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

SPONSOR Rubio **ORIGINAL DATE** 02/03/21 **LAST UPDATED** **HB** 154

SHORT TITLE Prescription Drug Affordability Act **SB**

ANALYST Chilton

REVENUE (dollars in thousands)

Estimated Revenue			Recurring or Nonrecurring	Fund Affected
FY21	FY22	FY23		
	$60.0	$60.0	Recurring	Prescription Drug Affordability Fund

(Parenthesis ( ) Indicate Revenue Decreases)

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY21	FY22	FY23	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total		$36.0	$36.0	$72.0	Recurring	Prescription Drug Affordability Fund

(Parenthesis ( ) Indicate Expenditure Decreases)

Related to 2020 Senate Bill 1 and 2019 Senate Bill 131

SOURCES OF INFORMATION
LFC Files

Responses Received From
Regulation and Licensing Department (RLD
Office of the Superintendent of Insurance (OSI)
Public School Insurance Authority (PSIA)
General Services Department (GSD)
Human Services Department (HSD)
Department of Health (DOH)

SUMMARY

Synopsis of Bill

House Bill 154 would create a five-member prescription drug affordability board, the purpose of which is to take action to protect state residents and other stakeholders from the high cost of prescription drugs, Board members would be appointed for their expertise in clinical medicine or health economics and would not be employees of or consultants to pharmaceutical companies or their trade associations.

A fifteen-member "prescription drug affordability stakeholder council" would also be created to advise the board. Its composition is specified in the bill, to represent each stakeholder group. Both groups would be jointly appointed by the governor and legislative leaders of both parties, and limits on conflicts of interest are specified for members of both groups.

The prescription drug affordability board would consider drugs having a high acquisition cost, specified in the bill, whether they be brand name or generic, as well as those whose cost had rapidly increased and any others deemed to create affordability challenges.

The board would look at the manufacturer's price concessions or rebates, the price of therapeutic alternatives and the overall impact of a drug's pricing on patient access to the medication, the cost of the medication in other jurisdictions, and the financial impact of the pricing on health, medical and social service costs. If the board determined a given medication to pose an affordability challenge, it would establish an upper payment limit that would apply to all purchases by patients, whether by mail or in person.

Office of Attorney General could pursue legal action against those violating provisions of the law. A manufacturer could appeal a board decision to the board within thirty days of the decision and then file for judicial relief as specified in Section 12-8-16 NMSA 1978, "Petition for judicial review."

Section 9 of the bill established a "prescription drug affordability fund" underwritten by assessments on manufacturers and distributors, both on the ground and virtual, repackagers and pharmacy benefit managers, based on their share of gross revenue from New Mexico drug sales, not to exceed $2 thousand per entity.

The prescription drug affordability board would submit information on its functions and deliberations to the Legislative Finance Committee and the interim Health and Human Services Committee. It would also study and report to the Legislature on the generic drug market and its functioning in the United States.

Where an upper payment limit was established, it would be applied to all state-sponsored and state-regulated plans, but not ERISA or Medicare part D plans. Providers directly dispensing or administering drugs to individuals could not charge more than the upper payment limit.

There is a severability clause; the effective date of the act would be September 30, 2021.

FISCAL IMPLICATIONS

There is no appropriation in House Bill 154.

Functioning of the Prescription Drug Affordability Board (PDAB) would be financed by assessments on pharmaceutical manufacturers and intermediaries, such as pharmacy benefit managers doing business in the state. The assessment on each would not exceed $2,000. DOH estimates that there are thirty such businesses; therefore the maximum to be assessed would be $60 thousand. DOH also estimates the cost of per diem and travel for members of the PDAB and the Prescription Drug Affordability Stakeholder Council would be approximately $36 thousand per year.

PSIA and GSD both note the possible positive future effect of PDAB decisions on drug budgets for their beneficiaries.

SIGNIFICANT ISSUES

Opponents of pharmaceutical price controls, including the developers and manufacturers of medications, point out the risk involved in investing the estimated ten years and $2.6 million required to bring a new drug to market, costs that must be recovered through sales of the drug. They note that many proposed new drugs never arrive at approval and sale.

Proponents of price control point to a much higher price paid for medications in the United States than in Canada or Europe. Although an often-cited statistic is that U.S. consumers must pay four times what Canadians pay, studies show a gap, but not such a large gap. In a 2002 study published by the World Health Organization, U.S. prices for 27frequently 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). 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, genericmedicines 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-pricesfor-american-consumers-experts-say/), states that 90 percent of the 4 billion annual U. S. prescription issued to Americans are filled with generic drugs, where the difference in price is much lower.

Studies have shown that as many as seven out of ten New Mexico consumers have failed to fill drug prescriptions and/or diminished the dose taken because of the high cost of their medications.

Laws 2020, Chapter 45 went into law in March 2020, establishing a program of importation of drugs from Canada. Such an action requires federal approval; in December 2020 the governor submitted an application to do so under Section 804 of the Food, Drug and Cosmetics Act.

DOH notes that

> There are 17 other states that have explored enacting a drug affordability board. Six have enacted legislation to create a board (ME, MD, MA, NH, NY and OH) and four states have pending legislation (MA, NJ, NY and PA). Eleven states have attempted to reduce

drug cost and pricing by proposing legislation. https://www.jdsupra.com/legalnews/state-drug-affordability-boards-53701/

Efforts to reduce medication costs for individuals who cannot afford high-cost medications may reduce financial hardships for New Mexicans. Improving the health status of New Mexicans is obtainable when high cost treatment regimens are obtainable as higher costs may lead to lower utilization rates.
https://www.ncbi.nlm.nih.gov/books/NBK493090/

Maryland has a prescription drug affordability board and they document that there is a significant impact on public health where people will be more capable of affording their medication, may help to prevent increases in insurance premiums, and it may assist in health agencies being able to afford important medication.

https://mdpha.org/content/uploads/Prescription-Drug-Affordability-Board.pdf

POSSIBLE CONFLICT OR OVERLAP with 2019 Senate Bill 131, which created an interagency pharmacies purchasing council.

RELATIONSHIP with Laws 2020, Chapter 45, which established a program to import medications from Canada to take advantage of price differences between the two countries.

TECHNICAL ISSUES

HSD notes that "Reimbursement for drugs in the Medicaid program is regulated at the federal level by the Centers for Medicare and Medicaid Services and rules are set forth in the Code of Federal Regulations (CFR) at 42 CFR 447.500 through 447.522. HSD may not have the flexibility to implement any recommendations that might be made by the Board around drug pricing, unless such recommendations fit within the precise parameters governed by federal regulation… Health plans regulated by ERISA and Medicare Part D plans are not bound by decisions of the board. Although not specifically identified in the bill, Medicaid may need to be similarly exempt from following the decisions of the Board if such upper payment limits do not align with what is allowed under federal rules. Intent to exempt Medicaid or not would assist with analysis."

The OSI suggests that the public at large be afforded a way to suggest drugs for price review by the board. It also points out a potential for conflict of interest if a member of the board or council himself/herself or a family member is taking one of the medications to be considered by the board. Recusal from decision-making in that case may be appropriate.

As pointed out by RLD, "Regarding conflicts of interest, board member recusal is required if the board member, or an immediate family member, has received or could receive "a financial benefit from any person that owns, manufactures *or provides prescription drug products, services or items to be studied by the board that in the aggregate exceeds five thousand dollars ($5,000) per year*." This provision appears to exclude pharmacists, and immediate family members of pharmacists, from serving on the PDA Board. Pharmacists may reasonably be expected to possess knowledge and collective expertise in health care economics, clinical medicine, pharmaceutical business models and supply chain models, and drug pricing trends relevant to the purposes of the PDA Board."

ALTERNATIVES

OSI suggests the following considerations:

1. "Amend the PDA Board member conflict of interest provision to allow a pharmacist (who does not have a financial interest in a manufacturer, wholesale drug distributor, or repackager business) to serve on the PDA Board;
2. Prohibit manufacturers, virtual manufacturers, wholesale distributors, virtual wholesale distributors, and repackagers from contributing to the PDA Fund;
3. Remove third party logistics providers from entities subject to PDA Fund license fees; and
4. Provide an exemption for licensed entity locations that only provide medications through patient assistance program(s)."

LAC/al