FISCAL IMPACT REPORT

SPONSOR	Sens. Stefanics, Stewart and Hamblen/ Rep. Szczepanski	**LAST UPDATED**	2/24/2025
		ORIGINAL DATE	2/19/2025
SHORT TITLE	Add Classes to Prior Authorization Drugs	**BILL NUMBER**	Senate Bill 39/aSTBTC
		ANALYST	Esquibel

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT*
(dollars in thousands)

Agency/Program	FY25	FY26	FY27	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
NMPSIA		$950.0	$1,000.0	$1,950.0	Recurring	NMPSIA Fund
RHCA		$2,193.0	$2,302.0	$4,495.0	Recurring	RHCA Fund
State Health Benefit Plan		See Fiscal Implications	See Fiscal Implications	See Fiscal Implications	Recurring	SHBP Fund
Total		$3,143.0	$3,302.0	$6,445.0	Recurring	Multiple

Parentheses ( ) indicate expenditure decreases.
*Amounts reflect most recent analysis of this legislation.

Sources of Information

LFC Files

Agency Analysis Received From
Department of Health (DOH)
Health Care Authority (HCA)
New Mexico Public School Insurance Authority (NMPSIA)
Regulation and Licensing Department (RLD)
Retiree Health Care Authority (RHCA)
Office of Superintendent of Insurance (OSI)
University of New Mexico Health Sciences Center (UNMHSC)

SUMMARY

Synopsis of STBTC Amendment to Senate Bill 39

The Senate Tax, Business and Transportation Committee amendment to Senate Bill 39 (SB39) changes the definition of an off-label medication or dose of medication to stipulate off-label means an FDA-approved medication that does not have an FDA-approved indication.

Synopsis of Senate Bill 39

Senate Bill 39 (SB39) would amend the Prior Authorization Act to prohibit prior authorization and step therapy—the insurance plan practice of requiring patients to try less expensive medication first—for medications that are prescribed for on-label or off-label use for the treatment of rare disease or medical condition that affects fewer than 200 thousand people in the

United States.

Off-label use is defined as a medication or medication dosage not approved by the federal Food and Drug Administration (FDA) for treatment of a specific condition or disease but has sufficient evidence to consider the medication and dosage medically necessary for treatment. Medical necessity determination requirements have been updated such that they must be completed by a healthcare professional from the same or similar practice specialty that typically manages the disease or condition in question. Medical necessity determinations are required to be completed within seven days or 24 hours in cases where the condition or disease may seriously jeopardize a person's life or health, affect a person's ability to regain maximum function, or subject a person to severe and intolerable pain. Medical necessity determinations not completed within the specified time limits will be deemed automatically approved.

This bill does not contain an effective date and, as a result, would go into effect 90 days after the Legislature adjourns if enacted, or June 20, 2025.

FISCAL IMPLICATIONS

The New Mexico Public School Insurance Authority (NMPSIA) reports under the provisions of the bill there could be a $1.9 million and potentially up to $12.9 million cost for medications and administrative fees and the loss of potential savings from medication utilization and rebates.

The Retiree Health Care Authority (RHCA) reports the agency would incur additional claims and administrative costs under the provisions of the bill and removing the need for prior authorization and step therapy would impair cost-containment efforts. RHCA estimates the cost at $2.1 million in the first year and an additional 5 percent in subsequent years.

The Health Care Authority (HCA) states health benefits plan would likely incur an indeterminate cost associated with the provisions of the bill.

SIGNIFICANT ISSUES

RHCA reports the federal Centers for Medicare and Medicaid Services (CMS) has guidelines for using on-label and off-label drugs in Medicare Advantage plans. CMS emphasizes that off-label drug use in step therapy programs must be supported by clinical research and widely accepted guidelines to ensure patient safety and efficacy. The National Committee for Quality Assurance (NCQA), which evaluates health plans through its Health Plan Accreditation program, supports policies that ensure step therapy protocols are transparent and evidence-based and include a straightforward process for exceptions when medically necessary. NCQA advocates patient protection and timely access to appropriate medications. Federal regulations ensure that step therapy programs are reviewed and approved by a Pharmacy and Therapeutics Committee, which includes practicing physicians and pharmacists. The committee bases its decisions on scientific evidence and standards of practice. The bill does not provide guidance to healthcare systems that might struggle to allocate resources appropriately, as it is unclear which diseases qualify as rare.

CONFLICT, DUPLICATION, COMPANIONSHIP, RELATIONSHIP

SB39 similar to Senate Bill 207, which also attempts to prohibit practices that restrict access to certain medications.

TECHNICAL ISSUES

The Office of Superintendent of Insurance (OSI) notes the term "off-label" may need to be clarified that the drug must be approved by the FDA, but the dosage to treat a specific condition or disease may not be approved.

OTHER SUBSTANTIVE ISSUES

The University of New Mexico Health Sciences Center (UNMHSC) notes prior authorization requirements often delay patient care, which can negatively affect clinical outcomes. Limiting step programs for vulnerable patients, such as those with cancer or autoimmune diseases, can ensure timely care that may prevent long-term complications and increase morbidity, remove unnecessary barriers to accessing care, and prevent adverse effects such as reduced quality of life, disruption of work, and increased risk of worsening conditions due to treatment delays. Reduced prior authorization requirements can also improve the efficiency of pharmacy operations.

The Department of Health (DOH) notes for children with rare diseases, receiving an accurate diagnosis and promptly starting treatment can be critical. Approximately 50 percent of individuals with rare diseases are children. Only 5 percent to 7 percent of rare diseases have an FDA-approved treatment. Due to the lack of FDA-approved treatments, most medication for rare disease is prescribed off-label. In general, insurers and pharmacy benefit managers will not reimburse off-label use of drugs or medical devices. To access therapies prescribed by their physician, patients may be required to mostly pay out of pocket or provide additional paperwork which delays medication access.

RAE/sgs/hg/sgs/hg/sgs