



# A LEGISLATIVE PROPOSAL FOR FEDERAL GUIDANCE ON MEDICAL CANNABIS AND CANNABINOID POLICY

DRAFTED FOR THE 118TH CONGRESS



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# THE MISSION OF AMERICANS FOR SAFE ACCESS (ASA) IS TO ENSURE SAFE AND LEGAL ACCESS TO CANNABIS FOR THERAPEUTIC USE AND RESEARCH.

WITH OVER 150,000 ACTIVE SUPPORTERS IN ALL 50 STATES, ASA IS THE LARGEST NATIONAL MEMBER-BASED ORGANIZATION OF PATIENTS, MEDICAL PROFESSIONALS, SCIENTISTS, AND CONCERNED CITIZENS WORKING TO OVERCOME POLITICAL, SOCIAL, AND LEGAL BARRIERS TO IMPROVE ACCESS TO MEDICAL CANNABIS FOR PATIENTS AND RESEARCHERS THROUGH LEGISLATION, EDUCATION, LITIGATION, GRASSROOTS EMPOWERMENT, ADVOCACY AND SERVICES FOR PATIENTS, GOVERNMENTS, MEDICAL PROFESSIONALS, AND MEDICAL CANNABIS PROVIDERS.

FEDERAL
GUIDANCE ON
MEDICAL CANNABIS
& CANNABINOID
POLICY IS
NECESSARY

# **KEY FACTS**

- Thirty-eight states, the District of Columbia, and four of five U.S. territories have comprehensive medical cannabis programs, with an additional ten states having cannabidiol legislation.
- 93% of Americans are in favor of medical cannabis policies.
- In 2020, the United Nations reclassified cannabis recognizing its medical benefits and over 60 countries have legalized the medical use of cannabis at the national level.
- The 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, requires signatories to designate a singular medical cannabis oversight body under Article 28.
- The Hemp Authorization of the 2018 Farm Bill removed cannabis with <.03% THC from the Controlled Substances Act (CSA) scheduling and tasked the Food and Drug Administration (FDA) with regulating these products. On January 26, 2023, the FDA concluded that current frameworks will not work for regulating Cannabidiol (CBD) and has called on Congress to create a new framework.
- The Medical Cannabis amendment to the Commerce-Justice-Science (CJS) Appropriations bill, first passed in 2014, instructs the Department of Justice (DOJ) and the Drug Enforcement Administration (DEA) not to spend resources enforcing federal cannabis laws if individuals are following state medical cannabis laws. This was meant to be a triage measure to end threats of state employees, raids, and prosecutions while Congress created new federal medical cannabis policies.
- In the Congressional Research Service (CRS) report "The Schedule I Status of Marijuana" issued on October 7, 2022, they concluded, "Options for Congress -Congress could choose to maintain the federal prohibition on marijuana, but if Congress wanted to address the Schedule I status, it could do a number of things: (1) amend the CSA to move marijuana to a less restrictive schedule; (2) create an entirely new schedule or other category for marijuana; or (3) remove it entirely from the CSA... The creation of a new schedule solely for marijuana would give Congress an opportunity to modify the criminality of marijuana under the CSA."
- On October 6, 2022, the White House issued a statement calling for "the Secretary of Health and Human Services and the Attorney General to initiate the administrative process to review expeditiously how marijuana is scheduled under federal law."
- The National Institute of Drug Abuse is going way outside its mission to monitor the medical use of cannabis because they are one of the only agencies with funding for cannabis.
- The Centers for Disease Control and Prevention (CDC) has \$0 in their budget to monitor cannabis and cannabis-derived products.
- State policymakers and regulators have not only been tasked with creating the infrastructure and regulations for a supply chain that remains illegal at the federal level, but now, as seen in 99 pieces of legislation introduced in 2022 alone, they must address a new health concern of seemingly federally legal unregulated cannabinoid market created by the 2018 Farm Bill.

# **KEY POINTS**

- As a matter of public safety and better use of federal resources, a new federal framework is needed for medical cannabis and cannabinoid regulation that harmonizes state, federal, and international law.
- The Schedule I classification under the Controlled Substances Act (CSA) is not an appropriate schedule for cannabis. None of the other schedules will work for the regulation of cannabis and cannabinoids as they are being distributed legally at the state level, requiring the creation of a new schedule for cannabis.
- 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 and cannabinoids for human consumption.
- The lack of Congressional action is creating more work for federal agencies.
- For 25 years, states have been implementing medical cannabis laws in direct conflict with federal law.
- State medical cannabis programs were first crafted by states to serve as a form of triage to get patients off the battlefield of the war on drugs. Similarly, the Medical Cannabis CJS amendment was meant to be a triage measure to stop the DOJ threats of state employees, raids, and prosecutions while Congress created new federal medical cannabis policies.
- The state-federal conflict on medical cannabis has required most federal agencies to create "workaround" policies for cannabis without the benefit of medical cannabis policy experts to guide them or additional resources to properly address such matters.
- 6 million Americans are using medical cannabis as a stand-alone or as an adjunct treatment to relieve symptoms or side effects experienced from other treatment methods. In many cases, patients, and their medical professionals report that cannabis and cannabinoids work where all traditional options have failed.
- In response to the U.S.'s pain and opioid epidemics, over 1/3 of Americans are turning to cannabis and cannabinoids to treat chronic pain and curb opioid use resulting in fewer opioid deaths in states where medical cannabis is available.
- The state-by-state compassionate use model leaves out those patients living in states reluctant to pass medical cannabis laws, federal employees and contractors, and veterans utilizing VA medical services. In states with medical cannabis laws, this model does not address many medical or logistical needs for patients, only serving a privileged class of Americans.

# FEDERAL GUIDANCE ON MEDICAL CANNABIS & CANNABINOID POLICY

To address the gap in state and federal cannabis policies, public health concerns, and to give federal agencies robust guidance they are asking of Congress, comprehensive medical cannabis legislation is required. The following legislative proposal has two primary functions: 1) Changing the schedule of cannabis into a newly created schedule (Schedule VI), and 2) Creating the Office of Medical Cannabis and Cannabinoid Control (OMC) housed under the U.S Department of Health and Human Services (HHS).

# THE SCHEDULING OF CANNABIS

It is fair to say there is a national consensus that cannabis does not belong in Schedule I of the Controlled Substances Act ("CSA"). A status shared with heroin and a classification claiming it is considered more dangerous than cocaine, methamphetamine, OxyContin, and fentanyl (all Schedule II substances). Schedule I status means a drug has a high potential for abuse and no accepted medical value.

Though its original placement in Schedule I was intended to be temporary, awaiting guidance from a specially formed commission (National Commission on Marihuana and Drug Abuse). Findings to decriminalize cannabis were later ignored, and medical cannabis patients have suffered from the effects of the prohibition of cannabis since the passage of the CSA in 1971. Over the last 5 decades, there have been several attempts to reschedule cannabis, but all have failed due to the definitions of the Schedules and a biased process. 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.

Since 1996, states have been authorizing programs for cannabis that operate completely outside the prevue of the CSA. The federal government's refusal to recognize the medical value of cannabis puts its current law at odds with not only a majority of its states but also with the United Nations and scientific findings from its own agencies.

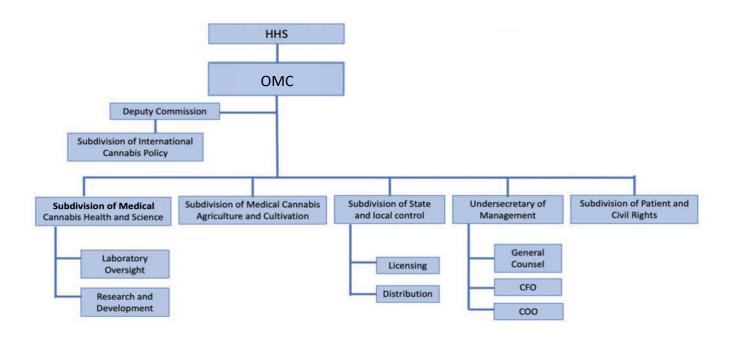
By amending 21 USC 812(b)(5) of CSA to create a new scheduling category for cannabis, Schedule VI, Congress will maintain moderate control over cannabis while allowing the greatest number of patients to access cannabis as a medicine.

# THE OFFICE OF MEDICAL CANNABIS & CANNABINOID CONTROL

Effective regulation of cannabis is strained by nearly a dozen agencies wanting to play a role in the decision-making process. The DOJ, FDA, HHS, DEA, Office of National Drug Control Policy (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.

The Administrative Procedures Act stipulates that there are two methods by which a new federal agency may be created. 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 and Cannabinoid Control, as laid out by the legislation and figure below, would create a central authority within the U.S. Government to regulate medical cannabis and cannabinoids under the newly created Schedule VI. The OMC will require initial federal funding however most operational funds will come from the reorganization of current cannabis oversight funding, licensing and permit fees, and private-public research partnerships.



A LEGISLATIVE
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# **AN ACT**

To establish the Office of Medical Cannabis and Cannabinoid Control, Create a new Schedule for Cannabis, 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 Patient Equity Act of 2023.

**SEC. 2 SENSE OF CONGRESS-** Expressing the sense of Congress that a new federal agency, the Office of Medical Cannabis and Cannabinoid Control, would be beneficial to public and individual health and a new Schedule under the Control Substance Act for cannabis would better reflect the current regulation of cannabis and cannabinoids in the US.

Whereas there are over six million patients legally using medical cannabis under state law in the United States;

Whereas forty-one states, the District of Columbia, and four of five U.S. territories have medical cannabis distribution laws, with an additional seven states having laws permitting cannabidiol (CBD);

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, which requires a singular medical cannabis oversight body under Article 28;

Whereas in 2020, the United Nations reclassified cannabis recognizing its medical benefits;

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

Whereas local level oversight of medical cannabis has led to greatly differing regulations on product safety, laboratory operations, pesticide use, civil protections, and other areas where federal guidance exists in other marketplaces;

Whereas since 2014 Congress has passed the Medical Cannabis amendment to the Commerce-Justice-Science (CJS) Appropriations bill restricting the Department of Justice (DOJ) and the Drug Enforcement Administration (DEA) from spending funds on enforcing federal cannabis laws if individuals are following state medical cannabis laws with no additional guidance from Congress;

Whereas the Hemp Authorization of the 2018 Farm Bill has created and unregulated class of cannabinoid products;

Whereas on January 26, 2023, the Food and Drug Administration (FDA) concluded that current frameworks will not work for regulating Cannabidiol (CBD) and has called on Congress to create a new framework;

Whereas Schedule I researchers who do obtain the proper license are 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 most federal agencies have called on Congress to resolve the conflict between state and federal laws; and

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 agency for the regulation of medical cannabis and cannabinoids and the creation of a new schedule (Schedule VI) under the CSA for 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 "assets" includes contracts, facilities, property, records, unobligated or unexpended balances of appropriations, and other funds or resources (other than personnel).
- (3) The term "cannabis" means marihuana as defined in title 21, United States Code, §802 (16).
- (4) 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.
- (5) 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.
- (6) The term "Commissioner" means the head of the Office of Medical Cannabis and Cannabinoid Control as defined in (13).
- (7) The term "Departments" means other executive and legislative agencies as defined under title 5, United States Code.
- (8) 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.
- (9) The term "functions" includes authorities, powers, rights, privileges, immunities, programs, projects, activities, duties, and responsibilities.
- (10) The term "key resources" means publicly or privately controlled resources essential to the minimal operations of the economy and government.
- (11) The term "local government" means—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
  - (b) a rural community, unincorporated town or village, or other public entity.
- (12) The term "Office of Medical Cannabis and Cannabinoid Control" means a centralized federal oversight agency for cannabis and cannabinoids as described in this chapter.
- (13) The term "personnel" means officers and employees.
- (14) The term "private sector" means businesses, associations, nonprofits or other entities organized under Federal, State, or Local laws for a non-governmental purpose.
- (15) 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
- (16) 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.
- (17) The term "Subdivision of Medical Cannabis Agriculture and Cultivation" means a sub-office of the Office of Medical Cannabis and Cannabinoid Control that oversees standards for cannabis cultivation and production.

- (18) The term "Subdivision of Medical Cannabis Science and Health" means a sub-office of the Office of Medical Cannabis and Cannabinoid Control that oversees medical cannabis science. development, and research.
- (19) 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.
- (20) The term "Schedule VI" means a newly created Schedule under the Controlled Substance act as defined by Title VIII of this legislation.

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 un- enforceability, 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 MEDICAL CANNABIS AND CANNABINOID CONTROL

# **SEC. 101 LEGISLATIVE AGENCY; MISSION**

- (1) There is established an Office of Medical Cannabis and Cannabinoid Control, as a legislative agency of the United States within the meaning of title 5, United States Code
- (2) Mission-
  - (a) IN GENERAL- the primary mission of the Office is to facilitate access to medical cannabis and cannabinoids for therapeutic use and research, regulate the production of medical cannabis products and cannabinoids for human consumption, and oversee the new Schedule VI. Including the following activities:
    - (i) Provide licensing and permitting process for any/all businesses involved in the Schedule VI supply-chain including but not limited to manufacturers, cultivators, specialty and other pharmacies, laboratories, and transporters;
    - (ii) Coordinate with State regulators to ensure this Act does not interrupt existing access including a process for existing medical cannabis businesses to qualify for the protections of this Act:
    - (iii) Coordinate cannabis-related issues across federal agencies in a manner that does not interrupt existing research or public health measures;
    - (iv) Provide minimum standards for labeling, packaging, product safety for cannabis, cannabis and cannabinoid products, and pesticide and agricultural guidelines for cannabis cultivation and cannabis products:
      - Assume the enforcement authority for Schedule VI substances;
    - (v) Coordinate research across federal agencies and private sector including the creation of a research priority map;
    - (vi) Develop process for cannabis formulations and products containing cannabinoids to conduct clinical trials including standardization guidance and pathway for health claims;
    - (vii) Assume primary oversight of marijuana as defined in 21 U.S.C. §802 (16); and
    - (viii) Carry out the functions of all entities transferred to the Office and serve as the focal point for government functions related to medical cannabis and cannabinoids.

(b) 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) Officer for Health Equity;
  - (v) Director of Office of International Cannabis Policy; and
  - (vi) 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 a subdivision of Cannabis Science & Health (hereinafter referred to as the "Subdivision").
  - (ii) **AUTHORITY** The subdivision shall be under the general authority of the Office but shall maintain independent discretion when making decisions about medical cannabis.
  - (iii) **UNDERSECRETARY** The subdivision shall be headed by an undersecretary 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-
  - To serve as the national focal point for medical cannabis, transferring authority from the National Institute on Drug Abuse, Drug Enforcement Administration, and Department of Health and Human Services;
  - (ii) To create and implement prescription protocols for Schedule VI substances;
  - (iii) To oversee medical cannabis research;
  - (iv) To carry out educational programs for medical cannabis practitioners;
  - (v) To carry out programs that improve access to medical cannabis; and
  - (vi) To develop process for cannabis formulations and products containing cannabinoids to conduct clinical trials including standardization guidance and pathway for health claims.
- (b) **DUTIES-** In carrying out its mission, the subdivision shall have the following duties,
  - (i) Provide recommendations and advice about cannabis and cannabis medicines to the Commissioner of the Food and Drug Administration, as needed;
  - (ii) Coordinate with the Department of Health and Human Services, the National Institute on Drug Abuse, and the Food and Drug Administration on policy matters and implementation as needed:
  - (iii) To establish and maintain advisory groups to assess the scientific needs of Federal, State and Local cannabis research facilities:
  - (iv) To establish minimum laboratory research standards in accordance with ISO 17025 and test and evaluate research processes that may be used by federal, state, local and private researchers and laboratories;

- (v) To establish a program that certifies, validates, or otherwise approves research study designs that explore potential of cannabis as a medicine;
- (vi) To coordinate with other federal agencies and Executive Office of the President to establish a coordinated Federal approach to researching medical cannabis;
- (vii) 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:
  - (A) Cannabis as a replacement for opioid therapies;
  - (B) Cannabis as a treatment for PTSD;
  - (C) Potency of medicine treating a variety of conditions;
  - (D) Development of an accurate biological or observational test to assess impairment;
  - (E) Cannabis a treatment option for cancer; and
  - (F) Cannabis as a treatment option for veterans.
- (viii) To develop and disseminate to State and Local departments of health training materials for regulators, law enforcement, and prosecutors; and
- (ix) 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:

- Ensure that colleges, universities, private research institutes, and companies from as many areas of the United States with different 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.
- (c) 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 to carry out duties including but limited to overseeing national proficiency testing programs, developing standardized methods, developing new tools for testing cannabinoids, contaminates and adulterants and to assist the Secretary with program oversight as needed.
  - (1) 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 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:
  - To serve as the national focal point for the production of medical cannabis and products containing cannabinoids for human or animal consumption, 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.
- (b) **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) Coordinate with the Department of Agriculture and Environmental Protection Agency on policy matters and implementation as needed;
  - (iii) Establish and maintain advisory groups to assess the needs of Federal, State and Local cannabis cultivators and producers:
  - (iv) 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:
  - (v) Establish a program that certifies, validates, or otherwise approves cultivators or cultivation facilities as organic;
  - (vi) Coordinate across agencies to create seed registry;
  - (vii) Train inspectors:
  - (viii) Create research and marketing orders;

- (ix) 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
- (x) 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 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 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) 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 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;
    - D) 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
    - E) 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

- (A) **NO PREEMPTION–** Nothing in this subsection preempts or limits any law of a State or Indian Tribe that
  - (I) Regulates the cultivation and production of cannabis; and
  - (II) Is more stringent than this subtitle.
- (B) **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 for amendment with suggestions as to how to improve the cultivation plan with best practices.
- (ii) **AMENDED PLANS-** If the Under Secretary returns a plan without approval for amendment, 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
- (iii) The Under Secretary may revoke approval of a state, Tribal or local plan in case of the second or further event of noncompliance.
- (d) **PENALTIES** The Under Secretary shall set penalties for noncompliance and production of cannabis 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, track and trace, 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") with regard to industrial hemp.

#### TITLE IV- MANAGEMENT

#### SEC. 401- UNDER SECRETARY FOR MANAGEMENT

- (a) **IN GENERAL** The Commissioner, acting through the Undersecretary for Management, shall be responsible for the management and administration of the office, including the following:
  - (i) The budget, appropriations, expenditures of funds, processing licenses and permit fees, 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 Undersecretary for Management all functions performed immediately before such transfer occurs with respect to the following programs:
  - (i) Cannabis cultivation and manufacturing licenses provided by the Drug Enforcement Administration
  - (ii) The Domestic Cannabis Eradication Program
  - (iii) 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 evictions for medical cannabis use in federally subsidized housing, 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 and any other Schedule VI permits.
- (b) **RESPONSIBILITIES** The Subdivision established under this subsection shall:
  - (i) Set minimum product and worker safety 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) Create protocols for interstate sales and transportation;
  - (v) Create vendor/licensee database;
  - (vi) Implement federal track and trace program;
  - (vii) Develop adverse event reporting system with recall protocols;
  - (viii) Provide State and Local governments with regular information, research, and support to assist efforts in ensuring safe and legal access to medical cannabis and medical cannabis products; and
  - (ix) 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 the 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

#### **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- NOTIFICATIONS TO AGENCIES

#### 1. Upon the passage of this Act, the following notices will apply to the mentioned agencies:

# (a) Department of Housing and Urban Development

Update leasing determination criteria, enforcement action criteria, and other policies to exempt the state-legal medical use of cannabis from drug-free housing policies and tax credits. Not more than 120 days after the enactment of this act, the Department of Housing and Development shall issue a memorandum to all Public Housing Agencies that it is unlawful to discriminate, retaliate, or take adverse action against an individual lawfully using or possessing cannabis for medical purposes under the laws that govern the state where housing assistance is provided.

#### (b) Internal Revenue Service

Amend 26 USC 280E to add "except with regard to state-legal cannabis products for medicinal purposes"

Not more than 120 days after the enactment of this act shall the Internal Revenue Service issue a memorandum for cannabis businesses reflecting their exemption from Section 280E and including guidance on now-eligible business deductions and credits.

## (c) Bureau of Alcohol, Tobacco, Firearms & Explosives

Remove the following warning from Form 4473 - The use or possession of marijuana remains unlawful under Federal law regardless of whether it has been legalized or decriminalized for medicinal or recreational purposes in the state where you reside.

#### (d) Department of the Treasury

Not more than 120 days after the enactment of this act shall the Treasury issue new regulatory guidance for financial institutions regarding the provision of services to state-licensed medical cannabis businesses. The new guidance will provide greater flexibility for banks and credit unions to serve legal cannabis businesses and reduce the public safety challenges associated with cannabis businesses having to operate entirely in cash.

#### (e) Department of Justice

Not later than 60 days after the date of enactment of this Act, the Department of Justice shall review and formalize cannabis enforcement guidelines contained in the DOJ Cole Memo dated 2013 for the enforcement of federal drug laws in states where cannabis or medical cannabis is legal.

Not later than 1 year after the date of the enactment of this Act, each Federal district shall conduct a comprehensive review and issue an order expunging each conviction or adjudication of juvenile delinquency for a non-violent Federal cannabis offense entered by each Federal court in the district before the date of enactment of this Act and on or after May 1, 1971. Each Federal court shall also issue an order expunging any arrests associated with each expunged conviction or adjudication of juvenile delinquency.

#### i. Expungement order:

- (1) NOTIFICATION.— To the extent practicable, each Federal district shall notify each individual whose arrest, conviction, or adjudication of delinquency has been expunged pursuant to this subsection that their arrest, conviction, or adjudication of juvenile delinquency has been expunged, and the effect of such expungement
- (2) RIGHT TO PETITION COURT FOR EXPUNGEMENT.— At any point after the date of enactment of this Act, any individual with a prior conviction or adjudication of juvenile delinquency for a non-violent Federal cannabis offense, who is not under a criminal justice sentence, may file a motion for expungement. If the expungement of such a conviction or adjudication of juvenile delinquency is required pursuant to this Act, the court shall expunge the conviction or adjudication, and any associated arrests. If the individual is indigent, counsel shall be appointed to represent the individual in any proceedings under this subsection
- ii. Sentencing Review for Individuals Under a Criminal Justice Sentence.—
  - (1) IN GENERAL.— For any individual who is under a criminal justice sentence for a non-violent Federal cannabis offense, the court that imposed the sentence shall, on motion of the individual, the Director of the Bureau of Prisons, the attorney for the Government, or the court, conduct a sentencing review hearing. If the individual is indigent, counsel shall be appointed to represent the individual in any sentencing review proceedings under this subsection.
  - (2) **POTENTIAL REDUCED RESENTENCING.** After a sentencing hearing under paragraph (1), a court shall—
    - (I) expunge each conviction or adjudication of juvenile delinquency for a nonviolent Federal cannabis offense entered by the court before the date of enactment of this Act, and any associated arrest;
    - (II) vacate the existing sentence or disposition of juvenile delinquency and, if applicable, impose any remaining sentence or disposition of juvenile delinquency on the individual as if this Act, and the amendments made by this Act, were in effect at the time the offense was committed; and
    - (III) order that all records related to a conviction or adjudication of juvenile delinquency that has been expunged or a sentence or disposition of juvenile delinquency that has been vacated under this Act be sealed and only be made available by further order of the court.
- iii. Effect of Expungement.— An individual who has had an arrest, a conviction, or juvenile delinquency adjudication expunged under this section—
  - (1) may treat the arrest, conviction, or adjudication as if it never occurred; and
  - (2) shall be immune from any civil or criminal penalties related to perjury, false swearing, or false statements, for a failure to disclose such arrest, conviction, or adjudication

2. Unless otherwise provided in this Act, not later than 1 year after the date of enactment of this Act, the Department of the Treasury, the Department of Justice, the Food & Drug Administration, the Bureau of Alcohol, Tobacco, Firearms & Explosives, and the Internal Revenue Service shall issue or amend any rules, standard operating procedures, and other legal or policy guidance necessary to carry out the implementation of this Act. After the 1-year period, any publicly issued sub-regulatory guidance, including any compliance guides, manuals, advisories, and notices, may not be issued without 60-day notice to appropriate congressional committees. Notice shall include a description and justification for additional guidance.

#### SEC. 603- 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;
  - (ii) 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.

#### SEC. 604- CONTINUITY OF CARE

#### (a) **GENERAL**

(i) The Office of Medical Cannabis and Cannabinoid Control should prioritize continuity of care in states where patients rely on cannabis for medicinal reasons, including ensuring businesses remain in operation and ensuring patients have access to medical cannabis while the Agency formalizes rules and guidelines

## (b) PROVISIONAL LICENSES

- (i) The Office of Medical Cannabis and Cannabinoid Control shall automatically award provisional licenses for state-legal medical cannabis business operations that hold a valid state license to do business in the state where the business is located
- (ii) Provisional licenses shall permit medical cannabis operators to continue operating in the normal manner
- (iii) Provisional licenses shall remain valid until 120 days after the Agency formalizes licensing rules and notifies state regulatory entities
- (iv) Businesses with provisional licenses shall receive priority consideration by the Agency when assigning formal licenses as to not disrupt medical supply

#### (c) PHYSICIAN RECOMMENDATIONS

- (i) Valid physician recommendations for medical cannabis in states where it is permitted shall remain valid through the expiration date on such recommendation or registration
- (ii) Current state-legal practices for physician recommendations and patient registry renewals shall remain in operation until 120 days after the Office of Medical Cannabis formalizes licensing and recommendation rules

#### 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 specialty 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 specialty pharmacies to adequately serve the patient population in the state, the Commissioner may either issue up to one additional federal medical cannabis specialty 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 in coordination with state regulators 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. 705- 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 established in the Office, those employees and assets of another government agency may be transferred to the Office.

# TITLE VIII- ESTABLISH SCHEDULE VI UNDER THE CONTROLLED SUBSTANCE ACT

# SEC. 801: AMEND CONTROLLED SUBSTANCE ACT-Amend 21 USC 812(b)(5) to include:

Schedule VI-

- (a) Products containing cannabis and/or cannabinoids for human and veterinary consumption (does not include industrial hemp, hemp-based nutritional or cosmetic products).
- (b) The drug or other substance has a currently accepted medical use in treatment in the United States.
- (c) The Office of Medical Cannabis and Cannabinoid Control shall have primary regulatory oversight for Schedule VI, including but not limited to licensing, research, oversight, implementation, and national coordination.

SEC. 802 Amend Criminal Code to Remove Schedule VI from CSA reference

SEC. 803 Amend Sentencing Guidelines to Remove Schedule VI from CSA reference

SEC. 804 Amend mention of CSA to Remove Schedule VI from CSA reference

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ASA is the largest national organization of patients, medical cannabis providers, medical professionals, scientists and concerned citizens promoting safe and legal access to cannabis for therapeutic use and research with over 150,000 supporters in all 50 states.