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

SPONSOR Padilla **ORIGINAL DATE / LAST UPDATED** 01/23/15 **HB**

SHORT TITLE Collection & Disposal of Unused Drugs **SB** 21

ANALYST Cerny

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY15	FY16	FY17	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total		Indeterminate	Indeterminate	TBD	Recurring	Board of Pharmacy

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION

LFC Files

Responses Received From
Regulation & Licensing Department (RLD)
Medical Board (MB)
New Mexico Environment Department (NMED)
Department of Health (DOH)

SUMMARY

Synopsis of Bill

Senate Bill 21 proposes to enact a new section of the Pharmacy Act to direct the New Mexico Board of Pharmacy, in consultation with the Environmental Improvement Board and the Drug Enforcement Administration, to promulgate rules to establish a dangerous drug take-back program that will:

- require each retail pharmacy in the state to collect unused dangerous drugs;
- provide for the safe disposal of the dangerous drugs in accordance with state and federal law; and
- indemnify and hold harmless wholesale drug distributors for actions taken in compliance with these new rules.

The Board of Pharmacy will establish a means of funding and may impose a reasonable fee, to cover costs of implementing this program.

FISCAL IMPLICATIONS

SB 21 carries no appropriation.

The statute states that the NMBOP shall establish a means of funding and may impose reasonable fees to cover the costs of executing the provisions of this section.

Verifying compliance during investigations and inspections will require increase time in the inspection/investigation of pharmacies.

SB 21 contains no timeline for implementation so it is difficult to estimate when revenues and any additional operating impact might accrue.

SIGNIFICANT ISSUES

RLD analysis states:

> Nationally, New Mexico has been number one in overdose deaths for several years. Recently, New Mexico improved from first to third nationally in part due to new efforts by the various health care boards and the NM Department of Health to reduce the injudicious prescribing of controlled substances. But the issue in overdose deaths is controlled substances.

This new section of the statute pertains to dangerous drugs only, which are defined in Section 16.9.17.7 of the NM Drug, Device and Cosmetic Act. These are essentially ephedrine-based drugs available only by prescription. Controlled substances are scheduled drugs covered under Section 30.31-1 through 30.31-41 NMSA 1978, the Controlled Substances Act and include opiates.

On September 9, 2014, the Drug Enforcement Administration (DEA) of the Department of Justice issued its final rule on the disposal of controlled substances (21 CFR Parts 1300, 1301, 1304, 1305, 1307, and 1317). The intention of this rule was to significantly expand the options available to collect controlled substances for the purpose of disposal. Providing individuals with a secure and convenient way to dispose of controlled substances will help prevent diversion and abuse of these substances and demonstrate sound environmental stewardship." (DEA, 2014).

Disposal may include take-back events, mail-back programs, and maintenance of collection receptacles at retail, institutional pharmacies, and long term care facilities. The new DEA rule does not require retail pharmacies to participate. However, if retail pharmacies decide to do so, they must register as an authorized disposal site, and follow strict regulations on the collection and disposal of these drugs, including procedures to prevent diversion of these substances.

The NBOP recognized the need for safe disposal of unused dangerous drugs and stipulated under NMAC 16.19.6.15 that patients may return dispensed legend medications (i.e., drugs requiring a prescription) and over-the-counter drugs to an authorized pharmacy for destruction. This regulation currently allows for pharmacies to take medication back on a voluntary basis. The regulation, as written, allows for pharmacies to take back controlled substances. In order to be authorized, the pharmacy must submit a protocol to the Board or its agent for approval that stipulates mechanisms of collection, destruction, security, the name of the contract disposal company; frequency of collection; and records of collection and disposal.

According to DOH analysis (per a communication with NMBOP on 12/22/14:

> To the Board's knowledge, no New Mexico pharmacy has registered with the DEA to become an authorized disposal site, because pharmacists perceive that the DEA"s requirements are onerous and costly for small pharmacies to implement.
>
> SB21's requirement that all retail pharmacies participate may be considered to be equally onerous, since the bill suggests that DEA regulations would have to be considered in the development of new rules. Further, companies that take back dangerous drugs for destruction ("authorized redistributors") also have to register with the DEA and comply with the provisions of the September 2014 final rule.

Many law enforcement agencies around New Mexico also participate in a drug take back program. In the Albuquerque area, every Albuquerque Police Department (APD) substation has a drug take back from 8am to 5pm Monday through Friday. Also the Department of Public Safety has a location for drug take back in Albuquerque. If an individual is unable to deliver their unwanted medications to one of these locations, they are instructed to render the medication unfit for human consumption. Then, place the medication in the trash. Individuals are instructed to avoid flushing medications into the water supply.

RLD analysis states that:

> There will be a cost to the pharmacy implementing this program. If only dangerous drugs are involved, the pharmacy, at a minimum, would have to send this unwanted medication to a reverse distributor for destruction. This can be expensive. Pharmacy is a competitive business. Since 2012, NM Board of Pharmacy records show that at least 32 pharmacies located within New Mexico have closed. If controlled substances are added, there will be another additional expense to the pharmacy to comply with Drug Enforcement Administration (DEA) requirements. The proposed statute states that the NM Board of Pharmacy shall establish a means of funding, and may impose a reasonable fee, to cover costs of executing the provisions of this section.

Medical Board analysis however emphasizes the need for such a program:

> Proper disposal of dangerous drugs (defined by the board of pharmacy as all drugs requiring prescription) is not widely understood or practiced by patients and practitioners. The Medical Board continues to work with the DEA on cases involving the redistribution and disposal of controlled substances by physicians. It is evident that a consistent, streamlined process such as a pharmacy take-back program would decrease generally unsafe or environmentally unsafe disposal, as well as the illegal redistribution of dangerous prescription drugs by patients or by physicians or physician offices.

PERFORMANCE IMPLICATIONS

Affected agencies would need to participate in committee meeting to promulgate rules and regulations and adhere to and enforce the compliance requirements.

If retail pharmacies dispose and/or incinerate drugs under the take-back program, the waste stream would fall under NM Solid Waste Rules, and be subject to different definitions. However if retail pharmacies collect and return drugs to approved sources for disposal/incineration, such actions would be regulated by the NBOP, not the Environmental Improvement Board.

OTHER SUBSTANTIVE ISSUES

The NMED Solid Waste Bureau in its analysis states the following concerns:

Any retail pharmacy that disposes/incinerates dangerous drugs under the take-back program would be subject to NM Solid Waste Rules.

- Presuming that retail pharmacies participating in the take-back program would not be disposing/incinerating dangerous drugs, NMED would not have any oversight over this program.
- Furthermore, it is unclear if substances accepted by a retail pharmacy under a tack-back program would include certain types of drugs considered hazardous waste under 40 CFR 261, Subparts C and D. These drugs (described in 20.9.3.30 NMAC) include antineoplastic drugs; Resource Conservation and Recovery Act P- and U-listed hazardous pharmaceutical wastes; and D-listed chemicals that cause a waste to exhibit toxicity characteristics.

CAC/bb/je