

Wholesale Distributor Licensing

The FDA is requiring wholesale distributors to report their licensing status and contact information to the FDA. This information will then be made available in a public database.¹⁰ Perhaps the sheer size of some of the wholesale distributors is driving this need on the contact information.

Third-Party Logistics Provider Licensing

The FDA is requiring that third-party logistic providers, those who provide storage and logistical operations related to drug distribution, obtain a state or federal license.¹¹ This is actually a very good and long overdue requirement. During the first year, ending November 27, 2014, third-party logistics providers reported to the secretary of Health and Human Services the state by which their facilities are licensed, the appropriate identification number of such license, and the name and address of the facilities and all trade names under which such facilities conduct business. By 2017, there are a series of regulations to be developed to govern the activities of third-party logistics providers to bring them into the fold of the pharmaceutical drug supply chain.¹²

The upcoming regulations will include the licensing process based on a to-be-developed accreditation program; drug-safe and secure storage practices, including a quarantine area for facilities; and written policies and procedures that address the receipt, security, storage, inventory, shipment, and distribution of a product. These policies and procedures shall also include the identity, record, and report of confirmed losses or thefts in the United States; correct errors and inaccuracies in inventories; provide support for manufacturer recalls; prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood; and ensure that any expired product is segregated from other products and returned to the manufacturer or repackager or destroyed. These policies and procedures shall also maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory, and quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency. (This appears to be directed at return logistics providers, which we will cover in Chapter 7.) These regulations also provide for periodic inspections by the licensing