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DEA inspections and audits warrant compliance plan, Part 1

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The federal law governing the manufacture, distribution, and use of prescription and illicit opioids is the Controlled Substances Act (CSA),[1] a statute that the Drug Enforcement Administration (DEA) is principally responsible for administering and enforcing. The DEA is an agency within the U.S. Department of Justice (DOJ). The mission of the DEA is: (1) to provide guidance on compliance with the CSA to ensure an adequate supply of controlled substances for legitimate needs; (2) to prevent, detect, and investigate the diversion of controlled substances; and (3) to engage in administrative, civil, and criminal enforcement actions against parties that violate the CSA or are otherwise involved in the diversion of controlled substances.[2] Drug diversion is the act of illegally obtaining or using prescription medications not intended by the prescriber, dispenser, manufacturer, or distributor of the controlled substances.

The CSA places controlled substances into one of five schedules based on the substance's medical use, potential for abuse, and safety or dependence liability.[3] The current list of controlled substances within their designated schedules may be found in 21 C.F.R. § 1308.11-15 . The order of the five schedules in which controlled substances are categorized reflects substances that are progressively less dangerous and addictive. Schedule I contains substances, such as 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. Schedule II contains substances such as prescription opioids that have recognized medical uses but may lead to severe psychological or physical dependence. Schedules III, IV, and V include substances that have recognized medical uses, such as Xanax, Ambien, and products containing codeine, that have low potential for abuse relative to controlled substances in Schedules I and II.[4]

The opioid crisis

The President's Commission on Combating Drug Addiction and the Opioid Crisis Report observed that "[t]he crisis in opioid overdose deaths has reached epidemic proportions … and currently exceeds all other drug-related deaths or traffic fatalities."[5] Opioids were involved in 47,600 overdose deaths in 2017 (67.8% of all drug overdose deaths).[6] In 2017 HHS declared a public health emergency[7] and announced a 5-point strategy to combat the opioid crisis.[8] One of the primary goals of the strategy is reducing the diversion of illicit controlled substances.[9]

The DEA's response to the opioid crisis has increasingly led to enforcement actions, and civil and criminal liability for pharmacies and pharmacists that dispense controlled substances. The DEA has increased its' regulatory audits and inspections of pharmacies through the use of regional task forces and other federal resources. The DEA is very aggressive in its investigations and enforcement actions, and often works in concert with the United States Attorney's Office, state Boards of Pharmacy, and local law enforcement.[10]

DEA registration requirements

The CSA requires pharmacies to register with the DEA and comply with the terms and conditions of the registration.[11] Before a pharmacy can apply for a DEA registration to prescribe controlled substances, the pharmacy must first meet state pharmacy licensing requirements.

To obtain a DEA registration, a pharmacy must apply using a DEA Form 224.[12] Pharmacies may submit the form by hard copy or online. A separate registration is required for each principal place of business where controlled substances will be dispensed. A DEA registration must be renewed every three years using DEA Form 224a, Renewal Application for DEA Registration. The DEA Certificate of Registration (DEA Form 223) must be maintained at the registered location in a readily retrievable manner and kept available for official inspection. A pharmacy that moves to a new physical location must request a modification of registration. A DEA registration cannot be transferred to another party unless the DEA provides express, written consent for the transfer to occur. A pharmacy that discontinues business activities either completely or only regarding controlled substances must return its DEA registration certificate and unused official order forms (DEA Form 222) to the DEA.[13]

The DEA has the authority to deny, suspend, or revoke a DEA registration upon a finding that the pharmacy has: (1) materially falsified any application filed; (2) been convicted of a felony relating to a controlled substance or a Schedule I chemical; (3) had their state license or registration suspended, revoked, or denied; (4) committed an act which would render the DEA registration inconsistent with the public interest; or (5) been excluded from participation in a Medicaid or Medicare program.[14]