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Complete Healthcare Compliance Manual 2024
Drug Diversion and Prescribing Practices

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What Are Drug Diversion and Prescribing Practices?

The U.S. Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) have defined drug diversion as "the illegal distribution or abuse of prescription drugs or their use for purposes not intended by the prescriber."[2] Despite increased scrutiny in recent years, drug diversion continues to be both a major American societal problem and an enforcement risk area because of its impact and contribution to the opioid crisis. Since 2000, more than 500,000 people have died from opioid-related overdoses.[3] By 2017, the problem of opioid addiction and overdose had reached such significance that the HHS secretary declared it a public health emergency (PHE) in October of 2017. Despite the passage of various laws and increased dedication of resources at state and federal levels to address the crisis, six years later, the PHE is still in effect and opioid deaths have continued to increase—particularly in the years since the onset of the COVID-19 pandemic.[4] Some of the most often cited contributors to the opioid crisis relate to factors resulting in overprescribing.[5] Thus, because inappropriate prescribing practices were perceived to have contributed to the opioid crisis, enforcement efforts since the onset of the PHE have considerably targeted individuals involved in the unlawful distribution and prescription of opioids.[6] Healthcare providers who prescribe opioids must be aware of the relevant compliance risks and institute proper safeguards for their practices.

Risk Area Governance

The Controlled Substances Act (CSA) 21 U.S.C. § 801

The CSA regulates the "importation, manufacture, distribution, and possession and improper use of controlled substances."[7] Through the CSA, the federal government classified all substances regulated by federal law into five schedules.[8] The schedules are determined based on the following factors: the substance's medical use, potential for abuse, and safety or dependence liability.[9] Most opioids fall within Schedule II or Schedule III. Schedule II drugs have a high potential for abuse which may lead to severe psychological or physical dependence, and have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. Examples of Schedule II narcotics include morphine, codeine, opium hydrocodone, and oxycodone. Schedule II drugs can only be dispensed to patients upon receipt of a signed written prescription by a Drug Enforcement Agency (DEA)-licensed practitioner or an electronic prescription meeting the DEA electronic prescriptions for controlled substance requirements.[10] For a Schedule II controlled substance, an oral order is only permitted in an emergency, and the prescriber must deliver a written prescription for the emergency quantity prescribed within seven days.[11] In addition, the prescriber must communicate the emergency oral prescription directly to the pharmacy without use of an agent. Refills of Schedule II drugs are not permitted; however, the prescribing practitioner can order multiple prescriptions at once up to a 90-day supply so long as certain conditions are met:

1. "Each separate prescription must be issued for a legitimate medical purpose by an individual practitioner

acting in the usual course of professional practice;

2. "The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription;
3. "The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;
4. "The issuance of multiple prescriptions is permissible under applicable state laws; and
5. "The individual practitioner complies fully with all other applicable requirements under the Act and these regulations well as any additional requirements under state law."[12]

A practitioner can send a facsimile of a Schedule II prescription in order to expedite the process, but the practitioner must subsequently provide the original prescription to the pharmacy prior to dispensing.[13] Schedule III drugs have "a potential for abuse less than drug or other substances in schedules I or II . . . a currently accepted medical use in treatment in the United States; Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence."[14] Examples of Schedule III narcotics include morphine and codeine combination products containing not more than certain dosages.

Unlike Schedule II controlled substances, the prescription requirements for filling Schedule III narcotics are less restrictive. For example, Schedules III, IV, and V narcotics can be dispensed upon receipt of a facsimile of a signed paper prescription from the practitioner or their agent. In addition, in lieu of a written prescription, the prescriber can call in the prescription without the circumstances qualifying as an emergency.[15]

Under the CSA's accompanying regulations, "a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . ."[16] Moreover, the U.S. Supreme Court has held that under the CSA's general drug trafficking provisions, physicians can be criminally prosecuted "when their activities fall outside the usual course of professional practice."[17]

In addition to the general requirements governing what constitutes a valid prescription, the CSA also contains specific provisions governing ordering controlled substances via the internet. The Ryan Haight Act of 2008 amended the CSA to prohibit the delivery, distribution, or dispensing of a controlled substance by using the internet without a valid prescription.[18] This requires that the prescription be issued for a legitimate medical purpose either by a practitioner having conducted at least one in-person medical evaluation or by a covering practitioner. The regulations provide seven telemedicine exceptions to the in-person examination requirement.[19] They include:

- The practice of telemedicine "while the patient is being treated by and physically located in, a qualifying hospital or clinic";
- The practice of telemedicine "while the patient is in the physical presence of a practitioner";
- The practice of telemedicine "by a practitioner who is an employee or contractor of the Indian Health Service";

- The practice of telemedicine "during a public health emergency declared by the Secretary";
- The practice of telemedicine when conducted by a practitioner who has received "a special registration" from the DEA administrator.
- The practice of telemedicine that occurs in a U.S. Department of Veterans Affairs medical emergency.

The practice of telemedicine in circumstances specified by DEA regulation.[20]

Section 2003 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act

Section 2003 requires providers to use electronic prescribing for Schedules II, III, IV, or V controlled substances covered under Medicare Part D prescription drug plans.[21] The provision went into effect beginning January 1, 2023. The mandate contains the following exceptions:

- "Prescriptions for controlled substances issued when the prescriber and dispensing pharmacy are the same entity.
- "Prescribers who issue 100 or fewer qualifying Part D controlled substance prescriptions per calendar year.
- "Prescribers who CMS determines are in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity.
- "Prescribers who have received a CMS-approved waiver because the prescriber is unable to conduct electronic prescribing of controlled substances due to circumstances beyond the prescriber's control."

In addition, the requirements for compliance with the section will not be effective for prescriptions made to beneficiaries treated in the long-term care (LTC) environment until January 1, 2025.

State Prescribing Laws

In addition to the federal CSA, each U.S. state maintains its own specific laws governing the prescription of controlled substances within the jurisdiction. Unlike the CSA, which limits opioid prescriptions to that which is a legitimate medical purpose and in the usual course of professional practice, some states prohibit prescriptions of certain drugs to a specific supply amount (i.e., three or seven days).[22] Similarly, some states cap the prescription's dosage to a specific morphine milligram equivalent (MME) (i.e., 90 MMEs per day). States may also have varying requirements for prescriptions to minors or special exceptions for professional judgment, cancer treatment, surgical pain, palliative care, and more. Similarly, states have varying rules regarding which advanced practice providers can legally prescribe controlled substances and which category of substances they can prescribe.[23] States also have varying requirements regarding use of electronic prescribing of controlled substances (EPCS). The majority of states now mandate its use.[24] The majority of states also now maintain prescription drug monitoring programs (PDMPs), which are databases where pharmacies submit information regarding controlled substances dispensation that includes the drug dispensed, the date of dispensation, the name of the prescriber, and the individual for whom the prescription was written. Many states now mandate prescribers to consult the PDMP prior to prescribing a controlled substance to identify potential abuse.

Anti-Kickback Statute (AKS) 42 U.S.C. § 1320a-7(b)

The statute prohibits offering, paying, soliciting, or receiving anything of value to induce or reward referrals to

generate federal healthcare program business. The AKS has been interpreted as applying to relationships between pharmaceutical manufacturers and those in a position to generate federal health care program business, including physicians and advanced practice providers.[25]

False Claims Act (FCA) 31 U.S.C. §§ 3729–3733

The federal FCA prohibits, among other things, (1) the submission of false or fraudulent claims and (2) knowingly making, using, or causing false statements or information to be made to obtain fraudulent claims payment. FCA violations occur when providers knowingly bill for services improperly. In addition, violations of both AKS and the Stark Law that can result through tainted claims that were submitted to federal healthcare programs, as well as the failure to refund identified overpayments, can each result in FCA liability.

State Law Equivalents of AKS and the FCA

Some states have enacted versions of the federal AKS and the FCA. State laws may be broader in scope and apply to both state programs such as Medicaid as well as claims submitted to commercial payers.

Eliminating Kickbacks in Recovery Act (EKRA) 18 U.S.C. § 220

The EKRA is another relatively newer enforcement tool against fraud in healthcare. It prohibits the payment of remuneration in return for patient referrals to a recovery home, clinical treatment facility, or laboratory. It covers all payors, not only federal healthcare programs.