F I S C A L I M P A C T R E P O R T

SPONSOR HJC **ORIGINAL DATE** 02/17/14 **LAST UPDATED** 02/18/14 **HB** 126/HJCS

SHORT TITLE Pharmacy Benefit Manager Act **SB**

ANALYST Clark

REVENUE (dollars in thousands)

Estimated Revenue			Recurring or Nonrecurring	Fund Affected
FY14	**FY15**	**FY16**		
	See Fiscal Implications	See Fiscal Implications	Recurring	Other State Funds

(Parenthesis ( ) Indicate Revenue Decreases)

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY14	FY15	FY16	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total	N/A	Up to $400 - $800	Up to $800 - $1,000	Up to $1,200 - $1,800	Recurring	Other State Funds

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION

LFC Files

Responses Received From
Regulation and Licensing Department (RLD)
Office of Superintendent of Insurance (OSI)

SUMMARY

Synopsis of Bill

The House Judiciary Committee Substitute for House Health, Government and Indian Affairs Committee Substitute for House Bill 126 enacts the Pharmacy Benefits Manager Regulation Act and requires any person acting as a pharmacy benefits manager (PBM) to hold a license issued by the Office of Superintendent of Insurance (OSI).

The bill takes the following substantive actions.

- It requires applicants to provide specified information as part of the licensure application process.

- It requires OSI to enforce the provisions of the act, allowing suspension or revocation of a license or denial of an application under specified conditions. If a license is revoked, the affected PBM shall immediately wind up its affairs and conduct no further business unless permitted by OSI.

- It provides that a person whose PBM license has been denied, suspended, or revoked may seek review pursuant to existing statute.

- It establishes maximum allowable cost pricing requirements for PBMs.

- It provides restrictions and requirements for PBM contracts with pharmacies.

- It provides that a PBM, whether licensed pursuant to the Pharmacy Benefits Manager Regulation Act or exempt from licensure pursuant to that act, shall be subject to the audit requirements of Section 61-11-18.2 NMSA 1978.

- It amends the statutory fee schedule for OSI, allowing the agency to collect specified fees in specified amounts from PBMs.

FISCAL IMPLICATIONS

There would be significant impacts to the internal revenues and operating budget of OSI, possibly including a significant expansion of staff and associated funding not present in the current budget. The bill provides for OSI to assess fees against PBMs, presumably in an attempt to cover the costs of administering the regulation of PBMs in the state; however, the bill does not provide an initial appropriation, which OSI reports would be necessary to hire the people and set up the systems necessary to begin regulating PBMs and collecting fees. Additionally, while the bill provides for fee collections, it does not appropriate those fees to OSI, preventing budget increases to hire people and pay for these systems beyond the allowable increases under the General Appropriation Act. Without additional budgetary authority, the agency could experience significant difficulty in performing the administration and oversight required by this bill.

The impact to OSI's operating budget is difficult to estimate; as PBMs are currently unregulated, there are no existing costs to review, and there is no accurate count of PBMs in New Mexico that OSI would have to license and regulate. If the number of PBMs is low and relatively few complaints are filed for OSI to investigate, the agency might be able to implement this new responsibility with just a few additional FTE.

However, OSI estimates the operating budget impact could be significant -- approximately $400 to $800 thousand in the first year and $800 thousand to $1 million per year thereafter -- and reports the development of an entirely new area of regulatory expertise could not be accomplished under the current OSI budget. OSI notes that since this is a function it does not presently perform, there are no budgeted resources with which to respond to the mandate of this bill. Since OSI has no staff with any relevant pharmaceutical expertise, OSI would need to hire an expert (although there are no funds in the current budget to do so) to perform a study to determine the resources required to support the expansion necessary to meet the requirements of this bill. While it is unknown exactly what training and support for this expansion will be required, OSI's preliminary estimate would require a minimum of 10 additional FTE, with associated resources. In addition to the recurring costs, OSI reports an initial appropriation of at

least $200 thousand would be necessary to contract with an expert in this field and to begin setting up an information tracking system.

Without an estimate of the number of PBMs that would be licensed pursuant to this bill, it is difficult to determine if the listed fees would be sufficient to carry out the provisions of this bill. OSI reports that in order to support the estimated staff necessary to carry out the provisions of this bill, initially there would need to be approximately 800 PBMs licensed and an additional 200 annually to continue to support the recurring costs.

SIGNIFICANT ISSUES

The American Pharmacists Association reports that a PBM is traditionally a third-party administrator of prescription drug programs and is primarily responsible for developing and maintaining the formulary, contracting with pharmacies, negotiating discounts and rebates with drug manufacturers, and processing and paying prescription drug claims.

RLD describes how, as unregulated entities, PBMs have had a significant negative impact in New Mexico pharmacy operations for many years and notes PBMs demand reimbursement for prescriptions previously dispensed and paid by third party insurance. RLD asserts many of the reasons listed as justification for reimbursement are inappropriate. Pharmacies have no recourse in disputing these charge-backs, as no entity regulates PBMs, which can hold up payments indefinitely while a pharmacy disputes a claim. There currently is no appeal process outside of the pharmacy benefit manager.

OSI notes it is in its first year of operation as a new standalone agency, after separating from the Public Regulation Commission on July 1, 2013. OSI is struggling to hire enough personnel to fulfill existing responsibilities and currently has a 28 percent vacancy rate. Additionally, the agency now has a significant increase in responsibilities due to the requirements under the Affordable Care Act.

OTHER SUBSTANTIVE ISSUES

OSI provides the following additional information in its analysis.

> OSI currently does not have the expertise or personnel to perform the tasks contemplated by this legislation. OSI would have to perform a job analysis, hire, and train additional personnel and create new programming to determine what would be needed to license and regulate the activity of the benefit managers identified in this legislation. It is anticipated it would take at least a year to put necessary rules and regulations in place and begin collecting revenues that would then have to be budgeted and then hire the appropriate staff.

The regulatory responsibility mandated by this bill could more appropriately fall under the umbrella of the Board of Pharmacy, which is administratively attached to the Regulation and Licensing Department. Its duties are described in its website as follows:

> The New Mexico Board of Pharmacy regulates the pharmaceutical industry that includes licensing pharmacists, pharmacy technicians, pharmacist interns, pharmacies, hospitals, nursing homes, public health clinics, drug research

> facilities, and boarding homes. The Board also educates the public about the proper use of prescription medications.
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> The Board of Pharmacy investigates complaints dealing with incorrectly filled prescriptions; controlled substance thefts; dispensing adulterated and unapproved drugs; failure to properly communicate side effects of prescription medications to patients; and other violations dealing with unprofessional conduct.
>
> The Board administers and enforces the Pharmacy Act, the Drug Device and Cosmetic Act, the Controlled Substance Act, the Drug Precursor Act, and the Drug Product Selection Act.

According to Section 61-11-1.1 NMSA 1978, the purpose of the Pharmacy Act, which is the responsibility of the Board of Pharmacy to carry out, is to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy, including the licensure of pharmacists and pharmacist interns and registration of pharmacy technicians; the licensure, control, and regulation of all sites or persons, in or out of state, who distribute, manufacture, or sell drugs or devices used in the dispensing and administration of drugs in New Mexico; and the regulation and control of such other materials as may be used in the diagnosis, treatment, and prevention of injury, illness, or disease of a patient or other person.

See "Appendix" for additional statutory references cited by OSI in its analysis.

ALTERNATIVES

OSI suggests funding a study and delaying implementation of the bill's requirements by at least one year to plan for and fund the provisions of this bill. Additionally, OSI suggests authority to regulate PBMs could instead be given to the Pharmacy Board.

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

Pharmacies will continue to struggle with frequent changes to audit and charge-back procedures established by PBMs.

JC/ds:jl

APPENDIX

The OSI analysis notes that Section 61-11-6 NMSA 1978 requires the New Mexico Board of Pharmacy to:

(1) adopt, amend or repeal rules and regulations necessary to carry out the provisions of the Pharmacy Act in accordance with the provisions of the Uniform Licensing Act [61-1-1 through 61-1-31 NMSA 1978];

(2) provide for examinations of applicants for licensure as pharmacists;

(3) provide for the issuance and renewal of licenses for pharmacists;

(4) require and establish criteria for continuing education as a condition of renewal of licensure for pharmacists;

(5) provide for the issuance and renewal of licenses for pharmacist interns and for their training, supervision and discipline;

(6) provide for the licensing of retail pharmacies, nonresident pharmacies, wholesale drug distributors, drug manufacturers, hospital pharmacies, nursing home drug facilities, industrial and public health clinics and all places where dangerous drugs are stored, distributed, dispensed or administered and provide for the inspection of the facilities and activities;

(7) enforce the provisions of all laws of the state pertaining to the practice of pharmacy and the manufacture, production, sale or distribution of drugs or cosmetics and their standards of strength and purity;

(8) conduct hearings upon charges relating to the discipline of a registrant or licensee or the denial, suspension or revocation of a registration or a license in accordance with the Uniform Licensing Act;

(9) cause the prosecution of any person violating the Pharmacy Act, the New Mexico Drug, Device and Cosmetic Act [Chapter 26, Article 1 NMSA 1978] or the Controlled Substances Act [Chapter 30, Article 31 NMSA 1978];

(10) keep a record of all proceedings of the board;

(11) make an annual report to the governor;

(12) appoint and employ, in the board's discretion, a qualified person who is not a member of the board to serve as executive director and define the executive director's duties and responsibilities; except that the power to deny, revoke or suspend any license or registration authorized by the Pharmacy Act shall not be delegated by the board;

(13) appoint and employ inspectors necessary to enforce the provisions of all acts under the administration of the board, which inspectors shall be pharmacists and have all the powers and duties of peace officers;

(14) provide for other qualified employees necessary to carry out the provisions of the Pharmacy Act;

(15) have the authority to employ a competent attorney to give advice and counsel in regard to any matter connected with the duties of the board, to represent the board in any legal proceedings and to aid in the enforcement of the laws in relation to the pharmacy profession and to fix the compensation to be paid to the attorney; provided, however, that the attorney shall be compensated from the money of the board, including that provided for in Section 61-11-19 NMSA 1978;

(16) register and regulate qualifications, training and permissible activities of pharmacy technicians;

(17) provide a registry of all persons licensed as pharmacists or pharmacist interns in the state;

(18) adopt rules and regulations that prescribe the activities and duties of pharmacy owners and pharmacists in the provision of pharmaceutical care, emergency prescription dispensing, drug regimen review and patient counseling in each practice setting;

(19) adopt, after approval by the New Mexico board of medical examiners [New Mexico medical board] and the board of nursing, rules and protocols for the prescribing of dangerous drug therapy, including vaccines and immunizations, and the appropriate notification of the primary or appropriate physician of the person receiving the dangerous drug therapy; and

(20) have the authority to authorize emergency prescription dispensing.

The board may:

(1) delegate its authority to the executive director to issue temporary licenses as provided in Section 61-11-14 NMSA 1978;

(2) provide by regulation for the electronic transmission of prescriptions; and

(3) delegate its authority to the executive director to authorize emergency prescription dispensing procedures during civil or public health emergencies.