

## Cannabis Considerations for Health Care Entities

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# CANNABIS CONSIDERATIONS FOR HEALTH CARE ENTITIES

VANESSA K. BURROWS\*

## I. INTRODUCTION

This article provides a brief overview of key federal laws that address marijuana and hemp and considerations for health care facilities and providers with respect to cannabis use by patients, compliance with Medicare Conditions of Participation, and research.<sup>1</sup> While many states in the U.S. permit the cultivation, distribution, and sale of marijuana, federal laws and guidance generally do not permit such activities.<sup>2</sup> Federal laws have limited exceptions, such as exceptions for the cultivation of marijuana that will be used in federally-sanctioned research.<sup>3</sup> Federal law also permits the sale of certain drugs approved by the Food and Drug Administration (“FDA”) that contain active ingredients that are present in botanical marijuana or that are synthetic versions of components in botanical marijuana.<sup>4</sup> Though an increasing number of states have changed their laws to license recreational and medical marijuana businesses or allow cultivation for personal use, marijuana remains a Schedule I controlled substance under the federal Controlled Substances Act (“CSA”).<sup>5</sup> As a result,

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1. In order to distinguish the parts and types of cannabis plants that are legal under federal law from the parts and types of cannabis plants that are not, this article will generally refer to marijuana in accordance with its federal definition, rather than cannabis.

2. Present day state laws and initiatives vary widely, and address topics as diverse as medical uses of marijuana, a health care provider’s financial interest in a licensed marijuana dispensary, recreational or “adult use” of marijuana, health insurance coverage and exclusions for medical use of marijuana, workers’ compensation fee schedules for medical cannabis, workers’ compensation benefits if an employee’s injury occurred while the employee was under the influence of marijuana, discrimination against employees or job applicants who use medical marijuana in accordance with state laws, workplace accommodations (or a lack thereof) for medical use of marijuana, employers’ abilities to restrict marijuana use, drug testing, drugged driving, and, before the enactment of the Agriculture Improvement Act of 2018 (“2018 Farm Bill”), access to cannabidiol (“CBD”).

3. See *infra* note 98 and accompanying text.

4. See *infra* note 57 and accompanying text.

5. Controlled Substance Act, 21 U.S.C. § 812.

distributing or dispensing marijuana, or possessing marijuana with the intent to distribute or dispense the drug, is against federal law.<sup>6</sup> Health care facilities and providers should weigh the potential consequences associated with violations of federal law when faced with questions about state-sanctioned activities.

## II. STATUS OF CANNABIS AND CANNABINOIDS UNDER FEDERAL LAWS, REGULATIONS, AND GUIDANCE

This section discusses the key federal laws, regulations, and guidance documents that provide the framework for federal control over cannabis and cannabis products, including food, dietary supplements, cosmetics, and FDA-approved drugs.<sup>7</sup> This section first explains the distinction between marijuana and hemp. The section then discusses the status of cannabis under federal laws, including the CSA, federal appropriations restrictions, the Federal Food, Drug, and Cosmetic Act (“FDCA”), and guidance from the Department of Justice (“DOJ”).

### *A. Federal Definitions of Marijuana and Hemp*

In recent years, Congress has bifurcated federal oversight of cannabis into separate regulatory schemes for marijuana and hemp, based on the concentration of delta-9 tetrahydrocannabinol (“THC”). Legislative changes began with the Agricultural Act of 2014 (“2014 Farm Bill”)<sup>8</sup>, which created a definition of “industrial hemp”: The Cannabis sativa L. plant or any part of the plant with a delta-9 THC concentration of not more than 0.3 percent on a dry weight basis.<sup>9</sup> The 2014 Farm Bill permitted limited research activities to be conducted on industrial hemp.<sup>10</sup> The law also regulated the growing and cultivating of industrial hemp by institutions of higher education and state departments of agriculture if the industrial hemp was grown or cultivated for research purposes in states that legalized such production.<sup>11</sup> Federal law would have otherwise criminalized growing and cultivation, because industrial hemp contains THC, a Schedule I controlled substance.<sup>12</sup> The 2014 Farm Bill did not legalize

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6. *Id.*

7. This article does not address the import and export of controlled substances.

8. Pub. L. No. 113-79.

9. 7 U.S.C. § 5940. This definition will be repealed effective September 30, 2021.

10. *Id.*

11. *Id.*

12. Guidance issued by FDA, U.S. Department of Agriculture, and the Drug Enforcement Administration (“DEA”) states that only (1) institutions of higher education; (2) persons employed by or under a production contract or lease with such institutions; (3) state agriculture departments; and (4) persons licensed, registered or otherwise authorized by state agricultural departments to conduct research were permitted to conduct research on industrial hemp under the agricultural pilot programs

distribution of industrial hemp across state lines, and it was and still is a violation of the CSA to distribute a controlled substance.<sup>13</sup> The 2014 Farm Bill also did not exempt industrial hemp from the CSA's definition of marijuana.

Until the enactment of the Agriculture Improvement Act of 2018 ("2018 Farm Bill") four years later on December 20, 2018, the CSA defined marijuana (spelled with a "h" in the statute instead of a "j") as follows:

The term "marihuana" means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.<sup>14</sup>

The 2018 Farm Bill amended the CSA's definition of "marihuana" to exclude hemp, as indicated by the italicized text:

[T]he term "marihuana" means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. [] *The term "marihuana" does not include – (i) hemp, as defined in [7 U.S.C. § 1639o]; or (ii) the mature stalks of such plant, . . .*<sup>15</sup>

The 2018 Farm Bill also amended the listing of THC in Schedule I to exclude THC in hemp and created a new definition of "hemp" that is similar to the 2014 Farm Bill's definition of industrial hemp.<sup>16</sup> Hemp is limited to the cannabis plant and its seeds, derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers with a delta-9 THC concentration of not more than 0.3 percent on a dry weight basis.<sup>17</sup> As a result, the 2018 Farm Bill excluded

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authorized by the 2014 Farm Bill. Statement of Principles on Industrial Hemp, 81 Fed. Reg. 53395 (Aug. 12, 2016).

13. 21 U.S.C. § 841(a)(1) (2018).

14. *Id.* § 802(16).

15. Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 5018 (emphasis added).

16. Pub. L. No. 115-334, § 10113, 132 Stat. 4908.

17. 7 U.S.C. § 1639o(1) (2018).

cannabinoids, such as cannabidiol (“CBD”), with very low concentrations of the psychoactive component delta-9 THC from the CSA’s definition of marijuana.<sup>18</sup>

Though hemp is no longer a Schedule I controlled substance, any cannabis-derived product that exceeds the 0.3 percent delta-9 THC concentration still falls within Schedule I.<sup>19</sup> Additionally, products derived from hemp plants that exceed the 0.3 percent delta-9 THC limits are considered marijuana.<sup>20</sup>

*B. The Controlled Substances Act and Drug Enforcement Administration (“DEA”) Regulations*

The CSA regulates the manufacture, possession, use, and distribution of certain drugs, substances, and precursor chemicals.<sup>21</sup> Under the CSA, substances are classified into five schedules (I-V); Schedule I is the most restrictive, and Schedule V is the least restrictive.<sup>22</sup> The Attorney General evaluates drugs and other substances for placement on one of the five schedules based on eight factors, including whether current scientific knowledge indicates that marijuana has a “currently accepted medical use,” the current pattern of abuse, and the risk to the public health.<sup>23</sup> In order to be placed on Schedule I, the following findings are required: (1) The drug or other substance has a high potential for abuse; (2) The drug or other substance has no currently accepted medical use in treatment in the United States; and (3) There is a lack of accepted safety for use of the drug or other substance under medical supervision.<sup>24</sup>

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18. *Hemp Production and the 2018 Farm Bill Hearing on the 2018 Farm Bill Before the Senate Committee on Agriculture, Nutrition, and Forestry*, FOOD & DRUG ADMIN. (2019), <https://www.fda.gov/news-events/congressional-testimony/hemp-production-and-2018-farm-bill-07252019> (providing testimony before 116th Congress of Amy Abernethy, MD, PhD, Principal Deputy Commissioner, Office of the Commissioner, FDA).

19. 21 U.S.C. § 812.

20. Implementation of the Agriculture Improvement Act of 2018, Interim Final Rule, 85 Fed. Reg. 51639, 51641 (Aug. 21, 2020) (to be codified at 21 C.F.R. pts. 1308, 1312).

21. See Comprehensive Drug Abuse Prevention and Control Act of 1970, Title II, Pub. L. No. 91-513, 84 Stat. 1242.

22. 21 U.S.C. § 812.

23. 21 U.S.C. § 811(c). The eight factors are: (1) Actual or relative potential for abuse. (2) Known scientific evidence of pharmacological effects. (3) Current scientific knowledge of the drug or substance. (4) History and current pattern of abuse. (5) Scope, duration, and significance of abuse. (6) Risk to public health. (7) Psychic or physiological dependence liability. (8) Whether the substance is an immediate precursor of an already scheduled substance. *Id.*

24. 21 U.S.C. § 812(b)(1).

Marijuana and THC (except THC in hemp<sup>25</sup>) are classified as Schedule I controlled substances.<sup>26</sup> The list of Schedule I controlled substances also includes heroin, lysergic acid diethylamide (“LSD”), and 3,4-methylenedioxymethamphetamine (ecstasy).<sup>27</sup> DEA regulations also list certain marijuana extracts as Schedule I controlled substances.<sup>28</sup> DEA issued guidance on its marijuana extract rule before the 2018 Farm Bill explaining that the rule did not include materials or products that are excluded from the CSA’s definition of marijuana, such as fiber produced from mature stalks of the plant.<sup>29</sup> In 2020, DEA updated the marijuana extract rule via an interim final rule that incorporated changes made by the 2018 Farm Bill and decontrolled hemp and hemp extracts. The interim final rule defined a “marijuana extract” in part as an extract “containing one or more cannabinoids that has been derived from any plant of the genus *Cannabis*, containing greater than 0.3 percent delta-9 [THC] on a dry weight basis.”<sup>30</sup> As a result, hemp and hemp-derived extracts with less than 0.3 percent delta-9 THC no longer fall within the revised definition of a marijuana extract.<sup>31</sup>

DEA has evaluated several petitions to reschedule marijuana from Schedule I into a different schedule. For example, in 2016, DEA denied a petition to initiate rulemaking proceedings to reschedule marijuana.<sup>32</sup> DEA determined that there was no currently accepted medical use of marijuana.<sup>33</sup> The denial of the petition explained:

In short, marijuana continues to meet the criteria for Schedule I control under the CSA because: . . . Marijuana has no currently accepted medical use in treatment in the United States. Based on the established

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25. The 2018 Farm Bill also excluded THC in hemp from Schedule I of the CSA. Agriculture Improvement Act of 2018, Pub. L. No. 115-334, § 12619(b) (codified at 21 U.S.C. § 812(c)(17)). The DEA had previously said that if a product contained even a trace amount of THC, it was a controlled substance under Schedule I. 21 U.S.C. § 811(g); 68 Fed. Reg. 14119, 14124 (Mar. 21, 2003).

26. 21 U.S.C. § 812(c)(10), (17) (“Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances . . . (10) Marijuana . . . (17) Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under section 1639o of title 7).”).

27. 21 U.S.C. § 812(c); 21 C.F.R. § 1308.11 (2020).

28. 21 C.F.R. § 1308.11(d)(23), (31), (58) (2020); 85 Fed. Reg. at 51641.

29. *Clarification of the New Drug Code (7350) for Marijuana Extract*, U.S. DEP’T OF JUST.; DRUG ENF’T ADMIN.; DIVERSION CONTROL DIV., [https://www.deaiversion.usdoj.gov/schedules/marijuana/m\\_extract\\_7350.html](https://www.deaiversion.usdoj.gov/schedules/marijuana/m_extract_7350.html) (last accessed Mar. 3, 2021).

30. 21 C.F.R. § 1308.11(d)(58) (2020); 85 Fed. Reg. at 51641.

31. 21 C.F.R. § 1308.11(d)(58) (2020).

32. Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53688 (Aug. 12, 2016).

33. *Id.*

five-part test for making such determination, marijuana has no ‘currently accepted medical use’ because: As detailed in the HHS evaluation, the drug’s chemistry is not known and reproducible; there are no adequate safety studies; there are no adequate and well controlled studies proving efficacy; the drug is not accepted by qualified experts; and the scientific evidence is not widely available.<sup>34</sup>

While marijuana is classified as Schedule I, DEA has scheduled other FDA-approved drugs that contain THC or CBD into other schedules because they have currently accepted medical uses in treatment in the U.S. For example, DEA classified an FDA-approved oral solution containing dronabinol, a synthetic THC, into Schedule II, which is for drugs that have a high potential for abuse and for which abuse may lead to severe psychological or physical dependence.<sup>35</sup> DEA classified a gelatin capsule version of synthetic dronabinol into Schedule III, which is for drugs with a potential for abuse less than the drugs in Schedules I and II and for which abuse may lead to moderate or low physical dependence or high psychological dependence.<sup>36</sup> Both dronabinol drugs are indicated for the treatment of anorexia associated with weight loss in adult patients with AIDS and nausea and vomiting associated with cancer chemotherapy in certain patients who failed to respond to conventional treatments.<sup>37</sup>

After FDA approved the CBD drug Epidiolex in 2018 for treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients two and older, the DEA placed FDA-approved CBD drugs that contain no more than 0.1 percent THC into Schedule V.<sup>38</sup> Schedule V drugs have a low potential for abuse relative to drugs in Schedule IV and are drugs for which abuse may lead to limited physical dependence or psychological dependence relative to drugs in Schedule IV.<sup>39</sup> Since FDA’s approval occurred before the enactment of the 2018 Farm Bill, the CBD that was the active ingredient in the drug was then considered an ingredient derived from marijuana.<sup>40</sup> The Schedule V

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34. *Id.*

35. 21 C.F.R. § 1308.12(f)(2) (2020).

36. *Id.* § 1308.13(g)(1).

37. See, e.g., *Highlights of Prescribing Information SYNDROS (Dronabinol) Oral Solution, CX*, FDA 1, [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/205525s0001bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/205525s0001bl.pdf) (last accessed Mar. 3, 2021).

38. Press Release, FDA, FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy (June 25, 2018), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms>; Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements, 83 Fed. Reg. 48950, 48951 (Sept. 28, 2018) (to be codified at 21 C.F.R. pts. 1308, 1312).

39. 21 U.S.C. § 812(b)(5).

40. 83 Fed. Reg. at 48951.

regulation was specific to Epidiolex and did not include any non-FDA-approved CBD products.<sup>41</sup> DEA recently removed Epidiolex from Schedule V in the same interim final rule that decontrolled hemp and hemp extracts, because under the 2018 Farm Bill, the FDA-approved CBD drug is no longer considered a controlled substance.<sup>42</sup>

### *C. Restrictions in Appropriations Laws and Related Signing Statements*

Members of the 117th Congress have introduced several bills that would reschedule marijuana under the CSA and are likely to continue to place restrictions on enforcement of marijuana laws in federal appropriations legislation. Broader legislative efforts related to sweeping regulatory changes for marijuana, such as legalization, are likely to face an uphill battle with an evenly divided Senate.<sup>43</sup> Congress may consider small-scale reforms tied to racial justice efforts, which could potentially garner support from President Biden, who has already signed executive orders focused on racial equity.<sup>44</sup> President Biden has previously expressed support for decriminalization.<sup>45</sup>

Members of Congress have incorporated several restrictions on enforcement of marijuana laws in appropriations legislation in past years.<sup>46</sup> Such restrictions attempt to limit how the DOJ, DEA, and U.S. Department of Agriculture can spend funds with respect to state laws on medical marijuana and federal pilot programs on industrial hemp.<sup>47</sup> For example, the Consolidated Appropriations Act, 2021, which provides appropriations for certain federal agencies through September 30, 2021, explains that the DOJ may not use any funds made available under the law to prevent certain listed states and territories from implementing their own laws that authorize the use, distribution,

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41. “A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.” 83 Fed. Reg. at 48952–53.

42. Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51639, 51640 (Aug. 21, 2020) (to be codified at 21 C.F.R. pts. 1308, 1312).

43. See, e.g., H.R. 365, 117th Cong. (2021) (rescheduling marijuana from schedule I to schedule III).

44. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, Exec. Order No. 13985, 86 Fed. Reg. 7009 (Jan. 20, 2021).

45. Tim Craig, *Biden, Once a Warrior in the ‘War on Drugs,’ May Slowly Retreat*, WASH. POST (Jan. 11, 2021 at 8:00am EST), <https://www.washingtonpost.com/politics/2021/01/11/biden-war-on-drugs>.

46. See, e.g., Consolidated Appropriations Act, 2020, Pub. L. No. 116-93, 133 Stat. 2431 (2019).

47. See, e.g., Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, § 530, 134 Stat. 1182, 1282 (2020) (prohibiting funds from being used to contravene the statute that established agricultural pilot programs for industrial hemp research).



possession, or cultivation of medical marijuana.<sup>48</sup> While such restrictions may alter the enforcement efforts of these federal authorities, such restrictions do not alter the federal laws discussed above and therefore should not be viewed by health care entities as granting permission to undertake activities that may be permissible under state law.

Additionally, the executive branch has challenged such restrictions. Former President Trump rejected the imposition of similar congressional restrictions on DOJ's use of appropriated funds for marijuana enforcement in a signing statement on the Consolidated Appropriations Act, 2020, stating:

Division B, section 531 of the Act provides that the [DOJ] may not use any funds made available under this Act to prevent implementation of medical marijuana laws by various States and territories. My Administration will treat this provision consistently with the President's constitutional responsibility to faithfully execute the laws of the United States.<sup>49</sup>

The actual impact of this particular signing statement is unclear, and legal scholars have questioned the legal effect of signing statements generally.<sup>50</sup> That said, such signing statements underscore the potential enforcement risks that health care entities face if they rely on state medical marijuana laws.

The signing statement echoes an earlier signing statement issued by then-President Trump in response to the Consolidated Appropriations Act, 2018: "Division B, section 537 provides that the [DOJ] may not use any funds to prevent implementation of medical marijuana laws by various States and territories. I will treat this provision consistently with my constitutional responsibility to take care that the laws be faithfully executed."<sup>51</sup> That signing

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48. *Id.*

49. *Statement by the President*, WHITEHOUSE.GOV (Dec. 20, 2019), <https://trumpwhitehouse.archives.gov/briefings-statements/statement-by-the-president-33>.

50. DOJ's Office of Legal Counsel, which opines on questions of law when requested by the President, has stated that a "President that places the statutory law [i.e., the appropriations laws] over the constitutional law . . . would fail in his duty faithfully to execute the laws" if he finds a provision unconstitutional or if he determines that a statutory law violates the Constitution. *Presidential Signing Statements Under the Bush Administration: Hearing Before the House Comm. of the Judiciary*, 110th Cong. 27 (2007) (statement of John P. Elwood, Deputy Assistant Attorney General, Office of Legal Counsel, DOJ). In contrast, an American Bar Association task force on signing statements has argued that statements that claim to disregard part of a law that the President has signed are contrary to the rule of law and the constitutional system of separation of powers. A.B.A., *Task Force on Presidential Signing Statements and the Separation of Powers Doctrine: Recommendation*, <https://balkin.blogspot.com/aba.signing.statments.report.pdf> (last accessed Mar. 3, 2021).

51. *Statement by President Donald J. Trump on Signing H.R. 244 into Law*, WHITEHOUSE.GOV (May 5, 2017), <https://trumpwhitehouse.archives.gov/briefings-statements/statement-president-donald-j-trump-signing-h-r-244-law/>.

statement referred to the incorrect section of the law; Section 537 of the Consolidated Appropriations Act, 2018, prohibited DOJ and DEA from using funds in contravention of the provision in the Agricultural Act of 2014 that permitted institutions of higher education and state departments of agriculture to cultivate industrial hemp for research or state agricultural pilot programs.<sup>52</sup> Section 538 of the same law prohibited DOJ from using funds made available under that Act to prevent such states, territories, and D.C. from implementing their own laws related to medical marijuana.<sup>53</sup> It is unclear why the signing statement did not also assert the same constitutional obligations with respect to the neighboring section of the law and its restrictions on DOJ's enforcement ability.

*D. The Federal Food, Drug, and Cosmetic Act and the 2018 Farm Bill*

FDA considers cannabis and cannabis derivatives such as CBD to be unapproved new drugs.<sup>54</sup> Under the FDCA, new drugs cannot legally be introduced or delivered for introduction into interstate commerce without FDA's prior approval or authorization.<sup>55</sup> The agency approves new drugs based on scientific data and information demonstrating the drug is safe and effective.<sup>56</sup> FDA has approved four drugs with active ingredients that are present in botanical marijuana or are synthetic versions of components in botanical marijuana.<sup>57</sup> There are many other cannabis products sold illegally in the marketplace that the FDA would consider to be unapproved new drugs, based on the claims made by

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52. Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, 132 Stat. 348, 444 (2018); Agricultural Act of 2014, 7 U.S.C. § 5940 (2018).

53. Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, 132 Stat. 348, 444-45 (2018).

54. *FDA and Cannabis: Research and Drug Approval Process*, FDA, <https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process> (last updated Oct. 01, 2020).

55. 21 U.S.C. §§ 331(d), 355(a).

56. *Id.* § 355(b).

57. *Researching the Potential Medical Benefits and Risks of Marijuana: Hearing before the Subcomm. on Crime and Terrorism, S. Comm. on the Judiciary*, 114th Cong. (2016) (statement of Douglas C. Throckmorton, M.D., Deputy Director for Regulatory Programs, Center for Drug Evaluation and Research, FDA). The four drugs are: (1) Marinol, which has the active ingredient: dronabinol, a THC. *Id.* FDA approved the drug in 1985 for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who failed to respond adequately to conventional antiemetic treatments. *Id.* FDA also approved the drug in 1992 for treatment of anorexia associated with weight loss in patients with AIDS. *Id.* (2) Syndros, which has the active ingredient dronabinol, a synthetic THC, and is FDA-approved for the same indications as Marinol. *Id.* (3) Cesamet, which has as an active ingredient the synthetic cannabinoid nabilone. *Id.* FDA approved Cesamet in 1985 for the treatment of nausea and vomiting associated with chemotherapy. *Id.* (4) Epidiolex, which has as the active ingredient purified CBD. *See supra* note 38. FDA approved Epidiolex in 2018 for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients two and older. *See supra* note 38.

such products with respect to the treatment or mitigation of certain diseases or conditions.

As noted above, the 2018 Farm Bill law created a new definition of “hemp” that differentiates hemp from the Schedule I drug marijuana.<sup>58</sup> Notably, the 2018 Farm Bill did not amend the FDCA.<sup>59</sup> FDA continues to regulate hemp-derived products under the agency’s existing authority.<sup>60</sup> Though hemp is now a legal substance under federal law, FDA regulates the addition of cannabis and derivatives of cannabis (e.g., CBD or THC) to food, deems food with such derivatives to be adulterated, and requires agency approval of new drug applications for hemp-derived drug products.<sup>61</sup> As a result, health care facilities and providers must exercise caution with respect to hemp-derived products and patient inquiries regarding their legality and potential uses.<sup>62</sup>

FDA issued an announcement asserting its authority over cannabis and cannabis-derived products concurrent with the signing of the 2018 Farm Bill.<sup>63</sup> The statement explained that FDA will continue to treat cannabis-derived compounds like any other drug, food, or dietary supplement that the agency regulates, regardless of the source of the cannabis-derived substance, e.g., plants classified as hemp.<sup>64</sup> The Commissioner’s statement also reminded the cannabis industry that even if the cannabis-derived substance is hemp-derived, it is unlawful to introduce foods that contain added CBD or THC into interstate commerce.<sup>65</sup> The statement also: (1) noted that it is a violation of the FDCA to market CBD and THC products as dietary supplements; and (2) asserted that FDA will take enforcement action against companies illegally selling any cannabis and cannabis-derived products that put consumers at risk and that are marketed in violation of the FDCA.<sup>66</sup>

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58. 7 U.S.C. § 1639r(c).

59. *See id.*

60. *See id.*

61. *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)*, FDA, <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd> (last updated Jan. 22, 2021).

62. *See id.*

63. FDA, STATEMENT FROM FDA COMMISSIONER SCOTT GOTTLIEB, M.D., ON SIGNING OF THE AGRICULTURE IMPROVEMENT ACT AND THE AGENCY’S REGULATION OF PRODUCTS CONTAINING CANNABIS AND CANNABIS-DERIVED COMPOUNDS (2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys>.

64. *Id.*

65. *Id.*

66. *Id.*

Since at least 2015, FDA has issued warning letters to companies that market unapproved new drugs that allegedly contain cannabis or CBD.<sup>67</sup> The warning letters typically note that the companies are making drug claims because the products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.<sup>68</sup> A company's failure to correct FDCA violations may result in additional legal action, including seizures of the violative products or injunctions.<sup>69</sup>

### *E. Department of Justice Guidance*

As of the date of this article, the Senate has not yet confirmed President Biden's nominee for Attorney General, Judge Merrick Garland, and it is unclear how the Biden Administration will reshape DOJ marijuana enforcement policies. Judge Garland stated during his confirmation hearing that marijuana is a nonviolent crime for which individuals are being incarcerated at significantly different rates in different communities and that the DOJ can focus its attention on violent crimes as opposed to marijuana possession.

Under the Obama Administration, the DOJ exercised restraint in enforcing federal drug laws against persons operating in states that legalized the growing of, trade in, and consumption of marijuana.<sup>70</sup> The DOJ also issued several policies on federal enforcement efforts with respect to marijuana in response to state legalization initiatives.<sup>71</sup>

Under the Trump Administration, Attorney General Jefferson Sessions repealed five of the Obama Administration's memoranda to all U.S. Attorneys regarding the enforcement of federal marijuana laws.<sup>72</sup> The repealed memoranda addressed various topics including a June 2011 memorandum which indicated the federal government would not focus its enforcement efforts on jurisdictions

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67. See *Warning Letters and Test Results for Cannabidiol-Related Products*, FDA, <https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products>.

68. See 21 U.S.C. § 321(g)(1)(B).

69. See, e.g., Letter from Donald D. Ashley, Dir., Office of Compliance, Ctr. for Drug Evaluation and Research, FDA to Patrice Romulus, Biota Biosciences LLC (April 9, 2020), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/biota-biosciences-llc-605164-04092020>.

70. Memorandum from David W. Odgen, Deputy Att'y Gen. on Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana to Selected U.S. Att'ys (Oct. 19, 2009); Memorandum from James M. Cole, Deputy Att'y Gen. on Guidance Regarding Marijuana Enforcement to All U.S. Att'ys (Aug. 29, 2013); Memorandum from James M. Cole, Att'y Gen. on Guidance Regarding Marijuana Related Financial Crime to All U.S. Att'ys (Feb. 14, 2014).

71. See *infra* note 73.

72. See Memorandum from Jefferson B. Sessions III, Att'y Gen. on Marijuana Enforcement to All U.S. Att'ys (Jan. 4, 2018), <https://www.justice.gov/opa/pr/justice-department-issues-memo-marijuana-enforcement> (announcing the rescission of previous guidance documents regarding federal enforcement with respect to the cultivation, distribution, and possession of marijuana).

seeking to authorize marijuana for medical use by individuals with serious illnesses (e.g. cancer) and their caregivers.<sup>73</sup> The Sessions memorandum enabled federal prosecutors to pursue marijuana enforcement based on “all relevant considerations,” including “federal law enforcement priorities set by the Attorney General; the seriousness of the crime; the deterrent effect of criminal prosecution; and the cumulative impact of particular crimes on the community.”<sup>74</sup> The Biden Administration will likely repeal the Sessions memorandum and institute its own marijuana enforcement guidance.

### III. MARIJUANA USE BY PATIENTS IN HOSPITALS AND OTHER HEALTH CARE FACILITIES

Hospitals, long-term care providers, and other facilities serving Medicare beneficiaries may face internal or external pressures to implement or change policies that would allow the possession or use of cannabis or recommendations for the use of medical marijuana. Such pressures may arise from various sources including: (1) patients who have received recommendations for medical marijuana; (2) the family members and registered medical marijuana caregivers of such patients; (3) physicians who have obtained state licenses that enable them to recommend marijuana as a course of medical treatment for their patients; and (4) advocacy organizations and others.<sup>75</sup> Since marijuana remains illegal at the federal level, it poses unique issues for health care facilities and providers seeking to accommodate such patients. For example, physicians, non-physician providers with prescribing authority, and pharmacists may not have access to adequate data to advise patients who are taking FDA-approved medications on

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73. *Id.* The revoked Obama Administration policies included the following:

(1) the October 2009 Ogden Memorandum regarding investigations and prosecutions in states authorizing medical use of marijuana; (2) the February 2014 memorandum regarding marijuana related financial crimes; and (3) the August 2013 Cole Memorandum that set forth eight enforcement priorities for the federal government: (a) Preventing the distribution of marijuana to minors; (b) Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels; (c) Preventing the diversion of marijuana from states where it is legal under state law in some form to other states; (d) Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity; (e) Preventing violence and the use of firearms in the cultivation and distribution of marijuana; (f) Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use; (g) Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; (h) Preventing marijuana possession or use on federal property. *Id.*; see *supra* note 70.

74. Memorandum from Jefferson B. Sessions III, Att’y Gen. on Marijuana Enforcement to All U.S. Att’ys (Jan. 4, 2018), <https://www.justice.gov/opa/pr/justice-department-issues-memo-marijuana-enforcement>.

75. Numerous organizations have advocated for changes related to medical marijuana programs including the Marijuana Policy Project and the Drug Policy Alliance. *Medical Marijuana*, DRUG POL’Y, <https://drugpolicy.org/issues/medical-marijuana> (last accessed Mar. 3, 2021).

the specific drug interaction risks posed by marijuana or derivatives such as CBD.<sup>76</sup> Additionally, marijuana products obtained from dispensaries may only be subject to state or local standards for contaminants, manufacturing, storage, and packaging, whereas manufacturers of drugs seeking FDA approval must adhere to current Good Manufacturing Practices and other FDA requirements.<sup>77</sup> Likewise, marijuana products sold at state-licensed dispensaries have not been the subject of clinical research prior to their introduction into commerce, such that manufacturers would be able to provide detailed information about a product's risks and benefits and safety considerations for certain populations or doses.

Some health care facilities may have implemented or considered implementing policies that permit patient use consistent with the provisions in state medical marijuana laws but with limited staff involvement or policies that permit patient use, but treat medical marijuana as a self-administered home therapy or as medication.<sup>78</sup> These policies may address topics such as: (1) whether patients are registered medical marijuana patients under state laws; (2) confirmation of the illness or condition that would make a patient eligible for a medical marijuana program under state law; (3) how the patient may obtain and store marijuana (i.e., through a registered caregiver and without health care facility employee involvement); (4) administration of the marijuana by the patient, a registered caregiver or facility employees; and (5) documentation of the marijuana products consumed by the patient.<sup>79</sup>

Such policies, while they may comply with state laws, are not without risk. Health care providers should review the applicable Medicare Conditions of Participation, requirements or conditions for coverage, and related quality standards and carefully evaluate the potential risks of creating policies or programs that would accommodate such patients or physicians. Noncompliance

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76. See NATIONAL ACAD. OF SCI., ENG'G, AND MED., *THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS: THE CURRENT STATE OF EVIDENCE AND RECOMMENDATIONS FOR RESEARCH* (2017); *What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD*, FDA, <https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis> (last updated Mar. 05, 2020).

77. See, e.g., Colorado Marijuana Rules, COLO. CODE REGS. § 212-3 (2021); 21 C.F.R. § 211.133 (2020).

78. See, e.g., *Medical Marijuana*, WASH. HEALTH CARE ASS'N, <https://www.whca.org/files/2013/04/sample-medical-marijuana-policy.pdf> (last accessed Mar. 3, 2021); *Medical Cannabis Template Policy*, MINNESOTA HOSP. ASS'N, (June 17, 2015), <https://www.mnhospitals.org/Portals/0/Documents/patientsafety/MedCannabis/Medical%20Cannabis%20Documentation.pdf> (last accessed Mar. 3, 2021).

79. *Supra* note 78.

with the Medicare Conditions of Participation or similar requirements may result in the termination of Medicare enrollment.<sup>80</sup>

For example, even if marijuana use is permissible under state law, hospitals must comply with the CSA and other federal laws that criminalize the possession and distribution of marijuana, as well as the federal requirements set forth in the Medicare Conditions of Participation in order to receive Medicare and Medicaid payments.<sup>81</sup> The Conditions of Participation require hospitals to comply with applicable federal laws related to the health and safety of patients<sup>82</sup> and set forth several requirements with respect to controlled substances such as marijuana.<sup>83</sup> Drugs must be prepared, controlled, and administered in accordance with federal and state laws and applicable standards of practice, which include compliance with federal laws, regulations, and guidelines on topics such as recordkeeping, security, and reports of abuses and losses of controlled substances.<sup>84</sup> All drugs must also be administered by or under the supervision of nursing or other personnel in accordance with federal and state laws, licensing requirements, and approved medical staff policies and procedures.<sup>85</sup>

The Conditions of Participation require the maintenance of current and accurate records for the receipt and disposition of all scheduled drugs, which would include marijuana,<sup>86</sup> but hospital and long-term care pharmacists could not dispense marijuana without risking violations of their own state licensing requirements, the CSA, and federal regulations, such as those that addresses drug regimen reviews and unnecessary drugs.<sup>87</sup> Pharmacists at hospitals, long-term care facilities, and other health care facilities would also be unable to provide adequate security for Schedule I controlled substances such as marijuana; current regulations impose additional requirements for the storage of Schedule II controlled substances but do not contemplate the storage of Schedule I controlled substances, which, by definition, have no currently accepted medical use in

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80. 42 C.F.R. § 489.53(a)(3) (2020); *see* CENTER FOR MEDICARE & MEDICAID SERVS, STATE OPERATIONS MANUAL APPENDIX A – SURVEY PROTOCOL, REGULATIONS AND INTERPRETIVE GUIDELINES FOR HOSPITALS, INTRODUCTION, Rev. 37 (2020), <https://www.cms.gov/files/document/som107appendicestoc.pdf> [hereinafter STATE OPERATIONS MANUAL] (stating that hospitals are required to comply with Medicare Conditions of Participation “in order to receive Medicare/Medicaid payment”).

81. 42 C.F.R. Part 482 (2020).

82. *Id.* § 482.11(a).

83. *Id.* § 482.25(b).

84. *Id.* §§ 482.25(b), 482.23(c)(1).

85. *Id.* § 482.23(c).

86. *Id.* § 482.25(a)(3).

87. *See id.* § 483.45(d) (stating that each long-term care resident’s drug regimen must be free from unnecessary drugs, which would include marijuana because there are no adequate indications for use for marijuana).

treatment.<sup>88</sup> Surveys of hospitals and other facilities, which examine the facilities' compliance with the Conditions of Participation, also include inspections of drug storage areas, so any storage of marijuana by a facility could lead to a citation for noncompliance.<sup>89</sup> The Centers for Medicare & Medicaid Services ("CMS") has stated that any noncompliance with requirements regarding pharmaceutical services, including supervised drug storage, must be evaluated to determine if a "condition-level" citation is warranted for substantial noncompliance with the CMS Conditions of Participation.<sup>90</sup> Drug dispensing must also be performed consistent with federal laws, such as the federal research requirements discussed below in Section IV.<sup>91</sup> Further, the Conditions of Participation address abuses of controlled substances, which must be reported to the individual responsible for pharmaceutical services and to the organization's CEO, as appropriate.<sup>92</sup>

As a result, hospitals, long-term care providers, and other facilities that must meet the Conditions of Participation or similar requirements should ensure that their facilities do not undertake activities that would jeopardize their eligibility to participate in Medicare or that would lead to citations for noncompliance with federal requirements.

As health care providers or facilities debate whether to move forward with any policies that would comply with state medical marijuana laws, they should consider whether their medical malpractice insurance will cover any physician recommendation for medical marijuana or any negative outcome that results from such a recommendation.<sup>93</sup> Physicians should also evaluate any state law protections for health care providers who recommend marijuana or the lack of such protections. For example, Massachusetts issued guidance addressing penalties and prosecutions under state law for advising a qualifying patient about the risks and benefits of medical use of marijuana and providing a qualifying

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88. *Id.* § 483.45(h).

89. See STATE OPERATIONS MANUAL, *supra* note 80; 42 C.F.R. § 482.25 (2020).

90. See STATE OPERATIONS MANUAL, *supra* note 80, at A-0489.

91. 42 C.F.R. § 482.25(b)(1) (2020); see also *infra* Section IV.

92. 42 C.F.R. § 482.25(b)(7) (2020).

93. State laws may impose requirements, including a mandate that physicians register as medical marijuana providers, and limitations on the types of patients and particular conditions for which medical marijuana may be recommended (e.g., AIDS, epilepsy, MS, glaucoma, and neuropathic chronic pain). COMMONWEALTH OF MASS., CANNABIS CONTROL COMM'N, GUIDANCE FOR HEALTHCARE PROVIDERS REGARDING THE MEDICAL USE OF MARIJUANA (2017), <https://www.mass.gov/doc/guidance-for-health-care-providers-on-the-medical-use-of-marijuana/download>. [hereinafter Mass. Guidance]. State laws may also require physicians to have attempted standard medical treatments or offered such treatments to patients prior to recommending marijuana. See *State Medical Marijuana Laws*, NAT'L CONF. OF STATE LEGIS. (Jan. 11, 2021), <https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx#3>.



patient with a recommendation for marijuana based on an assessment of the patient's medical history and condition.<sup>94</sup>

Health care facilities may also receive questions about policies that address the disposal of illegal drugs and smoke-free facilities or drug-free work environments. Policies that prohibit patient possession, self-administration, and use would help such facilities ensure compliance with federal requirements.<sup>95</sup> Policies that acknowledge marijuana use by patients participating in FDA expanded access programs or clinical trials that are conducted in accordance with federal requirements and approved by an Institutional Review Board, but impose restrictions on marijuana use in health care facilities, may also ensure compliance with federal laws.<sup>96</sup> FDA's expanded access program for marijuana for medical use facilitates the availability of investigational products to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy available.<sup>97</sup>

#### IV. MARIJUANA RESEARCH

Health care facilities may also receive inquiries from physicians and others about marijuana research. Though marijuana dispensaries may be ubiquitous, and a facility may be in close proximity to a marijuana dispensary that is licensed by the state or locality, in order to conduct research with marijuana, the CSA requires a person to register with the DEA and follow ordering, security, and other requirements.<sup>98</sup> Since research and development conducted in the U.S. outside of the CSA's regulatory scheme could trigger federal civil and criminal penalties for the manufacture, distribution, and possession of marijuana, health care facilities must ensure that interested researchers adhere to federal requirements.<sup>99</sup>

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94. See Mass. Guidance, *supra* note 93.

95. See, e.g., Mayo Clinic, *Medical Marijuana* (Nov. 27, 2019), <https://www.mayoclinic.org/healthy-lifestyle/consumer-health/in-depth/medical-marijuana/art-20137855> (discussing medical cannabis use on Mayo Clinic campuses in Arizona, Florida, and Minnesota).

96. See, e.g., Karen Nitkin, *New Policy Bars Medical Marijuana Use in Johns Hopkins Facilities*, JOHNS HOPKINS MED. (May 11, 2018), <https://www.hopkinsmedicine.org/office-of-johns-hopkins-physicians/best-practice-news/new-policy-bars-medical-marijuana-use-in-johns-hopkins-facilities> (announcing a new policy prohibiting patients from possessing or using medical marijuana in the facilities unless the patient is part of a clinical trial approved by the institutional review board).

97. *FDA and Cannabis: Research and Drug Approval Process*, FDA (2021), <https://www.fda.gov/newsevents/publichealthfocus/ucm421163.htm>.

98. 21 U.S.C. §§ 822, 823(f). DEA regulations govern orders for Schedule I controlled substances. 21 C.F.R. § 1305.06 (2020).

99. 21 U.S.C. §§ 841, 844. The CSA also provides for criminal forfeiture of property and proceeds derived from a violation of the CSA and civil forfeiture of property including equipment, money, records, research, and property used or intended to be used to violate the CSA. *Id.* §§ 853, 881. The CSA provides that any person who attempts or conspires to commit an offense under the Act is subject to the same penalties as those prescribed for the offense. *Id.* § 846.

The CSA makes it a federal crime to cultivate, possess, and distribute marijuana and other Schedule I drugs, except under limited exceptions for federally-approved research and the cultivation of marijuana for legitimate researchers.<sup>100</sup> The CSA enables research pertaining to medical uses and the development of new drugs, as opposed to research for purposes such as the commercial development of marijuana or THC products.<sup>101</sup> The CSA and related DEA regulations also govern providers and researchers interested in growing marijuana for their own studies.<sup>102</sup> The CSA prohibits human consumption of any quantity of a Schedule I controlled substance except during clinical research approved by FDA and conducted by a DEA-registered researcher.<sup>103</sup>

The Secretary of the U.S. Department of Health and Human Services (“HHS”) must determine the qualifications and competency of each practitioner seeking to register with the DEA, as well as the merits of the research protocol.<sup>104</sup> When determining if a research protocol has merit, the Secretary of HHS must consult with the Attorney General regarding procedures to adequately safeguard against diversion from legitimate medical or scientific use.<sup>105</sup> The Attorney General can then deny a practitioner’s registration under certain grounds, such as a felony conviction related to a controlled substance.<sup>106</sup> As of June 2020, there are 589 registered Schedule I researchers who have obtained DEA registrations to conduct research on marijuana, marijuana extracts, and marijuana derivatives.<sup>107</sup>

DEA-registered marijuana researchers receive supplies through the National Institute on Drug Abuse (“NIDA”) Drug Supply Program from the sole federally authorized marijuana grower, the University of Mississippi, which coordinates with law enforcement agencies on the transportation of marijuana.<sup>108</sup> The CSA and DEA policies limit the growth of marijuana for research purposes

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100. *Id.* §§ 822, 841, 842.

101. *Id.* §§ 822, 823, 828, 872(e).

102. Controls to Enhance the Cultivation of Marijuana for Research in the United States, 85 Fed. Reg. 82333, 82336 (Dec. 18, 2020) (to be codified at 21 C.F.R. pts. 1301 and 1318).

103. 21 U.S.C. § 811, 812, 823(f); *United States v. Oakland Cannabis Buyers’ Cooperative*, 532 U.S. 483, 490 (2001); 21 C.F.R. §§ 1301.18, 1301.32 (2020).

104. 21 U.S.C. § 823(f). Practitioners include physicians, scientific investigators or other persons licensed, registered or otherwise permitted by the U.S. or the jurisdiction in which the practitioner practices or does research, to distribute, dispense, or conduct research with respect to a controlled substance in the course of professional practice or research. *Id.* § 802(21).

105. *Id.* § 823(f).

106. *Id.* § 824(a).

107. Controls to Enhance the Cultivation of Marijuana for Research in the United States, 85 Fed. Reg. 82333, 82336 (Dec. 18, 2020) (to be codified at 21 C.F.R. pts. 1301 and 1318).

108. *NIDA Drug Supply Program*, NAT’L INST. ON DRUG ABUSE (June 27, 2017), <https://www.drugabuse.gov/research/research-data-measures-resources/nida-drug-supply-program>.

through registration requirements and production quotas.<sup>109</sup> Registrations of marijuana growers must be consistent with the public interest—which is determined based on factors such as compliance with state law and effective controls against diversion—as well as U.S. treaty obligations under the 1961 international Single Convention on Narcotic Drugs (“Single Convention”).<sup>110</sup>

Under the Obama Administration, the DEA issued a policy aimed at increasing the number of authorized growers in order to meet researcher demand for marijuana and CBD extracts.<sup>111</sup> The 2016 policy would have permitted persons to register with DEA to grow marijuana for researchers as well as “strictly commercial endeavors funded by the private sector and aimed at drug product development.”<sup>112</sup> The increased number of growers registered by DEA would have remained limited, as a statute requires that the manufacture be conducted by a number of establishments which can produce an adequate and uninterrupted supply of the controlled substance under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.<sup>113</sup> DEA received approximately 38 applications as a result of the 2016 policy statement; as of December 18, 2020, all applications are pending.<sup>114</sup>

In December 2020, the DEA issued a final rule to facilitate the cultivation of marijuana for research and other legal purposes, which became effective on the last full day of the Trump Administration.<sup>115</sup> The rule was drafted to ensure compliance with U.S. obligations under the Single Convention and the CSA.<sup>116</sup> The rule states that DEA anticipates approving more than one person to cultivate and harvest bulk marijuana.<sup>117</sup> The Biden Administration may re-examine this final rule, which does not address the cultivation of marijuana for commercial endeavors, as well as a separate set of U.S. Department of Agriculture regulations governing the commercial production of industrial hemp.<sup>118</sup>

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109. 21 U.S.C. §§ 822, 826.

110. *Id.* § 823(a); Controls to Enhance the Cultivation of Marihuana for Research in the United States, 85 Fed. Reg. 16292, 16294 (Mar. 23, 2020) (to be codified at 21 C.F.R. pts. 1301, 1318).

111. Applications to Become Registered Under the [CSA] to Manufacture Marijuana to Supply Researchers in the [U.S.], 81 Fed. Reg. 53846, 53848 (Aug. 12, 2016).

112. *Id.*

113. 21 U.S.C. § 823(a).

114. Controls to Enhance the Cultivation of Marihuana for Research in the United States, 85 Fed. Reg. 82333, 82347 (Dec. 18, 2020) (to be codified at 21 C.F.R. pts. 1301 and 1318).

115. *Id.* Since the rule took effect before January 20, 2021, it does not appear to be subject to President Biden’s regulatory freeze on last-minute regulations issued by the Trump Administration. Memorandum for the Heads of Executive Departments and Agencies, Regulatory Freeze Pending Review (Jan. 20, 2021), <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review/> [hereinafter Regulatory Freeze Memorandum].

116. 85 Fed. Reg. at 82339.

117. *Id.* at 82436–37.

118. Establishment of a Domestic Hemp Production Program, 86 Fed. Reg. 5596 (Jan. 19, 2021) (to be codified at 7 C.F.R. pt. 990). These regulations are subject to the regulatory freeze order because the

## V. CONCLUSION

Federal regulation of cannabis is evolving rapidly. The Biden Administration will undoubtedly seek to advance new laws and implement new regulations and policies consistent with President Biden's own priorities. Health care facilities and providers should monitor proposed congressional legislation, congressional hearings, DEA and FDA rulemakings, and DOJ, DEA, and FDA guidance in this evolving area of law to avoid any pitfalls and unnecessary risks. To understand the full scope of permissible and impermissible activities, health care facilities and providers should seek counsel with experience with federal marijuana laws, food and drug laws, and hemp laws. State marijuana laws and regulations cannot insulate health care entities from liability under federal law, including liability for aiding and abetting violations of the CSA or conspiring to violate the CSA. Future congressional legislation and executive branch proposals may address such matters, but until any changes in federal law occur, health care entities must take care to ensure that their operations fully comply with applicable cannabis laws.

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effective date was initially March 22, 2021. Regulatory Freeze Memorandum, *supra* note 115. As a result, the regulations may be postponed, modified, withdrawn or subject to other actions by the Biden Administration. *Id.*