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Prime Sponsor(s): Rep. Summers Bill Status: House Health and Environment

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TITLE:

CONCERNING CONTINUATION OF THE STATE BOARD OF PHARMACY, AND, IN CONNECTION THEREWITH, IMPLEMENTING THE RECOMMENDATIONS CONTAINED IN THE SUNSET REVIEW AND REPORT REGARDING THE BOARD AND RECODIFYING THE LAWS REGULATING PHARMACISTS, THE PRACTICE OF PHARMACY, AND THE MANUFACTURE, DISTRIBUTION, AND DISPENSING OF PRESCRIPTION DRUGS AND CONTROLLED SUBSTANCES.

Fiscal Impact Summary	FY 2012-2013	FY 2013-2014			
State Revenue					
Cash Funds					
Division of Registrations Cash Fund - Base Revenue*		\$1,084,690			
Division of Registrations Cash Fund - New Revenue	\$233,385	124,430			
State Expenditures Cash Funds					
Division of Registrations Cash Fund - Base Expenditures*		\$1,091,243			
Division of Registrations Cash Fund - New Expenditures	\$221,377	112,307			
FTE Position Change	1.0 FTE	6.8 FTE			
Effective Date: July 1, 2012.					
Appropriation Summary for FY 2012-2013: See State Appropriations section.					
Local Government Impact: None.					

^{*}Base revenue and expenditures reflect continuation of the program as it currently exists.

Summary of Legislation

This bill implements the recommendations from the Department of Regulatory Agencies (DORA) 2011 Sunset Review, and continues the Colorado State Board of Pharmacy (board) and the regulation of the practice of pharmacy through September 1, 2021. It also recodifies and relocates the laws regulating the practice of pharmacy and the laws pertaining to the licensing of addiction programs by the Department of Human Services. The bill:

- adds registration requirements for ambulatory surgical centers, medical clinics operated by hospitals, and long-term care facilities for seniors;
- repeals the rehabilitation evaluation committee and transfers its functions to the board;

- allows the board to increase license and renewal fees to cover the costs of the pharmacy peer assistance program and changes requirements for seeking assistance;
- establishes a new hospital satellite pharmacy registration so that the satellite can obtain its own registration from the federal Drug Enforcement Agency (DEA);
- reduces the regulatory requirements for veterinary prescription drugs;
- modifies disciplinary procedures; and
- allows a pharmacy intern to practice under the direct and immediate supervision of a registered manufacturer or regulated health care-related professional.

Fiscal impact of programs set to expire. This bill continues a program in the Division of Registrations in the DORA that is set to repeal, effective July 1, 2012. Under current law, state agencies may be appropriated funds to wind up the affairs of an expiring program for 12 months following the repeal date. To account for the wind-up period, the impact of extending the program beyond the current repeal date is shown as beginning in FY 2013-14, one year after the repeal date. There is no need for an appropriation of the board's base funding in FY 2012-13, since the program's authorization has not yet expired, and ongoing funding for the program is included in the department's base budget request for FY 2012-13.

The state revenue and state expenditures impact for FY 2013-14 reflect the board's anticipated fee revenue and base budget request beginning that year, plus increases to cover the implementation of this bill. The DORA's request for the State Board of Pharmacy in FY 2012-13 is \$1,091,243 and 5.75 FTE. The anticipated revenue is \$967,120 for FY 2012-13 and \$1,084,690 in FY 2013-14 to fund base expenditures.

State Revenue

This bill increases new revenue to the Division of Registrations Cash Fund by \$233,385 in FY 2012-13 and \$124,430 in FY 2013-14 from fees. It also continues fees collected under the current programs beginning in FY 2013-14.

Fee Impact on Individuals, Families or Business. Section 2-2-322, C.R.S., requires legislative service agency review of measures which create or increase any fee collected by a state agency. Fee calculations are based on the estimated costs of the bill, including centrally appropriated costs, and the estimated number of licenses provided. The actual fee amounts will be set by the board. Licenses and registrations issued by the board are good for two years. Pharmacists and pharmacy interns renew in odd years and pharmaceutical businesses renew in even years. Table 1 identifies the fee impact of this bill.

	Table 1. Fe	e Impact	on Indivi	duals, Fa	milies or	Busines	S		
Type of Fee	Current Fee	Propos	sed Fee	Fee C	hange		nber ected	Total F	ee Impact
Fiscal Year		12-13	13-14	12-13	13-14	12-13	13-14	12-13	13-14
	Original License/Registration								
Pharmacist	\$225	280	\$250	\$55	\$25	242	242	\$13,310	\$6,050
Intern	26	40	29	14	3	445	445	6,230	1,335
Prescription Drug Outlet	450	570	500	120	50	109	25	13,080	1,250
Manufacturer	450								
Other Outlet	100	200	110	100	10	200	5	20,000	50
Limited	50	61	55	11	5	1	1	11	5
Wholesaler	450	570	500	120	50	100	100	12,000	5,000
		J	Renewal I	License/R	Registrati	on			
Pharmacist	138		156		16		6,715	0	107,440
Intern	32		35		3		1,100	0	3,300
Prescription Drug Outlet	450	550		100		1,309		130,900	0
Manufacturer	450	550		100		20		2,000	0
Other Outlet	100	110		10		198		1,980	0
Limited	50	61		11		44		484	0
Wholesaler	225	270		45		742		33,390	0
	-			TOT	AL NEV	V FEES		\$233,385	\$124,430
				TOT	AL BASI	E FEES			\$1,084,690
					TOTAL	L FEES			\$1,209,120

State Expenditures

This bill requires new expenditures of \$221,377 and 1.0 FTE in FY 2012-13 and \$112,307 and 1.0 FTE in FY 2013-14 from the Division of Registrations Cash Fund in the DORA in addition to base resources starting in FY 2013-14. The majority of expenditures are attributed to the increase in outlets registered. Expenditures are shown in Table 2 and explained below.

Table 2. New Expenditures Under HB12-1311						
Cost Components	FY 2012-13	FY 2013-14				
Personal Services	\$181,055	\$93,905				
FTE	1.0	1.0				
Operating Expenses and Capital Outlay	6,072	991				
Legal Services	21,199	9,842				
Travel	8,251	7,569				
Board Expenses and Per Diem	4,800					
Base Expenditures		1,091,243				
TOTAL EXPENDITURES	\$221,377	\$1,203,550				

Colorado Board of Pharmacy, DORA. The fiscal note estimates that 309 new outlets will be included under the board. These include inpatient hospital satellite pharmacies, ambulatory surgical centers, medical clinics operated by hospitals, and long term care facilities. These will require application processing and inspections. Three temporary pharmacy specialists at a rate of \$40 per hour for 1,560 hours will be used to address the immediate inspection workload and an additional 1.0 FTE Pharmacist II will have ongoing inspection responsibility for the increase in outlets.

In addition to updating the board's rules based on the changes in the bill, the relocation of the entire pharmacy statute requires a revision of all the board's rules. Temporary paralegal staff at a rate of \$25 per hour for 990 hours and 150 hours legal services from the Department of Law at a cost of \$75.71 per hour, will be utilized for rule changes. Rule changes will also require three task force meetings to develop rules and two additional board meetings to adopt the rules.

The remaining expenditures are for outreach to pharmacy stakeholders to ensure compliance with the changes in the law, registration costs and enforcement. The fiscal note estimates the board will receive an additional 12 complaints annually. These require 12 hours of staff time for investigation. The fiscal note estimates that the board will issue 96 letters of admonition to licensees and registrants and refer nine of those to the Attorney General for a hearing. One case annually is expected to go to hearing incurring 40 hours of legal services. The board will also utilize 90 hours of legal services annually for support in interpreting the bill regarding complaint resolution and enforcement.

Department of Human Services. The department will retrain medical staff and pharmaceutical personnel to comply with the new regulations. This is expected to be addressed within existing appropriations.

Expenditures Not Included

Pursuant to a Joint Budget Committee policy, certain costs associated with this bill are addressed through the annual budget process and centrally appropriated in the Long Bill or supplemental appropriations bills, rather than in this bill. The centrally appropriated costs subject to this policy are summarized in Table 3.

Table 3. Expenditures Not Included Under HB12-1311*						
Cost Components	FY 2012-13	FY 2013-14				
Employee Insurance (Health, Life, Dental, and Short-term Disability)	\$6,199	\$6,199				
Supplemental Employee Retirement Payments	5,007	5,764				
TOTAL	\$11,206	\$11,963				

^{*}More information is available at: http://colorado.gov/fiscalnotes

State Appropriations

For FY 2012-13 the State Board of Pharmacy requires an appropriation of \$221,377 and 1.0 FTE from the Division of Registrations Cash Fund. Of this, the Department of Law requires \$21,199 in reappropriated funds.

Departments Contacted

Regulatory Agencies Law Human Services
Corrections Higher Education