The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1180
INTRODUCER:	Senator Latvala and others
SUBJECT:	Practice of Pharmacy
DATE:	March 19, 2015 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HP	**Pre-meeting**
2.			RI	
3.			FP	

I. Summary:

SB 1180 amends the Pharmacy Practice Act to define the term "office use compounding" and to provide in statute that the pharmacy practice act does not prohibit a veterinarian from dispensing a compounded drug to the owner or caretaker of his or her animal patient.

II. Present Situation:

Veterinary Medical Practice

The Board of Veterinary Medicine within the Department of Business and Professional Regulation is charged with the regulation of the practice of veterinary medicine under ch. 474, F.S., the Veterinary Medical Practice Act (Veterinary Act). The legislative purpose for the act is to ensure that every veterinarian practicing in Florida meets minimum requirements for safe practice and veterinarians who are not normally competent or who otherwise present a danger to the public are disciplined or prohibited from practicing in Florida.

The practice of veterinary medicine includes:

- Diagnosing the medical condition of animals and prescribing, dispensing, or administering drugs, medicine, appliances, applications, or treatment of whatever nature for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease thereof.
- Performing any manual procedures for the diagnosis of or treatment for pregnancy or fertility or infertility of animals.
- Representing oneself by the use of titles or words, or undertaking, offering, or holding oneself out, as performing any of these functions.
- Determining the health, fitness, or soundness of an animal.[1]

[1] Section 474.202(9), F.S.

Veterinary medicine includes, with respect to animals, surgery, acupuncture, obstetrics, dentistry, physical therapy, radiology, theriogenology, and other branches or specialties of veterinary medicine.[2]

With several exceptions, a person must be licensed as a veterinarian under the act, prior to practicing veterinary medicine in this state.[3] Veterinarians who hold a valid federal controlled substance registry number are authorized to prescribe and dispense controlled substances pursuant to ch. 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act.

Pharmacy Practice Act

Pharmacies and pharmacists are regulated under the Florida Pharmacy Act (Act) found in ch. 465, F.S.[4] The Board of Pharmacy (the board) is created within the Department of Health (DOH) to adopt rules to implement provisions of the Act and take other actions based upon duties conferred on it by the Act.

The practice of the profession of pharmacy includes:
- Compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug.
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations.
- Monitoring a patient's drug therapy, assisting the patient in managing his or her drug therapy, and reviewing the patient's drug therapy and communicating with the patient's prescribing health care provider or the provider's agent or other persons as specifically authorized by the patient, regarding the drug therapy.
- Transmitting information from persons authorized to prescribe medicinal drugs to their patients.
- Administering vaccines to adults.[5]

Compounding

Compounding is defined under the Act as combining, mixing, or altering the ingredients of one or more drugs or products to create another drug or product.[6] Under the board's rules,[7] compounding includes the preparation of:
- Drugs or devices in anticipation of prescriptions based on routine, regularly-observed prescribing patterns;
- Drugs or devices, pursuant to a prescription, that are not commercially available; [8] or
- Commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that

[2] Section 474.202(13), F.S.
[3] *See* ss. 474.203, 474.207, and 474.213, F.S.
[4] Other pharmacy paraprofessionals, including pharmacy interns and pharmacy technicians, are also regulated under the Act.
[5] Section 465.003(13), F.S.
[6] Section 465.003(18), F.S.
[7] *See* Rule 64B16-27.700, F.A.C.
[8] The term "commercially available product" means any medicinal product that is legally distributed in Florida by a drug manufacturer or wholesaler. *See* Rule 64B16-27.700, F.A.C.

> the compounded product will be prepared by the pharmacist. The reconstitution of commercially available products pursuant to the manufacturer's guidelines is permissible without notice to the practitioner.

The rule goes on to say that the preparation of drugs or devices for sale or transfer to pharmacies, practitioners, or entities for purposes of dispensing or distribution is not compounding and it not within the practice of the profession of pharmacy...[9]

Historically and continuing today, a practitioner might prescribe a compounded preparation when a patient requires a different dosage form, such as a liquid rather than a pill or tablet, a different dosage strength than is commercially available, a product free of certain allergens, or a product that is not commercially available. Compounding and dispensing in this manner is typically patient-specific.

More recently, the practice of compounding medications has evolved and expanded to include compounding for office use. "Office use" is not currently defined in Florida Statutes, but is defined in rules of the board.

"Office use" means the provision and administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy.[10] The rule authorizes a pharmacist to dispense and deliver a quantity of a compounded drug to a practitioner for office use by the practitioner provided:

- The quantity compounded does not exceed the amount a practitioner may use in his or her office before the expiration date of the drug;
- The quantity compounded is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice;
- The total quantity compounded does not exceed the pharmacy's capacity to comply with pharmaceutical standards;
- The pharmacy and practitioner enter into a written agreement that provides:
  - The compounded drug may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity;
  - The practitioner will record product identifying information in the patient's record;
  - The practitioner will provide notification to the patient regarding the reporting of an adverse reaction or complaint in order to facilitate a recall of the compounded product;
- The pharmacy maintains records of all compounded drugs ordered by practitioners for office use;
- The pharmacy labels the compounded drug with specified information; and
- The pharmacy is an outsourcing facility and complies with those requirements.

Until recently, the regulation of compounded medications was without clear guidelines or oversight responsibility by the FDA or state agencies. The FDA traditionally regulated the

[9] The rules continues, except that the supply of patient specific compounded prescription to another pharmacy under the provisions of s. 465.0265, F.S., and Rule 64B16-28.450, F.A.C., is authorized. These provisions pertain to centralized prescription filling for another pharmacy.
[10] Rule 16B16-27.700, F.A.C.

manufacture of prescription drugs, which typically includes making drugs (preparation, deriving, compounding, propagation, processing, producing, or fabrication) on a large scale for marketing and distribution of the product for unidentified patients. State boards of pharmacy historically have regulated the compounding of medications by a pharmacy under the practice of pharmacy that are requested for an identified patient.[11]

However, after a nationwide crisis in 2012 relating to contaminated human sterile drugs that had been compounded in pharmacies, enhanced regulation of sterile compounded human drugs was enacted at the federal level. President Barack Obama signed the Drug Quality and Security Act (DQSA)[12] into law on November 27, 2013. Under this law[13] a compounder of human drugs can become an outsourcing facility. An outsourcing facility is able to qualify for exemptions from, among other things, the FDA approval requirements for new drugs.

Compounding Animal Drugs

The DQSA does not cover the compounding of animal drugs.[14] In a footnote to FDA guidance on pharmacy compounding of human drug products after the DQSA, the FDA noted that the statutory and regulatory provisions governing the compounding of human drug products differ from those governing the compounding of animal products. All relevant statutory and regulatory requirements relating to the compounding of animal drug products remain in effect, subject to the requirements of section 512 of the Food Drug and Cosmetic Act.[15] Section 512 of the Food Drug and Cosmetic Act addresses the new animal drug approval requirements, which correspond to the approval process for new drugs for humans.

In the related information section on the FDA compounding website[16] information pertaining to animal drugs refers viewers to CPG Sec. 608.400 Compounding of Drugs for Use in Animals.[17] This document provides guidance to drug compounders, veterinarians, and the staff of the FDA on how the FDA intends to address compounding of drugs intended for use in animals. This guidance describes FDA's current thinking on what types of compounding might be subject to enforcement action. Generally the guidance articulates FDA's policy that it will defer to state

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[11] *See generally* U.S. Department of Health and Human Services, FDA, Regulatory Guidance for Compounded Drugs, *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm (last visited March 19, 2015).

[12] H.R. 3204, 113th Congress.

[13] section 503B

[14] U.S. Department of Health and Human Services, FDA, Compounding and the FDA: Questions and Answers, question 12, at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm (last visited March 19, 2015).

[15] U.S. Department of Health and Human Services, FDA, *Guidance for Pharmacy compounding of Human Drug Products Under Section 503A of the Federal Food, Drug and Cosmetic Act,* July 2014, footnote 3, available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm377052.pdf (last visited March 19, 2015).

[16] U.S. Department of Health and Human Services, FDA, Compounding, last updated March 6, 2015, at: http://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ (last visited March 19, 2015).

[17] The CPG is available at: http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074656.htm, (last visited March 19, 2019).

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 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 Food, Drug and Cosmetic Act, the FDA will consider enforcement action. The guidance lists 13 factors, any of which may trigger enforcement action. Two of the thirteen factors involve compounding drugs for use in situations where the health of the animal is not threatened and where suffering or death of the animal is not likely to result from failure to treat, and compounding drugs for third parties who resell to individual patients.

Dispensing Practitioner

Section 465.0276, F.S., in the Act relates to dispensing practitioners. Under this section, a person is prohibiting from dispensing medicinal drugs unless licensed as a pharmacist or otherwise authorized under the Act to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section of law.

This section requires a practitioner who dispenses medicinal drugs for human consumption for fee or remuneration of any kind to register with her or his professional licensing board as a dispensing practitioner, pay a registration fee, and comply with and be subject to all laws and rules applicable to pharmacists and pharmacies. Additional responsibilities are placed on practitioners who register under this section. Because veterinarians do not dispense medicinal drugs for human consumption, and the Veterinary Act does not have a corresponding registration requirement, veterinarians do not register with the Board of Veterinary Medicine.

Dispensing, Prescribing, and Administering

"Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer thereof or to one who represents that it is his or her intention not to consume or use the same but to transfer the same to the ultimate consumer or user for consumption by the ultimate consumer or user.[18]

"Prescribing" is issuing a prescription. For purposes of the bill, a "prescription" includes an order for drugs that is written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a practitioner licensed by the laws of the state to prescribe such drugs, issued in good faith and in the course of professional practice, intended to be filled or dispensed by another person licensed to do so.[19]

"Administer," for purposes of the bill, means the direct application of a drug, whether by injection, inhalation, ingestion, or any other means, to the body of a person or animal.[20]

[18] *See* ss 465.003(6) and 893.02(7), F.S.
[19] *See* ss. 465.003(14) and 893.02(20), F.S.
[20] *See* ss. 465.003(1) and 893.02(1), F.S.

III. Effect of Proposed Changes:

The bill defines office use compounding in the Florida Pharmacy Act to mean the provision and administration of a compounded drug to a patient by a practitioner in the practitioner's office or other treatment setting. In the case of veterinary drugs, office use compounding includes compounding for a veterinarian to dispense to the owner or caretaker of the animal patient.

Under the dispensing practitioner provisions in s. 465.0276, F.S., the bill adds a new subsection that provides nothing in this chapter or the rules adopted thereunder prohibit a veterinarian from dispensing a compounded drug to an animal patient or its owner or caretaker.

These provisions appear to grant authority for a pharmacy to compound a drug for a veterinarian to dispense. This language would then supersede the board's rule that governs compounding, at least with respect to drugs intended for use in or on animals, which states that the preparation of drugs for sale or transfer to practitioners for purposes of dispensing is not compounding and is not within the practice of the professional of pharmacy. As a practical matter, Florida licensed pharmacies may be reluctant to compound drugs for dispensing by a veterinarian because under federal law, that drug might be deemed an unapproved new animal drug or otherwise not comply with federal law and subject the pharmacy, pharmacist, and veterinarian to enforcement or professional discipline.[21]

Additional statutory sections are amended to conform cross-references.

The effective date of the bill is July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

[21] Department of Health, *Senate Bill 1180 Analysis* (February 27, 2015), pg. 5 (on file with the Senate Committee on Health Policy.

B. Private Sector Impact:

Veterinarians may find it easier to obtain compounded drugs to dispense to their patients and the animal's caregiver.

C. Government Sector Impact:

The Board of Pharmacy indicates it would need to amend its rules concerning office use compounding; however according to the DOH the costs for rulemaking could be absorbed within existing resources.[22]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 465.003, 465.0276, 409.9201, 458.331, 459.015, 465.014, 465.015, 465.0156, 465.016, 465.0197, 465.022, 465.023, 465.1901, 499.003, and 893.02.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

[22] *Id.*