019), independently requires notice-and-comment rulemaking for 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). Section 1871(a)(2) does not apply to the BEI for two independent reasons, either of which is sufficient to resolve this case.

First, Section 1871 governs rules adopted under Title XVIII of the Social Security Act. The phrase "under this subchapter" in § 1395hh(a)(2) refers to Title XVIII—the Medicare statute. The BEI was not adopted under Title XVIII. It was adopted under Section 1115A, codified in Title XI of the Social Security Act. Title XI and Title XVIII are separate statutory schemes. Section 1115A has its own grant of authority to the Secretary to test innovative payment models. It has its own preclusion provision barring judicial review of model elements, parameters, scope, and duration. 42 U.S.C. § 1315a(d)(2). And it contains no cross-reference to Section 1871's rulemaking requirements. Congress did not incorporate Section 1871 into Section 1115A. 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.

Second, even if Section 1871(a)(2) applied, these Plaintiffs are not within its zone of interests. Section 1871(a)(2) defines its protected interests by its own text: "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." The parties whose interests this language protects are identifiable from the text: beneficiaries whose coverage is affected by changes to the scope of benefits; providers whose reimbursement is affected by changes to the payment for services; and entities whose eligibility to participate in Medicare is affected by changes to eligibility standards.

No Plaintiff in this case falls within that class. The organizational Plaintiffs do not furnish services or benefits under Title XVIII. They do not receive services or benefits under Title XVIII. They are not eligible to do either. MMJ has no approved product and no Medicare relationship. Mr. Evans's claimed interest is not in the scope of his benefits, the payment for his services, or his

eligibility—it is in the nonexistence of a program he opposes. Dr. Finn practices in Arizona and does not participate in any CMMI model.

The D.C. Circuit's decision in *Mendoza v. Perez*, 754 F.3d 1002 (D.C. Cir. 2014), a case Plaintiffs themselves cite, confirms this framework. There, the court found both Article III standing and zone-of-interests satisfied because the relevant substantive statute (the INA) was specifically designed to protect the competitive interests of the American workers who brought the challenge. *Id.* at 1016-17. Here, that framework compels dismissal: neither Section 1115A nor Section 1871(a)(2) was designed to protect the interests these Plaintiffs assert. Plaintiffs also cannot invoke the Controlled Substances Act as a basis for their cause of action. *See Bonds v. Tandy*, 457 F.3d 409 (5th Cir. 2006) (CSA's zone of interests encompasses registrants and parties directly regulated by DEA, not advocacy organizations opposing drug policy).

D. No Statute Provides the Procedural Right Plaintiffs Claim.

The consequence of this analysis is straightforward. Section 553 does not apply because of the benefits exception. Section 1871(a)(2) does not apply because the BEI was adopted under Section 1115A, not Title XVIII. The CSA does not give these Plaintiffs a cause of action. No statute whose zone of interests encompasses these Plaintiffs provides a notice-and-comment obligation they can enforce.

Procedural standing requires a plaintiff to show that a procedural right was violated and that the procedure in question was "designed to protect some threatened concrete interest" of the plaintiff. *Lujan*, 504 U.S. at 573 n.8. Where no applicable statute protects the plaintiff's interest, there is no procedural right, and the procedural standing theory collapses. This Court need not decide whether the BEI is a legislative rule or whether CMMI models require notice-and-comment as a general matter. It need only observe that no statute whose zone of interests encompasses these

Plaintiffs provides the procedural right they claim was denied. Under *Lexmark*, that is sufficient to conclude they lack a cause of action.

III. Section 1115A Precludes Judicial Review.

Even if Plaintiffs could establish Article III standing and a cause of action, 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. 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, however, is an optional component of existing voluntary CMMI models. *Regeneron* is inapposite.

IV. Plaintiffs Cannot Satisfy the *Winter* Factors.

To obtain a 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*, 555 U.S. at 20. 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 multiple merits theories: (1) the BEI is a legislative rule requiring notice-and-comment; (2) the BEI is arbitrary and capricious; (3) the BEI exceeds CMS's statutory authority under the major questions doctrine; (4) the BEI conflicts with federal law; and (5) the BEI violates equal protection and due process. 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 is 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 CMMI 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.

Plaintiffs contend the BEI is a legislative rule because it imposes "binding obligations" on participating organizations. 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 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 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.

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 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 APA (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, identifying "benefits" as referring to programs like "veterans' pensions and old-age insurance payments." Medicare is an old-age insurance program. A voluntary component of a Medicare payment model is a clearer case than the examples the Manual provides.

Plaintiffs argue that because CMS does not pay for the products, the BEI is not a "benefit." But *Humana* applied the exemption to Medicare reimbursement regulations notwithstanding similar arguments—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." *Id.* Plaintiffs' PI brief does not cite *Humana*. That silence speaks loudly.

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 cite *Azar v. Allina Health Services*, 587 U.S. 566 (2019), 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 adopted under Title XVIII. The BEI was adopted under Section 1115A, codified in Title XI—a separate statutory scheme with no cross-reference to Section 1871. Applying Section 1871 to CMMI model components would nullify Section 1115A(d)(2)'s preclusion bar.

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.

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 Memo.). 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.

Plaintiffs' brief unfortunately refers to BEI products as "Schedule I substances" throughout. That characterization is legally false. Congress removed hemp from the Controlled Substances Act. Products meeting the Farm Bill's definition are not controlled substances. They are not illegal under federal law. Plaintiffs' case depends on collapsing a legal distinction Congress enacted. This Court should not permit it.

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. *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, shared decision-making, a $500 annual cap, CMS approval of implementation plans, CMS authority to reject or suspend participation, and quarterly reporting. CMS's inclusion of multiple layers of safeguards satisfies the standard of "reasoned decisionmaking." *State Farm*, 463 U.S. at 52.

4. The CY2027 Rule does not help Plaintiffs.

Plaintiffs invoke the Contract Year 2027 final rule, 91 Fed. Reg. 17,384 (Apr. 6, 2026), emphasizing CMS's statement that "any changes to SSBCI requirements will be made by requesting public comment on a proposed regulation through a Notice of Proposed Rulemaking." *Id.* at 17,433. But that statement is about Medicare Advantage Supplemental Special Benefits for the Chronically Ill (SSBCI)—a program administered under Title XVIII of the Social Security Act. The BEI is not an SSBCI. It is a CMMI model component administered under Section 1115A, Title XI. What CMS states about Title XVIII procedures says nothing about the separate statutory framework Congress created for CMMI models—a framework with its own grant of authority, its own preclusion provision, and sixteen years of consistent practice in which no voluntary model component has ever been subject to notice-and-comment rulemaking.

CMS's statement that its "authority does not extend to the direct regulation of cannabis-derived products" is likewise about CMS's Title XVIII regulatory authority. CMS is not "directly regulating" cannabis products through the BEI. Participating providers—not CMS—furnish

eligible hemp products at their own cost. CMS is testing whether that intervention reduces total cost of care. That is what CMMI does. Plaintiffs conflate two different statutory authorities—Title XVIII and Section 1115A—to manufacture an inconsistency that does not exist.

5. The major questions doctrine does not apply.

A voluntary BEI capped at $500 per beneficiary attached to a CMMI model is not a case of "vast economic and political significance." *West Virginia v. EPA*, 597 U.S. 697, 723 (2022). 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 pilot program—exactly the kind of incremental testing that Section 1115A authorizes.

Plaintiffs invoke the political attention the BEI has received. 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 id.* at 725. Here, Congress gave CMMI authority to test models. The BEI tests a model component.

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

The 2018 Farm Bill removed hemp from the CSA's definition of marijuana. Products meeting that definition are not Schedule I controlled substances. The BEI limits eligible 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" or facilitates "widespread access to substances that remain Schedule I under the CSA" is a slogan, not a legal statement. The

Appropriations Act provision Plaintiffs cite does not take effect until November 2026. There is no present conflict with a statute not yet in force.[3]

7. The constitutional claims are of no moment.

The equal protection claim alleges that CMS provided Charlotte's Web advance notice of the BEI while excluding MMJ. Agencies routinely consult stakeholders in developing programs. Consulting with hemp companies about a hemp program is rational. MMJ—a pharmaceutical developer pursuing FDA approval for prescription drugs—is not similarly situated to a company selling commercially available hemp products. The "class of one" theory under *Village of Willowbrook v. Olech*, 528 U.S. 562, 564 (2000), requires intentional differential treatment of similarly situated parties with no rational basis. Neither element is present. Moreover, Plaintiffs' equal protection claim is subject to rational basis review and, to survive a motion to dismiss under that review, a "plaintiff must plausibly allege facts showing that no reasonably conceivable state of facts could provide a rational basis for the challenged" action. *Sanchez v. Office of the State Superintendent of Educ.*, 45 F. 4th 388, 396 (D.C. Cir. 2022). As described above, the rational basis for the alleged differing treatment is self-evident.

The due process claim fares no better. There is no protected property interest in the expected future value of an unapproved pharmaceutical product. The BEI does not deprive MMJ of anything. MMJ can still pursue FDA approval. Its IND is unaffected. Its Orphan Drug Designation is unaffected. Its DEA registration application is unaffected. Investment-backed

[3] Plaintiffs may backpedal more than a dozen misstatements in their filing and clarify that the BEI does not provide access to Schedule I substances but provides access to products ***containing*** the Schedule I cannabinoids. That is nonsensical. As with the definition of marijuana, the statutory definition of tetrahydrocannabinols expressly carves out "tetrahydrocannabinols in hemp." 21 U.S.C. § 812(c) sched. I(c)(17). Contrary to Plaintiffs repeated misstatements, there is no such thing as a Schedule I cannabinoid in hemp.

expectations do not create due process rights against policy changes that make a future product potentially less commercially attractive.

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 "loath[] 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).

MMJ claims ongoing competitive and economic harm. But MMJ's claimed injuries—decreased investor confidence, competitive disadvantage, impaired future earnings—are speculative projections about a market MMJ has not entered and will not enter for years, based on products MMJ has not developed, contingent on authorizations MMJ has not obtained. Even accepting them at face value, they are fully remediable. Nothing about the BEI impedes MMJ from resolving its issues or advancing its drug development program. If the BEI is set aside, any claimed injury is restored in full. That is the definition of reparable harm. *See John Doe Co. v. CFPB*, 849 F.3d 1129, 1134 (D.C. Cir. 2017).

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—none of

which has occurred or is alleged to be imminent. *Clapper*, 568 U.S. at 410. Dr. Finn does not participate in any CMMI model. No patient has asked him to prescribe anything under the BEI.

Plaintiffs further assert procedural harm. But a procedural injury cannot independently establish irreparable harm when the underlying procedural claim fails on the merits. As explained above, the BEI is not a legislative rule subject to Section 553. There is no procedural right to vindicate. 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. *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." PI Memo. (ECF No. 28) at 32. 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 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.

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[4] Elsewhere, Plaintiffs describe 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"). The contrast between these sentiments and the positions taken in this lawsuit is striking.

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.

V. 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, a pharmaceutical company with no approved product, and two individuals—none of whom participates in the program they challenge. Their objections may be sincere. But sincerity is not standing. Even if Plaintiffs could cross the Article III threshold, they lack a cause of action under any statute whose zone of interests encompasses their claims. Even if they had a cause of action, Congress barred their claims under Section 1115A(d)(2). 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.

The Court should deny Plaintiffs' motion and dismiss the Amended Complaint.

Dated: April 20, 2026

Respectfully submitted,

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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)

[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., 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 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 20, 2026

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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)

[PROPOSED] ORDER

UPON CONSIDERATION of Defendants' Motion to Dismiss and Defendants' Memorandum of Points and Authorities (1) In Opposition to Plaintiffs' Motion for 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 and stay of agency action 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

Exhibit A

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, ACO REACH, EOM, or LEAD, that have the option of offering the Substance Access BEI. None has administered any substance under the BEI or is subject to any CMS regulation relating to the Substance Access BEI program.

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 20th day of April, 2026.

/s/ *Eliot Fishman*

Eliot Fishman
Director, Policy and Programs Group
Center for Medicare and Medicaid Innovation
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

CMS.gov

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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