THE MEDICAL CANNABIS & CANNABINOID ACT

FAQ

Americans for Safe Access
Advancing Legal Medical Cannabis Therapeutics

Americans for Safe Access

The mission of Americans for Safe Access (ASA) is to ensure safe and legal access to cannabis (marijuana) for therapeutic uses and research. Founded in 2002, ASA advocates for a national regulatory framework that invests in the development of standardized cannabis-based products, ensures a safe & consistent supply, fosters the integration of cannabis into patient treatment plans as a frontline medication, encourages insurance coverage, & prohibits employment, housing, parental & healthcare discrimination.

MEDICAL CANNABIS PATIENT-

[me-di-kəl ka-nə-bəs pā-shənt] n. a person living with a medical condition or experiencing symptoms for which cannabis or a cannabinoid-based therapeutic is the only treatment option, a more suitable option, or works as an adjunct treatment including side-effect mitigation to other available care options.






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Americans for Safe Access

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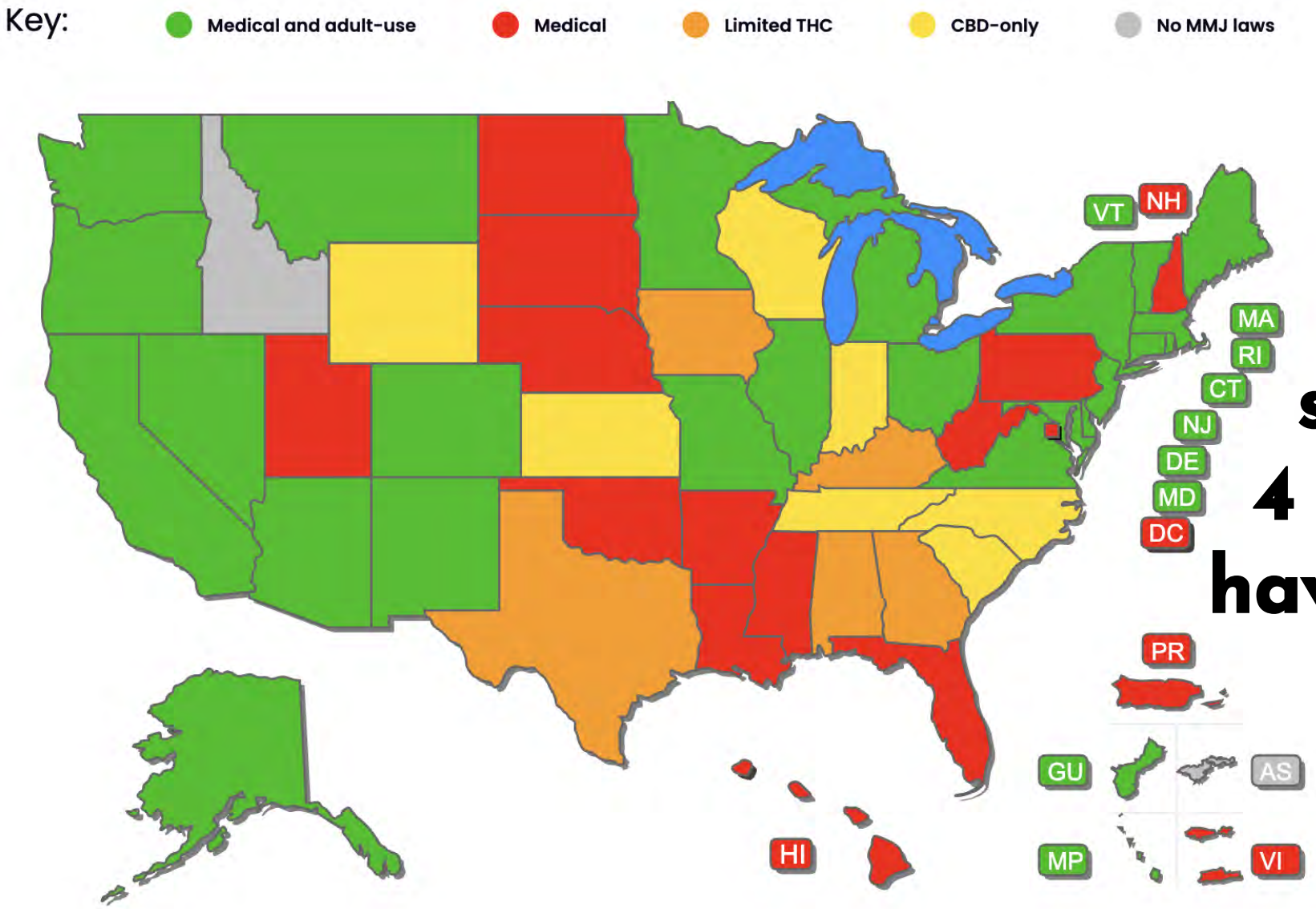
Q: WHY IS FEDERAL ACTION NEEDED?

Americans for Safe Access



Since 1996, states 49 states, 4 territories & D.C. have passed medical cannabis laws.

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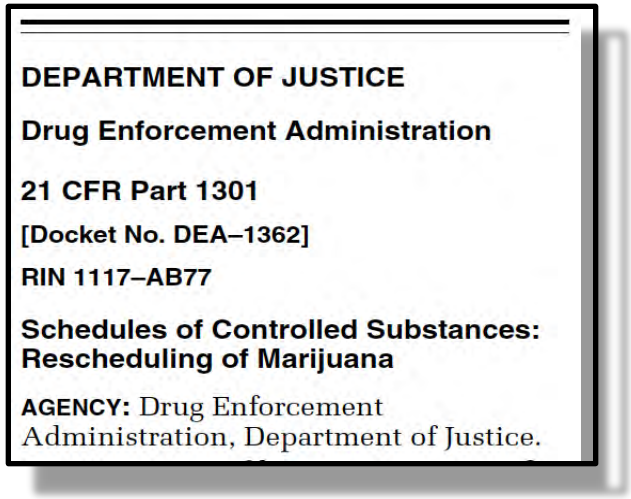
[T]he Office of the Assistant Secretary for Health found that more than **30,000 HCPs [Healthcare Providers] are authorized to recommend the use of marijuana for more than six million registered patients**, constituting widespread clinical experience associated with various medical conditions recognized by a substantial number of jurisdictions across the United States. For several jurisdictions, these programs have been in place for several years and include features that actively monitor medical use and product quality characteristics of marijuana dispensed.



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA–1362]

RIN 1117–AB77

Schedules of Controlled Substances: Rescheduling of Marijuana

AGENCY: Drug Enforcement Administration, Department of Justice.

- **DEA, DOJ: Notice of Proposed Rulemaking: Schedules of Controlled Substances: Rescheduling of Marijuana May 21, 2024**

The Medical Cannabis Amendment to the Commerce-Justice-Science (CJS) Appropriations bill, first passed in 2014, was meant to be a triage measure to stop raids and prosecutions while Congress dealt with federal medical cannabis policies. The amendment must be passed every year.

MEDICAL CANNABIS LAWS HAVE LIMITED FEDERAL PROTECTIONS

First passed by Congress in 2014 as the Rohrabacher-Farr Amendment, this amendment to the Commerce, Justice, & Science (CJS) Appropriations Bill created a "ceasefire" of federal interference in state medical cannabis laws.

> **None of the funds made available under this Act to the Department of Justice may be used**, with respect to any of the States of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming, or with respect to the District of Columbia, the Commonwealth of the Northern Mariana Islands, the United States Virgin Islands, Guam, or Puerto Rico, **to prevent any of them from implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana**.

QUANTITY	1st OFFENSE	2nd OFFENSE *
1,000 kg or more marijuana mixture; or 1,000 or more marijuana plants	Not less than 10 yrs. or more than life. If death or serious bodily injury, not less than 20 yrs., or more than life. Fine not more than life. Fine not more than $10 million if an individual, $50 million if other than an individual.	Not less than 20 yrs. or more than life. If death or serious bodily injury, life imprisonment. Fine not more than $20 moillion if an individual, $75 million if other than an individual.
100 kg to 999 kg marijuana mixture; or 100 to 999 marijuana plants	Not less than 5 yrs. or more than 40 yrs. If death or serious bodily injury, not less than 20 yrs., or more than life. Fine not more than life. Fine not more than $5 million if an individual, $25 million if other than an individual.	Not less than 10 yrs. or more than life. If death or serious bodily injury, life imprisonment. Fine not more than $20 moillion if an individual, $75 million if other than an individual.
More than 10 kgs hashish; 50 to 99 kg marijuana mixture More than 1 kg of hashish oil; 50 to 99 marijuana plants	Not less than 20 yrs. If death or serious bodily injury, not less than 20 yrs., or more than life. Fine $1 million if an individual, $5 million if other than an individual.	Not less than 30 yrs. If death or serious bodily injury, life imprisonment. Fine $2 million if an individual, $10 million if other than an individual.
Less than 50 kilograms marijuana (but does not include 50 or more marijuana plants regardless of weight) marijuana plants;	Not less than 5 yrs. Fine not more than $250,000, $1 million if other than an individual	Not less than 10 yrs. Fine $500,000 if an individual, $2 million if other than individual

The Hemp Authorization of the 2018 Farm Bill removed cannabis with <.3% THC from the CSA and failed to define "hemp products." The bill implied that the Food and Drug Administration (FDA) would regulate these products; however, in January 2023, the FDA told Congress they do not have the authority to regulate the products without new authorities.

CURRENT STATE OF CANNABIS PRODUCTS AVAILABLE IN U.S. MARKETS

REGULATED STATE MARKETS

&

UNREGULATED HEMP MARKET

WHITE PAPER

The Great Hemp Hoax:

Much of what's sold as "hemp" today isn't hemp at all — it's a mix of synthetic intoxicants and illicit THC masquerading as a legal, natural product.

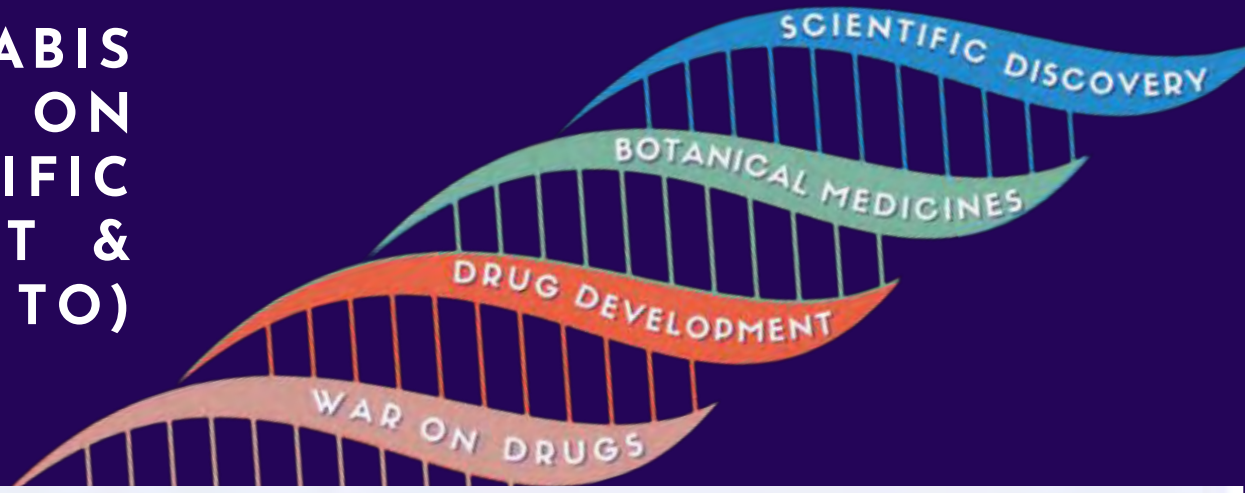
RESTORE PATIENTS' RIGHTS

DENIAL OF SERVICES	Federal prohibition prevents medical cannabis patients from accessing services such as subsidized housing, Veterans Affairs benefits, and Medicare.
PURSUIT OF HAPPINESS	Federal cannabis laws restrict the geographical mobility of patients, affecting their ability to travel, relocate for work, or pursue higher education.
HEALTHCARE AUTONOMY	Federal restrictions also extend to healthcare settings, where cannabis use is frequently prohibited in hospitals, hospices, and assisted living facilities.
ADA	Medical cannabis patients are not protected under the Americans with Disabilities Act (ADA) or the Fair Housing Act (FHA).
2ND AMENDMENT RIGHTS	Federal laws restrict the rights of medical cannabis patients to own firearms, conflating responsible medical use with unlawful drug use.

The U.S. Department of Health and Human Services has concluded that **cannabis has "accepted medical use in treatment in the United States."**

It is up to Congress to ensure that patients and their medical professionals have safe access.

THE U.S. HISTORY OF CANNABIS MEDICINES INCLUDES THE WAR ON DRUGS, THE EVOLUTION OF SCIENTIFIC DISCOVERY & DRUG DEVELOPMENT & U.S. MOVE AWAY FROM (& BACK TO) HERBAL MEDICINES.



1804 — 1st active ingredient to be isolated from plant- morphine from opium

1850 — Cannabis in U.S. Pharmacopeia

1906 — Pure Food & Drugs Act: created FDA

1906 — Ehrlich's "magic bullet" concept,- 1st single targeted therapy, Salvarsan

1913 — Eli Lily's Cannabis tincture on market

1937 — Marihuana Tax Act passed,

1942 — Cannabis removed US Pharmacopeia

1962 — Kefauver-Harris Drug Amendments- Proof of efficacy to FDA before marketing them

1964 — THC First Identified & Synthesized

1971 — Controlled Substances Act passed-Cannabis classified "No Accepted Medical Use"

1975 — Scientist discover "enkephalin" 1st endorphin: endogenous opioid peptides.

1978 — Federal Government IND Compassionate Use Program Supplies Patients with Cannabis

1992 — Scientists Discover 1st Endocannabinoid

2014 — CJS Amendment

2023 — HHS Finds Cannabis has "accepted medical use"

1996-2024 — 49 states passed medical cannabis laws/ 39 full access

1916 — 40% of official medicinal preparations in U.S. Pharmacopeia were crude plant extracts (299 preparations)

1950 — 19% of official medicinal preparations in U.S. Pharmacopeia were crude plant extracts

1990 — < 1% of official medicinal preparations in U.S. Pharmacopeia were crude plant extracts

2024 — 3% of official medicinal preparations in U.S. Pharmacopeia were crude plant extracts

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WHAT IS THE FUTURE FOR MEDICAL CANNABIS?

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Q:

What does integration of cannabis into U.S. healthcare systems mean?

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A:

- ✓ CMS-Medicare Coverage, VHA-Veterans Access
- ✓ Prescriptions (no ID card costs)
- ✓ Use of cannabis in hospitals, hospices, and assisted living facilities
- ✓ Available at pharmacies
- ✓ Protections under the ADA, Fair Housing Act
- ✓ Product availability
- ✓ Insurance coverage
- ✓ Consumer protection rights
- ✓ Standardized medical professional education and training
- ✓ Dispensing standards

Q: What does the MCCA do?

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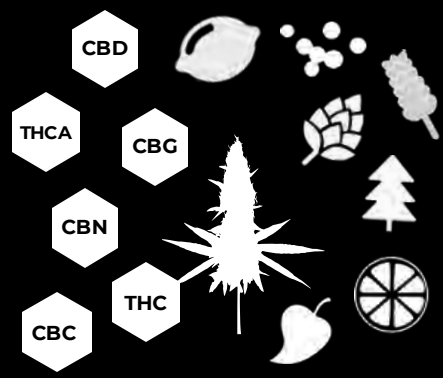
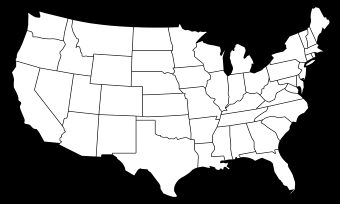
Advancing Legal Medical Cannabis Therapeutics

THE MEDICAL CANNABIS & CANNABINOID ACT



TRANSITION FROM COMPASSIONATE USE TO HEALTHCARE INTEGRATION

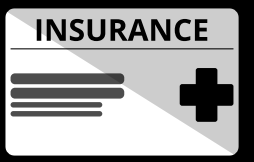


HEALTH CLAIMS & DOSAGE

STANDARDIZE TERMINOLOGY

PRODUCT PROTOCOLS

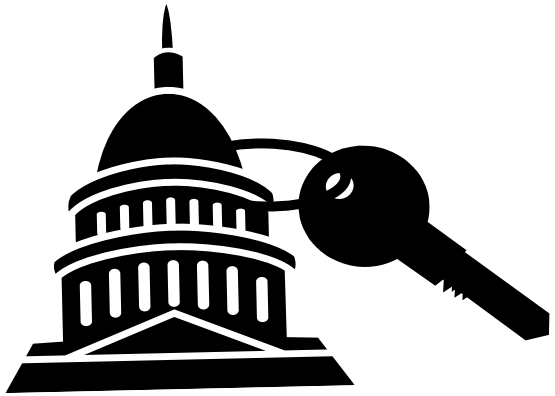
RESEARCH TOOLS



A

B

A: ASA



The Medical Cannabis & Cannabinoid Act (MCCA) creates a national medical cannabis through two primary functions: changing the schedule of cannabis to a newly created schedule (Schedule VI), and creating the **Office of Medical Cannabis & Cannabinoid Control (OMC)** housed under the U.S. Department of Health and Human Services (HHS).

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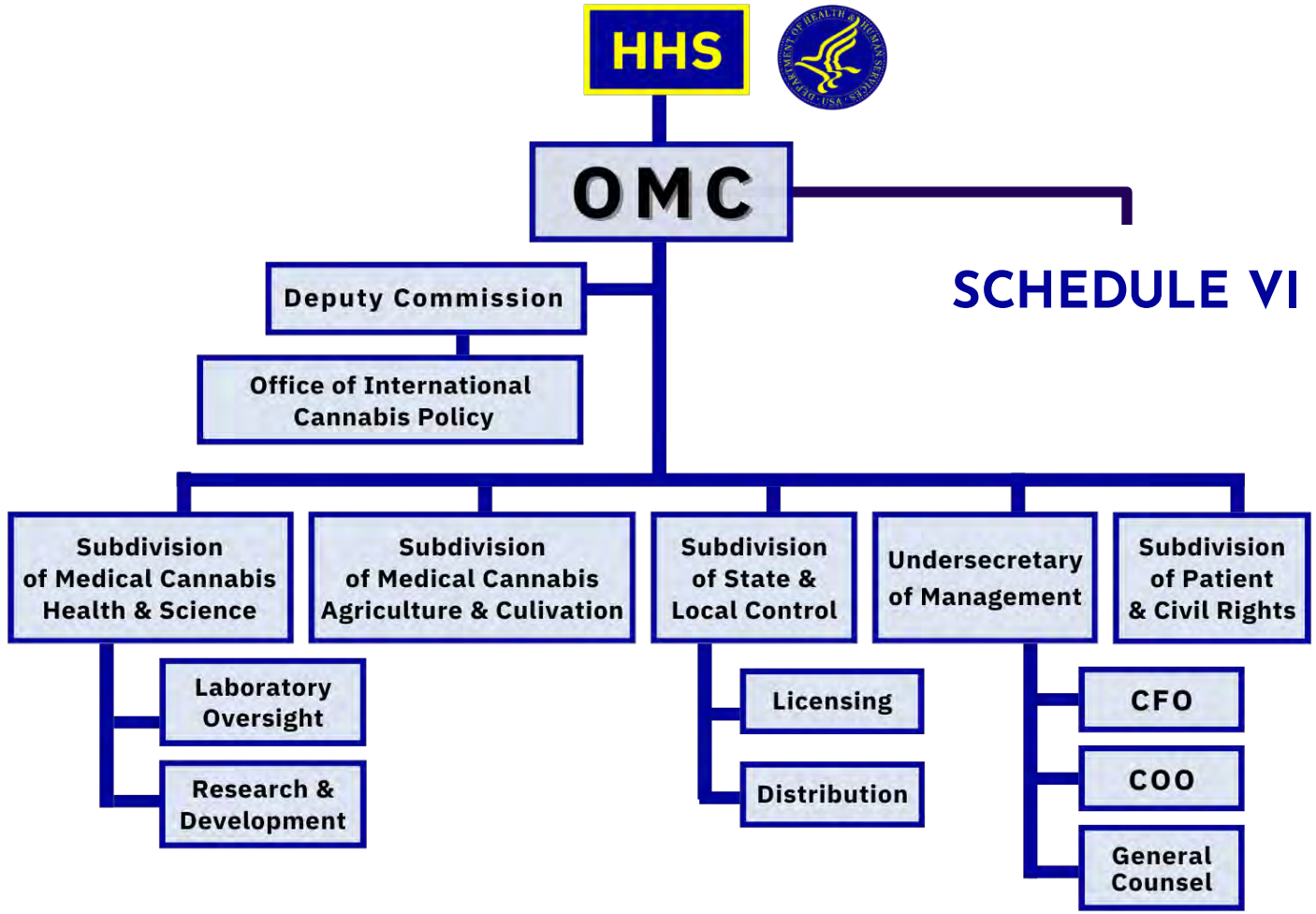
The Office of Medical Cannabis & Cannabinoid Control's mission is to facilitate access to medical cannabis for therapeutic use & research, regulate the production of medical cannabis & cannabinoid products, & oversee the new Schedule VI.

Housed in HHS

Brings US in compliance with UN Drug Treaties

Coordinates cannabis matters across federal agencies & with state regulators

Funded by agency reorganization, licensing & permitting fees, & public-private partnerships



SCHEDULE VI (& SCHEDULE VI-A)

- Regulated by OMC.
- Covers ALL cannabinoid products intended for human and animal consumption.
- Includes oversight for non-intoxicating cannabinoid products (Schedule VI-A).
- Laboratory, pharmacy, research and transportation permitting and cultivation, manufacturing, and distribution licensing (no restrictions for prior drug convictions for permits or licenses).
- Schedule VI permits granted to state licensed medical cultivators and manufactures in Phase 1 for continuity of access.
- Schedule VI specialty pharmacy licenses for access points/dispensaries.
- Interstate commerce allowed between VI permitted/licensed businesses.
- No criminal penalties associated with Schedule VI.
- Patients would have all protections granted to any other prescription recipient.
- OMC will create policy to transform state-based "physician recommendations" to specialized prescriptions.

NATIONAL CANNABIS PROGRAM ROLE OUT

Title I- Office of Medical Cannabis & Cannabinoid Control
Sec. 801: Amend Controlled Substance Act
Sec. 802- Amend Hemp Authorization Act.

FIRST 60 DAYS

- New Schedule Created: Schedule VI
- Office of Cannabis & Cannabinoid Control (OMC) established
- Commissioner & Under Secretory of OMC Appointed
- Direct agencies to update cannabis policies
- Provisional Schedule, VI & specialty pharmacy permits, issued with protocols for interstate distribution

Sec. 602- Notification to Agencies
Title VII- Implementation
Sec. 604- Continuity of care
Sec. 603- Reorganization Plan
Sec. 705– Advisory Committee

GUIDANCE FOR FEDERAL AGENCIES

HOUSING & URBAN DEVELOPMENT- Exempt the medical use of cannabis from drug-free housing policies & tax credits.

VETERAN AFFAIRS-Update policies to allow agency physicians to recommend medical cannabis, amend polices that impact VA benefits, & add cannabis therapeutics to intake forms.

OFFICE OF PERSONAL MANAGEMENT- Update hiring and employment policies concerning past or current cannabis use & create process for agencies to reinstate or appeal past actions.

DEPARTMENT OF JUSTICE- Review & formalize guidelines in 2013 DOJ Cole Memo & expunge all non-violent federal cannabis convictions & adjudications for & any arrests associated with each.

TRANSPORTATION SECURITY ADMINISTRATION-Cannabis does not need to be confiscated

BUREAU OF ALCOHOL, TOBACCO, FIREARMS & EXPLOSIVES- Remove cannabis warning from Form 4473

INTERNAL REVENUE SERVICE- Permit medical cannabis businesses with Schedule VI permits/licenses to file as legal business & create process for these business to refile tax returns with deductions to lower or eliminate tax debt.

GUIDANCE FOR FEDERAL AGENCIES

HEALTH & HUMAN SERVICES–Inform hospitals, health clinics, rehabilitation centers, hospice services providers, their medical professionals, or any other patient service provider that participating in medical cannabis programs or allowing clients/patients in their care to lawfully possess and/or consume cannabis products will not jeopardize HHS funding or any accreditations.

DEPARTMENT OF THE TREASURY- Provide guidance for financial institutions on providing banking services, loans, & any other financial services to Schedule VI licensed businesses.

THE STATE DEPARTMENT- Work visa eligibility includes employment with any business with a Schedule VI permit/license.

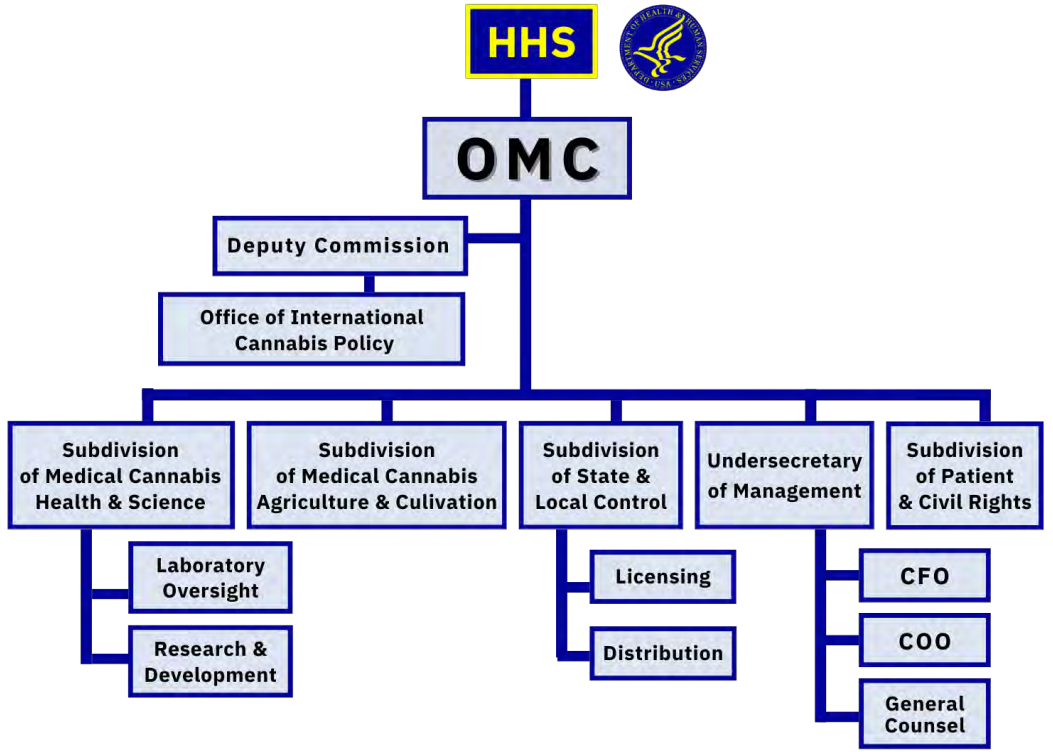
FOOD & DRUG ADMINISTRATION- Issue requirements for products containing cannabinoids to include 1) source of the cannabinoid 2) "The safety of this product has not been evaluated by the FDA" 3) "This product has not been tested for contaminates" or a QR code to Certificate of Analysis & 4) Batch number on labels.

ALL FEDERAL AGENCIES- Cannabis is no longer a factor for federal employees, contactors or officers.

NATIONAL CANNABIS PROGRAM ROLE OUT

FIRST 12 MONTHS

- Agency Staffed
- Schedule VI licensing program launched
- Advisory groups seated
- Initiate research priority map with NIH
- OTC guidelines for cannabinoid products
- Determination of NDA requirements for synthetic cannabinoid & terpene products
- Establish a safe additive list for Schedule VI products
- Labeling, research, & testing requirements for Schedule VI products established



Title I, Title II, Title III, Title IV, Sec. 404, Title V, Sec. 501, & Sec. 504-Staffing Subdivisions

Sec. 303- Transfer Of Functions
Sec. 305- Cannabis Production; State &Tribal Plans
Sec. 306- Effect on Industrial Hemp
Sec. 701- Licensing & Permits; General Provisions
Sec. 702- Specialty Licensing

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NATIONAL CANNABIS PROGRAM ROLE OUT

Sec. 701- Licensing & Permits
Title VI- Transition Subtitle A- Coordination with Agencies

Sec. 306- Effect on Industrial Hemp
Sec. 701- (d) Imports, Exports
Sec. 204- Research & Development Center
Sec. 704– Prescription Protocols

FIRST 24 MONTHS

- Guidance for "prescription system" & importation/exportation of Schedule VI ingredients & products issued
- Guidance to Centers for Medicare & Medicaid Services for Schedule VI product coverage
- OMC establishes private-public partnerships for research with NIH
- Each federal DOJ district completes comprehensive review & expungement of all adjudicated & non-adjudicated cannabis cases
- Initiate process for producing guidance document for health claims for Schedule VI products issued
- Guidance for environmental impact & sustainable agricultural practices

NIH

USDA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

SBA

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NATIONAL CANNABIS PROGRAM

PHASE I

= FINISHED PRODUCTS

= RAW INGREDIENTS

= PERMITTED BY STATE

= SCHEDULE VI PROVISIONAL PERMIT

= STATE/TRIBAL LICENSE

CULTIVATION

PROCESSORS

MANUFACTURERS

OMC

Schedule VI products with permits can move across US between permitted businesses

REQUIRE

(except B2B Transport)

TESTING LABS

B2B TRANSPORT

RESEARCHERS

HOME CULTIVATION

STATE-ID CARDS REMAIN VALID

DISPENSARY

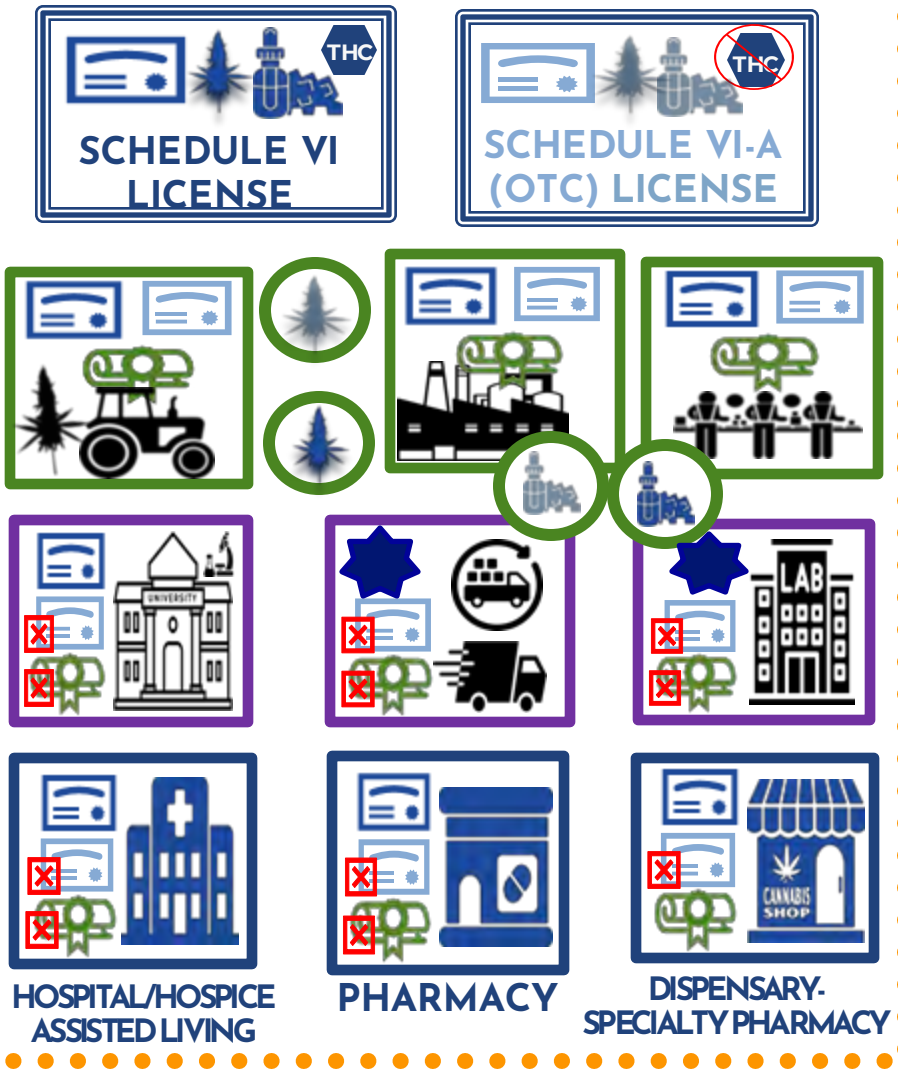
HOSPITAL/'HOSPICE ASSISTED LIVING

CBD & Hemp derived products will remain available in retail markets as they transition into regulated market.

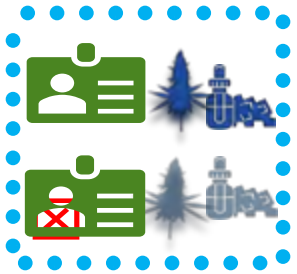
NATIONAL CANNABIS PROGRAM

PHASE II

SCHEDULE VI
LICENSES & PERMITS



STATE ID CARDS REMAIN IN EFFECT



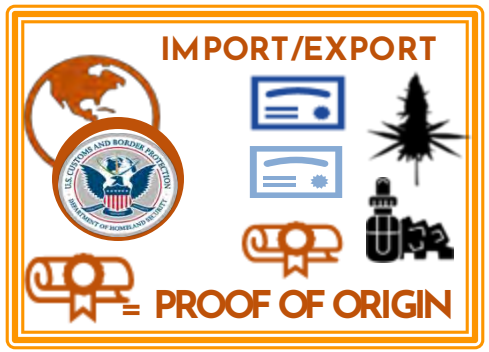
HOME CULTIVATION

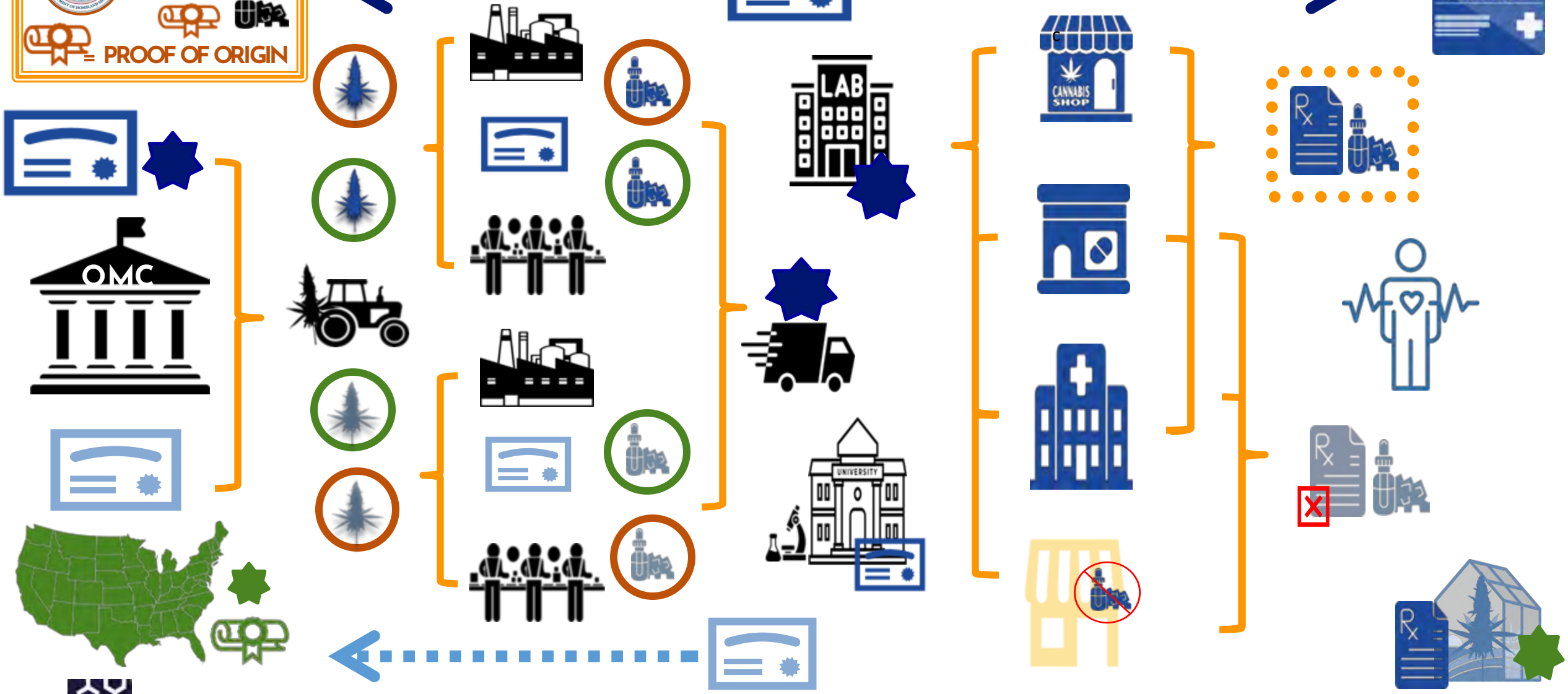
RETAIL OUTLETS

Schedule VI-A
License is not required for retailers, but selling unregulated Schedule VI products carries fines.

NATIONAL CANNABIS PROGRAM

PHASE III





OMC STRUCTURE & AGENCY TRANSITION

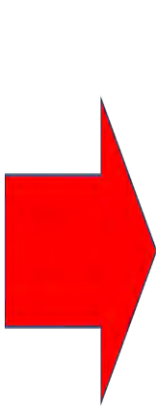
Sec. 603- Reorganization Plan

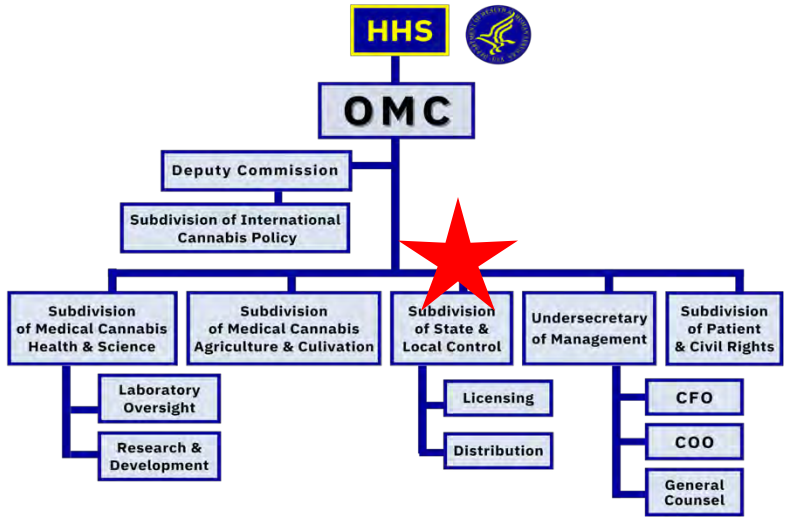
TITLE VII- Implementation

Sec. 305- Cannabis Production; State & Tribal Plans

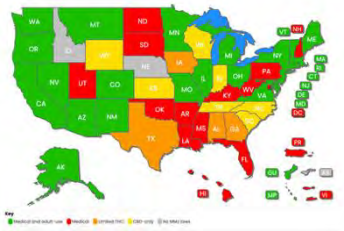
Sec. 705– Advisory Committee

SEC. 501- SUBDIVISION OF TRIBAL, STATE, & LOCAL CONTROL





- Work with state regulators on Schedule VI Permits for state licensed medical cannabis businesses
- Create protocols for interstate sales & transportation
- Create vendor/licensee database

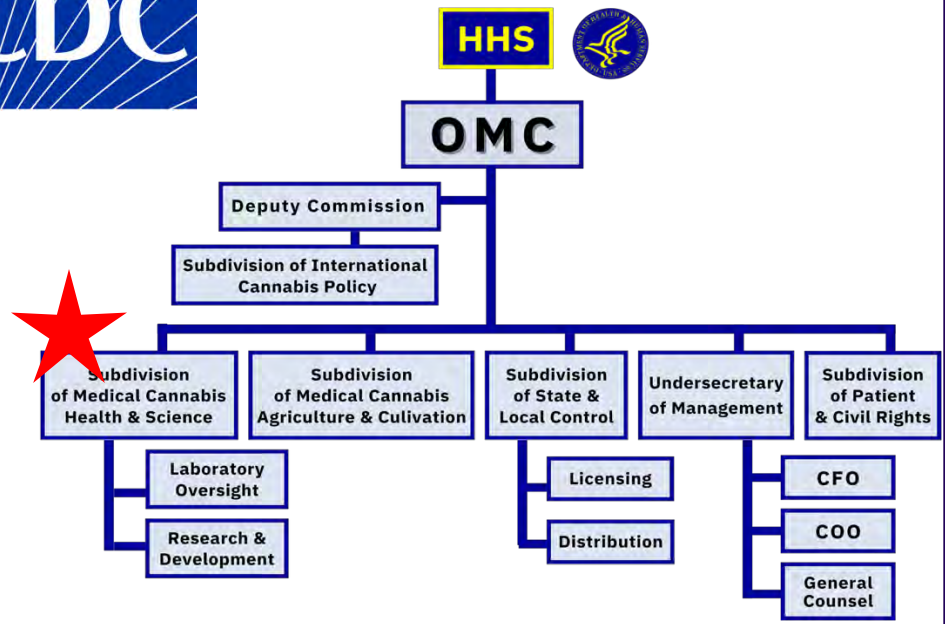


TITLE II- SUBDIVISION OF MEDICAL CANNABIS HEALTH & SCIENCE

OMC STRUCTURE & AGENCY TRANSITION

Sec. 201-206
Sec. 603- Reorganization Plan
Title VII- Implementation
Sec. 704– Prescription Protocols
Sec. 205 Research, Testing, & Evaluation
Sec. 705– Advisory Committee

- Work across agencies to create & fund research priority map
- Spearhead guidelines for standardization of testing & labeling
- Issue permits to laboratories for cannabis (schedule VI)
- Create prescription protocols & educate physicians



OMC STRUCTURE & AGENCY TRANSITION

Sec. 301-306

Sec. 603- Reorganization Plan

TITLE VII- Implementation

Sec. 305- Cannabis Production; State & Tribal Plans

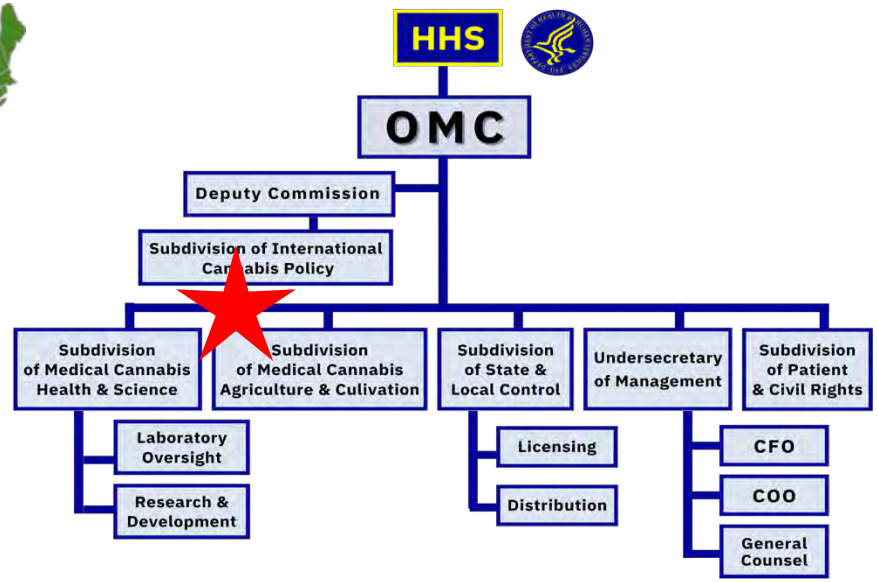
TITLE III- SUBDIVISION OF MEDICAL CANNABIS CULTIVATION & AGRICULTURE

NIDA NATIONAL INSTITUTE ON DRUG ABUSE

OMC

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

USDA



U.S. JUSTICE DEPARTMENT DRUG ENFORCEMENT ADMINISTRATION

- Work across agencies to create seed registry
- Pesticides guidance for cannabis for human consumption
- Train inspectors
- Create research & marketing orders

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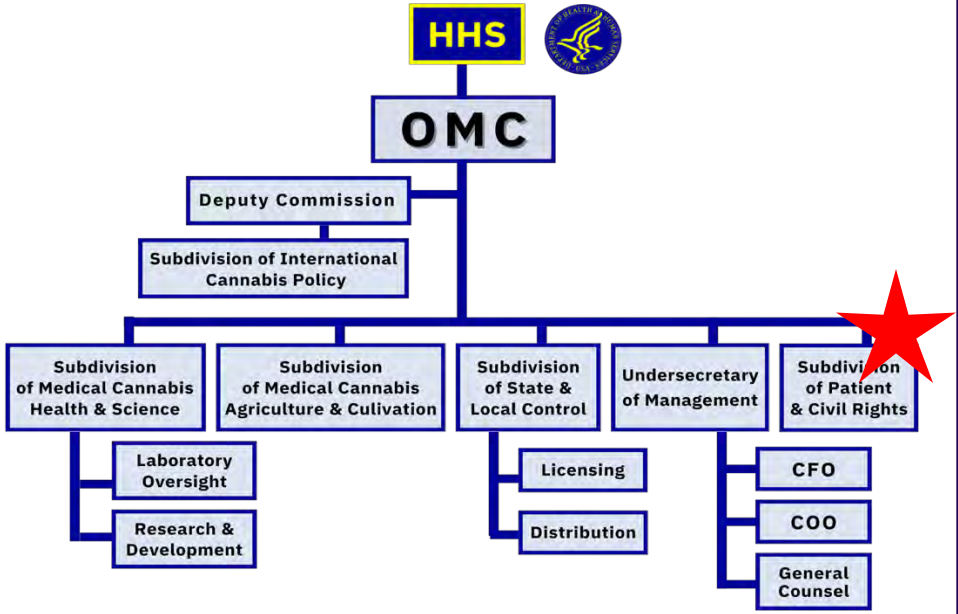
OMC STRUCTURE & AGENCY TRANSITION

Sec. 603- Reorganization Plan

Title VII- Implementation

SEC. 404- SUBDIVISION OF PATIENT & CIVIL RIGHTS

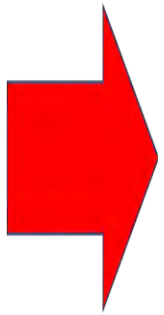


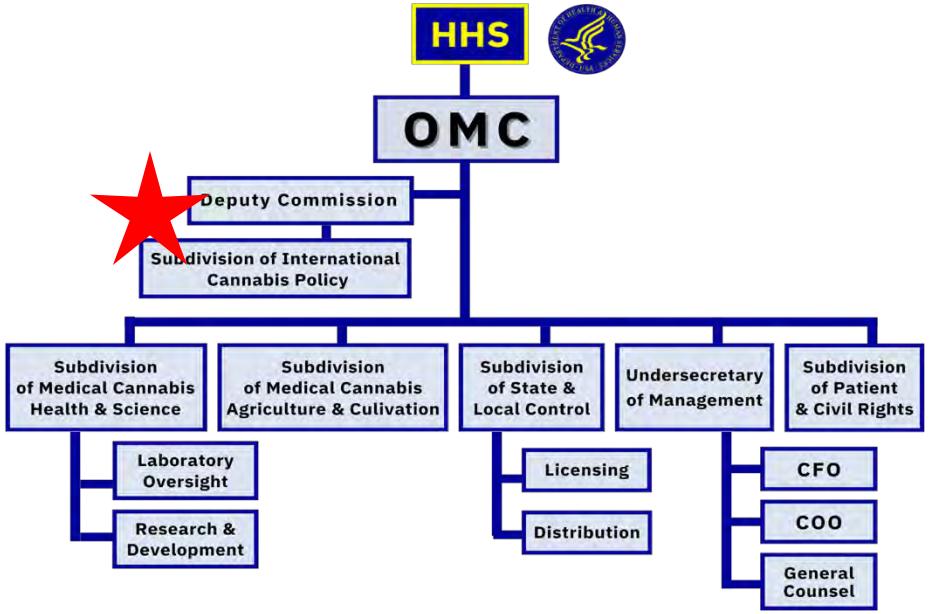
- Review & monitor the implementation to ensure patient rights are protected
- Work across agencies to ensure that patient rights are included in their policies
- Work with CMS to ensure cannabis medications are covered

SEC. 504-OFFICE OF INTERNATIONAL POLICY

OMC STRUCTURE & AGENCY TRANSITION

Sec. 603- Reorganization Plan
TITLE VII- Implementation
Sec. 701- (d) Imports, Exports





NIDA
NATIONAL INSTITUTE ON DRUG ABUSE

- OMC designated agency for Cannabis under UN single treaty
- Report to INCB on cannabis
- Establish & oversee cannabis/cannabinoid import/export procedures

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Q: WHY SCHEDULE VI?

Americans for Safe Access
Advancing Legal Medical Cannabis Therapeutics

WHY SCHEDULE VI?

CANNABIS FEDERAL CLASSIFICATION	SCHEDULE I	SCHEDULE III	DE SCHEDULE	SCHEDULE VI
Recognizes Medical Use of Cannabis		✓		✓
Regulates Cannabinoid & "Hemp Product" Market				✓
Harmonizes State & Federal Medical Cannabis Laws				✓
Removes Criminal Penalties for Cannabis Possession			✓	✓
Removes Criminal Penalties for Cannabis Cultivation & Distribution			✓	✓
Increases & Improves Patient Access				✓
Ensures Employment Protections				✓
Ensures Housing Protections				✓
Ensures Healthcare Rights				✓
Improves Access to Cannabis for Research		✓	✓	✓
Improves Quality of Cannabis Research				✓
Levels the Playing field for Research, Development, & Innovation				✓
Ensures Product Safety Across the Supply Chain				✓
Expands U.S. Definition of Medicine				✓

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A: ASA

Cannabis was placed in Schedule I as a political decision in 1970, not based on scientific evidence. Creating Schedule VI will correct this historical wrong, allowing cannabis to be classified based on its actual medicinal value and safety profile.

A: ASA

Cannabis is a complex botanical medicine with multiple active compounds that interact with the body in unique ways. A new Schedule VI will recognize its distinct nature, allowing for appropriate regulation that doesn't force it into an ill-fitting category designed for synthetic and single-compound drugs.

A: ASA

Creating Schedule VI acknowledges that cannabis is not just another drug—it's a botanical medicine with a unique profile. By placing cannabis in its own category, Schedule VI would allow for regulations tailored to its specific properties and uses.

CLEAR LEGISLATIVE INTENT

DEA is involved with all other schedules. The MCCA creates a new schedule under OMC oversight, moving cannabis and cannabinoids away from the DEA completely.

All of the current schedules are associated with penalties in other statutes. A new schedule is a clean slate.

DESCHEDULING DOES NOT MEAN AN UNREGULATED FREE MARKET

The laissez-faire relationship both Hemp and Cannabis have at the federal level is not going to last, and if we do not create an oversight body to treat cannabis differently than prescription drugs, tobacco, or alcohol, then all cannabis plant stakeholders will lose. The financial pressures on those driving the cannabis and hemp markets have replaced long-term vision with inaccurate soundbites to generate headlines for the next quarter.

DESCHEDULING DOES NOT MEAN DECRIMINALIZATION

The Controlled Substances Act (CSA) is only one section of criminal law statutes. If cannabis is regulated under the FDA like tobacco, it would be descheduled. However, any possession, cultivation, manufacturing, or distribution outside of the narrow allowance of the FDA would be subject to criminal penalties.

THE NEED FOR CODIFICATION

In reality, simply descheduling cannabis does little to protect patients or their rights. Without Scheudle-VI status (or another form of medical codification), nothing would prevent states from treating patients as criminals. Descheduling removes cannabis from the CSA and leaves regulation to the states, a unique and inconsistent approach for a medicinal product.

Q: WHY A NEW AGENCY?

ISN'T THIS ADMINISTRATION TRYING TO KILL AGENCIES?

Americans for Safe Access
Advancing Legal Medical Cannabis Therapeutics

The current administration is focusing on "efficiency," and while that may mean "killing" or "gutting" some agencies, it also involves creating new agencies, like the creation of DOGE.

FUNDS for OMC

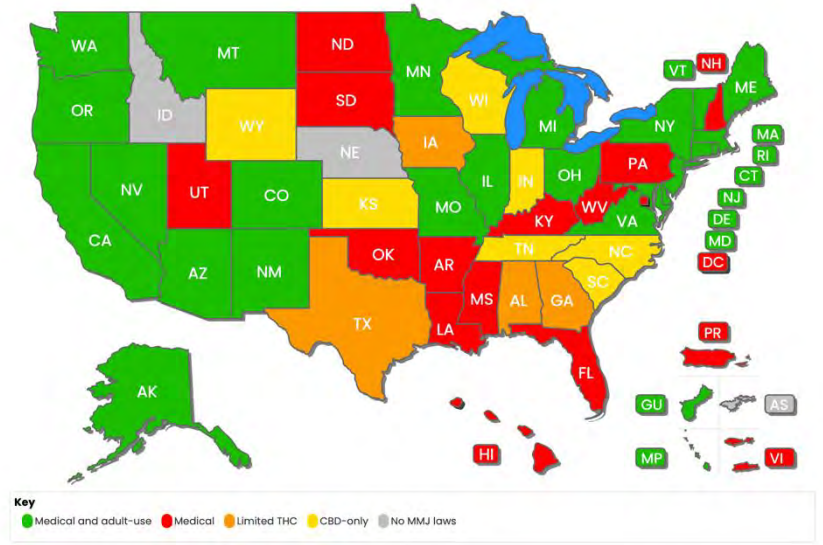
1) The reorganization of federal funding for cannabis

2) Licensing fees

3) Private-public partnerships for research.

Medical Cannabis represents a new product type (not a dietary supplement, foodstuffs, FDA-approved drug, etc.) with a supply chain that falls under several agencies; efficiently enforcing regulations would require an agency with the power of oversight.

The regulation of cannabis medicine is not simply enforcing regulations but also overseeing research to improve product development and inform standards of care. FDA and USDA deal with finished products, and NIH oversees research. OMC will do both by directing FDA, USDA, and NIH.

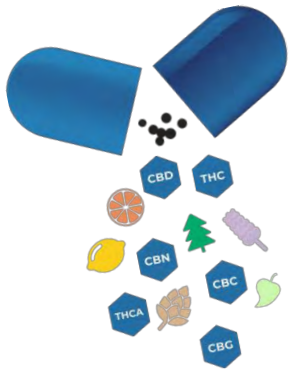


WHY A NEW AGENCY?

ASA


Controlled
FDA
ubstances Ac

NO FDA PATHWAY FOR COMPLEX BOTANICAL MEDICINES



Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

January 2023
Pharmaceutical Quality/Chemistry, Manufacturing, and Controls (CMC)

Drug Master Files

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Rick Ensor 240-402-2733, or (CBER) Office of Communication, Outreach and Development: 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

October 2019
Pharmaceutical Quality/CMC

Revision 1

Botanical Drug Development

Guidance for Industry

"The Agency recognizes the technical challenges in determining standard pharmacokinetic measurements of systemic exposure because a botanical drug product often consists of more than one chemical constituent and the active constituents may not be identified" page 14.

"The Agency recognizes that demonstrating each botanical raw material's contribution to safety and efficacy in a product with multiple botanical raw materials may not always be feasible" page 22.

ASA

A: This is what is outlined in the UN Single Drug Treaties, a model that is followed by most countries with national medical cannabis programs.

Report of the International Narcotics Control Board (INCB) for 2022: "Following the recommendation of WHO, the Commission on Narcotic Drugs decided in December 2020 to remove cannabis and cannabis resin from Schedule IV of the 1961 Convention…As far as the specific control measures for cannabis are observed, these medical cannabis programmes are in compliance with the conventions."

21 USC 811 **(d)INTERNATIONAL TREATIES, CONVENTIONS, AND PROTOCOLS REQUIRING CONTROL; PROCEDURES RESPECTING CHANGES IN DRUG SCHEDULES OF CONVENTION ON PSYCHOTROPIC SUBSTANCES(1)**If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section.

Q: WHY NOT CONTINUE WITH STATE-BASED LEGALIZATION & REGULATION?

Americans for Safe Access
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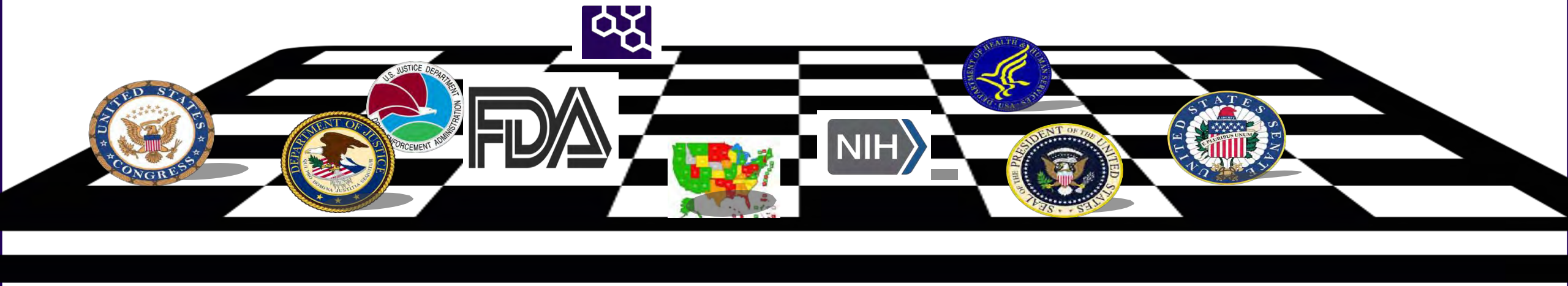


20+ YEARS PATIENTS WORK TOWARD A NATIONAL MEDICAL CANNABIS PROGRAM

A: ASA

State programs were never the goal of the medical cannabis movement. Medical cannabis programs were established as temporary measures to provide immediate relief to patients amidst the War on Drugs while we removed barriers at the federal level. HHS and FDA finding that cannabis has accepted medical use is the milestone we needed to move to a national medical cannabis program.

PATIENT ACCESS

Geography & economic status leave millions out of the programs.

State programs leave many patients vulnerable to the impact of prohibition.

Federal employees, contractors, & active military are left out of this system.

9,000,000	VETERANS USING VA HEALTH SERVICES
1,870,000	FEDERAL EMPLOYEES
112,846,000	AMERICANS LIVING WITH CHRONIC PAIN
2,100,000	AMERICANS IN SECTION 8 HOUSING (23% ARE DISABLED)
1,720,000	AMERICANS IN HOSPICE
630,000	US POSTAL WORKERS
37,900,000	AMERICANS LIVING IN POVERTY

PATIENT ACCESS

Medical cannabis patients can be evicted from federally funded housing, denied employment due to drug tests, and parents can face child custody challenges due to their patient status.

STATES HAVE FULFILLED THEIR ROLE AS "LABORATORIES OF DEMOCRACY"

STATE PROGRAMS ARE NOT MEETING PATIENTS' NEEDS

Initially created as "triage" to remove patients off the battlefield of the war on drugs, the state cannabis access experiment has run its course.

ASA

PATIENT ACCESS

Medical cannabis patients are excluded from protections under the Americans with Disabilities Act (ADA), further reinforcing inequality and rights afforded under the 2nd Amendment.

Veterans face additional barriers and stigma within the VA healthcare system due to their medical cannabis use.

PATIENT ACCESS

The ongoing federal prohibition of cannabis leaves patients vulnerable to safety risks, inconsistent product quality, and exposure to harmful substances. Patients relying on state programs face a patchwork of regulations and often lack access to safe, consistent products.

PATIENT ACCESS

Federal prohibition stifles the development of a unified regulatory framework, leading to insufficient consumer protections, inconsistent labeling standards, and a hodgepodge system that will eventually hinder interstate commerce.

PATIENT ACCESS

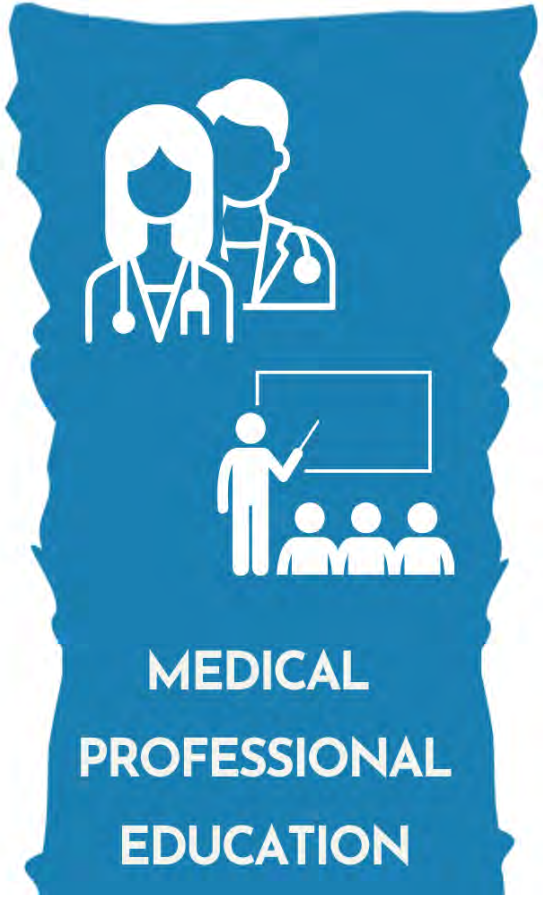
The lack of federal guidance also results in unreliable and inadequate knowledge about medical cannabis, both among the public and among healthcare professionals.

PRODUCT DEVELOPMENT

Geo-fencing the supply chain and the addressable market handicaps businesses' ability to survive financially.

Geo-fencing makes investments in R&D virtually impossible.

CLOSE GAPS TO IMPROVE PATIENT OUTCOMES



STATES ARE MERGING ADULT USE & MEDICAL CANNABIS PROGRAMS TO THE DETRIMENT OF PATIENTS

PROVIDERS MOVE TO SERVE ADULT-USE CONSUMERS.

Suppositories, sublinguals, high-CBD/low THC, 50/50 CBD/THC, & other cannabinoid profiles disappear.

DISCRIMINATION & STIGMA Adult-use laws do not include civil protections.

Excludes 18-21-year-old & pediatric patients.

LIMITED ACCESS: Cities frequently ban adult-use retail. Quantity restrictions don't accommodate patient needs.

Patients need access to experts to help guide them toward the right products & dosing guidelines.

Q: What happens to Adult Use programs under MCCA?

Americans for Safe Access
Advancing Legal Medical Cannabis Therapeutics

Nothing directly. However, MCCA does decriminalize cannabis.

Q: What happens to CBD & State Programs?

Americans for Safe Access
Advancing Legal Medical Cannabis Therapeutics

WHAT HAPPENS TO CBD?

Under the MCCA, **CBD and other hemp-derived cannabinoids remain available** to patients and consumers during the transition to federal oversight. CBD products will still be sold in retail stores but will now be subject to **basic federal labeling and safety disclosure requirements**.

Labels would include:

- The source of the cannabinoid (e.g., hemp extract)
- A statement noting whether the product has been evaluated for safety by the FDA
- A warning that the product has not been tested for contaminants or adulterants (or a QR code linking to a Certificate of Analysis)
- A batch number for tracking and transparency

WHAT HAPPENS TO CBD?

A:

All cannabis and cannabinoid-based products will be required to get a Schedule VI or Schedule VI-A permit from the Office of Medical Cannabis & Cannabinoid Control in coordination with the USDA or state agency.

Exceptions will include:

"non-cannabinoid containing products derived from the hemp plant, including industrial applications such as hempcrete, textiles, fiber, bioremediation, paper, plastics, fabric, and non-cannabinoid hemp products fit for human and animal consumption applications such as hemp seeds, hulls, hearts, terpenes, non-cannabinoid-hemp seed oil, animal feed, microgreens, leaf juicing, cosmetics, and fragrances" (Hemp products as defined by MCCA) and FDA-approved Cannabinoid Medicines.

These new requirements aim to help patients and consumers make informed choices and increase accountability in the market.

WHAT HAPPENS TO CBD?

Over the **long term**, OMC will issue guidance classifying botanical, synthetic or semi-synthetic cannabinoid products into three regulatory pathways:

Schedule VI-A (Over-the-Counter) For products with established safety profiles that can be taken without the supervision of a healthcare provider.

Schedule VI (Controlled Access): This applies to products with established safety profiles for clinical use that require supervision from a healthcare provider.

Schedule VI-B (Under evaluation): Products that have yet to demonstrate a safety profile (not health claims) will be required to do so before being distributed for human consumption. Some products currently in the marketplace may fall into this category.

ASA

WHAT HAPPENS TO STATE MEDICAL CANNABIS PROGRAMS?

The OMC will work in partnership with state regulators to issue **Schedule VI permits** to existing, licensed medical cannabis businesses. This ensures patients maintain access while states and the federal government coordinate efforts to improve safety, consistency, and access. Companies with dual licensing will have the option of serving the state adult-use market or getting a Schedule VI permit and serve a national patient market. Permitted dispensaries will qualify for Schedule VI specialty pharmacy license.

For patients and medical professionals, the enrollment protocols in each state will remain in place as the OMC develops protocols for something that looks more like a prescription. However, the protections associated with the ID card will be national and now fall under the Americans with Disabilities Act (ADA). They can also choose products from a national marketplace.

WHAT HAPPENS TO STATE MEDICAL CANNABIS PROGRAMS?

After all the "hemp-derived" companies and state-licensed producers opt in, the OMC will evaluate what additional licensing is needed to serve the national patient population and research needs. The OMC will then begin issuing Schedule VI licenses, transitioning from a state-by-state program to a national one.

As cannabis medicines integrate into U.S. healthcare, patients and healthcare providers will benefit from standardized product protocols—including labeling, testing, and product standardization.

Nothing in the MCCA precludes product manufacturers from seeking FDA approval through traditional drug development pathways.

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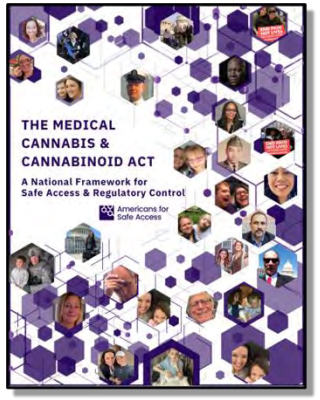

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