IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMART APPROACHES TO MARIJUANA
220 Maryland Ave NE, Washington, DC 20002,

CANNABIS INDUSTRY VICTIMS EDUCATING LITIGATORS
203 Main St, Suite 250, Flemington, NJ 08822,

AMERICANS AGAINST LEGALIZING MARIJUANA
P.O. Box 158, Carmichael, CA 95609

NORTH CAROLINIANS AGAINST LEGALIZING MARIJUANA
1854 Hendersonville Rd, Suite 205, Asheville, NC 28803,

CANNABIS IMPACT PREVENTION COALITION, LLC
418 Broadway, Suite N, Albany, NY 12207,

CANNABIS INDUSTRY VICTIMS SEEKING JUSTICE
418 Broadway, Suite N, Albany, NY 12207,

DRUG FREE AMERICA FOUNDATION
333 3rd Ave N, Suite 200, St. Petersburg, FL 33701,

SAVE OUR SOCIETY FROM DRUGS
333 3rd Ave N, Suite 200, St. Petersburg, FL 33701,

DRUG WATCH INTERNATIONAL
6981 Tepper Dr, Clifton, VA 20124,

Case No. 1:26-CV-01081-TNM

HILLSBOROUGH COUNTY ANTI-DRUG ALLIANCE
521 Lantern Circle, Temple Terrace, FL 33617,

ILLINOIS FAMILY INSTITUTE
PO Box 876, Tinley Park, IL 60477,

DAVID EVANS
10 Elmwood Lane, Asheville, NC 28803,

KENNETH FINN, M.D.
1716 Alpine Meadows Lane, Unit 1603, Prescott, AZ 86303

MMJ INTERNATIONAL HOLDINGS, INC.
101425 Overseas Highway, Suite 170, Key Largo, FL 33037,

MMJ BIOPHARMA CULTIVATION, INC.
101425 Overseas Highway, Suite 170, Key Largo, FL 33037,

and

MMJ BIOPHARMA LABS, INC.
101425 Overseas Highway, Suite 170, Key Largo, FL 33037,

Plaintiffs,

v.

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

THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

MEHMET OZ, M.D., in his official capacity as Administrator of the Centers for Medicare & Medicaid Services,

and

THE CENTERS FOR MEDICARE & MEDICAID SERVICES,

Defendants.

FIRST AMENDED COMPLAINT
FOR INJUNCTIVE AND DECLARATORY RELIEF

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I. INTRODUCTION[1]

1. On March 20, 2026, the Centers for Medicare & Medicaid Services ("CMS") created a program to distribute hemp-derived products containing the Schedule I substance delta-9 tetrahydrocannabinol ("THC") to Medicare beneficiaries. CMS called this program the Substance Access Beneficiary Engagement Incentive ("BEI"). The BEI imposes binding rules on participating health care providers. These rules include how doctors and patients officially sign up and which doctors are eligible to distribute these products, create detailed implementation plans that must first be approved by CMS, set THC limits and other product specifications, and require quarterly reporting by providers. The BEI does not involve the Food and Drug Administration ("FDA")'s medicine approval process.

2. CMS published no Notice of Proposed Rulemaking for the BEI, solicited no public comments, offered no reasonable explanation for its action, bypassed the Federal Register, gave 11 days' notice before the BEI's implementation, and contradicted *sub silentio* its own final rule (less than a year old) that declared cannabis products ineligible for supplemental Medicare coverage for chronically ill patients. 90 Fed. Reg. 15,792, 15,867 (Apr. 15, 2025).

3. The BEI violates the Administrative Procedure Act ("APA") in three ways:

   a. *First*, the BEI's obligations are the hallmarks of a legislative rule requiring notice-and-comment rulemaking under the APA. CMS's

[1] In accordance with Section 6 of this Court's Standing Order, Plaintiffs include attached a redline comparison of this First Amended Complaint with Plaintiffs' Original Complaint. *See* Exhibit A.

failure to solicit notice and comment violated 5 U.S.C. §§ 553 and 706(2)(D). CMS cannot evade notice-and-comment by embedding a substantive rule in a participation agreement.

b. *Second*, CMS reversed its prior rule without explanation, ignored well-documented health risks to elderly Americans (including a two-fold increase in cardiovascular death risk, an increase in the risk of developing or exacerbating mental health disorders, and pervasive contamination of CBD products), disregarded the absence of any FDA regulatory framework, and launched a program that violated the 0.4mg-per-container ceiling set by the 2026 Agriculture Appropriations Act by permitting the distribution of products with up to 3 mg of THC per serving. As such, the BEI is facially arbitrary, capricious, and not in accordance with law, in violation of 5 U.S.C. § 706(2).

c. *Third*, the BEI exceeds CMS's statutory authority in violation of the major questions doctrine. Section 1115A of the Social Security Act, under which the BEI is promulgated, allows CMS to test payment and delivery models for Medicare services. It does not allow CMS to sanction the possession and use of illegal and dangerous Schedule I substances by Medicare patients without clear congressional authorization.

4. The BEI violates the Constitution in two ways:

d. *First*, CMS's decision to provide advance notice of the BEI to hemp-industry stakeholders including Charlotte's Web, a major hemp product producer, while excluding similarly situated regulated parties such as the MMJ Plaintiffs, violates the Fifth Amendment's equal protection guarantee by intentionally treating similarly situated entities differently without any rational basis. The MMJ Plaintiffs, who have invested years and millions of dollars in the federal FDA botanical drug development pathway, received no notice of or opportunity to participate in the development of the BEI, while hemp-industry stakeholders who have not undertaken the same regulatory burdens were afforded advance notice and the opportunity to shape the program. This disparate treatment of similarly situated regulated parties—those developing cannabinoid products—without rational basis constitutes a class-of-one equal protection violation.

e. *Second*, CMS's implementation of the BEI without notice-and-comment rulemaking, and without affording directly affected regulated parties such as the MMJ Plaintiffs any opportunity to be heard, violates the Fifth Amendment's due process guarantee. The BEI retroactively undermines the investment-backed expectations of parties who entered the federal pharmaceutical regulatory pathway in reliance on an established and consistently applied framework,

and deprives them of the economic value of their regulatory compliance without any process whatsoever.

5. CMS's action represents an unprecedented and unlawful assertion of binding decision-making authority that will profoundly affect the health of elderly Americans. CMS took this action without the guardrails imposed by the administrative process, without any reasoned explanation, in conflict with the agency's own recent APA-compliant determination, and without statutory authority. Plaintiffs bring this action under the APA, 5 U.S.C. § 701–706, and under the Constitution, amend. V, to vacate the BEI, declare it unlawful, and permanently enjoin its implementation.

II. PARTIES

A. Plaintiffs

6. Smart Approaches to Marijuana, Inc. ("SAM") is a corporation headquartered at 220 Maryland Ave NE, Washington, D.C. 20002 and incorporated in Virginia. SAM's mission includes education and advocacy regarding the public health and safety impacts of marijuana and cannabis policy. SAM operates concrete programmatic activities, including public health education campaigns directed at healthcare providers and patients, direct information services regarding cannabis-related health risks, and research and policy analysis programs. SAM is a participant in the ongoing Drug Enforcement Administration marijuana rescheduling proceedings as an interested party in opposition to the Notice of Proposed Rulemaking. *See* Exhibit B. The BEI directly impairs SAM's core programmatic activities by requiring SAM to redirect staff and resources from its ongoing patient and provider education programs to monitor, analyze, and provide direct informational services to its members and stakeholders

regarding the BEI's implications for vulnerable seniors, as well as engage in this litigation. The BEI provides marijuana products via a medical source, meaning that SAM's expenditure of resources opposing rescheduling of marijuana in administrative proceedings has been rendered essentially moot. SAM's injury is not abstract policy disagreement but concrete impairment of specific programmatic activities with a consequent drain on organizational resources. *See Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). In addition, SAM's donor, volunteer, and consultant David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI. SAM also has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

7. Cannabis Industry Victims Educating Litigators ("CIVEL") is an organization based in New Jersey. CIVEL's mission includes educating legal professionals and the public about the harms caused by the cannabis industry. CIVEL represents the victims of the marijuana industry who have been, are being, or will actually be harmed by the challenged actions of CMS because the BEI will increase the use of marijuana, reduce the perception of its dangerousness, and lower medical standards for determining what constitutes a medicine. CIVEL thus has an active interest and not a mere casual interest in the problem presented. As a marijuana industry victims' legal support organization, CIVEL has a direct and particularized interest in the

implementation of federal and state law regarding "medical" marijuana in all of its forms. CIVEL operates concrete programmatic activities including legal education seminars, victim assistance programs, and community outreach. CIVEL is a participant in the ongoing administrative process opposing the rescheduling of cannabis before the Drug Enforcement Administration, and was granted associational standing by DEA Chief Administrative Law Judge John J. Mulrooney on November 19, 2024 in the matter of Schedules of Controlled Substances: Proposed Rescheduling of Marijuana, DEA Docket No. 1362, Hearing Docket No. 24-44. CIVEL was also recognized as having associational standing in *Botteon v. Murphy*, NJ Superior Court MID-L-002293 (2020), a New Jersey case concerning federal law preemption and the state marijuana law. The BEI has directly impaired CIVEL's core programmatic activities by requiring CIVEL to divert staff time and resources from its victim assistance and legal education programs to monitor, analyze, and respond to the BEI and its implications for vulnerable seniors. The BEI program will apply to thousands of medical care providers that CIVEL will have to educate and monitor, and with the increase in hemp injuries caused by the BEI, there will be more litigation, potentially against the providers or ACOs whose patients will be injured, requiring CIVEL to devote more expertise and financial and legal educational resources to handle those cases. This diversion of resources constitutes a concrete and demonstrable injury to CIVEL's organizational interests. In addition, CIVEL's Senior Counsel and Executive Director David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare

relationship due to the BEI. Additionally, CIVEL has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

8. Americans Against Legalizing Marijuana ("AALM") is a national non-profit volunteer organization based in California that is dedicated to providing information on the harms of marijuana to individuals and our country based on the premise "no use of any illegal drug and no illegal use of legal drugs." Such drugs include "medical" marijuana, hemp-based products, THC, CBD, and other cannabinoids. The BEI has directly affected and interfered with AALM's core programmatic activities beyond its issue advocacy or mission by requiring diversion of resources from its programs, including victim support and drug prevention education programs, public awareness campaigns, support and resources for medical professionals and attorneys working in fields impacted by cannabis use and abuse, and related operational activities. AALM's consultant David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI. Additionally, AALM has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

9. North Carolinians Against Legalizing Marijuana ("NCALM") is an organization based in Asheville, North Carolina, and is registered with the North Carolina Secretary of State for lobbying purposes. NCALM's mission includes opposing the legalization of medical hemp-derived and marijuana products in North Carolina and advocating that only medicines produced and distributed with standard best-practice pharmaceutical protocols and approved by the FDA should be available to patients. NCALM operates concrete programmatic activities including legislative advocacy, public education campaigns, and policy analysis regarding the risks of marijuana. The BEI has directly affected and interfered with NCALM's core programmatic activities beyond its issue-advocacy or mission, because the BEI authorizes the distribution of cannabis- and hemp-derived products that have not been approved by the FDA—the very outcome NCALM's programs are designed to prevent. NCALM's Executive Director David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI. Additionally, NCALM has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

10. Cannabis Impact Prevention Coalition, LLC ("CIPC") is a corporation organized under the laws of the State of New York. CIPC's mission is to prevent the negative social, health, public safety, and environmental impacts of marijuana. CIPC was

granted standing in *Cannabis Impact Prevention Coalition and Cannabis Industry Victims Seeking Justice, et al. v. Hochul*, Index No. 905386-23 (Albany County, NY), a case involving state laws regarding "medical" marijuana. CIPC operates concrete programmatic activities including public education, community outreach, and policy advocacy directed at reducing the harms caused by marijuana use. The BEI has directly affected and interfered with CIPC's core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its programs. This diversion constitutes a concrete organizational injury. CIPC's Executive Director David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI. Additionally, CIPC has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

11. Cannabis Industry Victims Seeking Justice ("CIVSJ") is a corporation organized under the laws of the State of New York. CIVSJ's mission is to make the marijuana industry legally accountable to its victims and to provide advocacy services to the many victims of the cannabis industry. CIVSJ was granted standing alongside Cannabis Impact Prevention Coalition, LLC in *Cannabis Impact Prevention Coalition and Cannabis Industry Victims Seeking Justice, et al. v. Hochul*, Index No. 905386-23 (Albany County, NY). CIVSJ operates concrete programmatic activities including victim advocacy, legal accountability initiatives, and public education regarding the harms

caused by the cannabis industry. The BEI has directly affected and interfered with CIVSJ's core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its programs. This diversion constitutes a concrete organizational injury. CIVSJ's Executive Director David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI. Additionally, CIVSJ has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

12. Drug Free America Foundation ("DFAF") is an incorporated nonprofit organization based in Florida. DFAF is a drug prevention and policy organization committed to developing strategies and educational programs that prevent drug use and promote sustained recovery. The BEI has directly affected and interfered with DFAF's core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its programs, including drug prevention education programs, student assistance initiatives, community outreach, workplace drug prevention programs, and related operational activities. DFAF's consultant and volunteer David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI. Additionally, DFAF has an informational interest in the administrative record that would have been developed had

the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

13. Save Our Society from Drugs ("SOS") is an incorporated nonprofit organization based in Florida. Its mission includes establishing, promoting, and enabling sound drug laws and policies that will reduce illegal drug use, drug addiction and drug-related illness and death. The BEI has directly affected and interfered with SOS's core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its programs, including drug prevention education programs, public awareness campaigns, community intervention initiatives, support and resources for professionals working in fields impacted by drug use and abuse, and related operational activities. SOS's consultant and volunteer David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI. Additionally, SOS has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

14. Drug Watch International ("DWI") is an incorporated nonprofit organization based in Virginia. Its mission includes promoting "healthy drug-free cultures" globally, advocating for the prohibition of and abstinence from all drugs including alcohol and tobacco, and opposing the legalization of drugs prohibited by national and international laws. The BEI has directly affected and interfered with DWI's

core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its programs. Since the BEI was announced, DWI's board and members have spent considerable time on collecting and disseminating information about cannabis- and hemp-derived products and the BEI to its stakeholders and constituents, thus diverting members from the mission of Drug Watch International, Inc., which seeks to prevent the abuse of all drugs, not just cannabis, through education, prevention, and treatment. DWI's injury is not abstract policy disagreement but concrete impairment of specific programmatic activities with a consequent drain on organizational resources. DWI's interest in preventing the expansion of access to drugs has been directly and demonstrably harmed by the BEI. DWI possesses extensive expertise and data regarding the public health risks of cannabis- and hemp-derived products and the impact of expanded drug access on communities, which it would have submitted to the agency as part of a formal rulemaking proceeding. DWI's member David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI. Additionally, DWI has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

15. Hillsborough County Anti-Drug Alliance ("HCADA") is an incorporated nonprofit organization based in Florida. Its mission includes engaging in community-based alcohol, tobacco, and substance abuse education and prevention activities, as well

as participation in the development of related planning strategies statewide. The BEI has directly affected and interfered with its core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its other programs and activities, including legislative advocacy, education, community outreach, and volunteering. Additionally, HCADA has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

16. Illinois Family Institute ("IFI") is an incorporated nonprofit organization based in Illinois. Its mission includes advancing public policy initiatives consistent with Judeo-Christian teachings and traditions, including opposition to access to illegal drugs, educating citizens so that they can better influence their local communities and the state. IFI possesses extensive expertise and data regarding the public health and moral risks of cannabis- and hemp-derived products and the impact of expanded drug access on communities. The BEI has directly affected and interfered with IFI's core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its programs. IFI would have submitted detailed comments to CMS opposing the BEI had the agency complied with the notice-and-comment requirements of 5 U.S.C. § 553. IFI has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

17. David Evans is a 78-year-old Medicare beneficiary and a three-time cancer survivor who was treated for two forms of cancer while on Medicare, making him a member of the population most vulnerable to the cardiovascular, neurological, cognitive, and drug-interaction harms documented in the peer-reviewed literature regarding cannabis- and hemp-derived products. Mr. Evans is aligned with an ACO REACH participant provider and has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI. Mr. Evans is also the owner of a critical care nursing home that may be asked to participate in the BEI process, and he would have sought the opportunity to participate in notice-and-comment rulemaking on behalf of the nursing home before the BEI was implemented. Mr. Evans has extensive personal knowledge of and experience with the harms caused by cannabis and hemp-derived products and possesses extensive evidence of these harms, which he was denied the opportunity to submit to CMS.

18. Kenneth Finn, M.D. is a physician who practices comprehensive pain medicine in Prescott, Arizona. Dr. Finn is Board Certified in Physical Medicine and Rehabilitation, Pain Medicine, and Pain Management, and is certified in Cannabis Science through the University of Colorado. Dr. Finn was an associate professor for the University of Colorado Medical School, is former President of the American Board of Pain Medicine, and has served on their Exam Council for over 25 years. He is editor of Cannabis in Medicine: An Evidence-Based Approach (2020) and is Co-Vice President of the International Academy on the Science and Impacts of Cannabis. Dr. Finn is employed by an Accountable Care Organization ("ACO"). As a physician who practices pain

medicine and has extensive experience with cannabis-related patient care, Dr. Finn will be directly affected by the BEI because the lack of satisfactory research into the cannabis products authorized under the BEI, and the absence of any dosing guidelines or care standards from the FDA, renders him unable to competently prescribe or administer such products for his patients. His practice may lose any Medicare patients who wish to access substances under the BEI. Dr. Finn must also follow the BEI's legal requirements for any patient he has that elects to receive substances under the BEI, should his ACO opt into the ACO REACH Model. Additionally, due to the known adverse health effects of cannabinoid substances, Dr. Finn and his practice are likely to receive an increase in emergency room visits and may be sued for malpractice by patients that overuse cannabinoid and hemp-derived products due to a lack of dosing requirements or widespread adulteration of such retail products. The BEI exposes Dr. Finn to significant malpractice liability without any regulatory safe harbor or physician indemnification, and creates a dangerous regulatory cliff: the FY 2026 Agriculture Appropriations Act, effective November 2026, resets the legal THC threshold to 0.4 mg total hemp-derived THC per container, potentially rendering products recommended to patients today Schedule I controlled substances by Fall 2026 and creating retroactive legal exposure for physicians. Dr. Finn is aware that approximately 1,500 deaths have been reported in connection with FDA-approved Epidiolex alone, yet products distributed under the BEI are afforded no comparable adverse event reporting mechanisms. Dr. Finn is a participant in the ongoing Drug Enforcement Administration marijuana rescheduling proceedings as an interested party in opposition to the Notice of Proposed Rulemaking.

See Exhibit B. Dr. Finn was deprived of his right to participate in notice-and-comment rulemaking as an interested party. Additionally, Dr. Finn has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of his participatory interest in shaping the regulatory process through providing comments.

19. MMJ International Holdings, Inc. ("MMJIH") is a corporation incorporated in Delaware with its principal business address at 101425 Overseas Highway, Suite 170, Key Largo, Florida 33037. MMJIH is a life sciences company established for the purpose of developing pharmaceutical cannabinoid therapeutics under the FDA's botanical drug development framework, including the Botanical Drug Development Guidance for Industry. MMJIH serves as the parent company of MMJ BioPharma Cultivation, Inc. and MMJ BioPharma Labs, Inc., overseeing regulatory strategy, clinical development planning, chemistry, manufacturing, and controls preparation, and Investigational New Drug ("IND") submissions for cannabinoid-based treatments targeting Huntington's disease and multiple sclerosis. MMJIH has assembled a team of nationally recognized scientists and regulatory professionals, submitted IND applications to the FDA, and obtained Orphan Drug Designation for Δ9-tetrahydrocannabinol and cannabidiol for the treatment of Huntington's disease pursuant to Section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360bb). Over the past approximately eight years, MMJIH and its subsidiaries have invested over $10 million into advancing pharmaceutical cannabinoid therapeutics through the formal federal FDA botanical drug development pathway and the DEA controlled-substance registration framework. The BEI has directly

and concretely injured MMJIH by (1) creating a federally supported pathway for the distribution of non-FDA-approved cannabinoid products to Medicare beneficiaries, thereby undermining the economic assumptions underlying MMJIH's multi-year pharmaceutical development investment, (2) diminishing the anticipated reimbursement differentiation between FDA-validated therapies and non-approved cannabinoid products, (3) adversely affecting investor confidence and capital-raising efforts, and (4) creating competitive disadvantage relative to entities that have not undertaken the rigorous scientific validation and regulatory compliance that MMJIH has pursued. MMJIH was excluded from any notice of the BEI and was deprived of the opportunity to participate in notice-and-comment rulemaking, despite being a directly affected regulated party with concrete interests at stake. Additionally, MMJIH has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

20. MMJ BioPharma Cultivation, Inc. ("MMJBC") is a corporation incorporated in Delaware with its principal business address at 101425 Overseas Highway, Suite 170, Key Largo, Florida 33037. MMJBC is a subsidiary of MMJIH formed to support the cultivation and production of pharmaceutical-grade cannabis plant material required for extraction and formulation of the active botanical drug substance used in MMJIH's IND programs. In December 2018, MMJBC submitted an application to the DEA for registration as a bulk manufacturer of marijuana active pharmaceutical ingredient for use in FDA-authorized clinical trials and drug development. MMJBC's cultivation facility in

Westerly, Rhode Island was designed to employ state-of-the-art automated growth chambers capable of generating medical marijuana with exacting and repeatable secondary metabolite profiles at production levels consistent with federal research supply requirements. MMJBC's bulk manufacturing registration application remains pending before the DEA Administrator. The BEI has directly and concretely injured MMJBC as part of the integrated pharmaceutical development platform it operates with MMJIH and MMJBL, by undermining the economic viability of the federal FDA and DEA regulatory pathway upon which MMJBC's operations depend. MMJBC was excluded from any notice of the BEI and was deprived of the opportunity to participate in notice-and-comment rulemaking. Additionally, MMJBC has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

21. MMJ BioPharma Labs, Inc. ("MMJBL") is a corporation incorporated in Delaware with its principal business address at 101425 Overseas Highway, Suite 170, Key Largo, Florida 33037. MMJBL is a subsidiary of MMJIH established to perform analytical testing, formulation support, and regulatory-grade characterization of botanical extracts used in MMJIH's drug development program. MMJBL obtained a DEA Schedule I analytical laboratory registration, issued following a DEA inspection and approval of the laboratory's physical security systems, recordkeeping controls, and diversion-prevention safeguards, consistent with its Rhode Island state authorization. The BEI has directly and concretely injured MMJBL as part of the integrated pharmaceutical development

platform it operates with MMJIH and MMJBC, by undermining the economic viability of the federal FDA and DEA regulatory pathway upon which MMJBL's operations depend. MMJBL was excluded from any notice of the BEI and was deprived of the opportunity to participate in notice-and-comment rulemaking. Additionally, MMJBL has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

B. Defendants

22. Defendant Robert F. Kennedy, Jr. is the Secretary of Health and Human Services. He is sued in his official capacity. Secretary Kennedy oversees the Department of Health and Human Services, which houses the Centers for Medicare & Medicaid Services, and bears ultimate responsibility for the adoption and implementation of the BEI.

23. Defendant United States Department of Health and Human Services ("HHS") is an executive department of the United States government responsible for administering federal healthcare programs, including the Medicare program.

24. Defendant Mehmet Oz, M.D. is the Administrator of the Centers for Medicare & Medicaid Services. He is sued in his official capacity. Administrator Oz publicly announced in December 2025, at the signing ceremony for Executive Order No. 14370, that "millions of Americans on Medicare" would become eligible to receive cannabis products "as early as April of next year—and at no charge if their doctors

recommend them." Administrator Oz has played a central role in the development and public promotion of the BEI.

25. Defendant Centers for Medicare & Medicaid Services ("CMS") is a federal agency within HHS. CMS administers the Medicare program and operates the Center for Medicare & Medicaid Innovation ("Innovation Center"), which developed and published the BEI.

III. JURISDICTION AND VENUE

26. Plaintiffs bring this action under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706, and the Constitution, amend. V. The APA provides a right of review under 5 U.S.C. § 702 for persons adversely affected or aggrieved by agency action and under 5 U.S.C. § 704 for final agency action for which there is no other adequate remedy in a court.

27. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, 5 U.S.C. §§ 701-706 (APA) and 28 U.S.C. § 2201 (Declaratory Judgment Act). The relief requested is authorized by 28 U.S.C. § 2201 (declaratory judgment), 28 U.S.C. § 2202 (injunctive relief), and 5 U.S.C. §§ 701-706 (APA).

28. This Court has jurisdiction pursuant to 28 U.S.C. § 1331, which grants the district courts "original jurisdiction of all civil actions arising under the . . . laws . . . of the United States."

29. Venue is appropriate in this Court pursuant to 28 U.S.C. § 1391(e)(1) because the defendants are officers and agencies of the United States and this action is

brought where the agency defendants maintain their principal offices. Venue is also appropriate under 5 U.S.C. § 703.

30. An actual, justiciable controversy exists between the parties within the meaning of 28 U.S.C. § 2201.

31. The federal Government has waived sovereign immunity in this action pursuant to 5 U.S.C. § 702.

32. Plaintiffs have exhausted all administrative remedies.

33. The agency action is final and ripe for review.

34. All Plaintiffs have standing because they are injured in fact because of the defendants' actions or omissions and this Court has the power to redress those injuries.

A. Final Agency Action

35. The BEI constitutes final agency action because it (1) "mark[s] the consummation of the agency's decision-making process" and is "not . . . of a merely tentative or interlocutory nature" and (2) is an action "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (cleaned up); *see also United States Army Corps of Eng'rs v. Hawkes Co.*, 578 U.S. 590, 597 (2016). The BEI was published to CMS's website on March 20, 2026, with an effective date of April 1, 2026. It imposes binding requirements regarding participant election, submission of an implementation plan, eligibility determinations, and quarterly reporting to CMS. These requirements complete CMS's decision-making and produce concrete legal consequences for participating organizations and Medicare beneficiaries

aligned with them. *See Bennett*, 520 U.S. at 178 (action is final where it has "direct and appreciable legal consequences").

B. The Section 1115A Review Bar Does Not Apply

36. Section 1115A of the Social Security Act, 42 U.S.C. § 1315a(d)(2), bars judicial review of "the selection of models for testing," "the selection of organizations, sites, or participants," and "the elements, parameters, scope, and duration" of Innovation Center models.

37. Plaintiffs do not challenge any of these enumerated decisions. Plaintiffs challenge the procedures CMS used to adopt and publish the BEI by bypassing APA rulemaking and exceeding its statutory authority. *See Regeneron Pharmaceuticals, Inc. v. United States HHS*, 510 F. Supp. 3d 29, 42 (S.D.N.Y. 2020) (holding that Section 1115A "does not bar review of the propriety of the procedures used" to establish models); *see also Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986) (recognizing a "strong presumption that Congress intends judicial review of administrative action").

C. Medicare Channeling Does Not Apply

38. Plaintiffs do not seek benefits determinations, reimbursement calculations, or participant-specific Medicare payment review. No adequate administrative remedy exists for this pre-enforcement APA challenge to CMS's procedural deficiencies in adopting the BEI. *See Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1, 19 (2000) (channeling requirements do not apply where they would result in "complete preclusion of judicial review").

IV. STANDING

A. Competitor Standing

39. MMJ Plaintiffs have competitor standing under the doctrine established in *Sherley v. Sebelius*, 610 F.3d 69 (D.C. Cir. 2010), and its progeny.

40. MMJ Plaintiffs are direct and current competitors in the cannabinoid therapeutics market. MMJIH, through its subsidiaries MMJBC and MMJBL, has invested over $10 million and eight years into developing pharmaceutical-grade cannabinoid therapeutics through the formal FDA botanical drug development pathway. MMJIH has submitted IND applications to the FDA for cannabinoid treatments targeting Huntington's disease (IND file number 137754) and multiple sclerosis (IND file number 140712). The FDA granted Orphan Drug Designation for MMJIH's Huntington's disease program. MMJBC has a pending bulk manufacturing application before the DEA for cultivation of pharmaceutical-grade cannabis for clinical trials, and MMJBL holds an active DEA Schedule I analytical laboratory registration.

41. The BEI causes an actual and imminent increase in competition against MMJ Plaintiffs. The BEI expands the competitive landscape by creating a federally supported pathway for non-FDA-approved cannabinoid products to reach Medicare beneficiaries—the same patient population that MMJ Plaintiffs' FDA-validated therapies would target.

42. The competitive injury to MMJ Plaintiffs is concrete and imminent. The BEI subjects MMJ Plaintiffs to direct competition from entities distributing non-FDA-approved cannabinoid products through Medicare without undertaking any of the

rigorous pharmaceutical development requirements that MMJ Plaintiffs have spent years and millions of dollars satisfying.

43. Moreover, MMJ Plaintiffs have suffered competitive injury because the challenged agency action permits entities (hemp-product distributors) to compete in a market (cannabinoid therapeutics for Medicare beneficiaries) where the plaintiffs (MMJ Plaintiffs pursuing FDA approval) previously enjoyed regulatory protection. This amounts to increased competitive activity that courts have recognized constitutes Article III injury.

44. MMJ Plaintiffs' competitive injuries are fairly traceable to the BEI and redressable by a favorable decision. Before the BEI, there was no federally supported reimbursement pathway for non-FDA-approved cannabinoid products in Medicare. The BEI created one. MMJ Plaintiffs' competitive disadvantage flows directly from the BEI's existence. An injunction vacating or staying the BEI would eliminate the competing access pathway, restoring the regulatory framework that previously required cannabinoid therapeutics to proceed through FDA approval before becoming eligible for Medicare reimbursement.

45. Finally, MMJ Plaintiffs satisfy the prudential standing requirement that their interests fall within the "zone of interests" protected by the statutes they invoke. MMJ Plaintiffs' interest in maintaining the integrity of the FDA drug approval framework, and in preventing CMS from creating alternative access pathways that circumvent that framework, falls squarely within the zone of interests protected by the

APA's procedural requirements and the statutory framework governing federal healthcare reimbursement for pharmaceutical products.

B. Organizational Standing

46. All Plaintiffs except for David Evans and Kenneth Finn, M.D. (collectively, the "Organizational Plaintiffs") have organizational standing to sue.

47. Organizational Plaintiffs' primary interest is in proper use of the FDA regulatory process for any cannabinoid products approved for medical use, as well as preventing the expansion of access to cannabis, hemp, and cannabinoid products not approved through this process. They have standing to challenge CMS's action in creating and instituting the BEI on their own behalf due to concrete and demonstrable injury to these respective interests.

48. Moreover, CMS's action has impaired specific, concrete programmatic activities undertaken by certain Organizational Plaintiffs, including direct patient education services, clinician training programs, community health intervention programs, and victim assistance operations, by requiring diversion of resources from these programs to counteract the public health and societal effects of the BEI. This constitutes an injury to each Organizational Plaintiff's respective organizational interests. *See People for the Ethical Treatment of Animals v. United States Department of Agriculture*, 797 F.3d 1087, 1094 (D.C. Cir. 2015).

49. Certain Organizational Plaintiffs have standing to challenge the BEI because counteracting it requires diversion of resources from their efforts to prevent rescheduling of cannabis through the administrative process. Specifically, SAM and

CIVEL are directly involved in ongoing DEA administrative proceedings opposing cannabis rescheduling.

50. MMJ Plaintiffs additionally have standing based on direct competitive and economic injury. The BEI created a federally supported pathway for the distribution of non-FDA-approved cannabinoid products to Medicare beneficiaries, thereby directly and concretely injuring MMJ Plaintiffs by undermining the economic assumptions underlying their multi-year, multi-million-dollar pharmaceutical development investment in the federal FDA botanical drug development pathway; diminishing the anticipated reimbursement differentiation between FDA-validated therapies and non-approved cannabinoid products; adversely affecting investor confidence, capital-raising efforts, and strategic partnership positioning; and creating competitive disadvantage relative to entities that have not undertaken the rigorous scientific validation and regulatory compliance that MMJ Plaintiffs have pursued. These injuries are concrete and particularized, actual and imminent, fairly traceable to CMS's adoption of the BEI, and redressable by a favorable decision vacating or enjoining the BEI.

51. MMJ Plaintiffs' standing is further supported by their status as directly affected regulated parties operating under active DEA oversight and FDA IND authorization. The BEI creates a two-track regulatory system in which entities like MMJ Plaintiffs that have complied with the federal pharmaceutical regulatory framework are subjected to the full weight of FDA and DEA regulatory requirements, while the BEI permits entities that have not undertaken any of those regulatory burdens to access a federally supported cannabinoid distribution pathway. An injunction vacating or staying

the BEI would eliminate the competing pathway, restoring the regulatory framework upon which MMJ Plaintiffs relied and protecting their investment in the FDA approval process.

C. Procedural Standing

52. All Plaintiffs assert the denial of their right to participate in notice and comment rulemaking under 5 U.S.C. § 553. They have suffered a "reasonably increased risk of injury" to their particularized interests due to CMS's decision to create and institute the BEI without the required procedure. *Cap. Area Immigrants' Rts. Coal. v. Trump*, 471 F. Supp. 3d 25, 38 (D.D.C. 2020); *see also Mendoza v. Perez*, 754 F.3d 1002, 1010 (D.C. Cir. 2014); *Massachusetts v. EPA*, 549 U.S. 497, 517–18 (2007); *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 94–95 (D.C. Cir. 2002). A plaintiff "who alleges a deprivation of a procedural protection to which he is entitled never has to prove that if he had received the procedure the substantive result would have been altered. All that is necessary is to show that the procedural step was connected to the substantive result." *Veneman*, 289 F.3d at 94–95.

53. Plaintiffs' concrete interests include: (1) the health and safety of their individual members who are Medicare beneficiaries exposed to the BEI, including Mr. Evans, who is a three-time cancer survivor particularly vulnerable to the health risks posed by the BEI, (2) the professional interests of physicians affected by the BEI, including Dr. Finn, who faces concrete professional and economic harm, (3) the informational interest in the administrative record that would have been developed through notice and comment rulemaking, (4) the participatory interest in shaping the regulatory outcome

through the procedures Congress established, and (5) the competitive and economic interests of MMJIH, MMJBC, and MMJBL (collectively, the "MMJ Plaintiffs"), whose multi-year investment in compliance with the FDA pharmaceutical regulatory pathway is directly impaired by CMS's creation of a competing access pathway for Medicare patients to access non-FDA-approved cannabinoid products without notice or opportunity for comment. These are not abstract interests in "having the procedure observed." They are concrete, particularized interests that the notice-and-comment process is designed to protect.

54. Plaintiffs SAM and CIVEL are also involved in ongoing administrative proceedings opposing the DEA's efforts to expand access to cannabis through rescheduling under the Controlled Substances Act. *See* Exhibit B (order granting SAM and CIVEL standing in DEA administrative proceeding). They are injured specifically by their inability to comment on the BEI, which expands distribution of cannabinoid products to Medicare patients, as they are involved in administrative proceedings opposing rescheduling of cannabis that remain ongoing.

55. MMJ Plaintiffs are directly affected regulated parties operating under active DEA oversight and FDA IND authorization. They were deprived of any notice of the BEI, and of any opportunity to comment—effectively, of due process. Had CMS conducted notice-and-comment rulemaking, MMJ Plaintiffs would have submitted detailed comments addressing, among other things, the protection of the FDA drug approval framework, patient safety and dose reproducibility, reliance interests of sponsors following the established FDA pathway for botanical drugs, competitive harm to FDA-

compliant developers, the impact on clinical trial incentives, and the need for coordination between CMS and FDA.

D. Individual and Associational Standing

56. David Evans is a 78-year-old Medicare beneficiary with individual standing to sue. Mr. Evans is a three-time cancer survivor who was treated for two forms of cancer while on Medicare, as well as a concussion due to a fall. His cancer may return and he will have to face additional treatment while on Medicare. As a senior citizen enrolled in Medicare, Mr. Evans is a member of the population most vulnerable to the cardiovascular, neurological, cognitive, and drug-interaction harms documented in the peer-reviewed literature regarding these products.

57. Mr. Evans is a Medicare beneficiary who is aligned with Hopscotch Primary Care, PLLC. This provider has joined ACO REACH as part of Physicians Healthcare Collaborative ACO. Because his primary care provider participates in ACO REACH, Mr. Evans faces imminent implementation of a program that will make hemp-derived THC products and other cannabis-derived products available through his healthcare provider beginning April 1, 2026. He may be offered products under the BEI by his own healthcare provider.

58. Mr. Evans was deprived of his right to participate in notice-and-comment rulemaking as an interested party. Mr. Evans is opposed to expanded access to cannabis- and hemp-derived products that have not been proven safe and effective through the FDA approval process, and does not want such unapproved products provided by or through his Medicare provider, due to their serious and well-documented health risks.

Mr. Evans also possesses extensive evidence of the harms caused by these products, including personal knowledge derived from decades of professional and volunteer experience assisting persons harmed by cannabis use. Because there was no opportunity for public comment on the BEI, Mr. Evans could not submit this evidence to CMS.

59. Mr. Evans is also the owner of a critical care nursing home that may be asked to participate in the BEI process. As the owner, he would have sought the opportunity to participate in notice-and-comment rulemaking on behalf of the nursing home before the BEI was implemented.

60. Dr. Kenneth Finn is a physician with individual standing to sue. Dr. Finn practices comprehensive pain medicine in Prescott, AZ. He is employed by an ACO. As a physician who practices pain medicine, and a nationally recognized expert in the harmful effects of unregulated hemp-derived and cannabinoid products, Dr. Finn is directly and concretely affected by the BEI. The BEI requires participating physicians to make individual clinical determinations that the use of eligible hemp products is appropriate for specific beneficiaries, yet CMS does not provide clinical guidelines, evidence-based thresholds, or diagnostic criteria to support such determinations. CMS has explicitly stated it "does not make claims regarding the therapeutic value of these products," yet the program requires physicians to make a documented clinical determination that hemp use is "safe and appropriate" for a specific patient. Making that determination without recognized clinical guidelines, an FDA approval framework, or an established evidence base creates significant professional risk, particularly in the elderly Medicare population. The BEI also exposes Dr. Finn to significant malpractice

liability: adverse events traceable to physician-endorsed hemp use create direct malpractice exposure, and unlike DEA-registered controlled substance frameworks or FDA-approved drug programs, the BEI contains no explicit indemnification language for participating physicians, no regulatory safe harbor protecting physicians who rely in good faith on their ACO's implementation plan, and no mechanism for physicians to obtain binding CMS guidance on borderline eligibility questions before dispensing. Furthermore, the BEI creates a dangerous regulatory cliff for physicians: the FY 2026 Agriculture Appropriations Act, effective November 2026, resets the legal THC threshold to 0.4 mg total hemp-derived THC per container, potentially rendering products recommended to patients today Schedule I controlled substances by Fall 2026 and creating retroactive legal exposure for physicians whose patient charts document endorsement of now-illegal products. CMS has not provided guidance on how participating physicians should wind down or transition patients if the threshold change takes effect.

61. Dr. Finn was deprived of his right to participate in notice-and-comment rulemaking as an interested party. Additionally, Dr. Finn has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of his participatory interest in shaping the regulatory process through providing comments.

62. The following Plaintiffs have associational standing: SAM, CIVEL, AALM, NCALM, CIPC, CIVSJ, DFAF, SOS, and DWI (collectively, the "Associational Plaintiffs").

63. At least one identified member of each Plaintiff, namely Mr. David Evans, has standing to sue in his own right. Mr. Evans is (1) a donor, consultant, and volunteer for SAM, (2) Executive Director and Senior Counsel of CIVEL, (3) a donor, consultant, and member of AALM, (4) Executive Director of NCALM, CIPC, and CIVSJ, (5) a consultant and volunteer of DFAF, (6) a consultant and volunteer of SOS, and (7) a member of DWI.

64. The interests each Associational Plaintiff seeks to protect—including public health, product safety, and lawful agency procedure—are germane to their purposes.

65. Finally, neither the claims asserted nor the declaratory and injunctive relief requested requires the participation of individual members.

V. LEGAL STANDARD

66. Under 5 U.S.C. § 706(2), a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; [or] without observance of procedure required by law . . . ."

67. The court must examine whether the agency has "examined the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 43 (1983). Agency action must be "reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

68. Under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), courts must "exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the [APA] requires." *Id.* at 413. Courts "need not and under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous." *Id.*

VI. FACTUAL ALLEGATIONS

A. The CMS Innovation Center

69. Section 1115A of the Social Security Act, 42 U.S.C. § 1315a, established the Center for Medicare & Medicaid Innovation ("Innovation Center") within CMS. The Innovation Center's statutory purpose is to test "innovative payment and service delivery models" to reduce program expenditures "while preserving or enhancing the quality of care" for "individuals who are enrolled under such titles and . . . for defined populations with deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." 42 U.S.C. § 1315a(a)(1).

70. The specific models at issue are ACO REACH (a model for accountable care organizations), the Enhancing Oncology Model or EOM (a model for oncology care), and the LEAD Model (an upcoming model for community-level addiction and overdose treatment). These are payment and delivery models.

71. ACO REACH brings together doctors, hospitals and other healthcare providers into a single team called an Accountable Care Organization (ACO). *See Innovation Models: ACO REACH*, Ctrs. for Medicare & Medicaid Servs., https://www.cms.gov/priorities/innovation/innovation-models/aco-reach. These teams coordinate patient care, making sure patients get the right tests, follow-up, and

preventative services to reduce duplication or unnecessary procedures. *Id.* If the ACO keeps costs below a benchmark while meeting quality standards, the team shares in the savings thereby encouraging providers to work together efficiently to focus on preventive care, chronic disease management, and patient outcomes rather than simply the number of services delivered. *Id.* Currently, there are approximately 74 ACOs made up of approximately 126,000 providers and organizations providing care to approximately 1.7 million Medicare beneficiaries. *Id.*

72. The EOM focuses on Medicare patients with certain cancers and tests a new way of paying oncology practices. *See Innovation Models: EOM*, Ctrs. for Medicare & Medicaid Servs., https://www.cms.gov/priorities/innovation/innovation-models/eom. Participating clinics are given bundled payments or target budgets for patients' entire course of cancer treatment, rather than being paid separately for every test or procedure. *Id.* The incentive is that if the clinic keeps costs within the target and meets quality and outcome goals, it can earn shared savings bonuses. *Id.* Based on the most recent publicly available information, the total number of Medicare participants is unknown. *Id.* However, 28 physician group practices and one commercial payer are participating, accounting for approximately 2,000 practitioners across more than 350 care sites. *Id.*

73. The BEI also applies to another payment model, LEAD, which does not begin until January 1, 2027. *See LEAD (Long-Term Enhanced ACO Design) Model*, Ctrs. for Medicare & Medicaid Servs., https://www.cms.gov/priorities/innovation/innovation-models/lead.

74. Section 1115A was designed to test new payment and care delivery approaches for Medicare and Medicaid. The purpose of Innovation Center models under Section 1115A is to improve care quality, lower costs, and promote value-based care by encouraging best medical and financial practices through financial incentives or shared savings/risk arrangements—not to serve as a distribution system for specific consumer products.

B. CMS's Position on Cannabis Products

75. In April 2025, CMS issued a final rule, effective June 3, 2025, that states 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) (codifying "cannabis products" as non-allowable special supplemental benefits for the chronically ill ("SSBCI")).

76. To date, CMS has not rescinded this rule.

77. Yet, the BEI allows access to cannabis products for Medicare Advantage beneficiaries. This contradictory position was issued without any reasoned explanation.

C. Executive Order No. 14370

78. On December 18, 2025, President Donald J. Trump signed Executive Order No. 14370, titled "Increasing Medical Marijuana and Cannabidiol Research."

79. At the signing ceremony, CMS Administrator Oz publicly stated that "millions of Americans on Medicare" would become eligible to receive cannabis and hemp-derived products "as early as April of next year—and at no charge if their doctors recommend them." This announcement predated any agency action by three months and signaled a predetermined outcome.

D. The Substance Access BEI

80. On March 20, 2026, CMS published the BEI on its website.

81. The BEI is an optional feature embedded in participation agreements for ACO REACH and EOM (effective April 1, 2026) and the LEAD Model (effective January 1, 2027).

82. For participants in ACO REACH and EOM who elect the BEI, it is a binding, generally applicable framework that imposes legal obligations on participants and their aligned beneficiaries.

83. The BEI imposes the following mandatory program mechanics, which include: (a) participant election; (b) submission of a CMS-required implementation plan; (c) CMS approval of the implementation plan, with CMS retaining authority to reject or suspend participation; (d) physician determination of beneficiary eligibility, including that the beneficiary is over 18 years of age and does not have a disqualifying condition[2]; (e) shared decision-making with beneficiaries; (f) cannabis and hemp-derived products provided are limited to 0.3% delta-9 THC per dry weight of the product and in products that are ingested orally, no more than 3 mg per serving of total tetrahydrocannabinols; (g) a $500 annual cap per beneficiary; and (h) quarterly reporting obligations.

[2] Beneficiaries are not eligible for the BEI if they are not aligned to a participating organization, meets the model's frailty exclusion, is pregnant or breastfeeding, or if a physician does not determine the product is appropriate. *See Substance Access Beneficiary Engagement Incentive*, Centers for Medicare & Medicaid Services (accessed Mar. 27, 2026), https://www.cms.gov/priorities/innovation/substance-access-beneficiary-engagement-incentive. Public-facing CMS documents do not reveal the actual list of "disqualifying conditions" for the BEI.

84. CMS claims that Medicare does not pay for the cannabis products or hemp-derived THC products approved under the BEI directly, and that they are funded at the expense of participants. However, the limited information available about the BEI makes this unclear.

85. On April 1, 2026, the BEI went into full effect.

E. Absence of Notice and Comment

86. CMS issued no notice of proposed rulemaking and solicited no public comments before announcing and instituting the BEI.

87. CMS provided no formal administrative record before announcing and instituting the BEI.

88. CMS provided no reasonable or reasoned explanation for the BEI or for its departure from its April 2025 final rule, 90 Fed. Reg. 15,792, 15,867.

89. The BEI was not published in the Federal Register, but was announced on March 20, 2026 with a near-immediate effective date of April 1, 2026.

90. Public statements by hemp-industry stakeholders and later reporting suggest that selected stakeholders had advance notice of the BEI before CMS publicly announced the BEI.

91. On December 18, 2025, Charlotte's Web announced that it was prepared to participate as a CBD provider in a potential Innovation Center pilot. *Charlotte's Web Serves as a Premier CBD Partner for Landmark Medicare and Medicaid Pilot Program*, Charlotte's Web (Dec. 18, 2025), https://investors.charlottesweb.com/press-releases/press-release-

details/2025/Charlottes-Web-Serves-as-a-Premier-CBD-Partner-for-Landmark-Medicare-and-Medicaid-Pilot-Program/default.aspx.

92. Charlotte's Web co-founder Jared Stanley confirmed on February 13, 2026 that the program was "internally finalized" by CMS weeks prior, without public announcement or opportunity to comment, and referred to a "briefing" when discussing the pilot program's anticipated scope. Kyle Jaeger, *Federal Agency Finalized Rule for CBD Medicare Coverage Pilot Program Weeks Ago, Key Hemp Stakeholder Says*, Marijuana Moment (Feb. 13, 2026), https://www.marijuanamoment.net/federal-agency-finalized-rule-for-cbd-medicare-coverage-pilot-program-weeks-ago-key-hemp-stakeholder-says/.

93. On information and belief, Charlotte's Web, a major hemp company, along with other hemp companies that received briefings and communications from CMS regarding the BEI, collaborated with CMS in shaping and finalizing the BEI.

94. At no point was the public afforded any opportunity to participate in the development of the BEI.

95. At no point was MMJIH or any of its subsidiaries, who are directly affected by the BEI's market-distorting effects, afforded any opportunity to participate in the development of the BEI.

96. CMS knows how to comply with the APA when it chooses to do so. On April 6, 2026, CMS published the Contract Year 2027 final rule in the Federal Register after full notice-and-comment rulemaking, receiving about 42,632 comments. *See* 91 Fed. Reg. 17,384 *et seq.* (Apr. 6, 2026) ("CY2027 Rule").

97. In the CY2027 Rule, CMS acknowledged that it "does not regulate cannabis and hemp-derived cannabis products" and that its "authority does not extend to the direct regulation of cannabis-derived products." *Id.* at 17,432–17,433. CMS further stated 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.

98. The CY2027 Rule confirmed that the only cannabis-derived products currently permissible under applicable federal law are hulled hemp seed, hemp seed protein powder, and hemp seed oil—not the panoply of hemp-derived THC and CBD products that the BEI authorizes for medical distribution. *Id.* at 17,432.

99. The contrast between CMS's adherence to APA procedures for the CY2027 Rule and its complete bypass of notice-and-comment for the BEI demonstrates the arbitrariness of the action at issue, contradicts the premise of the BEI by limiting hemp-derived products for distribution, and underscores the unlawfulness of the BEI's implementation.

F. Conflict with the 2026 Agriculture Appropriations Act

100. The 2026 Agriculture Appropriations Act, signed by the President, sets a total THC limit of 0.4 mg per container for hemp-derived products, effective November 2026.

101. CMS's BEI permits 3 mg of total THC per serving, which is more than seven times the statutory limit.

102. CMS's only response to this conflict has been that it "will adjust its definition in accordance with the law." *See Substance Access Beneficiary Engagement*

Incentive, Centers for Medicare & Medicaid Services (accessed Mar. 27, 2026), https://www.cms.gov/priorities/innovation/substance-access-beneficiary-engagement-incentive.

103. CMS has provided no details on when or how this adjustment will occur nor why it promulgated a program in explicit conflict with clearly established law.

104. Accordingly, CMS launched a program it already knows to be inconsistent with enacted federal law.

G. Conflict with Established and Documented Health Risks of Existing Cannabis and Hemp-Derived THC Products for Medicare Populations

105. The BEI allows elderly Americans to access cannabis products, which contain substances that provably cause harm to their health.

106. A 2025 narrative review published in the Journal of the American Medical Association ("JAMA") of 124 recent randomized controlled trials and meta-analysis found that the evidence that cannabis "treats" disorders such as pain, anxiety, post-traumatic stress disorder ("PTSD"), insomnia, and most other hyped uses is weak or non-existent. M. Hsu et al., Therapeutic Use of Cannabis and Cannabinoids: A Review, JAMA (Nov. 26, 2025).

107. The position of the American Psychiatric Association ("APA") as of December of 2025 is that "[t]here is insufficient evidence that cannabis is an effective treatment for any psychiatric disorder." AM. PSYCHIATRIC ASS'N, *Position Statement in Opposition to Cannabis as Medicine for Psychiatric Disorders* (approved by Board of Trustees Dec. 2025 and Assembly Nov. 2025).

108. The scientific evidence documenting cardiovascular, neurological, and other health risks from cannabis and hemp-derived THC products is substantial and directly relevant to the Medicare population, which consists predominantly of adults over 65 (the population most vulnerable to these harms).

109. Heart disease is the leading cause of death among Americans over 65.

110. A June 2025 meta-analysis published in *Heart* (BMJ), encompassing 24 studies and approximately 200 million participants, found that cannabis use was associated with a two-fold risk of cardiovascular death, a 29% higher risk of acute coronary syndrome, and a 20% higher risk of stroke. Wilhelm Storck et al., *Cardiovascular Risk Associated with the Use of Cannabis and Cannabinoids: A Systematic Review and Meta-Analysis*, 111 Heart 1047 (2025).

111. A 2024 study published in the *Journal of the American Heart Association*, analyzing data from approximately 434,000 U.S. adults, found that daily cannabis users had a 25% higher risk of heart attack and a 42% higher risk of stroke compared to non-users, with risk increasing in a dose-response fashion with more frequent use. Abra M. Jeffers et al., *Association of Cannabis Use with Cardiovascular Outcomes Among US Adults*, 13 J. Am. Heart Ass'n e030178 (2024).

112. A May 2025 study published in *JAMA Cardiology* by researchers at the University of California, San Francisco, found that chronic cannabis use—whether smoked or consumed as THC-containing edibles—was associated with vascular endothelial dysfunction comparable to that observed in tobacco smokers. Vascular function in chronic cannabis users was reduced by approximately 50% compared to non-

users. *See* Leila Mohammadi et al., *Association of Endothelial Dysfunction with Chronic Marijuana Smoking and THC-Edible Use*, JAMA Cardiology (May 28, 2025).

113. Memory and cognitive impairment are already prevalent concerns among older adults. THC products appear to worsen these outcomes.

114. A 2025 study found that individuals who presented to the emergency room due to cannabis use were at a 1.5-fold to 3.9-fold increased risk of dementia diagnosis within five years, relative to individuals with all-cause acute care visits and the general population. Daniel T. Myran *et al.*, *Risk of Dementia in Individuals With Emergency Department Visits or Hospitalizations Due to Cannabis*, 82 JAMA Neurology 570–79 (June 2025).

115. A 2021 study found that long-term marijuana users scored significantly lower on measures of executive function, processing speed, and general cognition than non-users, and that more frequent and more recent use was negatively associated with working memory. Katie Stypulkowski & Rachel E Thayer, *Long-Term Recreational Cannabis Use Is Associated with Lower Executive Function and Processing Speed in a Pilot Sample of Older Adults*, J. Geriatric Psychiatry Neurology (Sept. 2021).

116. A 2020 study found that fewer than 250 older adults have been included in cannabis studies to date, meaning that there is a substantial body of potential harm to that population that remains unknown to science. Brooke Porter *et al.*, *Cannabidiol (CBD) Use by Older Adults for Acute and Chronic Pain*, 47 J. Gerontological Nursing 7, 6–15 (July 2021).

117. A study examining trends in emergency department visits associated with cannabis use among older adults in California from 2005 to 2019 found that cannabis-related emergency department visits increased by 1,804%, with older Black adults having the highest visit rate and the largest absolute increase. B. Han et al., *Trends in Emergency Department Visits Associated with Cannabis Use Among Older Adults in California, 2005–2019*, 71 J. Am. Geriatr. Soc. 4, 1267–74 (Apr. 2023).

118. CMS did not address this research gap before launching a program directed at older adults.

119. A study examining the health effects of cannabis use for medical and non-medical purposes in older adults found that the available evidence suggests cannabis use may be associated with greater frequencies of depression, anxiety, cognitive impairment, substance use and problematic substance use, accidents and injuries, and acute healthcare use. D. Wolfe et al., *Impacts of Medical and Non-Medical Cannabis on the Health of Older Adults: Findings from a Scoping Review of the Literature*, PLOS ONE (Feb. 17, 2023).

120. Commercially available CBD products are pervasively contaminated and mislabeled. M.O. Bonn-Miller et al., *Labeling Accuracy of Cannabidiol Extracts Sold Online*, 318 JAMA 17 at 1708–09 (2017).

121. A peer-reviewed 2022 study published in *Science of the Total Environment*, analyzing 516 CBD products sold in the United States, found that only 42% of products fell within ±10% of the CBD content claimed on the manufacturer's label. Among 121 edible CBD products tested, lead was detected in 42%, mercury in 37%, arsenic in 28%, and cadmium in 8%. Four edible products exceeded the California Proposition 65

threshold for daily lead consumption in two servings. Hannah Gardener et al., *Heavy Metal and Phthalate Contamination and Labeling Integrity in a Large Sample of US Commercially Available Cannabidiol (CBD) Products*, 851 Sci. Total Env't 158110 (2022).

122. These contamination and accuracy risks are especially acute for older adults, who must carefully manage their medical intake and who are particularly vulnerable to pathogen and toxin exposures. Stacy Cooper Bailey et al., *Longitudinal Investigation of Older Adults' Ability to Self-Manage Complex Drug Regimens*, 68 J. Am. Geriatrics Soc'y 569 (2020); John F. Risher et al., *The Elderly as a Sensitive Population in Environmental Exposures: Making the Case*, 7 Int'l J. Envtl. Res. Pub. Health 228 (2010).

123. A 2025 study found that even small doses of CBD can cause significant elevations in liver enzymes (specifically alanine aminotransferase and aspartate aminotransferase), indicative of possible liver injury, which can lead to fatigue and jaundice—issues of special concern for older adults seeking to avoid unnecessary hospitalizations. Jeffry Florian, *et al.*, *Cannabidiol and Liver Enzyme Level Elevations in Healthy Adults: A Randomized Clinical Trial*, 185 JAMA Internal Medicine 9, 1070–78 (July 2025).

124. A 2021 review found that a wide variety of drugs in common use by older people, from blood pressure medications to antifungals, belong to a class called CYP3A4 inhibitors that can interact with CBD and increase the bioavailability of its active chemicals, leading to possible adverse effects. Brooke Porter *et al.*, *Cannabidiol (CBD) Use by Older Adults for Acute and Chronic Pain*, 47 J. Gerontological Nursing 7, 6–15 (July 2021).

125. The same review noted that older adults can suffer from a condition in which protein binding is inhibited, which can also lead to elevated bioavailability and unintentionally higher dosing. *Id.*

126. It also noted that patient safety is a concern with CBD use, and that poison phone calls for CBD have increased from 3 in 2014 to 2,218 in 2020. *Id.*

127. CMS created and instituted the BEI despite the extensive scientific evidence demonstrating that cannabis products, hemp-derived THC products, and CBD will harm elderly Americans.

128. To date, CMS has not conducted or published any analysis of whether the products permitted under the BEI are lawful under federal law, safe for the Medicare populations at issue, or consistent with the agency's obligations under existing statutory frameworks. CMS has explicitly stated it "does not make claims regarding the therapeutic value of these products," yet the BEI requires participating physicians to make a documented clinical determination that hemp use is "safe and appropriate" for a specific patient—without providing clinical guidelines, evidence-based thresholds, or diagnostic criteria to support such determinations.

129. CMS has not addressed the cardiovascular risks documented in peer-reviewed meta-analyses, the vascular dysfunction findings involving THC edibles, the pervasive contamination and mislabeling of commercially available CBD products, the drug-interaction risks for older adults on common medications, or the near-total absence of clinical research on cannabis use in populations over 65.

130. Neither the FDA nor the BEI imposes any meaningful safeguards to prevent product adulteration, ensure quality control, or require independent testing. Products distributed under the BEI are afforded no adverse event reporting mechanisms comparable to those required for FDA-approved pharmaceuticals, and approximately 1,500 deaths have been reported in connection with FDA-approved Epidiolex alone—a product that, unlike BEI-authorized products, underwent rigorous FDA safety review.

H. Federal Legal Status of Cannabis Products and Hemp-Derived THC Products

131. Cannabis, including delta-9 THC, remains a Schedule I controlled substance under the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801–901.

132. Current retail hemp-derived THC products are derived by distilling delta-9 THC and other cannabinoids from hemp plants into a concentrated substance and mixing it into consumable products. As such, hemp-derived THC products contain illegal Schedule I compounds, sometimes (due to mislabeling and poor regulation) in amounts higher than the 0.3% permitted for hemp-derived products under Federal law. The hemp-derived product industry exploits this regulatory loophole for profit, to the tune of $5.5 billion. Beau R. Whitney, *An Economic Impact Analysis of the Hemp Cannabinoid Industry in Texas* (Mar. 2025), https://texashempbusinesscouncil.com/wp-content/uploads/2025/07/2024-An-Economic-Impact-Analysis-of-the-Hemp-Cannabinoid-Industry-in-Texas-Whitney-Economics-03-25-Public-Facing-1.pdf.

133. The FDA has not approved hemp-derived THC products for medical use. Epidiolex, a CBD product that may be used to treat rare seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex, has been approved

by the FDA, but has not been tested for safety for people over the age of 55. *See EPIDIOLEX New Drug Application Letter*, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/210365orig1s000ltr.pdf.

134. Besides the existing botanical drug approval framework, the FDA has stated that no federal regulatory framework for CBD or hemp-derived products exists.

135. The FDA has identified specific safety risks associated with CBD and hemp-derived THC products, including liver injury, drug interactions, and harm to vulnerable populations, and has stated that it has "not found adequate information showing how much CBD can be consumed, and for how long, before causing harm."

136. These FDA warnings are consistent with the peer-reviewed evidence of cardiovascular, neurological, contamination, drug-interaction, and other health risks from current retail cannabinoid and hemp-derived products detailed above.

I. MMJ Plaintiffs' Regulatory History and Competitive Injury

137. MMJIH initiated formal regulatory engagement with the FDA's Center for Drug Evaluation and Research in August 2018 through submission of Pre-Investigational New Drug meeting requests for its cannabinoid drug candidates MMJ-001, intended for treatment of Huntington's disease, and MMJ-002, intended for treatment of multiple sclerosis. The FDA acknowledged these submissions and opened regulatory files, including IND file number 137754 associated with the Huntington's disease program and IND file number 140712 associated with the multiple sclerosis program.

138. On January 29, 2019, the FDA's Office of Orphan Products Development granted Orphan Drug Designation for Δ9-tetrahydrocannabinol and cannabidiol for the "treatment of Huntington's disease" pursuant to Section 526 of the Federal Food, Drug, and Cosmetic Act. *See* 21 U.S.C. § 360bb.

139. MMJBC submitted an application to the DEA in December 2018 for registration as a bulk manufacturer of marijuana-active pharmaceutical ingredient for use in FDA-authorized clinical trials.

140. The DEA commenced its pre-registration Section 303 investigation on June 22, 2021, which concluded with a final on-site visit on October 24, 2021, during which all DEA questions were satisfactorily answered, all security systems and protocols were reviewed, and MMJBC demonstrated that all security and diversion conditions followed applicable regulations.

141. MMJBC's bulk manufacturing registration application remains pending before the DEA Administrator.

142. MMJBL obtained a DEA Schedule I analytical laboratory registration following DEA inspection and approval of its facility's physical security systems, recordkeeping controls, and diversion-prevention safeguards.

143. Over the past approximately eight years, the MMJ Plaintiffs have invested over $10 million into pharmaceutical cannabinoid development through the formal FDA regulatory pathway.

144. These investments include, but are not limited to: (1) IND submissions and regulatory engagement with the FDA, (2) orphan drug designation positioning for

Huntington's disease, (3) DEA registration activity, including the Schedule I analytical laboratory registration and the pending bulk manufacturing application, (4) formulation development and stability studies conducted in collaboration with Catalent Pharma Solutions, (5) analytical testing and chromatographic characterization performed by Avanti Rx Analytics Inc., (6) regulatory consulting engagements with Haffner Associates, LLC, (7) a development summit and portfolio strategy engagement with Parexel International (IRL) Limited, (8) FDA regulatory counsel services provided by Baker & Hostetler LLP, and (9) engagement of Seaport Global Securities LLC as lead financial advisor in connection with a proposed capital raise of approximately $45 million in debt and equity securities.

145. MMJ Plaintiffs undertook these investments with the clear expectation that FDA approval would provide the necessary regulatory foundation for coverage determinations of cannabinoid-based treatments and therapeutics by Medicare and other third-party payers.

146. The BEI permits clinician-guided distribution of hemp-derived cannabinoid products outside the FDA drug approval framework, while MMJ Plaintiffs pursuing IND-based botanical drug development remain subject to full pharmaceutical regulatory requirements.

147. By introducing federally supported access to non-FDA-approved cannabinoid products, CMS has weakened incentives for investment in validated botanical drug development programs, created a competitive disadvantage for FDA-compliant developers, and directly impacted the MMJ Plaintiffs' Huntington's disease

program by undermining recruitment pathways, investor confidence, and long-term exclusivity expectations associated with IND-stage cannabinoid therapeutics targeting serious neurological disease.

148. MMJ Plaintiffs were excluded from prior notice of the BEI, while other purveyors of cannabis- and hemp-derived THC and CBD products—including Charlotte's Web—received advance notice of and may have collaborated with CMS in shaping the BEI. These entities operate outside the FDA IND-authorized pharmaceutical development pathway and would benefit from the BEI's reimbursement structure without undertaking the rigorous scientific validation and regulatory compliance that MMJ Plaintiffs have pursued.

149. The ongoing operation of the BEI causes continuing and compounding harm to the MMJ Plaintiffs. Each day the BEI remains in effect, unvalidated cannabinoid products gain market access and consumer acceptance in the Medicare population, the competitive landscape for cannabinoid therapeutics is further distorted, the MMJ Plaintiffs' regulatory investments are further devalued, and the integrity of the federal drug-approval framework upon which the MMJ Plaintiffs relied is further eroded.

VII. PLAINTIFFS' CLAIMS FOR RELIEF

First Claim for Relief
THE BEI VIOLATED THE APA'S NOTICE-AND-COMMENT REQUIREMENTS
(Violation of 5 U.S.C. §§ 552(a)(1), 553, 706(2)(D))

150. The plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1 through 149 as though fully set forth herein.

151. The BEI constitutes a "legislative rule" in that it imposes legally binding obligations on participating organizations, creates a new benefit structure, establishes detailed eligibility criteria, requires CMS approval processes, and has "the force and effect of law." *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 96 (2015) (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 302–303 (1979)). A legislative rule is one that "effects a substantive regulatory change to the statutory or regulatory regime." *Mendoza v. Perez*, 754 F.3d 1002, 1006 (D.C. Cir. 2014) (quotation omitted).

152. Agencies cannot "avoid notice and comment simply by mislabeling their substantive pronouncements." *See Azar v. Allina Health Services*, 587 U.S. 566, 575 (2019) (courts look to "the *contents* of the agency's action, not the agency's self-serving *label*, when deciding whether statutory notice-and-comment demands apply" (emphasis in original)).

153. "[A]ny contract provisions that are legislative [in character] are subject to § 553's notice and comment requirements." *American Hospital Ass'n v. Bowen*, 834 F.2d 1037, 1054 (D.C. Cir. 1987). CMS "may not hide behind its authority to contract in order to evade the APA." *Id.* (quoting district court).

154. No exception to the APA's notice-and-comment requirement applies. The BEI is not an interpretive rule because it does not merely clarify an existing statute or regulation. Rather, the BEI creates entirely new programmatic requirements. *See Tennessee v. Dep't of Educ.*, 104 F.4th 577, 608 (6th Cir. 2024) (legislative rules have "the force and effect of law" and are "subject to notice and comment"). The BEI is not a general statement of policy because it has binding effect through mandatory implementation

mechanics on participating providers. And it is not a rule of agency organization, procedure, or practice because it directly affects the rights and obligations of participating organizations and Medicare beneficiaries.

155. The BEI is not a benefits determination exempt from notice and comment under 5 U.S.C. § 553(a)(2). CMS itself asserts that the BEI does not involve Medicare paying for products directly. No new entitlement is created and no Medicare claim is submitted. Instead, the BEI imposes a binding regulatory framework on participating providers that governs what products they may distribute, how they must screen patients, what implementation plans they must submit for CMS approval, and what reports they must file. Such a framework is not a benefit within the meaning of 5 U.S.C. § 553(a)(2) and is not exempt from notice or comment. Reading 5 U.S.C. § 553(a)(2) to exempt the BEI from notice-and-comment would eviscerate those protections precisely when they are most needed: when CMS is adopting an unprecedented program implicating public health, federal drug law, and healthcare policy.

156. Section 1115A does not expressly exempt CMS from APA rulemaking requirements. Under 5 U.S.C. § 559, a subsequent statute supersedes the APA's rulemaking provisions only if it "does so expressly." An exemption is express only when Congress "has established procedures so clearly different from those required by the APA that it must have intended to displace the norm." *Asiana Airlines v. FAA*, 134 F.3d 393, 397 (D.C. Cir. 1998). Section 1115A contains no such express exemption.

157. CMS adopted and published a generally applicable policy with legal effect without the Federal Register publication required for substantive rules under the APA

and the Federal Register Act, 44 U.S.C. § 1505. The failure to publish in the Federal Register independently violates 5 U.S.C. § 552(a)(1). *See Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000) (an agency "can inform those affected simply by posting its new guidance or memoranda or policy statement on its web site," but this does not satisfy statutory publication requirements for substantive rules).

158. The precedent from CMS's own prior use of Section 1115A authority is instructive. When CMS issued an Interim Final Rule implementing Most Favored Nation ("MFN") drug pricing using Section 1115A authority without notice-and-comment, multiple federal courts enjoined the rule for failing to satisfy the good-cause exception. *See Regeneron Pharms.*, 510 F. Supp. 3d at 29. The same principle applies here: CMS cannot use Section 1115A to avoid the APA's core procedural protections simply by embedding a policy change in a participation agreement rather than a formal rule.

159. The BEI was adopted and published without observance of procedure required by law, in violation of 5 U.S.C. § 706(2)(D).

Second Claim for Relief
THE BEI IS ARBITRARY AND CAPRICIOUS
(Violation of 5 U.S.C. § 706(2)(A))

160. The plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1 through 159 as though fully set forth herein.

161. The BEI is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

162. First, CMS's decision to allow access to cannabis- and hemp-derived products to Medicare recipients, without analysis or explanation, differs from its

approach in a final rule issued only one year ago that cannabis- and hemp-derived products were ineligible for Medicare coverage. CMS has also provided no explanation for its sudden decision to allow access to substances it previously affirmed, in its published April 2025 rule, were illegal under federal law. When an agency changes course, it must provide "a reasoned explanation for disregarding facts and circumstances that underlay or were engendered by the prior policy." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 516 (2009)). An "unexplained inconsistency" renders a changed policy arbitrary and capricious. *Children's Hospital Ass'n of Texas v. Azar*, 933 F.3d 764, 773 (D.C. Cir. 2019). CMS quietly inserted the BEI into participation agreements without any explanation for why the prior position is no longer appropriate and has not, to date, provided any analysis for its action.

163. Second, CMS entirely failed to consider important hazards that arise from this policy reversal. The agency did not address:

f. the federal legal status of the products under the CSA;

g. the substantial and growing peer-reviewed evidence of adverse health outcomes or risks associated with the use of cannabis- and hemp-derived THC products by an aging and vulnerable population, namely the risk of cardiovascular harm, liver injury, dangerous drug interactions with medications commonly used by older adults, cognitive harms risk, and pervasive contamination and mislabeling;

h. the absence of an FDA regulatory framework for CBD;

i. the near-total absence of clinical research on cannabis use in populations over 65; or

j. the conflict with the FY2026 Agriculture Appropriations Act's THC limits.

Each of these failures independently renders the BEI arbitrary and capricious. *See State Farm*, 463 U.S. at 43 (agency action is arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem").

164. Third, CMS's THC limit of 3 mg per serving directly conflicts with the 2026 Agriculture Appropriations Act's limit of 0.4 mg per container, effective November 2026. CMS's admission that it "will adjust its definition in accordance with the law" is itself an acknowledgment that the current program conflicts with enacted and unambiguous federal law. A deliberate decision to launch a program that the agency already knows will be inconsistent with federal law is arbitrary agency action.

165. Fourth, CMS has not demonstrated that the BEI satisfies the statutory prerequisites of Section 1115A, which limits testing to models for "defined populations with deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." 42 U.S.C. § 1315a(a)(1). The BEI is available to any aligned beneficiary over age 18 without a disqualifying condition. Far from targeting a defined population or reasonably limiting eligibility based on statutory criteria, the model's scope effectively encompasses nearly all Medicare beneficiaries, regardless of clinical outcomes or incurred expenditures, so long as they are aligned with an ACO REACH, EOM, or LEAD participating provider.

166. Accordingly, the BEI is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of 5 U.S.C. § 706(2)(A).

Third Claim for Relief
THE BEI EXCEEDS CMS'S STATUTORY AUTHORITY AND VIOLATES THE MAJOR QUESTIONS DOCTRINE
(Violation of 5 U.S.C. § 706(2)(C))

167. The plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1 through 166 as though fully set forth herein.

168. Under *West Virginia v. EPA*, 597 U.S. 697 (2022), in "extraordinary cases" where an agency asserts authority of vast economic and political significance, "the agency . . . must point to 'clear congressional authorization' for the power it claims." *Id.* at 723 (quoting *Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014)). The major questions doctrine applies when the agency's action is "unheralded" and represents a "transformative expansion" of its authority under vague statutory language, and the regulation is of "vast economic and political significance." *Nebraska v. Su*, 121 F.4th 1, 14 (9th Cir. 2024).

169. CMS has acted in excess of its statutory authority under Section 1115A by creating—for the first time in history—federally sanctioned access to cannabis products and hemp-derived THC products through Innovation Center program amendments, without APA rulemaking, without clear congressional authorization, and in violation of federal law.

170. No Innovation Center precedent exists for distributing specific consumer products to beneficiaries. Innovation Center models are used to test payment methods, not to increase access to unapproved drugs.

171. Congress never authorized CMS to use the Innovation Center to facilitate access to products containing substances listed as Schedule I under the CSA.

172. The political and policy significance of the program, as evidenced by Administrator Oz's public statements and the Executive Order that preceded it, is considerable.

173. The BEI's potential reach across multiple models covering substantial Medicare populations, the unprecedented nature of CMS's facilitating access to any specific consumer product, and the absence of any prior Innovation Center precedent for distributing specific products to beneficiaries all confirm that this is an extraordinary assertion of authority requiring clear congressional authorization. *See Missouri v. Biden*, 112 F.4th 531, 537 (8th Cir. 2024) (applying the major questions doctrine where the government asserted "an unheralded power to regulate a significant portion of the American economy" under a long-extant statute (quoting *Util Air Regul. Grp.*, 573 U.S. at 324)).

174. Under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), the court must exercise independent judgment and not merely defer to CMS's assertion that its action falls within Section 1115A authority.

175. The BEI exceeds CMS's statutory jurisdiction, authority, or limitations, in violation of 5 U.S.C. § 706(2)(C).

Fourth Claim for Relief
THE BEI IS NOT IN ACCORDANCE WITH LAW
(Violation of 5 U.S.C. § 706(2)(A))

176. The plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1 through 175 as though fully set forth herein.

177. The BEI is "not in accordance with law" because it conflicts with controlling federal statutes.

178. The BEI's THC limits conflict with the 2026 Agriculture Appropriations Act, which sets a total THC limit of 0.4 mg per container for hemp-derived products, effective November 2026.

179. The BEI conflicts with the Controlled Substances Act. It facilitates access to products that contain substances illegal under the CSA, including cannabis, delta-9 THC, and other cannabinoids.

180. The FDA has only approved Epidiolex, a CBD medication, but has not approved any other hemp-derived THC products for medical use and has identified specific safety risks including liver injury, drug interactions, and other harms.

181. CMS did not conduct or publish any compliance analysis for the BEI before creating and authorizing it. 90 Fed. Reg. 15,792, 15,867 (Apr. 15, 2025). *See PDK Labs., Inc. v. DEA*, 362 F.3d 786, 797–98 (D.C. Cir. 2004) (an agency must "bring its experience and expertise to bear" and evaluate the statutory status of a drug-related product when that status is unclear). In fact, a prior APA-compliant process completed less than one year prior determined that the health effects of medical marijuana, containing the same or comparable ingredients as hemp-derived cannabinoids, were not sufficient to justify use by Medicare patients.

Fifth Claim for Relief
CMS DENIED EQUAL PROTECTION

(Violation of U.S. Const. amend. V)

182. The MMJ Plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1 through 181 as though fully set forth herein.

183. The Fifth Amendment's equal protection guarantee, applicable to the federal government through the Due Process Clause, prohibits the government from treating similarly situated parties differently without a rational basis.

184. The BEI creates a two-track regulatory system that violates the equal protection guarantee. The MMJ Plaintiffs are companies that have complied in good faith with the federal pharmaceutical regulatory framework—investing years and over $10 million into IND submissions, orphan drug designation, DEA registrations, CMC development, and clinical trial preparation—and are subjected to the full weight of FDA and DEA regulatory requirements. Meanwhile, the BEI permits entities that have not undertaken any of these regulatory burdens, including Charlotte's Web and other hemp-industry stakeholders, to access a federally supported cannabinoid reimbursement pathway for the same Medicare patient populations.

185. On information and belief, CMS provided advance notice of the BEI to hemp-industry stakeholders including Charlotte's Web, while excluding similarly situated regulated parties such as MMJ Plaintiffs from any notice of or opportunity to participate in the development of the BEI. Charlotte's Web co-founder Jared Stanley confirmed on February 13, 2026 that the program was "internally finalized" by CMS weeks prior, without public announcement or opportunity to comment, and referred to a "briefing" when discussing the pilot program's anticipated scope.

186. This disparate treatment of similarly situated regulated parties—those developing cannabinoid therapies for the same patient populations—was intentional and lacks any rational basis. Both the MMJ Plaintiffs and the hemp-industry stakeholders who received advance notice seek to provide cannabinoid products to Medicare beneficiaries. Yet CMS chose to inform and involve only the latter group in the BEI's development, while deliberately excluding the former.

187. The MMJ Plaintiffs have been singled out for differential treatment as a "class of one" because they were intentionally treated differently from others similarly situated and there is no rational basis for the difference in treatment. *See Village of Willowbrook v. Olech*, 528 U.S. 562, 564 (2000) ("Our cases have recognized successful equal protection claims brought by a 'class of one,' where the plaintiff alleges that she has been intentionally treated differently from others similarly situated and that there is no rational basis for the difference in treatment." (citations omitted)).

188. The government's selective engagement with certain cannabinoid industry participants while excluding others who have undertaken greater regulatory compliance constitutes arbitrary and irrational government action.

Sixth Claim for Relief
CMS DENIED PROCEDURAL DUE PROCESS
(Violation of U.S. Const. amend. V)

189. All Plaintiffs who have asserted procedural injury reallege and incorporate by reference the allegations contained in Paragraphs 1 through 188 as though fully set forth herein.

190. The Fifth Amendment's Due Process Clause prohibits the federal government from depriving persons of liberty or property without due process of law. Procedural due process requires, at a minimum, notice and an opportunity to be heard before the government takes action that affects a party's protected interests. Substantive due process prohibits arbitrary government action that infringes on fundamental rights or destroys property interests without adequate justification.

191. All Plaintiffs who asserted the denial of their right to participate in notice-and-comment rulemaking under 5 U.S.C. § 553 suffered a procedural due process violation. CMS implemented the BEI without conducting traditional notice-and-comment rulemaking, without affording any opportunity for public participation, and without publishing the BEI in the Federal Register. The BEI took effect on April 1, 2026, just eleven days after its publication on CMS's website.

192. The Plaintiffs, as interested parties with concrete interests at stake—including the health and safety of Medicare beneficiaries, the informational interest in the administrative record, the participatory interest in shaping the regulatory process, and the competitive and economic interests of the MMJ Plaintiffs—were entitled to notice and an opportunity to participate in a rulemaking proceeding that would fundamentally alter the reimbursement landscape for cannabinoid products in the Medicare system. CMS afforded them no such opportunity.

193. The BEI also implicates substantive due process concerns by retroactively undermining the investment-backed expectations of MMJ Plaintiffs. MMJ Plaintiffs entered the federal pharmaceutical regulatory pathway in reliance on an established and

consistently applied framework: cannabinoid therapies intended for treatment of disease must proceed through FDA drug approval before becoming eligible for Medicare reimbursement. Over approximately eight years, the MMJ Plaintiffs invested over $10 million into pharmaceutical cannabinoid development through this formal FDA regulatory pathway.

194. The BEI's creation of an alternative reimbursement channel for unapproved cannabinoid products without notice, without comment, and without any opportunity for affected parties to be heard deprives the MMJ Plaintiffs of the economic value of their regulatory compliance without any process whatsoever. This arbitrary government action, which undermines the reliance interests of parties who followed the established federal pathway in good faith, constitutes a denial of substantive due process.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and grant the following relief:

a. A declaration that the BEI was adopted and published in violation of the APA's notice-and-comment requirements, 5 U.S.C. § 553, and the Federal Register publication requirements of 5 U.S.C. § 552(a)(1);

b. A declaration that the BEI is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A);

c. A declaration that the BEI exceeds CMS's statutory authority under Section 1115A and is in excess of statutory jurisdiction, authority, or limitations under 5 U.S.C. § 706(2)(C);

d. A declaration that the BEI violates the Fifth Amendment's equal protection guarantee by intentionally treating similarly situated regulated parties differently without any rational basis;

e. A declaration that the BEI violates the Fifth Amendment's Due Process Clause by depriving Plaintiffs of procedural due process and by arbitrarily undermining the substantive due process rights of the MMJ Plaintiffs;

f. An order vacating and setting aside the BEI;

g. A permanent injunction prohibiting Defendants from implementing, applying, or enforcing the BEI;

h. An award of costs and attorneys' fees as permitted by law; and

i. Such other and further relief as the Court deems just and proper.

Date: April 13, 2026

Respectfully submitted,

/s/Connor W. Mighell

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CERTIFICATE OF SERVICE

I hereby certify that, on April 13, 2026, I electronically filed the foregoing First Amended Complaint for Declaratory and Injunctive Relief and its attendant Exhibits, and this Certificate of Service, along with an attached Corporate Disclosure Statement, with the Clerk of Court for the United States District Court for the District of Columbia by using the CM/ECF system.

/s/Connor W. Mighell
Connor W. Mighell