


Colorado Legislative Council Staff
STATE
FISCAL IMPACT
No State General Fund Impact

Drafting Number: LLS 05-0633
Prime Sponsor(s): Rep. McFadyen
 Sen. Johnson

Date: February 14, 2005
Bill Status: House Health and Human Services
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TITLE: CONCERNING A PHARMACIST WHO COMPOUNDS DRUGS ADMINISTERED TO A PATIENT IN A PRACTITIONER'S OFFICE.

Fiscal Impact Summary	FY 2005/2006	FY 2006/2007
State Revenues		
Cash Fund - Division of Registrations Cash Fund		\$508,506
State Expenditures		
Cash Fund - Division of Registrations Cash Fund	\$270,846	\$237,660
Cash Fund Exempt - Transfer to Department of Law*	7,696	7,696
FTE Position Change	2.0 FTE	2.0 FTE
Other State Impact: TABOR		
Effective Date: Upon Signature of the Governor		
Appropriation Summary for FY 2005/2006:		
Department of Regulatory Agencies:	\$270,846 CF and 2.0 FTE	
Department of Law:	7,696 CFE*	
Local Government Impact: None		

**These funds are included in the cash funds expenditure total.*

Summary of Legislation

This bill specifies that compounding drugs is included in practicing pharmacy. It removes the sale of compounded drugs from the requirements of the "casual sale" of prescription drugs and removes the requirement that compounded drugs be the result of a practitioner's prescription drug order or for the purpose of research, teaching or chemical analysis. The bill also sets the following requirements for a pharmacist compounding drugs:

- the drug must be administered to the patient in the practitioner's office or under the practitioner's supervision;
- the drug must be compounded in a registered prescription drug outlet in quantities consistent with the expiration dates of the ingredients;
- the drug cannot be offered for resale;
- the pharmacist must maintain a record of the compounded drug order and preparation;
- and

- the compounded drugs may only be sold or given to wholesalers of drugs, licensed hospitals, other registered prescription drug outlets and practitioners authorized to prescribe drugs.

State Revenues

The bill has a cash funds revenue impact of \$508,506 Division of Registrations Cash Fund in FY 2006-07. The fiscal note assumes that the 2-year license fees for Prescription Drug Outlets will increase to meet the expenses of this bill, and the next renewal year is 2007.

Pursuant to Section 2-2-322, C.R.S., which requires legislative service agency review of legislative measures which include the creation or increase of any fee collected by a state agency, the following analysis is provided.

Table 1. Fee Impact On Individuals, Families Or Business					
Type of Fee	Current Fee	Proposed Fee	Fee Change	# of Affected Individuals	Total Fee Impact*
Prescription Drug Outlets License FY 2006-07	\$240	\$449	\$209	1,132	\$508,506

**Total does not sum due to rounding.*

State Expenditures

This bill will increase expenditures of the Department of Regulatory Agencies by an estimated \$270,846 cash funds in FY 2005-06 and \$237,660 in FY 2006-07. Of the total, \$7,696 is a cash funds exempt transfer to the Department of Law each year.

Department of Regulatory Agencies. The following assumptions were made to arrive at the expenditure estimate:

- 95 Colorado pharmacies will engage in significant amounts of compounding, with 10 percent annual growth;
- inspections and testing will be required to sufficiently ensure safe product development, production and packaging;
- initial inspections will require approximately 80 hours of inspector time, based on FDA estimates adjusted for the smaller scale of Colorado pharmacies;
- inspectors will require training in scientific methods as offered by the FDA;
- initial inspections will occur over a 2-year period;
- 15 percent of compounding pharmacies will be randomly selected for sterility and chemical analysis to be performed by a contractor; and
- 10 additional complaints will be made to the State Board of Pharmacy, requiring 125 hours of legal services.

In total, expenditures are estimated at \$270,846 in FY 2005-06 and \$237,660 in FY 2006-07. See Table 2 for expenditure detail.

Department of Law. The Department of Regulatory Agencies anticipates the need for 125 hours of legal services each year. The fiscal note assumes that of the 10 anticipated complaints, the State Pharmacy Board will take action on 2. It is assumed that one will settle and one will be litigated, in total requiring 125 hours of legal services. See Table 2 for expenditure detail.

Table 2. Department of Regulatory Agencies Expenditures Detail

	FY 2005-06	FY 2006-07
Personal Services - 2.0 Pharmacy II FTE	\$158,956	\$158,956
Lab Testing - Contract	\$17,850	\$17,850
Operating	\$2,448	\$2,208
Training and Travel	\$77,320	\$50,640
Capital & IT	\$6,576	\$310
Legal Services - Transfer to Department of Law	\$7,696	\$7,696
Total - Department of Regulatory Agencies	\$270,846	\$237,660

Note. The Department of Regulatory Agencies anticipated the need for 2.5 FTE and related expenses. The fiscal note reduced the FTE to 2.0 to reduce capital, training and travel expenditures. However, this change may extend initial inspections into FY 2007-08.

State Appropriations

For FY 2005-06, the fiscal note indicates the Department of Regulatory Agencies should receive an appropriation of \$270,846 and 2.0 FTE Division of Registrations Cash Funds.

For FY 2006-07, the fiscal note indicates the Department of Law should receive an appropriation of \$7,696 cash funds exempt.

Departments Contacted

Regulatory Agencies

Human Services

Health Care Policy and Financing