



**Colorado
Legislative
Council
Staff**

HB16-1324

**REVISED
FISCAL NOTE**

(replaces fiscal note dated April 12, 2016)

FISCAL IMPACT: State Local Statutory Public Entity Conditional No Fiscal Impact

Drafting Number: LLS 16-0881

Date: April 26, 2016

Prime Sponsor(s): Rep. Ginal
Sen. Sonnenberg

Bill Status: Senate Agriculture

Fiscal Analyst: Erin Reynolds (303-866-4146)

BILL TOPIC: VETERINARY ACCESS COMPOUNDED PHARMACEUTICAL DRUGS

Fiscal Impact Summary	FY 2016-2017	FY 2017-2018
State Revenue	<u>\$21,500</u>	<u>\$20,675</u>
Cash Funds	21,500	20,675
State Expenditures	<u>\$10,701</u>	<u>\$31,603</u>
Cash Funds	10,701	31,603
TABOR Impact		\$20,675
Appropriation Required: \$10,701 – Department of Regulatory Agencies (FY 2016-17).		
Future Year Impacts: Ongoing revenue and expenditure increase.		

Summary of Legislation

Under current law, a veterinarian cannot maintain an office stock of compounded drugs for later distribution or administration to patients. The *reengrossed* bill allows:

- a compounding pharmacy that possesses a valid manufacturing registration from the federal Drug Enforcement Administration to compound and distribute a drug to a veterinarian for office use or office stock;
- a veterinarian to administer to an animal patient a compounded drug maintained for office use; and
- a veterinarian to dispense to a human client for later administration to an animal patient a compounded drug, maintained as part of the veterinarian's office stock, in an amount not to exceed 5 days' worth of doses, if a patient has an emergency condition that the compounded drug is necessary to treat and the veterinarian cannot access, in a timely manner, the compounded drug through a compounding pharmacy.

The Colorado Board of Pharmacy (board) may authorize and license a pharmacy outlet located outside of Colorado to provide compounded veterinary drugs for office use or office stock. Nonresident pharmacy licensees must provide the board with a copy of the most recent state inspection report and information about their state's inspection procedure and criteria for board approval as satisfactorily demonstrating proof of compliance with Colorado regulations. In addition, the nonresident pharmacy must pay for a third-party inspection of its facilities to be submitted to

the board. The board may promulgate rules concerning its review of these reports, and as necessary concerning compounded veterinary pharmaceuticals. The Colorado Board of Veterinary Medicine, in consultation with the board, must also define the term "companion animal" by rule, as patients covered by the bill must be companion animals.

Background

Pharmacy and Veterinary Medicine Boards. The Colorado Board of Pharmacy licenses, inspects facilities, investigates complaints, and enforces disciplinary actions related to pharmacists, pharmacy interns, in-state and nonresident pharmacies, in-state and nonresident prescription drug outlets, satellite pharmacies, specialized prescription drug outlets, and other outlets. The Colorado Board of Veterinary Medicine licenses, investigates complaints, and enforces disciplinary actions related to veterinarians and academic veterinarians. Both boards consist of seven members (five professionals and two public members) and meet every other month.

Compounded drugs. A compounded drug is a drug that is manipulated — mixed, diluted, concentrated, flavored, or otherwise changed. Examples of compounding include mixing two injectable drugs in the same syringe, creating an oral suspension from crushed tablets, or creating a transdermal gel for a drug typically ingested otherwise. Drug compounding is regulated by the federal Food and Drug Administration (FDA) and state regulatory authorities, however, the FDA does not regulate animal drugs.

Nonresident prescription drug outlets. Under current state law, nonresident prescription drug outlets (nonresident pharmacies) must register with DORA to do business in the state, filling and shipping patient-specific prescriptions. Currently, only drugs for human consumption are authorized to be sold by these entities. DORA currently receives a report of FDA inspection from nonresident prescription drug outlets to satisfy its inspection requirement. The FDA does not inspect animal drugs.

Assumptions

The fiscal note assumes the following:

- five nonresident pharmacies will seek licensure to sell compounded animal drugs to veterinarians in Colorado;
- a new license type will be created for this group, renewed annually;
- one complaint-driven, nonresident pharmacy inspection by DORA will occur each year; and
- four new complaints per year in the Boards of Pharmacy and Veterinary Medicine related to compounded animal drugs will require adjudication.

State Revenue

The bill will increase state cash fund revenue in DORA **by \$21,500 in FY 2016-17 and \$20,675 in FY 2017-18** from the DPO Cash Fund.

Fee impact on nonresident pharmacies. State law requires legislative service agency review of measures which create or increase any fee collected by a state agency. The fee amounts displayed in Table 1 are estimates only; actual fee calculations and renewal schedules are set administratively by the DORA based on the cash fund balance, estimated program costs, and the estimated number of licensees.

Table 1. Fee Impact on Nonresident Pharmacies Under HB16-1324						
Fiscal Year	Type of Fee	Current Fee	Proposed Fee	Fee Change	Number Affected	Total Fee Impact
FY 2016-17	Nonresident Pharmacy Original	\$450	\$4,750	\$4,300	5	\$21,500
FY 2017-18	Nonresident Pharmacy Renewal	240	4,375	4,135	5	20,675
TOTAL TWO-YEAR FEE IMPACT						\$42,175

TABOR Impact

This bill increases state revenue from licensing fees, which will increase the amount of money required to be refunded under TABOR. TABOR refunds are paid out of the General Fund.

State Expenditures

The bill will increase state cash fund expenditures in DORA **by \$10,701 in FY 2016-17 and by \$31,603 in FY 2017-18** from the DPO Cash Fund. Expenditures are outlined in Table 2 and discussed below.

Table 2. Expenditures Under HB16-1324		
Cost Components	FY 2016-17	FY 2017-18
Legal Services	\$9,501	\$30,403
Out-of-State Inspections	1,200	1,200
TOTAL	\$10,701	\$31,603

Legal services. The Boards of Pharmacy and Veterinary Medicine will require 100 hours of legal services to support the rulemaking process — 50 hours per board — at a rate of \$95.01 for a total of \$9,501. In addition, four complaints per year will drive adjudication costs of 80 hours per case, for a total of \$30,403 per year beginning in FY 2017-18.

Out-of-state inspections. Because the fiscal note assumes that five nonresident pharmacies will seek licensure to sell compounded animal drugs to Colorado veterinarians, it is expected that one pharmacy per year will be inspected by DORA when there is a complaint — see Departmental Difference section. Travel costs for this inspection are estimated at \$1,200 and include airfare, meals, lodging, rental car, and incidentals. To the extent that additional nonresident pharmacies distribute compounded animal drugs into the state, or receive complaints against them, these costs will increase.

Outreach. DPO will make a coordinated outreach effort to pharmaceutical and veterinary licensees, which includes website updates, emails, and webinar sessions. These workload impacts can be accomplished within existing appropriations.

Effective Date

The bill takes effect January 1, 2017.

State Appropriations

In FY 2016-17, the bill requires and includes a cash funds appropriation of \$10,701 from the Division of Professions and Occupations Cash Fund to the Department of Regulatory Agencies. Of this, \$9,501 is reappropriated to the Department of Law.

Departmental Difference

Beginning in FY 2016-17, DORA estimates that the Division of Professions and Occupations will have additional costs of \$6,000 per year, paid from the DPO Cash Fund, to perform complaint-driven out-of-state inspections on nonresident pharmacies. These costs are based on DORA's expectation that 30 nonresident pharmacies will seek Colorado licensure, and that five of these will have complaints. The fiscal note assumes that five nonresident pharmacies will seek licensure. Based on this smaller estimate of licensees, the fiscal note estimates a correlating number of complaint-driven inspections: one per year.

State and Local Government Contacts

Law Regulatory Agencies