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State Regulation of Medical Device Distribution: Managing a Complex Regulatory Scheme

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Although most medical device companies focus the bulk of their regulatory resources on compliance with federal requirements imposed by the Food and Drug Administration (FDA), a significant portion of device regulation falls within the purview of state agencies, particularly with respect to device distribution. State regulation in this area has long been a significant burden for companies that market and distribute devices nationally. Currently, approximately half of the 50 states regulate the distribution of devices, but the laws regulating device distribution vary from state to state. These state laws differ, for example, in the types of device products that are subject to regulation; the activities and entities that are subject to regulation; the requirements for licensure; and the requirements related to facilities, processes, and quality controls. Federal guidelines for wholesale drug distributors, mandated by the Prescription Drug Marketing Act (PDMA), have helped to establish a level of consistency among the state laws and regulations governing prescription drug distribution, but no such guidelines have been established for medical devices.

The patchwork of state laws and regulations applicable to device distribution has presented a tremendous challenge for device manufacturers and distributors, particularly given that, unlike the drug industry, most device companies

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are in the small to mid-sized range. These complexities become even more difficult to manage with the increased use of national carriers, as device companies seek to reduce costs by downsizing their sales force. In the absence of federal legislation to provide more uniformity, device companies must continue to be mindful of the various state requirements and maintain systems and processes to manage their regulatory obligations.

Managing the Challenges Presented in Evaluating State Regulatory Requirements

The number of states that have laws or regulations governing medical device distribution—approximately half—has remained relatively constant over the last several years. However, there are significant differences in how each state regulates device distribution activities. Moreover, in those states that choose to regulate in this area, devices are often treated almost as an afterthought. Very few states have a regulatory framework designed specifically for medical devices. Rather, working under the apparent assumption that drugs and devices are generally the same or "close enough," these states use legal and regulatory schemes that were designed for the pharmaceutical industry to regulate medical devices. This, combined with the variability among the states in the degree of device regulation and regulators' understanding of the device industry, can create significant challenges. Device companies, therefore, must be prepared to manage the inherent limitations of these state regulatory schemes, and the differences among the states in the regulatory requirements applicable to device distribution.

There are also significant differences in how each state interprets and enforces its laws related to device distribution. In some states, for example, although the state laws and regulations allow the state regulators to oversee device distribution activities and to require licensure for entities engaged in such activities, the state regulators have chosen as a matter of policy not to enforce these requirements due to a lack of resources. This has created an added layer of confusion and complexity for device manufacturers and wholesalers seeking to determine their regulatory and licensure obligations, because these state regulators do not always announce their enforcement policy (e.g., in a written guidance, on the state regulator's website, or in any other written regulatory document). In many cases, device distributors only learn about a state's enforcement policy by contacting the relevant state regulatory authority directly.

Thus, prior to launching a device product for the first time, it is important that device companies take the time not only to evaluate the specific state laws and regulations applicable to device distribution, but also to ensure they understand how those laws and regulations are enforced in each state. With respect to the latter step, device companies may have difficulties in determining which state regulatory authority to contact. Although most states regulate device distribution through the state Board of Pharmacy or Board of Wholesale Distributors, some states utilize an FDA-like agency, while others have multiple agencies that share the responsibilities in this area (e.g., California and Pennsylvania). Device companies, therefore, must ensure they contact the correct regulatory agency (or agencies) in each state when seeking clarification on the applicability of the state's regulatory and licensure requirements.

Scope of States' Regulation for Device Distribution

After determining whether a state actively regulates and enforces device distribution laws and regulations, device companies must then assess the scope of each state's regulatory requirements, and whether it falls within that scope. One of the first questions that should be considered is the type of devices subject to regulation by the state. Most states that regulate device distribution regulate only prescription or "legend" devices, but the states differ in how they define these terms. For device manufacturers familiar with FDA regulatory requirements, these differences in definitions can be perplexing. For example, the New York Board of Pharmacy distinguishes between products labeled as (1) "Federal law prohibits dispensing without a prescription" or "Rx only," and (2) those labeled as "Federal law restricts this device to sale by or on the order of a physician." Although FDA considers both types of label statements to be applicable to prescription devices, the New York Board of Pharmacy considers devices labeled with the former language to be prescription devices (subject to regulation and licensure requirements) and the latter to be non-prescription (not subject to regulation or licensure requirements).

In addition, some states only regulate a subset of prescription devices that are considered "durable medical equipment" or "home medical equipment." These device categories generally include equipment that has been prescribed by a physician for use in the home (e.g., hospital beds, sleep apnea devices, infusion pumps, walkers). Thus, a device company may not be required to obtain a license in certain states if the company's devices do not qualify as durable or home medical equipment.

Device distributors also need to assess whether the activities they engage in within a state are subject to regulation. Some states only regulate entities engaged in wholesale distribution activities (i.e., distribution to hospitals, clinics, retailers, and not to individual patients), while others regulate only retailers and other entities that dispense directly to patients. Further, for those states regulating wholesale distributors, some regulate only the entity that holds title to the devices when they are distributed into the state. Other states, such as California, regulate not only device distributors, but also third-party logistics providers that provide only warehousing and logistics services, and do not take title to the devices that they handle. And at least one state (Pennsylvania) requires a device distributor to register with the state only if it employs sales representatives in the state.

Device companies also must consider whether any regulatory exemptions may apply. For example, many states exempt FDA-registered device manufacturers from oversight, provided that the manufacturers only distribute devices of their own manufacture.

State Licensure Requirements

One of the most important considerations for device distributors in assessing their state regulatory obligations is the state licensure or registration requirements. Advance planning is critical for companies launching their first device product, due to the lead time needed in some states to provide all the supporting documentation and information required for the license application. For example, some states (e.g., California and Maryland) require fingerprints and background checks for certain employees, and a few states require a $100,000 surety bond (e.g., Arizona). Several states require an inspection or a recent inspection report before approving a license/registration application. Maryland requires out-of-state facilities to either be accredited under the Verified-Accredited Wholesale Distributors (VAWD) program by the National Association of Boards of Pharmacy (NABP), or to have had an inspection by a state agency that Maryland has determined has an acceptable inspection program.

For distributors seeking to distribute devices in all 50 states plus the District of Columbia, the order in which license applications are submitted can be important. For example, when obtaining nonresident licenses to ship into other states, most states require that a distributor first obtain a license in its home state before it can apply for the nonresident license. If a distributor's home state is one that has a long processing period, this can significantly lengthen the timeline for a market launch. Additionally, some states (e.g., Georgia) require applicants to provide verification of every state in which the distributor is licensed. Thus, it may be easier to obtain licensure in these states earlier in the process, when the distributor has only a few state licenses.

Facility and Related Requirements

Beyond licensure, device distributors also will need to understand and manage the various state requirements related to facility controls, quality controls, personnel, security, record-keeping, and supplier/customer diligence (i.e., confirmation that suppliers and customers are appropriately licensed to sell or purchase medical devices). These requirements also vary from state to state, with some states imposing more detailed and onerous obligations, and others having more general and flexible requirements.

Device companies engaged in distribution must draft and implement appropriate procedures and processes to ensure compliance with these state requirements prior to beginning any device distribution activities (e.g., for quality control, environmental monitoring, first-in-first-out requirements, monitoring of expiration dates, complaint handling, returned products, and recordkeeping). This is particularly important if the distribution facility is located in a state that requires an inspection prior to licensure. Additionally, distributors must ensure their distribution warehouses are of adequate size and construction, have a separate area for quarantined products, and have appropriate security controls. Some

states (e.g., Arizona and Montana) require distributors to submit a floor plan of the facility with their license application to demonstrate that the applicant meets the state's requirements related to facility and security controls. Distributors also must evaluate whether there are specific state requirements relevant to personnel, such as requiring that personnel handling prescription devices have adequate training, technical qualifications, education, and experience. Certain states also require a designated representative or other licensed person at each facility (e.g., Maryland and Utah).

Potential Federal Legislation

One issue that many device distributors have been following closely is the potential for federal legislation in this area. In particular, distributors have been keeping an eye on legislation drafted by the House Energy and Commerce Committee, referred to as the "21st Century Cures Act." An earlier draft of this proposed legislation included a section entitled the "Device Distribution Licensing Act of 2015," which was proposed and supported by a coalition of device distributors. The most recent version of the 21st Century Cures Act did not include these provisions.

If enacted, the proposed Device Distribution Licensing Act would significantly impact the state license requirements for prescription device manufacturers, distributors, and third-party logistics providers, as it would create a closed distribution chain for prescription medical devices, modeled after the one created for prescription drug distribution under the Drug Quality and Security Act of 2013. It would impose licensure and other requirements for prescription device manufacturers, wholesale distributors, third-party logistics providers and dispensers, and also would require FDA to issue regulations defining standards for licensing wholesale distributors and third-party logistics providers that handle prescription medical devices.

Conclusion

Compliance with state device distribution laws and regulations remains a challenge for companies distributing prescription devices to all 50 states. To manage these requirements, advance planning is key, and must include developing a good understanding of the state requirements applicable to your devices. While federal legislation, such as the Device Distribution Licensing Act, still could be revived and offer some level of uniformity for device distributors in the future, it does not appear that such relief will be available soon.