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Legal Sidebar

Recent Developments in Opioid Regulation Under the Controlled Substances Act

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In recent years, policymakers have devoted significant attention to opioid regulation, seeking in particular to combat the epidemic of opioid misuse and overdoses. Opioids are drugs derived from the opium poppy or emulating the effects of opium-derived drugs. Some opioids have legitimate medical uses related to pain management, while others have no recognized medical use. Both pharmaceutical opioids (such as oxycodone, codeine, and morphine) and non-pharmaceutical opioids (such as heroin) may pose a risk of abuse and dependence and may be dangerous or even deadly in certain doses.

As part of its response to the opioid crisis, Congress has considered how to regulate non-pharmaceutical analogues to the powerful opioid fentanyl. At the same time, courts, advocates, and the executive branch have grappled with the legal status of supervised consumption sites—facilities where illicit drug users can consume opioids under the supervision of trained staff, receive medical intervention in case of an overdose, and access services including addiction treatment. In addition, in December 2022, Congress enacted legislation relaxing certain regulatory requirements for medical providers offering treatment for opioid use disorder (OUD).

This Legal Sidebar provides information for Congress on recent developments in opioid regulation, with a focus on regulation under the federal Controlled Substances Act (CSA). The Sidebar first provides background information on the legal status of opioids. It then discusses recent legal developments related to fentanyl analogues, supervised consumption sites, and treatment for OUD. The Sidebar closes with a summary of selected proposals from the 117th and 118th Congresses addressing other issues related to opioid regulation.

Background on Opioid Regulation

Opioids are subject to regulation under multiple provisions of federal and state law. At the federal level, prescription opioids are regulated under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Many pharmaceutical and non-pharmaceutical opioids are controlled substances under the CSA. (Many other prescription drugs are not controlled substances.) Opioids are also often subject to state controlled substance laws. This Legal Sidebar focuses on regulation of opioids under the CSA.

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The CSA regulates drugs and other substances—whether medical or recreational, legally or illicitly distributed—that pose a risk of abuse and dependence. Substances become subject to the CSA through placement in one of five lists, known as Schedules I through V. A lower schedule number carries greater restrictions, so controlled substances in Schedule I are subject to the most stringent controls. Schedule I controlled substances have no currently accepted medical use, and it is illegal to produce, dispense, or possess them except in the context of federally approved scientific studies. By contrast, substances in Schedules II through V have accepted medical uses and may be dispensed for medical purposes, usually by prescription. A substance can be placed in a CSA schedule, moved to a different schedule, or removed from CSA control either by legislation or through an administrative rulemaking process overseen by the Drug Enforcement Administration (DEA) and based on criteria in the CSA.

A substance not specifically designated for control in Schedules I through V may be subject to the CSA as a *controlled substance analogue*. A controlled substance analogue is a substance not otherwise approved by the Food and Drug Administration or scheduled under the CSA that has (1) a chemical structure substantially similar to that of a controlled substance in Schedule I or II *or* (2) an actual or intended effect that is "substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect ... of a controlled substance in schedule I or II." A substance that meets those criteria and is intended for human consumption is treated as a controlled substance in Schedule I.

A number of pharmaceutical and non-pharmaceutical opioids are controlled substances. For instance, fentanyl is in Schedule II, as it has recognized medical uses. Methadone, oxycodone, and hydromorphone—medications used for multiple purposes including to treat pain—are also in Schedule II. Cough medicines containing small amounts of codeine are in Schedule V. Some non-pharmaceutical substances chemically related to fentanyl are in Schedule I. To the extent other opioids are not specifically scheduled under the CSA, they may still fall under CSA control as controlled substance analogues.

Fentanyl Analogues

One question before the 118th Congress is how to regulate analogues of fentanyl. The 116th and 117th Congresses enacted legislation in this area, building on action by DEA, but some questions remain. As noted above, fentanyl itself is in Schedule II, and some analogues of fentanyl are controlled in Schedule I or II. However, it is possible to modify the fentanyl molecule, producing substances that are chemically related to fentanyl but are not individually scheduled under the CSA.

DEA has the authority to place a substance in Schedule I temporarily when "necessary to avoid an imminent hazard to the public safety." DEA exercised that authority on February 6, 2018, by issuing a temporary scheduling order (Fentanyl TSO) that placed certain "fentanyl-related substances" in Schedule I for two years. While previous scheduling actions by DEA and Congress generally identified a specific substance or a list of discrete substances for control, the Fentanyl TSO instead imposed controls on a broad class of fentanyl-related substances that met specific criteria related to their chemical structure. While that class of substances is finite, it includes thousands of chemicals. As one researcher testified before Congress, the effects, potential for abuse and dependence, and medical utility of many of those substances are unknown.

Perhaps because of those uncertainties, DEA did not initiate permanent scheduling of the class of substances subject to the Fentanyl TSO, though the agency has continued to take temporary and permanent scheduling actions with respect to specific fentanyl analogues, including selected fentanyl-related substances subject to the Fentanyl TSO. By statute, DEA rulemaking permanently scheduling a controlled substance must be supported by certain factual findings. January 2020 testimony from an official in the Department of Health and Human Services (HHS) suggested that, given the large number of substances subject to the order, it was not feasible to make the individualized findings required to

schedule each substance permanently. Congress is not required to make the same findings to schedule a substance via legislation.

On February 6, 2020, Congress enacted the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which temporarily extended the Fentanyl TSO until May 6, 2021. Congress has since extended the Fentanyl TSO several times. The most recent extension expires December 31, 2024. If the temporary scheduling expires, some unscheduled opioids related to fentanyl may remain subject to regulation under the CSA as controlled substance analogues. However, DEA has explained that it must prove additional elements in analogue prosecutions, so such "prosecutions are time-consuming, resource-intensive, and difficult for investigators," and their outcomes may be unpredictable.

Some stakeholders, including DEA and HHS, have called for Congress to impose permanent controls on the class of fentanyl-related substances subject to the Fentanyl TSO or a similar class of fentanyl analogues. A previous CRS Legal Sidebar discusses some questions Congress might consider when deciding whether and how to regulate fentanyl analogues, including how to define the category of substances subject to control, how those substances should fit into the CSA's criminal enforcement and sentencing regimes, and whether placing fentanyl analogues in Schedule I might impede research into potential medical uses.

Members of the 117th Congress introduced multiple legislative proposals that would have permanently scheduled a class of fentanyl analogues. Some proposals would have permanently placed the class of substances subject to the Fentanyl TSO in Schedule I. Some would have scheduled the class of fentanyl-related substances subject to the Fentanyl TSO plus certain specific substances. Some proposals sought to facilitate research on substances subject to class-wide scheduling or provide for expedited descheduling if a fentanyl-related substance were found not to pose a risk of abuse and dependence. In addition, some legislative proposals would have provided that mandatory minimum sentences under the CSA would not apply to those who committed certain offenses involving fentanyl-related substances.

Some Members of the 118th Congress have also introduced legislation to permanently schedule fentanyl-related substances. On February 1, 2023, the House Energy and Commerce Committee held a hearing on the regulation of fentanyl-related substances.

Supervised Consumption Sites

Another recent issue related to opioid regulation is the legal status of supervised consumption sites under a provision of the CSA, 21 U.S.C. § 856 (Section 856). Supervised consumption sites are facilities that pursue a *harm reduction strategy* by permitting the use of controlled substances in the presence of staff who can administer overdose-reversal medications, distributing medical supplies such as sterile syringes, and offering referrals to substance use treatment. Congress first enacted Section 856 in 1986 in response to concerns about "crack houses"—premises where illicit drugs such as crack cocaine were manufactured, stored, distributed, and used. Congress amended the provision in 2003 to target facilities hosting "raves" where attendees distributed and used drugs such as MDMA.

Section 856 contains two criminal prohibitions. The first, Section 856(a)(1), prohibits an entity from maintaining premises for its own illicit drug-related activities. The second, Section 856(a)(2), imposes criminal penalties on those who "manage or control any place ... and knowingly and intentionally rent, lease, profit from, or make available for use, with or without compensation, the place for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance." Essentially, the second provision prohibits making premises available for illicit drug-related activity by third parties. Supervised consumption sites and their staff generally do not produce, distribute, or otherwise handle drugs, so legal questions related to such facilities center on Section 856(a)(2).

In 2018, a nonprofit called Safehouse announced plans to open a supervised consumption site in Philadelphia. The U.S. Department of Justice (DOJ) sued Safehouse to block the proposed facility, arguing that the supervised consumption site would violate Section 856. As discussed in a previous CRS Legal Sidebar, in October 2019, a federal district court ruled that the planned facility would not violate the CSA because Section 856 does not apply to supervised consumption sites such as Safehouse.

The United States appealed. On January 12, 2021, in *United States v. Safehouse*, the U.S. Court of Appeals for the Third Circuit reversed the district court. Safehouse argued that in operating a supervised consumption site it lacked the requisite intent to violate Section 856. A majority of the three-judge panel disagreed, holding that Safehouse need not "have the purpose that its visitors use drugs" but rather "need only 'knowingly and intentionally' open its site to visitors who come 'for the purpose of ... using' drugs." In any event, the court concluded that, in "offer[ing] visitors a space to inject themselves with drugs," Safehouse would violate Section 856 because the organization "itself has a significant purpose that its visitors use heroin, fentanyl, and the like." In response to Safehouse's argument that this application was not what Congress intended when it enacted and amended Section 856, the majority held that the text of the statute was clear, so the court need not look beyond the text to other indicia of congressional intent.

One member of the Third Circuit panel dissented. Judge Roth contended that text of Section 856 is ambiguous, and the majority erred in construing the ambiguous text in a way that imposed broad criminal liability. She would have also held that Safehouse lacked the requisite intent to violate Section 856 because it "is not motivated at least in part by a desire for unlawful drug activity to occur and ... in fact wants to reduce drug activity." The Supreme Court declined to review the Third Circuit's decision.

At the time of writing, Safehouse has not commenced operation. However, other states and localities have also begun considering whether to authorize such facilities. At the time of the district court decision in the Safehouse litigation, there were already multiple reports of a supervised consumption site operating in secret in an undisclosed location, and local governments and other organizations outside Philadelphia had begun to consider similar facilities. In July 2021, Rhode Island enacted legislation authorizing supervised consumption sites under state law. The Illinois, Massachusetts, and New Mexico state legislatures have also considered legislation related to supervised consumption sites. The California legislature passed legislation in 2022 that would have allowed supervised consumption sites to operate on a trial basis in three cities, but the governor vetoed it, expressing concerns that the legislation might inadvertently "[w]orsen[ ] drug consumption challenges" in those cities.

In November 2021, two supervised consumption sites began operating openly in New York City with the approval of the city government. The city reported that the sites were used 2,000 times in their first three weeks of operation and averted at least 59 potential overdose deaths. While DOJ actively opposed the operation of supervised consumption sites under the Trump Administration, to date the Biden Administration has not sought to invoke the CSA against such facilities. In February 2022, DOJ stated that it was "evaluating supervised consumption sites, including discussions with state and local regulators about appropriate guardrails for such sites, as part of an overall approach to harm reduction and public safety."

In the meantime, uncertainty remains as to the legality of supervised consumption sites under the CSA. Congress could resolve that uncertainty by enacting legislation. If Congress decided to allow supervised consumption sites to operate, it could consider the breadth of such authorization. One option would be to exempt supervised consumption sites from CSA control entirely. Alternatively, Congress might choose to exempt from federal prosecution facilities operating in compliance with state and local law, as it has done with state-sanctioned medical marijuana activities through a series of appropriations riders. Another option would be for Congress to impose specific registration requirements for supervised consumption sites under the CSA, as it has done for entities that administer medication-assisted treatment (MAT) for opioid addiction.

If Congress decided not to allow supervised consumption sites, it could amend Section 856 to prohibit those facilities explicitly (as it did with other activities in 2003) or enact separate legislation to ban supervised consumption sites. Congress could also use its spending power to limit supervised consumption sites. For example, a proposal from the 117th Congress would have prohibited federal funds from being "used by any Federal agency to operate or control ... an injection center" that violates Section 856. Others would have limited the availability of federal funds to states, localities, Indian tribes, and other entities that operate supervised consumption sites in violation of Section 856.

Opioid Treatment Programs

Another recent development in opioid law involves a change to the CSA provision regulating medical providers that administer medication-assisted treatment. MAT is the combined use of medication and other services to treat addiction. Three medications are currently used in MAT for OUD: methadone, buprenorphine, and naltrexone. Methadone is in Schedule II under the CSA, buprenorphine is in Schedule III, and naltrexone is not a controlled substance.

Under the CSA, health care providers, including those who offer MAT, must register with DEA to legally administer or dispense controlled substances. The CSA also requires certain "practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment"—known as opioid treatment programs, or OTPs—to obtain an additional registration from DEA for such activities. As outlined in a previous CRS In Focus, under the Drug Addiction Treatment Act of 2000 (DATA 2000, P.L. 106-310), physicians who met certain requirements could obtain a waiver to treat opioid addiction with MAT using controlled substances without a separate DEA registration (i.e., outside an OTP). Among other limitations, DATA waivers (also known as X-Waivers) were available only for practitioners using medications in Schedules III through V. For most of the time the waivers were available, buprenorphine was the only medication on the market that met the conditions for a DATA waiver, meaning that practitioners could obtain DATA waivers to treat patients outside of OTPs using buprenorphine but not methadone. (No DEA registration is required to administer MAT using naltrexone, because it is not controlled under the CSA.)

In December 2022, Congress enacted the Restoring Hope for Mental Health and Well-Being Act (Division FF, Title I of the Consolidated Appropriations Act, 2023). Section 1262 of the law repealed the DATA waiver requirement, amending 21 U.S.C. § 823 to provide that a separate registration is not required for practitioners dispensing narcotic drugs in Schedules III, IV, or V for MAT to treat OUD. On January 12, 2023, DEA issued guidance to registrants explaining that, as a result of the new legislation, a DATA waiver is no longer required to treat patients with buprenorphine for OUD. (A standard DEA registration to administer or dispense controlled substances is still required.) It further stated, "DEA fully supports this significant policy reform," which "will increase access to buprenorphine for those in need." The Substance Abuse and Mental Health Services Administration in HHS, which was involved in administering the DATA waiver provision, stated that it would immediately stop accepting waiver applications. Any practitioner with a standard DEA registration to dispense controlled substances can now treat individuals with buprenorphine for OUD, provided it is consistent with state law.

Other Legislative Proposals

Outside the issue areas discussed above, the 117th Congress saw multiple proposals related to opioid regulation under the CSA. (Numerous additional proposals that would have altered how opioids are regulated under the FD&C Act or other provisions of law are outside the scope of this Sidebar.)

Some proposals sought to change the regulatory obligations of CSA registrants authorized to handle opioids. The MATE Act of 2021 (S. 2235) sought to "require physicians and other prescribers of controlled substances to complete training on treating and managing patients with opioid and other

substance use disorders." That proposal was enacted with minor modifications as Section 1263 of the Restoring Hope for Mental Health and Well-Being Act. Another proposal that was not enacted, the LABEL Opioids Act (H.R. 1026/S. 2353), would have required certain opioid medications subject to the CSA to bear a "clear, concise warning that the opioid dispensed can cause dependence, addiction, and overdose." The Harm Reduction Through Community Engagement Act of 2022 (H.R. 8917) would have imposed additional registration requirements for opioid treatment programs. The Opioid QuOTA Act of 2021 (H.R. 6150/S. 3327) would have required publication of the annual quotas that apply to each registered opioid manufacturer.

Other proposals sought to amend the CSA's criminal provisions that apply to unauthorized activities involving opioids. Some proposals would have increased criminal penalties for certain fentanyl-related offenses, imposing life in prison or the death penalty. Others would have lowered the amounts of fentanyl or fentanyl analogues required to trigger existing mandatory minimum sentences. Some proposals would have targeted misrepresenting the content of a substance containing fentanyl or the manufacture of counterfeit substances that contain fentanyl and bear identifying marks of another product. Another proposal would have authorized special agents of Homeland Security Investigations to perform certain enforcement functions under the CSA.

The 118th Congress is also considering issues related to opioid regulation. In addition to the regulation of fentanyl-related substances discussed above, Congress may consider whether to impose CSA controls on xylazine, a sedative drug used in veterinary medicine. Xylazine is not an opioid, but it is sometimes combined with drugs of abuse such as illicit fentanyl and can pose serious health risks if consumed by humans. Xylazine is not currently a controlled substance, and stakeholders debate whether the substance should be scheduled. One legislative proposal would place xylazine in Schedule III under the CSA.

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