

Multistate Pharmacies: A Prescription for Navigating the Regulatory Maze

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A version of this article was republished in [Law360](#) on October 3, 2023.

In today's pharmacy world, most pharmacies, whether large national chains or small regional businesses, are required to hold licenses and registrations in several states. Unfortunately, there is no universal pharmacy license on a federal level that would permit a pharmacy to operate in all 50 states. For pharmacies with multiple locations and/or operations that cross state lines, this complex patchwork of state requirements and licenses can be a regulatory maze.

This also means that small errors can add up and lead to disciplinary actions from a state regulatory board. When one state imposes an adverse action on a pharmacy license, many other states' pharmacy boards consider it a reportable event. Therefore, a pharmacy operating in a multistate capacity must proactively address the common pitfalls to mitigate its operational and legal risks. Otherwise, a pharmacy may find both its home and out-of-state pharmacies under the microscope of regulatory scrutiny.

Licensure Requirements

Before submitting a pharmacy application, it is essential to become familiar with the license requirements of the particular state where the license is required. Depending on the scope of operations and services of the pharmacy (e.g., operating as a retail, out-of-state mail-order, long-term care, or institutional pharmacy), the pharmacy may be required to submit a specific type of license application and/or service-specific supporting documentation. But without reviewing the particulars of the applicable statutes and regulations, there is increased risk of submitting the incorrect license application or failing to submit a complete application. This can result in lengthy operational delays, slowdown a pending pharmacy acquisition transaction, or even trigger a license denial — the latter which may ultimately be a reportable disciplinary event to other states where the pharmacy is licensed.

Even after the correct application is selected, completing the licensure application process can present a new array of challenges.

Inspections

Some states will require a compliance inspection, even when the applicant pharmacy is located outside the state. This inspection is typically where pharmacies will either be delayed in their application process or outright denied — often because the home state pharmacy failed to comply with the outside state's requirements. For other states,

evidence of the pharmacy's most recent home state inspection will be required when applying for an out-of-state license in other jurisdictions, adding greater emphasis on pharmacies ensuring compliance with their home state inspection requirements when seeking out-of-state licensure.

Pharmacist-in-Charge

States have diverse requirements for Pharmacist-in-Charge (PIC) on nonresident pharmacy applications. For example, some states require that a PIC for nonresident pharmacies must be licensed in the state where the pharmacy is seeking nonresident licensure, while other states may only require the PIC to be licensed in the pharmacy's home state. Additionally, for pharmacies operating or intending to operate as a nonresident pharmacy in several different jurisdictions, certain states may impose caps on the number of states in which a single pharmacist can serve as a PIC. It's crucial for pharmacies to understand and comply with the specific requirements of each state where they plan to provide services.

Controlled Substance Requirements

Controlled substance requirements can vary significantly at the state level. For instance, some states have additional requirements beyond the federal Drug Enforcement Administration (DEA) registration. As such, in some states, pharmacies must apply for a separate state-level registration to legally dispense controlled substances. Additionally, Prescription Drug Monitoring Program (PDMP) requirements vary significantly from state to state. PDMPs are state-run databases used to track the prescribing and dispensing of controlled prescription drugs to patients. While several states have consolidated their PDMP requirements into a unified system, not all states have done so. This means that the specific requirements for reporting, accessing, and using PDMP data can differ depending on the state. Therefore, it's essential for pharmacies and practitioners to understand and comply with both federal and state-specific requirements when dispensing controlled substances.

Managing Renewals and Changes of Information

Nearly every state requires routine (e.g., annual or biennial) renewals of pharmacy licenses, whether resident or nonresident. Any changes to ownership (as discussed below), PIC, address, disciplinary history, or other notable pharmacy information may be required to be disclosed upon license renewals. However, most states will also require disclosure of certain information changes outside of the renewal process. Such affirmative disclosure requirements are highly state-dependent with significant variance in the types of information triggering disclosure, the timing of disclosure, and method of disclosure, causing pharmacies to inadvertently fail to submit a required disclosure. These oversights, however minor, can create significant issues down the road if the applicable board of pharmacy becomes aware of the discrepancy in information. Failure to timely disclose a reportable change of information could result in disciplinary action for the pharmacy, or throw a wrench in an ongoing acquisition transaction — particularly if the pharmacy is undergoing a change of ownership.

Change of Ownership and Other Transactions

Changes of ownership (CHOWs) are typically a large hurdle for pharmacies to overcome when engaged in a merger or acquisition transaction. For example, if a pharmacy is licensed in multiple states, the transaction may be deemed a CHOW in one or more states, requiring regulatory approval from, or notice to, a particular state (with

state-specific timing requirements associated therewith). Some states may not permit a transfer of licensure and instead will require submission of an entirely new licensure application, with some states requiring application approval prior to the acquiror commencing pharmacy operations post-closing. To complicate matters, states may also have different definitions of what constitutes a CHOW or their regulations fail to address the CHOW triggers or processes clearly. It's also important for an acquiror to have a complete understanding of its target pharmacy's CHOW obligations in all states where it's licensed, to ensure that disclosures and approvals are properly coordinated to allow for a timely closing of the transaction.

Operational Requirements

Pharmacies must also consider aligning their operations to the requirements of all states in which they are licensed, as there are often specific operational regulations for pharmacies. For example, many states require any nonresident pharmacy to provide a toll-free telephone service to facilitate communication between the state's residents and the pharmacy at least six days per week, for a minimum of 40 hours per week. However, other states may just generally require a toll-free number during regular hours of operation, or may require that stricter hours be kept. Another example is that states have varied telemedicine requirements, and though those requirements typically focus on the patient-provider relationship, some states impose additional related requirements onto the pharmacies. A pharmacy's failure to follow another state's operational requirements, often leads to discipline. This occurs all too frequently as many pharmacies prioritize adherence to regulations within their home state, sometimes overlooking the requirements of other states that the pharmacy is licensed in.

Conclusion

Multistate pharmacies play a pivotal role in enhancing nationwide health care access by effectively expanding the availability of prescription medications, particularly to vulnerable communities. However, multistate pharmacies must ensure that they are properly equipped to face the regulatory hurdles that come with operating across multiple states. Most violations of these regulatory hurdles will result in fines, probation, suspension, or even revocation, depending on the severity of the violation. Consider this your prescription for compliance: stay informed, stay proactive, and always be ready to adapt to the ever-changing regulatory landscape.

As always, Troutman Pepper's Health Science Practice Group stands ready to offer comprehensive support for all matters pertaining to pharmacy licensure. For more information, please contact the authors of this article to learn more about how you can proactively protect your pharmacy.

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