



ARIZONA STATE SENATE
Fifty-Second Legislature, First Regular Session

FACT SHEET FOR S.B. 1039

pharmacy board; regulation; transactions

Purpose

Makes various changes to Arizona State Board of Pharmacy (Board) statutes including requirements related to resident and nonresident pharmacies, wholesalers and product records.

Background

Established in 1903, the Board regulates the practice of pharmacy and the distribution, sale and storage of prescription medications, prescriptive devices and nonprescription medications. The Board consists of nine Governor-appointed members, including six pharmacists, one pharmacy technician and two consumer members who are appointed for five-year terms and are eligible to receive \$200 a day in compensation. According to the Joint Legislative Budget Committee, the budget includes \$2,017,600 and 18 FTE Positions from the Arizona State Board of Pharmacy Fund in FY 2015 for the operating budget.

Current statute requires full-service wholesale permittees to establish and maintain inventories and records of all transactions regarding the receipt and distribution of prescription-only drugs including pedigrees for all prescription-only drugs that leave the normal distribution channel (A.R.S. § 32-1984). The pedigree must include: 1) the name of the prescription-only drug; 2) the dosage form and strength of the drug; 3) the size of the container; 4) the number of containers; 5) the lot number of the prescription-only drug; 6) the name of the finished dosage form; and 7) all necessary identifying information regarding each sale in the chain of distribution of the product from the manufacturer through the acquisition and sale by any full service wholesale permittee and until final sale to a pharmacy or other person dispensing or administering the drug.

In November 2013, President Obama signed the Drug Quality and Security Act (Act), which amends the Federal Food, Drug and Cosmetic Act with respect to the regulation of compounding drugs. Specifically, the Act exempts compounded drugs from new drug requirements, labeling requirements and track and trace requirements if the drug is compounded by or under the direct supervision of a licensed pharmacist in a registered outsourcing facility and meets applicable requirements. Title II of the Act establishes requirements to facilitate the tracing of prescription drug products through the pharmaceutical supply distribution chain and preempts state and local requirements related to tracing drugs through the distribution system.

There is no anticipated fiscal impact to the state General Fund associated with this legislation.

Provisions

Dispensing, Compounding and Sale of Drugs

1. Allows a resident pharmacy to compound drugs for distribution to a resident medical practitioner and requires that such compounded drug:
 - a) be for the purpose of administration to the medical practitioner's patient; and
 - b) not exceed five percent of the total number of drug dosage units dispensed and distributed by the resident pharmacy on an annual basis.
2. Allows a resident pharmacy to dispense and ship compounded drugs into another state or jurisdiction only to fulfill a valid patient-specific prescription order. Prohibits a resident pharmacy from distributing compounded drugs into another state or jurisdiction.
3. Allows a nonresident pharmacy to dispense and ship compounded drugs into this state if:
 - a) the nonresident pharmacy has a current board-issued permit; and
 - b) the dispensing and shipping of the compounded drugs is for the purpose of fulfilling a patient-specific prescription order.
4. Restricts a nonresident pharmacy from distributing compounded drugs into this state.
5. Modifies the timeframe a proprietor, manager or pharmacist in charge must provide documents to an authorized Board agent, from four working days to two business days after receiving a request.
6. Adds authorized officers of the law to those who may request such records.
7. Adds product tracing records to that list of required documents.
8. Redefines *third party logistics provider* as a person who:
 - a) provides or coordinates warehousing or other logistics services for drugs on behalf of a manufacturer, repackager, wholesaler or pharmacy;
 - b) does not take ownership of the drugs; and
 - c) does not have the responsibility to direct the sale or disposition of the drugs.

Exemptions from Wholesaler Requirements

9. Modifies the definition of wholesale distribution to exclude a public health emergency declaration.
10. Exempts a person who sells, purchases, distributes, transfers or trades a drug for public health emergency declarations from requirements for wholesalers.
11. Maintains the exemption from wholesaler requirements for persons who sell, purchase, distribute, transfer or trade a drug for emergency medical reasons, but states that a drug shortage that is not caused by a public health emergency does not constitute an emergency medical reason, with exceptions.

12. Specifies that a pharmacy-to-pharmacy transfer of a drug to fill a prescription order for a specific identified patient meets the definition of an emergency medical reason.

Full-service Wholesale Permittees

13. Removes the requirement that a full-service wholesale permittee (permittee)'s designated representative must have been employed full-time for at least three years in a pharmacy or with a permittee in a capacity related to the dispensing and distribution, and record keeping related to, prescription drugs.
14. Adds product tampering to the list of crimes that a permittee's designated representative (representative) must not have been convicted.
15. Mandates, instead of allows, the Board to require the representative to submit a full set of fingerprints to the Department of Public Safety (DPS) for the purpose of obtaining a state and federal criminal records check, and requires, instead of allows, the Board to charge each applicant a fee as determined by DPS.
16. Allows the Board to accept a bond of \$25,000 if the permittee's annual gross receipts of the previous tax year were \$10 million or less. Requires, instead of allows, the Board to waive the bond requirement if the permittee has previously obtained a comparable surety bond or other equivalent means of security for the purpose of licensure in another state where the permittee has a valid license in good standing.
17. Requires the Board to waive the bond requirement if the permittee is government owned and operated.
18. Removes the current requirements and restrictions regarding permittee returns and exchanges, and instead allows a permittee to accept them pursuant to the requirements of state and federal law.
19. Allows permittees to furnish prescription only drugs to drug repackagers and other wholesalers.

Product Records and Other Documents

20. Adds product tracing records, as required by state or federal law, to the list of records maintained by each permittee.
21. Requires each permittee to maintain inventory and transaction records for at least six years, and requires the permittee to make these records available to the Board upon request or inspection.

Miscellaneous

22. Adds to the definition of *compounding* the combining, admixing, mixing, diluting, pooling, reconstituting or otherwise altering of a drug or bulk drug substance by or under the

supervision of a pharmacist in a federally registered outsourcing facility to create a sterile drug for the purpose of distribution to pharmacies and medical practitioners.

23. Defines *drug repackager* as an individual or establishment that:
 - a) is currently registered with the U.S. Food and Drug Administration (FDA); and
 - b) meets FDA requirements to purchase, repackage, relabel or otherwise alter the manufacturer's original package of an approved drug product with the intent to resell that item to persons or businesses that are authorized to possess or resell the repackaged or relabeled drug.

24. Defines *outsourcing facility* as a facility that:
 - a) is currently registered with the FDA as an outsourcing facility; and
 - b) meets the FDA requirements to engage in the compounding and distribution of sterile drugs.

25. Defines *product tracing records* as records, if required by federal law, documenting the movement of prescription-only drugs throughout the pharmaceutical supply chain.

26. Repeals A.R.S. § 32-1984 relating to pedigrees and electronic files.

27. Makes technical and conforming changes.

28. Becomes effective on the general effective date.

Prepared by Senate Research

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