

# BUSINESS LAW TODAY

## A Practical Roadmap for Transitioning State Licenses for Sales of Prescription Drugs and Devices in Corporate Transactions

By [Andrew J. Hull](#)

### Introduction

Pharmaceutical companies, such as manufacturers, distributors, and pharmacies that dispense, distribute, and sell prescription drugs and devices are subject to state licensing and other regulatory requirements. Corporate transactions involving these companies, including mergers, acquisitions, changes of ownership, or even corporate restructurings, can trigger a requirement to transition or obtain new licenses on top of the many other corporate and tax matters that are also at play. Moreover, there are many traps for the unwary for failure to follow the state requirements on transitioning these licenses that can delay a corporate transaction or result in potential suspension of authority to conduct business.

Pharmaceutical companies are required to maintain these state licenses as manufacturers, distributors, etc., in each of the states in which their facilities are located and in most states in which their products are shipped or sold. These state licenses may seem a small issue in the overall structure of a large transaction, but they present an important regulatory detail that must be addressed in order for the new company to

conduct business and to complete the transaction. As such, a buyer must sort through the licensing laws and regulations of nearly each (if not all) of the 50 states and the District of Columbia in order to ensure that the purchased company continues to lawfully operate in each jurisdiction after the change of ownership.

Submitting the appropriate change-of-ownership applications and notifications, as well as waiting for the states to respond, is a timely process, and many companies are left surprised when they reach the closing deadline but are still awaiting authorization to continue to do business in certain states. In the corporate transaction world where a seamless transition of operations is a necessity, such delays can cause regulatory concern as well as logistical difficulties and business interruptions to the parties (and their customers).

This article explores the licensing issues facing buyers and discusses the variations in state laws that affect change-of-ownership requirements. The analysis and guidance provided in this article applies to both regular state pharmaceutical licenses and state controlled substances licenses. Buy-

ers should note that controlled substances licenses are often handled by separate state agencies. This article also describes the risks of noncompliance with these licensing laws and provides a practical roadmap for addressing these issues in order to help avoid a disruption of business operations or state disciplinary action.

For purposes of this article, all relevant state licensing agencies are referred to as “pharmacy boards.” However, many of these agencies operate under different names, or a state may have an agency that regulates the practice of pharmacy and a separate agency that regulates the manufacturing or distributing of pharmacy products.

It is also important to note that, under the federal Drug Supply Chain Security Act (DSCSA), the FDA is required to implement national standards for the licensing of wholesale distributors and third-party logistics providers (3PLs) by December 31, 2016 (see 21 U.S.C. §§ 360eee-2–3). Although these regulations will create some changes in how licensing is conducted in the future, states will continue to maintain licensing authority over pharmaceutical companies.

### The Three Important Questions

When a change of ownership of a pharmaceutical company is about to occur, there are three fundamental questions that a buyer should be able to answer.

#### 1. Does the Seller Have All Appropriate Licensing for Each State in Which It Does Business?

The answer to this question should be determined during the diligence period before an offer is even made because it could affect the value of the deal and the potential for a buyer to have to expend resources not only to transition the existing licenses but also potentially to obtain “delinquent” licenses in some states. The latter may also involve potential penalties as discussed below.

Whether the selling company has all necessary licenses depends on state law and the relevant pharmacy board’s interpretation of that law, as well as the type of activities the company is conducting in each state. For example, the mere listing of the company’s name as the manufacturer on a product label can necessitate a nonresident manufacturer or distributor license in a state where that product is sold, whereas some states may not require a nonresident distributor license unless the out-of-state distributor has sales representatives in that state.

Typically, a distributor license is required in most, if not all, states to which a distributor physically ships its products, and most states also require manufacturers to maintain some form of licensure if their products are sold in those states. A seller’s lack of appropriate licensure should factor into a buyer’s assessment of overall regulatory risk.

#### 2. What Type of Transaction Is Taking Place?

There are multiple forms of deal structures, each likely constructed for optimal value, liability, and tax purposes for the particular transaction. Although state agencies rarely delve into each and every facet of these structures, certain basic details can determine whether a change of ownership will, in fact, occur under the state’s law and, if so, what effect that change of ownership

will have on that state’s licensing requirements. For instance, most states will want to know if the name, federal tax identification number, and address are staying the same. Additionally, they will want to know whether the transaction involves a purchase of assets or is a stock purchase. In the event of a stock purchase, the states must know the percentage of shares whose owners are changing.

As a practical matter, stock purchases—where the corporate name, tax identification, and identity remain unchanged—are less onerous in regards to transitioning the licenses in the various states. Asset purchases and creation of new companies generally require filing an application for a new license. These requirements are discussed in more detail below.

#### 3. Does a State Require a New License or Is a Notification to Update State Records Sufficient?

For those states in which the seller’s facility is licensed, the buyer must determine whether it must apply for a *new license* for the facility or if some form of *notification* of the change of ownership is all that is required. The answer to this question depends on a host of factors, including the structure of the transaction, state law (where present), and the pharmacy boards’ interpretations of their laws. Although most state licensing authorities maintain a website, the content and detail regarding the necessary requirements vary by state, and often the most critical question, i.e., how long it will take to process a change of ownership, is not provided.

As such, many buyers must contact the pharmacy boards directly with the specifics of their transactions in order to ensure compliance with each pharmacy board’s requirements. Law firms or state licensing consultants can provide buyers with this information based on a review of the regulations as well as expertise and experience in these transactions. As described in the next section, the action required (i.e., new application or notification) varies by state, and it can have a significant impact on the transition of business operations after the deal closes.

### Variations in State Change-of-Ownership Requirements

There are three basic categories of states when it comes to change-of-ownership licensing requirements. Some states require only that the facility, through its new ownership, notify the appropriate pharmacy board of the change of ownership (notification states). Some states require an application for a new license, but will allow the facility to continue operations under the old license while the application is pending if the application is received within a certain period before or after closing (continued operations or CO states). A small handful of states also require an application for a new license, but will not allow continued operations after closing while the application is pending (non-continued operations or non-CO states).

The pharmacy boards in non-CO states take a strict view of their pharmacy laws that require proper licensure in order to engage in any form of manufacturing, distributing, or pharmacy practice in their states, even though the facility and its operations were fully licensed under the old ownership. Notable non-CO states include California, Florida, Maine, Maryland, and Oregon. Non-CO states present the most significant challenges to buyers looking for a seamless continuation of operations upon closing.

### Logistics and Timing

Corporate transactions often are controlled by strict schedules that are created at signing and culminate at closing. During this time period, the buyer must work with the seller to apply for new licenses (or submit notifications as appropriate) to effectuate the change of ownership of the licensed facility. This process can be time consuming for multiple reasons.

First, the applications can be long and request information that will take time to obtain, including information about the owners, employees, customers, and products. For example, in some states the background information required ranges from a representative’s personal residence address from seven years ago (see Idaho State Bd.

of Pharmacy, [Designated Representative Personal Information Statement](#); Md. Bd. of Pharmacy, [Application for Wholesale Distributor Permit](#)), to the personal residence addresses, Social Security numbers, and dates of birth of the facility's directors, officers, or owners (see, e.g., State of Fla. Dep't of Bus. & Prof'l Regulation, [Out-of-State Prescription Drug Wholesaler Application](#); N.Y. State Bd. of Pharmacy, [Application for Initial Registration or Transfer of Ownership of Manufacturer, Repacker and/or Wholesaler of Drugs, Prescription or Medical Gases](#)). Some applications ask specific questions about the facility's customers (see, e.g., N.M. Bd. of Pharmacy, [Wholesale Drug Distributor Application](#)), or require a full description of the facility, including its square footage, alarm systems, and temperature and humidity controls (see, e.g., State of Del. Bd. of Pharmacy, [Application for Distributor \(Pharmacy-Wholesale\) Permit](#); Md. Bd. of Pharmacy, [Application for Wholesale Distributor Permit](#)). The bottom line is that these applications require detailed knowledge of the purchased or to-be-purchased facility and its operations and management, as well as that of the new ownership.

Second, many states also require certain personnel to undergo criminal background checks (including fingerprinting). In practice, it can take some states up to two months and longer to process these background checks. Many of the pharmacy boards outsource these background checks to other federal or state agencies or to private contractors.

Third, many pharmacy boards are short-staffed and work with a significant backlog. As a result, it may take some states up to eight to ten weeks to review an application and grant a new license.

Fourth, some pharmacy boards will not grant a new license until the closing between the buyer and seller has taken place. If the applications are submitted early, these pharmacy boards likely will review the applications, but they will wait to issue new licenses until they receive a final bill of sale or other similar closing document.

Finally, most pharmacy boards will not

issue a new license until the state in which the facility is located (referred to as the home state or resident state) has issued the new license.

All of these factors show why a new owner may struggle to have all of its newly acquired facility's licenses in place in order to continue operations in each state immediately after closing, especially when working within a truncated closing schedule. Such buyers may find themselves facing the following questions: What if all of the new licenses are not granted at or by closing? Should the facility cease operations in states in which it is still waiting for new licenses to issue? What is the risk of not doing so? What will happen to its customers in states in which the facility ceases to operate while its applications are pending post-closing?

These questions can certainly generate consternation for a buyer as the closing deadline approaches when the buyer is still waiting to receive new change-of-ownership licenses from numerous pharmacy boards in jurisdictions where the facility does business. These companies are concerned about any disruption of business and the effect that disruption will have on its customer relations and overall sales.

#### **What Should a New Owner Do If It Is Still Waiting on the Issuance of Licenses Post-Closing?**

Before answering this question, it is helpful to step back and look at the big picture. The majority of states, as discussed above, are either notification states or CO states. This means that, if the buyer makes the appropriate notifications and submits its new applications within a timely manner, then it can continue its operations in those states after closing. In other words, there will be no disruption of the facility's operations in those states.

There are a handful of states (i.e., the non-CO states), however, where the pharmacy boards will not allow the facility to operate in their states post-closing until the facility receives its new licenses. If a license has not been granted in these states by or at closing, the facility should cease

its business operations in that state. From communications with pharmacy board personnel over the years, the pharmacy boards in non-CO states consider continued operations post-closing without a new license to constitute the unauthorized practice of pharmacy, manufacturing, distributing, etc. (i.e., an illegal activity under the state's pharmacy or other relevant laws). In most states, such activity constitutes grounds for revocation of a license or denial of an application (see, e.g., Cal. Bus. & Prof. Code §§ 4161, 4304; Md. Code Ann., Health Occ. §§ 12-601, 12-6C-03(a)) and could result in civil penalties (see, e.g., Md. Code Ann., Health Occ. § 12-6C-11(a)). Accordingly, upon closing of the transaction, a new buyer of a facility should cease operations in each non-CO state until it receives appropriate licensure.

#### **Risk of Noncompliance**

A common question many buyers in such a position ask is what, if any, risk exists for continuing operations in non-CO states while the new applications are still pending after closing.

We are aware of pharmacy boards and other state licensing authorities taking enforcement action against companies for operating in their states without a nonresident license (see, e.g., [Final Consent Order, In re Calvin Scott & Company, Inc.](#), Case No. PI 11-115 (Md. Bd. Pharmacy Apr. 9, 2013) (exacting a fine and formal disciplinary action for the distribution of prescription drugs into Maryland without a Maryland wholesale distributor permit)). There appears to be less risk of enforcement action against companies continuing operations under their old licenses for a brief period of time while waiting for their new change-of-ownership licenses to be issued. Certainly, states may use some enforcement discretion when a company has made a good-faith effort to timely file a notice/application for a change of ownership. That said, a risk of enforcement clearly exists and should not be ignored. The pharmacy boards in non-CO states have the authority to enforce this particular strict interpretation of their pharmacy laws. Thus, it is important to understand the

requirements in each state and communicate with the state authorities to minimize the potential of having to make a difficult decision—that is, to stop shipping into the state or face a potential fine or, worse, denial of the pending application.

Some buyers make the business decision that the financial and reputational harm in discontinuing operations post-closing in any non-CO states where applications are still pending outweighs the risk of enforcement actions by the pharmacy boards in those states. Others take the conservative approach of strictly complying with the licensure laws in those states, especially if the buyer or the purchased facility has a history of noncompliance with state pharmacy laws. Still others may take a measured risk approach and choose either to continue or temporarily discontinue sales into a particular state depending on the amount of sales and the effect of ceasing shipping on their bottom line.

Prospective buyers, however, are not necessarily forced to choose between the Scylla of discontinuing operations and the Charybdis of embracing the risk of violating state pharmacy law. As discussed below, with proper planning and coordination, a buyer can obtain all necessary licenses in order to continue operations in each state in which it does business immediately after closing.

#### **A Roadmap for Prospective Buyers**

The following roadmap provides a practical schedule of actions that a prospective buyer can follow in order to help ensure a seamless transition of operations during the change of ownership. This roadmap contains suggestions only, and prospective buyers should keep in mind that the details of each transaction may likely necessitate variations to these suggestions. As such, it is essential that a prospective buyer obtain the advice of an experienced law firm or state-licensing consultant.

#### **Diligence Stage:**

- Obtain a list of all pharmacy board licenses held by the target facility.
- Determine whether the target facility has all necessary pharmacy board and other

relevant licenses in light of its business operations.

- When making an offer appears likely, determine which states are notification states, CO states, and non-CO states based on the proposed transaction details.
- Determine which states will also require fingerprinting and background checks.

#### **Offer Stage:**

- Raise the issue of applying for new licenses with the seller and explain the necessity of the seller coordinating with the prospective buyer if and when the deal reaches the signing stage.
- If the deal appears likely, start preparing the applications for the home state and for any non-CO states where licensure is necessary. Prospective buyers should fill out the applications as completely as practicable and then make a list of information needed from the seller.
- If non-CO states are at issue, negotiate a closing period that takes into consideration a time period for obtaining new licenses, keeping in mind that certain non-CO states can take up to eight to ten weeks to grant a new license upon receipt of an application.
- Arrange for the seller to work with the buyer to submit all applications and notifications according to the suggested timetable in the next stage, or designate a point person at the seller's facility to provide all necessary information to the buyer.
- Consider the possibility of preconditioning the closing date on the successful receipt of licenses in all non-CO states.
- Consider seeking representations and warranties from the seller that relate to the ability to obtain appropriate licenses pre- and post-closing, including an escrow amount for lost sales if the buyer does not receive appropriate licenses upon closing or within a designated post-closing period.

#### **Signing to Closing Stages:**

- Within the first two days (i.e., immediately) after signing:

- finalize and submit the home-state application and any non-CO state applications; and
- prepare and submit the background check applications and fingerprint cards for each pharmacy board requiring background checks.
- Within the first two weeks (i.e., as soon as practicable) after signing:
  - finalize and submit all CO state applications; and
  - notify all notification states of the upcoming closing date and change-of-ownership details (typically a letter should suffice, although some states have specific notification forms).
- *Note:* Be sure to comply with each state's application and notification requirements, given that many states require the application or notification be submitted within a certain time period in order for the facility to continue operating under its current license post-closing.
- Work closely with the home state and non-CO state pharmacy boards to confirm receipt of the applications. Many pharmacy board personnel will work with you to ensure that a new license is granted at or before closing if you have given them adequate time to review your application and provide them with completed (not partially completed) applications at the beginning. If possible, determine who at the pharmacy board will be responsible for processing the application and ensure that this person has your contact information for any questions or missing information. For pharmacy boards that require a copy of the home-state license or of the final bill of sale, attempt to coordinate with them so that the license can be issued as soon as these documents are made available.
- On the day of closing, send the final bill of sale (or similar document) to all pharmacy boards requiring such documentation.

This suggested roadmap is not a guarantee for ensuring that the buyer will obtain all appropriate licensing approvals prior to or at closing. The process is more art than

science. It requires knowledge of each pharmacy board's policies and practices, and it involves a distinct human element in coordinating with pharmacy board personnel.

#### **Conclusion**

Navigating any form of corporate transaction is time-consuming and requires detailed work. The added detail in transactions involving pharmaceutical companies of ensuring appropriate state licensure adds yet another level of nuance and difficulty.

This roadmap provides buyers and their corporate counsel with some of the information needed to ensure that these regulatory details do not present an issue after closing. In these transactions, buyers and their transaction counsel should seek out regulatory experts to assist in navigating the state licensing process to avoid added delays and costs in completing the deal.

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