LFC Requester:	RubyAnn Esquibel

# AGENCY BILL ANALYSIS - 2025 REGULAR SESSION

### WITHIN 24 HOURS OF BILL POSTING, UPLOAD ANALYSIS TO

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(Analysis must be uploaded as a PDF)

#### **SECTION I: GENERAL INFORMATION**

{Indicate if analysis is on an original bill, amendment, substitute or a correction of a previous bill}

Bill Number: 2.13.25 Check all that apply:

SB39 Original X Correction
Amendment Substitute

Elizabeth "Liz" Stefanics; Reena

Szczepanski; Mimi Stewart;

Sponsor: Carrie Hamblen

Add Classes to Prior

Short Add Classes to Prior Authorization Drugs

Agency Name and Code New Mexico Retiree Health Care

Number: Authority 34300

Person Writing Mark Hayden

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#### **SECTION II: FISCAL IMPACT**

# **APPROPRIATION (dollars in thousands)**

Appropriation		Recurring	Fund	
FY25	FY26	or Nonrecurring	Affected	

(Parenthesis ( ) indicate expenditure decreases)

#### **REVENUE** (dollars in thousands)

Estimated Revenue			Recurring	Fund
FY25	FY26	FY27	or Nonrecurring	Affected

(Parenthesis ( ) indicate revenue decreases)

# **ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)**

	FY25	FY26	FY27	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total	\$165	\$2,193	\$2,302	\$6,583	Recurring	Heath Care Fund

#### **SECTION III: NARRATIVE**

#### **BILL SUMMARY**

Synopsis: This Act amends the Prior Authorization Act to add more classes of drugs that are not subject to prior authorization or step therapy protocols. A health insurer shall not impose step therapy requirements before authorizing coverage for a medication approved by the Federal Food and Drug Administration that is prescribed to now include in through this Act "on-label or off-label use" for the treatment of an autoimmune disorder, cancer, a substance use disorder, and now adding "a rare disease," pursuant to a medical necessity determination, except in cases in which a biosimilar, interchangeable biologic or generic version is available. A new definition is added for "rare disease," which means a disease or medical condition that affects fewer than two hundred thousand people in the United States. A new definition for "off-label" means a medication or a dosage of a medication that is not approved by the Federal Food and Drug Administration as a treatment for a specific condition or disease but is prescribed to a covered person because there is sufficient clinical evidence for a prescribing clinician to reasonably consider the medication to be medically necessary to treat the covered person's condition or disease.

#### FISCAL IMPLICATIONS

The Bill impacts the New Mexico Retiree Health Care Authority (NMRHCA) with additional claim and administrative costs. Removing the need for prior authorization and step therapy also removes cost containment measures. The change greatly impacts the pharmaceutical claim cost and savings in the use of more expensive drugs, the lack of clinical management, which determines medical necessity, and the widely used treatment guidelines that CMS considers best practices. There could be an increased risk of fraudulent claims without the checks and balances provided by prior authorization by the insurer and an increased risk of overuse or misuse of certain treatments. Both are deemed to be costly.

The lack of step therapy and cost containment measures is estimated to cost NMRHCA commercial plans \$2.1 million in the first full year and is projected to increase by 5% in subsequent years. This was determined by reviewing the current programs in place for 2024, with the anticipated five percent increase every year after.

New Mexico Retiree Health Care Authority members enrolled in non-Medicare plans will be impacted. The program will experience higher pharmaceutical claim costs without savings from cost containment, which will be passed to members in increases to premiums. Members may also experience more out-of-pocket costs at the point of service in additional deductibles, coinsurance, and/or copays if plan design changes are made to mitigate premium increases.

#### **SIGNIFICANT ISSUES**

The increase in cost would significantly be impacted by the pharmaceutical claim cost in the use of more expensive drugs, the lack of clinical management, which determines medical necessity, and the support of widely used treatment guidelines or clinical literature that the Centers for Medicare & Medicaid Services (CMS) a federal agency considers best practices. In comparison, CMS has specific guidelines for using on-label and off-label drugs in Medicare Advantage (MA) plans. CMS emphasizes that any off-label 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. It 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 (P&T) 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. Providers might diagnose rare diseases inconsistently, leading to misdiagnoses.

The new provisions would allow the use of medications for their approved purpose (on-label use) or an unapproved purpose (off-label use) if deemed medically necessary. Off-label uses of drugs often lack clinical trial data, which could result in less predictable outcomes and increased risk for patients such as NMRHCA members.

#### PERFORMANCE IMPLICATIONS

Easier access to off-label drugs might result in their overuse or misuse, as patients and healthcare providers might opt for these treatments without exhausting other, potentially more cost-effective options. The efficacy of off-label, high-priced therapies is unproven.

#### **ADMINISTRATIVE IMPLICATIONS**

Insurers will need to adjust their processes to meet the prior authorization determinations. Medical necessity determinations shall be automatically approved in 7 days and 24 hours for emergency determinations, which would be applied to 3 instances for covered persons as outlined in the Bill: as jeopardizing life or overall health, affecting the ability to regain maximum function, or subjecting them to server or intolerable pain. Insurers might face challenges in managing and approving these treatments, leading to administrative burdens and less time for clinical review.

Although removing prior authorization might reduce administrative costs, it could also have other administrative implications, such as managing increased claim volumes and dealing with more complex cases without the step therapy protocol. There may also be increased grievances related to determining medical necessity and defining the "rare diseases."

# CONFLICT, DUPLICATION, COMPANIONSHIP, RELATIONSHIP

Related to Senate Bill 207

#### **TECHNICAL ISSUES**

There could be impacts to implementation for healthcare professionals and health insurers with added administrative requirements including making medical necessity/rare disease determinations, training providers, added grievances and ensuring compliance of new requirements.

# **OTHER SUBSTANTIVE ISSUES**

SB39 conflicts with the authority granted to the Board of Directors under 10-7C-5. Authority Created and 10-7C-6 Board created; membership; authority for the New Mexico Retiree Health Care Authority, as it relates to the administration of the Retiree Health Care Act.

# **ALTERNATIVES**

None.

# WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

The current programs would stay in place.

# **AMENDMENTS**

None.