

# Arizona Veterinary or is it Pharmacy

FDA - 2015

**1970's**

Veterinary Pharmacist  
considered unlawful practice of Veterinary  
Medicine  
complaints all from veterinarians

**NOW**

**Niche Pharmacy Practice  
Veterinarian Partners**

Consumer & Pharmacy Complaints

**State of Arizona  
Senate**

**Fifty-second Legislature  
First Regular Session 2015**

**SENATE BILL 1039 AN ACT Amending sections 32-1901,  
32-1961, 32-1963, 32-1981, 32-1982 and 32-1983,  
Arizona Revised Statutes; repealing section 32-1984,  
Arizona Revised Statutes; relating to the  
Arizona state board of pharmacy.**

**8. "Compounding":**

**(a) Means either of the following:**

- i) The preparation, mixing, assembling, packaging or labeling of a drug a pharmacy by a pharmacist or an intern or pharmacy technician under the pharmacist's supervision, for the purpose of dispensing to a patient based on a valid prescription order**
- (ii) 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.**

(b) Compounding Pursuant to subdivision (a), item (i) of this paragraph, includes both of the following:

(i) The preparation of drugs in anticipation of prescription orders prepared based on routine, regularly observed prescribing patterns. And

(ii) The preparation of drugs as an incident to research, teaching or chemical analysis or for administration by a medical practitioner to the medical practitioner's patient and not for sale or dispensing.

Compounding Pursuant to subdivision (a), item (i) of this paragraph,

does not include either of the following:

(i) The preparation of commercially available products from bulk compounds.

or(ii) The preparation of drugs for sale to pharmacies, practitioners or entities for the purpose of dispensing or detrin

**58. "Outsourcing facility" means a facility that is currently registered with the United States food and drug administration as an outsourcing facility and that meets the requirements of that agency to engage in the compounding and distribution of sterile drugs.**

## **32-1961. Dispensing, compounding and sale of drugs; limitations**

**A. A resident pharmacy may compound drugs for distribution to a resident medical practitioner for the purpose of administration to the medical practitioner's patient. The amount of drug a resident pharmacy distributes under this subsection may not exceed five percent of the total number of drug dosage units dispensed and distributed by the resident pharmacy on an annual basis.**



B. A resident pharmacy may dispense and ship compounded drugs into another state or jurisdiction only pursuant to a valid patient-specific prescription order and in compliance with the applicable laws of the receiving state or jurisdiction. A resident pharmacy may not distribute compounded drugs into another state or jurisdiction.

**C. A nonresident pharmacy with a current board-issued permit may dispense and ship compounded drugs into this state only pursuant to a valid patient-specific prescription order. A nonresident pharmacy may not distribute compounded drugs into this state.**

**D. A person is prohibited from compounding a drug that is commercially available**

**4. "Third-party logistics provider" means a person who receives prescription-only drugs only from the original manufacturer, who delivers the prescription-only drugs at the direction of that manufacturer and who does not purchase, sell, trade or take title to prescription-only drugs provides or coordinates warehousing or other logistics services for drugs on behalf of a manufacturer, drug repackager, wholesaler or pharmacy but who does not take ownership of the drugs and does not have the responsibility to direct the sale or disposition of the drugs.**

**Bill Number: S.B. 1039**

**Barto Floor Amendment**

**drafted by: Leg Council FLOOR AMENDMENT EXPLANATION**

**The Barto amendment excludes veterinary compounded drugs from restrictions on dispensing, shipping and distributing compounded drugs into another state or jurisdiction. This amendment also specifies that a drug shortage for veterinary medications constitutes an emergency medical reason, and therefore is excluded from the regulation of wholesale distribution.**

**Fifty-second Legislature**

**First Regular Session**

**Barto**

**S.B. 1039 BARTO**

**FLOOR AMENDMENTSENATE AMENDMENTS TO S.B. 1039(Reference to printed bill) Page 11, line 34, after the period insert "This subsection does not apply to veterinary compounded drugs."Page 14, line 3, after "patient" insert "or a drug shortage for veterinary medications"Amend title to conform**



Arizona State Board of Pharmacy

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Dear Committee Members:

The members of the Arizona State Board of Pharmacy oppose the amendments as presented for SB 1039, and respectfully request the committee remove the amendments from the bill.

Compounding under the practice of pharmacy in Arizona is defined as the "compounding of drugs pursuant to or in anticipation of a prescription order." This is the traditional definition of pharmacy compounding practice and is utilized in some manner in all states and in federal legislation.

In general, it is the FDA that regulates and approves the manufacturing of drugs. There are exceptions for the compounding of drugs by a pharmacy, but the exceptions are intended to be limited. Per the FDA, "Compounded drugs are not FDA approved. This means that FDA does not verify the safety, or effectiveness of compounded drugs. Consumers and health professionals rely on the drug approval process to ensure that drugs are safe and effective and made in accordance with Federal quality standards. Compounded drugs also lack an FDA finding of manufacturing quality before such drugs are marketed."

While the DQSA does not apply specifically to drugs compounded for animals, this does not mean that the FDA has been silent on the issue. Attached is CPG Section 608.400 Compounding of Drugs for Use in Animals. In the discussion section, "The Federal Food, Drug, and Cosmetic Act (the Act) does not distinguish compounding from manufacturing or other processing of drugs for use in animals. FDA acknowledges the use of compounding within certain areas of veterinary practice." **However, FDA is greatly concerned about veterinarians and pharmacies that are engaged in manufacturing and distributing unapproved new animal drugs in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the Act.**

In the policy section of the CPG, the FDA states "Generally, the FDA will defer to state authorities regarding the day-to-day regulation of compounding by veterinarians and pharmacists of animal and human drugs that are intended for use in animals." **However, when the scope and nature of the activities of veterinarians and pharmacists raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new animal drug, adulteration, or misbranding provisions of the Act, FDA has determined that it will seriously consider enforcement action.**

In drafting the current changes to statute, the Board considered all areas of pharmacy compounding practice, any applicable federal legislation and guidance, and the scope of the practice of pharmacy. It is the Board's opinion that the amendments exceed the scope of practice of pharmacy.