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Overview of the President's December 18th Executive Order and the Implications When Marijuana is Rescheduled to Schedule III under the U.S. Controlled Substances Act

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TOP-LINE SUMMARY

The President signed an Executive Order on December 18, 2025, ordering his administration to move expeditiously to reschedule marijuana to Schedule III under the U.S. Controlled Substances Act. A final rule to reschedule marijuana has not yet been issued by the Department of Justice. The timeline for a final rule remains unknown, and until there is a final rule, marijuana remains Schedule I.

Rescheduling marijuana to Schedule III will:

- Remove the applicability of section 280E of the federal tax code, allowing marijuana businesses to deduct all standard business expenses in accordance with federal law, even if the Schedule III marijuana product is not a U.S. Food and Drug Administration (FDA) approved drug.
- Potentially make it easier to obtain and maintain a U.S. Drug Enforcement Administration (DEA) registration as a Schedule III research facility to research marijuana.

Unless otherwise specified through new agency rules or policies, rescheduling marijuana will not:

- Change the federal status of state-regulated markets, which would remain non-compliant with U.S. federal law.
- Allow marijuana products that are not FDA-approved drugs to be prescribed by a doctor for a medical condition.
- Legalize interstate commerce. Interstate commerce of Schedule III drugs requires approval from the FDA, and necessary approvals and licenses under the Controlled Substances Act, as issued by DEA.
- Allow for the use of real-world cannabis products in human research, unless they meet FDA requirements for safety and quality through an Investigational New Drug (IND) Application.
- Change existing industry guidance from the Financial Crimes Enforcement Network (FinCEN), unless new guidance is released by the U.S. Department of Treasury.
- Change federal drug testing requirements, unless otherwise specified by appropriate federal agencies.
- Change criminal penalties for individuals found to be trafficking marijuana.

On December 18, 2025, the President signed an Executive Order entitled, "Increasing Medical Marijuana and Cannabidiol Research." Through the Executive Order the President orders:

1) The Attorney General (AG) to:
    a. Take all necessary steps to complete the rulemaking process related to rescheduling marijuana to Schedule III under the U.S. Controlled Substances Act (21 U.S.C.) in the most expeditious manner in accordance with Federal law, including 21 U.S.C. 811 *(which is the part of the U.S. Controlled Substances Act that authorizes the AG to issue a Final Order placing a substance in the Schedule the AG deems most appropriate while bypassing the procedures described by other subsections of the CSA in order to comply with international treaty obligations)*.
2) The Assistant to the President and Deputy Chief of Staff for Legislative, Political, and Public Affairs to work with Congress to:
    a. Update the statutory definition of final hemp-derived cannabinoid products to allow American to benefit from access to appropriate full-spectrum CBD products while preserving the Congress's intent to restrict the sale of products that pose serious health risks.

b. Consult with appropriate executive departments and agencies to develop a regulatory framework for hemp-derived cannabinoid products, including developing guidance on an upper limit of milligrams of THC per serving, with considerations on per container limits and CBD to THC ratio requirements.

3) The Secretary of Health and Human Services, the Commissioner of Food and Drugs, the Administrator of the Centers for Medicare and Medicaid Services, and the Director of the National Institutes of Health to develop research methods and models utilizing real-world evidence to improve access to hemp-derived cannabinoid products in accordance with Federal law and to inform standards of care.

While not part of the Executive Order, during the signing of the Executive Order, the President and the Administrator of the Centers for Medicare and Medicaid Services (CMS) announced a pilot program that would launch in the next year through the CMS Innovation Center (which exists to design, test, and expand new healthcare delivery and payment models without requiring congressional approval) to provide reimbursement to some Medicare patients for certain CBD treatments. Details about this program have not been released by CMS.

WHAT REMAINS UNKNOWN FOLLOWING THE EXECUTIVE ORDER?

What the process and timeline will be for a Final Rule on the Schedule III designation. There are a few possible approaches the Attorney General and the U.S. Department of Justice (DOJ) could take to implement the President's order to complete the rulemaking process for rescheduling. It is not yet known which approach they will take. *Marijuana remains Schedule I until the DOJ files and implements a Final Rule that indicates otherwise.*

What litigation will follow a final rescheduling rule, and what impact litigation will have on the implementation of the rule.

Whether Congress will act to change federal law to amend the recently enacted definition of *final hemp-derived cannabinoid product* or to establish a regulatory framework for hemp-derived cannabinoid products or full spectrum CBD products. It should be noted that "full spectrum" is not defined in federal law.

What new agency rules or policies will follow the Executive Order, such as those related to employee drug testing or to research standards utilizing real world data.

The details of the CMS Innovation Center Pilot Program that was outlined by the President and the CMS Administrated for CBD reimbursement for some patients under Medicare, including details about patient eligibility and eligible product criteria for the pilot.

The timing and process for designated health agencies to establish guidance on an upper limit of milligrams of THC per serving, with considerations on per container limits and CBD to THC ratio requirements.

WHAT WILL MOVING MARIJUANA TO SCHEDULE III UNDER THE CONTROLLED SUBSTANCES ACT MEAN?

Drugs and substances are classified into 5 schedules under the U.S. Controlled Substances Act depending on the drug's acceptable medical use and the abuse or dependence potential of the drug. Schedule I drugs have no currently accepted medical use and have the highest potential for abuse and the potential to create severe psychological and/or physical dependence; Schedule V drugs have currently accepted medical use and have the lowest potential for abuse in terms of scheduled drugs. Schedule III drugs and substances are those defined as having currently accepted medical use in the U.S. and as having less potential for physical and psychological dependence than Schedule II drugs.

Most controlled substances that are Schedules II-V need a prescription for patient access, however, not all controlled drugs are prescription only. Unless otherwise specified by agency policy or rule, all substances Schedules II-V require U.S. Food and Drug Administration (FDA) approval, regardless of whether they are prescribed or available over the counter.

WHAT WILL HAPPEN TO STATE-REGULATED MARIJUANA MARKETS UNDER SCHEDULE III?

State-regulated marijuana markets are not dispensing FDA-approved drugs, so it is likely that very little will change with regard to their structure and function. They will continue to operate under state laws and remain noncompliant with federal laws.

Will all state-regulated marijuana products be required to be accessed through a pharmacy?

No – not unless new guidance, rules, or policies are released by relevant federal agencies. State-regulated marijuana products are not FDA-approved drugs, they do not meet current requirements as prescribed Schedule III drugs. FDA approved drugs typically require three phases of clinical trials and a final approval determining the drugs are safe and effective to treat a specific indication or condition. Furthermore, any pharmacy that dispenses federally approved prescription drugs, including Scheduled drugs, requires a U.S. Drug Enforcement Administration (DEA) license. To date, pharmacies have been prohibited from stocking and dispensing marijuana under their DEA license.

Is interstate commerce legal under a Schedule III designation?

No. Rescheduling a substance to Schedule III does not automatically legalize interstate commerce for state-licensed or state-regulated businesses. Interstate commerce for Schedule III drugs requires approval from the FDA and necessary approvals and licenses under the controlled substances act as issued by the DEA. Unless new guidance, rules, or policies are released by relevant federal agencies, state-legal marijuana products will still be considered unapproved drugs under the Federal Food, Drug, and Cosmetic Act (FD&C), making their interstate manufacture, distribution, and sale a violation of federal law.

WHAT WILL MOVING MARIJUANA TO SCHEDULE III MEAN FOR THE REGULATED MARIJUANA INDUSTRY?

Deduction of business expenses: The biggest impact a move to Schedule III will have for the regulated marijuana industry is related to the federal statute 26 U.S. Code §280E, which pertains to tax deductible business expenditures. This section of federal code specifies that no deduction or credit (other than standard business deductions or credits for cost of goods sold) is allowed during the taxable year for any business or trade that is considered trafficking in controlled substances that are Schedule I or II. Moving marijuana to Schedule III removes this federal requirement and allows marijuana businesses to deduct all standard business expenses in accordance with federal law. These deductions are within the tax code itself and are specific to unlawful Schedule I and II substances, thus moving marijuana to Schedule III removes the applicability of section 280E, even if the Schedule III product is not an FDA approved drug.

FinCEN Guidance still applies: The illegal commerce and sale of a Schedule III substance still violates the Controlled Substances Act and current U.S. Banking Requirements. Thus, existing industry guidance under Financial Crimes Enforcement Network (FinCEN) of the U.S. Department of Treasury still applies and the status quo is maintained in terms of industry access to financial services. It is unknown if rescheduling will prompt an update or change to FinCEN guidance. Current FinCEN guidance that maintains access to financial institutions still follows the priorities set out under the rescinded Cole Memorandum (2013 U.S. Department of Justice).

WHAT WILL A MOVE TO SCHEDULE III MEAN FOR MARIJUANA RESEARCH?

Rescheduling marijuana to Schedule III may facilitate research on cannabis by easing some of the requirements for security and for obtaining a DEA registration.

It could become easier to obtain and maintain a DEA registration as a Schedule III facility: Research with a Schedule III drug or substance still requires DEA registration, but the process for obtaining and maintaining a DEA Schedule III registration is easier than for Schedule I, including less rigorous security requirements and tracking of protocols.

It will not necessarily change the availability of marijuana research material: Marijuana research has required researchers to access marijuana from a limited number of government-approved sources, restricting the types of products available for research. Unless new guidance, rules, or policies are released by relevant

federal agencies, rescheduling marijuana will not necessarily change this requirement, as it relates to the DOJ's interpretation of compliance with United Nations treaties.

Regardless of marijuana's Schedule, unless otherwise specified by the FDA, an Investigational New Drug (IND) application is mandatory from the FDA to conduct human clinical trials with any new drug or substance. The IND serves as an exemption to facilitate interstate transport and use of unapproved products within the scope of the clinical trial and ensures the safety of research subjects engaged in preclinical trials. *Unless otherwise specified, rescheduling marijuana will not allow the use of real-world products that are not FDA-approved to be used in human research, unless they meet the FDA requirements for safety and quality in support of an IND.*

Underlying all of this are specific provisions under the Medical Marijuana and Cannabidiol Research Expansion Act (MCREA), signed into law in 2022 that set research requirements for marijuana as a substance, regardless of Schedule classification. Rules to effectuate DEA licensing under MCREA have not been promulgated. It remains unclear if the Schedule III research requirements can and will be used by DEA given the passage of MCREA. While less restrictive than Schedule I requirements, research requirements under MCREA are more restrictive than those under Schedule III.

WHAT ELSE COULD BE POTENTIALLY IMPACTED BY A MOVE TO SCHEDULE III?

Drug testing requirements for federal workers across the federal government:
Rescheduling marijuana will not automatically change drug testing requirements for federal workers. Drug testing requirements are not tied to the Schedule and moving marijuana to Schedule III would not make recreational use of marijuana federally legal. Schedule III drugs are still controlled substances that require a prescription. Unless otherwise specified by the federal government and specific agencies, federal employees would remain subject to drug testing for marijuana and THC and existing workplace policies would remain in place. The U.S. Department of Health and Human Services (HHS) sets guidelines for federal drug testing for most federal employees (excluding safety-sensitive positions and employees of the Department of War [formerly the Department of Defense]). While rescheduling marijuana could prompt HHS to reassess testing requirements, individual federal agencies retain the authority to set stricter workplace drug-testing policies than what HHS sets. The Department of War (formerly the Department of Defense) retains their own authority for drug testing. Any references to marijuana and THC testing are unlikely to be impacted by rescheduling.

The U.S. Department of Transportation (DOT) sets drug-testing requirements for safety-sensitive employees in the aviation, trucking, railroad, and mass transit, pipeline, and maritime industries. This includes pre-employment testing, random testing, testing based on reasonable suspicion, post-accident testing, and return-to-duty and follow up testing. Drug testing is tied to five different drug classes with a "safety carve-out" and is not tied to the Schedule. Unless otherwise specified by the relevant federal agencies, drug testing of marijuana and THC for safety sensitive jobs will remain the same at the federal level. ***For safety-sensitive jobs not subject to federal DOT regulations, testing requirements may be governed by state law and may be dependent on certain drug classes or Schedules.***

WHAT WILL NOT CHANGE UNDER SCHEDULE III?

Unless otherwise specified by changes to policies and rules in the relevant federal agencies, the following areas will not change when marijuana is rescheduled to Schedule III:

Criminal penalties for individuals: Federal criminal penalties are specific to marijuana, regardless of its drug Schedule. Unless otherwise specified, these existing criminal penalties for federal trafficking (i.e., the possession, distribution, and sale) of marijuana would remain. However, there are guidelines related to sentencing that are based on a drug's schedule and could provide judges with discretion.

Federal legality: Marijuana products that are not FDA-approved drugs remain federally illegal, even if moving marijuana to Schedule III. Unless there is new federal guidance, state-licensed marijuana businesses will still be

noncompliant with federal law and unless otherwise specified, will remain embargoed from bankruptcy courts, the ability to obtain federal trademarks, the ability to obtain certain federal services, and more.

Banking and financial access: See the section above about how FinCEN guidance still applies. A Scheduling change does not impact the eligibility of plant-touching marijuana companies to be listed on public exchanges in the U.S.; they will still be prohibited absent legislative action.

Federal law still prohibits DOJ from enforcing controlled substance act violations related to or against those complying with state medical marijuana laws. However, these protections would still need to be reauthorized annually as they are provided through an annual appropriations rider by Congress. These protections only apply to medical marijuana.

WHAT ELSE REMAINS UNKNOWN THAT COULD IMPACT IMPLEMENTATION OF RESCHEDULING?

Several unknown questions remain and complicate our ability to identify exactly what a shift to Schedule III would mean for marijuana. We do not know:

Whether the DEA will treat marijuana like other Schedule III drugs or enact specific additional requirements or guidance if needed to comply with international treaties.

Whether the DOJ will put out new federal guidance pertaining to marijuana as a Schedule III substance. The 2013 DOJ Cole memorandum was rescinded and not replaced, though the eight policy priorities from that memo remain in effect within federal guidance (e.g., FinCEN guidance for financial institutions).

How federal agencies may change guidance and what new procedures they may enact based on a Schedule change, and/or based on other provisions in the Executive Order.

How state laws and regulations may change based on a new federal schedule for marijuana**.**