DEA INSPECTIONS AND AUDITS WARRANT COMPLIANCE PLAN, PART 1

by Michael A. Dowell

Michael A. Dowell
RPh, JD
(mdowell@hinshawlaw.com) is Health Law Partner in the Downtown Los Angeles office of Hinshaw & Culbertson, LLP.

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]

Pharmacy controlled substances compliance requirements

The CSA imposes compliance requirements on pharmacies, which are summarized below.

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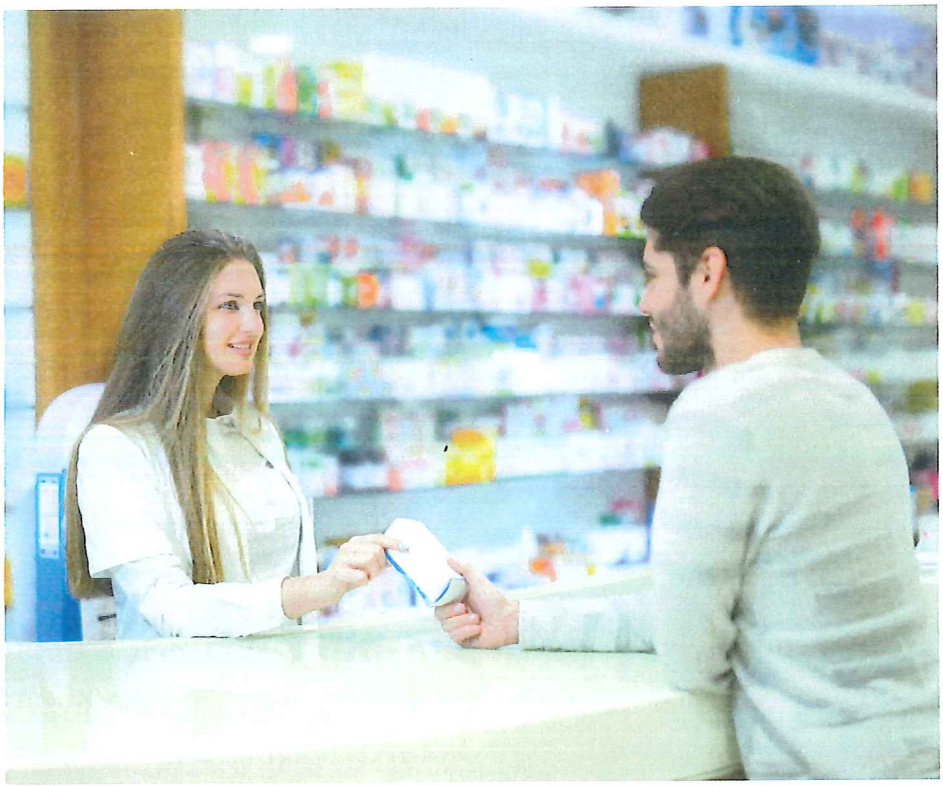
Record keeping requirements

Records must be created and maintained when controlled substances are ordered, received, compounded, dispensed, transferred, disposed of, or subject to theft or loss. The types of controlled substances records that must be maintained and made available for inspection or audit include but are not limited to: (1) the DEA Certificate of Registration; (2) executed and unexecuted DEA Form 222 order forms for Schedule II medications; (3) power of attorney to sign DEA Form 222 authorization forms; (4) purchase order receipts and invoices related to Schedule III, IV and V medications; (5) inventory records, including initial, biennial, and newly scheduled drug inventories, dated as of beginning or close of business; (6) records of controlled substances dispensed (i.e., prescriptions and Schedule V logbook); (7) reports of



theft or significant loss (DEA Form 106); (8) inventory of controlled substances surrendered for disposal (DEA Form 41); (9) records of transfers of controlled substances between pharmacies; (10) records of controlled substances distributed by sales to other DEA registrants, returns to vendors, or distributions to reverse distributors; and (11) self-certification certificate and logbook (or electronic equivalent) as required under the Combat Methamphetamine Epidemic Act of 2005.[15]

Inventory requirements

The CSA requires all pharmacies to maintain complete and accurate inventories of each controlled substance received, sold, delivered, or otherwise disposed of.[16] The CSA requires that an inventory of controlled substances in a pharmacy be conducted initially when a DEA registration has been issued, and biennially thereafter. At the initial inventory, the record of the inventory must include the following: (1) date of the inventory; (2) whether the inventory was performed at the start or close of the business day; (3) name of each controlled substance that was inventoried; (4) finished dosage form of each controlled substance; (5) number of dosage units of each finished dosage form in the commercial container; (6) number of commercial containers of each finished dosage form; and a (7) count of each controlled substance as mentioned above.

The biennial inventory requires documentation of the same information as the initial inventory and may be completed on any date within two years of the previous inventory date. This inventory record must be maintained at the registered location for at least two years from the date that the inventory was conducted. In 2017, Duncan Pharmacy agreed to a $50,000 dollar settlement with the DOJ to resolve, amongst other things, allegations that it failed to conduct and maintain a biennial inventory.[17] Similarly, in 2017, CVS Pharmacy Inc. (CVS) agreed to a $5 million dollar settlement to resolve, amongst other things, failure to conduct a biennial inventory on one specific day.[18]

Controlled substance ordering requirements

Schedule I and II controlled substances may be ordered by filling out a DEA Form 222 or by electronically completing the DEA Controlled Substance Ordering System (CSOS). When ordering Schedule II medications, the number of packages, size of the package, and name of the item must be filled out completely on the form. The form must be signed and dated by an authorized individual. For each pharmacy, there may be more than one person who is authorized to obtain and execute official DEA Form 222 order forms. The pharmacy must grant a "power of attorney" to each authorized person. The power of attorney must be signed by the individual receiving authorization responsibilities and by the person who signed the most recent application for registration or renewal registration for the pharmacy. Official DEA Form 222 order forms for Schedule II controlled substances must be maintained separately from other business records in the pharmacy.[19]

For Schedules III through V controlled substances, the pharmacy must maintain shipment invoices/packing slips in a readily retrievable manner. In 2017, CVS agreed to a $5 million settlement with the DOJ to resolve federal CSA allegations that its pharmacies in the Eastern District of California failed to

keep and maintain complete and accurate records regarding controlled substances.[20] CVS failed to comply with DEA recordkeeping requirements as demonstrated by its failure to: (1) record the amount received and the date received of Schedule II drugs on DEA-222 forms; (2) maintain DEA-222 forms and keep them separate from other records; (3) record the date of acquisition of controlled substances in Schedules II through V; (4) maintain invoices for drugs in Schedules III through V and keep the records separate from non-controlled substance records; and (5) conduct a biennial inventory on one specific day.[21]

Dispensing record requirements

Pharmacies must maintain dispensing records of controlled substances listed in Schedules I and II separately from all other records maintained by the pharmacy. Likewise, inventories and records of controlled substances in Schedules III, IV, and V must be maintained separately or in such a form that they are readily retrievable from the ordinary business records of the pharmacy. Electronic prescription records may be archived in an electronic format; however, the archiving is subject to additional requirements regarding security and retrievability. All dispensing records related to controlled substances must be maintained and be available for inspection for a minimum of two years.[22]

In 2018 Lakeside Pharmacy agreed to pays $75,000 for failing to keep accurate records regarding highly addictive and frequently abused opioids, including fentanyl. In addition to paying $75,000 in settlement to the government, Lakeside Pharmacy committed to implementing new inventory control procedures to ensure full accountability of all controlled substances.[23] In 2016, CVS agreed to a $600,000 settlement with the DOJ to resolve allegations that its pharmacies in the New England area failed to keep paper Schedule III–V prescriptions either in a separate prescription file or readily retrievable location away from other prescription records; and failed to keep Schedule III, IV, and V purchase invoices in a readily accessible location separate and apart from other records required to be kept under law.[24]

Security requirements

All DEA pharmacies must "provide effective controls and procedures to guard against theft and diversion of controlled substances."[25] "In evaluating the overall security system of a pharmacy, the DEA will focus on the adequacy of the pharmacy's system for monitoring the receipt, handling, transfer, disposal, dispensing, theft or loss of controlled substances."[26] Pharmacies must store controlled substances in a "securely locked, substantially constructed cabinet."[27]

Pharmacies are prohibited from hiring employees who have been convicted of a drug-related felony or who have had a DEA registration denied or revoked,[28] and should carefully screen individuals before hiring them as employees.[29] In 2018, Effingham Health System agreed to a $4.1 million settlement to resolve allegations that the hospital pharmacy failed to develop effective security controls and procedures to guard against theft and loss of controlled substances, leading to a significant diversion of opioids.[30] Similarly, in 2018 the University of Michigan Health System agreed to a $4.3 million settlement to resolve allegations that the hospital pharmacy stored and dispensed controlled substances from multiple off-site ambulatory care locations that did not have DEA registrations and failed to develop and implement security controls and procedures to prevent the theft and diversion of opioids from the off-site ambulatory care locations.[31]

Electronic prescription records may be archived in an electronic format; however, the archiving is subject to additional requirements regarding security and retrievability.

Dispensing, transfer, disposal and destruction requirements

A pharmacy is not permitted to dispense a controlled substance unless the pharmacy has received a prescription that complies with specified prescribing, prescription, corresponding responsibility, and/or transfer, disposal, or destruction requirements.

Prescription requirements

Pharmacies may not dispense a Schedule II controlled substance to a patient without a written or electronic prescription from a practitioner, except in emergency situations. Controlled substances in Schedules III through V may be dispensed by a pharmacy

pursuant to either a written, oral, or electronic prescription, including a facsimile of a written prescription.[32] When a prescription is received electronically, the prescription and all required annotations must be stored electronically.

A prescription for a controlled substance must be dated and signed on the date when issued, and musts include the patient's full name and address, and the practitioner's full name, address, and DEA registration number. The prescription must also include: (1) drug name; (2) strength; (3) dosage form; (4) quantity prescribed; (5) directions for use; and (6) number of refills authorized (if any). Schedule II prescriptions may not be refilled; a new prescription must be written every time. Prescriptions classified as Schedule III or IV controlled substances may be refilled up to five times in a 6-month period. Schedule V prescriptions may be refilled as authorized by the prescriber.[33]

It is the prescriber's responsibility to know controlled substance prescription requirements and conform to those requirements; however, pharmacies and pharmacists have a corresponding responsibility. In 2017, Costco Wholesale agreed to pay $11.75 million to settle allegations that its pharmacies improperly filled prescriptions for controlled substances,[34] because the pharmacies filled prescriptions that did not contain all required information, lacked valid DEA numbers, or were for substances beyond the prescribers' scope of practice.

Valid prescription requirement and corresponding responsibility

A prescription for a controlled substance is not effective unless it has been issued for a legitimate medical purpose by a practitioner acting in the usual course of their professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but pharmacists have a corresponding responsibility to ensure the prescription is filled for a legitimate medical purpose and in the normal course of the practitioner's professional practice.[35]

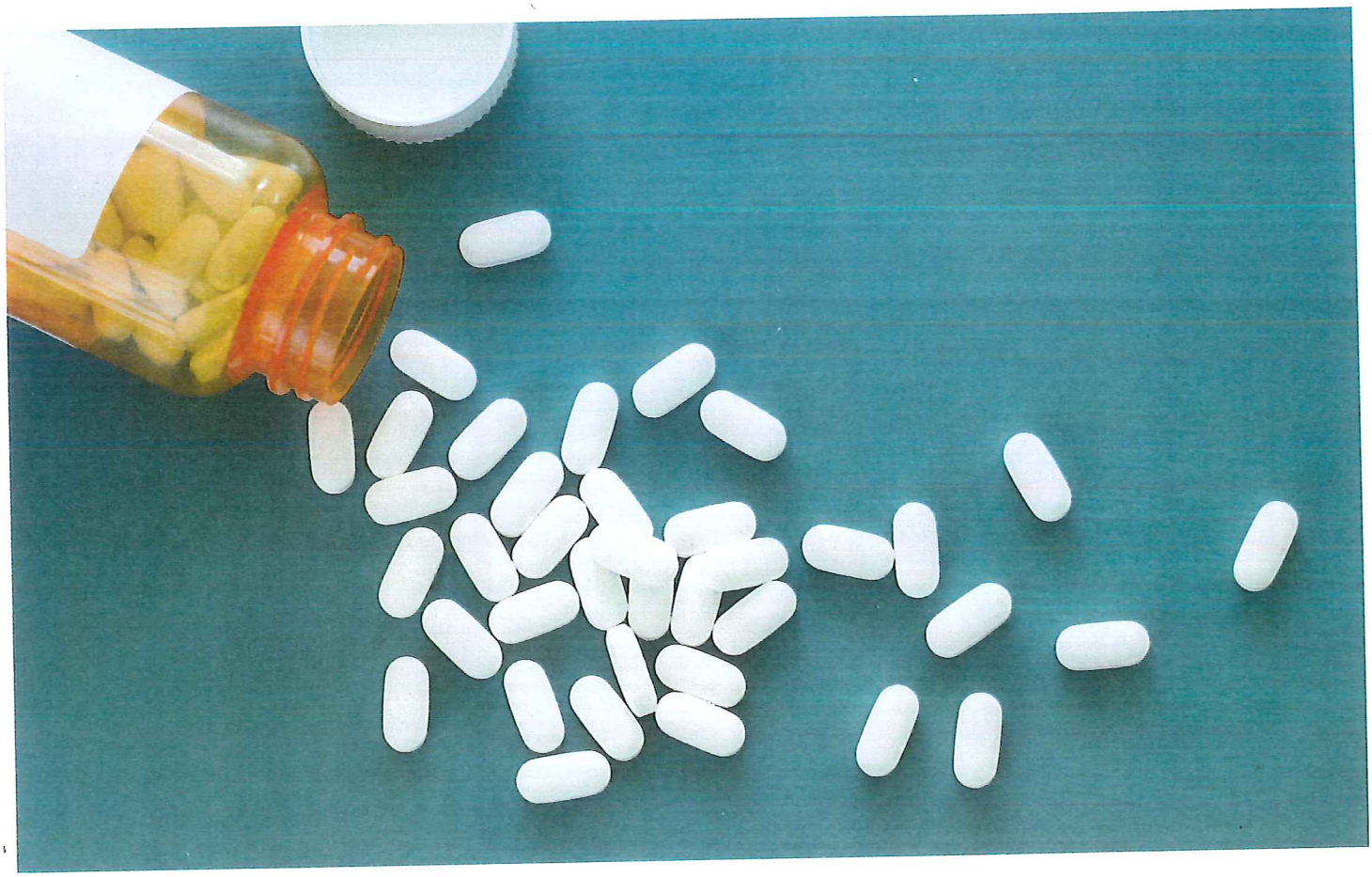
Breaches of the pharmacist's corresponding responsibility may be imputed to the pharmacy, resulting into action against the pharmacy license and/or DEA registration.[36] A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription before the prescription is dispensed. A pharmacist should not dispense a prescription of doubtful, questionable, or suspicious origin. An order purporting to be a prescription that was not issued in the usual course of professional treatment is not a prescription within the meaning and intent of the CSA, and a 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 diverting controlled substances.[37]

In 2018, the DEA revoked the registrations of Trinity Pharmacy I,[38] Trinity Pharmacy II,[39] and Zion Clinic Pharmacy.[40] Each of these DEA registration revocations was based on the DEA's standard for corresponding responsibility. The Trinity and Zion cases clarified the "scienter" (i.e., knowledge) requirement that is necessary for a DEA finding that a pharmacy violated its corresponding responsibility. The DEA must demonstrate "either that: (1) The pharmacist filled a prescription notwithstanding their "actual knowledge" that the prescription lacked a legitimate medical purpose; or (2) the pharmacist was "willfully blind" or "deliberately ignorant" to the fact that the prescription lacked a legitimate medical purpose."[41]

In order to demonstrate "willful blindness," the DEA must "prove that the pharmacist had a subjective belief that there was a high probability that a fact existed [to negate validity of the prescription] and he/she took deliberate actions to avoid learning of that fact."[42] In Zion, the DEA included a list of red flags for pharmacies that would support a finding of the requisite scienter or knowledge to support a corresponding responsibility violation: (1) multiple customers filling prescriptions written by the same prescriber for the same drugs in the same quantities; (2) customers with the same last name and street address presenting similar prescriptions on the same day or within a short time span; (3) two short-acting opiates prescribed together; (4) patients traveling long distances to fill opioid prescriptions; (5) drug cocktails; (6) payment by cash; (7) unusually large quantity of a controlled substance; (8) pattern prescribing; (9) irregular dosing instructions; (10) lack of individualized therapy or dosing; (11) early fills/refills; and (12) other pharmacies' refusals to fill the prescriptions.[43]

Transfer requirements

A pharmacy may transfer controlled substances to another pharmacy, the original wholesale distributor, or the original manufacturer. In any transfer



of Schedule II substances, the receiving pharmacy must issue an official order form (DEA Form 222). The transfer of Schedules III, IV, and V controlled substances must be documented in writing to show names, addresses, and DEA registration numbers of the parties involved in the transfer, and the drug name, dosage form, strength, quantity, and date transferred. The records involving the transfer of controlled substances must be kept readily available by the pharmacy for two years for inspection by the DEA.[44]

In 2017, Duncan Pharmacy agreed to a $50,000 dollar settlement with the DOJ to resolve allegations that it transferred controlled substances between pharmacies without the proper documentation, failed to conduct and maintain a biennial inventory, failed to execute powers of attorney authorizing pharmacists to issue orders for Schedule I and II controlled substances on behalf of the pharmacy, and failed to dispense controlled substances under the correct practitioner's name and DEA registration number.[45]

Disposal or destruction requirements

The CSA requires pharmacies to document the amount, date, and manner of destruction and disposal of controlled substances. A pharmacy may transfer controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. When a pharmacy transfers Schedule II controlled substances to a reverse distributor for destruction, the reverse distributor must issue an official order form (DEA Form 222) or the electronic equivalent to the pharmacy. When Schedules III, IV, and V controlled substances are transferred to a reverse distributor for destruction, the pharmacy must maintain a record of distribution that lists the drug name, dosage form, strength, quantity, and date transferred.[46] In 2016, Northern Maine Medical Center agreed to a $125,000 settlement to resolve allegations that it's hospital pharmacy failed to maintain and keep records of its destruction of Schedule II through V controlled substances.[47] CT

Part 2 of this two-part article will be published in the December 2019 issue of *Compliance Today*.

Endnotes

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4. Id.§ 812(b).
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12. 21 U.S.C. § 822(a).
13. 21 C.F.R. § 1301.52(b).
14. 21 U.S.C.§ 823(a).
15. Title VII of Public Law 109-177.
16. 21 U.S.C. § 827(a)(3); 21 C.F.R. § 1304.21(a).
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Takeaways

- The Controlled Substances Act regulates the manufacture, distribution, and use of prescription and illicit opioids.
- DEA actions to thwart opioid drug abuse and diversion may result in pharmacy board and/or DEA scrutiny of pharmacy compliance with applicable laws and anti-diversion efforts.
- Pharmacies must be prepared to respond to DEA/Pharmacy Board inspections, search warrants, and enforcement actions.
- The best defense against a DEA enforcement action is a diligent, thoughtful, and comprehensive compliance program tailored to the pharmacy's business.
- The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but pharmacists have a corresponding responsibility to ensure the prescription is filled for a legitimate medical purpose.