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

SPONSOR Papen **ORIGINAL DATE** 1/23/2020 **LAST UPDATED** 2/13/2020 **HB**

SHORT TITLE Wholesale Prescription Drug Importation Act **SB** 1/aSPAC/aSFC/ec

ANALYST Chilton

REVENUE (dollars in thousands)

Estimated Revenue			Recurring or Nonrecurring	Fund Affected
FY20	FY21	FY22		
	Unknown, but balanced by costs	Unknown, but balanced by costs	Recurring	Wholesale Prescription Drug Importation Fund

(Parenthesis ( ) Indicate Revenue Decreases)

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY20	FY21	FY22	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total		DOH costs unknown, but balanced by revenues	DOH costs unknown, but balanced by revenues	DOH costs unknown, but balanced by revenues	Recurring	Wholesale Prescription Drug Importation Fund
		SIC costs unknown	SIC costs unknown	SIC costs unknown	Recurring	General Fund

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION

LFC Files

Responses Received From
Administrative Office of the Courts (AOC; stated had no comment)
Aging and Long-Term Services Department (ALTSO)
Office of the Attorney General (NMAG)
Department of Health (DOH)
New Mexico Medical Board (NMMB)
Office of the Superintendent of Insurance (OSI)
General Services Department (GSD)
Human Services Department (HSD)
State Investment Council (SIC)

SUMMARY

Synopsis of SFC Amendment

The Senate Finance Committee amendment removes the appropriation for the wholesale drug importation fund, substituting language stating that the fund would be subject to legislative appropriations.

In addition the amendment makes the following changes:

- Makes it clear that DOH could contract with one or more than one state drug wholesalers
- Removes the sentence making the state investment officer responsible for investing the fund.

Synopsis of SPAC Amendment

The Senate Public Affairs amendment makes several additions:

1. Requiring DOH to hold a public hearing on the proposed program before requesting federal approval;
2. Noting that the requirement for compliance with federal regulations apply to the drug importation portion of the program;
3. Adding "verification and identification" [of drugs to be imported] as aspects of the federal regulations that are to be complied with;
4. Removing redundancy in referring to drugs to be imported; and
5. Requiring consultation with the Board of Pharmacy with respect to carrying out duties deemed to be necessary to implement the program of drug importation.

Synopsis of Original Bill

The Wholesale Prescription Drug Importation Act appropriates $350 thousand from the general fund to the Department of Health for the purpose of setting up a program whereby the state would import prescription medications from Canada (and perhaps other countries) through a wholesaler or wholesalers for resale to New Mexico consumers. Such a program depends on federal implementation of a law passed by Congress in 2003 to allow drug importation from Canada. The law required the secretary of the federal Department of Health and Human Services establish regulations for such a program before it could be placed into effect, but that is not anticipated to happen until spring or summer 2020.

The act would require DOH to convene an interagency committee composed of the secretaries of Health, Human Services and General Services departments, the executive director of the Board of Pharmacy, and the superintendent of insurance, to oversee the design and creation of a program to obtain wholesale prescription drugs in Canada or in other countries allowed by federal law to export drugs into the United States.

Drugs eligible for importation would not violate federal patent law, could not be controlled substances, would, according to Section 2 of the bill, "generate cost savings," or according to Section 4 of the bill, "generate significant cost savings" for New Mexicans, and, would meet U.S. federal drug administration standards for safety and effectiveness. Wholesalers would have to assure that they would comply with federal law on tracking and tracing imported drugs. Drugs obtained in this manner could not be re-distributed beyond the state's borders. Mark-ups

by intermediaries would not be allowed to jeopardize cost savings to consumers.

Implementation of the plan would require approval by the secretary of the federal Department of Health and Human Services. Once federal approval was obtained, DOH would have up to six months to implement the program. Implementation would also include contracting with one or more wholesalers and one or more Canadian suppliers, consultation with stakeholders (including pharmacies, insurance plans, healthcare providers and consumers), developing a process to register health plans, pharmacies and providers wishing to act as intermediaries, and making a list of eligible drugs and their prices for consumers and all stakeholders.

Each year, DOH would report to the governor and the Legislature on the drugs made available, the savings generated, the numbers of participating intermediaries, and other information about the plan and an audit of the plan.

This bill contains an emergency clause and would become effective immediately on signature by the governor.

FISCAL IMPLICATIONS

The appropriation of $350 thousand contained in this bill is a recurring expense to the general fund. Any unexpended or unencumbered balance remaining at the end of each fiscal year shall revert to the general fund.

This bill creates a new fund, the wholesale prescription drug importation fund, and provides for continuing appropriations to operate the program. However, DOH intends to make the program otherwise cost neutral: Charges for drugs to health plans, pharmacies and consumers would balance the cost of their acquisition as well as the cost of administering the program. LFC has concerns with including continuing appropriation language in the statutory provisions for newly created funds, because earmarking reduces the ability of the Legislature to establish spending priorities.

SIC notes that it would manage the new fund in consultation with the Department of Health, and in keeping with DOH's need for distributions from the fund to accomplish the program's ends. It states that it aims for a seven percent annual return on funds it invests, but that varies depending upon payout needs.

Agencies involved in the advisory committee would incur personnel costs.

GSD notes "The State of New Mexico's group health benefits plan may appreciate savings from the importation of wholesale prescription drugs, as members of the plan will presumably pay less markup on drugs imported and utilized to fill member prescriptions. Because DOH is required in SB1 to prioritize consumer savings, any importation, no matter how small, should come with savings that will inure to the benefit of the consumer."

SIGNIFICANT ISSUES

ALTSO notes that "In calendar year 2019, one in five calls to the Aging & Disability Resource Center were requests for help paying for prescriptions. This is a fraction of the total New Mexicans in need of this assistance. Many of the callers were either rationing their medication

due to the cost or not taking their medications at all. There is a known link between food insecurity and cost-related medication underuse. Medication underuse is also strongly correlated to self-neglect reports to Adult Protective Services. These issues negatively impact consumers, family, caregivers, state, and community resources. New Mexicans on a limited or fixed income often are forced to choose between their life-saving medications and their quality of life."

U.S. consumers pay a higher price for prescription medications than consumers in other countries. In a 2002 study published by the World Health Organization, U.S. prices for 27 frequently used brand name drugs were 40 per cent higher in the U.S. than in Canada. (https://www.who.int/intellectualproperty/events/en/R&Dpaper2.pdf?source=your_stories_page).

TABLE 9 Average Foreign-to-Canadian Price Ratios, Bilateral Comparisons, 2017

	Canada	France	Italy	Germany	Sweden	Switzerland	United Kingdom	United States
At Market Exchange Rates								
Average price ratio 2017	1.00	0.75	0.95	1.12	0.93	1.12	0.94	3.36
Average price ratio 2016	1.00	0.77	0.92	1.09	0.95	1.09	0.99	3.08
At Purchasing Power Parities								
Average price ratio 2017	1.00	0.79	1.12	1.20	0.83	0.88	0.98	3.25
Average price ratio 2016	1.00	0.83	1.09	1.22	0.84	0.87	0.97	3.15
Number of patented	1,381	675	775	1,016	845	889	991	1,100
Sales ($millions)	16,784.86	9,679.62	12,611.57	14,379.87	12,960.85	14,183.17	13,567.44	15,575.41

Generic drugs were less expensive in the U.S. than in Canada in 2002, according to the WHO study, but by 2017, according to the Canadian Patented Medicine Prices Review Board, generic medicines cost 8 percent more in the United States than in Canada.

On the other hand, a December 2019 article on the CBS news site, (https://www.cbsnews.com/news/prescription-drugs-imported-from-canada-wont-lower-prices-for-american-consumers-experts-say/), states that 90 percent of the 4 billion annual U. S. prescription issued to Americans are filled with generic drugs. The article gives other reasons, including Canadian reluctance to participate, for its conclusion, "Experts [are] 'not optimistic' about Trump plan to import drugs from Canada."

DOH makes the following points in favor of adopting the program proposed in SB1:

- The high cost of prescription drugs in the United States has clinical consequences. Almost a quarter of 648 respondents to a 2015 poll reported that they or another family member did not fill a prescription in the last year because of cost. In other studies, patients who were prescribed a costly branded product rather than a more

affordable generic alternative were found to adhere to their regimen less well than those receiving a similar generic drug and to have worse health outcomes. Nonadherence due to all causes has been estimated to contribute nationally to $105 billion in avoidable health care costs annually. (http://jamanetwork.com/journals/jama.fullarticle/254691)

- SB1 has the potential to impact all New Mexicans with some acute or chronic medical conditions through providing access to lower cost prescription drugs. This can increase adherence to prescribed therapies, thereby impacting health conditions and leading to improved health status over time.

NMAG points out the federal comment period for proposed regulations for a drug importation program will not be completed until March 9, 2020, and that promulgation of final rules will not come until after that time. NMAG also points to the need for protection of sensitive patient information under a program, such as that anticipated by SB1.

DHS notes that the federal government currently prohibits the importation of controlled substances, biologics, drugs for infusion and injection, and certain inhaled or parenteral drugs, while SB 1 would only prohibit importation of controlled substances. This would leave open the possibility that the other categories prohibited under current federal regulations change to allow the other types of medication to be imported, New Mexico's program would be able to do so without requiring further legislation.

ADMINISTRATIVE IMPLICATIONS

SIC notes the following implications regarding its activities:

Taking on additional assets with new strategic goals may result in additional resource needs at the SIC, though determining the specific need is challenging. Active management costs more money to invest than passively managed assets, and similarly, advisory services from external experts may or may not require additional compensation above existing contract levels to perform the new services needed for this new fund.

The SIC staffing level has not increased over the past decade (it's actually decreased), though the total assets under management by the SIC have nearly doubled, which would indicate any additional needs of the Council could be addressed through the normal annual budgeting process.

TECHNICAL ISSUES

Drugs to be included in the program are to generate "cost savings" (Section 2) or "significant cost savings" (Section 4), although the term "significant" is not defined in the bill. The difference should be resolved and the term "significant" defined.

The bill implies but does not specify that imported drugs would be provided to pharmacies, insurance plans, or healthcare providers, but does not state that explicitly.

NMAG makes the following suggestions:

- In Section 2(D)(4) (p. 2, line 12), consider clarifying that this provision refers to controlled substances as defined by the NM Controlled Substances Act, NMSA 1978 Sections 30-31-1 to -41.
- In Section 2(F) (p. 2, lines 15-17), consider clarifying that the definition of a licensed "state drug wholesaler" contemplates a pharmaceutical wholesaler license issued by the NM Regulation and Licensing Department.

- In Section 4(A) (p. 3, line 19) the term "licensed drug wholesaler" is used. Consider changing to the defined term "state drug wholesaler," which includes a licensing requirement.

- Section 7(A) (p. 5, line 17) refers to contracts with "one or more New Mexico licensed drug wholesalers and New Mexico licensed drug distributors," which appears to conflict with Sections 4(A) and (E), which each refer to a single drug wholesaler.

- Section 12's reference to "the public peace, health and safety" (p. 8, lines 10-11) implies that SB1 seeks to invoke the inherent police power of the state of New Mexico. *See State ex rel. City of Albuquerque v. Lavender*, 1961-NMSC-096, ¶ 24 ("Laws providing for preservation of the public peace, health and safety are essentially police measures and represent an exercise of this inherent power."). This appears to be at odds with the requirement that any drug import program created by SB1 adhere to an as-yet-to-be-initiated federal statutes and regulations that would likely preempt any conflicting New Mexico statutes or regulations. *See State v. Herrera*, 2014-NMCA-003, ¶ 10 ("There is a strong presumption against preemption, especially in areas involving historic police powers of the states.") (Internal quotations and modifications omitted.)

LAC/al/sb/rl