HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS

BILL #:	CS/CS/HB 1049	**FINAL HOUSE FLOOR ACTION:**	
SPONSOR(S):	Health & Human Services Committee; Health Quality Subcommittee; Peters and others	118 **Y's**	0 **N's**
COMPANION BILLS:	CS/CS/SB 1180	**GOVERNOR'S ACTION:**	Pending

SUMMARY ANALYSIS

CS/CS/HB 1049 passed the House on April 16, 2015. The bill was amended by the Senate on April 27, 2015, and subsequently passed the House on April 28, 2015.

Pharmacy benefits managers (PBMs) provide a variety of services, including developing and managing pharmacy networks, developing drug formularies, providing mail order and specialty pharmacy services, rebate negotiation, therapeutic substitution, disease management, utilization review, support services for physicians and beneficiaries, and processing and auditing claims. Health plan sponsors contract with PBMs to provide these services, and payment terms are established in the contract. The bill provides that in a contract between PBMs and pharmacies, the PBM must update the maximum allowable cost (MAC) at least every seven days and maintain a process that will eliminate drugs from MAC lists or modify drug prices to remain consistent with changes in pricing data used in formulating MAC prices and product availability.

The bill also provides 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. 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. 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. 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.

Subject to the Governor's veto powers, the effective date of this bill is July 1, 2015.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Current Situation

Florida Regulation of Pharmacies and Pharmacists

Pharmacies and pharmacists are regulated under the Florida Pharmacy Act (the Act) in Chapter 465, F.S. The Board of Pharmacy (the board) was created within the Department of Health (DOH) to adopt rules to implement provisions of the Act and take other actions as required in the Act.[1] Each pharmacy is subject to inspection[2] and discipline[3] by DOH for violations of applicable state or federal laws relating to a pharmacy. Any pharmacy located outside of this state which ships, mails, or delivers, in any manner, a dispensed drug into this state is considered a nonresident pharmacy, and must register with the board as a nonresident pharmacy.[4]

Pharmacy Benefits Managers and Pharmacies

Advances in pharmaceuticals have transformed health care over the last several decades. Many health care problems are prevented, cured, or managed effectively using prescription drugs. As a result, national expenditures for retail prescription drugs grew from $120.9 billion in 2000 to $271.1 billion in 2013.[5] Health plan sponsors, which include commercial insurers, private employers, and government plans, such as Medicaid and Medicare, spent $222.6 billion on prescription drugs in 2013 and consumers paid $45.9 billion out of pocket for prescription drugs that year.[6]

Health plan sponsors contract with pharmacy benefits managers (PBMs) to provide specified services, which may include developing and managing pharmacy networks, developing drug formularies, providing mail order and specialty pharmacy services, rebate negotiation, therapeutic substitution, disease management, utilization review, support services for physicians and beneficiaries, and processing claims.[7] Payments for the services are established in contracts between health plan sponsors and PBMs.[8] For example, contracts will specify how much 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[9] for brand-name drugs and maximum allowable cost price for generic drugs, plus a dispensing fee.[10]

The shift to generic drugs has saved consumers more than $1 trillion over a decade[11], but it has adversely affected independent pharmacists according to recent news articles. In 2000, about 50 percent of U.S. prescription drugs were generic. Now, generics represent about 84 percent of the market.[12] The increasing use of generics is pushing the dollar volume of prescription-drug sales down.

---

[1] S. 465.005, F.S.
[2] S. 465.017, F.S.
[3] S. 465.016, F.S.
[4] See s. 465.0156, F.S., however, the board may grant an exemption from the registration requirements to any nonresident pharmacy, which confines its dispensing activity to isolated transactions under s. 465.0156(2), F.S.
[5] Centers for Medicare and Medicaid Services, *National Health Expenditures 2013 Highlights, available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf (last visited April 28, 2015).
[6] Id.
[7] Program Policy Analysis & Government Accountability. (Office of Program Policy Analysis & Government Accountability, *Legislature Could Consider Options to Address Pharmacy Benefit Manager Business Practices*, Report No. 07-08 (Feb. 2007), *available at* http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/0708rpt.pdf (last visited May 5, 2015).
[8] Id.
[9] 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.
[10] Supra, note 7
[11] Timothy W. Martin, *Drugstores Press for Pricing Data,* WALL STREET JOURNAL, March 27, 2013. *available at* http://www.wsj.com/articles/SB10001424127887323466204578382990730159644 (last visited May 5, 2015)
[12] Id.

In response, drugstores have requested that PBMs be required to share pricing information that would help drugstores negotiate bigger reimbursements and avoid dispensing drugs that are money losers.[13]

Currently, there are no Florida laws that regulate PBMs or their contracts.

Federal PBM Transparency Requirements

The Patient Protection and Affordable Care Act of 2010 requires Medicare Part D plans and qualified health plan issuers that have their own PBM or contract with a PBM to report to the federal Department of Health and Human Services aggregate information about rebates, discounts, or price concessions that are passed through to the plan sponsor or retained by the PBM.[14] In addition, the plans must report the difference between the amount the plan pays the PBM and the amount that the PBM pays its suppliers.[15] The reported information is confidential, subject to certain limited exceptions.[16]

Maximum Allowable Cost

Maximum allowable cost (MAC) price lists set the upper limit amount that a PBM plan will reimburse a contracted pharmacy for generic drugs and some brand-name drugs with generic versions, known as multi-source brands. State Medicaid programs have utilized MAC pricing as a cost-control tool. States with MAC programs typically publish lists of selected generic and multi-source brand drugs along with the maximum price at which Medicaid will reimburse for those drugs. In general, pharmacies will receive payment no higher than the MAC price when billing Medicaid for drugs on a state's MAC list.[17] PBMs also use MAC price lists as a cost-control tool.

Compounding

Compounding is a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools.[18] 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).[19] 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.[20]

Compounded drugs can pose both direct and indirect health risks.[21] 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.[22] 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.[23] However, in other cases, compounders may lack sufficient controls (e.g., equipment, training, testing,

---

[13] Id.
[14] 42 U.S.C. s. 1320b-23.
[15] Id.
[16] Id.
[17] Richard G. Abramson, M.D. et al., *Generic Drug Cost Containment in Medicaid: Lessons from Five State MAC Programs*, HEALTH CARE FINANCING REVIEW, Spring 2004 Vol. 25 No. 3 available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/04springpg25.pdf (last visited May 5, 2015)
[18] *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 361 (2002).
[19] U.S. Food and Drug Administration, *Compounding and the FDA: Questions and Answers*, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm (last visited May 5, 2015).
[20] *Id*.
[21] U.S. Food and Drug Administration, *Compounded Menopausal Hormone Therapy Questions and Answers*, http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm183088.htm (last visited May 5, 2015).
[22] *Id*.
[23] *Id*.

or facilities) to ensure product quality or to compound complex drugs like sterile or extended-release drugs.[24]

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.[25] 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.
- 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.[26]

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.[27] 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.[28]

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.[29] However, federal rules currently require that compounded medications only be modified versions of FDA-approved medications.[30] 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.[31]

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.[32] The FDA states that, generally, state boards of pharmacy continue to have primary responsibility for oversight and

[24] *Id*.
[25] Rule 64B16-27.700, F.A.C.
[26] Rule 64B16-27.700(1), F.A.C.
[27] S. 465.033(6), F.S.
[28] S. 465.003(1), F.S.
[29] *Id*.
[30] *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.
[31] 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 May 4, 2015).
[32] *Supra*, note 19.

regulation of the practice of pharmacy, including traditional pharmacy compounding.[33] 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)[34] and the Food, Drug, and Cosmetic Act (FDCA).[35] The FDA has indicated its intention to continue to cooperate with state authorities to address pharmacy compounding activities that may violate the FDCA.[36]

Compounding in Veterinary Medicine

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.[37] Compounding is usually necessary when an animal is suffering from a medical condition and there is no FDA-approved human or veterinary product available and medically appropriate to treat the patient.[38] 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.[39]

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.[40] However, the AVMA cautions that compounded medications should be used judiciously.[41]

The FDA has issued a Compliance Policy Guide s. 608.400 entitled "Compounding of Drugs for Use in Animals,"[42] 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.[43] Another incident occurred in 2014, when eight Florida horses and two from Kentucky were sickened from a compounded drug.[44] 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.[45]

---

[33] *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)
[34] 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).
[35] U.S. Food and Drug Administration, *Compounding – Compounding Quality Act,* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm (last visited May 5, 2015).
[36] 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.
[37] Michael J. White, *Unraveling the confounding world of Compounding*, JAVMANews (Feb. 13, 2013), https://www.avma.org/News/JAVMANews/Pages/130301o.aspx (last visited May 5, 2015).
[38] *Id*.
[39] *Id*.
[40] *Id*.
[41] *Id*.
[42] 61 FR 34846 (June 26, 1996) (updated July 8, 2003 at 68 FR 41591)
[43] 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 MAy 5, 2015).
[44] 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 May 5, 2015).
[45] *Id*.

Florida Regulation of Veterinarians

Veterinarians are licensed and regulated under the Board of Veterinary Medicine[46] under the Department of Business and Professional Regulation (DBPR).[47] As part of the practice of veterinary medicine, veterinarians are authorized to prescribe, dispense, and administer drugs or medicine to their animal patients.[48] Veterinarians who dispense medications from an office are subject to regulation and inspection by DBPR.[49]

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.[50]

Effect of Proposed Changes

PBMs and MAC Pricing

CS/CS/HB 1049 defines a "pharmacy benefits manager" as a person or entity doing business in the state of Florida that contracts to administer or manage prescription drug benefits of behalf of a health insurance plan to residents of the state of Florida. Additionally, the bill defines "maximum allowable cost" to mean the per-unit amount that a PBM reimburses a pharmacist for a prescription drug excluding dispensing fees, prior to the application of copayments, coinsurance, and other cost-sharing charges.

The bill increases transparency in PBM pricing of drugs on its MAC lists; it establishes contractual requirements between a PBM and a contracted pharmacy.

The bill requirements include updating the MAC pricing information every seven calendar days and maintain a process that will eliminate drugs from MAC lists or modify drug prices to remain consistent with changes in pricing data used in formulating MAC prices and product availability.

Compounding

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.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

[46] S. 474.204, F.S.
[47] Ch. 61G18, F.A.C.
[48] S. 474.202(9), F.S.
[49] 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).
[50] *Id*. (emphasis added).

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The imposition of new contractual obligations for PBMs to periodically update MAC pricing may impact the operations of PBMs and will require PBMs to alter the terms of contracts with plan sponsors and contracted pharmacies. Additionally, independent pharmacists may realize costs savings associated with more competitive prices for pharmaceuticals on the PBM's MAC list.

D. FISCAL COMMENTS:

None.