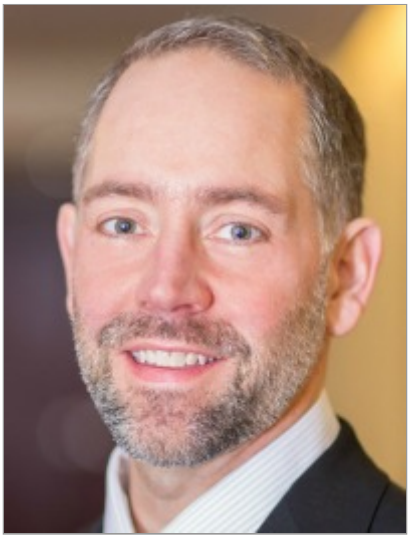
A Prescription For Sound DEA Compliance



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Law360, New York (April 15, 2015, 4:31 PM ET) -- Pill counts and filling out medication logs may not generate rave patient reviews or boost the earnings of a medical practice. But, the performance of these mundane tasks promotes the priorities of patient safety, ensuring a ready supply of medications at a practice location to optimize patient care and deterrence of theft and diversion. Accurate and consistent controlled substance record keeping also may shortcut an audit or diversion investigation by the U.S. Drug Enforcement Administration where the registrant has complied with the law and is not at fault. Ultimately, the responsibility for proper dispensing, prescribing and record keeping rests with registrant practitioner, who should be knowledgeable of the following DEA regulatory fundamentals.[1]

DEA-Regulated Drugs

In the clinical setting, controlled substances are pharmaceutical medications the federal government has categorized into five schedules based on currently accepted medical uses and the potential for abuse and dependence. Street drugs, such as cocaine or heroin, listed under Schedule I, lack an accepted medical use in the U.S. and cannot be prescribed or dispensed under federal law. Despite the growing scientific support for the medical use of marijuana, and decriminalization in states such as Alaska, Colorado and Washington, this controlled substance remains a Schedule I drug a registrant cannot prescribe lawfully under federal law.[2] Otherwise, Schedule I drugs are authorized for research purposes only.

Schedule II contains most narcotic painkillers, including fentanyl, meperidine and oxycodone. Schedule III contains medications, such as acetaminophen with codeine and anabolic steroids, with less potential for abuse, as with Schedule IV medications, such as alprazolam and diazepam, and Schedule V medications that contain minute amounts of certain narcotic and stimulant drugs, such as promethazine cough syrup with codeine. The controlled substance schedules change when new medications are added or existing medications are reclassified. For example, the pain reliever tramadol became a Schedule IV drug in 2014. The federal government publishes an updated list of all schedules each year.[3]

The DEA does not regulate legend drugs, defined as medications that require a prescription under state law or by regulation of the state pharmacy board or commission and that instead are subject to state regulatory enforcement.[4] For this reason, the DEA opposes use of a registration number on prescriptions for legend drugs to avoid confusion in administrative enforcement.

Generally, all professionals who handle controlled substances are required to have a DEA registration. Such professionals include individual practitioners such as dentists, physicians and veterinarians, midlevel practitioners (e.g., nurse anesthetists, physician assistants and advanced registered nurse practitioners) and pharmacists.[5]

A qualifying practitioner must apply to the DEA for a registration for each principal place of business or

professional practice where the practitioner stores or dispenses controlled substances listed in Schedules II through Schedule V.[6] The term "dispense" is broadly defined as: (a) prescribing a controlled substance to be filled at a pharmacy; (b) giving a patient a controlled substance to take later; and (c) giving a patient a controlled substance to swallow or through injection.[7] If the practitioner also uses a separate office where prescriptions are issued to patients but controlled substances are not regularly administered, dispensed or stored, an additional registration is not required.

Internal Compliance

A registrant should implement a robust compliance program at the practice location where controlled substances are stored or dispensed. The program should include written policies that address, and ideally go well beyond, the core requirements of the Controlled Substances Act and related provisions of the Code of Federal Regulations that govern the DEA.[8] For example, while a registrant must maintain controlled substance records for a minimum of two years under the law, a better practice may be to keep such records at least three or four years to demonstrate a longer history of compliance during an audit or investigation.[9]

Relevant clinic staff should receive training and regular refreshers on CSA provisions and the related federal regulations. Staff members should sign training acknowledgements indicating their understanding of controlled substance requirements and agreement to abide by them. Likewise, a registrant should consider as a best practice requiring a written agreement with each independent medical professional contractor (e.g., a locum tenens physician) that controlled substance inventory will be dispensed only for a legitimate purpose within the usual course of professional practice and otherwise may not be removed from the location. Lastly, a registrant should consider screening procedures including criminal history checks of prospective personnel for positions with potential access to controlled substances.

Significantly, the DEA interprets the CSA as setting forth the exclusive lawful uses of controlled substances and takes the view that if an act related to a controlled substance is not explicitly permitted, it is prohibited. Again, registrants have the sole responsibility for satisfying and demonstrating their compliance obligations.

In a nutshell, the regulatory scheme is designed to empower the DEA to "zero out" every medication dose during an audit or investigation, meaning to trace each dose from manufacturer to distributor to registrant to end-user patient. The DEA expects registrants to follow this scheme precisely. The DEA's closed system of tracing promotes patient safety, deters diversion and allows the DEA to document incidents of noncompliance.

DEA Audits and Inspections

The DEA is authorized to audit and inspect medical clinics to review CSA compliance regarding the dispensing and prescribing of scheduled medications and record keeping.[10] Required controlled substance records must be readily retrievable at the registered location.[11] Generally, a DEA diversion investigator will conduct the inspection. A medication discrepancy from the records may result in a finding of record-keeping noncompliance and almost certainly will prompt the investigator to look for evidence of diversion.

Depending on circumstances, DEA inspections may proceed with the voluntary consent of the registrant, through an administrative inspection warrant or under a criminal search warrant. The DEA may request voluntary consent from a registrant prior to a random audit or when investigating a complaint of CSA noncompliance. The DEA may obtain an administrative search warrant if the registrant refuses consent. A criminal search warrant requires the DEA to present information to the judge issuing the warrant supporting probable cause to believe that a criminal violation has been, or is being, committed.

When the DEA identifies a compliance issue, its enforcement response depends upon many factors generally tied to culpability. Thus, a registrant's first-time oversights may be addressed through face-to-face communication, a letter of admonition or by the DEA requiring the registrant to enter a memorandum of understanding documenting the oversights and setting forth the registrant's obligations.

Neglectful violations of a more serious nature, typically involving repeated issues, may warrant a civil fine of up to $10,000 per occurrence.[12] Serious regulatory and criminal violations may warrant the DEA's initiation of administrative registration revocation proceedings when the public interest is affected.[13] Criminal violations, including controlled substance diversions by a registrant, writing unlawful prescriptions and the knowing failure to make or keep required records, may be referred for prosecution. Significant noncompliance problems identified by the DEA also may result in state licensing issues when the line is crossed into unprofessional conduct and risk to patient safety, even in the absence of criminal acts.[14]

Checklists

While the DEA's regulatory scheme has complex and specific requirements, the checklist below offers a starting point for a checkup of a registrant's basic compliance. Some practices are required by state law to use a pharmacist consultant to review and implement these and additional requirements.[15] Generally speaking, the busier a practice, the greater the reason for a registrant to consider consulting with an attorney for a comprehensive review of policies and practices or to address compliance issues that may be of concern to the DEA.

DEA Registrant Checklist for Basic Compliance

Controlled Substances

- Maintain all controlled substance stock in locked storage.[16]

- Group controlled substance stock by medication types. Consider using "tall man letters," e.g., HYDROcodone and oxyCODONE, to distinctly label medications with look-alike pharmaceutical names to avoid dispensing errors.

- Do not destroy controlled substance stock (e.g., if past expiration) without authorization from the local DEA special agent in charge (written permission may be granted once a year) or through a registered "reverse distributor"[17] when documented in a DEA Form 41 sent to the DEA; unpackaged inventory generally may not be returned to a supplier.

- For "wastage" of controlled substances that are not fully exhausted, i.e., where some of the medication remains in a vial, tube or syringe after administration but cannot or may not be further utilized, the remainder of medication may be disposed on-site if two employees of the registrant personally observe the rendering of all the remainder irretrievable.[18] A registrant may wish to consider using commercially available secure containers designed for pharmaceutical wastage, especially in light of emerging environmental concerns and regulations. The observing employees must record the destruction of pharmaceutical wastage in the dispensing log.[19]

- Notify the local DEA office of any significant loss of controlled substances, diversion or theft. The DEA has a specific form — DEA Form 106 — for reporting available on its diversion control website.

- Biennial inventory of all controlled substance stock.[20]

Records

- Controlled substance acquisition invoices: Invoices must contain all required data, e.g., the DEA registration numbers of the supplier and the practitioner at the clinic, addresses for both and date the controlled substances were received from the supplier (not the ordering date).

- DEA Form 222 records of Schedule II controlled substances maintained in complete chronological set (e.g., in a binder): A registrant must complete a Form 222 to order Schedule II controlled substances, submitting the original and duplicate pages of the triplicate form to the supplier and retaining the triplicate copy for the registrant's records. The registrant must record on the triplicate copy the number of bulk containers furnished for each item and date received.[21] The supplier then forwards the original to the local DEA office.[22] Unaccepted or defective Form 222s also must be kept.

- Maintain a separate binder for all Schedule II controlled substance inventory; for Schedule III through Schedule IV medications, a similar separate binder is recommended.[23] Each inventory must contain a complete and accurate record (written or promptly transcribed) of all controlled substances on hand on the date the inventory is taken.[24]

- Controlled substance dispensing log: The log must contain each patient's name and address, the drug dispensed to the patient and quantity and dispensing date.[25]

- Buprenorphine prescription and dispensing log for registrants with additional DEA approval to treat patients with this medication for drug addiction.[26]

Prescriptions

- Dated, signed on the date when issued, including the patient's full name and address, and the practitioner's full name, address and DEA registration number.[27]

- Drug name, strength, dosage form, quantity prescribed, directions for use and number of refills.[28]

- Issued to or for an ultimate user/patient for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.[29]

- Written on a tamper-resistant prescription pad that complies with state law.[30]

- Electronic prescriptions in compliance with authentication and message security standards under 21 CFR 1311, et seq.[31]

Conclusion

The DEA vigorously enforces the regulatory scheme for controlled substances. A registrant who establishes policies and practices designed to comply with this scheme will be well-prepared for a random DEA audit or inspection. Any lack of compliance with prescription and record-keeping requirements may trigger a wide range of consequences detrimental to a medical practice and the patients it serves. As noted above, a registrant may wish to consider consulting with an attorney to review certain practices and policies, address compliance issues that may be of concern to the DEA, and for representation in administrative, civil and criminal enforcement proceedings.

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[1] This article contains an overview of federal prescribing and dispensing regulation of controlled substances and basic registrant obligations. For more specific information, the endnotes below contain citations to relevant authority and resources. Additionally, a registrant may wish to consider consulting with an attorney for a comprehensive review of controlled substance practices and policies and to address specific compliance issues that may be of concern to the DEA.

[2] Although a DEA registrant cannot prescribe marijuana due to its Schedule I classification, authority exists that a registrant may make a medical marijuana "recommendation" to a patient in compliance with state law. Conant v. Walters, 3009 F.3d 629 (9th Cir. 2002) (holding that under the First Amendment, the federal government was enjoined from investigating a physician or revoking the physician's DEA registration based solely upon the physician's professional recommendation for medical use of marijuana made without specific intent to aid the patient in acquiring marijuana). Washington law, for example, allows a physician to sign and date an authorization on tamper-resistant paper stating that in the physician's opinion, the patient may benefit from the medical use of marijuana. RCW 69.51A.010, -.030.

[3] 21 USC 812; 21 CFR 1308.11-1308.15. The DEA's Office of Diversion Control maintains a current list of scheduled controlled substances here. Also available at the ODC's website is the DEA's Practitioner's Manual, which discusses a registrant's general legal obligations, required security of controlled substances, record keeping, valid prescription requirements and opioid addiction treatment programs. For a review of the law underlying the DEA's regulatory scheme, the relevant CSA provisions are codified at 21 USC 801-890 and the DEA's regulations at 21 CFR 1300-1316. These provisions also are generally available at the DEA's website as legal resources.

[4] See, e.g., RCW 69.41.010(12). It is a Class C felony in Washington to possess a legend drug without a prescription and a Class B felony "for any person to sell, deliver, or possess any legend drug except upon the order or prescription of a physician ..." RCW 69.41.030(1); RCW 69.41.030(2). Legend drugs also are regulated under the federal Food, Drug and Cosmetic Act and enforcement by the U.S. Food and Drug Administration.

[5] 21 CFR 1301.11.

[6] 21 CFR 1301.11-1301.12.

[7] 21 CFR 802(10).

[8] 21 USC 802, et seq.; 21 CFR 1300, et seq.

[9] 21 CFR 1304.04(a). This regulation permits a registrant to obtain approval from the local DEA office to keep financial and shipping records (but not order forms) in a central location apart from the registered location for administering and dispensing controlled substances.

[10] 21 USC 880.

[11] 21 CFR 1304.03(b), 1304.04(f).

[12] 21 USC 842(a)(5), 842(c)(1)(B).

[13] 21 CFR 1301.36.

[14] For example, it is unprofessional conduct in Washington for a registrant to fail to "keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law" as required by RCW 69.50.306. See RCW 18.130.180(1).

[15] In Washington, ambulatory surgical facilities must employ a pharmacist consultant to establish policies and procedures regarding controlled substances and legend drugs, ordering processes and verification of medication receipt. WAC 246-330-200(4)(a)-(c).

[16] 21 CFR 1301.75. The regulation further provides that pharmacists and institutional practitioners may disperse Schedule II through Schedule V controlled substances "throughout the stock of noncontrolled substances in a manner as to obstruct the theft or diversion of the controlled substances." 21 CFR 1301.75(b).

[17] 21 CFR 1307.11.

[18] 21 CFR 1317(d).

[19] 21 CFR 1304.22(c).

[20] 21 USC 827(a)(1); 21 CFR 1304.11(c).

[21] 21 CFR 1305.13(e).

[22] 21 CFR 1305.13(a), (d).

[23] 21 CFR 1304.04(f).

[24] 21 CFR 1304.11(a).

[25] 21 CFR 1304.22(c).

[26] 21 CFR 1304.03(c).

[27] 21 CFR 1306.05(a).

[28] Id.

[29] 21 CFR 1306.04; compare RCW 69.50.308(g) (Washington prescription requirements).

[30] For example, Washington practitioners must use "tamper-resistant prescription pads or paper for written outpatient prescriptions, including over-the-counter drugs, for medical assistance clients." WAC 182-530-1075. While the DEA is not mandated to enforce this and other state regulations, a condition of obtaining or renewing a DEA registration is "compliance with applicable state and local law." 21 USC 823(a)(2).

[31] An in-depth discussion of the DEA's requirements for registrant digital certificates, electronic orders and prescriptions is beyond the scope of this article. For additional reading, see Kenneth Baumgartner, Controlled Substances Handbook, Part 1311 ("Digital Certificates") (2013).

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