


Colorado Legislative Council Staff Fiscal Note
STATE
FISCAL IMPACT

Drafting Number: LLS 10-0027
Prime Sponsor(s): Sen. Carroll M.
 Rep. Tyler

Date: February 16, 2010
Bill Status: Senate Health and Human Services
Fiscal Analyst: Bill Zepernick (303-866-4777)

TITLE: CONCERNING INCREASED TRANSPARENCY REPORTING REQUIREMENTS FOR CERTAIN PHARMACEUTICAL MANUFACTURERS.

Fiscal Impact Summary	FY 2010-2011	FY 2011-2012	FY 2012-2013
State Revenue			
Cash Funds			
Department of State Cash Fund - Fines		\$0	> \$1.0 million
Department of State Cash Fund - Fees		196,875	196,875
State Expenditures			
Cash Funds			
Department of State Cash Fund	\$271,975	\$109,930	\$814,160
FTE Position Change	1.0 FTE	2.0 FTE	2.0 FTE
Effective Date: August 11, 2010, assuming the General Assembly adjourns May 12, 2010, as scheduled and no referendum petition is filed.			
Appropriation Summary for FY 2010-2011: See State Appropriations section.			
Local Government Impact: None.			

Summary of Legislation

SB10-126 requires certain manufacturers of drugs, medical devices, and other medical supplies to file annual disclosure statements with the Secretary of State. In these statements, manufacturers must disclose: (1) any payment made to a health practitioner; and (2) any health practitioner that has an ownership interest in the manufacturer. Disclosure statements must be filed each year by March 31, beginning in 2011.

Payment disclosure. If the manufacturer has provided payments or anything of value to a health care practitioner, it must file a disclosure statement annually to report each payment made in the prior calendar year, as well as the total amount paid to all health practitioners. The disclosure statement must include specific information about each payment made and the doctor to whom it was made. Manufacturers must also report payments made to other persons or entities on behalf of or at the request of a health practitioner. The disclosure statement must indicate whether the manufacturer adheres to the ethical guidelines for interacting with health practitioners created by a pharmaceutical industry trade association.

Ownership disclosure. A manufacturer or group purchasing organization is required to file a disclosure statement annually to report any health practitioner, or immediate family members of a health practitioner, who have an ownership interest in the manufacturer or group purchasing organization, and the value and terms of the ownership interest held by each health practitioner. Manufacturers are not required to report ownership interests acquired from publicly traded stocks or mutual funds.

Penalties for noncompliance. Any manufacturer that fails to file a required disclosure statement in a timely manner shall be fined between \$1,000 and \$10,000 for each payment or ownership interest not reported, up to \$150,000. If a manufacturer *knowingly* fails to file in a timely manner, the fine increases to between \$10,000 and \$100,000 for each payment or ownership interest not reported, up to \$1 million. An administrative hearing must be conducted before imposing any fine.

Duties of the Department of State. The department is required to develop an online filing system, make information disclosed by manufacturers available to the public through a searchable website, set filing fees, and adopt any rules necessary to implement the bill. The website must include a way for health care practitioners to submit corrections to information provided by manufacturers. The department must also file an annual report to the Governor and the General Assembly analyzing data submitted by manufacturers and listing any violations and enforcement actions taken.

State Revenue

Although the bill requires manufacturers to file in March 2011, the department will not complete the electronic filing and data processing systems required by the bill until July 2011. In addition, it is unclear if manufacturers will be able to disclose information for 2010 because the bill, if enacted, would likely not be signed into law until May 2010, and many manufacturers would not have systems in place to track the required information. Therefore, it is assumed that manufacturers will not file until March 2012.

The bill increases revenue to the Department of State Cash Fund from two sources - filing fees collected from manufacturers, and fines imposed on manufacturers for noncompliance.

Filing fees. The department will have increased revenue of \$196,875 per year beginning in FY 2011-12. There are an estimated 31,500 pharmaceutical and medical device manufacturers nationwide, and 50 percent of manufacturers (15,750) are estimated to be required to file a disclosure statement each year. This analysis assumes a filing fee of \$12.50, which will cover all start-up and ongoing costs in the department, based on a 5-year cost recovery model. The actual fee amount will be set by the Secretary of State based on the number of filings received.

Fee Impact on 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. The table below identifies the fee impact of this bill.

<i>Table 1. Annual Fee Impact on Business</i>			
<i>Type of Fee</i>	<i>Proposed Fee</i>	<i>Number Affected</i>	<i>Total Fee Impact</i>
Disclosure Statement Filing Fee	\$12.50	15,750	\$196,875

Fines. Because the fiscal note assumes that manufacturers will not file until March 2012, fine revenue is not expected to be received until FY 2012-13. The amount and level of fine revenue paid by manufacturers who fail to file disclosure statements in a timely manner cannot be determined. This is because it is unknown how many manufacturers will not comply with the bill, how many payments or ownership interests they must report, and what fine amount will be imposed by the Secretary of State. The department will require several months following the March 31 filing date to process forms, mail notices, and refer cases to an administrative law judge (ALJ) to impose a fine. It is assumed that any costs for administrative hearings which will be paid from fine revenue.

Assuming 15 percent of manufacturers (2,363) do not file in a timely manner and a minimum fine of \$1,000 for a single infraction is imposed, fine revenue would be \$2.3 million. However, due to uncertainty concerning compliance and the number of manufacturers that will file, the fiscal note estimates revenue of at least \$1.0 million in FY 2012-13.

State Expenditures

The bill increases costs by \$271,975 and 1.0 FTE in FY 2010-11, \$109,930 and 2.0 FTE in FY 2011-12, and \$814,160 and 2.0 FTE in FY 2012-13. These costs are summarized in Table 2 and the following sections.

Table 2. Expenditures Under SB10-126			
Cost Components	FY 2010-11	FY 2011-12	FY 2012-13
Personal Services	\$50,708	\$103,360	\$103,360
FTE	1.0	2.0	2.0
Operating Expenses and Capital Outlay	5,430	6,570	1,900
Legal Services	27,137	0	0
Computer Programming	188,700	0	0
Administrative Hearings	0	0	\$708,900
TOTAL	\$271,975	\$109,930	\$814,160

Personal services, operating expenses, and capital outlay. The department will require staff in FY 2010-11 to develop program rules and work with a contractor to design the required data systems. In FY 2011-12 a program assistant will be added, bringing total staff to 2.0 FTE. Staff will process disclosure statements, answer questions from manufacturers, monitor compliance, refer cases to administrative hearings, and perform other tasks as necessary. Standard operating expenses and capital outlay are shown in Table 2.

Legal services. In FY 2010-11 the department will require 360 hours of legal services from the Department of Law to promulgate rules and provide guidance on program implementation. This will result in costs of \$27,137 and 0.2 FTE in FY 2010-11.

Computer programming. One-time costs of \$188,700 for 2,550 hours of computer programming in FY 2010-11 are anticipated. This analysis assumes a rate of \$74 per hour for a contractor to develop a searchable website and system for online submission of disclosure statements as required by the bill.

Administrative hearings. The department must conduct a hearing prior to imposing a fine on a manufacturer that fails to file in a timely manner. This analysis assumes that the department will refer these cases to ALJs in the Department of Personnel and Administration. It is estimated that 15 percent of manufacturers will file late or omit information on their disclosure statements at the first filing in March 2012, resulting in 2,363 cases being referred to an ALJ. Allowing 3 months for the staff to review disclosure statements and refer cases to ALJs, costs for administrative hearings will not be incurred until FY 2012-13. At an average cost of \$300 per hearing, these cases will result in costs of \$708,900 in the Department of State in FY 2012-13. It is assumed that fine revenue will be sufficient to cover the costs of conducting hearing. If this increase results in the need for additional ALJs, this staffing will be address through the annual budget process.

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 SB10-126*			
Cost Components	FY 2010-11	FY 2011-12	FY 2012-13
Employee Insurance (Health, Life, Dental, and Short-term Disability)	\$5,680	\$14,220	\$14,220
Supplemental Employee Retirement Payments	1,886	4,677	5,325
TOTAL	\$7,566	\$18,897	\$19,545

*More information is available at: <http://www.colorado.gov/cs/Satellite/CGA-LegislativeCouncil/CLC/1200536133924>

State Appropriations

The bill requires an appropriation of \$271,975 and 0.8 FTE to the Department of State from the Department of State Cash Fund. Of this amount, \$27,137 should be reappropriated to the Department of Law with an additional 0.2 FTE.

Departments Contacted

State	Law	Personnel and Administration
Judicial	Regulatory Agencies	Health Care Policy and Financing