ARIZONA HOUSE OF REPRESENTATIVES

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SB 1234: pharmacy board; virtual manufacturers
Sponsor: Senator Shamp, LD 29
Committee on Regulatory Affairs

Overview

Prescribes requirements for *virtual manufacturers* to comply with Current Good Manufacturing Practice (CGMP) regulations and includes applicable requirements for when a contracted manufacturer is in another country.

History

The United States Food and Drug Administration monitors drug manufacturers for compliance with its Current Good Manufacturing Practice (CGMP) regulations to ensure the quality of drug products. CGMP regulations consist of minimum requirements for the methods, facilities and controls for the manufacturing, processing and packaging of drug products. For a new and generic drug to enter the market, the FDA must determine whether the manufacturer complies with CGMP regulations (CGMP).

Virtual manufacturers are required to ensure that the facility is inspected when an initial or renewal application for determining the contracted manufacturer's CGMP compliance if the manufacturer is in another country. *Virtual manufacturer* includes own-label distributors that contract with a manufacturer to produce a drug or device and with another entity to package and label the drug or device, which then is sold under the name of the distributor or another name (A.A.C. R4-23-110)

The State Board of Pharmacy (Board) regulates the practice of pharmacy to protect the health safety and welfare of Arizona citizens. The Board is authorized to issue specified permits in the field of pharmacy which include: 1) a pharmacy permit; 2) a drug manufacturer's permit; 3) a drug packager or drug prepackager permit; and 4) a durable medical equipment or compressed medical gas distributor or supplier permit. The Board is tasked with prescribing and furnishing the requirements for a pharmacy permit application. Statute outlines the grounds for the denial or revocation of a pharmacy permit by the Board (A.R.S. §§ 32-1929, 32-1930).

Provisions

1. Defines *virtual manufacturer* as an entity that:
   a) contracts for the manufacture of a device including private label distributors;
   b) owns either the FDA new drug application or abbreviated drug application number for a drug or the unique FDA device identification number for a prescription device;
   c) does not physically manufacture the drug or device; and
   d) contracts with an FDA registered manufacturer for the physical manufacture of the drug or device. (Sec. 1)

☐ Prop 105 (45 votes)	☐ Prop 108 (40 votes)	☐ Emergency (40 votes)	☐ Fiscal Note

2. Requires a *virtual manufacturer* located in Arizona or any other jurisdiction, that is responsible for the shipment of prescription drugs or devices into Arizona, to make professionally reasonable efforts to ensure that FDA registered manufacturing entity complies with applicable CGMP regulations. (Sec. 2)
3. Directs *virtual manufacturers* of prescription drugs to contract with a permitted drug manufacturer in Arizona unless the contracted manufacturer is located in another country. (Sec. 2)
4. Makes conforming changes. (Sec. 1)