Tuesday, July 20, 2021

The much-anticipated proposed Senate bill that would legalize marijuana on the federal level was made public on July 14, 2021, by its lead sponsor, Senate Majority Leader Charles Schumer (D-New York). Called the Cannabis Administration and Opportunity Act, it removes marijuana from the Controlled Substances Act (CSA) and allows states to determine their own cannabis laws, similar to the way alcohol is federally regulated. Revenue generated by federal taxes would support restorative justice and public health and safety research.

The bill’s Senate sponsors note that federal cannabis reforms are especially urgent as more states legalize the adult and medical use of cannabis. They point to the fact...
that today more than 90 percent of Americans believe cannabis should be legal for either adult or medical use.

Though movement on cannabis legalization in the Senate is a welcome development, the proposed legislation contains elements that are of concern to many within the cannabis industry. In addition, there are significant gaps in the draft bill that will need to be clarified in the final version, which is not expected to be voted on until September 2021 at the earliest. The bill’s sponsors are seeking public comment from various stakeholders on several important topics, discussed below. In the meantime, important details on how cannabis will be regulated are omitted.

Federal Legalization

The Cannabis Administration and Opportunity Act removes cannabis from the CSA and directs that a new definition of cannabis be established within the Federal Food, Drug and Cosmetic Act for regulation of cannabis in food, dietary supplements, drugs and cosmetics. The new definition would retain the existing exception for hemp.

State law would continue to control the possession, production and distribution of cannabis. Shipment of cannabis into a state in violation of state law would remain prohibited, notwithstanding federal decriminalization. Federal criminal penalties are proposed for cannabis diversion, which is defined as the unlawful possession, production, distribution or purchase of 10 pounds or more of cannabis in violation of federal or state law. The bill further clarifies, however, that a state may not prohibit the interstate commerce of cannabis transported through its borders for lawful delivery into another state. This is similar to the current protections in place for the interstate transportation of hemp and hemp-derived products.

Federal Regulatory Jurisdiction

The legislation would transfer primary federal regulatory responsibility over cannabis from the Drug Enforcement Administration (DEA) to the Alcohol and Tobacco Tax and Trade Bureau (TTB), the Food and Drug Administration (FDA), and the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF).

The FDA would have primary federal regulatory authority over the manufacture and marketing of cannabis products. TTB would have authority over the taxation of cannabis products and trade practices, including implementing a new federal track-and-trace process and enforcing prohibitions on unfair competition. ATF would have investigative and enforcement obligations over diversion and other criminal matters involving cannabis products, similar to its existing mandate with respect to alcohol and tobacco products.

This transfer of jurisdiction generally is expected to follow similar agency responsibilities that have been established for alcohol and tobacco, and the bill directs the heads of the above-mentioned agencies to enter into a memorandum of understanding regarding their respective responsibilities.

Mandated Federal Research
The extent of possible health benefits or harms of cannabis use remains unknown due to the DEA's strict limitations on research related to cannabis. The bill's sponsors point out these restrictions have deprived researchers of the ability to study "the impairing effects of in order to develop effective tests for driving under the influence of cannabis, the effects of cannabis use on fetal development and other crucial gaps in our national understanding of this widely used substance."

The bill therefore directs federal departments and agencies to study and report on several areas important to public health and safety, including:

- The Government Accountability Office (GAO) is directed to include a number of societal metrics that may be impacted by cannabis legalization, including traffic-related deaths and injuries, hospitalizations and poison control center calls, violent crime rates, employment statistics, rates of cannabis use and various other criteria.

- The United States Department of Health and Human Services (HHS) and National Institutes of Health are directed to conduct or support research on the impacts of cannabis, including the effects of cannabis on the human brain, the impact on various health conditions, and identification of potential medical benefits and uses of cannabis.

- The Department of Transportation and HHS are directed to collect data on cannabis-impaired driving and to continue research on development of an impairment standard.

- HHS and the Centers for Disease Control and Prevention are directed to study public health prevention strategies, develop public education materials, and award up to five grants to states to collect data, raise awareness and enhance the use of state data linkage systems with respect to impaired driving.

- The Veterans Administration and Indian Health Service are directed to provide recommendations and opinions regarding the medical use of cannabis or drugs containing cannabis.

- The Bureau of Labor Statistics is directed to regularly compile and publicize data on the demographics of business owners and employees in the cannabis industry.

**Restorative Justice and Opportunity Programs**

The bill creates three grant programs aimed at creating opportunity for those harmed by the War on Drugs. These programs will fund nonprofits, make loans to assist small businesses and provide funding to implement state cannabis licensing programs that minimize barriers for individuals who have been adversely affected. To be eligible, states and localities first must take steps to create an automatic process to expunge criminal records for nonviolent cannabis offenses.

Within one year of enactment, each federal district will be directed to expunge any arrests and convictions for nonviolent federal cannabis offenses. An individual who receives an expungement may treat the arrest or conviction as if it never occurred,
and shall be immune from civil or criminal penalties related to perjury, false statement or failure to disclose the arrest or conviction. A noncitizen may not be denied any benefit or protection under the immigration laws based on events relating to cannabis.

**Federal Excise Tax**

Although cannabis businesses are subject to federal income taxes and state excise taxes, cannabis products currently are not subject to any federal excise tax. The bill would impose a federal excise tax on cannabis products in a manner similar to the tax imposed on alcohol and tobacco. The general rate of tax would be 10 percent in the first year, followed by annual increases up to 25 percent over the next three years. Beginning in year five, the tax would be levied on a per-ounce rate in the case of cannabis flower, or a per-milligram of THC rate in the case of any cannabis extract. The applicable rate on a per-ounce or per-milligram of THC basis would be equal to 25 percent of the prevailing price of cannabis sold in the United States in the prior year. Small cannabis producers with less than $20 million in sales annually would be eligible for a 50 percent reduction in their tax rate via a tax credit. Producers with more than $20 million in sales would be eligible for a tax credit on their first $20 million of cannabis sold annually, with sales above that amount subject to tax at the full rate.

**Federal Sales Permit**

A sales permit would be required from the U.S. Department of the Treasury, similar to what is required for alcohol products. Any producer of cannabis products also would be required to register with the FDA. Cannabis manufacturing facilities would be required to be maintained in a manner that prevents tax evasion or diversion. Manufacturers also would be required to maintain a bond to ensure cannabis excise taxes are paid. A federal cannabis permit may be denied or revoked if the premises is inadequate to prevent tax evasion or diversion, if operations do not comply with federal or state law, or if an applicant fails to disclose material information or makes a false statement.

**An FDA Center for Cannabis Products**

The bill would establish within the FDA a new Center for Cannabis Products that would regulate the “cannabis aspect” of all products containing cannabis (except products that make claims regarding the treatment or prevention of disease, which are regulated as drugs). The Center for Cannabis Products would be responsible for establishing various requirements related to cannabis products, including good manufacturing practices, cultivation standards, product standards, product labeling information, product distribution information and mandatory recall parameters. Manufacturers of cannabis products would owe various reporting obligations to the Center for Cannabis Products. State and local governments may enact rules more stringent than requirements established by the FDA.

**Cannabis in Food and Cosmetics**
Food and cosmetics that contain cannabis would (1) continue to be regulated by the Center for Food Safety and Applied Nutrition and (2) be regulated as cannabis products by the Center for Cannabis Products.

**Cannabis in Dietary Supplements**

Under the current draft of the bill, cannabis products would not be regulated as dietary supplements, but manufacturers would be authorized to make structure-function claims about the benefits of their product in the same manner allowed for dietary supplements. As with existing law for dietary supplements, these structure-function claims must be supported by competent and reliable scientific evidence and accompanied by a statement on the label that advises: “These statements have not been evaluated by the U.S. Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.”

**Cannabis Vape Products**

The proposed bill contains little information specifically relating to cannabis vaping products, other than prohibiting “electronic cannabis product delivery systems from containing natural or artificial flavors.”

**Legal Pathway for CBD in Dietary Supplements**

The bill would create a legal pathway for the use of CBD in dietary supplements. However, dietary supplements would be deemed adulterated if they contain more than a level of CBD per recommended daily servings set by the FDA. In some cases, dietary supplements containing CBD may be required to submit new dietary ingredients notifications to the FDA. The bill also provides the FDA with more comprehensive enforcement tools. Synthetic CBD is excluded from the definition of dietary supplements.

**Industry Reactions**

Reaction to the proposed Cannabis Administration and Opportunity Act has been mixed. Certainly removal of marijuana from Schedule 1 of the CSA will remedy many of the problems that plague the cannabis industry, such as better access to financial and insurance services. The legislation’s efforts to enlist the federal government to widely study and report on cannabis-related issues should result in much better data on the economic, health and public safety impact of cannabis. The restorative justice aspects of the draft bill represent a sweeping change from the status quo.

Many have raised alarm, however, over a proposed 25 percent federal excise tax on top of already onerous state and local taxes that make it difficult to combat a thriving illicit market. Lack of detail on how the FDA will be directed to regulate cannabis products also is a cause of concern. Although the legislation is largely premised on regulating cannabis like alcohol, cannabis is a much more complex pharmacological substance than alcohol. It is therefore reasonable to ask whether, regardless of the legislation’s stated intent to protect the states’ ability to determine their own cannabis laws, state regulations will be preempted when
inconsistent with the FDA’s final rulemaking on cannabis products.

Public comments are currently being solicited by the bill’s Senate sponsors with the goal of introducing a final version for floor vote after the summer recess. Though the final version of the Cannabis Administration and an Opportunity Act is unlikely to be passed into law, this draft bill provides a good window into what broad federal marijuana legalization will resemble when it finally happens.

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