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Legal Authorities Under the Controlled Substances Act to Combat the Opioid Crisis

Updated December 18, 2018

Congressional Research Service
https://crsreports.congress.gov
R45164

CRS REPORT
Prepared for Members and
Committees of Congress

Summary

According to the Centers for Disease Control and Prevention, the annual number of drug overdose deaths involving prescription opioids (such as hydrocodone, oxycodone, and methadone) and illicit opioids (such as heroin and non-pharmaceutical fentanyl) has more than quadrupled since 1999. A November 2017 report issued by the President's Commission on Combating Drug Addiction and the Opioid Crisis also observed that "[t]he crisis in opioid overdose deaths has reached epidemic proportions in the United States ... and currently exceeds all other drug-related deaths or traffic fatalities." How the current opioid epidemic happened, and who may be responsible for fueling it, are complicated questions, though reports suggest that several parties likely played contributing roles, including pharmaceutical manufacturers and distributors, doctors, health insurance companies, rogue pharmacies, and drug dealers and addicts. Many federal departments and agencies are involved in efforts to combat opioid abuse and addiction, including a law enforcement agency within the U.S. Department of Justice, the Drug Enforcement Administration (DEA), which is the focus of this report.

The primary federal law governing the manufacture, distribution, and use of prescription and illicit opioids is the Controlled Substances Act (CSA), a statute that the DEA is principally responsible for administering and enforcing. The CSA and DEA regulations promulgated thereunder establish a framework through which the federal government regulates the manufacture, distribution, importation, exportation, and use of certain substances which have the potential for abuse or psychological or physical dependence, including opioids. Congress enacted the CSA in 1970 to facilitate the availability of controlled substances for authorized medical, scientific, research, and industrial purposes, while also preventing these substances from being diverted out of legitimate channels for illegal purposes such as drug abuse and drug trafficking activities. The CSA aims to protect the public's health and safety from dangers posed by highly addictive or dangerous controlled substances that are diverted into the illicit market, while also ensuring that patients have access to pharmaceutical controlled substances for legitimate medical purposes such as the treatment of pain.

This report describes the current federal legal regime governing opioids and other controlled substances under the CSA and its implementing regulations, including (1) the classification of various plants, drugs, and chemicals into one of five schedules based on the substance's medical use, potential for abuse, and safety or dependence liability; (2) who must register with the DEA in order to receive authorization to handle the substances (such as drug manufacturers, wholesale distributors, doctors, hospitals, pharmacies, and scientific researchers); (3) what obligations registrants must satisfy in order to maintain a valid registration (such as keeping records of drug inventories and transactions, submitting reports to the DEA, and providing security measures to safeguard controlled substances); and (4) the DEA's administrative, civil, and criminal authorities for enforcing regulatory compliance with the CSA (such as suspending or revoking a registrant's legal authority to handle controlled substances if the DEA Administrator finds that the registrant has "committed such acts as would render his registration ... inconsistent with the public interest."). The report then examines DEA initiatives and actions taken, pursuant to its legal authorities under the CSA, which specifically target the abuse of opioids. The report concludes by describing the legislative response to the opioid epidemic, including a summary of the amendments to the CSA made by legislation enacted by the 115th Congress, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (P.L. 115-271).

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The alarming rise in drug overdose deaths involving opioids over the past two decades[1] has prompted the federal government to examine the causes of the public health crisis, identify possible solutions to counteract the problem, and take actions to address the crisis.[2] The primary federal law governing the manufacture, distribution, and use of prescription and illicit opioids is the Controlled Substances Act (CSA or the act),[3] which is administered and enforced by the Drug Enforcement Administration (DEA) in the U.S. Department of Justice.[4] The CSA provides the legal regime through which the federal government (1) regulates and facilitates the lawful production, possession, and distribution[5] of controlled substances, including opioids; (2) prevents diversion[6] of these substances from legitimate purposes; and (3) penalizes unauthorized activities involving controlled substances.[7]

The regulatory framework under the CSA relies primarily on a registration system: the act requires persons who handle controlled substances (such as drug manufacturers, wholesale distributors, exporters, importers, health care professionals, hospitals, pharmacies, and scientific researchers) to register with the DEA and comply with the terms and conditions of the registration.[8] Through this registration mechanism, the CSA creates a "closed system" of distribution[9] in which distribution may lawfully occur among registered handlers of controlled substances, referred to under the act as "registrants."[10] To monitor the amount of particularly

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[1] Centers for Disease Control and Prevention, *Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants—United States, 2015–2016*, 67 MORBIDITY AND MORTALITY WEEKLY REPORT No. 12 (Mar. 30, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6712-H.pdf.

[2] *See, e.g.*, THE PRESIDENT'S COMMISSION ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS: FINAL REPORT (2017); *see also The Drug Enforcement Administration's Role in Combating the Opioid Epidemic: Hearing Before the H. Comm. on Energy & Commerce, Subcomm. on Oversight and Investigations*, 115th Cong. (2018); *Combating the Opioid Crisis: Prevention and Public Health Solutions: Hearing Before the H. Comm. on Energy & Commerce, Subcomm. on Health*, 115th Cong. (2018); *The Opioid Crisis: An Examination of How We Got Here and How We Move Forward: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions*, 115th Cong. (2018); *Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act: Hearing Before the S. Judiciary Comm*., 115th Cong. (2017); *The Federal Response to the Opioid Crisis: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions*, 115th Cong. (2017).

[3] Congress enacted the CSA as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, P.L. 91-513, 84 Stat. 1236 (codified as amended at 21 U.S.C. §§ 801-904 (2012)).

[4] While the CSA directs the Attorney General to enforce its provisions, the CSA also permits him to delegate such responsibilities to any other officer or employee of the Department of Justice. 21 U.S.C. § 871(a). Pursuant to 28 C.F.R. § 0.100(b), the Attorney General has assigned much of the authority to implement and enforce the CSA to the DEA Administrator. Accordingly, the term "DEA Administrator" will be used instead of the term "Attorney General" with respect to any references in the CSA to the Attorney General for the remainder of this report.

[5] The CSA broadly defines "distribution" to include virtually every transfer of possession. 21 U.S.C. § 802(11) ("The term 'distribute' means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical.").

[6] The DEA has explained that the term "diversion," used in the context of the CSA, refers to "the redirection of controlled substances which may have lawful uses into illicit channels." Drug Enf't Admin., *Controlled Substances Quotas,* 83 Fed. Reg. 32,784 (July 16, 2018).

[7] This report focuses only on federal regulation of controlled substances under the Controlled Substances Act and does not discuss other federal laws that may apply to controlled substance medications, such as the Federal Food, Drug, and Cosmetic Act, P.L. 75-717, 52 Stat. 1057 (1938) (chiefly enforced by the U.S. Food and Drug Administration), or any state laws pertaining to medical practices and public health and safety.

[8] 21 U.S.C. § 822. In addition, the CSA grants the DEA Administrator broad authority to issue rules and regulations "relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances.... " *Id*. § 821.

[9] Drug Enf't Admin., *Electronic Prescriptions for Controlled Substances,* 75 Fed. Reg. 16,236, 16,237 (Mar. 31, 2010).

[10] According to 21 C.F.R. § 1300.02(b), the term "registrant" means "any person who is registered [with the DEA]

dangerous drugs that enters this distribution system,[11] the CSA requires the DEA to establish a quota system that restricts the total amount of certain controlled substances that may be annually produced or manufactured.[12]

In order to minimize theft and diversion and to help the DEA monitor the flow of controlled substances in the United States,[13] the CSA and its implementing regulations subject registrants to strict requirements regarding recordkeeping, maintaining the security of their controlled substance inventories, and reporting certain information to the DEA.[14] The "closed system" of distribution, along with registrant compliance with the CSA's regulatory requirements, helps to ensure that a particular controlled substance is always accounted for by a DEA-registered entity,[15] from its creation until it is dispensed[16] to a patient[17] or is destroyed.[18] Note that patients are not required to register with the DEA[19] because the controlled substances in their possession "are no longer part of the closed system of distribution and are no longer subject to DEA's system of corresponding accountability."[20]

A registrant's failure to meet its obligations under the CSA can result in a controlled substance being diverted from legitimate channels. For example, "[d]istributors that blindly sell pharmaceutical controlled substances to rogue pharmacies, and practitioners[21] who issue prescriptions without a legitimate medical purpose are diverting."[22] Such diversion can contribute to drug abuse and addiction,[23] which, in turn, increase the number of overdose deaths and

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pursuant to [21 U.S.C. §§ 823 or 958]."

[11] *Improving Management of the Controlled Substances Quota Process, Hearing Before the S. Caucus on Int'l Narcotics Control,* 114th Cong. 2 (2015) (statement of Joseph T. Rannazzisi, DEA).

[12] 21 U.S.C. § 826(a).

[13] *Improving Predictability and Transparency in DEA and FDA Regulation: Hearing Before the H. Comm. on Energy & Commerce, Subcomm. on Health,* 113th Congress 1 (2014) (statement of Joseph T. Rannazzisi, DEA).

[14] *See, e.g.,* 21 C.F.R. § 1304.11(a) ("Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.... "); *id*. § 1301.71(a) ("All applicants and registrants shall provide effective controls to guard against theft and diversion of controlled substances."); 21 U.S.C. § 832 ("Each registrant shall—design and operate a system to identify suspicious orders for the registrant … and upon discovering a suspicious order or series of orders, notify the Administrator of the Drug Enforcement Administration….").

[15] *Improving Predictability and Transparency in DEA and FDA Regulation: Hearing Before the H. Comm. on Energy & Commerce, Subcomm. on Health,* 113th Congress 1 (2014) (statement of Joseph T. Rannazzisi, DEA).

[16] The CSA defines "dispense" to mean "to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery." 21 U.S.C. § 802 (10).

[17] The CSA refers to an individual patient as an "ultimate user," meaning "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household." *Id*. § 802(27).

[18] Drug Enf't Admin., *Definition and Registration of Reverse Distributors*, 70 Fed. Reg. 22,591 (May 2, 2005).

[19] 21 U.S.C. § 822(c)(3).

[20] DEA, *Definition and Registration of Reverse Distributors*, 68 Fed. Reg. 41,222, 41,226 (proposed July 11, 2003).

[21] The CSA defines the term "practitioner" to mean "a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research." 21 U.S.C. § 802(21).

[22] *Improving Predictability and Transparency in DEA and FDA Regulation: Hearing Before the H. Comm. on Energy & Commerce, Subcomm. on Health,* 113th Congress 2 (2014) (statement of Joseph T. Rannazzisi, DEA).

[23] *Id.*

emergency room visits, two defining features of the current opioid epidemic.[24] In addition, some users who abuse prescription opioids may also start using cheaper and potentially easier to obtain illicit opioids such as heroin, which provide similar euphoric effects.[25]

The CSA provides civil and criminal penalties for any unlawful[26] manufacture, distribution, importation, exportation, or possession of controlled substances.[27] Such violations may include (1) "regulatory" offenses committed by registrants who do not adhere to their responsibilities under the CSA, thereby increasing the risk of diversion, and (2) illicit trafficking or possession crimes that occur outside the "closed system" of authorized controlled substance distribution that primarily involve non-registrants.[28]

This report first provides a brief overview of the opioid epidemic and then describes in greater detail the current federal legal regime governing opioids and other controlled substances under the CSA and its implementing regulations. After that, the report examines DEA actions taken that are specifically targeted at addressing opioid abuse and describes recently enacted laws amending the CSA that impact the opioid regulatory system, including the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (P.L. 115-271), enacted by the 115th Congress. The report concludes by discussing other legislative options that the 116th Congress could consider to amend the CSA further to address the opioid epidemic.

Brief Background on the Opioid Epidemic[29]

The Centers for Disease Control and Prevention (CDC) has declared that the nation "is in the midst of an opioid overdose epidemic," citing statistics that show the number of overdose deaths involving opioids (including prescription opioids and illegal opioids such as heroin and non-

[24] *America's Addiction to Opioids: Heroin and Prescription Drug Abuse, Hearing Before the S. Caucus on Int'l Narcotics Control*, 113th Cong. 3-4 (2014) (statement of Dr. Nora D. Volkow, Director, Nat'l Inst. on Drug Abuse); *see also* Masters Pharm., Inc. v. DEA, 861 F.3d 206, 211 (D.C. Cir. 2017)("Breakthroughs in the development of prescription opioid painkillers have vastly increased their popularity. But that popularity has taken a toll. Opioids are heavily addictive and often lethal in high doses.").

[25] *Id.* at 4, 8; *see also* Nat'l Inst. on Drug Abuse, *Prescription Opioid Use is a Risk Factor for Heroin Use*, https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use (last visited Apr. 3, 2018).

[26] "Unlawful" in this context means any actions involving controlled substances that are not authorized under the CSA. *See* Drug Enf't Admin., *Electronic Prescriptions for Controlled Substances*, 75 Fed. Reg. 16,236, 16,237 (Mar. 31, 2010) ("The Controlled Substances Act is unique among criminal laws in that it stipulates acts pertaining to controlled substances that are permissible. That is, if the CSA does not explicitly permit an action pertaining to a controlled substance, then by its lack of explicit permissibility the act is prohibited.").

[27] 21 U.S.C. §§ 841-865.

[28] This report is focused primarily on the CSA's non-criminal regulatory provisions pertaining to activities permitted by the CSA. For a listing of the CSA's criminal provisions regarding *unauthorized* trafficking, possession, or other prohibited activities involving controlled substances, *see* CRS Report RL30722, *Drug Offenses: Maximum Fines and Terms of Imprisonment for Violation of the Federal Controlled Substances Act and Related Laws*, by Brian T. Yeh.

[29] For more information about the opioid epidemic, see CRS Report R44987, *The Opioid Epidemic and Federal Efforts to Address It: Frequently Asked Questions*, by Lisa N. Sacco and Erin Bagalman; CRS Report R45279, *Buprenorphine and the Opioid Crisis: A Primer for Congress*, by Johnathan H. Duff; CRS In Focus IF11041, *The Opioid Epidemic and the U.S. Labor Market*, by Sarah A. Donovan and Johnathan H. Duff; CRS In Focus IF10219, *Opioid Treatment Programs and Related Federal Regulations*, by Johnathan H. Duff; CRS Legal Sidebar LSB10226, *State and Local Governments Pursue Judicial Solutions to the Opioid Epidemic*, by Jennifer A. Staman; and CRS Report R45218, *The Opioid Epidemic and the Food and Drug Administration: Legal Authorities and Recent Agency Action*, by Jennifer A. Staman.

pharmaceutical fentanyl) has more than quadrupled since 1999, and on average 115 Americans now die each day from an opioid overdose.[30] Former Attorney General Jeff Sessions referred to the opioid epidemic as "the deadliest drug crisis in American history,"[31] and President Trump in October 2017 directed the Secretary of Health and Human Services to declare the crisis a national public health emergency.[32]

The CSA defines the term "opioid" to mean "any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability."[33] Opioids can include prescription pain relief drugs[34] such as hydrocodone, oxycodone, codeine, morphine, and fentanyl,[35] as well as illegal drugs such as heroin and non-pharmaceutical (illicitly produced) fentanyl.[36] While doctors may prescribe U.S. Food and Drug Administration (FDA)-approved opioids to patients to alleviate their pain, particularly following surgery or injury or for serious health conditions such as cancer, some individuals may choose to abuse opioids for non-medical reasons (such as to experience feelings of relaxation or to get "high") or by taking them in a higher dosage or through different means than prescribed by their doctor (such as by snorting or injecting the substance into a vein).[37] The CDC has estimated that more than 40% of all opioid overdose deaths in the United States in 2016 involved an FDA-approved prescription opioid.[38]

How the opioid epidemic occurred, and who is responsible for fueling it, are complicated questions, though reports have suggested that many parties are likely involved to some extent, including pharmaceutical manufacturers[39] and distributors,[40] doctors,[41] health insurance

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[30] Centers for Disease Control and Prevention, *Opioid Overdose: Understanding the Epidemic*, https://www.cdc.gov/drugoverdose/epidemic/index.html (last visited Apr. 3, 2018).

[31] Press Release, U.S. Dep't of Just., Off. of Pub. Aff., Department of Justice Awards Nearly $59 Million to Combat Opioid Epidemic, Fund Drug Courts (Sept. 22, 2017), https://www.justice.gov/opa/pr/department-justice-awards-nearly-59-million-combat-opioid-epidemic-fund-drug-courts.

[32] U.S. DEP'T OF HEALTH & HUM. SRVS., DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS (Oct. 2017), https://www.hhs.gov/sites/default/files/opioid%20PHE%20Declaration-no-sig.pdf; *see also* Brianna Ehley, *Trump Administration Extending Opioid Emergency Declaration*, POLITICO (Jan. 19, 2018, 8:14 PM), https://www.politico.com/story/2018/01/19/trump-opioids-emergency-declaration-extension-300590. For information about what the declaration of a public health emergency does to provide the Secretary of Health and Human Services with additional authorities and resources to address the emergency, *see* U.S. Dep't of Health & Hum. Srvs., *Public Health Emergency Declaration*, https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx (last visited Apr. 11, 2018).

[33] 21 U.S.C. § 802(18).

[34] Prescription drugs are medications that may be marketed in the United States only after the U.S. Food and Drug Administration has approved their safety and effectiveness. For more information on this topic, see CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by Agata Dabrowska and Susan Thaul.

[35] NAT'L INST. ON DRUG ABUSE, DRUG FACTS: PRESCRIPTION OPIOIDS 1 (Jan. 2018), https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/drugfacts-prescriptionopioids.pdf.

[36] Nat'l Inst. on Drug Abuse, *Opioids*, https://www.drugabuse.gov/drugs-abuse/opioids (last visited Apr. 11, 2018).

[37] NAT'L INST. ON DRUG ABUSE, DRUG FACTS: PRESCRIPTION OPIOIDS 1-2 (Jan. 2018).

[38] Centers for Disease Control and Prevention, *Opioid Overdose: Prescription Opioid Overdose Data*, https://www.cdc.gov/drugoverdose/data/overdose.html (last visited Apr. 3, 2018).

[39] Alana Semuels, *Are Pharmaceutical Companies to Blame for the Opioid Epidemic?*, THE ATLANTIC (June 2, 2017), https://www.theatlantic.com/business/archive/2017/06/lawsuit-pharmaceutical-companies-opioids/529020/.

[40] David Meyer & Geoffrey Smith, *DEA Whistleblower Blasts Drug Distributors, Congress Over Opioid "Collusion,"* FORTUNE (Oct. 16, 2017), http://fortune.com/2017/10/16/rannazzisi-dea-drug-distributors-opioids/.

[41] Mandy Oaklander, *How Doctors Are Fueling the Opioid Epidemic*, TIME (Feb. 17, 2017), http://time.com/4675325/doctors-opioid-epidemic/.

companies,[42] rogue pharmacies,[43] and drug dealers and addicts.[44] The National Institute on Drug Abuse has described the origins of the opioid overdose crisis as follows:

> In the late 1990s, pharmaceutical companies reassured the medical community that patients would not become addicted to prescription opioid pain relievers, and healthcare providers began to prescribe them at greater rates. This subsequently led to widespread diversion and misuse of these medications before it became clear that these medications could indeed be highly addictive.[45]

The President's Commission on Combating Drug Addiction and the Opioid Crisis[46] also cited excessive prescribing of opioids since 1999 as a significant contributor to the proliferation of opioids.[47] The Commission identified several other factors that have influenced the current opioid crisis, including large scale production and distribution of addictive opioids, widespread availability of illicit heroin and fentanyl, unethical physician prescribing practices and rogue pharmacies that fill those illegitimate prescriptions, and a lack of education for medical professionals and patients in prescribing and using opioids, respectively.[48]

Overview of the CSA

This section provides a general overview of the CSA's closed system of distribution that regulates opioids and other types of controlled substances, including the schedules in which the substances are placed and the regulatory requirements and obligations that registrants must satisfy, such as (1) registering with the DEA, (2) keeping accurate and complete records of controlled substance inventories and transactions, (3) implementing security measures to safeguard controlled substances from theft or diversion, (4) reporting certain information to the DEA (including suspicious controlled substance orders), (5) meeting production quotas, and (6) prescribing controlled substances only for legitimate medical purposes.

Scheduling of Controlled Substances

The CSA places various plants, drugs, and chemicals (such as narcotics, stimulants, depressants, hallucinogens, and anabolic steroids) into one of five schedules based on the substance's medical

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[42] Katie Thomas & Charles Ornstein, *Amid Opioid Crisis, Insurers Restrict Pricey, Less Addictive Painkillers,* N.Y. TIMES (Sept. 17, 2017), https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurance-companies.html.

[43] Press Release, Drug Enf't Admin. Pub. Aff., DEA Large-scale Operation Targets 26 Pharmacies in Three States in Attack Against Illicit Opioid Abuse and Trafficking (Nov. 9, 2017), https://www.dea.gov/divisions/hq/2017/hq120517.shtml.

[44] Nathaniel Popper, *Opioid Dealers Embrace the Dark Web to Send Deadly Drugs by Mail,* N.Y. TIMES (June 10, 2017), https://www.nytimes.com/2017/06/10/business/dealbook/opioid-dark-web-drug-overdose.html.

[45] Nat'l Inst. on Drug Abuse, *Opioid Overdose Crisis*, https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (last visited Apr. 3, 2018); *see also Fentanyl: The Next Wave of the Opioid Crisis: Hearing Before the H. Comm. on Energy & Commerce, Subcomm. on Oversight and Investigations,* 115th Cong. 5 (2017) (statement of Dr. Wilson Compton, Deputy Dir., Nat'l Inst. on Drug Abuse).

[46] Established by Exec. Order No. 13,784, 82 Fed. Reg. 16,283 (Apr. 3, 2017).

[47] THE PRESIDENT'S COMMISSION ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS: FINAL REPORT 19-23 (2017), https://www.whitehouse.gov/ondcp/presidents-commission/; *see also* Substance Abuse & Mental Health Srvs. Admin., *Prescription Drug Misuse and Abuse,* https://www.samhsa.gov/topics/prescription-drug-misuse-abuse (last visited Apr. 4, 2018) ("The problem of prescription drug abuse and overdose is complex, involving insufficient oversight to curb inappropriate prescribing, insurance and pharmacy benefit policies, and a belief by many people that prescription drugs are not dangerous.").

[48] *Id.*

use, potential for abuse, and safety or dependence liability.[49] Opioids are types of narcotic drugs.[50] To restrict access to chemicals used in the illicit manufacture of certain controlled substances, the CSA also regulates specified "listed chemicals."[51] Furthermore, the CSA regulates controlled substance "analogues," which are substances that are not controlled but have chemical structures substantially similar to those of controlled substances found in Schedule I or II.[52]

The order of the five schedules in which controlled substances are categorized reflects substances that are progressively less dangerous and addictive.[53] Schedule I contains substances, such as the hallucinogen lysergic acid diethylamide (LSD) and the illicit opioid heroin, that have "a high potential for abuse" with "no currently accepted medical use in treatment in the United States" and that cannot safely be dispensed under a prescription.[54] Schedule I substances may be used only for bona fide, federal government-approved research studies.[55] In contrast, schedules II, III, IV, and V include substances that have recognized medical uses, such as prescription opioids like oxycodone, codeine, and morphine, and may be manufactured, distributed, prescribed, dispensed, and possessed in accordance with the CSA.[56]

The CSA provides an administrative mechanism for substances to be controlled (added to a schedule);[57] decontrolled (removed from the scheduling framework altogether); and rescheduled or transferred from one schedule to another.[58] Federal rulemaking proceedings to add, delete, or change the schedule of a drug or substance may be initiated by the DEA, the U.S. Department of Health and Human Services (HHS), or by petition by any interested person.[59] The DEA Administrator must request from HHS a scientific and medical evaluation and recommendation as to whether the drug or substance should be controlled or removed from control.[60] The DEA Administrator then must evaluate all of the relevant data and make a final determination as to whether the drug or substance should be controlled or removed entirely from control.[61]

In making such determination, the DEA Administrator is required to consider statutory factors such as the drug's actual or relative potential for abuse; scientific evidence of its pharmacological

[49] 21 U.S.C. § 812(b).

[50] 21 C.F.R. § 1300.01 (definition of "narcotic drug").

[51] 21 U.S.C. §§ 830; 802 (33-35). Listed chemicals are divided into two categories: List I and List II. While both categories of chemicals can be used to manufacture controlled substances illicitly, List I chemicals are more strenuously regulated under the CSA than List II chemicals because List I chemicals are "important to the manufacture of the controlled substances." *Id.* § 802(34).

[52] *Id.* § 802(32)(A) and (B).

[53] When Congress enacted the CSA in 1970, it established "initial schedules" of controlled substances, *id.* § 812(c), but specified that the schedules "shall be updated" periodically, *id.* § 812(a). The current list of controlled substances within their designated schedules may be found in 21 C.F.R. §1308.11-15.

[54] 21 U.S.C. § 812(b).

[55] *Id.* § 823(f).

[56] *Id.* § 812(b).

[57] The CSA defines the term "control" to mean "to add a drug or other substance, or immediate precursor, to a schedule under [§ 812 of the act], whether by transfer from another schedule or otherwise." *Id.* § 802(5).

[58] *Id.* § 811 specifies the administrative scheduling procedures.

[59] *Id.* § 811(a).

[60] *Id.* § 811(b). The medical and scientific evaluations are binding on the DEA with respect to such matters and form a part of the scheduling decision. The recommendation on the initial scheduling of a substance is binding only to the extent that if HHS recommends that the drug or substance not be controlled, the DEA may not add it to its schedules. *Id.*

[61] *Id.*

effect; the current state of scientific knowledge regarding the drug or substance; the risk to the public health from the drug; and whether the substance is an immediate precursor[62] of a substance already controlled under the act.[63] After the DEA Administrator makes this determination, he must make specific findings concerning the drug or substance that dictate the schedule in which the drug or substance will be placed.[64]

For example, in 2009, the DEA requested from HHS an evaluation and recommendation concerning whether to reschedule hydrocodone combination products (HCPs) such as Vicodin® from Schedule III to Schedule II.[65] After evaluating the scientific and medical evidence showing, among other things, significant diversion of HCPs and the health and safety risks created by people who abuse HCPs, HHS then recommended to DEA that HCPs should be reclassified to the more restrictive Schedule II,[66] In 2014, DEA published a final rule that administratively reschedules HCPs from Schedule III to Schedule II, thereby subjecting anyone who manufactures, distributes, or dispenses HCPs to the more stringent regulatory requirements (and administrative, civil, and criminal sanctions) that are applicable to Schedule II controlled substances.[67]

Congress may also change the scheduling status of a drug or substance at any time through enactment of legislation. For example, Congress passed the Synthetic Drug Abuse Prevention Act of 2012[68] that permanently added two synthetic cathinones (central nervous system stimulants) to Schedule I of the CSA, along with cannabimimetic substances (commonly referred to as synthetic marijuana).[69]

Emergency or Temporary Scheduling

The CSA authorizes the DEA Administrator to place a drug or substance that is not currently controlled, on a temporary basis, into Schedule I when he finds such scheduling "necessary to avoid an imminent hazard to the public safety."[70] The DEA Administrator may not issue a temporary scheduling order until 30 days after he notifies both the public and the HHS Secretary of his intent to issue the temporary scheduling order and of his justification for issuing the order.[71] Furthermore, the DEA Administrator must consider the HHS Secretary's comments regarding the

[62] The CSA defines an "immediate precursor" to mean a substance that (1) the DEA Administrator has determined to be and has "designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;" (2) "is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance;" and (3) is necessary to control "to prevent, curtail, or limit the manufacture of such controlled substance." 21 U.S.C. § 802 (definition of "immediate precursor").

[63] *See id.* § 811(c)(1)-(8) (complete listing of factors the DEA Administrator must consider when determining control or removal of substances from schedules).

[64] *See id.* § 812(b) ("[A] drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance.").

[65] Drug Enf't Admin., *Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II*, 79 Fed. Reg. 49,661, 49,662 (Aug. 22, 2014).

[66] *Id.* at 49.663.

[67] *Id.* at 49,680.

[68] P.L. 112-144, 126 Stat. 1130 (2012).

[69] For more information on this law and this topic generally, *see* CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea.

[70] 21 U.S.C. § 811(h)(1).

[71] *Id.*

temporary order.[72] A drug or substance may be temporarily scheduled for two years and possibly longer—up to an additional year—if formal scheduling procedures have been initiated.[73] As discussed below in the report, DEA has exercised its emergency scheduling authority eight times to control seventeen substances structurally related to the opioid fentanyl by placing them temporarily in Schedule I.[74]

Scheduling in Order to Satisfy International Treaty Obligations

Treaty obligations may require the DEA Administrator to control or reschedule a substance if existing controls under federal law are less stringent than those required by a treaty.[75] The United States is a party to three United Nations drug control treaties that impose certain international obligations relating to the manufacture, distribution, use, and possession of controlled substances, including the Single Convention on Narcotic Drugs of 1961,[76] which was designed to establish effective control over international and domestic traffic in narcotics, coca leaf, cocaine, and marijuana.[77] The United States is also party to the Convention on Psychotropic Substances of 1971,[78] which was designed to establish similar control over stimulants, depressants, and hallucinogens. Finally, the United States is a party to the 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances,[79] which requires parties, among other things, to control precursor chemicals used in the illicit manufacture of drugs and to take measures to combat money laundering crimes related to drug trafficking.

Who Must Register with the DEA?

The CSA requires any person who seeks to manufacture, distribute, dispense, or conduct research involving any controlled substance (such as drug manufacturers, wholesale distributors, physicians, hospitals, pharmacies, and scientific researchers) to obtain a registration from the

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[72] *Id.* § 811(h)(4).

[73] *Id.* § 811(h)(2).

[74] Drug Enf't Admin., *Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I,* 83 Fed. Reg. 5,188, 5,189 (Feb. 6, 2018).

[75] The procedures for scheduling actions to meet obligations under international treaties are found at *id.* § 811(d).

[76] Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407.

[77] For example, in response to petitions from the public to transfer marijuana from Schedule I of the CSA to Schedule II, the DEA explained how the United States obligations under the international drug control treaties constrain the agency's choice of schedules with respect to marijuana:

> The DEA Administrator is obligated under [21 U.S.C.] section 811(d) to control marijuana in the schedule that he deems most appropriate to carry out the U.S. obligations under the Single Convention. It has been established in prior marijuana rescheduling proceedings that placement of marijuana in either schedule I or schedule II of the CSA is ''necessary as well as sufficient to satisfy our international obligations'' under the Single Convention. NORML v. DEA, 559 F.2d 735, 751 (D.C. Cir. 1977). As the United States Court of Appeals for the DC Circuit has stated, ''several requirements imposed by the Single Convention would not be met if cannabis and cannabis resin were placed in CSA schedule III, IV, or V.'' *Id.* Therefore, in accordance with section 811(d)(1), DEA must place marijuana in either schedule I or schedule II.

Drug Enf't Admin., *Denial of Petition to Initiate Proceedings to Reschedule Marijuana,* 81 Fed. Reg. 53,687, 53,689 (Aug. 12, 2016).

[78] Convention on Psychotropic Substances, Feb. 21, 1971, 32 U.S.T. 543.

[79] Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, Dec. 20, 1988, S. TREATY DOC. No. 101-4 (1989).

DEA,[80] unless they are exempt.[81] Registrations specify the extent to which the DEA has authorized registrants to manufacture, possess, distribute, or dispense controlled substances.[82] The DEA currently regulates more than 1.73 million registrants.[83] The CSA authorizes the DEA Administrator to charge reasonable fees relating to the registration and control of the manufacturing, distribution, and dispensing of controlled substances under the act.[84]

The CSA directs the DEA Administrator to register an applicant if the Administrator determines that, among other things, it would be consistent with the "public interest" to do so.[85] The CSA provides several criteria that the DEA Administrator must consider in assessing whether registering an applicant is consistent with the "public interest." The criteria differ depending on the substance involved and whether the applicant is a manufacturer, distributor, or practitioner, but include general factors such as those relating to public health and safety and compliance with state and local laws.[86] Manufacturers and distributors of controlled substances must obtain a registration from the DEA annually, and those who dispense controlled substances must obtain registrations that may not be issued for less than one year or more than three years.[87] The registration of an individual terminates when the person dies, ceases legal existence, or discontinues business or professional practice.[88] A registration cannot be transferred to someone else unless the Administrator provides his express, written consent for such a transfer to occur.[89]

In some instances, applicants must apply for several separate registrations in order to comply with the CSA. For example, separate registrations are generally required for each principal place of business or professional practice where controlled substances are manufactured, distributed,

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[80] 21 U.S.C. § 822(a).

[81] *Id.* § 822(c) (agents of registrants, common carriers, and patients who lawfully possess controlled substances); 21 C.F.R. §§ 1301.23-1301.24 (certain military personnel, and law enforcement officials). These exemptions are discussed in further detail in the next section.

[82] 21 U.S.C. § 822(b).

[83] U.S. Dep't of Just., FY 2019 Budget and Performance Summary – Drug Enforcement Administration (DEA) 2, https://www.justice.gov/jmd/page/file/1033151/download (last visited Mar. 22, 2018).

[84] 21 U.S.C. § 821; *see also* 21 C.F.R. § 1301.13(e)(1) (chart detailing specific types of registrations and respective fees). The DEA is required to set these fees at a level that ensures the recovery of the full cost of conducting its controlled substance and chemical diversion control activities. 21 U.S.C. § 886a(1)(C).

[85] *Id.* § 823(a). With respect to manufacturers of controlled substances in schedules I or II, the statute also requires the DEA Administrator to determine whether such registration is consistent with "United States obligations under international treaties, conventions, or protocols in effect on" May 1, 1971. *Id.*

[86] *Id.* §§ 823(a)-(f).

[87] *Id.* § 822(a). Registrants can seek to renew their registrations by submitting a renewal application to the DEA. U.S. DEP'T OF JUST., DEA, RENEWAL APPLICATION FOR REGISTRATION UNDER CONTROLLED SUBSTANCES ACT OF 1970, https://apps.deadiversion.usdoj.gov/webforms/jsp/regapps/common/renewalAppLogin.jsp (last visited Mar. 21, 2018). In the renewal process, registrants must report any criminal activity they have engaged in and any other changes to their professional or legal status that could impact their ability to handle controlled substances. U.S. DEP'T OF JUST., DEA FORM 224A, RENEWAL APPLICATION FOR REGISTRATION, § 4, https://www.reginfo.gov/public/do/DownloadDocument?objectID=9770701 (last visited Mar. 21, 2018). For example, a registrant must notify the DEA of any criminal convictions against the registrant in connection with controlled substances and any suspension, revocation, restriction, or denial of the registrant's state license or registration relating to controlled substances. *Id. See also* U.S. GOV'T ACCOUNTABILITY OFF., GAO-16-310, DEA SHOULD TAKE ADDITIONAL ACTIONS TO REDUCE RISKS IN MONITORING THE CONTINUED ELIGIBILITY OF ITS REGISTRANTS 22 (2016) ("If the registrant does not self-report any liabilities and there are no changes to the information contained in the registrant's record (such as changes to the registrant's name, address, or state license number), then the renewal is automatically approved without further checks against state licensure websites.").

[88] 21 C.F.R. § 1301.52(a).

[89] *Id.* § 1301.52(b).

imported, exported, or dispensed.[90] For example, a physician who is regularly engaged in dispensing controlled substances at one location must register to dispense controlled substances at other locations if he chooses to dispense controlled substances at these other locations.[91]

Exceptions to the Registration Requirement

The CSA allows for exceptions and also exempts certain individuals from some or all of its regulatory requirements. For example, individuals exempted from registration requirements include, among others, officers or employees of the DEA, officers of the U.S. Customs Service, offers or employees of the FDA, and any other federal officers who are authorized to possess, import, or export controlled substances in the course of their official duties.[92] Officers or employees of any state, or political subdivision of a state, who are engaged in enforcement of state or local laws relating to controlled substances, are also exempt from registering with the DEA.[93] A person who has lawfully obtained, and who possesses, a controlled substance for his own legitimate medical use (a patient) is also not required to register.[94]

In addition, only those actually engaged in activities relating to manufacturing, distributing, and dispensing controlled substances are required to obtain registration, but related or affiliated persons who are not engaged in such activities are not required to register. For example, a stockholder or parent corporation of a corporation that manufactures controlled substances is not required to obtain registration, nor are employees of a registered manufacturer, distributor, or dispenser.[95]

The DEA Administrator may, by regulation, waive the registration requirement for certain manufacturers, distributors, or dispensers, if he finds it consistent with the public health and safety.[96]

Regulatory Obligations of Registrants Under the CSA

The CSA imposes specific obligations on registrants in an effort to reduce the potential diversion of controlled substances out of legitimate distribution channels.[97] In particular, the CSA imposes legal duties relating to (1) recordkeeping by registrants, (2) measures ensuring the secure storage of controlled substances handled by registrants, (3) reporting certain information to the DEA, (4)

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[90] 21 U.S.C. § 822(e)(1); 21 C.F.R. § 1301.12.

[91] *See* United States v. Clinical Leasing Serv., Inc., 925 F.2d 120, 122 (5th Cir. 1991) (explaining that the "plain language" of 21 C.F.R. § 1301.12 requires that "a physician must be separately registered at each physical location in which he administers controlled substances as a regular part of his professional practice.").

[92] 21 C.F.R. § 1301.24(a)(1).

[93] *Id.* § 1301.24(a)(2). For additional registration exceptions, see *id*. §§ 1301.22-1301.23.

[94] 21 U.S.C. § 822(c).

[95] 21 C.F.R. § 1301.11(a); 21 U.S.C. § 822(c).

[96] 21 U.S.C. § 822(d). For example, in November 2014, the DEA published a rule that waived the requirement of registration for certain individuals who directly administer a particular diagnostic pharmaceutical that contains a radioactive component. Drug Enf't Admin., *Exemption From Registration for Persons Authorized Under U.S. Nuclear Regulatory Commission or Agreement State Medical Use Licenses or Permits and Administering the Drug Product DaTscan™*, 79 Fed. Reg. 70,085 (Nov. 25, 2014). The DEA later removed this exemption after it had administratively removed the radioactive component from the schedules of controlled substances. Drug Enf't Admin., *Removal of Exemption From Registration for Persons Authorized Under U.S. Nuclear Regulatory Commission or Agreement,* 81 Fed. Reg. 9,763 (Feb. 26, 2016).

[97] *Responding to the Prescription Drug Abuse Epidemic: Hearing Before the S. Caucus on Int'l Narcotics Control,* 112th Cong. 4-5 (2012) (statement of Joseph T. Rannazzisi, DEA).

prescribing and dispensing controlled substance medications by registered doctors and pharmacists, and (5) the quantity of controlled substance that may be produced by manufacturers.

Recordkeeping

All registrants are required by the CSA to maintain complete and accurate inventories and records of all regulated transactions involving controlled substances and listed chemicals.[98] For example, a registrant must make a complete and accurate record of each substance manufactured, received, sold, delivered, or otherwise disposed of by the registrant.[99] Furthermore, inventories must be available for inspection by the DEA for at least two years.[100] The CSA declares that it is unlawful for any person to "refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required" by the CSA.[101] It is also unlawful for any person knowingly or intentionally "to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed" under the CSA.[102]

In certain circumstances, the CSA recordkeeping provisions do not apply. For example, the provisions do not apply to the prescribing or administering of a controlled substance listed in Schedules II-V by practitioners acting in the lawful course of their professional practice *unless* such substance is prescribed or administered in the course of maintenance or detoxification treatment of an individual.[103] As discussed below, this has implications for the drugs typically used in the treatment of opioid addiction, two of which are controlled substances, while the other is not.

Security Measures

For the purposes of ensuring the secure storage and distribution of controlled substances and listed chemicals, all applicants for DEA registration and registrants must generally "provide effective controls and procedures to guard against theft and diversion of controlled substances."[104] DEA regulations also detail specific security requirements for different types of applicants and registrants. For example, non-practitioners (i.e., manufacturers, distributors, and narcotic treatment programs) are required to store Schedule I and II substances in electronically monitored safes, steel cabinets, or vaults that meet or exceed certain specifications.[105] Licensed practitioners must store controlled substances in a "securely locked, substantially constructed cabinet"[106] and must notify the DEA of the theft or significant loss of any controlled substances within one

[98] 21 U.S.C. § 827(a).

[99] *Id.* § 827(a)(3); 21 C.F.R. § 1304.21(a).

[100] 21 U.S.C. § 827(b)(3); 21 C.F.R. § 1304.04(a).

[101] 21 U.S.C. § 842(a)(5).

[102] *Id.* § 843(a)(4).

[103] *Id.* §§ 827(c)(1)(A), 827(c)(1)(B). Thus, the prescribing or administering of methadone for the treatment of narcotic addiction must be in conformity with the CSA's recordkeeping provisions.

[104] 21 C.F.R. § 1301.71 (general security requirements and standards for measuring compliance); *see also* 21 U.S.C. § 823 (requiring the DEA Administrator, when determining whether a registration is consistent with the public interest, to consider if the applicant or registrant has in place "effective controls against diversion.").

[105] *See* 21 C.F.R. §§ 1301.72(a)(1)(i)-(iii) (specifications required for safes and steel cabinets storing Schedule I and II drugs or substances); *see also id.* §§ 1301.72(a)(2) and 1301.72(a)(3)(i)-(vi) (specifications required for vaults storing Schedule I and II drugs or substances).

[106] *See id.* § 1301.75 (physical security controls for practitioners).

business day of discovering such loss or theft.[107] Furthermore, all practitioners are prohibited from hiring employees who have been convicted of a drug-related felony or who have had a DEA registration denied or revoked.[108] DEA regulations recommend that non-practitioners carefully screen individuals before hiring them as employees, to ensure that job applicants do not have convictions for crimes or have not engaged in unauthorized use of controlled substances.[109]

Reporting

The CSA requires manufacturers, distributors, and pharmacies to report periodically to the DEA every sale, delivery, disposal, or dispensing of any controlled substance.[110] Registered pharmacies that are authorized to dispense controlled substances by means of the Internet must also report to the DEA Administrator the type and total quantity of each controlled substance that the pharmacy has dispensed each month via the Internet.[111] In addition, the CSA requires manufacturers, distributors, and dispensers of controlled substances (1) to design and operate a system (that is compliant with applicable federal and state privacy laws) that will alert the registrant of suspicious orders of controlled substances, and (2) upon discovering a suspicious order or series of orders, to inform the DEA Administrator and the Special Agent in Charge of the DEA Field Division Office.[112] The CSA defines "suspicious orders" as those that may include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.[113]

Manufacturers and distributors of Schedule I and II drugs must file reports[114] with the DEA through the Automated Reports and Consolidated Orders System (ARCOS),[115] which is an automated drug reporting system that allows the agency to "monitor[] the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level.... "[116] Certain narcotics listed in Schedules III and IV are also covered by the ARCOS reporting requirements.[117] According to the DEA, U.S. attorneys and DEA investigators may use ARCOS controlled substances transaction information "to strengthen criminal cases in the courts."[118]

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[107] *Id*. § 1301.76(b).

[108] *Id*. § 1301.76(a).

[109] *Id*. § 1301.90.

[110] 21 U.S.C. § 827(d).

[111] *Id*. § 827(d)(2). However, pharmacies are exempt from such reporting requirement if they do not exceed in a given month either of two thresholds: (1) 100 or more prescriptions dispensed, or (2) 5,000 or more dosage units of all controlled substances combined. *Id.*

[112] *Id*. § 832, as added by P.L. 115-271, § 3292(b).

[113] 21 U.S.C. § 802(57), as added by P.L. 115-271, § 3292(a).

[114] 21 C.F.R. §§ 1304.31 and 1304.32.

[115] *Id*. § 1304.33.

[116] Drug Enf't Admin., *Automation of Reports and Consolidated Orders System (ARCOS)*, https://www.deadiversion.usdoj.gov/arcos/index.html (last visited Apr. 4, 2018).

[117] 21 C.F.R. § 1304.33(d).

[118] Drug Enf't Admin., *Automation of Reports and Consolidated Orders System (ARCOS)*, https://www.deadiversion.usdoj.gov/arcos/index.html (last visited Apr. 4, 2018).

Quotas

The CSA includes a production quota system that requires the DEA to establish the total amount of each basic class of Schedule I and II controlled substances and certain listed chemicals[119] that may be manufactured in a given calendar year, in order "to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks."[120] The DEA establishes this quota, referred to as the aggregate production quota (APQ), for approximately 200 Schedule I and II controlled substances.[121] The DEA assigns individual production quotas to controlled substance manufacturers that prevent the APQ from being exceeded.[122] The CSA allows a registrant to apply for an increase in his individual manufacturing quota if it is necessary "to meet his estimated disposal, inventory, and other requirements during the remainder of that year."[123]

By regulation, the DEA Administrator must consider the following factors in making his APQ determinations: (1) the total disposal of the controlled substance during the current year and two preceding years; (2) trends in the national rate of new disposal of the controlled substance; (3) total inventories (actual or estimated) of "the class and all substances manufactured from the class [of controlled substances listed in Schedule I or II];" (4) projected demand for a particular controlled substance; (5) the extent of any diversion of the controlled substance in the class; (6) relevant information obtained from the Department of Health and Human Services and from the states; and (7) other relevant factors affecting the use of controlled substances including changes in the currently accepted medical use of a controlled substance, the economic and physical availability of the raw materials necessary to produce a controlled substance, and recent unforeseen emergencies (i.e., natural disasters).[124]

A registrant may not manufacture a Schedule I or II controlled substance or a specified listed chemical that is (1) not expressly authorized by his registration and by the individual quota assigned to him by the DEA, or (2) in excess of that quota.[125]

Prescription Requirements

The CSA provides specific requirements that practitioners and pharmacists must observe when prescribing and dispensing controlled substances in Schedules II-V to patients for legitimate medical purposes.[126] As noted, controlled substances classified as Schedule I drugs are deemed to have no accepted medical purpose in the United States, and thus they may only be used for research,[127] and may not be prescribed or dispensed to patients.[128] DEA regulations hold both the

[119] These listed chemicals are ephedrine, pseudoephedrine, and phenylpropanolamine, which are ingredients commonly found in over-the-counter cold medicines that may be used in the production of methamphetamine and amphetamine. Drug Enf't Admin., CMEA (Combat Methamphetamine Epidemic Act) Questions & Answers, https://www.deadiversion.usdoj.gov/meth/q_a_cmea.htm (last visited Apr. 10, 2018).

[120] 21 U.S.C. § 826(a)(1).

[121] *Improving Management of the Controlled Substances Quota Process, Hearing Before the S. Caucus on Int'l Narcotics Control*, 114th Cong. 3 (2015) (statement of Joseph T. Rannazzisi, DEA).

[122] 21 U.S.C. § 826(b).

[123] *See id*. § 826(e).

[124] 21 C.F.R. §§ 1303.11(b)(1)-(7).

[125] 21 U.S.C. §§ 842(b).

[126] *Id*. § 829.

[127] *Id.* § 823(f).

[128] *Id*. § 812(b)(1).

prescribing practitioner and the pharmacist who fills the prescription responsible for ensuring that the controlled substance is properly prescribed and dispensed.[129] A DEA manual prepared for pharmacists to help them understand their obligations under the CSA explains that

> A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances.[130]

Practitioners

Under the CSA, only licensed medical practitioners are authorized to prescribe controlled substances listed in Schedules II-V to patients.[131] A prescription for a controlled substance must be "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[132] A pharmacist may not dispense to a patient a Schedule II controlled substance without a written prescription[133] from a practitioner, except in certain cases where the practitioner administers the controlled substance directly to the patient.[134] However, in the case of an "emergency situation,"[135] a practitioner may orally authorize a pharmacist to fill a prescription for a Schedule II controlled substance.[136] Controlled substances in Schedules III-V may be dispensed by a pharmacy pursuant to either a written or oral prescription, including a facsimile of a written prescription.[137] These substances may also be administered or dispensed directly by the practitioner in the course of his professional practice without a prescription.[138] Practitioners are permitted to sign and transmit electronic prescriptions for controlled substances,

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[129] 21 C.F.R. § 1306.04(a) ("The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.").

[130] DRUG ENF'T ADMIN., PHARMACIST'S MANUAL 30 (2010). *See also* Drug Enf't Admin., A Pharmacist's Guide to Prescription Fraud, https://www.deadiversion.usdoj.gov/pubs/brochures/pharmguide.htm (last visited Dec. 12, 2018) ("The dispensing pharmacist must maintain constant vigilance against forged or altered prescriptions. The law holds the pharmacist responsible for knowingly dispensing a prescription that was not issued in the usual course of professional treatment.").

[131] *See* 21 C.F.R. § 1306.03 (persons entitled to issue prescriptions).

[132] *Id.* § 1306.04(a)(1); United States v. Moore, 423 U.S. 122, 124 (1975) (holding that "registered physicians can be prosecuted" under 21 U.S.C. § 841 "when their activities fall outside the usual course of professional practice.").

[133] 21 U.S.C. § 829(a); *see also* 21 C.F.R. § 1306.05 (manner of issuance of prescriptions for Schedule II controlled substances).

[134] 21 U.S.C. § 829(a); *see also* 21 C.F.R. § 1306.11(b) (authorizing individual practitioners to administer or dispense controlled substances directly to patients without prescription).

[135] 21 C.F.R. § 290.10 defines an "emergency situation" as a situation in which the prescribing practitioner finds that (1) "immediate administration of the controlled substance is necessary" to treat the patient properly, (2) "no appropriate alternative treatment is available," including the use of a drug that is not a Schedule II controlled substance, and (3) "it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing."

[136] 21 U.S.C. § 829(a); 21 C.F.R. § 1306.11(d).

[137] 21 U.S.C. § 829(b). If the prescription is made orally, the pharmacist must promptly reduce to writing all of the information required to be in a prescription under 21 C.F.R. § 1306.05, except for the signature of the practitioner. *Id.* § 1306.21(a).

[138] 21 U.S.C. § 829(b); 21 C.F.R. § 1306.21(b).

assuming that the electronic prescription complies with detailed requirements set forth in the applicable federal regulations.[139]

Pharmacists

Pharmacists may partially fill a prescription for Schedule II substances under certain circumstances, such as pursuant to a request by the patient or the practitioner who wrote the prescription.[140] Pharmacists are prohibited from refilling prescriptions for Schedule II substances.[141] A pharmacist may fill or refill prescriptions for controlled substances in Schedules III and IV, however, up to five times within six months after the date on which the prescription was issued, unless the prescribing practitioner authorizes a renewal of the prescription.[142] A pharmacy may process electronic prescriptions for controlled substances if the pharmacy uses a computer application that complies with several requirements specified in the applicable federal regulations.[143] A controlled substance that is a prescription drug may not be delivered, distributed, or dispensed by means of the Internet without a "valid prescription,"[144] which the CSA defines as a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one medical evaluation of the patient in the physical presence of the practitioner.[145]

What Are the Potential Consequences for Violating the CSA?

The CSA contains a variety of criminal sanctions for *illicit* possession, manufacture, and distribution of controlled substances that occurs outside the closed system of distribution.[146] For example, the CSA outlaws "simple possession" of a controlled substance[147] (referring to a person knowingly or intentionally possessing a controlled substance) "unless such substance was obtained directly, or pursuant to" a valid prescription issued by a medical practitioner, "or except as otherwise authorized by" the CSA.[148] The CSA also prohibits any person from knowingly or

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[139] Drug Enf't Admin., *Electronic Prescriptions for Controlled Substances*, 75 Fed. Reg. 16,235, 16,307 (Mar. 31, 2010).

[140] 21 U.S.C. § 829(f).

[141] *Id*. § 829(a) ("No prescription for a controlled substance in schedule II may be refilled.").

[142] *Id*. 829(b); 21 C.F.R. § 1306.22(a).

[143] 21 C.F.R. § 1311.205. The requirements include providing the pharmacy with the ability to sign digitally and archive the controlled substance prescriptions and allowing the pharmacy to limit employee access for annotating, altering, or deleting controlled substance prescription information. *Id*.

[144] 21 U.S.C. § 829(e).

[145] *Id.*

[146] Many of these criminal penalties appear in 21 U.S.C. § 841, which provides that "[e]xcept as authorized by" the CSA, "it shall be unlawful for any person knowingly or intentionally" to commit the unlawful acts specified in § 841(a).

[147] Generally speaking, the CSA's simple possession statute is used to prosecute those found in possession of quantities of controlled substances that are consistent with "personal use" amounts and when the evidence suggests that the possession is for the purpose of personal use, rather than for resale or distribution. *See* United States v. Mack, 343 F.3d 929, 934 (8th Cir. 2003) ("We frequently rely on drug quantity as evidence of defendants' intended purpose for disposition of their drugs, i.e. personal use or sale.").

[148] 21 U.S.C. § 844(a). With the exception of simple possession of flunitrazepam (commonly used as a "date rape" drug), a first-time simple possession offense is a federal misdemeanor punishable by a maximum term of imprisonment of 1 year. (Simple possession of flunitrazepam is punishable by a term of imprisonment of up to 3 years). Anyone who commits a federal simple possession offense after a single prior conviction under federal or state drug laws is subject to a mandatory minimum sentence of 15 days and up to 2 years in prison; those who have multiple prior drug offense

intentionally acquiring or obtaining possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.[149] It is unlawful for any person knowingly or intentionally to "traffic" in controlled substances; illegal drug trafficking[150] generally refers to distributing or dispensing, or to possessing with intent to distribute or dispense, a controlled substance, *unless* the particular activity is authorized by law.[151] The CSA's criminal penalties for trafficking in controlled substances vary depending on whether the individual is a first-time offender or a repeat offender, the type of substance involved, and the quantity of the type of substance involved.[152] For example, a federal drug trafficking offense committed by a first-time offender involving a Schedule II substance such as codeine is punishable by a term of imprisonment of up to 20 years and a fine of up to $1,000,000.[153] For a second offense, the fine increases to $2,000,000 and the maximum imprisonment term increases to 30 years.[154]

The focus of this report, however, is on the CSA penalty provisions specifically applicable to persons registered with the DEA. The CSA sets forth certain "regulatory" offenses involving listed chemicals,[155] failure to comply with CSA requirements and obligations that registrants must satisfy as a condition of registration,[156] and other prohibited acts by registrants who manufacture, distribute and dispense controlled substances.[157]

For example, a registrant authorized to distribute or dispense any controlled substance is prohibited from distributing, dispensing, or manufacturing controlled substances in a manner that is not authorized by his particular registration.[158] As noted above, registrants may not refuse or negligently fail to maintain accurate records of controlled substances, and may not refuse to

convictions face a mandatory minimum sentence of 90 days and up to 3 years in prison. *Id.*

[149] *Id*. § 843(a)(3). A violation of this may result in a term of imprisonment of not more than four years or a fine of up to $250,000, or both; second offenses involving this section increase the maximum imprisonment term to eight years. *Id.* § 843(d)(1).

[150] The CSA and its implementing regulations do not define the term "traffic" or "trafficking," though the CSA does expressly use the term "drug traffickers" in one provision, 21 U.S.C. § 862, and the term "traffic" in three other sections, *id.* §§ 801, 801a, 873. The U.S. Sentencing Guidelines, which greatly influence the sentences that federal judges impose on those convicted of federal crimes, defines a "drug trafficking offense" as "an offense under federal, state, or local law that prohibits the manufacture, import, export, distribution, or dispensing of, or offer to sell a controlled substance (or a counterfeit substance) or the possession of a controlled substance (or a counterfeit substance) with intent to manufacture, import, export, distribute, or dispense." U.S.S.G. § 2L1.2, Application Notes (2). For more information about the Sentencing Guidelines, see CRS Report R41696, *How the Federal Sentencing Guidelines Work: An Overview*, by Charles Doyle.

[151] 21 U.S.C. § 841(a)(1).

[152] For a listing of the CSA's criminal provisions regarding unauthorized trafficking, possession, or other prohibited activities involving controlled substances, *see* CRS Report RL30722, *Drug Offenses: Maximum Fines and Terms of Imprisonment for Violation of the Federal Controlled Substances Act and Related Laws*, by Brian T. Yeh.

[153] 21 U.S.C. § 841(b)(1)(C). These penalties apply only if no death or serious bodily injury results from the use of such unlawfully trafficked substance. If such health consequences occur, however, the authorized penalty is a mandatory minimum sentence of 20 years and up to life in prison. *Id.*

[154] *Id.* If death or serious bodily injury results from the use of such substance that has been trafficked by a repeat offender, the authorized penalty is a mandatory minimum sentence of life in prison. *Id.*

[155] *Id*. § 841(c); (e)-(f).

[156] *Id*. §§ 842, 843.

[157] *Id*. § 843.

[158] *Id*. § 842(a)(2). As noted above, registrations specify the extent to which the DEA has authorized registrants to manufacture, possess, distribute, or dispense controlled substances. Thus, for example, a pharmacist is authorized to dispense controlled substances to individuals only pursuant to a valid prescription issued by a DEA-licensed practitioner and may not dispense such substances without that prescription.

furnish such records when required to do so by law enforcement officials[159] (such as the requirement that registrants report to the DEA any "suspicious orders of controlled substances)."[160] It is unlawful for registrants to prohibit law enforcement officials from entering their premises for inspections authorized by the CSA.[161] Similarly, practitioners and pharmacists may not dispense or distribute a controlled substance drug in violation of the CSA's statutory prescription requirements.[162]

The CSA also proscribes certain acts committed by a registrant related to the manufacture and distribution of controlled substances and listed chemicals. Registrants may not knowingly or intentionally (1) distribute Schedule I and II substances without a valid order form;[163] (2) use an invalid registration number during the course of handling or acquiring controlled substances;[164] (3) furnish false or fraudulent material information in a record or report required by the act;[165] or (4) present false or fraudulent identification when receiving a listed chemical.[166] Registrants who violate the aforementioned provisions may be subject to injunctive or declarative actions filed by the Attorney General in federal district court in addition to the general penalties described in the next paragraph.[167] Manufacturers may also not produce Schedule I or II controlled substances or specified listed chemicals that are not expressly authorized by their registration or in excess of the individual production quotas assigned to them by the DEA.[168]

Registrants who fail to adhere to the CSA's regulatory requirements or who engage in certain prohibited acts may face administrative consequences, civil and criminal fines, and even the possibility of imprisonment.[169] The CSA provides that violations of its regulatory requirements generally do not constitute a crime and that "imposition of a civil penalty ... shall not give rise to any disability or legal disadvantage based on conviction for a criminal offense,"[170] unless the violation was committed *knowingly*, in which case the CSA authorizes imprisonment of up to one or two years.[171]

State Regulation of Controlled Substances

In addition to federal oversight of controlled substances and registrants who handle them, Congress has permitted state governments to regulate the use of controlled substances under their own state controlled substances acts.[172] The U.S. Supreme Court has stated that the CSA

[159] *Id*. § 842(a)(5).

[160] *Id*. § 832, as added by P.L. 115-271, § 3292(b).

[161] 21 U.S.C. § 842(a)(6).

[162] *Id.* § 842(a)(1).

[163] *Id.* § 843(a)(1).

[164] *Id.* § 843(a)(2).

[165] *Id.* § 843(a)(4)(A).

[166] *Id.* § 843(a)(4)(B).

[167] *Id.* § 843(f).

[168] *Id*. §§ 842(b).

[169] *Id.* § 842(c) (providing penalties for committing prohibited acts set forth in *id.* § 842(a)); *Id*. § 843(d) (penalties for committing prohibited acts set forth in *id.* § 843(a)).

[170] *Id*. § 842(c)(3).

[171] *Id*. § 842(c)(2).

[172] *Id*. § 903 ("No provision of this title shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State.... ").

"manifests no intent to regulate the practice of medicine generally" and has observed that its "structure and operation ... presume and rely upon a functioning medical profession regulated under the States' police powers"[173] that may be used "to protect the health, safety and welfare of their citizens."[174] For example, all states have prescription drug monitoring programs (PDMPs) that maintain statewide electronic databases of prescription controlled substances dispensed to patients within their jurisdictions; such information may be used by those working in law enforcement, professional licensing bodies, and health care to identify patterns of prescribing, dispensing, or receiving controlled substances that could indicate abuse or diversion.[175] States may also subject certain controlled substance medications to stricter regulation than the CSA requires. For example, the states of Oregon[176] and Mississippi[177] have passed laws that require anyone to obtain a prescription for drugs containing pseudoephedrine (a nasal decongestant commonly found in over-the-counter cold, allergy, and sinus medications), which is an important ingredient in producing illicit methamphetamine,[178] whereas the substance is regulated as a listed chemical under the CSA that does not require a prescription to dispense.[179]

The operation of several provisions of the CSA depends on state laws and state regulatory bodies. For example, if a physician wants to obtain a DEA registration to dispense controlled substance medications, he must first be "authorized to dispense ... controlled substances under the laws of the State in which he practices."[180] In addition, the DEA Administrator must be satisfied that issuing the applicant a registration would be "[]consistent with the public interest," a determination that requires the DEA Administrator to consider several statutory factors, including the "recommendation of the appropriate State licensing board or professional disciplinary authority"; the applicant's previous convictions for federal or state controlled substances offenses; and the applicant's "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances."[181] Despite the latitude that Congress has given to states to regulate controlled substances, however, the CSA nevertheless generally preempts, or overrides, state laws regarding controlled substances when "there is a positive conflict between" a CSA provision and "that State law so that the two cannot consistently stand together."[182]

DEA's Legal Authorities for Enforcing the CSA

The DEA's Office of Diversion Control is responsible for preventing, detecting, and investigating violations of the CSA involving controlled pharmaceuticals[183] while also "ensuring an adequate

[173] Gonzales v. Oregon, 546 U.S. 243, 270 (2006).

[174] Gonzales v. Raich, 545 U.S. 1, 66 (2005) (O'Connor, J., dissenting).

[175] For more information about PDMPs, *see* CRS Report R42593, *Prescription Drug Monitoring Programs*, by Lisa N. Sacco, Johnathan H. Duff, and Amanda K. Sarata.

[176] Or. Rev. Stat. Ann. § 475.973 (2018) (scheduling pseudoephedrine as a Schedule III substance under Oregon law).

[177] Miss. Code Ann. § 41-29-117(d) (2017) (scheduling pseudoephedrine as a Schedule III substance under Mississippi law).

[178] Drug Enf't Admin., *Implementation of the Methamphetamine Production Prevention Act of 2008*, 76 Fed. Reg. 74,696 (Dec. 1, 2011).

[179] 21 U.S.C. § 830.

[180] *Id*. § 823(f).

[181] *Id.*

[182] *Id*. § 903.

[183] *Id*. §§ 878(a), 880.

and uninterrupted supply for legitimate medical, commercial, and scientific needs."[184] The Office of Diversion Control also manages the regulation of registrants, promulgates regulations concerning the handling of controlled substances, and establishes controlled substance production quotas.[185] The Assistant Attorney General for the DOJ's Criminal Division conducts, handles, or supervises all criminal and civil litigation to enforce the CSA.[186] Several federal courts have held that the CSA does not contain an express or implied cause of action provision under which private parties or state,[187] local, or tribal governments may sue registrants for noncompliance with their CSA obligations,[188] noting instead that the CSA expressly authorizes only the Attorney General and the U.S. Department of Justice to enforce federal controlled substances laws.[189]

Investigations

The DEA can conduct a variety of investigations to monitor and ensure registrant compliance with the CSA and its implementing regulations.[190] As mentioned earlier, registrants may not prevent law enforcement officials from entering their premises for any inspections authorized by the CSA.[191] The three types of investigations that the DEA may undertake can be classified as regulatory, complaint, and criminal.[192] Regulatory investigations can include scheduled inspections of registrants, usually every two, three, or five years, although such inspections generally are directed at manufacturers, wholesale distributors, and importers/exporters rather than physicians and pharmacies (who receive such oversight from state regulators).[193] The DEA

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[184] Drug Enf't Admin., *DEA Programs: Diversion Control / Prescription Drug Abuse,* https://www.dea.gov/ops/diversion.shtml (last visited March 26, 2018).

[185] U.S. GOV'T ACCOUNTABILITY OFF., GAO-15-471, MORE DEA INFORMATION ABOUT REGISTRANTS' CONTROLLED SUBSTANCES ROLES COULD IMPROVE THEIR UNDERSTANDING AND HELP ENSURE ACCESS 10 (2015).

[186] 28 C.F.R. § 0.55(c).

[187] The CSA does, however, include a limited provision authorizing a state to bring a civil action in federal court on behalf of its residents to enforce CSA provisions relating to internet pharmacies and unlawful dispensing of controlled substances by means of the internet. 21 U.S.C. § 882(c).

[188] *See, e.g.,* McKesson Corp. v. Hembree, No. 17-CV-323-TCK-FHM, 2018 WL 340042, at *5 (N.D. Okla. Jan. 9, 2018) ("The CSA does not provide a private right of action. Instead, it delegates the power of enforcement of federal drug policy to the federal government.") (citations omitted); Smith v. Hickenlooper, 164 F. Supp. 3d 1286, 1292 (D. Colo. 2016), *aff'd sub nom.* Safe Streets All. v. Hickenlooper, 859 F.3d 865 (10th Cir. 2017) ("[T]here is nothing in the CSA which expressly permits private enforcement of the Act's provisions. I also find ... that the CSA implicitly precludes private enforcement, and that Plaintiffs may not, by invoking the court's equitable powers, circumvent Congress's exclusion of private enforcement.") (quotations and citations omitted); Shmatko v. Arizona CVS Stores LLC, No. CV-14-01076-PHX-DGC, 2014 WL 3809092, at *2 (D. Ariz. Aug. 1, 2014) ("Federal law unequivocally holds ... that the ... CSA do[es] not create private rights of action that can give rise to a federal question."); Schneller ex rel. Schneller v. Crozer Chester Med. Ctr., 387 F. App'x 289, 293 (3d Cir. 2010) ("The Comprehensive Drug Abuse Prevention and Control Act is a statute enforceable only by the Attorney General and, by delegation, the Department of Justice."); Bowling v. Haas, No. CIV.A. 3:07-032-KKC, 2010 WL 3825467, at *3 (E.D. Ky. Sept. 23, 2010) ["[C]ourts have uniformly held that the right to enforce the provisions of the CSA ... is possessed exclusively by the Attorney General ... and that no right of action, either expressed or implied, exists in favor of a private litigant."); Ringo v. Lombardi, No. 09-4095-CV-C-NKL, 2010 WL 3310240, at *2 (W.D. Mo. Aug. 19, 2010) ("Consideration of the text of the CSA in its entirety indicates that Congress did not expressly provide a private right of action and did not intend to imply a private right of action.").

[189] 21 U.S.C. §§ 871(a), (b); 883.

[190] *Id.* § 822(f); 21 C.F.R. § 1301.31.

[191] 21 U.S.C. § 842(a)(6).

[192] *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-15-471, MORE DEA INFORMATION ABOUT REGISTRANTS' CONTROLLED SUBSTANCES ROLES COULD IMPROVE THEIR UNDERSTANDING AND HELP ENSURE ACCESS 11-12 (2015).

[193] *Id.*

may initiate complaint investigations after it has received a tip about potential diversion by the registrant or if the DEA has identified any unusual drug transactions involving the registrant.[194] Finally, the DEA may conduct criminal investigations regarding potential criminal activities involving diversion of controlled substances.[195] Criminal investigations can be directed at either registrants or nonregistrants, such as an individual suspected of stealing drugs from a pharmacy or one who is trafficking in unlawfully obtained controlled substances.[196] Following an investigation of a registrant that reveals violations of the CSA and its implementing regulations, the DEA can take certain enforcement actions, as discussed in the following section.

Enforcement Actions

The DEA has discretion[197] to initiate enforcement actions to seek a variety of administrative, civil, and criminal penalties against a registrant who is not in compliance with the CSA, depending on the severity of the offense and taking into consideration factors such as whether the registrant has previously violated a CSA regulatory requirement.[198] This section focuses on the administrative actions that the DEA may take against a registrant or an applicant for registration.

Letter of Admonition or Informal Hearing

A noncompliant registrant could face several types of corrective actions. For example, the DEA can issue a warning letter referred to as a Letter of Admonition (LOA) to a registrant suspected of conduct inconsistent with his obligations under the CSA and its implementing regulations.[199] The DEA can also hold an Informal Hearing (IH) concerning the registrant; either administrative action "provide[s] registrants an opportunity to recognize and acknowledge their infractions, and immediately correct them."[200]

Administrative Proceedings to Deny, Revoke, or Suspend a Registration

The DEA Administrator has the authority to deny, revoke, or suspend registrations under certain circumstances.[201] However, before the DEA Administrator can take such an action, the agency must generally provide the applicant or registrant with notice and an opportunity to demonstrate why the registration should not be denied, revoked, or suspended.[202] This notice is referred to as

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[194] *Id.* at 12.

[195] *Id.*

[196] *Id.*

[197] *See Improving Predictability and Transparency in DEA and FDA Regulation: Hearing Before the H. Comm. on Energy & Commerce, Subcomm. on Health,* 113th Congress 6 (2014) (statement of Joseph T. Rannazzisi, DEA) ("The decision to take administrative, civil, and/or criminal action against a DEA registrant rests with the DEA and the prosecuting U.S. Attorneys.").

[198] U.S. GOV'T ACCOUNTABILITY OFF., GAO-15-471, MORE DEA INFORMATION ABOUT REGISTRANTS' CONTROLLED SUBSTANCES ROLES COULD IMPROVE THEIR UNDERSTANDING AND HELP ENSURE ACCESS 12-13 (2015)

[199] *Improving Predictability and Transparency in DEA and FDA Regulation: Hearing Before the H. Comm. on Energy & Commerce, Subcomm. on Health,* 113th Congress 6 (2014) (statement of Joseph T. Rannazzisi, DEA).

[200] *Id.*

[201] 21 U.S.C. § 824(a).

[202] *Id.* § 824(c). 21 U.S.C. § 824(a) states in pertinent part: "A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the [Administrator] upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this

an Order to Show Cause or OTSC.[203] Such an order provides the basis for the proposed denial, revocation, or suspension (including an identification of the laws or regulations that the applicant or registrant is alleged to have violated)[204] and also notifies the applicant or registrant of the opportunity to submit to the DEA a corrective action plan (CAP).[205] The OTSC instructs the applicant or registrant to appear at a hearing before a DEA Administrative Law Judge (ALJ) that must be conducted in accordance with the Administrative Procedure Act (APA).[206] If the registrant submits a CAP, the DEA Administrator is required to determine "whether denial, revocation, or suspension proceedings should be discontinued."[207]

After examining the evidence and arguments submitted by the parties, the ALJ is required to submit a report to the DEA Administrator that explains his recommended ruling, findings of fact, conclusions of law, and decision regarding the proposed denial, revocation, or suspension.[208] "As soon as practicable after" receiving the ALJ's record and report,[209] the DEA Administrator is required to publish in the *Federal Register* a final order in the proceeding that adopts, modifies, or rejects the ALJ's recommended decision.[210] The CSA also provides that if the DEA Administrator suspends or revokes an existing registration, all controlled substances owned or possessed by the registrant may "be placed under seal ... until the time for taking an appeal has elapsed or until all appeals have been concluded.... "[211] Once a revocation order becomes final

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chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial recommended by competent State authority;

(4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a—7(a) of [the Social Security Act, which excludes certain individuals and entities from participation in Medicare and State healthcare programs].... "

[203] *Id.* § 824(c)(1).

[204] *Id.* § 824(c)(2)(A); 21 C.F.R. § 1301.37(c).

[205] 21 U.S.C. § 824(c)(2)(C). Generally, a CAP is a document that describes corrective actions that the registrant or applicant has taken or proposes to take to address any CSA compliance issues identified by the DEA in the OTSC. *Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act: Hearing Before the S. Judiciary Comm.*, 115th Cong. 7-8 (2017) (statement of Demetra Ashley, DEA).

[206] 21 U.S.C. § 824(c)(4) (requiring that the proceedings be conducted in accordance with "subchapter II of chapter 5 of title 5, United States Code"). The standard of proof used in these administrative proceedings is "preponderance of the evidence." *See, e.g.*, Sea Island Broad. Corp. v. FCC, 627 F.2d 240, 243 (D.C. Cir. 1980) ("The use of the 'preponderance of evidence' standard is the traditional standard in civil and administrative proceedings. It is the one contemplated by the APA, 5 U. S. C. § 556 (d)."); Collins Sec. Corp. v. SEC, 562 F.2d 820, 823 (D.C. Cir. 1977) ("The traditional standard of proof in a civil or administrative proceeding is the preponderance standard.... ").

[207] 21 U.S.C. § 824(c)(3).

[208] 21 C.F.R. § 1316.65.

[209] *Id.* § 1316.67.

[210] John J. Mulrooney, II & Andrew J. Hull, *Drug Diversion Administrative Revocation and Application Hearings for Medical and Pharmacy Practitioners: A Primer for Navigating Murky, Drug-Infested Waters*, 78 ALB. L. REV. 327, 394 (2014/2015). In issuing this final order, the DEA Administrator should consider the ALJ's recommended decision and factual findings, *see* Morall v. DEA, 412 F.3d 165, 179 (D.C. Cir. 2005) (explaining that although the "DEA is the ultimate fact finder, the agency's decision is vulnerable when it does not take the ALJ's findings into consideration.").

[211] 21 U.S.C. § 824(f).

(meaning all judicial appeals have been exhausted), these controlled substances "shall be forfeited to the United States" and "[a]ll right, title, and interest in such controlled substances ... shall vest in the United States.... "[212]

Immediate Suspension Orders

Simultaneously with the institution of administrative proceedings to revoke or suspend a registration (or at any time after the DEA Administrator issues an OTSC notifying the registrant that the DEA is taking action to revoke or suspend a registration),[213] the DEA Administrator may exercise emergency power to suspend immediately any existing registration for a limited time period in order to avoid "an imminent danger to the public health or safety."[214] This agency action is often referred to as an "immediate suspension order" (ISO), and does not require the DEA to provide the registrant with prior notice or a formal hearing.[215] The CSA specifies that the suspension "shall continue in effect until the conclusion of [the] proceedings [to revoke or suspend the registration on a final basis], including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction."[216]

Prior to the enactment into law of the Ensuring Patient Access and Effective Drug Enforcement Act (EPAEDEA) of 2016,[217] the CSA did not expressly define the phrase "imminent danger to the public health or safety," and, as a result, courts held that the DEA Administrator possessed "significant discretion" to determine when the continued registration of a registrant constituted such a threat.[218] As an example of the latitude that courts afforded the DEA Administrator's

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[212] *Id. See also* 21 C.F.R. § 1301.36(f) ("[U]pon service of the order of the Administrator revoking or suspending registration, the registrant shall, as instructed by the Administrator: (1) Deliver all controlled substances in his/her possession to the nearest office of the Administration or to authorized agents of the Administration; or (2) Place all controlled substances in his/her possession under seal ... ").

[213] *Id.* § 1301.36(e).

[214] 21 U.S.C. § 824(d)(1).

[215] *Id.* § 824(d).

[216] *Id.* § 824(d)(1).

[217] Ensuring Patient Access and Effective Drug Enforcement Act of 2016, P.L. 114-145, 130 Stat. 353 (codified at 21 U.S.C. §§ 823, 824).

[218] In re Burka, 684 F. Supp. 1300, 1305 (E.D. Pa. 1988) (stating that "Congress has granted the DEA Administrator significant discretion in making the preliminary determination of whether a registration should be temporarily suspended.... "); *see also* Holiday CVS, LLC v. Holder, 839 F. Supp. 2d 145, 164 (D.D.C. 2012), *vacated as moot*, 493 F. App'x 108 (D.C. Cir. 2012) (noting that "the CSA vests the *Administrator* with the authority to" determine whether imminent danger exists); Cardinal Health, Inc. v. Holder, 846 F. Supp. 2d 203, 225 (D.D.C. 2012) ("Far from providing 'precise guidelines' that restrict the meaning of 'imminent danger,' the Act vests the Administrator with discretion to make such a determination. In addition, the statute contemplates that an ISO will be issued in emergency circumstances, prior to an administrative hearing or the development of a formal evidentiary record. Thus, given the degree of discretion vested with the Administrator as well as the summary and urgent nature of an ISO, the Court's review 'must be correspondingly relaxed.'") (citation omitted). However, in at least two cases prior to enactment of the 2016 EPAEDEA, courts did reject DEA's ISO determination that the alleged violations met the "imminent danger" standard. *See, e.g.*, Bates Drug Stores v. Holder, Case No. CV–11–0167–EFS, 2011 WL 1750066 *3 (E.D. Wash. 2011) ("[T]he Court has serious doubts that the alleged violations ... pose an *imminent* danger to public health and safety. There is nothing in the record indicating that any Bates patient has been harmed or injured by the alleged violations. Nor is there any evidence that any controlled substance was dispensed to an improper individual, for an improper purpose, or in an improper dosage.... On this record, the Court finds that serious questions exist as to whether the Suspension Order supports a finding that Bates' practices posed an imminent danger to the public health and safety."); *see also* Norman Bridge Drug Co. v. Banner, 529 F.2d 822, 826, 829 (5th Cir. 1976) (holding that the lower court's decision that there was no imminent danger to the public health and safety was not clearly erroneous due to, among other things, the DEA being aware of the facts alleged to justify issuance of the ISO for seven months prior to issuing the order).

imminent danger finding, a federal district court permitted the DEA to rely on pharmacy controlled substances sales data from 2008 to support an ISO issued in early 2012.[219]

The EPAEDEA amended the CSA to provide, for the first time, a statutory definition of the phrase "imminent danger to the public health or safety," which limits the DEA Administrator's discretion to issue an ISO and creates new evidentiary requirements that he must satisfy before issuing such an order.[220] Under the EPAEDEA, the DEA's authority to issue an ISO depends on the agency's ability to prove two things: (1) "an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur" due to the failure of the registrant to comply with the CSA's requirements, including those obligating the registrant "to maintain effective controls against diversion,"[221] and (2) the probability that such a threat will occur without an immediate suspension of a registration, which the statute requires to be a "substantial likelihood."[222] Some have suggested that the legislative changes made by the EPAEDEA considerably weaken the power of the DEA to issue an ISO against a distributor or manufacturer,[223] although others have argued that the addition of a statutory definition of "imminent danger to the public health or safety" was necessary in order to prevent "a completely subjective determination made solely by the DEA" that "summarily eliminate[s] the registrant's ability to handle controlled substances before any due process hearing."[224]

In response to the ISO, a registrant could seek immediate judicial review of the ISO in federal court,[225] arguing that the DEA acted arbitrarily and capriciously[226] in violation of the APA.[227] However, a registrant faces a difficult burden in convincing a court to enjoin the DEA's enforcement of the ISO pending resolution of the revocation or suspension proceedings.[228] In

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[219] *Holiday CVS,* 839 F. Supp. 2d at 164 (stating that "the DEA could reasonably rely on sales trends from past years to show a pattern of inadequate anti-diversion efforts, which ultimately culminated in the need for immediate suspension in February 2012.").

[220] P.L. 114-145, 130 Stat. 354 (codified at 21 U.S.C. § 824(d)(2)).

[221] 21 U.S.C. § 824(d)(2).

[222] *Id.*

[223] *See* John J. Mulrooney, II & Katherine E. Legal, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters,* 101 MARQ. L. REV. 333, 347 (Winter 2017) ("If it had been the intent of Congress to completely eliminate the DEA's ability to ever impose an immediate suspension on distributors or manufacturers, it would be difficult to conceive of a more effective vehicle for achieving that goal."); *see also* Scott Higham & Lenny Bernstein, *The Drug Industry's Triumph Over the DEA,* WASH. POST, Oct. 15, 2017, at A01 ("In April 2016, at the height of the deadliest drug epidemic in U.S. history, Congress effectively stripped the Drug Enforcement Administration of its most potent weapon against large drug companies suspected of spilling prescription narcotics onto the nation's streets.").

[224] *Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act: Hearing Before the S. Judiciary Comm.*, 115th Cong. 6 (2017) (statement of John M. Gray, Healthcare Distribution Alliance). According to a supporter of the EPAEDEA, such an immediate prohibition on the legal right of the registrant to handle controlled substances as a result of an ISO could "limit access to needed medications by legitimate patients." *Id.*

[225] 21 U.S.C. § 877 provides that "any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision."

[226] *See Holiday CVS*, 839 F. Supp. 2d at 158 ("As courts in this Circuit and elsewhere have recognized, the arbitrary and capricious standard of review applies to APA claims challenging the issuance of an ISO under 21 U.S.C. § 824(d).").

[227] 5 U.S.C. § 706(2).

[228] *Id.* ("The reviewing court shall—hold unlawful and set aside agency action, findings, and conclusions found to be—arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law ... [or] unsupported by substantial evidence.... ").

order to obtain such preliminary injunctive relief,[229] a registrant "must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest."[230] The CSA provides that a reviewing court must use a "substantial evidence" standard in considering the DEA's findings of facts with respect to an ISO,[231] though a court applies the APA's arbitrary and capricious standard of review when considering the DEA's reason for deciding to adopt, modify, or reject the ALJ's recommendation concerning an ISO.[232] A federal appellate court has explained its review of the DEA's issuance of an ISO under the APA as follows: "To uphold DEA's decision, ... we must satisfy ourselves that the agency examined the relevant data and articulated a satisfactory explanation for its action including a rational connection between the facts found and the choice made."[233]

A registrant served with an ISO could also request "an expedited administrative hearing"[234] before an ALJ on the merits of the revocation or suspension at a time before that indicated in the OTSC.[235] DEA regulations specify that the DEA Administrator "shall" grant the request for an earlier hearing and "fix a date for such hearing as early as reasonably possible."[236]

DEA's Response to the Opioid Abuse Crisis

This section describes selected DEA actions intended to help alleviate the opioid crisis.

DEA Actions Against Registrants

As discussed earlier in this report, the CSA provides the DEA with a variety of criminal, civil, and administrative tools to hold manufacturers, distributors, pharmacies, and physicians accountable for actions that violate the CSA's regulatory requirements. The DEA has used these authorities in

[229] A preliminary injunction is "'an extraordinary and drastic remedy, one that should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion.'" Mazurek v. Armstrong, 520 U.S. 968, 972 (1997) (per curiam)(citation omitted).

[230] *See* Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 20 (2008).

[231] 21 U.S.C. § 877 ("Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive."). According to the Supreme Court, substantial evidence "means evidence which is substantial, that is, affording a substantial basis of fact from which the fact in issue can be reasonably inferred. Substantial evidence is more than a scintilla, and must do more than create a suspicion of the existence of the fact to be established." NLRB v. Columbian Enameling & Stamping Co., 306 U.S. 292, 299-300 (1939) (citations omitted); *see also* Brainard v. Sec'y of Health & Hum. Servs., 889 F.2d 679, 681 (6th Cir. 1989) ("Substantial evidence is more than a scintilla of evidence but less than a preponderance.... ").

[232] *See* Morall v. DEA, 412 F.3d 165, 177 (D.C. Cir. 2005) ("Although 21 U.S.C. § 877 does not specify a standard for reviewing the agency's reasoning as distinguished from its factfinding, the APA provides the appropriate default standard: A court must set aside agency action it finds to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.... An agency [decision is] arbitrary and capricious if the agency ... entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise,") (internal quotations and citations omitted); *see also* MacKay v. DEA, 664 F.3d 808, 817 (10th Cir. 2011) ("Under the Administrative Procedure Act, we may set aside the Deputy Administrator's decision only if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law ... [or] unsupported by substantial evidence.... ") (internal quotations and citations omitted).

[233] *Morall*, 412 F.3d at 177 (internal quotations and citations omitted).

[234] *See, e.g,* Novelty Distribs. v. Leonhart, 562 F. Supp. 2d 20, 23 (D.D.C. 2008).

[235] 21 C.F.R. § 1301.36(h).

[236] *Id.*

connection with the opioid crisis. For example, in February and March 2018, the DEA "surged its enforcement and administrative resources" to target prescribers and pharmacies suspected of diverting large amounts of opioid drugs, resulting in 147 revoked registrations and 28 arrests.[237] In addition, in July 2017, CVS Pharmacy Inc. agreed to a $5 million settlement payment as well as an administrative compliance plan with the DEA, to resolve the federal government's allegations that nine of its pharmacies in the Eastern District of California had failed to keep and maintain accurate records of its controlled substances, in violation of the CSA's recordkeeping requirements.[238] In early 2016, CVS also paid $8 million to the United States to settle allegations that certain CVS pharmacies in Maryland had dispensed controlled substances, including the opioids oxycodone, fentanyl, and hydrocodone, in violation of the CSA by failing to comply with their duty to ensure that the prescriptions were issued for legitimate medical purposes.[239] In 2013, Walgreens agreed to pay $80 million in civil penalties to resolve DEA administrative actions and civil penalty investigations concerning "an unprecedented number of record-keeping and dispensing violations" occurring at six Walgreens pharmacies and a Walgreens drug distribution center in Florida that allegedly resulted in oxycodone and other prescription opioids to be diverted.[240] As part of this settlement, Walgreens agreed to several terms and conditions, including ending its practice of "compensat[ing] its pharmacists based on the volume of prescriptions filled."[241]

The DEA has also focused its attention on wholesale distributors of prescription opioids, which ship the drugs from drug manufacturers to pharmacies, and their compliance with the CSA's recordkeeping and reporting requirements.[242] Several DEA investigations into these wholesale distributers resulted in civil penalty settlements. In January 2017, one of the largest U.S. drug distributors, McKesson Corporation, agreed to pay a $150 million civil payment to resolve DEA allegations that it had, in violation of CSA regulatory requirements, "failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances distributed to its independent and small chain pharmacy customers."[243] The federal government alleged that "[f]rom 2008 until 2013, McKesson supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills, frequently misused products that are part of the

[237] Press Release, U.S. Dep't of Just., Off. of Pub. Aff., DEA Surge in Drug Diversion Investigations Leads to 28 Arrests and 147 Revoked Registrations (Apr. 2, 2018), https://www.justice.gov/opa/pr/dea-surge-drug-diversion-investigations-leads-28-arrests-and-147-revoked-registrations.

[238] Press Release, U.S. Dep't of Just., U.S. Att'y Off., Dist. of Md., CVS Pharmacy Inc. Pays $5M to Settle Alleged Violations of the Controlled Substance Act (July 11, 2017), https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violations-controlled-substance-act.

[239] Press Release, U.S. Dep't of Just., U.S. Att'y Off., Dist. of Md., United States Reaches $8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances (Feb. 12, 2016), https://www.justice.gov/usao-md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawful-distribution-controlled.

[240] Press Release, U.S. Dep't of Just., U.S. Att'y Off., S.D. of Fla, Walgreens Agrees To Pay A Record Settlement Of $80 Million For Civil Penalties Under The Controlled Substances Act (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

[241] *Id.*

[242] *See* Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* WASH. POST, Oct. 22, 2016, http://wapo.st/2etAUdQ?tid=ss_mail&utm_term=.e09794f54343 ("The Drug Enforcement Administration targeted these middlemen for a simple reason. If the agency could force the companies to police their own drug shipments, it could keep millions of pills out of the hands of abusers and dealers. That would be much more effective than fighting 'diversion' of legal painkillers at each drugstore and pain clinic.").

[243] Press Release, U.S. Dep't of Just., Off. of Pub. Aff., McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs (Jan. 17, 2017), https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

current opioid epidemic."[244] In addition to the monetary penalty, the settlement requires McKesson to (1) suspend for several years sales of controlled substances from a number of its distribution centers, (2) agree to certain "enhanced compliance obligations" that include periodic auditing and staffing and organization improvements; and (3) accept the oversight of an independent monitor to assess the company's adherence with the compliance terms.[245]

Another major pharmaceutical drug distributor, Cardinal Health, Inc., agreed in December 2016 to pay $44 million to the federal government to settle allegations that it had failed to notify the DEA when it filled unusually large and frequent orders for controlled substances requested by pharmacies located in Maryland, Florida, and New York, and that it had failed to maintain effective controls against diversion.[246] The settlement agreement between Cardinal Health and the federal government included an admission by the company that "from January 1, 2009 to May 14, 2012, it failed to report suspicious orders to the DEA as required by the CSA."[247]

In 2014, the DEA took an administrative action to revoke the registration of Masters Pharmaceuticals, Inc. (Masters), a bulk supplier of prescription medications to many U.S. pharmacies, after concluding that the company had not satisfied its legal obligation to monitor and report to the DEA suspicious orders for controlled substances.[248] Masters had previously entered into a settlement agreement with the DEA in 2009 in which Masters agreed to pay $500,000 and implement a compliance system to detect suspicious orders of controlled substances and prevent the substances from being diverted into illegal channels.[249] However, in the years following the settlement, the DEA grew to suspect that Masters's employees were not detecting and reporting to the DEA suspicious orders of oxycodone products.[250] In 2013, the DEA issued an Order to Show Cause why Masters's registration should not be revoked, in light of allegations that Masters had ignored its duty to report suspicious orders after its computer system had flagged controlled substance orders that were unusual in size, frequency, or pattern.[251] The DEA Administrator concluded that Masters's repeated violations of the suspicious orders reporting requirement warranted revocation of its registration to distribute controlled substances.[252] Masters challenged the DEA's revocation decision in federal court, arguing among other things that the DEA's factual conclusions were not supported by the record.[253] In June 2017, the U.S. Court of Appeals for the D.C. Circuit denied Masters's petition for review, seeking to overturn the DEA's final order, after the court found "no prejudicial error in DEA's decision."[254]

In addition to these actions against distributors, the DEA has also investigated opioid manufacturers for their failure to report suspicious orders of controlled substances that occurred downstream in the drug supply chain. In July 2017, the DEA confirmed it had reached a $35

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[244] *Id.*

[245] *Id.*

[246] Press Release, U.S. Dep't of Just., U.S. Att'y Off., Dist. of Md., Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act (Dec. 23, 2016), https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

[247] *Id.*

[248] Masters Pharm., Inc. v. DEA, 861 F.3d 206, 211 (D.C. Cir. 2017).

[249] *Id.* at 213.

[250] *Id.* at 214.

[251] *Id.*

[252] *Id.* at 215

[253] *Id.*

[254] *Id.* at 212.

million civil penalty settlement with Mallinckrodt LLC, a drug manufacturer that is one of the largest makers of the highly addictive generic pain reliever oxycodone.[255] This settlement resolved allegations that the company committed several violations of the CSA from 2008 until 2011 by supplying to drug distributors that, in turn, supplied pharmacies and pain clinics, "an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[256] The DEA described this settlement as "groundbreaking" in part because it is the first time the DEA has been able to hold a drug manufacturer responsible for detecting and reporting suspicious orders relating to downstream sales between its distributor customers and the distributors' customers (pharmacies).[257] This settlement agreement also apparently contains the first public statement of the DEA's position[258] that "controlled substance manufacturers need to go beyond 'know your customer' to use otherwise available company data to 'know your customer's customer' to protect these potentially dangerous pharmaceuticals from getting into the wrong hands."[259] Under the settlement, Mallinckrodt agreed to analyze data it collects involving "chargebacks," which are reimbursements the company offers to their drug distributor customers based on the distributor's discounted sale of its drugs to pharmacies and pain clinics, in order to monitor and report to the DEA any suspicious orders of oxycodone placed by the distributor's customers.[260] Commentators have argued that the legal basis of the DEA imposing an obligation on a drug manufacturer to "know your customer's customer," and its ability to hold the company "responsible for what happens to its drugs once the distributors send them to their customers,"[261] may be uncertain.[262] Moreover, one observer has characterized the DEA's action as "creat[ing] ... a new requirement by announcing it in a press release" and has argued instead that such a change needs to be made in accordance with notice and comment rulemaking requirements under the

[255] Press Release, U.S. Dep't of Just., Off. of Pub. Aff., Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders. [hereinafter *Mallinckrodt Settlement*].

[256] *Id.*

[257] *Id.*

[258] *See* John A. Gilbert, *DEA Announces "Groundbreaking" Guidance that is Inconsistent with the Settlement they are Announcing – Time at Last for Rulemaking?* (July 20, 2017), http://www.fdalawblog.net/2017/07/dea-announces-groundbreaking-guidance-that-is-inconsistent-with-the-settlement-they-are-announcing-t/ (last accessed Apr. 12, 2018) ("[W]e could find no prior public statement from DEA that a manufacturer must report such third party transactions as suspicious under 21 C.F.R. § 1301.74(b).").

[259] *Mallinckrodt Settlement, supra* note 255. An investigation by the Washington Post reveals that, prior to the settlement agreement, "the DEA had provided conflicting guidance to Mallinckrodt about its responsibilities to report suspicious orders" from its customer's customers. Lenny Bernstein & Scott Higham, *The Government's Struggle to Hold Opioid Manufacturers Accountable*, WASH. POST, Apr. 2, 2017, https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/. For example, a DEA supervisor in St. Louis had informed the company in 2010 "that it had a responsibility to keep close tabs on its customers, the distributors, as well as the distributor's customers, the pharmacies and doctors." *Id.* Yet a DEA investigator in New York had informed Mallinckrodt that "no one in her region, including her supervisor, had heard anything about 'know your customer's customer[']" and noted that "the regulations do not reflect such a requirement." *Id.*

[260] *Mallinckrodt Settlement, supra* note 255.

[261] Bernstein & Higham, *supra* note 259.

[262] *See, e.g.*, Brian T. O'Connor & Andrew O'Connor, *DOJ Settlement Looks to Set New Benchmarks for Suspicious Order Monitoring* (July 14, 2017), https://www.ropesgray.com/en/newsroom/alerts/2017/07/DOJ-Settlement-Looks-to-Set-New-Benchmarks-for-Suspicious-Order-Monitoring (last accessed Apr. 12, 2018) ("The legal basis for those "requirements" remains uncertain at best, and DOJ's statements leave open many questions about how far manufacturers must go to comply with DEA rules.").

APA.[263] As of the date of this report, the DEA's position that manufacturers "need to go beyond 'know your customer'" practices has not been challenged in court.

Emergency Scheduling of Illicit Fentanyl

Fentanyl is a powerful synthetic opioid[264] analgesic that mimics the effects of morphine and heroin, but is 50 to 100 times more potent.[265] Pharmaceutically produced fentanyl is a Schedule II prescription drug that may be used by patients to manage severe pain after surgery, for example, and can be administered via injection, in lozenges, or transdermal patch.[266]

Most fentanyl overdoses do not involve prescription fentanyl, but rather non-pharmaceutical fentanyl that is illicitly produced in clandestine laboratories located abroad, in particular in Mexico and China.[267] A recent investigation by a Senate subcommittee revealed that "many Americans are purchasing fentanyl and other illicit opioids online and having them shipped here through the international mail system."[268] Such illicit fentanyl can be mixed with other opioids such as heroin to increase its effects, and can be sold as a powder or as tablets that are "intended to mimic the appearance of prescription opioid medications such as oxycodone or hydrocodone.[269] According to the 2018 National Drug Threat Assessment published in October 2018 by the DEA, fentanyl "is a major contributor to the continuing epidemic of drug overdose deaths" in the United States and "[s]ynthetic opioids are now involved in more deaths than any other illicit drug."[270] In July 2018, then-Attorney General Sessions announced the formation of "Operation Synthetic Opioid Surge," an initiative in which the Justice Department will be focusing its prosecutorial priorities on "every readily provable case involving the distribution of fentanyl, fentanyl analogues, and other synthetic opioids, regardless of drug quantity," within 10 areas of the nation that are experiencing some of the highest drug overdose death rates.[271]

However, making the problem more difficult for the federal government in stopping illicit fentanyl traffickers are "[o]verseas chemical manufacturers, aided by illicit domestic distributors, [who] currently attempt to evade regulatory controls by creating structural variants of fentanyl that are not directly listed under" the CSA.[272] The DEA has stated that fentanyl-related compound

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[263] Gilbert, *supra* note 258.

[264] For more information about synthetic drugs generally, *see* CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Lisa N. Sacco and Kristin Finklea.

[265] NAT'L INST. ON DRUG ABUSE, DRUG FACTS: FENTANYL 1 (June 2016), https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/fentanyldf_06032016_final.pdf.

[266] *Id.*

[267] Drug Enf't Admin., *FAQ's – Fentanyl and Fentanyl-Related Substances*, https://www.dea.gov/druginfo/fentanyl-faq.shtml (last visited Apr. 5, 2018).

[268] STAFF OF S. COMM. ON HOMELAND SECURITY & GOV'T AFF., PERMANENT SUBCOMM. ON INVESTIGATIONS, 115TH CONG., COMBATTING THE OPIOID CRISIS: EXPLOITING VULNERABILITIES IN INTERNATIONAL MAIL 2 (2018).

[269] *Fentanyl: The Next Wave of the Opioid Crisis: Hearing Before the H. Comm. on Energy & Commerce, Subcomm. on Oversight and Investigations*, 115th Cong. 1 (2017) (statement of Kemp Chester, Acting Dir. of Nat'l Drug Control Pol'y).

[270] DRUG ENF'T ADMIN., 2018 NATIONAL DRUG THREAT ASSESSMENT 27 (Oct. 2018).

[271] Press Release, U.S. Dep't of Just., Off. of Pub. Aff., Attorney General Jeff Sessions Announces the Formation of Operation Synthetic Opioid Surge (S.O.S.) (July 12, 2018), https://www.justice.gov/opa/pr/attorney-general-jeff-sessions-announces-formation-operation-synthetic-opioid-surge-sos.

[272] Press Release, U.S. Dep't of Just., Off. of Pub. Aff., Department of Justice Announces Significant Tool in Prosecuting Opioid Traffickers in Emergency Scheduling of All Fentanyls (Nov. 9, 2017), https://www.justice.gov/opa/pr/department-justice-announces-significant-tool-prosecuting-opioid-traffickers-emergency.

"[m]anufacturers and distributors will continue to stay one step ahead of any state or federal drug-specific banning or control action by introducing and repackaging new products that are not listed as such in any of the controlled substance schedules."[273] Since 2015, DEA has exercised its emergency scheduling authority eight times to control 17 substances structurally related to fentanyl by placing them temporarily in Schedule I.[274] In February 2018, the DEA issued a broader temporary scheduling order that attempts to schedule all fentanyl-related substances that are not otherwise controlled in any schedule, by creating a definition of a new class of substances that is structurally related to fentanyl by virtue of one or more specified modifications to the substance's formulation.[275] It remains to be seen whether the DEA's attempt to schedule proactively an entire class of illicit fentanyl substances simultaneously, including substances that have not yet been introduced into the U.S. market by drug traffickers, will be subject to a legal challenge[276] under the APA, claiming the DEA's action to be inconsistent with its emergency scheduling authority under the CSA.[277]

Aggregate Production Quotas for Certain Schedule II Opioids

As discussed previously in this report, the DEA limits the quantity of Schedule I and II controlled substances (referred to as aggregate production quotas, or APQs) that may be produced in a given calendar year. According to the Acting Assistant Administrator of the DEA's Diversion Control Division, "since 2014, DEA has observed a decline in prescriptions written for certain Schedule II opioids," including oxycodone, hydrocodone, fentanyl, and morphine.[278] In November 2017, the DEA responded to the decreased demand for these drugs when it released the 2018 APQs,[279] which reduce by nearly 20% (compared to the 2017 levels) the amount of prescription opioids that can be manufactured in 2018.[280] According to a DEA spokesperson, this decrease in APQs "can be attributed to combined local, state, and federal activities and interventions, including creating new partnerships, enforcing current regulations, and dissemination of provider education and guidance documents.... "[281] Several organizations representing hospitals, anesthesiologists, and pharmacists have raised their concerns to the DEA that the new APQs could exacerbate the problem they are experiencing with "critical shortages" of injectable opioid medications,

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[273] *Fentanyl: The Next Wave of the Opioid Crisis: Hearing Before the H. Comm. on Energy & Commerce, Subcomm. on Oversight and Investigations,* 115th Cong. 3 (2017) (statement of Louis Milione, DEA).

[274] Drug Enf't Admin., *Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I,* 83 Fed. Reg. 5,188, 5,189 (Feb. 6, 2018).

[275] *Id.* at 5189.

[276] *See* John A. Gilbert & Larry K. Houck, *DEA Proposes a New Strategy to Ban Illicit Fentanyl-Related Substances* (Jan. 19, 2018), http://www.fdalawblog.net/2018/01/dea-proposes-a-new-strategy-to-ban-illicit-fentanyl-related-substances/ (last visited Apr. 12, 2018) (questioning whether DEA's attempt to temporarily schedule fentanyl-related products by broadly defining a class of products based on a definition of their potential formulation "can withstand the expected challenges from defense attorneys related to whether this type of scheduling is consistent with the CSA.").

[277] 5 U.S.C. § 706 ("The reviewing court court shall – (2) hold unlawful and set aside agency action ... found to be – (A) ... not in accordance with law").

[278] *Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act: Hearing Before the S. Judiciary Comm.*, 115th Cong. 4 (2017) (statement of Demetra Ashley, DEA).

[279] Drug Enf't Admin., *Final Adjusted Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2017,* 82 Fed. Reg. 51,293 (Nov. 3, 2017).

[280] *Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act: Hearing Before the S. Judiciary Comm.*, 115th Cong. 4 (2017) (statement of Demetra Ashley, DEA).

[281] *Id.*

including morphine, fentanyl, and hydromorphone, which are used to treat the pain needs of patients undergoing interventional procedures (such as colonoscopy or cardiac catheterization) and surgeries.[282] These organizations suggest that the DEA "temporarily reallocate or revise APQ to allow other manufacturers to supply product until the shortages resolve," and also note that their request is "specific to these injectable medications and does not extend to other dosage forms or opioid products."[283]

In August 2018, the DEA released proposed APQs for 2019 that would require further reductions in the quantity of Schedule II opioids that may be manufactured in the United States in 2019.[284] The proposed 2019 APQ for Schedule I and II controlled substances "decreases manufacturing quotas for the most six frequently misused opioids for 2019 by an average ten percent as compared to the 2018 amount," including oxycodone, hydrocodone, oxymorphone, hydromorphone, morphine, and fentanyl.[285]

Congressional Actions Addressing the Opioid Epidemic

Existing legal authorities supplied DEA with the tools for the agency's efforts to combat opioid abuse as described in the previous section. In recent years, Congress has also taken action to address perceived deficiencies in the federal regulatory regime governing opioids. To date, the most comprehensive legislative response to the overprescribing and abuse of opioids is the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (P.L. 115-271) (the SUPPORT for Patients and Communities Act, or the SUPPORT Act) that President Trump signed into law on October 24, 2018. Title III, subtitle B of the SUPPORT Act contains provisions that amend the CSA in various ways to address the opioid epidemic, as described in the following sections.[286]

Expanding Disposal Options for Unwanted Opioid Medication

Young adults and teenagers who seek to abuse prescription opioids may find access to expired or unwanted controlled substance medication from their parents' medicine cabinets[287] or even the trash.[288] One approach to addressing the prescription opioid abuse problem is to reduce the

[282] Letter from Am. Hosp. Ass'n, et al., to Robert W. Patterson, Acting Admin., DEA (Feb. 27, 2018), https://www.aha.org/system/files/2018-02/180227-joint-letter-to-dea-re-apq-for-iv-opioids.pdf.

[283] *Id.* at 2.

[284] Drug Enf't Admin., *Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2019,* 83 Fed. Reg. 42,164 (Aug. 20, 2018).

[285] Press Release, U.S. Dep't of Just., Off. of Pub. Aff., Justice Department, DEA Propose Significant Opioid Manufacturing Reduction in 2019 (Aug. 16, 2018), https://www.justice.gov/opa/pr/justice-department-dea-propose-significant-opioid-manufacturing-reduction-2019.

[286] For a more thorough discussion and analysis of these changes and of other provisions of the SUPPORT Act, see CRS Report R45405, *The SUPPORT for Patients and Communities Act (P.L. 115-271): Food and Drug Administration and Controlled Substance Provisions*, coordinated by Agata Dabrowska; and CRS Report R45423, *Public Health and Other Related Provisions in P.L 115-271, the SUPPORT for Patients and Communities Act*, coordinated by Elayne J. Heisler and Johnathan H. Duff.

[287] *See* 155 CONG. REC. E386 (daily ed. Feb. 25, 2009) (extension of remarks of Rep. Jay Inslee) ("Family medicine cabinets all across America have turned into the drug dealers of today.").

[288] Partnership for Drug-Free Kids, *Safeguard Against Medicine Abuse: Securing and Disposing Medications*,

availability of such drugs by having patients properly dispose of their unwanted opioid medications that have accumulated in their homes.[289] For example, patients may want to get rid of their expired or unused drugs by returning them to pharmacies or giving them to their prescribing physicians. Yet, when Congress originally drafted the CSA, "it did not account for circumstances in which controlled substances were lawfully dispensed to and possessed by an ultimate user but not fully used."[290] To make it easier and more convenient for patients to dispose of unwanted controlled substances, including opioid medications, Congress enacted the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act).[291] The Disposal Act amended the CSA to allow a patient to deliver controlled substances to an entity that is authorized by federal law to dispose of them, provided that such disposal occurs in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.[292] These implementing regulations, issued by the DEA in September 2014, substantially expand the options and opportunities available to patients for safe and secure disposal of their unwanted prescription opioid and other controlled substance medication.[293]

The DEA regulations governing secure disposal of controlled substances allow three primary options for patient disposal of controlled substances. The first option is for federal, state, tribal, or local law enforcement agencies to conduct periodic drug "take-back" events to collect controlled substances from unwanted users; private entities or community groups may also partner with law enforcement to hold community take-back events.[294] Second, DEA-registered manufacturers, distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, or retail pharmacies that wish to become collectors of unwanted controlled substances for disposal purposes must seek authorization from DEA to do so.[295] Authorized collectors may then conduct "mail-back" programs that utilize the mail system for convenient transfer of the unwanted controlled substances, although the physical packages in which the drugs are shipped must comply with certain requirements (for example, tamper-resistance and tracking numbers) that DEA has specified.[296] The third option permits law enforcement agencies or authorized collectors to manage, maintain, and empty secure collection receptacles at their DEA registered location.[297] A long-term care facility may also dispose of controlled substances on behalf of its residents (or former residents) by using on-site collection receptacles that are installed, managed, and maintained by authorized retail pharmacies or hospitals/clinics with an on-site pharmacy.[298] Finally, the regulations provide requirements that collectors must follow regarding methods of

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https://drugfree.org/article/safeguard-against-medicine-abuse-securing-and-disposing-medications/ (last visited Apr. 4, 2018).

[289] Press Release, Drug Enf't Admin. Pub. Aff., Drug Enforcement Administration Collects Record Number of Unused Pills as Part of its 14th Prescription Drug Take Back Day (Nov. 7, 2017), https://www.dea.gov/divisions/hq/2017/hq110717.shtml.

[290] Drug Enf't Admin., *Disposal of Controlled Substances,* 77 Fed. Reg. 75,784, 75,786 (proposed Dec. 21, 2012).

[291] P.L. 111-273, 124 Stat. 2858 (codified at 21 U.S.C. § 822).

[292] *Id.*

[293] Drug Enf't Admin., *Disposal of Controlled Substances,* 79 Fed. Reg. 53,520 (Sept. 9, 2014).

[294] *Id.* at 53,568, adding 21 C.F.R. § 1317.65(a).

[295] *Id.* at 53,567, adding 21 C.F.R. § 1317.40(a).

[296] *Id.* at 53,568, adding 21 C.F.R. § 1317.70(a). Mail-back programs may also be administered by federal, state, tribal, or local law enforcement.

[297] *Id.*, adding 21 C.F.R. § 1317.75(a).

[298] *Id.* at 53,569, adding 21 C.F.R. § 1317.75(d)(2)(iii) and 21 C.F.R. § 1317.80.

destroying controlled substances and destruction procedures, in order to render the collected controlled substances "non-retrievable."[299]

Congress also enacted prescription drug disposal and take-back provisions as part of the Comprehensive Addiction and Recovery Act (CARA) of 2016.[300] Section 201 of CARA authorizes the creation of a grant program at the Department of Justice addressing the problems of opioid addiction and abuse, through which the Attorney General may award grants to states, units of local governments, and Indian tribes to fund their activities relating to opioid abuse, including "[d]eveloping, implementing, or expanding a prescription drug take-back program."[301] Section 203 of CARA requires the Attorney General, in coordination with the DEA Administrator, the Secretary of Health and Human Services, and the Director of the Office of National Drug Control Policy, to coordinate with "covered entities" to expand or make available disposal sites for unwanted prescription drugs.[302] The law defines "covered entities" to include state, local, or tribal law enforcement agencies, drug manufacturers and distributors, retail pharmacies, narcotic treatment programs, hospitals or clinics with an onsite pharmacy, and long-term care facilities.[303]

Congress included two chapters relating to drug disposal in the SUPPORT for Patients and Communities Act that was enacted in October 2018. The first chapter addresses the difficulties faced by home hospice employees regarding disposal of pharmaceutical controlled substances. Under the Disposal Act of 2010, a member of a hospice patient's household may dispose of an unused controlled substance medication after the patient dies,[304] but a home hospice employee cannot do so unless authorized by law (such as state law).[305] Chapter 3 of subtitle B, title III of the SUPPORT Act, referred to as the "Safe Disposal of Unused Medication Act," amends the CSA to allow an employee of a "qualified hospice program"[306] to dispose of a controlled substance after (1) the death of a person receiving hospice care, (2) the expiration of the controlled substance, or (3) a modification in the plan of care of the hospice patient if the employee is the physician of the person receiving hospice care and has a DEA registration.[307] This chapter also requires the Comptroller General of the United States, head of the Government Accountability Office (GAO), to study and report to Congress, not later than 18 months after the SUPPORT Act's enactment on October 24, 2018, on the federal requirements applicable to the management and disposal of controlled substances in the home, as well as the challenges encountered by select qualified hospice programs regarding the disposal of controlled substances.[308]

Chapter 6 of subtitle B, title III of the SUPPORT Act, referred to as the "Access to Increased Drug Disposal Act of 2018," addresses the relatively low number of pharmacies and other DEA-

[299] *Id.*, adding 21 C.F.R. § 1317.90 and 21 C.F.R. § 1317.95. The regulations define "non-retrievable" to mean a controlled substance that has been permanently and irreversibly altered such that it is "unavailable and unusable for all practical purposes." *Id.* at 53,560, adding 21 C.F.R. § 1300.05.

[300] P.L. 114-198, 130 Stat. 695, 712, 717 (codified at 34 U.S.C. § 10701, 21 U.S.C. § 822a).

[301] 34 U.S.C. § 10701(a)(9).

[302] 21 U.S.C. § 822a(b).

[303] *Id.* § 822a(a).

[304] *Id.* § 822(g)(4).

[305] Drug Enf't Admin., *Disposal of Controlled Substances,* 79 Fed. Reg. 53,520, 53,546 (Sept. 9, 2014).

[306] The SUPPORT Act defines a "qualified hospice program" as a hospice program that has written policies and procedures for disposal of the controlled substance after the patient's death that are in place when the controlled substance is first ordered and that documents the disposal in the patient's clinical record after disposal is completed. 21 U.S.C. § 822(g)(5)(B)(iii), as added by P.L. 115-271, § 3222(a).

[307] 21 U.S.C. § 822(g)(5)(A).

[308] P.L. 115-271, § 3223.

registered entities eligible to collect unused prescription drugs for disposal who have voluntarily sought DEA authorization to become registered collectors.[309] This chapter does not directly amend the CSA but instead provides the Attorney General (acting through the Assistant Attorney General for the Office of Justice Programs) with authority to make grants to states in an effort to increase participation rates of eligible collectors as authorized collectors.[310] A state seeking a grant award under this chapter must submit an application that (1) designates a single state agency responsible for complying with the conditions of the grant, (2) describes a plan to increase the participation of eligible collectors as authorized collectors, and (3) explains how the state will select eligible collectors to be served under the grant.[311] The Attorney General is required to award these grants to five states, and at least three of these states must be "in the lowest quartile of States based on the participation rate of eligible collectors as authorized collectors, as determined by the Attorney General."[312]

Increasing Flexibility With Respect to Medication-Assisted Treatment for Opioid Addiction

Certain prescription drugs may be used to treat opioid abuse and facilitate recovery from addiction; this type of practice is commonly referred to as "medication-assisted treatment" or MAT.[313] Currently, the main prescription drugs used in MAT are methadone, buprenorphine, which are controlled substances under the CSA, and naltrexone, which is not scheduled under the CSA. The CSA requires any practitioner wanting to administer and dispense methadone (a Schedule II substance) for the purpose of maintenance treatment[314] or detoxification treatment[315] to obtain annually a separate DEA registration for that purpose,[316] referred to as a "Narcotic Treatment Program" or NTP registration. (NTPs are also regulated by the Substance Abuse and Mental Health Services Administration (SAMHSA) in the Department of Health and Human Services, as well as by state methadone authorities).[317] However, a practitioner may apply for and receive a waiver from this separate registration requirement (commonly known as a "DATA waiver") if the controlled substance to be used for addiction treatment outside of a NTP is a

[309] U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-25, PREVENTING DRUG ABUSE: LOW PARTICIPATION BY PHARMACIES AND OTHER ENTITIES AS VOLUNTARY COLLECTORS OF UNUSED PRESCRIPTION DRUGS 7, 13-16 (2017) (finding that approximately 3% of eligible entities have volunteered to act as authorized collectors, a low rate of participation that could be attributed to the costs associated with purchasing, installing, and managing the disposal bins and some confusion over how to comply with the DEA regulations governing these activities).

[310] P.L. 115-271, § 3253.

[311] *Id.* § 3254.

[312] *Id.* § 3256.

[313] For more information, see CRS In Focus IF10219, *Opioid Treatment Programs and Related Federal Regulations*, by Johnathan H. Duff.

[314] 21 U.S.C. §§ 802(29) ("The term 'maintenance treatment' means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.)".

[315] *Id.* §§ 802(30) ("The term 'detoxification treatment' means the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.").

[316] *Id.* § 823(g)(1).

[317] DRUG ENF'T ADMIN., 1 NARCOTIC TREATMENT PROGRAMS: BEST PRACTICE GUIDELINES (2000), https://www.deadiversion.usdoj.gov/pubs/manuals/narcotic/narcotic.pdf.

Schedule III, IV, or V substance, such as buprenorphine (a Schedule III drug).[318] If a medical professional wishes to prescribe the third type of drug used in MAT, naltrexone, he need not be registered with the DEA to do so because naltrexone is not a controlled substance under the CSA.

One section of CARA amended the CSA to expand temporarily the types of practitioners who may, without being separately registered with the DEA as a NTP, dispense buprenorphine or other narcotic drug in Schedule III, IV, or V, for treating opioid dependence outside of a NTP. Prior to CARA, only "qualified physicians"[319] were permitted to dispense such narcotics for these purposes; CARA temporarily (until October 1, 2021) expands the categories of practitioners to include a qualifying nurse practitioner or physician assistant.[320] The DEA issued a final rule, effective January 22, 2018, that implemented the changes made to the CSA by CARA.[321] Note that CARA did not make any changes to who may dispense methadone.

Congress included several provisions relating to MAT in the SUPPORT Act. Chapter 1 of subtitle B, title III of the SUPPORT Act[322] amends the CSA by removing the time limit imposed by CARA during which nurse practitioners and physician assistants may dispense controlled substances for maintenance and detoxification treatment under a DATA waiver, effectively making CARA's temporary authority permanent.[323] This chapter also allows clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives to obtain DATA waivers until October 1, 2023.[324]

In addition, the SUPPORT Act addresses issues relating to controlled substances that require a physician to administer them to a patient by injection or implantation in a medical office. For example, buprenorphine is a schedule III controlled substance prescribed for treatment of opioid use disorders that may require administration via injection or implantation.[325] However, under the CSA prior to its amendment by the SUPPORT Act, a pharmacist was prohibited from dispensing a controlled substance to anyone other than the ultimate user; as such, the pharmacist could not give a particular controlled substance prescribed for a patient directly to that patient's physician.[326] The SUPPORT Act amends the CSA by allowing a pharmacy, under specified conditions, to deliver a controlled substance to a practitioner, pursuant to a prescription, to be administered by the practitioner to the patient by injection or implantation for the purpose of maintenance or detoxification treatment.[327] The physician must administer the controlled

[318] 21 U.S.C. § 823(g)(2), 21 C.F.R. § 1301.28.

[319] 21 U.S.C. § 823(g)(2)(G)(ii) (listing the specific statutory requirements for a physician to be considered a "qualified" one for purposes of dispensing narcotic drugs for maintenance or detoxification treatment).

[320] *Id.* § 823(g)(2)(G)(iii)(II), (iv).

[321] Drug Enf't Admin., *Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder*, 83 Fed. Reg. 3,071 (Jan. 23, 2018) (codified at 21 C.F.R. § 1301.28).

[322] P.L. 115-271, §§ 3201-3204.

[323] *Id.* § 3201(b).

[324] *Id.* § 3201(c).

[325] For more information, see CRS Report R45279, *Buprenorphine and the Opioid Crisis: A Primer for Congress*, by Johnathan H. Duff.

[326] The CSA defines an "ultimate user" as a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household. 21 U.S.C. § 802(27). The CSA also defines "dispense" to mean "to deliver a controlled substance to an ultimate user ... by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance." *Id.* § 802(10).

[327] P.L. 115-271, § 3204(a), adding new section 309A to the CSA (codified at 21 U.S.C. § 829a).

substance to the patient within 14 days after the physician has received the controlled substance.[328] The Attorney General, in coordination with the Secretary of Health and Human Services, may reduce the number of days within which the physician must administer the controlled substance if such reduction will reduce risk of diversion or protect public health; however, the Attorney General cannot make a modification that is less than seven days.[329] The SUPPORT Act requires the GAO to study and submit a report to Congress on access to and potential diversion of controlled substances administered by injection or implantation not later than two years after the Act's enactment.[330]

Providing Manufacturers and Distributors Certain ARCOS Data

As discussed previously in this report, manufacturers and distributors of Schedule I and II drugs must report their controlled substances transactions to the DEA through the Automated Reports and Consolidated Orders System (ARCOS).[331] Chapter 7 of subtitle B, title III of the SUPPORT Act,[332] referred to as the "Using Data to Prevent Opioid Diversion Act of 2018," is intended "to provide drug manufacturers and distributors with access to anonymized information through ARCOS to help drug manufacturers and distributors identify, report, and stop suspicious orders of opioids and reduce diversion rates."[333] This chapter amends the CSA to require the DEA Administrator to make certain data available to registered manufacturers and distributors through the ARCOS system on a quarterly basis; it covers the total number of registrants that distribute controlled substances to a pharmacy or practitioner registrant and the total quantity and type of opioids distributed to each pharmacy and practitioner registrant.[334] These provisions impose an affirmative obligation on manufacturers and distributors to review this ARCOS information[335] and establish new civil and criminal penalties for failure to do so.[336] Furthermore, these provisions provide that the DEA Administrator may consider a failure of a manufacturer or distributor to review this information in determining whether to initiate administrative actions against the registrant for non-compliance with CSA requirements.[337]

The legislation also requires the Attorney General to submit to Congress within one year of enactment of the act a report that provides information about how the Attorney General is using data in ARCOS to identify and stop suspicious activity.[338]

[328] *Id.*

[329] *Id.*

[330] P.L. 115-271, § 3204(b).

[331] 21 C.F.R. §§ 1304.31 and 1304.32.

[332] P.L. 115-271, §§ 3271-3274.

[333] *Id.* § 3272(a).

[334] *Id.* § 3273(a)(2), adding new 21 U.S.C. § 827(f)(1).

[335] 21 U.S.C. § 827(f)(3)(A).

[336] P.L. 115-271, § 3273(c), amending 21 U.S.C. § 842.

[337] 21 U.S.C. § 827(f)(3)(B).

[338] P.L. 115-271, § 3274.

Adding Considerations for DEA Opioid Quotas

Chapter 8 of subtitle B, title III of the SUPPORT Act,[339] referred to as the "Opioid Quota Reform Act," amends the CSA[340] by adding statutory considerations for the DEA in establishing annual production quotas (APQ) for schedule I and II controlled substances.[341] In establishing the annual medical, scientific, and research need for a controlled substance, the DEA Administrator may, if he determines it will help to address "overproduction, shortages, or diversion of a controlled substance, establish an aggregate or individual production quota," or a procurement quota that he has set by regulation, "in terms of pharmaceutical dosage forms prepared from or containing the controlled substance."[342] In addition, in establishing annual quotas for the production of fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone, the SUPPORT Act requires the DEA Administrator to estimate the amount of diversion of these particular controlled substances that occurs in the United States and then make appropriate reductions from the quota the DEA Administrator would have otherwise established had such diversion not been considered.[343]

Strengthening Requirements to Detect and Report Suspicious Orders

Prior to being amended by the SUPPORT Act, the statutory text of the CSA did not require registrants to design and operate a system to disclose to them any suspicious orders of controlled substances and to report such orders to the DEA; rather, such requirements appeared in DEA regulations.[344] The CSA's definitions section also lacked a definition of the term "suspicious order." Chapter 9 of subtitle B, title III of the SUPPORT Act,[345] referred to as the "Preventing Drug Diversion Act of 2018," adds a statutory definition of "suspicious order" to the CSA that essentially adopts the language of the existing regulatory definition.[346] These provisions also add a new section to the CSA entitled "Suspicious Orders," which requires a DEA registrant to take essentially the same actions as those required under the DEA regulation: (1) to design and operate a system (that is compliant with applicable federal and state privacy laws) that will alert the registrant of suspicious orders of controlled substances, and (2) upon discovering a suspicious order or series of orders, to inform the DEA Administrator and the Special Agent in Charge of the DEA Field Division Office.[347] The SUPPORT Act provisions also require the DEA Administrator, within a year of the act's enactment, to establish a centralized database for storing suspicious

[339] P.L. 115-271, §§ 3281-3282.

[340] 21 U.S.C. § 826.

[341] In making his APQ determinations, the DEA Administrator is also required to consider several factors provided by regulation, 21 C.F.R. §§ 1303.11(b)(1)-(7), as described earlier in this report under the "Quotas" section.

[342] P.L. 115-271, § 3282(a), adding new 21 U.S.C. § 826(a)(2).

[343] *Id.*, adding new 21 U.S.C. § 826(i)(1).

[344] 21 C.F.R. §1301.74(b).

[345] P.L. 115-271, §§ 3291-3292.

[346] P.L. 115-271, § 3292(a), adding new 21 U.S.C. § 802(57).

[347] P.L. 115-271, § 3292(b), adding new 21 U.S.C. § 832. However, there are a few differences between the statutory requirements concerning suspicious orders under the new CSA suspicious orders section and the regulatory requirements under 21 C.F.R. §1301.74(b). For example, the new statutory provision directs the registrant to notify the DEA Administrator in addition to the DEA Field Division Office about suspicious orders (the regulations specify only the latter as the point of contact) and requires the registrant to ensure that the system used to identify suspicious orders complies with federal and state privacy laws (the applicable regulations do not reference privacy laws). Compare P.L. 115-271, § 3292 (adding 21 U.S.C. § 832) with 21 C.F.R. § 1301.74(b).

orders reports; if a registrant submits a suspicious order to this database, the registrant is considered to have complied with the notification requirement mentioned above.[348] The DEA Administrator must share information regarding suspicious orders for prescription controlled substances in a state with an entity designated by the governor or chief executive officer of that state.[349]

The SUPPORT Act also establishes a maximum criminal fine of $500,000 for registered manufacturers or distributors of opioids who intentionally fail to report suspicious orders for opioids.[350]

Other Legislative Proposals That the 116th Congress Could Consider to Amend the CSA

The 116th Congress may consider legislation to amend the CSA beyond the changes made by the SUPPORT Act. These potential additional amendments to the CSA may resemble opioid legislation introduced, but not enacted to date, in the 115th Congress. Legislative proposals introduced in the 115th Congress include the following:

- **Changes to the DEA's Authority to Deny, Revoke, or Suspend a Registration, and to Issue Immediate Suspension Orders.** The DEA Opioid Enforcement Restoration Act of 2017 (H.R. 4095) would repeal the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (EPAEDEA) (P.L. 114-145), discussed above in the section describing the DEA's authority to issue "immediate suspension orders," and would restore the sections of the CSA amended by such act as if it had not been enacted into law.[351] This bill would thus delete the definition of "imminent danger to the public health or safety" that the EPAEDEA had added to the CSA provision governing the DEA Administrator's power to suspend immediately an existing registration for a temporary period of time to avoid such a harm, thereby returning to the DEA significant discretion in interpreting this phrase that is a necessary finding to support an immediate suspension order.[352] The bill would also remove the option afforded by the EPAEDEA for the registrant or applicant to submit a "corrective action plan" to the DEA prior to the agency's denial, revocation, or suspension of his registration. The Opioid Immediate Suspension Order Act of 2017 (H.R. 4073) would also delete the statutory definition of "imminent danger to the public health or safety" for purposes of immediately suspending a registration but, unlike H.R. 4095, the bill would not disturb the "corrective action plan" provision that P.L. 114-145 had added to the CSA.[353]
- **Establishing an Opioid Prescription Limit.** Current federal law does not restrict the particular quantity of opioids that may be prescribed by a

[348] 21 U.S.C. § 832(b).

[349] *Id.* § 832(c).

[350] P.L. 115-271, § 3273(c)(2)(B)(ii), adding new 21 U.S.C. § 842(c)(2)(D)

[351] H.R. 4095, § 2, 115th Cong. (2017).

[352] For more information about this, see section of this report entitled "Immediate Suspension Orders," *supra.*

[353] H.R. 4073, § 2, 115th Cong. (2017).

practitioner.[354] The Opioid Addiction Prevention Act of 2017 (S. 892) would, among other things, amend the CSA to prohibit the DEA Administrator from registering, or renewing the registration of, a practitioner who is licensed under state law to prescribe controlled substances in schedule II, III, or IV, unless the practitioner certifies to the DEA that he will not prescribe any schedule II, III, or IV opioid for the initial treatment of "acute pain" (except opioids approved by the FDA for treating drug addiction) in an amount greater than a seven-day supply of the drug (with no refills allowed), or exceeding an opioid prescription limit established under state law, whichever is lesser.[355] The bill would define "acute pain" to mean "pain with abrupt onset and caused by an injury or other process that is not ongoing" and excludes chronic pain, pain associated with cancer, hospice or other end-of-life care, or pain being treated as part of palliative care.[356] The CARA 2.0 Act of 2018 (S. 2456) would also impose a supply limitation on opioid prescriptions, requiring practitioners to certify, as a precondition for DEA registration or renewal of registration, that they will not prescribe any opioid (other than an addiction-treatment opioid) for the initial treatment of acute pain in an amount exceeding a three-day supply.[357]

- **Medical Education and Prescriber Education Initiatives**.[358] The Safer Prescribing of Controlled Substances Act (S. 1554) would, among other things, amend the CSA to require physicians, dentists, and scientific investigators who wish to dispense or conduct research with controlled substances to complete training that provides them with information concerning best practices for pain management (including alternatives to prescribing controlled substances), responsible prescribing of opioids, methods for diagnosing and treating substance use disorders, and tools to manage diversion of controlled substances such as prescription drug monitoring programs and the use of drugs to treat opioid overdoses.[359] The bill would also make such required training a precondition to the DEA's granting or renewing the registration of these types of practitioners. The Opioid Preventing Abuse through Continuing Education (PACE) Act of 2017 (H.R. 2063) would impose similar practitioner education requirements as a condition for registration to prescribe or dispense opioids,[360] though the specifics of the training differ from S. 1554.
- **Increasing Penalties for Fentanyl Trafficking.** Several bills, including the Stop Trafficking in Fentanyl Act of 2017 (H.R. 1354), the Comprehensive Fentanyl Control Act (H.R. 1781), the Stop Trafficking in Fentanyl Act of 2018 (S. 2481), and the Ending the Fentanyl Crisis Act of 2018 (H.R. 5459, S. 2635), would reduce the quantity (in grams) of fentanyl that triggers mandatory minimum

[354] DRUG ENF'T ADMIN., PHARMACIST'S MANUAL 34 (2010) ("While some states and many insurance carriers limit the quantity of controlled substances dispensed to a 30-day supply, there are no express federal limits with respect to the quantities of drugs dispensed via a prescription.").

[355] S. 892, § 2, 115th Cong. (2017).

[356] *Id.* § 2.

[357] S. 2456, § 3, 115th Cong. (2018).

[358] For more information regarding this topic, see CRS Insight IN10844, *Policy Options to Increase Physician Training Education in Proper Opioid Prescribing*, by Elayne J. Heisler.

[359] S. 1554, § 2, 115th Cong. (2017).

[360] H.R. 2063, § 2, 115th Cong. (2017).

sentences for anyone who, in violation of the CSA, knowingly or intentionally manufactures, distributes, or dispenses fentanyl or fentanyl analogues (or possesses such substances with intent to engage in these prohibited activities).[361] Under current law, a trafficking offense involving 400 grams or more of a mixture or substance containing a detectable amount of fentanyl, or 100 grams or more of a mixture or substance containing a detectable amount of a fentanyl analogue, is punishable by a term of imprisonment of at least 10 years and up to life in prison (or a minimum sentence of 20 years to life in prison, if death or serious bodily injury results from the use of the trafficked fentanyl).[362] The bills would reduce these quantities to 20 grams and 5 grams, respectively. In addition, under current law, a drug trafficking offense involving 40 grams or more of a mixture or substance containing a detectable amount of fentanyl, or 10 grams or more of a mixture or substance containing a detectable amount of a fentanyl analogue, is punishable by a term of imprisonment of at least 5 years but not more than 40 years (or a minimum of 20 years to life in prison, if death or serious bodily injury results from the use of the trafficked fentanyl).[363] The bills would reduce these quantities to 2 grams and 0.5 grams, respectively.

Author Information

Brian T. Yeh
Legislative Attorney

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[361] H.R. 1354, § 2, 115th Cong. (2017); H.R. 1781, § 3(a)(1), 115th Cong. (2017); S. 2481, § 2, 115th Cong. (2018); S. 2635, § 2, 115th Cong. (2018); H.R. 5459, § 2, 115th Cong. (2018).

[362] 21 U.S.C. § 841(b)(1)(A)(vi).

[363] *Id*. § 841(b)(1)(B)(vi).