



# State Regulation of Medical Device Distribution: Strategic Planning Needed to Address Varying Requirements

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**T**he road to obtaining federal marketing approval/clearance has been long—the device testing was completed, the study data summarized, the application submitted (along with responses to the Food and Drug Administration’s (FDA’s) questions and requests for additional information), and the long-awaited letter from FDA granting clearance or approval has been received—and now the devices are *finally* ready for U.S. distribution, right? Well, maybe ...

In addition to federal regulation by FDA, medical device companies are now facing increasingly complex and burdensome state regulatory requirements for the distribution of their device products. Consequently, it is vitally important for companies to consider how their ability

to launch and distribute new devices may be affected by the various state requirements. A well-planned distribution strategy may mean the difference between a smooth launch and a huge headache. This article summarizes key aspects of states’ regulation of the device distribution chain, and strategic considerations for effective distribution planning.

## State Regulation: Differences and Similarities

Device distribution in the United States presents unique challenges. While all states have established regulatory programs and requirements governing the drug distribution chain, many (approximately half) of the states have no regulatory oversight for medical device distribution. Of those states that do regulate device distribution, the regulatory



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schemes used are quite varied. While there are federal guidelines and minimum requirements for the states' regulation of drug distribution under the Prescription Drug Marketing Act (PDMA), no comparable guidelines exist for the regulation of medical device distribution. Therefore, as discussed below, the regulatory schemes enacted by the various states have far less consistency.

## Regulatory Agencies

Assessing the applicable regulatory requirements within a particular state can be difficult, because it is often not immediately apparent which state agency (if any) governs device distribution. Most states that have device distribution regulatory requirements have chosen to delegate responsibility for this program to the same agency tasked with overseeing drug distribution, which is usually the state Board of Pharmacy (e.g., Arizona, Idaho, Kansas and Maryland). However, this approach is not universal. For example, some states use an FDA-like agency to oversee device distribution (e.g., New Jersey's Food and Drug Safety Program). Always the regulatory over-achiever, California has given two agencies jurisdiction over the device distribution chain: the Medical Device Safety Section of the Food and Drug Branch (for retail distribution) and the Board of Pharmacy (for wholesale distribution).

## Types of Devices

Once the appropriate agency and regulatory scheme have been identified, the next step is to determine whether a particular state regulates the device product your company intends to market. The types of devices regulated by each state vary significantly. For

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example, some states restrict regulation to "durable medical equipment" or "home medical equipment." In states where the regulatory scheme for device distribution was built on the existing framework used for drug distribution, the requirements often apply only to prescription devices (a.k.a. "legend" devices) or devices that are drug-related (e.g., syringes or infusion pumps). Kentucky and Arizona have taken this concept even further by requiring distributors to be licensed only if their devices are labeled "Rx only," but not if the devices are labeled "Caution: Federal law restricts this device to sale by or on the order of a physician." FDA created confusion in Kentucky, when it issued labeling guidance in early 2000, allowing device manufacturers to abbreviate the required caution statement regarding the order of a physician to "Rx only." Prior to issuance of this guidance, the "Rx only" legend was used primarily, if not only, by drug manufacturers and distributors. Device manufacturers have initiated discussions with the Kentucky Board of Pharmacy to try to correct the uneven regulation arbitrarily created by use of different words for prescription devices.

## Regulated Activities

It is also important to determine what types of distribution chain activities each state regulates. Some states regulate entities engaged in wholesale distribution activities (distribution to hospitals, clinics, retailers or other

distributors), while others regulate only retailers and other entities that dispense directly to patients. For example, in states that license "durable medical equipment" or "home medical equipment" manufacturers-suppliers, these requirements usually apply only to companies that ship directly to patients or end-users (e.g., Florida, Illinois and Mississippi).

For those states that regulate distribution at the wholesale level, there is significant variation in what activities are included in the definition of "wholesale distribution." Some states focus on whether an entity has physical possession of the device products when they are distributed into or within the state, while others focus on whether the entity has title to the products. Certain states also include brokers and other entities that arrange for the sale of devices to be "wholesalers." For example, Maryland's wholesaler license requirements apply to all entities that "direct or control" the distribution of devices in Maryland (e.g., by arranging sales or drop shipment), whether or not such entities have physical possession of the device products. Pennsylvania, on the other hand, takes a completely different approach by requiring a device company to register as a distributor only when the company employs sales representatives in the state.

It is also important to consider what is excluded from the definition of "wholesale distribution." For example, several states that regulate wholesale

distribution have exemptions for device manufacturers that only distribute products of their own manufacture (e.g., California).

## License/Registration Requirements

The most consistent state requirement for medical device distributors is the requirement to be licensed or registered with the state. However, the *process* for obtaining such licensure/registration varies significantly among the states, making advance planning a necessity for companies launching their first device product. Although some license/registration applications are simple and straightforward, many can be quite lengthy, requiring the submission of extensive background information and a surety bond (usually around \$100,000).

For example, Maryland and California require photographs and fingerprints for certain employees, which are used to perform criminal background checks. Some states also require an inspection before approving an application. In Maryland, the Board of Pharmacy requires a pre-approval inspection for distributors, but will only inspect in-state facilities. Out-of-state facilities must either be accredited under the Verified-Accredited Wholesale Distributors (VAWD) program by the National Association of Boards of Pharmacy (NABP), or have had an inspection by a state agency

that Maryland has determined has an acceptable inspection program. Because of the extensive application packages required in some states and the limited resources of state agencies, the application process can take weeks or even months. Therefore, significant advance planning is required to ensure that all required licenses are obtained before the planned product launch date.

## Strategic Considerations

Given these and other state-by-state differences, new device manufacturers must think strategically about nationwide distribution of their devices. As part of any distribution plan, strategic issues to consider include: whether to use a third-party distributor; how to include prescription warnings on device labeling; the location of warehouse facilities; when, how, and in what order to submit state license applications; whether inspections are required; and how to monitor changes in state laws.

To significantly lower (and possibly eliminate) state regulatory burdens, one option to consider is the use of a contract distributor or third-party logistics provider that already has the necessary state licenses and registrations. If the third-party distributor handles the physical shipping and distribution and also takes title to the products, the manufacturer may not be required to obtain its own state licenses, except in those states

where the manufacturer has warehouses or other holding facilities.

If it is not feasible to use third parties for all U.S. distribution activities, manufacturers should allot sufficient time to obtain state licensure in their pre-launch plan. Because each state has a different organization and level of available resources, the license application processing times can vary significantly, and new manufacturers and/or device distributors need to account for these differences in developing their distribution plan. Moreover, many states require that a distributor have an approved license in its home state *before* it can apply for a license as a non-resident distributor. Thus, the time required to obtain the home-state license (or a letter from the state authorities stating that no license is required in that state) in advance of submitting applications in other states also must be considered as part of the plan.

Although many states have regulated device distribution for several years or more, it is possible that the number venturing into this area may increase in the next few years as the states seek other sources of revenue. States also are extending regulation to areas beyond distribution, such as restrictions on device marketing and interactions with healthcare professionals (e.g., Massachusetts and Nevada). As a result, companies may need to add to their regulatory staff to keep track of the myriad of state requirements. Device manufacturers and distributors not only need to be aware of state regulatory requirements at the time of market launch, but also must implement a mechanism for monitoring changes in state laws post-market, as additional states expand their regulatory reach to medical devices. ▲

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