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Medication for Health System Growing Pains: Solutions to Common Mistakes in Expanding Pharmacy Operations

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Health care growth, through new operations or affiliations, is on the rise and creates integrated health care experiences for both patients and providers. It also provides new opportunities to achieve operational and cost efficiencies, including at the pharmacy level. But the complexity of the pharmacy laws as applied to the storage, dispensing, and transfer processes aimed at achieving efficiencies between service providers can lead to confusion or even unintentional violations. At the same time, this increased affiliation activity seems to coincide with an uptick in enforcement actions by the federal Drug Enforcement Agency (DEA) against hospitals, pharmacy chains, and pharmacists. These six- and seven-figure settlements for seemingly mundane documentation and recordkeeping violations make the regulatory compliance of health system pharmacies and practices that much more important.

This article will explain some basics of DEA regulations and how to avoid common pitfalls experienced by expanding hospital systems.

Regulatory Overview

The DEA regulates facilities that perform activities with respect to "controlled substances." A controlled substance is "a drug or other substance . . . included in [one of five schedules of drugs included in the Controlled Substances Act]."[1] Manufacturers, distributors, dispensers, pharmacies, and prescribers must hold a registration with the DEA to handle, store, distribute, and dispense controlled substances.[2]

But the registration requirements do not end there. Each separate location that is a person's or establishment's principal place of business requires a separate registration.[3] One location cannot be "covered by"

another location's DEA registration. So, if a single hospital entity has multiple locations or satellite facilities housed under the same corporation, each location that handles controlled substances needs a DEA registration.

Registrations are also activity-specific, and a single location engaged in more than one activity must have a separate registration for each activity.[4] For example, if a facility performs both distribution and dispensing activities, it must maintain two separate registrations, and it must also keep its dispenser controlled substance stock and activity separate from its distributor stock and activity.

Health professionals licensed to practice medicine and prescribe controlled substances must also individually register with the DEA to dispense controlled substances.[5] Facilities that do not perform activities that require registration are not required to register with the DEA.[6]

Avoiding Common Pitfalls

While the DEA's regulations seem to be written in a straightforward manner, as with regulatory compliance generally, their application to operations is more nuanced. As health systems deal with essentially two regulatory schemes, one at the state and one at the federal level, keeping all the balls in the air may prove to be a difficult exercise for even the most experienced pharmacy director, particularly where the state law provides exceptions that the federal law does not. Below are some common pitfalls with which expanding health systems may be faced. Generally, the pitfalls may be avoided by a vigilant pharmacy and regulatory compliance team that is well-versed in the state and federal regulatory requirements.

Common Pitfall #1: Not Performing a Comprehensive Compliance Audit on Both Old and New Pharmacies

An old English proverb states that one could not know the direction they are going if they do not know where they have been. Similarly, before making licensing and registration changes to a hospital or practice, the compliance or pharmacy team should perform an audit. This audit should uncover nonconformities and possibly even diversions that could be corrected and reported before the state Board of Pharmacy and DEA begin examining the records after new license and registration applications are submitted. The integration of new practices and hospitals presents a natural opportunity for these audits to be performed as part of the normal due diligence process. Even if it is determined that no new licensure is required at the time of the corporate change, a compliance audit is still an important step, especially if it has not been performed regularly. The health system compliance team should also include the pharmacy operations in its risk-based compliance audit plan.

Common Pitfall #2: Not Following Proper Discontinuation Procedures

Although it is counterintuitive, the simple act of changing a registrant's name may require a new DEA registration number and corresponding inventory. Certain mergers and acquisitions may prompt a change in the name of the registrant. The effect of these relatively easy corporate changes on the validity of a registrant's state pharmacy license or DEA registration may not always be obvious. As soon as the pharmacy's or practice's new name is determined, the responsible pharmacist or prescriber should contact the state Board of Pharmacy to determine if any changes should be made to ensure the state license continues to be valid. While some states do not require any immediate changes to the licensure, other states require the pharmacy or practice to completely retire the existing license number associated with the old name and apply for an entirely new number with the new name.

DEA regulations state that the registration "shall terminate, without any further action by the Administration, if and when such person dies, ceases legal existence, [or] discontinues business or professional practice . . . ."[7] Accordingly, the DEA may require that the current registration be retired and that the hospital or practice apply for a new DEA registration when the state Board of Pharmacy has the same requirement when a corporate name is changed. In this case, the hospital or practice must submit an application as a new registrant and pay the fee in order to receive a new DEA registration. In addition, the DEA perceives this as the discontinuation/transfer of the business to the new DEA registration. Advance planning is key in this instance because the pharmacy or practice has documentation, recordkeeping, and inventory requirements associated with the perceived "discontinuation" under the old number that may be scrutinized as part of the application for a new registration and license. Failing to meet these regulatory requirements may result in penalties.

It is imperative to interface with the local DEA contact so that they are aware of why the hospital or practice is asking for a new registration, especially as this type of application may require an inspection to be approved. Retiring one number and replacing it with a new one may seem like a simple exercise, but it is important to consider the framework in which DEA considers the change of registration when considering the scope of regulatory requirements, such as keeping final and initial inventory records for the hospital and practice's stocks.

The newly-named hospital or practice may start to do business with its new registration number once it receives it.[8] However, do not throw away the DEA registration associated with the old name just yet, as a formal transfer of business activities and inventory must be completed before the new registration may be used. When a registrant wishes to transfer the business activities to another registrant (as is the case if a hospital changes its name), the registrant must notify the DEA at least 14 days in advance of the date of the proposed transfer.[9] When notifying DEA, the registrant must submit:

- The names, addresses, registration numbers, and business activities of the registrant-transferor and the registrant-transferee;
- Identify whether the business activities will be continued at the same location or if the business activities will be moved to another location;
- Inform the DEA whether the registrant-transferor has a quota to manufacture or procure any controlled substance in Schedule I or II; and
- State the date on which the transfer of the controlled substances will occur.[10]

On the transfer date, the registrant-transferor must perform "a complete inventory of all controlled substances being transferred . . . ."[11] This inventory is the registrant-transferor's final inventory and the registrant-transferee's initial inventory.[12] Any Schedule I or II controlled substances should be transferred to the registrant-transferee using DEA Forms 222.[13] Other records, such as invoices, should be kept for the transfers of Schedule III-V controlled substances.[14] Leftover DEA Forms 222 from the registrant-transferor should be mailed back to the DEA.[15] The registrant-transferee is then responsible for custody and maintenance of these inventory records.[16]

These discontinuation procedures are also applicable to a more standard business discontinuation, for example, if a health system ceases doing business at one of its locations. In large or growing systems, the pharmacy licenses of a facility may sometimes be an afterthought. However, to follow proper pharmacy law protocols, advance notice and planning is often required. With any closure, a health system should include pharmacy management in the discussion early on and be sure to follow the discontinuation procedures outlined above.

Common Pitfall # 3: Too Many Transfers Among Registrants in the Same Health System Without a Distribution Registration

Consider this scenario: a health system has multiple locations and services (such as physician practices, a rehabilitation/post-acute care facility, and a tertiary care hospital), all under the same corporate entity but properly having separate pharmacy licenses and registrations. For a variety of reasons, the hospital orders all controlled substances from a supplier at a bulk discount and then transfers these substances to its other locations as needed. Does the hospital need a DEA distributor registration? It depends. Practitioners (hospitals and prescribers) registered as "dispensers" with the DEA may transfer/distribute controlled substances to other DEA registrants without registering as a distributor with the DEA.[17] However, if the "total number of dosage units of all controlled substances which will be distributed by [the hospital] . . . will exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by [the hospital] during that calendar year, [the hospital] shall obtain a registration to distribute controlled substances."[18] Transfers in excess of this 5% threshold without a corresponding distributor registration are subject to penalty.

There is an exception to the 5% limitation for retail pharmacies that supply long term care facilities (LTCF). Distributions by retail pharmacies to LTCFs do not count towards the 5% threshold if all the following conditions are met:

1. The pharmacy must be registered with the DEA as a retail pharmacy;
2. The transfers must be to an automatic dispensing machine at a LTCF; *and*
3. The automatic dispensing machine must be registered to the retail pharmacy.[19]

For centralized hospital systems that draw on a central hospital pharmacy to fill each location's pharmacies each day, there may be a problem if the transfers exceed the 5% threshold annually and the central hospital is not registered with DEA as a distributor. The DEA considers each location to be a separate registrant, with ownership irrelevant to the transfer itself and to the 5% limit.[20] Conversely, some state laws allow related licensees to make unlimited transfers without obtaining a wholesale distributor license. This disconnect between the federal and state requirements can lead to confusion and possible oversight of the federal requirements. A conversation with the state Board of Pharmacy and how it views transfers among entities with common ownership may be helpful in preventing, or working through, potential violations.

Common Pitfall # 4: Locum Tenens and Practicing "Under Another's Registration"

There are also commonly overlooked rules respecting the registrations for hospital-owned physician practices. The DEA requires that each location obtain and maintain its own registration, even when different locations operate under common ownership.[21] The DEA also requires that prescribers who practice at two different locations obtain and maintain registrations at different locations.[22] Prescribers who are already registered with the DEA at one location in a state need not register at a second location in a state "where controlled substances are prescribed but neither administered nor otherwise dispensed . . . and where no supplies of controlled substances are maintained."[23] In other words, a prescriber need not hold a DEA registration for a second location at which the prescriber simply prescribes controlled substances. As soon as the prescriber starts to store controlled substances, however, this triggers the need for the prescriber to register at the second location. In addition, prescribers who see patients at a hospital may, with the hospital's permission, "when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered . . . ."[24]

However, a hospital's existing DEA registration does not automatically extend to the prescribers in a recently-acquired practice, and the prescribers cannot automatically operate under the hospital's registration. To allow the prescribers to operate under the hospital's registration while at the hospital, the DEA requires the following:

- The dispensing, administering, or prescribing is done in the course of the prescriber's professional practice, and the prescriber acts only within the course of his/her employment in the hospital or institution;
- The prescriber is authorized to write prescriptions by the jurisdiction in which they practice, which the hospital or institution verifies;
- The hospital or institution authorizes the prescriber to administer, dispense, or prescribe under its registration and designates a specific internal code number for each authorized prescriber; and
- The hospital or institution keeps a current list of the internal codes and corresponding prescribers, and makes it available to law enforcement or other registrants.[25]

Hospitals and institutions should ensure that doctors and nurse practitioners issuing prescriptions to patients within the hospital's or institution's walls have permission to do so under its DEA registration. Otherwise, the hospital may risk an enforcement action for potential diversion.

Conclusion

Pharmacy and compliance directors should be aware of the common pitfalls when integrating health system pharmacy practices. Careful attention, oversight, and an appetite for regulatory compliance may help health systems to avoid penalties, especially as DEA confronts the opioid crisis with increased enforcement actions. And when in doubt, call the regulators for guidance in advance of any change in operations.

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1 21 U.S.C. § 802(6).
2 21 C.F.R. § 1301.11(a).
3 21 C.F.R. § 1301.12(a).
4 21 C.F.R. § 1301.13(e).
5 21 U.S.C. § 823(f).
6 21 C.F.R. § 1301.11(a).
7 21 C.F.R. § 1301.52(a).
8 21 C.F.R. § 1301.35(a).
9 21 C.F.R. § 1301.52(d).
10 21 C.F.R. § 1301.52(d)(1-5).
11 21 C.F.R. § 1301.52(e)(1).
12 21 C.F.R. § 1301.52(e)(1), 21 C.F.R. § 1304.11.
13 21 C.F.R. § 1305.03.
14 21 C.F.R. § 1304.22.
15 21 C.F.R. § 1305.18
16 21 C.F.R. § 1301.52(e)(2).
17 21 C.F.R. § 1307.11(a).
18 21 C.F.R. § 1307.11(b).
19 21 C.F.R. § 1307.11(c).
20 21 U.S.C. § 822(e), 21 C.F.R. § 1301.12(a).
21 21 C.F.R. § 1301.12(a).
22 *Id.*
23 21 C.F.R. § 1301.12(b)(3).
24 21 C.F.R. § 1301.22(c).
25 21 C.F.R. § 1301.22(c)(1)-(6).