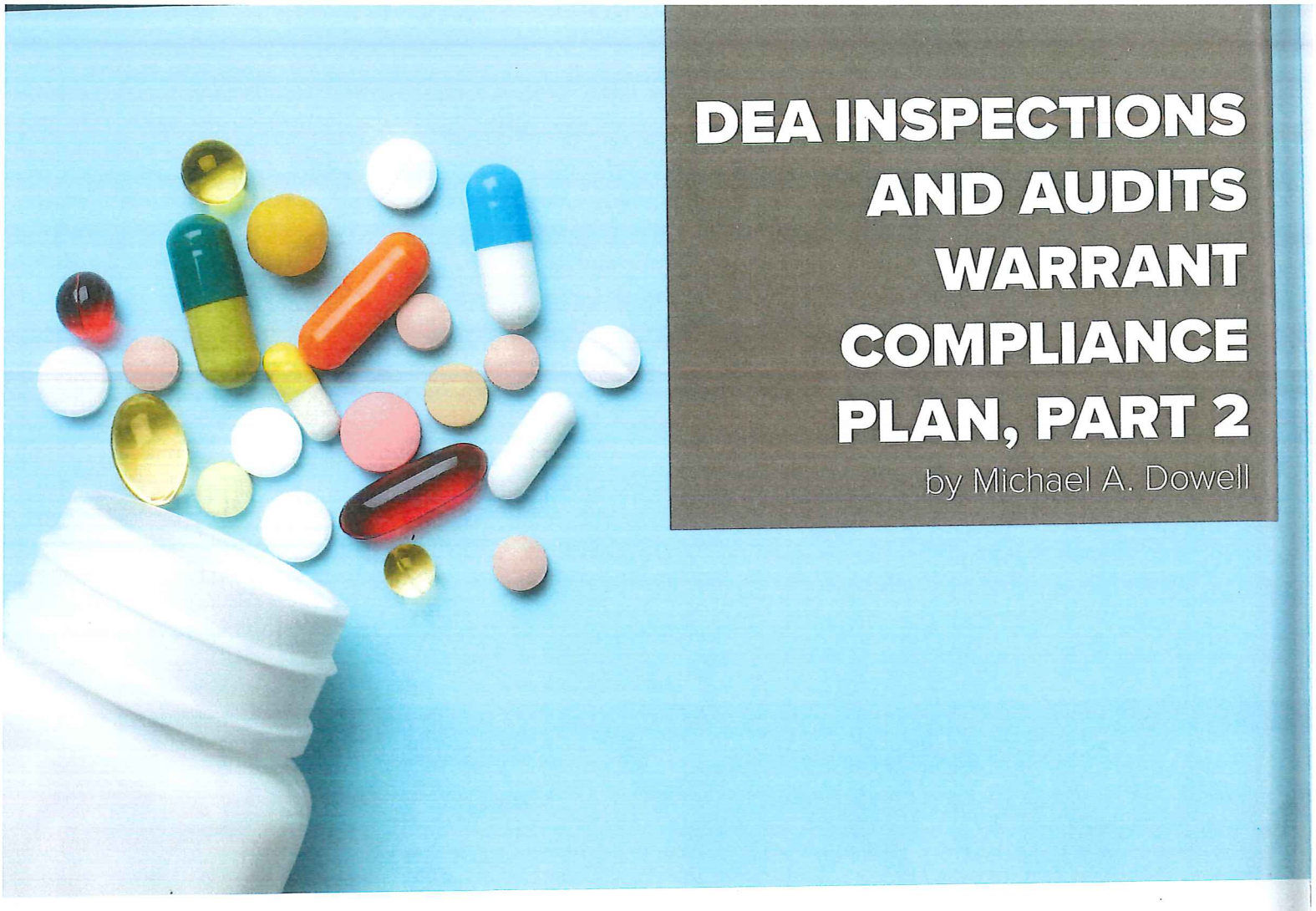

DEA INSPECTIONS AND AUDITS WARRANT COMPLIANCE PLAN, PART 2

by Michael A. Dowell

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Last month we looked at how the Drug Enforcement Administration (DEA) administers and enforces the federal law governing the manufacture, distribution, and use of prescription and illicit opioids under the Controlled Substances Act (CSA). Part 1 covers the record-keeping requirements, security requirements, and dispensing requirements for pharmacies under the CSA. Part 2 reviews the reporting requirements as well as issues involved in the development of a controlled substance compliance program.

Reporting requirements

The CSA requires pharmacies to report periodically to the DEA every sale, delivery, disposal, or dispensing of any controlled substance.[1]

Internet dispensing

Pharmacies that are authorized to dispense controlled substances by means of the internet must report to the DEA the total quantity of each controlled substance that the pharmacy has dispensed each month. However, pharmacies are exempt from this reporting requirement if, in each month the report is required, they do not exceed either of two thresholds: (1) 100 or more prescriptions dispensed, or (2) 5,000 or more dosage units of all controlled substances combined.[2]

Theft or significant loss

Within one business day of the discovery of a theft or significant loss of any controlled substance, the pharmacy must: (1) notify the DEA and police, and (2) complete DEA Form 106 documenting the loss or theft.

In 2018, CVS Pharmacy (CVS) agreed to pay $1.5 million to resolve

a Department of Justice (DOJ) investigation that certain of its pharmacy stores located in Nassau and Suffolk counties on Long Island, New York, violated the CSA by failing to timely report the loss or theft of controlled substances, including hydrocodone, an opioid that is one of the most commonly diverted controlled substances. The DOJ indicated that "[t]he failure to promptly report the loss or theft of prescription drugs as required by law contributes to the opioid epidemic, which has caused devastating harm to individuals and our community."[3]

DEA inspections

The DEA's principal method to monitor and ensure pharmacy compliance with the CSA and its implementing regulations are "inspections."[4] The CSA authorizes diversion investigators to inspect "controlled premises," which are places where pharmacies may "lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of controlled substances or listed chemicals or where records relating to those activities are maintained."[5] A DEA inspection may include a review of security measures, record-keeping procedures, inventory records, and a controlled substances audit. Investigators can inspect, copy, and verify required records and reports, and inspect finished and unfinished drugs, equipment, containers, labeling, processes, and controls.[6] Investigators may also inventory controlled substances on-hand.

The three types of inspections that the DEA may undertake are: (1) regulatory, (2) complaint, and (3) criminal.[7] Regulatory investigations can include pre-registration inspections and cyclic inspections of pharmacies. Pre-registration inspections are usually scheduled appointments. Cyclic inspections may be scheduled or unannounced, and they occur every two, three, or five years.[8]

Complaint investigations may be started on the basis of third-party information obtained by the DEA or state regulators, or other information the DEA obtains regarding the diversion of controlled substances. The Automation of Reports and Consolidated Order System (ARCOS) is an automated reporting system used by the DEA to monitor the flow of controlled substances from their point of manufacture to the point of sale or distribution at the dispensing/retail level, such as hospitals, pharmacies, practitioners, and teaching institutions.[9]

The DEA also conducts investigations into criminal activities involving diversion of controlled substances that may involve DEA pharmacies or non-pharmacies, such as prescription forgery, illegal prescribing, or diversion of controlled substances.[10]

Pre-registration inspections

Once the DEA receives a completed DEA Form 510 application, DEA personnel from the local DEA field office will contact the pharmacy to schedule an on-site inspection of the premises. An on-site inspection will be conducted for every new application, regardless of whether the pharmacy currently holds a DEA registration or has been inspected previously by the DEA. Pre-registration inspections will generally address the following areas: (1) review of the DEA Form 510 application; (2) obtain background information on pharmacy officers and individuals who will be responsible for controlled substance ordering, handling, and security; (3) review of state licenses to verify that the pharmacy has obtained all required state licenses; (4) review the applicant's proposed supplier and customer lists; (5) review of the pharmacy's controlled substances policies and procedures; and (6) inspection and testing of the pharmacy's physical security, including storage vaults, safes, cages, and alarm systems.[11]

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Cyclic inspections

The DEA makes cyclical inspections (every 3–5 years), which may include scheduled or unannounced inspections.[12] Cyclic inspections may address the areas noted for review in a pre-registration inspection and will also inspect, copy, and verify required controlled substance records and reports to ensure that they are complete, accurate, and available for at least two years.[13] Cyclic inspections may include an audit of various controlled substances.[14]

DEA notices of inspection and DEA warrants

DEA inspections are usually a two- to four-hour process and are conducted by two or more DEA diversion investigators who are assigned to the nearest DEA field office.

The notice of inspection

The inspection starts with a DEA Form 82, Notice of Inspection of Controlled Premises. The DEA does not require a search warrant to conduct a DEA inspection to determine compliance with the CSA unless the DEA is participating in a criminal investigation with other agencies.[15] The DEA investigators ask the responsible employee for informed consent by having them sign a Notice of Inspection (DEA Form 82). Informed consent is a written statement by the pharmacist stating that they have been informed of their constitutional right not to have an administrative inspection, that anything of incriminating nature can be used against the pharmacy in a criminal prosecution, and that they voluntarily consent. Pharmacies may withhold consent or, if given, can withdraw consent at any time. Withholding or withdrawing consent requires investigators to obtain an administrative inspection warrant or search warrant; however, the DEA may conduct a DEA inspection without informed consent or an administrative search warrant if:

- the pharmacy is applying for initial DEA registration, or
- the books and records are being inspected pursuant to an administrative subpoena, or
- there is an imminent danger to public health or safety, and
- there was no prior opportunity to apply for a warrant.[16]

Administrative search warrants for DEA inspections

If the pharmacy representative refuses to give informed consent to the DEA audit, the DEA may obtain an administrative inspection warrant from the U.S. Federal District Court. An administrative inspection warrant does not require the DEA to show probable cause. To obtain an administrative search warrant, the DEA is required only to describe the nature and extent of the inspection and any items that they wish to seize. Courts routinely grant administrative search warrants to the DEA, upon request. If the DEA presents an administrative search warrant to conduct a DEA audit or inspection, the pharmacy must comply. Refusal to comply is grounds for arrest. Whenever a pharmacy receives a DEA administrative search warrant, the pharmacist or pharmacy representative should contact a pharmacy law attorney immediately.

DEA enforcement actions

DEA inspections can result in alleged "regulatory" offenses involving failure to comply with CSA requirements and obligations that pharmacies must satisfy as a condition of registration,[17] and other prohibited acts by pharmacists who manufacture, distribute, and dispense controlled substances.[18] The DEA can initiate a variety of enforcement actions for violations of the CSA or its implementing regulations—administrative, civil, and criminal.[19] Pharmacists who fail to adhere to the CSA's regulatory requirements or who engage in certain prohibited acts may face revocation or suspension of their DEA registration, administrative consequences, criminal and/or civil charges, criminal and/or civil fines (each alleged violation carries with it a civil penalty of up to $10,000), and the possibility of imprisonment.[20]

In addition, violations of the CSA are frequently used by the DOJ as a basis for False Claims Act (FCA) violations. For example, Rhine Drug Company and Pharmacist Andrew "Carter" Clements, Jr., agreed to pay a total of $2.175 million to resolve allegations that they violated the FCA and the Controlled Substances Act due to submission of claims to Medicare for drugs that were not dispensed to patients and failure to keep or furnish accurate records of controlled substances as required under pertinent sections of the CSA.[21]

Administrative actions

Administrative actions are handled primarily by DEA and can include: (1) a letter of admonition to advise the pharmacy of any violations and necessary corrective action; (2) a memorandum of agreement that outlines things the pharmacy agrees to do to become compliant and the obligations of the DEA when violations are corrected or not corrected; (3) an order to show cause that can initiate revocation or suspension of a DEA registration; and (4) an immediate suspension order that is issued when violations pose an imminent threat to public health or safety.[22] The DEA may revoke or suspend a controlled substance registration without having to provide an order to show cause[23] in cases of imminent danger to public health or safety.[24]

For example, on February 7, 2019, the DOJ filed a complaint and an ex parte motion for a temporary restraining order, seeking injunctive relief and civil monetary penalties against two Tennessee pharmacies. The complaint alleged that the pharmacies violated the CSA by knowingly dispensing

controlled substances without a valid prescription in violation of the CSA, and knowingly and intentionally distributed and dispensed controlled substances outside the usual course of the pharmacy practice. The DOJ also alleged violations of the FCA in connection with funds paid by Medicare for the controlled substances that were dispensed.[25]

Orders to show cause and immediate suspension orders are collectively known as "registrant actions." After receiving notice of a registrant action, a pharmacy may either allow the DEA to issue a final decision or request a hearing through the DEA's Office of Administrative Law Judges. If the pharmacy requests a hearing, an administrative law judge (ALJ) will issue a recommended decision to the DEA. The DEA then issues a final decision by adopting, modifying, or rejecting the ALJ's recommended decision. It is very important that pharmacies are represented by competent pharmacy law counsel when faced with a registrant action, because loss of DEA registration privileges usually results in sale or closure of the pharmacy.

Developing and implementing a controlled substance compliance program

The DEA looks favorably on a pharmacy that has implemented an effective compliance program, and in the event of a CSA violation, the existence of an effective compliance program will greatly diminish the civil penalty amount the DEA ultimately seeks. A compliance program ensures that policies, procedures, and operations of the pharmacy are consistent with the laws, regulations, and rules established for the pharmacy. The Affordable Care Act made compliance programs mandatory for all persons/entities participating in Medicare and Medicaid programs, and these programs must effectively prevent and detect criminal, civil, and administrative violations. Most pharmacies already have compliance programs related to HIPAA; OSHA; and Medicare and Medicaid fraud, waste, and abuse. Thus, the expansion of existing pharmacy compliance programs to include DEA-controlled substance requirements should not be an overwhelming task.

Canned compliance programs

Many pharmacies purchase off-the-shelf compliance programs and fail to customize them to their needs, and/or use compliance programs that rely on policies and procedures not applicable to the pharmacy's business operations. Having a compliance program that is tailored to a pharmacy's business is critical, because every pharmacy—even those pharmacies in the same pharmacy sub-industry—faces different risks. A "canned" compliance program, or one not tailored to the unique circumstances of each practice, is almost certainly not going to be effective, given that compliance programs should be designed to "fit" within an organization's culture and infrastructure. A customized compliance program increases the likelihood that compliance efforts will become part of the regular routine in the pharmacy and increases the likelihood that the pharmacy's managers and employees will accept, and cooperate in, the pharmacy's compliance program efforts. Thus, it is important that, even if a pharmacy purchases "canned" compliance tools, such as a policy and procedure manual and forms, the pharmacy should customize those policies, procedures, and tools for their own organization.

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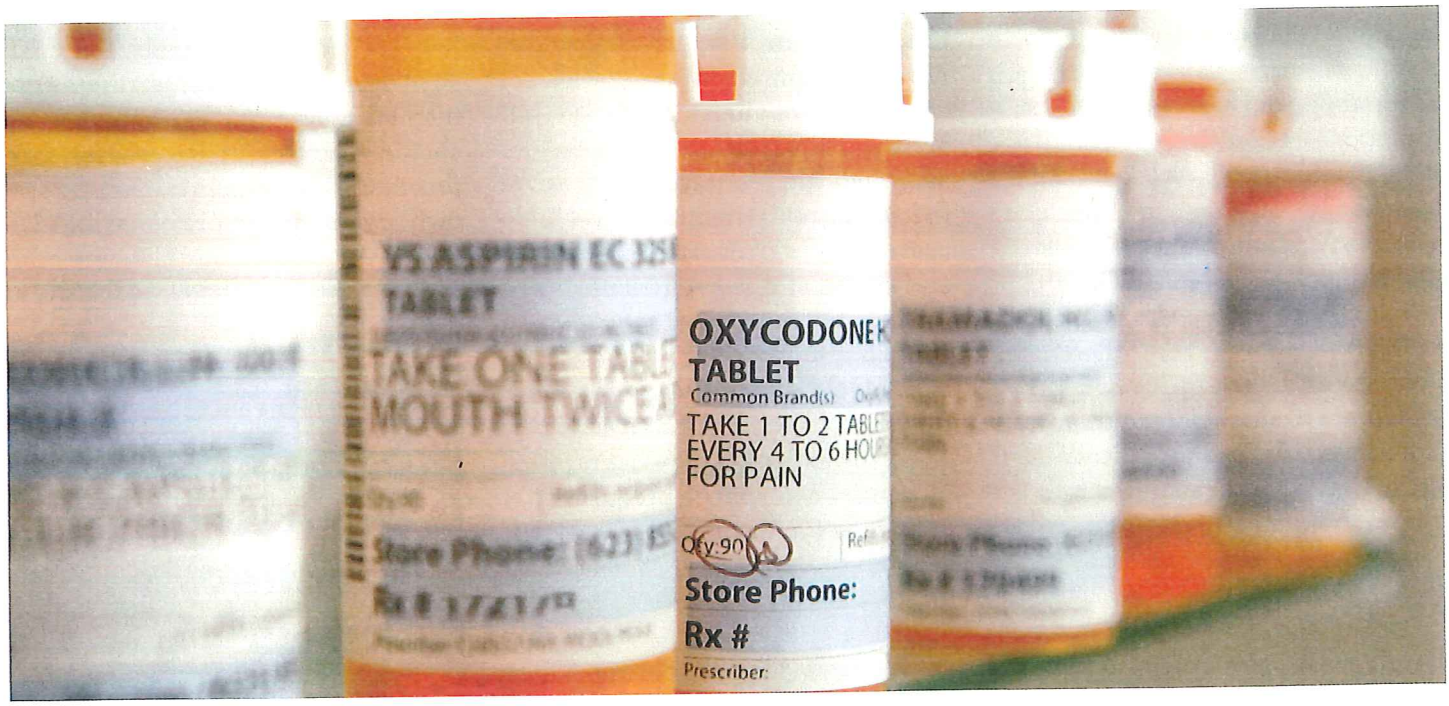
The role of legal counsel

Some may choose to involve legal counsel versed in pharmacy law in a pharmacy's controlled substances compliance initiatives and programs. Legal counsel can advise the pharmacy's owners and board of directors on their controlled substance compliance program duties and obligations and, if no compliance program exists, can guide the pharmacy through the preliminary steps to creating a compliance program infrastructure. When advisable, legal counsel can lead and assist with investigations and may provide risk assessments and gap analyses, all under the protection of attorney-client privilege. Pharmacy law counsel may also assist in the drafting, customizing, and implementation of compliance policies and procedures and training.



Compliance program structure and elements

Pharmacies should consider implementing the following eight key elements of a controlled substance compliance program that are set forth in the Office of Inspector General's (OIG) compliance program guidance documents: (1) Compliance program administration, (2) Policies and procedures, (3) Education and training, (4) Mandatory reporting requirements, (5) Documentation, (6) Monitoring and self-assessments, (7) Investigations and corrective action, and (8) Disciplinary enforcement.

Relevant factors in compliance program design for pharmacy-controlled substances include the size and nature of the pharmacy's operations, the complexity of pharmacy operations, budgetary and staffing constraints, and historical compliance history. Pharmacies should implement pharmacy industry compliance recommendations in order to ensure full compliance with the DEA regulations, including but not limited to the following actions.

1. Compliance program administration—Compliance officer

Pharmacies should appoint a compliance officer who will lead efforts to address loss prevention and diversion detection, reporting, and incident investigation. The compliance officer is responsible for implementing and enforcing the compliance program requirements, as well as assisting the pharmacy's workforce with interpreting and responding to regulatory inquiries. The compliance officer should report in writing directly to the pharmacy's board of directors regarding compliance matters, monitor day-to-day compliance issues, and report as needed.

Evaluation of compliance risks: Risk assessment is a key component of an effective compliance program. Risk assessment includes (1) risk identification, (2) risk assessment, and (3) risk ranking/prioritization. After pharmacies identify compliance risks, they should prioritize areas of focus in the compliance program. For example, risks of controlled substances inventory shortages can be reduced by increased security, pharmacy staff oversight, and random manual counts of Schedule II controlled substances.

2. Written policies and procedures

The compliance program should include written policies that address the core requirements of the CSA and address all controlled substances risk areas, including ordering, receiving, dispensing/distribution, prescribing, administration, returns, waste, and removal. Policies and procedures should also address physical controls, purchasing and other controls, employee screening/background checks, security safeguards, records documentation, monitoring/self-auditing, enforcement, and how to handle DEA inspections. Pharmacies should maintain, review, and regularly update controlled substance

policies and procedures to ensure that they always comply with DEA requirements.

3. Education and training
Pharmacy staff education and training should be provided through new employee orientation, periodic required in-services, and department-specific training that includes all employees, the board of directors, and other affected individuals, as applicable. Failure to attend or complete required compliance training should result in progressive corrective action. Staff members should be required to sign education and training acknowledgements indicating their understanding of CSA requirements and their agreement to abide by them. Education and training can also be used as corrective action to address specific problem areas or vulnerabilities identified by the pharmacy.

4. Mandatory reporting requirements
Pharmacies should require their workforce to report issues of suspected noncompliance to the compliance officer of the board of directors. Pharmacy staff should be able to use any of the following modes of communication to report issues to the compliance officer: (1) a written summary forwarded by fax, email, interoffice mail, or US mail; (2) orally in person or by telephone; or (3) calling a voicemail box to provide confidential, anonymous reporting, if desired. The pharmacy should adopt written confidentiality and nonretaliation policies to encourage the reporting of incidents of potential noncompliance.

5. Monitoring and auditing
Pharmacies must maintain active controlled substance compliance monitoring and auditing activities to ensure that compliance activities are occurring and are effective.

Monitoring is a "real-time" assessment of whether ongoing activities or operations are in compliance with applicable legal requirements. Auditing is a retroactive assessment of compliance with legal requirements. Random or periodic audits by independent third parties will help the pharmacy discover internal thefts or losses.

6. Investigations and corrective action
The compliance officer should develop and implement an investigation process for when a compliance violation is reported or detected. After completion of the investigation, the compliance officer should develop and implement a remediation corrective action plan designed to prevent a reoccurrence of the violation, which may include: (1) additional or modified education or training; (2) corrective action/disciplinary action; (3) developing new policies and procedures; (4) revising existing policies and procedures; (5) additional and/or modified monitoring and auditing; and (6) reporting to outside agencies (e.g., DEA, CMS, OIG, state boards of pharmacy).

7. Disciplinary enforcement
The pharmacy's policies and procedures should include clear and specific disciplinary policies and describe the consequences of violating the organization's standards of conduct. The pharmacy should change locks or key card access and update lists of employees who have authorized access to the warehouse, cage, and vault after relevant personnel changes.

8. Documentation
Pharmacies should query state prescription drug monitoring programs, verify all opioid prescriptions, and document how red flags are resolved. Pharmacies should file required controlled substance records and reports daily; should review the filed records weekly to ensure records are current, complete, and accurate; and should review trend and pattern reports on a quarterly basis. Pharmacies should maintain required records and reports for at least two years unless state law requires them to be maintained for a longer period of time, and pharmacies should ensure that controlled substances awaiting return or destruction are properly secured and documented.

The pharmacy's policies and procedures should include clear and specific disciplinary policies and describe the consequences of violating the organization's standards of conduct.

Drug diversion prevention and detection
Pharmacy liability risks
Hospital and retail pharmacies face significant legal, financial, operational, and reputational risks, as well as regulatory fines and penalties as the result of employee

drug diversion and inadequate internal controls. For example, in September 2015, Massachusetts General Hospital (MGH) agreed to pay $2.3 million to resolve allegations that lax controls enabled MGH employees to divert controlled substances for personal use. Two nurses had stolen large volumes of opioids from automated dispensing machines. The subsequent DEA audit of MGH's controlled substances revealed more than 20,000 missing opioid pills.[26]

Compliance officer liability risks

Recently, two healthcare organization chief compliance officers were charged for their individual roles in the opioid crisis. On July 18, 2019, the DOJ announced charges of "conspiring to distribute controlled substances without a legitimate medical purpose" against pharmaceutical distributor Miami-Luken, two of its former employees (including former chief compliance officer James Barclay), and two pharmacists.[27] According to the DOJ, the distributor, compliance officer, and pharmacists "unlawfully enriched themselves" by profiting from the distribution and dispensing of controlled substances and "failed to maintain effective controls against the diversion of controlled substances."[28]

Similarly, on April 23, 2019, the DOJ announced charges against pharmaceutical distributor Rochester Drug Co-Operative (RDC) and its chief executive office and chief compliance officer William Pietruszewski.[29] According to the DOJ, at the direction of its senior management, including the compliance officer, RDC supplied large quantities of oxycodone, fentanyl, and other dangerous opioids to pharmacy customers that its own compliance staff determined were dispensing those drugs to individuals who had no legitimate medical need for them. "RDC distributed controlled substances to those pharmacies even after identifying 'red flags' of diversion, including dispensing highly abused controlled substances in large quantities; dispensing primarily controlled substances; dispensing quantities of controlled substances in amounts consistently higher than accepted medical standards; accepting a high percentage of cash for controlled substance prescriptions; dispensing to out-of-state patients; and filling controlled substances prescriptions issued by practitioners acting outside the scope of their medical practice, under investigation by law enforcement, or on RDC's 'watch list.'"

Drug diversion prevention and detection

The DEA is increasingly examining hospital and retail pharmacy drug diversion prevention and whether hospital and retail pharmacies have effective programs in place. Hospital and retail pharmacies therefore must ensure that their drug diversion prevention and detection programs include rigorous controls and that monitoring is functioning and effective. Compliance activities should include: (1) identification of staff at risk for diversion; and (2) written policies and procedures and strict oversight and monitoring of opioid drug procurement, storage/physical security, preparation and dispensing, prescribing, administration, waste, and removal.[30] Retail pharmacies should carefully screen all employees and provide all staff with red flags training and training regarding prescription drug monitoring programs and/or laws restricting prescriptive authority for healthcare professionals.

Conclusion

The DEA is devoting significant resources to fight against opioid abuse, and aggressive DEA action against drug abuse and diversion can result in pharmacy board and/or DEA investigations, pharmacy board disciplinary actions, DEA enforcement actions, and criminal or civil charges. Given this climate of increased enforcement, it is essential that hospital and retail pharmacies act quickly to mitigate controlled substances compliance risks. Establishing a comprehensive controlled substance compliance program, including preparing for a DEA audit, conducting a biennial controlled substances inventory, establishing proper monitoring processes, and developing policies and procedures can significantly improve a pharmacy's controlled substance management. Documentation and record keeping are the keys to controlled substances compliance. Pharmacies should look to DEA guidance and state board of pharmacy guidelines for proper documentation and record-keeping requirements.

Successfully navigating a DEA inspection or enforcement action requires the help of experienced pharmacy law counsel skilled in DEA registrations, audits, and inspection matters at the earliest opportunity. Legal counsel can assist the pharmacy in developing and implementing a controlled substance compliance program, can conduct an internal audit to spot and address problems, and can help implement an audit plan for employees to use during an audit. The DEA will often try to

conduct on-site interviews with pharmacy managers before they have an opportunity to consult with legal counsel. In acting without legal representation, pharmacies often cause irreparable harm to their defense, or they make other mistakes that lead to unnecessary investigations or allegations of misconduct.

The federal government's focus on diversion is highly unlikely to diminish, particularly because resolution of the opioid crisis is a high priority for federal and state governments. Recent federal case law decisions permit the DEA to broadly expand the scope of audits and inspections, and therefore their frequency is expected to increase because Congress has significantly increased federal funds to combat the opioid prescription drug epidemic. The best defense against a DEA enforcement action is a diligent, thoughtful, and comprehensive compliance program tailored to the pharmacy's business. CT

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Takeaways

- The Controlled Substances Act regulates the manufacture, distribution, and use of prescription and illicit opioids, and the CSA is enforced by the Drug Enforcement Administration.
- DEA actions to thwart opioid drug abuse and diversion may result in state pharmacy board and/or DEA scrutiny of pharmacy compliance with applicable laws and anti-diversion efforts.
- Pharmacies must be prepared to respond to DEA/state 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.
- Pharmacy DEA compliance programs should address record keeping (e.g., inventory, ordering, dispensing), security (e.g., pharmacy, drug storage), dispensing (e.g., prescription, corresponding responsibility, transfer, disposal), and reporting (e.g., theft, internet) requirements.