ARTICLE 03

WHOLESALE DISTRIBUTOR LICENSES
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Many life sciences companies mistakenly believe that having complied with FDA law, the only relevant state registration or licensing obligations are corporate registrations to conduct business. In reality, they may be subject to some significant additional obligations.

One “registration” obligation commonly overlooked is the requirement that wholesale manufacturers and distributors (i.e., those selling to other than the end-user), as well as others involved in the device industry, such as 3PLs and re-labelers, obtain a wholesale distribution license. Non-compliance can result in penalties to the company and its customers, and, at least of equal concern, interruption of business until a required filing is complete.

The federal Prescription Drug Marketing Act (PDMA) was enacted in 1988. The PDMA includes a provision requiring wholesale distributors of prescription drugs to be state licensed and requires the FDA to establish minimum requirements for state licensing schemes. State licensure of device manufacturers is not required by federal law, however. Notwithstanding that fact, many state licensure schemes adopted for PDMA compliance extend to wholesale distributors of prescription devices. The intention to include devices may not always be obvious, as rather than explicitly call out devices as separately regulated, many of these laws reach devices by incorporating devices into the definition of “drugs.”

Deciding whether or not these laws are applicable to any particular company requires a company- and state-specific analysis. The first step is to determine whether you are engaged in a regulated activity; the answer will change from state to state. California’s law is fairly typical in that “a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any (dangerous) drug or device…. 1 However, in some states the law applies to pharmaceuticals and not devices, in others to pharmaceuticals and some devices, and in still others to both pharmaceuticals and most regulated devices. Also, there are myriad exceptions that may or may not be applicable, depending on the facts. Some states exempt licensed manufacturers who distribute only their own product while other states exempt certain types of products.

Indiana’s approach is fairly typical in scope but liberal in its exceptions. It applies to entities that are re-packers; own-label distributors; jobbers; brokers; warehouses, including manufacturers’ and distributors’ warehouses, chain drug warehouses and wholesale drug warehouses; independent wholesale drug traders; retail and hospital pharmacies that conduct wholesale distributions; and reverse distributors. However, it exempts: FDA-approved manufacturers; medical gas manufacturers or distributors that manufacture or distribute medical gases only; as well as veterinary supply distributors that distribute legend

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1. California Code, Business and Professions Code - BPC § 4043
One registration obligation commonly overlooked is the requirement that wholesale manufacturers and distributors obtain a wholesale distribution license.

These laws impose substantial operational requirements on both device and pharmaceutical companies. For example, Louisiana requires the adoption of certain policies and procedures and California requires fingerprinting, a trained “responsible person” and a bond. What is more, these requirements vary widely from state to state.
Enforcement

There are a variety of mechanisms through which the state may become aware that a company is not registered. For example, customers or competitors may simply report the non-conformance to the state. In this regard, at least with respect to pharmaceuticals, the FDA encourages purchasing physicians to verify the source of the drugs they purchase; it says: “Prescription drugs should only be purchased from wholesale drug distributors licensed in the United States. To verify a wholesale drug distributor is licensed in the state(s) where it is conducting business...access your state licensing authority’s database or contact information.”

Also, states may cross-reference registrations required for transparency reporting (a.k.a. State Sunshine Acts) with licensure requirements (Massachusetts’s licensure application requires an attestation that the applicant has a distributor license). Finally, states could cross-reference the licensing database with the Sunshine Act reporting database maintained by CMS, which could indicate the presence of a company in a particular state. Failing to register puts you at risk of state enforcement action, which, in our experience, can include an order to suspend shipping to the state until the matter is rectified. In addition, unregistered companies put their customers at risk. For example, in Texas the state prosecuted physicians who had purchased IUDs from an unregistered company called Medical Device King. The Texas Medical Society explained, “Texas...is cracking down on physicians who purchase medical products and drugs deemed illegal to use in the United States.” In some instances, the physicians purchased misbranded products or medical devices from outside the United States.

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3. AG Targets Doctors for Illegal Drug, Device Purchases
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Contact Us
Learn more about wholesale distributor licenses by contacting Sheva Sanders or Tricia Kaufman, attorneys with deep experience in the life sciences industry.