



ENDING THE FEDERAL CONFLICT: CHANGING THE PARADIGM ON MEDICAL CANNABIS



THE MISSION OF AMERICANS FOR SAFE ACCESS (ASA) IS TO ENSURE SAFE AND LEGAL ACCESS TO CANNABIS (MARIJUANA) FOR THERAPEUTIC USES AND RESEARCH. ASA WORKS WITH OUR GRASSROOTS BASE OF OVER 100,000 MEMBERS AND SUPPORTERS AND OUR PROFESSIONAL ADVISORY GROUPS TO EFFECT CHANGE THROUGH PUBLIC EDUCATION, SUPPORT SERVICES, PROFESSIONAL DEVELOPMENT, RESEARCH, LITIGATION, AND DIRECT ADVOCACY AT THE LOCAL, STATE, AND FEDERAL LEVEL.



KEY POINTS

- A NEW FEDERAL FRAMEWORK IS NEEDED FOR MEDICAL CANNABIS REGULATION THAT HARMONIZES THE DISPARITY BETWEEN STATE AND FEDERAL.
- U.S. CANNABIS POLICY IS CURRENTLY OUT OF ALIGNMENT WITH U.S. COMMITMENTS TO INTERNATIONAL DRUG TREATIES.
- DOZENS OF COUNTRIES HAVE LEGALIZED THE MEDICAL USE OF CANNABIS AT THE NATIONAL LEVEL.
- OVERSIGHT OF CANNABIS MUST BE TRANSFERRED TO A NEW FEDERAL AGENCY RESPONSIBLE FOR PROMOTING AND FACILITATING RESEARCH AND REGULATING THE PRODUCTION AND DISTRIBUTION OF CANNABIS AS MEDICINE.
- DOZENS OF STATES, FOUR TERRITORIES, AND THE DISTRICT OF COLUMBIA HAVE PASSED LAWS TO ESTABLISH COMPREHENSIVE MEDICAL CANNABIS PROGRAMS, AND MORE THAN A DOZEN ADDITIONAL STATES HAVE PASSED LAWS GRANTING THEIR CITIZENS ACCESS TO, OR PROTECTION FROM ARREST OR PROSECUTION FOR POSSESSION OF, ONE OR MORE CONSTITUENTS OF CANNABIS WHEN USED FOR A MEDICAL PURPOSE.
- CANNABIS' SCHEDULING STATUS UNDER U.S. FEDERAL LAW IS OUTDATED AND STALLS COMPREHENSIVE RESEARCH ON CANNABIS' MEDICINAL PROPERTIES.

CHANGING THE PARADIGM ON MEDICAL CANNABIS

Creating Federal Oversight and Creating a New Classification

Since the passage of the Controlled Substances Act (“CSA”), the conversation surrounding cannabis has always been tethered to cannabis’ Schedule I status. Though its original placement in Schedule I was intended to be temporary, medical cannabis patients have suffered from the effects of prohibition since the Controlled Substances Act went into effect on May 1, 1971. Schedule I status means that a drug has a high potential for abuse and no accepted medical value.¹ Efforts to end prohibition have focused on a dichotomy of rescheduling or descheduling, but the question of what happens after a rescheduling, descheduling or creation of a new scheduling category has been left undiscussed.

The overwhelming majority of substances listed in the Controlled Substances Act are synthetic compounds, not natural products. Cannabis (and perhaps a few other natural substances) does not organically fit into the schedules described by the CSA. The U.S. government has not recognized the medical value of cannabis, putting current law at odds with science. However, the National Institute on Drug Abuse (NIDA) acknowledges that “THC itself has proven medical benefits in particular formulations.”² Additionally, two NIDA-funded studies demonstrated a reduction in opioid overdose deaths in states with medical cannabis dispensaries.³

Step 1. Amend CSA exemptions to include cannabis (“marihuana” under the CSA) or develop a new Scheduling Category for Cannabis

21 U.S.C § 802(6) currently defines a controlled substance as “a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.”⁴

ASA proposes to add cannabis (listed as “marihuana” in the CSA) as an exemption to this list, remove references to it elsewhere under the CSA, and create a new Internal Revenue Code Provision defining, and establishing the regulatory framework for, cannabis. As described below, this would delegate jurisdictional authority to a new federal agency, much like alcohol and tobacco have been delegated to the Bureau of Alcohol, Tobacco, Firearms and Explosives.

Alternatively, recognizing that one of the main factors the Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) consider in determining abuse potential is recreational use of a substance, ASA proposes a new scheduling parameter that maintains moderate controls but allows the greatest number of patients to access cannabis as a medicine.



It is time the United States follow the lead of other countries, and in particular, those nations where the regulation and control of cannabis is placed in a centralized agency.

¹ 21 U.S.C. §812(b)(1)

² Nat’l Ins. on Drug Abuse, *Is Marijuana Safe and Effective as Medicine?*, (last updated June 2018), <https://www.drugabuse.gov/publications/research-reports/marijuana/marijuana-safe-effective-medicine>

³ *Id.*

⁴ 21 U.S.C. §802(6)

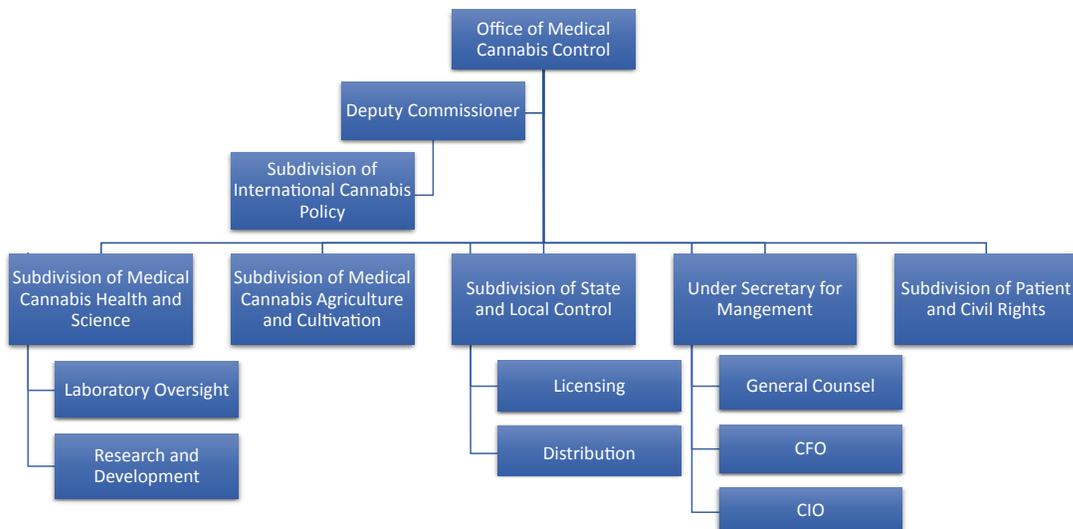
Based on its recognized medical potential and varying potential for abuse, cannabis should be placed in a new schedule, Schedule V(A), meaning that a prescription would be required for cannabis, but it would be widely accessible for patients and could be recommended by physicians as a first-line medication.

Step 2. Create new federal Agency with centralized regulatory authority

Effective regulation of cannabis is strained by nearly a dozen agencies wanting to play a role in the decision making process. The Department of Justice, FDA, HHS, DEA, ONDCP, and other smaller agencies all clamor to provide input into federal scheduling decisions. It is time the United States follow the lead of other countries, and in particular, those nations where the regulation and control of cannabis is placed in a centralized agency. Without consistent oversight, cannabis cannot be produced and distributed as a medicine. For example, as long as HHS and the DEA have joint jurisdiction, movement cannot happen. This is because the primary goal of HHS is to enhance the health and well-being of Americans, while the primary function of the DEA is to act as a law enforcement agency that uses criminal and civil penalties to complete its mission.

The Administrative Procedures Act stipulates that there are two methods by which a new federal agency may be created.⁵ The President can create a new agency through an executive order, or Congress can create it by way of an enabling statute that outlines the scope of the agency’s power. Executive agencies can be created by the President with broad authority, like the Department of State, Department of Justice, or the Department of Transportation. Congress can also create agencies through statute. For example, the FDA was created via the enabling legislation of the Federal Food, Drug, and Cosmetic Act.

The Office of Medical Cannabis Control, as laid out by the legislation and figure below, would create a central authority within the U.S. Government to regulate cannabis once it has been exempted from the Controlled Substances Act or rescheduled. Particularly important would be the Office of Cannabis Health and Science, which would assume responsibility for the roles currently filled by NIDA, HHS, and the FDA. The Office of Cannabis Health and Science would conduct research and provide guidance for new medical applications of the cannabis plant and cannabis products.



5 5 U.S.C. ch. 5, subch. I § 500 et seq.

AN ACT

To establish the Office of Medical Cannabis Control, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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SEC. 1 SHORT TITLE- This Act may be cited as the Medical Cannabis Control Act of 2019

SEC. 2 SENSE OF CONGRESS

Expressing the sense of Congress that a new federal agency, the Office of Medical Cannabis Control, would be beneficial to public and individual health.

Whereas there are over two million medical cannabis patients and over 20,000 cannabis businesses in the United States.

Whereas thirty-three states, the District of Columbia, and four of five U.S. territories have comprehensive medical cannabis legislation.

Whereas oversight authority of medical cannabis has been handled on the state and local level, rather than through the federal government, putting the United States at odds with the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol,⁶ which requires a singular medical cannabis oversight body under Article 28.

Whereas on January 24, 2019 the World Health Organization (WHO) presented a letter to the Secretary-General of the United Nations calling for a change in scheduling under international law by removing cannabis and cannabis resin from Schedule IV of the Single Convention on Narcotic Drugs, and by removing cannabidiol completely from international control, acknowledging the medical value of cannabis.

Whereas over thirty countries in Europe, North America, South America, Africa, Asia, and Oceania have passed medical cannabis laws consistent with international treaty parameters.

Whereas the United States and its territories have created a patchwork of licensing, regulation, and enforcement laws that lack uniformity.

Whereas current federal oversight from the Drug Enforcement Administration (DEA) and the National Institute on Drug Abuse focuses on punitive measures and the harms of cannabis, rather than the expansion of therapeutic outcomes, which is inconsistent with the WHO's recommendations.

Whereas due to resource constraints and political ideations, the DEA has failed to act on over two dozen legitimate requests for research licenses.

Whereas Schedule I researchers who do obtain the proper license may be forced to import cannabis from other countries or obtain cannabis that does not mirror what is otherwise available in state markets to patients.

Whereas administrators of the Food and Drug Administration and other agencies have called on Congress to resolve the conflict between state and federal laws.

Whereas the Investigational New Drug program, which previously had oversight over cannabis, has not enrolled a new patient since 1992, making the program functionally nonexistent.

⁶ United Nations, *Treaty Series*, vol. 976, No 14152

Whereas research in the Journal of the American Medical Association has shown cannabis can play a critical role in reducing opioid overdose deaths, up to 25%, when compared to states without medical cannabis programs, and cannabis is widely used for alleviating the symptoms of numerous other medical conditions.

Now, therefore, be it

Resolved by the United States Congress that it is the sense of Congress that a new federal oversight agency for medical cannabis would be beneficial to public and individual health.

SEC 3 DEFINITIONS

In this Act, the following definitions shall apply:

- (1) The term “appropriate congressional committee” means any committee of the House of Representatives or the Senate having legislative or oversight jurisdiction under the Rules of the House of Representatives or the Senate, respectively, over the matter concerned.
- (2) The term “ASTM Guidelines” means guidelines developed by the American Society for Testing and Materials, including but not limited to guidelines developed for cannabis under their D37 committee.
- (3) The term “assets” includes contracts, facilities, property, records, unobligated or unexpended balances of appropriations, and other funds or resources (other than personnel).
- (4) The term “cannabis” means marihuana as defined in title 21, United States Code, §802 (16).
- (5) The term “Cannabis Headquarters Laboratory” means a federal laboratory created in consultation with the National Academies of Sciences, appropriate federal agencies and other experts that serves as the national model for cannabis laboratory testing. The laboratory may provide functions of testing and development of cannabis and cannabis products.
- (6) The term “cannabis products” means products derived from the cannabis plant, including but not limited to products made from the extraction of one or more cannabinoids.
- (7) The term “Commissioner” means the head of the Office of Medical Cannabis Control as defined in (13).
- (8) The term “Departments” means other executive and legislative agencies as defined under title 5, United States Code.
- (9) The term “executive agency” means an executive agency and a military department, as defined, respectively, in sections 105 and 102 of title 5, United States Code.
- (10) The term “functions” includes authorities, powers, rights, privileges, immunities, programs, projects, activities, duties, and responsibilities.
- (11) The term “key resources” means publicly or privately controlled resources essential to the minimal operations of the economy and government.
- (12) The term “local government” means—
 - (a) a county, municipality, city, town, township, local public authority, school district, special district, intrastate district, council of governments (regardless of whether the council of governments is incorporated as a nonprofit corporation under State law), regional or interstate government entity, or agency or instrumentality of a local government;
 - (a) an Indian tribe or authorized tribal organization, or in Alaska a Native village or Alaska Regional Native Corporation; and
 - (a) a rural community, unincorporated town or village, or other public entity.
- (13) The term “Office of Medical Cannabis Control” means a centralized federal oversight agency for cannabis as described in this chapter.
- (14) The term “personnel” means officers and employees.
- (15) The term “private sector” means businesses, associations, nonprofits or other entities organized under Federal, State, or Local laws for a non-governmental purpose.
- (16) The term “Non-Federal Agencies” means state and local departments of health, state and local cannabis oversight authorities, and other entities not organized under Federal law
- (17) The term “State” means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any possession of the United States.

- (18) The term “Subdivision of Medical Cannabis Agriculture and Cultivation” means a sub-office of the Office of Medical Cannabis Control that oversees standards for cannabis cultivation and production.
- (19) The term “Subdivision of Medical Cannabis Science and Health” means a sub-office of the Office of Medical Cannabis Control that oversees medical cannabis science, development and research.
- (20) The term “United States,” when used in a geographic sense, means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, any possession of the United States, and any waters within the jurisdiction of the United States.

SEC. 4 CONSTRUCTION; SEVERABILITY

Any provision of this Act held to be invalid or unenforceable by its terms, as applied to any person or circumstance, shall be construed as to give it maximum effect permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event such provision shall be deemed severable from this Act and shall not affect the remainder thereof, or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

SEC. 5. EFFECTIVE DATE

This Act shall take effect sixty (60) days after the date of enactment.

TITLE I- OFFICE OF CANNABIS CONTROL

SEC. 101 LEGISLATIVE AGENCY; MISSION

- (a) There is established an Office of Medical Cannabis Control, as a legislative agency of the United States within the meaning of title 5, United States Code
- (b) Mission-
- (i) IN GENERAL- the primary mission of the Office is to-
- (A) ensure that there is a safe, legal and consistent way for Americans to access cannabis for research and cannabis therapies. The office ensures the consumer safety of cannabis and cannabis products, conducts research, issues licenses to manufacturers and cultivators, distributes to speciality pharmacies, and removes enforcement authority from the Department of Justice. The office seeks to advance science and knowledge related to cannabis to improve individual and public health;
- (B) provide oversight for the licensure, production, manufacture, distribution, sale, and use of medical cannabis;
- (C) provide minimum standards for labeling, packaging, product safety for cannabis and cannabis products, and pesticide and agricultural guidelines for cannabis cultivation and cannabis products;
- (D) approve new applications and formulations of cannabis and cannabis products;
- (E) provide oversight for research and development of new applications of cannabis and cannabis products;
- (F) provide licensing processes for existing and new medical cannabis facilities;
- (G) retain primary oversight of marijuana as defined in 21 U.S.C. §802 (16); and
- (H) carry out the functions of all entities transferred to the office and serve as focal point for government functions related to medical cannabis.
- (ii) RESPONSIBILITY FOR CANNABIS ENFORCEMENT ACTIONS- except as specifically provided by law with respect to entities transferred to this Office under this Act, primary responsibility for enforcement actions shall not be vested in the Office, but rather in State and local enforcement bodies with jurisdiction over the acts in question.

SEC. 102. COMMISSIONER, DUTIES

- (a) COMMISSIONER-
- (i) IN GENERAL- There is a Commissioner of Medical Cannabis Control appointed by the President with the Advice and Consent of the Senate
- (ii) HEAD OF OFFICE- The Commissioner is the head of the Office and shall have direction, authority, and control over it.
- (iii) FUNCTIONS VESTED IN COMMISSIONER- All functions of all officers, employees, and organizational units of the Office are vested in the Commissioner

- (b) FUNCTIONS- The Commissioner–
 - (i) Except as otherwise provided by this Act, may delegate any of the Commissioner’s functions to any officer, employee or organizational unit of the office;
 - (ii) Shall have the authority to make contracts, grants, and cooperative agreements, and enter into agreements with other agencies, as may be necessary and proper to carry out the Commissioner’s duties under this act or otherwise provided by laws; and
 - (iii) Shall take reasonable steps to ensure that information and databases maintained by the Office are compatible with each other and with appropriate databases of other Departments.
- (c) COORDINATION WITH NON-FEDERAL AGENCIES– With respect to cannabis, the Commissioner shall coordinate through the Office of State and Local Coordination (established under section 401) with state and local departments of health, cannabis oversight bodies, the private sector, and other relevant authorities by –
 - (i) Coordinating with state and local cannabis boards, licensing authorities, and with the private sector to ensure adequate controls, equipment, and training activities;
 - (ii) Coordinating, and as appropriate, consolidating the Federal Government’s communications and systems of communications relating to cannabis with state and local government personnel, the private sector, other entities and the public; and
 - (iii) Distributing or, as appropriate coordinating, the distribution of warnings and recall notices of cannabis or cannabis products to state and local government personnel, the private sector, other entities and to the public.
- (d) ISSUANCE OF REGULATIONS– The issuance of regulations by the Commissioner shall be governed by the provisions of chapter 5 of title 5, United States Code, except as specifically provided in this Act, in laws granting regulatory authorities that are transferred by this Act, and in laws enacted after the date of enactment of this Act.

SEC. 103 OTHER OFFICERS

- (a) DEPUTY COMMISSIONER; UNDER SECRETARIES. – There are the following officers, appointed by the President, by and with the advice and consent of the Senate:
 - (i) Deputy Commissioner of Medical Cannabis Control, who shall be the Officer’s first assistant for purposes of subchapter III of chapter 33 of title 5, United States Code,
 - (ii) An Under Secretary for Medical Cannabis Science & Health;
 - (iii) An Under Secretary for Cannabis Agriculture & Cultivation;
 - (iv) An Under Secretary for Management; and
 - (v) A General Counsel, who shall be the chief legal officer of the Office.
- (b) OTHER OFFICERS – To assist the Commissioner in the Performance of the Commissioner’s functions, there are the following officers appointed by the president:
 - (i) Chief Financial Officer;
 - (ii) Chief Information Officer;
 - (iii) Officer for Civil and Patient Rights;
 - (iv) Director of Office of International Cannabis Policy; and
 - (v) Director of Office of State and Local Control
- (c) PERFORMANCE SPECIFIC FUNCTIONS. – Subject to the provisions of this Act, every officer of the Office shall perform the functions specified by law for the official’s office or prescribed by the Commissioner.

TITLE II- SUBDIVISION OF CANNABIS SCIENCE AND HEALTH

SEC. 201- ESTABLISHMENT OF SUBDIVISION, UNDER SECRETARY

- (a) ESTABLISHMENT
 - (i) IN GENERAL– There is hereby established with the cooperation of the Department of Health and Human Services, the National Institute on Drug Abuse, and the Food and Drug Administration, a subdivision of Cannabis Science & Health (hereinafter referred to as the “Subdivision”).
 - (ii) AUTHORITY- The subdivision shall be under the general authority of the assistant secretary of Health and Human Services and the Office of Medical Cannabis but shall maintain independent discretion when making decisions about medical cannabis.

- (iii) UNDER SECRETARY- The subdivision shall be headed by an under secretary who shall be an individual appointed based on approval of the Office of Personnel Management of the executive qualifications of the individual.

SEC. 202- MISSION OF SUBDIVISION; DUTIES

- (a) MISSION- The mission of the subdivision shall be-
 - (i) To serve as the national focal point for medical cannabis, removing authority from the National Institute on Drug Abuse, Drug Enforcement Administration, and Department of Health and Human Services;
 - (ii) To oversee medical cannabis research;
 - (iii) To carry out educational programs for medical cannabis practitioners;
 - (iv) To carry out programs that improve access to medical cannabis; and
 - (v) To develop new applications of cannabis and cannabis products for medical purposes.
- (b) DUTIES- In carrying out its mission, the subdivision shall have the following duties,
 - (i) Provide recommendation and advice about cannabis and cannabis medicines to the Commissioner of the Food and Drug Administration, as needed;
 - (ii) To establish and maintain advisory groups to assess the scientific needs of Federal, State and Local cannabis research facilities;
 - (iii) To establish minimum laboratory research standards in accordance with ISO 17025 and ASTM guidelines and test and evaluate research processes that may be used by federal, state, local and private researchers and laboratories;
 - (iv) To establish a program that certifies, validates, or otherwise approves research study designs that explore potential of cannabis as a medicine;
 - (v) To coordinate with other federal agencies and Executive Office of the President to establish a coordinated Federal approach to researching medical cannabis;
 - (vi) To carry out research, development, testing, evaluation and cost benefit analyses in fields that improve the safety and effectiveness of cannabis medicines, including but not limited to:
 - (1) Cannabis as a replacement for opioid therapies;
 - (2) Cannabis as a treatment for PTSD;
 - (3) Potency of medicine treating a variety of conditions;
 - (4) Development of an accurate biological or observational test to assess impairment; and
 - (5) Cannabis as a treatment option for veterans;
 - (vii) To develop and disseminate to State and Local departments of health training materials for regulators, law enforcement, and prosecutors; and
 - (viii) To support research fellowships in support of its mission.
- (c) COMPETITION REQUIRED- Except as otherwise expressly provided by law, all research and development carried out by or through the Subdivision shall be carried out on a competitive basis.
- (d) TRANSFER OF FUNDS- The Subdivision may transfer funds to other federal agencies or provide funding to non-Federal entities through grants, cooperative agreements, or contracts to carry out its duties under this section.

SEC. 203- TRANSFER OF FUNCTIONS

- (a) AUTHORITY TO TRANSFER FUNCTIONS- The Attorney General, and other Secretaries as appropriate, shall transfer to the Subdivision any program or activity of another government agency that is consistent with the mission of the Office.
- (b) TRANSFER OF PERSONNEL AND ASSETS- With respect to any function, power, duty or any program or activity that is established in the Office, those employees and assets of another government agency may be transferred to the Office.

SEC. 204- FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS

The Commissioner, acting through the Under Secretary of Medical Cannabis Science and Health, shall have the authority to establish or contract with one (1) or more federally funded research and development centers to

provide independent analysis of cannabis issues, the use of medical cannabis, production of medical cannabis and cannabis medicines, or to carry out other responsibilities under this Act.

SEC. 205- CONDUCT OF RESEARCH, DEVELOPMENT, DEMONSTRATION, TESTING AND EVALUATION

(a) IN GENERAL- The Commissioner, acting through the Under Secretary for Cannabis Science and Health, shall carry out the responsibilities described in Section 202(b) through both extramural and intramural programs.

(b) EXTRAMURAL PROGRAMS

(i) IN GENERAL- The Commissioner, acting through the Under Secretary for Cannabis Science and Health, shall operate extramural research, development, demonstration testing and evaluation programs so as to:

- (1) Ensure that colleges, universities, private research institutes, and companies from as many areas of the United States with different grow climates for cannabis as practicable participate;
- (2) Ensure that research funded is of high quality; and
- (3) Distribute funds through grants, cooperative agreements and contracts.

(ii) UNIVERSITY-BASED CENTERS FOR CANNABIS RESEARCH

(1) ESTABLISHMENT- The Commissioner, acting through the Under Secretary of Cannabis Science and Health, shall establish within (one) 1 year of the date of enactment a university-based center or centers for cannabis research. The purpose of this center or centers is to enhance public health understanding of cannabis medicines.

(2) CRITERIA FOR SELECTION- In selecting colleges or universities as centers for cannabis research, the Commissioner shall consider the following criteria:

- a) Demonstrated expertise in agriculture and cultivation practices, particularly with cannabis;
- b) Demonstrated expertise in developing controlled trials;
- c) Demonstrated expertise in providing medical services;
- d) Strong affiliations with animal and plant diagnostic laboratories;
- e) Demonstrated expertise in food safety;
- f) Demonstrated expertise in water and waste-water operations;
- g) Affiliation with Department of Agriculture Laboratories or training centers; and
- h) Demonstrated expertise in interdisciplinary public policy research and communication outreach regarding science and public policy.

(3) AUTHORIZATION OF APPROPRIATIONS- There are authorized to be appropriated such sums as may be necessary to carry out this section.

(iii) INTRAMURAL PROGRAMS

(1) CONSULTATION- In carrying out the duties under section 202, the Commissioner, acting through the Under Secretary of Medical Cannabis Science and Health, may draw upon the expertise of any laboratory of the federal government or private entity.

(2) LABORATORIES- The Commissioner acting through the Under Secretary of Medical Cannabis Science and Health, may establish a headquarters laboratory for the Office at any site and may establish additional laboratory units at other laboratories or sites.

(3) CRITERIA FOR CANNABIS HEADQUARTERS LABORATORY- If the Commissioner chooses to establish a headquarters laboratory pursuant to paragraph (2), then the Commissioner shall do the following:

- a) Establish criteria for the selection of the cannabis headquarters laboratory in consultation with the National Academy of Sciences, appropriate federal agencies, and other experts;
- b) Publish criteria in the Federal Register;
- c) Evaluate all appropriate laboratories or sites against the criteria;
- d) Select a laboratory or site on the basis of the criteria; and
- e) Report to appropriate Congressional committees on which laboratory was selected, how the selected laboratory meets the established criteria, and what duties the cannabis headquarters laboratory should perform.

SEC. 206- MISCELLANEOUS PROVISIONS

- (a) CLASSIFICATION- Notwithstanding privacy protections under the Health Insurance Portability and Accountability Act (Pub. L. 104-191) and other privacy statutes, to the greatest extent practicable research conducted by the office shall be available to the public.
- (b) REGULATIONS- The Commissioner, acting through the Under Secretary of Medical Cannabis Science and Health, may issue necessary regulations with respect to research, development, testing, medical products, and evaluation activities of the Subdivision, including the conducting, funding and reviewing of such activities.

TITLE III- SUBDIVISION OF CANNABIS AGRICULTURE AND CULTIVATION**SEC. 301- ESTABLISHMENT OF SUBDIVISION, UNDER SECRETARY**

- (a) ESTABLISHMENT
 - (i) IN GENERAL- There is hereby established with the cooperation of the United States Department of Agriculture, the United States Environmental Protection Agency, and the National Institute on Drug Abuse an Office of Cannabis Agriculture & Cultivation (hereinafter referred to as the "Subdivision").
 - (ii) AUTHORITY- The Subdivision shall be under the general authority of the assistant secretary of the Department of Agriculture and Office of Medical Cannabis but shall maintain independent discretion when making decisions about medical cannabis cultivation and production.
- (b) UNDER SECRETARY- The Subdivision shall be headed by an Under Secretary, who shall be an individual appointed based on approval of the Office of Personnel Management of the executive qualifications of the individual.

SEC. 302- MISSION OF SUBDIVISION; DUTIES

- (a) MISSION- The mission of the Subdivision shall be:
 - (i) To serve as the national focal point for the agricultural production of medical cannabis, removing authority from the National Institute on Drug Abuse;
 - (ii) To oversee the cultivation and production of cannabis in the United States;
 - (iii) To carry out educational programs for cannabis cultivators, including distribution of best practices; and
 - (iv) To provide guidance on sustainable farming and cultivation processes for cannabis.
- (a) DUTIES- In carrying out its mission, the Subdivision shall have the following duties:
 - (i) Provide recommendation and advice about cannabis and cannabis cultivation to the Secretary of the United States Department of Agriculture;
 - (ii) Establish and maintain advisory groups to assess the needs of Federal, State and Local cannabis cultivators and producers;
 - (iii) Establish minimum standards for approved and banned pesticides and good manufacturing practices that shall be used by federal, state, local and private cultivators and cultivation facilities;
 - (iv) Establish a program that certifies, validates, or otherwise approves cultivators or cultivation facilities as organic;
 - (v) Coordinate with other federal agencies and executive office of the president to establish a coordinated Federal approach to provide farming subsidies to those who cultivate cannabis to be used for medical purposes; and
 - (vi) Support research fellowships in support of its mission
- (c) TRANSFER OF FUNDS- The Subdivision may transfer funds to other federal agencies or provide funding to non-Federal entities through grants, cooperative agreements, or contracts to carry out its duties under this section.

SEC. 303- TRANSFER OF FUNCTIONS

- (a) AUTHORITY TO TRANSFER FUNCTIONS - The Attorney General, and other Secretaries as appropriate, shall transfer to the Subdivision any program or activity of another government agency that is consistent with the mission of the Subdivision.
- (b) TRANSFER OF PERSONNEL AND ASSETS- With respect to any function, power, duty or any program or activity that is established in the office, those employees and assets of another government agency may be transferred to the Subdivision.

SEC. 304- FEDERALLY FUNDED SUBSIDIES; CROP INSURANCE

- (a) SUBSIDISATION PLANS- The Commissioner, acting through the Under Secretary of Cannabis Agriculture and Cultivation, shall have the authority to develop subsidization programs for cannabis cultivators who submit a production plan pursuant to Section 305.
- (b) CROP INSURANCE- Cannabis Cultivators who present the Under Secretary with an approved plan are eligible to receive crop insurance as defined in Pub. L. 115-334, tit. XI and 7 U.S.C. § 508 et. seq.

SEC. 305- CANNABIS PRODUCTION; STATE AND TRIBAL PLANS

(a) SUBMISSION OF PLANS-

(i) IN GENERAL- A State, Indian Tribe, or locality desiring to have primary regulatory authority over the cultivation and production of cannabis shall submit to the Under Secretary, through consultation with a state department of agriculture or tribal government, a plan under which the State or Indian tribe monitors and regulates that production as described in paragraph (ii)

(ii) CONTENTS- A State, Indian Tribe or Locality plan referred to in paragraph (i)

(1) Shall only be required to include:

- a) A practice to maintain relevant information regarding land on which cannabis is produced in the State or territory, including a legal description of the land;
- b) A procedure for testing, using post decarboxylation or other reliable methods, levels of delta-9 tetrahydrocannabinol, cannabidiol and other cannabinoids to determine concentration levels of cannabis produced in the State or territory;
- c) A procedure to test cannabis for pesticides, heavy metals, bacteria and other contaminants that are harmful to individual or public health;
- d) A procedure for conducting annual inspections of, at minimum, a random sample of cannabis producers to ensure that cannabis is produced according to at least the minimum standards provided by this subchapter;
- e) A certification that the State, Indian Tribe or locality has the resources and personnel to carry out procedures described in clauses (a) to (d); and
- f) May include any other practice or procedure established by State or Indian tribe, as applicable to the extent this practice or procedure is consistent with this subtitle.

(iii) RELATION TO STATE AND TRIBAL LAW

(1) NO PREEMPTION - Nothing in this subsection preempts or limits any law of a State or Indian Tribe that -

- a) Regulates the cultivation and production of cannabis; and
- b) Is more stringent than this subtitle.

(2) REFERENCES IN PLANS - A State, Tribal, or Local plan may refer to a state or local law or regulation regarding the production of cannabis provided that it is consistent with this subtitle.

(b) APPROVAL

(i) IN GENERAL- Not later than 60 days after receipt of the plan, the Under Secretary shall

- (1) Approve of the plan; or
- (2) Send the plan back with suggestions as to how to improve the cultivation plan with best practices

(ii) AMENDED PLANS- If the Under Secretary returns a plan with suggestions for improvement, the State, tribe or locality shall submit an amended plan incorporating the suggestions of the Under Secretary within 60 days of receipt of notice from Under Secretary.

(c) AUDIT OF COMPLIANCE-

(i) IN GENERAL- The Under Secretary may conduct an audit of a State, Locality, or Tribe to ensure that the jurisdiction is providing a sufficient supply of cannabis to the patient population and the cannabis being produced is free of substances that would endanger individual or public health.

(ii) NONCOMPLIANCE- If the Under Secretary determines through an audit conducted under paragraph (i) that a jurisdiction is not materially in compliance with a state or tribal plan approved under (b)(i)-(ii)

- (1) The Under Secretary shall collaborate with the jurisdiction to develop a corrective action plan in the first instance of noncompliance; and

- (2) The Under Secretary may revoke approval of a state, Tribal or local plan in case of the second or further event of noncompliance.
- (iii) PENALTIES- The Under Secretary shall set penalties for noncompliance and production of cannabis that is deemed harmful to individual or public health.

SEC. 306- MISCELLANEOUS PROVISIONS

- (a) REGULATIONS- The Commissioner, acting through the Under Secretary for Cannabis Agriculture and Cultivation, may issue necessary regulations with respect to research, development, testing, and evaluation activities of the Office, including the conducting, funding and reviewing of such activities.
- (b) PERSONAL CULTIVATION- Nothing in this section shall prohibit an individual from cultivating cannabis for personal use, if legal in the State, and individual cultivators may take advantage of the provisions of this Act.
- (c) EFFECT ON INDUSTRIAL HEMP- Nothing in this chapter supersedes or preempts Pub. L. No. 115-334 ("The 2018 Farm Bill") except for the transfer of authority from the Food and Drug Administration as described elsewhere in this chapter.

TITLE IV- MANAGEMENT

SEC. 401- UNDER SECRETARY FOR MANAGEMENT

- (a) IN GENERAL- The Commissioner, acting through the Under Secretary for Management, shall be responsible for management and administration of the office, including the following:
 - (i) The budget, appropriations, expenditures of funds, accounting and finance;
 - (ii) Procurement;
 - (iii) Human resources and personnel;
 - (iv) Information Technology and communications systems;
 - (v) Facilities, property, equipment and other material resources; and
 - (vi) Any other duties the Commissioner may designate.
- (b) TRANSFER OF FUNCTIONS- There shall be transferred to the Under Secretary for Management all functions performed immediately before such transfer occurs with respect to the following programs:
 - (i) The Investigational New Drug Program
 - (ii) The Cannabis Farm at the University of Mississippi
 - (iii) The Cannabis Eradication Program
 - (iv) All adjudications performed by the Drug Enforcement Administration

Sec. 402- CHIEF FINANCIAL OFFICER

The Chief Financial Officer shall report to the Commissioner or to another official of the office as the commissioner may designate.

Sec. 403- CHIEF INFORMATION OFFICER

The Chief Information Officer shall report to the Commissioner or to another official of the office as the commissioner may designate.

SEC. 404- ESTABLISHMENT OF OFFICER FOR PATIENT AND CIVIL RIGHTS

- (a) IN GENERAL- Recognizing that medical cannabis users have long been discriminated against, and the vestiges of this discrimination still exist, the Commissioner shall appoint in the Office an Officer for Patient and Civil Rights who shall:
 - (i) Review and assess information alleging abuses of patient rights, civil liberties, and policies that previously had a disparate racial impact, including but not limited to federal housing evictions for medical cannabis use, denial of firearm sales to medical cannabis patients, and disparities in arrest rates. The Officer shall also coordinate with the Office of State and Local Coordination to determine if state-based discrimination occurred in situations including employment, medical care, and custody determinations; and
 - (ii) Make public through the internet, radio, television or other media the responsibilities, functions and contact information of the Officer.

- (b) REPORT- The Commissioner shall submit to the President of the Senate, the Speaker of the House of Representatives, and the appropriate committees and subcommittees of Congress on an annual basis a report on the implementation of this section, including the use of funds appropriated to carry out this section, and detailing any allegations of abuses described under subsection (a)(1) and any actions taken by the Office in response to such allegations.

TITLE V- COORDINATION WITH NON-FEDERAL ENTITIES; GENERAL PROVISIONS

Subtitle A- Coordination with Non-Federal Entities

SEC. 501 SUBDIVISION FOR STATE AND LOCAL GOVERNMENT COORDINATION

- (a) ESTABLISHMENT- Recognizing that State and Local governments have already put substantial thought into policies regarding the regulation of medical cannabis, there is established within the Office of the Commissioner the Subdivision for State and Local Government Coordination to oversee and coordinate departmental programs for, and relationships with, State and Local governments, including determining the awarding of licenses for cultivation and manufacturing businesses as well as the licensing of specialty pharmacies.
- (b) RESPONSIBILITIES- The Subdivision established under this subsection shall:
- (i) Set minimum standards for states regarding the regulation of cannabis cultivation and production and cannabis distribution and access. States may establish more stringent policies, but may not allow policies below the federal threshold;
 - (ii) Coordinate the activities of the Subdivision related to State and Local government;
 - (iii) Assess, and advocate for, the resources needed by State and Local governments to implement a national strategy for improving access to medical cannabis;
 - (iv) Provide State and Local governments with regular information, research, and support to assist efforts in ensuring safe and legal access to medical cannabis; and
 - (v) Develop a process for receiving meaningful input from State and Local governments to assist in the development of the national strategy for improving access to medical cannabis.

SUBTITLE B- MISCELLANEOUS PROVISIONS

SEC. 502- ADVISORY COMMITTEES

- (a) IN GENERAL- The Commissioner may establish, appoint members to, and use the services of advisory committees as the Commissioner may deem necessary. The Commissioner may appoint members of Federal or State governments or individuals from the public or nonprofit sector.
- (b) TERMINATION- Any advisory committee established by the Commissioner shall terminate two (2) years after the date of its establishment, unless the Commissioner makes a written determination to extend the advisory committee to a specified date, which shall not be more than two (2) years after the date on which a determination is made.

SEC. 503- MILITARY ACTIVITIES

Nothing in this authority should be deemed to affect the ability of the Department of Defense or the Department of Veterans affairs to conduct medical cannabis research.

SEC. 504 SUBDIVISION OF INTERNATIONAL CANNABIS POLICY

- (a) ESTABLISHMENT- There is established within the Office of the Commissioner a Subdivision of International Cannabis Policy. The Subdivision shall be headed by a Director who shall be a senior official appointed by the Commissioner.
- (b) DUTIES OF THE DIRECTOR- The Director shall have the following duties:
- (i) Liaise with the World Health Organization for international decisions related to medical use of cannabis;
 - (ii) Promote information and education exchanges with nations that have developed medical cannabis programs, including the sharing of best practices;

- (iii) Identify areas for information and training exchanges where the United States has demonstrated weaknesses with medical cannabis policy; and
- (iv) Plan and undertake international conferences, exchange programs, and training activities.

TITLE VI- TRANSITION; REORGANIZATION PLAN

SEC 601- DEFINITIONS

For the purposes of this title:

- (1) The term "agency" includes any entity, organizational unit, program, or function.
- (2) The term "transition period" means the 12-month period beginning on the effective date of this Act.

SEC 602- REORGANIZATION PLAN

- (a) SUBMISSION OF PLAN- Not later than sixty (60) days after the enactment of this Act, the President shall transmit to the appropriate Congressional committees a reorganization plan regarding the following:
 - (i) The transfer of functions, personnel, assets, and obligations from agencies including, but not limited to, the DEA, NIDA, DOJ, HHS, and ONDCP to the Office pursuant to this Act; and
 - (ii) Any consolidation, reorganization, or streamlining of agencies transferred to the Office pursuant to this Act.
- (b) PLAN ELEMENTS- The plan transmitted under subsection (a) shall contain, consistent with this Act, such elements as the President deems appropriate, including any of the following:
 - (i) Identification of any cannabis-related agency functions transferred to the Office;
 - (i) Specification of which steps should be taken by the Commissioner to organize the Office, including delegation or assignment of functions transferred to the Office among officers of the Office in order to permit the Office to carry out the functions transferred under the plan;
 - (iii) Specification of funds available to each agency that will be transferred to the Office as a result of transfers under the plan; and
 - (iv) Specifications of proposed allocations within the Office of unexpended funds transferred in connection with transfers under the plan.
- (c) MODIFICATION OF PLAN- The President may, on the basis of consultations with the appropriate Congressional committees, modify or revise any part of the plan until that plan becomes effective.

TITLE VII- IMPLEMENTATION

SEC 701- LICENSING; GENERAL PROVISIONS

- (a) IN GENERAL- The Office shall grant federal licenses for cultivation, manufacturing or distribution to all those businesses that obtained or will obtain state medical cannabis licenses for cultivation, manufacturing or distribution in states implementing, with respect to those businesses, at least the minimum standards for regulation, as established by the Office pursuant to SEC 501 (b) (i) of this Act. The Office shall also establish a mechanism for granting federal licenses to applicants applying directly to the Office. The Office should develop regulations for dealing with such applications.
- (b) LICENSING PROVISIONS- The Office shall record the areas in which, and the plot(s) of land on which, the cultivation of cannabis for the purpose of producing or manufacturing of cannabis for medical purposes is federally permitted.
- (c) ONLY LICENSED BUSINESSES PERMITTED- Only cultivators and manufacturers federally licensed by the Office on the basis of appropriate state licenses or through its own mechanism shall be permitted to participate in the inter-state trade and in international trade of medical cannabis products.
- (d) IMPORTS, EXPORTS- The Office, in the respect to cannabis produced for medical purposes, shall have the exclusive right to import, and export, This exclusive right is not extended to medical cannabis products.

SEC 702- SPECIALITY LICENSING

- (a) IN GENERAL- The Office will issue federal speciality pharmacy licenses for dispensaries with state medical cannabis licenses that are operating on the date of the effective date of this act or will be approved for operation by the state in the future, in states implementing at least the minimum standards for the regulation of such cannabis businesses, as established by the Office pursuant to § 501 (b) (i) of this Act.

- (b) EXISTING LICENSES; SPECIALTY PHARMACIES- If in the opinion of the Commissioner there are not enough licensed speciality pharmacies to adequately serve the patient population in the state, the Commissioner shall may either issue up to one additional federal medical cannabis speciality pharmacy license for every five (5) existing pharmacy licenses issued under state law or allow the importation by individuals of medical cannabis and medical cannabis products from other states.
- (c) ADMINISTRATIVE REVIEW- the denial of a license by the Office is deemed a final agency action and is subject to judicial review under the Administrative Procedures Act.

SEC 703- DISTRIBUTION; GUIDELINES

- (a) IN GENERAL- The Office will develop a system to grant licenses to distribute medical cannabis and will give existing distributors and distribution networks preference when it comes to the issuance of licenses.
- (b) PHARMACIES- The Office will develop a system to ensure that pharmacies can obtain cannabis and cannabis products from licensed cultivators and manufacturers on a patient population basis to ensure there is an uninterrupted supply of medical cannabis.

SEC 704- PRESCRIPTION PROTOCOLS

- (a) IN GENERAL- The Office shall consult with the Secretary of Health and Human Services, pharmacists, and healthcare practitioners in developing prescription protocols for the prescribing of medical cannabis and medical cannabis products.
- (b) GUIDELINES- In consultation with the Secretary of Health and Human Services, the Office shall develop guidelines that allow the prescription of medical cannabis pursuant to existing prescription protocols.

SEC 70 5- ADVISORY COMMITTEE

- (a) IN GENERAL- The Commissioner shall establish, appoint members of, and use the services of advisory committees as the Commissioner may deem necessary. For the licensing advisory committee, the Commissioner shall appoint directors of state-based medical cannabis offices, or their designees, to advise on the process of issuing licenses.
- (b) TERMINATION- Any advisory committee established by the Commissioner shall terminate two (2) years after the date of its establishment unless the Commissioner makes a written determination to extend the advisory committee to a specified date, which shall not be more than two (2) years after the date on which a determination is made.

SEC 706- TRANSFER OF FUNCTIONS

- (a) AUTHORITY TO TRANSFER FUNCTIONS- The Secretary of Health and Human Services, the Director of the National Institute on Drug Abuse, the Administrator of the Drug Enforcement Administration, and other Secretaries and officials as appropriate shall transfer to the Office any program or activity of another government agency that is consistent with the mission of the Office, including but not limited to the oversight of licensing of cannabis cultivation and manufacturing as permitted by the 1961 Single Convention on Narcotic Drugs and subsequent international treaties.
- (b) TRANSFER OF PERSONNEL AND ASSETS- With respect to any function, power, duty, or any program or activity that is established in the Office, those employees and assets of another government agency may be transferred to the Office.

www.AmericansforSafeAccess.org

Americans for Safe Access (ASA) was founded in 2002 and has over 100,000 advocates in all 50 states and US territories. ASA is the largest national member-based organization of patients, medical professionals, scientists and concerned citizens promoting safe and legal access to cannabis for therapeutic use and research. ASA works to overcome political, social and legal barriers by creating policies that improve access to medical cannabis for patients and researchers through legislation, education, litigation, research, grass-roots empowerment, advocacy and services for patients, governments, medical professionals, and medical cannabis providers.

ASA's legislative proposals are based on patient needs and are vetted through a network of stakeholders. For an in-depth review of topics pertaining to medical cannabis, oversight needs, please download Medical Cannabis in America: The Medical Cannabis Briefing Book at www.safeaccessnow.org/briefingbook116 or use your camera function to scan the QR code below.

The briefing book is designed to guide Congress and federal agencies' decisions on medical cannabis policies. It provides an overview of the basics of cannabis therapeutics, state medical cannabis programs, the impact of the state-federal conflict, and resources to address ending the federal conflict.

