HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 1049 Practice of Pharmacy
SPONSOR(S): Health & Human Services Committee; Health Quality Subcommittee; Peters and others
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N, As CS	Langston	O'Callaghan
2) Business & Professions Subcommittee	12 Y, 0 N	Anstead	Luczynski
3) Health & Human Services Committee	16 Y, 0 N, As CS	Langston	Calamas

SUMMARY ANALYSIS

Compounding is the practice in which a licensed pharmacist, or other legally permitted individual, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient when the health needs of that patient cannot be met by a medication approved by the U.S. Food and Drug Administration.

The practice of veterinary medicine, defined in the Veterinary Medical Practice Act, ch. 474, F.S., includes prescribing, dispensing, and administering drugs to treat animals.

The bill specifies that the Florida Pharmacy Act, ch. 465, F.S., and the rules adopted under it, do not prevent a veterinarian from administering a compounded drug to an animal that is a patient or dispensing a compounded drug to that animal's owner or caretaker. Additionally, the bill specifies that the provision allowing veterinarians to administer and dispense compounded drugs to their patients or caregivers does not affect the Florida Pharmacy Act.

There is no fiscal impact on state or local governments.

The bill provides for an effective date of July 1, 2015.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Compounding

Compounding is a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools.[1] It is a practice in which a licensed pharmacist or other legally permitted individual combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient when the health needs of that patient cannot be met by a medication approved by the U.S. Food and Drug Administration (FDA).[2] For example, compounding could be necessary when a patient with an allergy needs a medication to be made without a certain dye or an elderly patient or a child is unable to swallow a pill and needs a medicine in a liquid form that is not otherwise available.[3]

Compounded drugs can pose both direct and indirect health risks.[4] Compounded drugs may be unsafe and pose direct health risks because of the use of poor quality compounding practices; they may be sub- or super-potent, contaminated, or otherwise adulterated.[5] Some pharmacists are well trained and well equipped to compound certain medications safely, but not all pharmacists have the same level of skills and equipment, and some drugs may be inappropriate for compounding.[6] However, in other cases, compounders may lack sufficient controls (e.g., equipment, training, testing, or facilities) to ensure product quality or to compound complex drugs like sterile or extended-release drugs.[7]

Regulation of Compounded Medications

Florida

Compounding is defined in s. 465.003(18), F.S., as the combining, mixing, or altering the ingredients of one or more drugs or products to create another drug or product.

The Florida Administrative Code defines compounding as the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient, or for administration by a practitioner or the practitioner's agent.[8] This definition also specifically includes the professional act of preparing a unique finished product containing any ingredient or device and the preparation of:

- Drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.
- Drugs or devices which are not commercially available, pursuant to a prescription.

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[1] *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 361 (2002).
[2] U.S. Food and Drug Administration, *Compounding and the FDA: Questions and Answers*, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm (last visited March 30, 2015).
[3] *Id*.
[4] U.S. Food and Drug Administration, *Compounded Menopausal Hormone Therapy Questions and Answers*, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm183088.htm#MenopausalHormoneTherapy (last visited March 30, 2015).
[5] *Id*.
[6] *Id*.
[7] *Id*.
[8] Rule 64B16-27.700, F.A.C.

- Commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient is aware that the pharmacist will prepare the compounded product. The reconstitution of commercially available products pursuant to the manufacturer's guidelines is permissible without notice to the practitioner.[9]

Section 465.0276, F.S., provides that only a licensed pharmacist, or other person authorized under ch. 465, F.S., or a practitioner authorized by law, may dispense medicinal drugs. Dispensing is defined as the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent.[10] Dispensing is broader than administration. Administration is defined as obtaining and giving a single dose of medicinal drug by a legally authorized person to a patient for his or her consumption.[11]

Federal

Compounded drugs are not FDA-approved; this means that the FDA does not verify the safety, or effectiveness of compounded drugs and these drugs lack an FDA finding of manufacturing quality before such drugs are marketed.[12] However, federal rules currently require that compounded medications only be modified versions of FDA-approved medications.[13] In other words, compounded medications should only be prepared using FDA-approved drugs that have been crushed, had a flavor added, or otherwise changed from the original form.[14]

The FDA has traditionally regulated the 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.[15] The FDA states that, generally, state boards of pharmacy continue to have primary responsibility for oversight and regulation of the practice of pharmacy, including traditional pharmacy compounding.[16] However, the FDA retains some authority over the entities compounding the drugs through the "Compounding Quality Act," in Title I of the Drug Quality and Security Act (DQSA)[17] and the Food, Drug, and Cosmetic Act (FDCA).[18] The FDA has indicated its intention to continue to cooperate with state authorities to address pharmacy compounding activities that may violate the FDCA.[19]

<u>Compounding in Veterinary Medicine</u>

The American Veterinary Medical Association (AVMA) states that the use of compounded medications offers myriad benefits to veterinarians, particularly when dealing with animals that require very small or very large doses of a particular medication or for which the traditional route of administration might not be optimal or even feasible.[20] Compounding is usually necessary when an animal is suffering from a

[9] Rule 64B16-27.700(1), F.A.C.
[10] S. 465.033(6), F.S.
[11] S. 465.003(1), F.S.
[12] *Id*.
[13] *See* 21 U.S.C. § 353a(b)(3) (2014) for drugs compounded for human use and 21 C.F.R. § 530.13(a) (2014) for drugs compounded for animal use.
[14] American Veterinary Medical Association, *Compounding: FAQ for Pet Owners*, https://www.avma.org/KB/Resources/FAQs/Pages/Compounding-FAQ-for-Pet-Owners.aspx (last visited March 13, 2015).
[15] *Supra*, note 2.
[16] *Id*., *see also* U.S. Food and Drug Administration, "Compliance Policy Guide s. 608.400: Compounding of Drugs for Use in Animals," 61 FR 34846 (June 26, 1996) (updated July 8, 2003 at 68 FR 41591)
[17] The DQSA describes the conditions under which certain compounded human drug products are entitled to exemptions from three sections of the FDCA. *See* FDCA, s. 503(A), 21 U.S.C. § 353a (2014).
[18] U.S. Food and Drug Administration, *Compounding – Compounding Quality Act*, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm (last visited March 13, 2015).
[19] U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *Guidance – Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act* (July 2014), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377052.pdf.
[20] Michael J. White, *Unraveling the confounding world of Compounding*, JAVMANews (Feb. 13, 2013), https://www.avma.org/News/JAVMANews/Pages/130301o.aspx (last visited March 30, 2015).

medical condition and there is no FDA-approved human or veterinary product available and medically appropriate to treat the patient.[21] In some situations, veterinarians may find it necessary to compound from a source that has not been approved by the FDA to relieve the animal's suffering, in these cases, veterinarians and pharmacists must carefully assess whether the use is consistent with state and federal law and FDA policy.[22]

The AVMA notes that while the benefits of compounded medications for animals are not readily apparent because compounding may affect the absorption and depletion of a drug resulting in drug concentrations that are above or below the therapeutic range, it is an essential tool that provides therapeutic flexibility for difficult or irregular cases.[23] However, the AVMA cautions that compounded medications should be used judiciously.[24]

The FDA has issued a Compliance Policy Guide s. 608.400 entitled "Compounding of Drugs for Use in Animals,"[25] to provide guidance to FDA's field and headquarters staff with regard to the compounding of animal drugs by veterinarians and pharmacists for use in animals. The FDCA does not distinguish compounding from manufacturing or other processing of drugs for use in animals; however, the DQSA does not apply to animals.

The most widely covered incidents relating to compounding in veterinary medicine in Florida involved horses. In 2009, 21 polo horses died at the United States Open Polo Championship in Florida as the result of a mathematical error by the compounding pharmacy that altered the strength of an ingredient in a medication given to the horses.[26] Another incident occurred in 2014, when eight Florida horses and two from Kentucky were sickened from a compounded drug.[27] Both of the horses from Kentucky and two of the eight horses from Florida died or had to be euthanized; the six remaining horses in Florida suffered neurological problems.[28]

Florida Regulation of Veterinarians

Veterinarians are licensed and regulated under the Board of Veterinary Medicine[29] under the Department of Business and Professional Regulation (DBPR).[30]

As part of the practice of veterinary medicine, veterinarians are authorized to prescribe, dispense, and administer drugs or medicine to their animal patients.[31] Veterinarians who dispense medications from an office are subject to regulation and inspection by DBPR.[32]

Compounded drugs for animals are not addressed in the Veterinary Medical Practice Act, ch. 474, F.S., nor are they addressed in DBPR's rules regulating veterinarians. However, in addition to authorization to prescribe, dispense, and administers drugs and medicine, veterinarians may engage in "treatment of *whatever* nature" to prevent, treat, or cure any wound, injury, or disease of one of their patients. This authority allows them to compound drugs.[33]

Effect of Proposed Changes

[21] *Id*.
[22] *Id*.
[23] *Id*.
[24] *Id*.
[25] 61 FR 34846 (June 26, 1996) (updated July 8, 2003 at 68 FR 41591)
[26] Katie Thomas, *Polo Ponies Were Given Incorrect Medication*, New York Times (April 23, 2009), *available at* http://www.nytimes.com/2009/04/24/sports/othersports/24polo.html (last visited March 30, 2015).
[27] Carlos E. Medina, *Report: 2 thoroughbreds in Ocala, 2 in Kentucky die after being given compounded drug*, The Gainesville Sun (May 18, 2014), *available at* http://www.gainesville.com/article/20140518/ARTICLES/140519684 (last visited March 30, 2015).
[28] *Id*.
[29] S. 474.204, F.S.
[30] Ch. 61G18, F.A.C.
[31] S. 474.202(9), F.S.
[32] Florida Department of Health, *2015 Agency Analysis Senate Bill 1180* (Feb. 27, 2015) (SB 1180 is identical to HB 1049, as filed.) (on file with Health and Human Services Committee staff).
[33] *Id*. (emphasis added).

The bill amends s. 465.0276, F.S., to clarify the impact of the Florida Pharmacy Act and the Board of Pharmacy's rules on a veterinarian's authority to administer or dispense compounded drugs. Specifically, the bill states that nothing in ch. 465, F.S., or the rules adopted under it prevent a veterinarian from administering a compounded drug to an animal patient or dispensing compounded drugs to the animal's owner or caretaker. Additionally, the bill specifies that the provision allowing veterinarians to administer and dispense compounded drugs to their patients or caregivers does not affect the Florida Pharmacy Act.

The act will take effect July 1, 2015.

B. SECTION DIRECTORY:

Section 1: Amends s. 465.0276, F.S., relating to dispensing practitioners.

Section 2: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The Department of Health notes that pharmacists may be unwilling to continue dispensing compounded drugs to veterinarians if those compounded drugs are going to be dispensed or sold by the veterinarians.[34]

D. FISCAL COMMENTS:

None.

[34] *Id.*

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 16, 2015, the Health Quality Subcommittee adopted a strike-all amendment to HB 1049 and reported the bill favorably as a committee substitute. The amendment:

- Removes the definition of "office use compounding" from the bill; and
- Provides the Florida Pharmacy Act or rules adopted by the Board of Pharmacy do not prevent veterinarians licensed under ch. 474, F.S., from administering a compounded drug to his or her animal patient, or dispensing a compounded drug to the animal patient's owner or caretaker.

On April 1, 2015, the Health & Human Services Committee adopted an amendment to CS/HB 1049 and reported the bill favorably as a committee substitute. The amendment adds a statement that the provision allowing veterinarians to administer and dispense compounded drugs to their patients or caregivers does not affect the Florida Pharmacy Act.

The analysis is drafted to the committee substitute.