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 Regulated Industries

BILL:	CS/CS/SB 1180
INTRODUCER:	Regulated Industries, Health Policy Committee and Senator Latvala and others
SUBJECT:	Practice of Pharmacy
DATE:	April 15, 2015 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HP	**Fav/CS**
2.	Kraemer	Imhof	RI	**Fav/CS**
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 1180 amends ch. 465, F.S., the Florida Pharmacy Act (Pharmacy Act), to provide that a veterinarian licensed under the Veterinary Medical Practice Act (ch. 474, F.S.) is not prohibited from administering a compounded drug to any animal under the veterinarian's care, or dispensing a compounded drug to the animal's owner or caretaker. Regulation of the practice of pharmacy as set forth in the Pharmacy Act is not affected.

The bill creates s. 465.1862 to define the terms "maximum allowable cost" (MAC) and "pharmacy benefits manager" (PBM) and to require certain provisions in contracts between a pharmacy and a PBM. A PBM contracts with health insurance plans, such as a health maintenance organization or insurer, to manage the cost and quality of the plans' drug benefits and may provide a variety of related services. The maximum-allowable cost (MAC) is the payment for the unit ingredient costs for off-patent prescription drugs (generics). The PBM, an insurer, or a health maintenance organization may develop a MAC list based on a proprietary survey of wholesale prices and other factors. The bill requires a PBM to update pricing information weekly, and to adopt procedures that will timely eliminate drugs from MAC lists, or modify drug prices to remain consistent with pricing data used to formulate prices and product availability.

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 Veterinary 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[1] 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; and
- Determining the health, fitness, or soundness of an animal.

Veterinary medicine includes, with respect to animals, surgery, acupuncture, obstetrics, dentistry, physical therapy, radiology, theriogenology,[2] and other branches or specialties of veterinary medicine.[3]

With several exceptions, a person must be licensed as a veterinarian under the Veterinary Act, prior to practicing veterinary medicine in this state.[4] 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.[5]

Pharmacy Practice Act

Pharmacies and pharmacists are regulated under the Florida Pharmacy Act (Pharmacy Act) found in ch. 465, F.S.[6] The Board of Pharmacy (the board) is created within the Department of Health (DOH) to adopt rules to implement provisions of the Pharmacy Act and take other actions based upon duties conferred on it. 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;

[1] *See* s. 474.202(9), F.S.
[2] Theriogenology is a branch of veterinary medicine dealing with reproduction.
[3] *See* s. 474.202(13), F.S.
[4] *See* ss. 474.203, 474.207, and 474.213, F.S.
[5] *See* s. 893.02(21), F.S.
[6] Other pharmacy paraprofessionals, including pharmacy interns and pharmacy technicians, are also regulated under the Act.

- 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; and
- Administering vaccines to adults.[7]

Compounding

Compounding is defined under the Pharmacy Act as combining, mixing, or altering the ingredients of one or more drugs or products to create another drug or product.[8] Under the board's rules,[9] 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; [10] 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 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 preparation of drugs or devices for sale or transfer to pharmacies, practitioners, or entities for purposes of dispensing or distribution is not compounding and is not within the practice of the profession of pharmacy.[11]

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 law, but is defined by rule as the providing and administering of a compounded drug to a patient in a practitioner's office or in a health care facility, such as a hospital, ambulatory surgical center, or pharmacy.[12]

[7] *See* s. 465.003(13), F.S.
[8] *See* s. 465.003(18), F.S.
[9] *See* Rule 64B16-27.700, F.A.C.
[10] The term "commercially available products" means any medicinal product that is legally distributed in Florida by a drug manufacturer or wholesaler. *See* Rule 64B16-27.700, F.A.C.
[11] *See* Rule 16B16-27.700(2), F.A.C., which further provides that supplying patient-specific compounded prescriptions to another pharmacy as permitted by law and regulated by rule is authorized. These provisions pertain to centralized prescription filling for another pharmacy.
[12] *See* Rule 16B16-27.700(3), F.A.C.

"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.[13] 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 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.[14]

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)[15] into law on November 27, 2013. Under the DQSA,[16] a compounder of human drugs may become an outsourcing facility, which is able to qualify for exemptions from, among other things, the FDA approval requirements for new drugs.

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[13] *Id.*

[14] *See generally* U.S. Department of Health and Human Services, FDA, Guidance, Compliance & and Regulatory Information for Compounded Drugs, at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm (last visited April 6, 2015).

[15] *See* http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ (last visited April 6, 2015.

[16] *See* Section 503B of the Food, Drug, and Cosmetic Act (known as the Compounding Quality Act) at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376732.htm (last visited April 6, 2015).

Compounding Animal Drugs

According to the FDA, the DQSA does not cover the compounding of animal drugs.[17] 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.[18] 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.

The FDA has issued compliance policy guidance[19] intended to provide guidance and instructions to FDA staff, the industry, and the public for obtaining information to help fulfill the FDA's plans regarding the compounding of drugs for use in animals. This guidance describes FDA's current thinking on what types of compounding might be subject to enforcement action, and articulates the FDA's policy that it 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 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 Pharmacy 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 Pharmacy 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

[17] *See* note 14 *supra* (response to question 12).
[18] *See* 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) at footnote 3, at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm377052.pdf (last visited April 6, 2015).
[19] *See* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074656.htm (last visited April 6, 2015.)

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; or
- One who represents that it is his or her intention not to consume or use the drug, but to transfer it to the ultimate consumer or user for consumption by that person.[20]

"Prescribing" is issuing a prescription. 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.[21] "Administer" means the direct application of a drug, whether by injection, inhalation, ingestion, or any other means, to the body of a person or animal.[22]

Prescription Drug Costs

Advances in pharmaceuticals have transformed health care over the last several decades. In 2013, retail prescription drug spending totaled $272.1 billion which was an increase of 3.3 percent from 2012; the increase has been attributed by the Centers for Medicare and Medicaid Services to price increases for brand name and specialty drugs, increased spending on new medicines, and increased utilization. [23] The projected growth for prescription drug spending in 2014 was 6.8 percent and 6.4 percent for 2015.[24]

Regulation of Pharmacies and Pharmacy Benefits Management Companies

Pharmacies and pharmacists are regulated under the Pharmacy Act in ch. 465, F.S. The board adopts rules to implement provisions of the pharmacy act and takes other actions according to duties conferred on it by the Pharmacy Act.[25] Each pharmacy is subject to inspection by the DOH and may be disciplined for violations of applicable laws and rules relating to a pharmacy.[26]

A pharmacy benefits manager (PBM) administers the prescription drug part of a health plan on behalf of the plan sponsor (self-insured employers, insurers, and health maintenance organizations. Currently, PBMs are not subject to regulation in Florida. Some states, such as

[20] *See* ss. 465.003(6) and 893.02(7), F.S.
[21] *See* ss. 465.003(14) and 893.02(20), F.S.
[22] *See* ss. 465.003(1) and 893.02(1), F.S.
[23] *See* Centers for Medicare and Medicaid Services, *National Health Expenditure Projections 2013-2023,* http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2013.pdf (last visited: April 15, 2015).
[24] Id.
[25] *See* sections 465.005 and 465.022, F.S.
[26] *See* sections 465.015 and 465.016, F.S.

Connecticut, Georgia, Kansas, Louisiana, Maryland and South Dakota, require PBMs to either register with state insurance regulators or be licensed as third-party administrators.[27]

Although PBMs are not subject to licensure in Florida, a PBM may obtain accreditation from various impartial, external organizations (accrediting bodies) that determine if certain national standards are being met. Accreditation is an evaluative, rigorous, transparent, and comprehensive process in which a health care organization undergoes an examination of its systems, processes, and performance by an impartial external organization (accrediting body) to ensure that it is conducting business in a manner that meets predetermined criteria and is consistent with national standards.

Pharmacy Benefits Managers and Pharmacies

While PBMs provide pharmacy claims processing and mail-order pharmacy services to their customers, many provide additional services, including rebate negotiations with drug manufacturers, development of pharmacy networks, formulary management, prospective and retrospective drug utilization reviews, generic drug substitutions, and disease management programs. The decision of plan sponsors to use PBMs to control pharmacy benefit costs, however, can shift business away from retail pharmacies.

Maximum Allowable Cost Pricing List

Contracts between a PBM and health plan sponsors specify how much the health plan sponsors will pay PBMs for brand name and generic drugs. These prices are typically set as a discount off the average wholesale price (AWP)[28] for brand-name drugs and at a MAC[29] for generic drugs (and sometimes brand drugs that have generic versions), plus a dispensing fee. The MAC represents the upper limit price that a plan will pay or reimburse for generic drugs and sometimes brand drugs that have generic versions available (multisource brands). A MAC pricing list creates a standard reimbursement amount for identical products, and is a common cost management tool developed from a proprietary survey of wholesale prices in the marketplace, taking into account market share, inventory, reasonable profits margins, and other factors.

The federal Medicare Part D program and 45 state Medicaid programs use some type of MAC price lists to reduce costs.[30] The MAC price lists are used by many private employer prescription drug plans for retail generic prescriptions.
The purpose of the MAC pricing list is to ensure that the pharmacy or its buying groups are motivated to seek and purchase generic drugs at the lowest price in the marketplace. If a pharmacy procures a higher-priced product, the pharmacy may not make as much profit or may lose money on that purchase. If a pharmacy purchases generic drugs at a more favorable price, it will be more likely to make a profit.

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[27] Joanne Wojcik, *States Try to Regulate Pharmacy Benefit Managers*, Business Insurance (August 22, 2010), *available at* http://www.businessinsurance.com/article/20100822/ISSUE07/308229997 (last visited April 15, 2015).
[28] Average Wholesale Price is the retail list price (sticker price) or the average price that manufacturers recommend wholesalers sell to physicians, pharmacies and others, such as hospitals.
[29] Maximum Allowable Cost is a price set for generic drugs and is the maximum amount that the plan sponsor will pay for a specific drug.
[30] Medicaid Drug Pricing in State Maximum Allowable Cost Programs, Office of Inspector General, OEI-03-11-00640, (August 29, 2013) *available at* https://oig.hhs.gov/oei/reports/oei-03-11-00640.asp (last visited April 15, 2015).

In addition to negotiating rebates with drug manufacturers, PBMs negotiate with retail pharmacies to obtain various discounts on prescription drug prices. Additionally, PBMs try to assure adequate access for those enrolled in the various health plans to obtain their prescription drugs. A PBM may also be responsible for the development and management of a drug formulary, which is a list of drugs that a health plan uses to make reimbursement decisions.

Many PBMs offer incentives to health plan participants to select less-costly generic drugs rather than more expensive brand-name drugs.

In November 2014, U.S. Senator Bernie Sanders (I-Vt.) led a Senate hearing about recent pricing spikes in some generic drugs. The hearing followed a joint investigation Senator Sanders led with U.S. Representative Elijah Cummings (D-Md.).[31] One of the comments made during the hearing quoted that a small percentage of certain generic drugs increased more than 1,000 percent in the past year.[32] Included in the hearing materials was data showing that one-half of generic medicines went up in price between last summer and this summer with the price of some common medicines rising by over 500 percent.[33] In such an environment, a static MAC list could result in inadequate reimbursement to a pharmacy despite its best efforts to purchase from the lowest cost source.

Federal Pharmacy Benefits Managers Transparency Requirements

On March 23, 2010, President Obama signed into law Public Law No. 111-148, the Patient Protection and Affordable Care Act (PPACA), and on March 30, 2010, President Obama signed into law Public Law No. 111-152, the Health Care and Education Affordability Reconciliation Act of 2010, amending PPACA. The law[34] requires Medicare Part D plans and qualified health plan issuers who either have their own PBM or contract with a PBM to report to the U.S. Department of Health and Human Services (HHS) aggregate information about rebates, discounts, or price concessions that are passed through to the plan sponsor or retained by the PBM. In addition, each plan must report the difference between the amount the plan pays the PBM and the amount that the PBM pays its suppliers (spread pricing). The reported information is confidential, subject to certain limited exceptions.

III. Effect of Proposed Changes:

The bill provides that a veterinarian licensed under the Veterinary Medical Practice Act (ch. 474, F.S.) is not prohibited by ch. 465, F.S., and the adopted rules from administering a compounded

[31] Senator Sanders and Representative Cummings have also filed legislation that would require drug makers to extend rebates to Medicaid when drug makers raise prices greater than inflation. This is the current federal law for brand-name drugs. S*ee http://www.sanders.senate.gov/newsroom/press-releases/drugmakers-mum-on-huge-price-hikes* (last visited April 15, 2015).
[32] Ed Silverman, *Should Generic Drug Makers Pay Medicaid Rebates Tied to Inflation?* Wall Street Journal Pharmalot (Nov. 24, 2014) http://blogs.wsj.com/pharmalot/2014/11/24/should-generic-drug-makers-pay-medicaid-rebates-tied-to-inflation/ (last visited: Mar. 27, 2015).
[33] U.S. Senate Subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor and Pensions, *Ranking Member Cummings and Chairman Sanders Investigate Staggering Price Increases for Generic Drugs* (Oct. 2, 2014) http://www.sanders.senate.gov/download/face-sheet-on-generic-drug-price-increases?inline=file (last visited: Mar. 27, 2015).
[34] 42 U.S.C. s. 1320b-23.

drug to any animal under the veterinarian's care, or dispensing a compounded drug to the animal's owner or caretaker.

The bill creates s. 465.1862, F.S., respecting pharmacy benefits manager contracts," in the Florida Pharmacy Act, and defines the following terms:

- "Maximum allowable cost," which is the per-unit amount that a pharmacy benefits manager reimburses a pharmacist for a prescription drug excluding dispensing fees but before any application of copayments, coinsurance, and other cost-sharing charges; and
- "Pharmacy benefits manager," which is a person or entity doing business in this state which contracts to administer or manage prescription drug benefits to residents of Florida on behalf of a health insurance plan defined in s. 627.6482, F.S.[35]

The bill provides that in each original or renewal contract between a PBM and a pharmacy, the contract must require the PBM to:

- Update MAC pricing information at least every 7 days; and
- Maintain a process to timely eliminate drugs from MAC lists, or modify drug prices to remain consistent with pricing data used to formulate prices and product availability.

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.

[35] *See* ss. 627.6482(6), F.S., which defines that "health insurance" as any hospital and medical expense incurred policy, minimum premium plan, stop-loss coverage, health maintenance organization contract, prepaid health clinic contract, multiple-employer welfare arrangement contract, or fraternal benefit society health benefits contract, whether an individual policy or group policy, but excluding motor vehicle polices for medical payments or personal injury protection, liability insurance supplemental coverage, or workers' compensation.

B. Private Sector Impact:

Veterinarians who are licensed and practicing under the Florida Veterinary Practice Act, ch. 474, F.S., may administer a compounded drug to any animal under the veterinarian's care, or dispense a compounded drug to the animal's owner or caretaker without concern that such activities are prohibited by the provisions of the Pharmacy Act, ch. 465, F.S., or the rules adopted thereunder.

Pharmacies and pharmacy benefits managers must absorb the cost of verifying its contracts or contract renewals include provisions requiring the update maximum allowable cost pricing information at least every 7 days, and adopt procedures that will timely either eliminate drugs from MAC lists, or modify drug prices to remain consistent with pricing data used to formulate prices and product availability.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 465.0276 of the Florida Statutes.

This bill creates section 465.1862 of the Florida Statutes.

IX. Additional Information:

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

CS by Regulated Industries on April 15, 2015:
The CS amends s. 465.0276, F.S., respecting dispensing practitioners, to provide that veterinarians who are licensed and practicing under the Florida Veterinary Medical Practice Act, ch. 474, F.S., may administer a compounded drug to any animal under the veterinarian's care, or dispense a compounded drug to the animal's owner or caretaker. The CS removes the exception stating that licensed veterinarians engaging in activities allowed by the Veterinary Medical Practice Act are not limited by the provisions of ch. 465, F.S., the Pharmacy Act, or any adopted rules.

The CS creates s. 465.1862 to define the terms "maximum allowable cost" (MAC) and "pharmacy benefits manager" (PBM) and to require certain provisions in contracts between a pharmacy and a PBM. The CS requires a PBM to update pricing information

weekly, and to adopt procedures that will timely either eliminate drugs from MAC lists, or modify drug prices to remain consistent with pricing data used to formulate prices and product availability.

CS by Health Policy on March 23, 2015:
The CS removes the new definition for office use compounding and the new provision stating that nothing in the chapter or rule prohibit a veterinarian from dispensing a compounded drug to an animal patient or its owner or caretaker. Instead, the CS provides that neither the Florida Pharmacy Act nor pharmacy rules limit a veterinarian from engaging in an activity allowed under the Veterinary Practice Act.

B. Amendments:

None.