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## Drug Wholesaling in Florida—The Top Five Myths



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Florida boasts the most stringent pharmaceutical distribution regulations in the United States. When they do business in Florida, some of the most sophisticated drug companies in the world discover the hard way that their compliance protocols need retooling. The Florida Department of Business and Professional Regulation (“DBPR”) dispatches inspectors on a routine basis to drug wholesalers and their customers to investigate compliance with Florida law.

When investigators discover violations, the repercussions can be substantial, including potential criminal prosecution; administrative fines up to \$5,000 per violation per day; greater criminal fines; lost business from license suspension, revocation, or non-renewal; and attorney’s fees and costs.<sup>1</sup> Companies commonly also have to report these violations to authorities in other jurisdictions. Five myths are central to most of these violations. Wholesalers that take them into account are much less likely to face adverse administrative action in Florida.

<sup>1</sup> § 499.066(3), Fla. Stat. (administrative penalties and fines); § 499.0051, Fla. Stat. (criminal fines up to \$600,000); § 499.067, Fla. Stat. (suspension or revocation).

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### The ‘Adulterated Drug’ Myth

The first myth is that an “adulterated drug” is always hazardous to human health. In Florida, an “adulterated drug” includes one that has been “purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so.”<sup>2</sup> Untainted drugs shipped for entirely valid purposes, but without proper licenses or with improper pedigree papers are adulterated in Florida. Selling or offering to sell a drug that is adulterated is illegal.<sup>3</sup> Worse, it is a felony to sell or deliver a “contraband prescription drug,”<sup>4</sup> which is defined as including an adulterated drug.<sup>5</sup>

Non-residents selling drugs into Florida have two primary licenses to choose between to do business in Florida: (1) the non-resident prescription drug manufacturer permit<sup>6</sup> (the “manufacturer permit”) or (2) the out-of-state prescription drug wholesale distributor permit (the “wholesaler permit”).<sup>7</sup> There are a variety of separate permit options for in-state entities. Consistent with common usage, a “manufacturer” under Florida

<sup>2</sup> § 499.006(10), Fla. Stat.

<sup>3</sup> § 499.005(1), Fla. Stat.

<sup>4</sup> § 499.0051(6), Fla. Stat.

<sup>5</sup> § 499.003(12), Fla. Stat.

<sup>6</sup> § 499.01(2)(c), Fla. Stat. (“A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States. . . .”)

<sup>7</sup> § 499.01(2)(c)1, Fla. Stat. (“[a] person that distributes prescription drugs for which the person is not the manufacturer must [] obtain an out-of-state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to engage in the wholesale distribution of such prescription drugs. . . .”)

law is a “person who prepares, derives, manufactures, or produces a drug, device or cosmetic.”<sup>8</sup> With numerous exceptions, a “wholesale distributor” (“wholesaler”) is a person who distributes prescription drugs to persons other than a consumer or patient.<sup>9</sup> Having the right permits, as well as compliant pedigree papers and audit trail documents, is critical to avoid DBPR labeling a drug “adulterated.”

### Wholesaler Permit Myths

Nonresident manufacturers commonly believe that they must have a wholesaler permit to wholesale drugs in Florida. This is the second myth that causes unnecessary problems for nonresident manufacturers. Obtaining and maintaining a Florida prescription drug wholesale distributor permit (whether out-of-state or in-state) is generally more difficult than a manufacturer permit. A primary reason is that a wholesale distributor must employ in a managerial position a certified “designated representative” (“CDR”), who has passed a written Florida examination and has at least two years of full-time work experience in recordkeeping for a licensed pharmacy or licensed prescription drug wholesale company.<sup>10</sup>

A wholesaler may not operate for more than ten business days without a CDR on staff.<sup>11</sup> The CDR must be on duty during normal operating hours.<sup>12</sup> This gives CDRs tremendous leverage within a firm and makes their departure on two weeks’ notice especially difficult. This hardship may be alleviated simply by choosing the manufacturing permit over the wholesaler permit. A manufacturer permit entitles a drug manufacturer both to manufacture and engage in wholesale distribution.<sup>13</sup> Nonresident manufacturing includes wholesaling under Florida law.

A related myth leading wholesalers to obtain unnecessary wholesaler permits assumes manufacturing involves producing drugs. Although this is part of the definition of a manufacturer under Florida law, non-residents which wholesale, but do not manufacture drugs can avoid the wholesaler permit in several ways such as (1) when the non-manufacturer is part of an “affiliated group” with a Florida licensed manufacturer<sup>14</sup> (2) when acting as a private label distributor that does not repackage,<sup>15</sup> or (3) in the event of intra-

company transfers.<sup>16</sup> A non-resident seller, transferor or deliverer on a wholesale basis of drugs manufactured by a company within an affiliated group with or as a private label distributor for the manufacturer may choose the manufacturer license in lieu of the wholesaler permit.

Likewise, intracompany sales or transfers of a drug from a nonresident that is licensed as a wholesaler by its state of residence to a Florida-licensed wholesaler are permitted if both wholesale distributors conduct business under the same name.<sup>17</sup> Even sophisticated drug companies mistakenly broaden these exemptions beyond the statutory confines. Not exempt from the Florida wholesaler permit are intercompany transfers between nonresidents or a non-resident and licensed resident without the same name unless by an affiliated manufacturer; or transfers on a wholesale basis of drugs manufactured by an unaffiliated company.

### The Sales Office Myth

The third myth is that sales offices for wholesalers and retailers do not need a permit. Many sophisticated drug companies have sales offices not co-located with their manufacturing or shipping facilities. They assume that if the manufacturing and shipping facilities are licensed, nothing more is required. But Florida law defines a “wholesale distributor” to include any person engaged in wholesale “distribution” of prescription drugs into Florida,<sup>18</sup> which includes sales, offers to sell, or offers to deliver drugs.<sup>19</sup> Consequently, even sales offices must ordinarily be licensed if they are selling or offering to sell drugs into Florida.

### The Pedigree Paper Myth

Florida enforces “cradle to grave” audit trail requirements for drugs, meaning that drug wholesalers must maintain documentation about the name, strength, dosage form and quantity of drugs; their source and its Florida permit number; the purchaser and its Florida permit number; the recipient (if different from the purchaser) and its Florida permit number; related dates of receipt, distribution or disposition; and related financial information.<sup>20</sup> In addition to a general recordkeeping requirement, wholesale distributors must maintain detailed pedigree papers in a specific format.<sup>21</sup> For large companies, different divisions or subsidiaries may be involved at each step from the manufacture to the sale and delivery of drugs. Sometimes, the drug pedigrees do not fully reflect this; other times, they state on their face corporate names or trade names not involved whatsoever in the transaction.

<sup>8</sup> § 499.003(31)(a), Fla. Stat.; accord § 499.003(30), Fla. Stat. (“manufacture” means “the preparation, deriving, compounding, propagation, processing, producing or fabrication of any drug, device or cosmetic.”)

<sup>9</sup> § 499.003(54), Fla. Stat.

<sup>10</sup> § 499.012(16)(a)(b), Fla. Stat.

<sup>11</sup> § 499.012(16)(f), Fla. Stat.

<sup>12</sup> § 499.012(16)(d), Fla. Stat.

<sup>13</sup> § 499.01(2)(c), Fla. Stat. (“A non-resident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs . . . located outside of this state or outside the United States and that engages in the wholesale distribution in this state of such prescription drugs.”)

<sup>14</sup> § 499.003(31)(e), Fla. Stat. (the term “affiliated group” means an affiliated group as defined in s. 1504 of the Internal Revenue Code of 1986, as amended).

<sup>15</sup> *Id.* at 31(c). Other exceptions include, *inter alia*, transfers of drugs among health care entities that are under common control; transfers to public agencies; donations to charitable organizations, distribution of drug samples. See § 499.003(54), Fla. Stat.

<sup>16</sup> § 499.01(2)(e)2., Fla. Stat.

<sup>17</sup> *Id.* at (4)(c) (exempting from licensure the “intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor in its state of residence to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name.”)

<sup>18</sup> § 499.003(55), Fla. Stat.

<sup>19</sup> § 499.003(17), Fla. Stat. (“to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver.”)

<sup>20</sup> § 499.0121(6)(a), Fla. Stat.; Rule 61N-1.012(2)(a), Fla. Admin. Code.

<sup>21</sup> § 499.01212, Fla. Stat.

The fourth myth is that as long as one of the corporations on the pedigree is properly licensed, nothing more is required. To the contrary, all of the corporate names and addresses in the pedigree must be properly licensed. Furthermore, Florida enforces a “one-document” rule, pursuant to which all of the documents related to a particular drug’s pathway through the channel of trade must be together (if not on a single page).<sup>22</sup> Florida also requires that the pedigree be readily retrievable for inspection at the licensed site or, if maintained at a central location outside of Florida and not electronically retrievable, available for inspection within two working days at the request of a state official.<sup>23</sup>

### The Permit Status Myth

The last myth that commonly trips up drug companies which wholesale in Florida arises from the erroneous assumption that sellers may rely upon buyers for updates concerning their permit status. To the contrary, Florida imposes a bilateral duty upon buyers and sellers to ensure that the other is properly licensed.<sup>24</sup> This is an ongoing duty at the point of sale. Because the licensing

status of companies is continually subject to revocation, not merely annual relicensure, this requirement imposes upon both sides an obligation to consult the Florida license database before consummating a transaction. DBPR has stated informally that, because it updates its electronic licensure database electronically each week, companies selling into Florida should be updating their own client licensure databases weekly.

### Conclusion

For companies that wholesale drugs in multiple jurisdictions, complying with Florida drug licensing laws can be frustrating. To continue to do business in Florida, they must either tailor their protocols specifically for Florida or standardize them consistent with Florida law. Regular training and software programming around bright line protocols consistent with Florida law are critical because institutional gravity constantly pulls toward the minimum uniform regulatory standard. When this happens, the five myths reassert themselves. It is always cheapest for counsel to assist with this preemptively, rather than once DBPR issues a notice of violation or notice of intent not to renew a license.

<sup>22</sup> Rule 61N-1.012(2)(a), Fla. Admin. Code.

<sup>23</sup> § 499.0121(6)(c), Fla. Stat.

<sup>24</sup> § 499.005(15), Fla. Stat. (making unlawful “[t]he sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from

the person selling or transferring the prescription drug”); § 499.005(14), Fla. Stat. (making unlawful “[t]he purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient.”)