



**Colorado
Legislative
Council
Staff**

HB16-1324

FISCAL NOTE

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

Drafting Number: LLS 16-0881 **Date:** March 17, 2016
Prime Sponsor(s): Rep. Ginal **Bill Status:** House Health, Insurance, & Environment
 Sen. Sonnenberg **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>\$12,941</u> | <u>\$31,603</u> |
| Cash Funds | 12,941 | 31,603 |
| State Expenditures | <u>\$12,941</u> | <u>\$31,603</u> |
| Cash Funds | 12,941 | 31,603 |
| TABOR Impact | \$12,941 | \$31,603 |
| Appropriation Required: \$12,941 - Department of Regulatory Agencies (FY 2016-17). | | |
| Future Year Impacts: Ongoing revenue and expenditure increase. | | |

Note: While multiple agencies were canvassed for this analysis, not all agencies were able to respond with complete information within the time frames provided. The fiscal note will be updated when more information becomes available.

Summary of Legislation

The bill allows veterinarians to:

- receive and store a compounded drug without a patient-specific prescription from an in-state or non-resident prescription drug outlet; and
- dispense the compounded drug, in an amount not to exceed five days' worth of doses, to an animal in an emergency condition if the veterinarian cannot access the compounded drug in a timely manner.

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 non-resident prescription drug outlets, satellite pharmacies, specialized prescription drug outlets, and other outlets. The board

currently consists of five licensed pharmacists and two public members. The Colorado Board of Veterinary Medicine licenses, investigates complaints, and enforces disciplinary actions related to veterinarians and academic veterinarians. The board currently consists of five licensed veterinarians and two public members.

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.

Non-resident prescription drug outlets. Under current state law, non-resident prescription drug outlets 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 non-resident prescription drug outlets to satisfy its inspection requirement.

Assumptions

The fiscal note assumes the following:

- DORA will begin implementing the bill July 1, 2016.
- At least one non-resident prescription drug outlet will require state inspection beginning in FY 2016-17.
- There will be five new complaints per year under the bill based on current complaint levels in the Boards of Pharmacy and Veterinary Medicine.

State Revenue

The bill will increase state cash fund revenue in DORA **by \$12,941 in FY 2016-17 and \$31,603 in FY 2017-18** from the DPO Cash Fund. DORA will be required to nominally raise fees on licensees to cover the costs under the bill. The licensed population to which these fees will apply is unknown at this time, but is expected to be pharmacies, veterinarians, or both. This fiscal note will be revised as additional information becomes available.

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 \$12,941 in FY 2016-17 and by \$31,603 in FY 2017-18** from the DPO Cash Fund. Expenditures are outlined in Table 1 and discussed below.

| Cost Components | FY 2016-17 | FY 2017-18 |
|---|-------------------|-------------------|
| Board Per Diem and Travel Reimbursement | \$2,240 | \$0 |
| Legal Services | 9,501 | 30,403 |
| Out-of-State Inspections | 1,200 | 1,200 |
| TOTAL | \$12,941 | \$31,603 |

Reimbursement — rulemaking. The Boards of Pharmacy and Veterinary Medicine will be required to hold rulemaking meetings to implement the bill, resulting in per diem payments to 14 board members and travel reimbursement costs for two rural members. Per diem is \$50 per meeting per member, for a total of \$700 for the two board meetings. Travel reimbursement costs for meals, lodging, and airfare are expected to total \$770 per rural member. In total, per diem and reimbursement costs are expected to be \$2,240 in FY 2016-17.

Legal services — rulemaking and enforcement. In FY 2016-17, DORA 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 FY 2017-18 and future years, it is assumed that there will be an increase in complaints related to compounded drugs administered by veterinarians or sold by prescription drug outlets at an estimated rate of five per year. Four of these are assumed to drive adjudication costs of 80 hours per case, for total costs of \$30,403.

Out-of-state inspections. Because the FDA does not regulate animal drugs, the fiscal note assumes that at least one non-resident prescription drug outlet will be inspected annually by DORA, and additionally when there is a complaint. Travel costs for this inspection are estimated at \$1,200 per inspection, including airfare, meals, lodging, rental car, and incidentals. To the extent that additional non-resident prescription drug outlets 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 upon signature of the Governor, or upon becoming law without his signature.

State Appropriations

In FY 2016-17, the Department of Regulatory Agencies requires an appropriation of \$12,941 from the Division of Professions and Occupations Cash Fund.

State and Local Government Contacts

Law Regulatory Agencies