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

SPONSOR Feldman **ORIGINAL DATE** 01/22/09 **LAST UPDATED** 03/18/09 **HB**

SHORT TITLE Prescription Drug Donation **SB** 40/aSPAC/aHCPAC/ aHJC

ANALYST C. Sanchez

APPROPRIATION (dollars in thousands)

Appropriation		Recurring or Non-Rec	Fund Affected
FY08	**FY09**		
	NFI		

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION
LFC Files

Responses Received From
Regulation and Licensing Department (RLD)
Department of Health (DOH)
New Mexico Health Policy Commission (NMHPC)

SUMMARY

Synopsis of HJC amendment

The House Judiciary amendment to Senate Bill 40 removes the HCPAC amendment which read "no person shall be liable for the bad faith of another person".

Synopsis of HCPAC Amendment

The House Consumer and Public Affairs Committee amendment requires the Board of Pharmacy to promulgate rules and develop a standardized consent form in order for a licensed practitioner to supply donated prescription drugs to an individual patient. SB 40aa requires that a prescription drug dispensed to a patient must be registered with the drug manufacturer in accordance with the Federal Food and Drug Administration (FDA) requirement shall not be donated or supplied under the provision of the section. **In addition the amendment provides that no person shall be held harmless due to the bad faith of another person**.

The House Consumer and Pubic Affairs Committee amendment strikes the Senate Public Affairs Committee amendment on page 2 line 8.

Synopsis of SPAC Amendment

Senate Bill 40 amends the Pharmacy Act NMSA 61-11-1 et seq. by exempting licensed practitioners, who are receiving and supplying donated prescription drugs, from the other licensure provisions of the Act. Licensed practitioners would be allowed to accept and dispense donated prescription drugs to individual patients as long as the patient is apprised of the source of the donated drugs and consents to receiving them.
The Public Affairs Committee amendment adds the requirement for the Board of Pharmacy to promulgate rules that implement the re-dispensing/re-use of donated prescription drugs by licensed health care practitioners. The Board is also required to develop a standardized consent form that patients receiving donated prescription drugs would be required to sign. The consent form would notify the patient of the source and other information as determined by the Board.

Synopsis of Original Bill

Senate Bill 40 amends the Pharmacy Act NMSA 61-11, by exempting licensed practitioners, who are receiving and supplying donated prescription drugs, from the other licensure provisions of the Act. Licensed practitioners would be allowed to accept and dispense donated prescription drugs to individual patients as long as the patient is apprised of the source of the donated drugs and consents to receiving them.

FISCAL IMPLICATIONS

NFI

SIGNIFICANT ISSUES

Lack of health insurance and prescription drug coverage affects a large proportion of New Mexicans. Prescription drug costs are significantly increasing and an increasing number of New Mexicans are reducing or skipping their doses or going altogether without their medications. Some individuals may not be able to receive necessary treatment due to lack of resources. SB40 would provide an option for treating these patients.

From the perspective of programs treating Human Immunodeficiency Virus (HIV), the ability to use donated HIV medications might be useful for post-exposure prophylaxis. Patients who have been exposed to HIV need to start treatment immediately and cannot wait for a source of reimbursement to be established. SB40 would allow the licensed practitioner to supply the necessary medications without the concern of cost to the patient. Some patients recently diagnosed with HIV need to be started on medications quickly in order to avert disease progression. It often takes a few weeks to enroll patients in programs that will support their treatment. SB40 would allow patients to have access to donated HIV medications that could be used to initiate treatment until reimbursement sources are established.

Similar legislation has been passed in 37 other states although not all are yet operational. Georgia was the first in 1997 and Kansas was the most recent in 2008 to pass reuse legislation. In addition six states have similar laws that focus only on cancer related drugs: Colorado, Florida, Kentucky, Minnesota, Nebraska and Wisconsin. Most laws allow the return of prescription drugs in single use or sealed packaging from state programs, nursing homes and other medical facilities. In addition all existing programs require that donated drugs must not be expired and

must have a verified future expiration date; controlled substances as defined by the federal Drug Enforcement Administration are usually excluded; a state-licensed pharmacist or pharmacy must be part of the verification and distribution process and each patient who is to receive a drug must have a valid prescription in his/her own name.

According to the Department of Health, access to health insurance and prescription drug coverage affects those who are poor, unemployed, underemployed, indigent and undocumented residents who tend to forgo treatment until their medical conditions become more urgent. SB40 would contribute to providing improved and timely access to needed medicines for these population groups in the state, including rural residents, the poor and indigent, and the uninsured and underinsured, and in those who live in areas without commercial pharmacies.

ADMINISTRATIVE IMPLICATIONS

According to the NM Health Policy Commission, the Pharmacy Act provides the Board of Pharmacy with rule making authority [61-11-6 NMSA 1978], enabling the Board of Pharmacy to adopt and amend rules and regulations necessary to carry out the provisions of the Pharmacy Act. The Board of Pharmacy will need to establish a mechanism and protocol for licensed practitioners to obtain donated prescription drugs and decipher between contaminated and non-contaminated donated prescription drugs.

For the health and safety of patients, it is imperative for the Board of Pharmacy to identify the responsible entity that will secure the potential donated prescription drugs. Also, it is crucial for the development of standards outlining acceptable drugs that can be donated and redistributed for use. The Board of Pharmacy will need to identify entities that may accept and dispense donated drugs.

The following is a list of the adopted rules and regulations of the Pharmacy Board that will be affected if SB40 becomes a statute under the Pharmacy Act:

- 16.19.6.11 Minimum Equipment and Accessory Standards – Section A: Sterile Pharmaceutical Preparation
- 16.19.6.14A Prohibition of Resale of Drugs
- 16.19.6.15 Disposition of Dangerous Drugs or Controlled Substances
- 16.19.6.18 Labeling or to Label – Section A: Prescription Drug Dispensing Container Requirements
- 16.19.6.23A Prescriptions

Lastly, SB40 would enable licensed practitioners to supply donated prescription drugs, but it does not describe how licensed practitioners need to be accountable for the additional prescription drugs that were not originally dispensed to entities that distribute pharmaceutical prescriptions. This bill as it stands, also needs to amend the Drug Records to be Kept section [61-11-8 NMSA 1978] of the Pharmacy Act.

In addition, the Drug Records to be Kept section of the Pharmacy Act [61-11-8- NMSA 1978] needs to be amended to include prescription drug donations. This will allow pharmaceutical dispensing entities to be accountable for prescription drug donations.

TECHNICAL ISSUES

According to the Pharmacy Board and RLD, Senate Bill 40 does not address, or waive, the legal requirements of the Drug Device and Cosmetic Act NMSA 26-1. Specifically:

1. NMSA 26-1-16B says "All official compendium requirements for the preservation, packaging, labeling and storage of dangerous drugs are applicable where drugs are held for dispensing to the public, whether by a pharmacy, clinic, hospital or practitioner." Drugs that are not held under the proper storage conditions may be deemed "adulterated."
2. Adulterated: NMSA 26-1-10A "if it has been produced, prepared, packed or held under insanitary conditions whereby it may have been contaminated with filth." The donated drugs would be coming in from a variety of sources including patients or patient's families. The storage of drugs in their place of residence may not meet the temperature and moisture restrictions listed in the United States Pharmacopeia (USP) the official compendium. The other elements of NMSA 26-1-10 would also be applicable in this case. The expiration date on drugs placed in a dispensing vial is set at one-year maximum by the USP. The manufacturer's expiration date is no longer valid once a drug has been removed from its original package.
3. Misbranding: NMSA 26-1-11 many of the elements of this section would be applicable. Drugs that have already been dispensed to a patient no longer have the required labeling or other required information. The dispensing labels from a pharmacy do not list the drug's manufacturer nor do they include the "Rx Only" or "Caution: federal law prohibits dispensing without prescription." Most of the prescription drugs brought in from a patient would be considered misbranded.
4. NMSA 26-1-3 Prohibited Acts; C: the receipt or delivery in commerce of any drug or device that is adulterated, misbranded or a counterfeit drug which is not a controlled substance.

OTHER SUBSTANTIVE ISSUES

The Bill does not address who (patients, practitioners, hospitals, pharmacies, clinics, or other licensed entity) the practitioner would be accepting donated prescription drugs from. This Bill would allow the donation of prescription drugs from any source which could potentially be a significant amount. If such drugs are collected by a practitioner but never re-dispensed to one of their patients, a significant amount of pharmaceuticals would remain in their custody and must be destroyed. The Bill does not limit the number of times the previously dispensed product may be accepted back by the practitioner for re-use.

The prescription drugs would not have an effective paper trail for drug recalls. Drug wholesalers track lot number to the pharmacy level not to the patient. Pharmacies contact every patient who received a recalled drug. Practitioners are not usually included in recall notices unless they are listed as a purchaser from a drug distributor.

The Bill does not include the language that would be included in the informed consent a patient must give prior to receiving donated prescription drugs or whether or not consent must be verbal or written.

Drug Manufacturers typically will not guarantee their product once it has left the licensed health care chain of custody.

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

The Pharmacy Act, Section 61-11-22, NMSA 1978 (being Laws 1969, Chapter 29, Section 21) would not be amended to include an exemption allowing licensed practitioners to supply donated prescription drugs at low or no costs for use by the licensed practitioner's patients.

CS/mt:svb