

**LFC Requester:****Eric Chenier****AGENCY BILL ANALYSIS - 2025 REGULAR SESSION****WITHIN 24 HOURS OF BILL POSTING, UPLOAD ANALYSIS TO****[AgencyAnalysis.nmlegis.gov](http://AgencyAnalysis.nmlegis.gov) and email to [billanalysis@dfa.nm.gov](mailto:billanalysis@dfa.nm.gov)****(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}***Date Prepared:** 2/10/2025*Check all that apply:***Bill Number:** SB39Original  Correction Amendment  Substitute **Sponsor:** Elizabeth Stefanic, Reena Szczepanski, Mimi Stewart and Carrie Hamblen**Agency Name and Code Number:**

Office of Superintendent of Insurance - 440

**Short Title:** Prior Authorizations for Rare Diseases**Person Writing:** Viara Ianakieva**Phone:** 505-508-9073 **Email:** Viara.Ianakieva@osi.n**SECTION II: FISCAL IMPACT****APPROPRIATION (dollars in thousands)**

Appropriation		Recurring or Nonrecurring	Fund Affected
FY25	FY26		
N/A	N/A	N/A	N/A

(Parenthesis ( ) indicate expenditure decreases)

**REVENUE (dollars in thousands)**

Estimated Revenue			Recurring or Nonrecurring	Fund Affected
FY25	FY26	FY27		
N/A	N/A	N/A	N/A	N/A

(Parenthesis ( ) indicate revenue decreases)

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

	FY25	FY26	FY27	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
<b>Total</b>	N/A	N/A	N/A	N/A	N/A	

(Parenthesis ( ) Indicate Expenditure Decreases)

Duplicates/Conflicts with/Companion to/Relates to:  
Duplicates/Relates to Appropriation in the General Appropriation Act

### **SECTION III: NARRATIVE**

#### **BILL SUMMARY**

Senate Bill 39 (SB39) amends the Prior Authorization Act, NMSA 1978, Section 59A-22B-8 to prohibit prior authorization &/or step therapy for medications that are prescribed, for on-label or off-label use, for the treatment of a rare disease. Rare disease is defined in SB39 as a disease or medical condition that affects fewer than two hundred thousand people in the United States. Off-label use is defined as a medication or medication dosage not approved by the FDA for treatment of a specific condition or disease but has sufficient evidence to consider the medication/dosage medically necessary for treatment. Medical necessity determination requirements have been updated such that they must be completed by a health care professional from the same or similar practice specialty that typically manages the disease or condition in question. Lastly, medical necessity determinations are required to be completed within 7 days, or 24 hours in cases where the condition or disease may seriously jeopardize a person's life/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.

#### **FISCAL IMPLICATIONS**

None

#### **SIGNIFICANT ISSUES**

None.

#### **PERFORMANCE IMPLICATIONS**

OSI may receive an increased number of grievances related to medically necessary treatment of rare diseases, if carriers fail to comply.

#### **ADMINISTRATIVE IMPLICATIONS**

If the bill is enacted, OSI will be required to update its existing Prior Authorization Rule, 13.10.31 NMAC.

#### **CONFLICT, DUPLICATION, COMPANIONSHIP, RELATIONSHIP**

Duplication and possible conflict: SB207 Add Classes to Prior Authorization Drugs.

#### **TECHNICAL ISSUES**

None.

#### **OTHER SUBSTANTIVE ISSUES**

The term "off-label" is unclear as currently defined in SB39. As currently written, it reads: "a medication or a dosage of a medication that is not approved by the federal food and drug administration for a specific condition or disease". It is important to indicate that the drug must be approved by the FDA, but the indication or dosage to treat a specific condition or disease may not be approved. As currently written, the bill may be construed to require coverage of non-FDA approved medications which may be contrary to federal law.

#### **ALTERNATIVES**

None.

### **WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL**

Residents of New Mexico suffering from rare diseases may not be able to receive timely care covered by their insurance plan since most rare disease treatments are considered off-label use by the FDA.

### **AMENDMENTS**

Page 4, Lines 1-7:

"off-label" means ~~an FDA approved medication or a dosage of a medication that~~ does not have an FDA approved indication ~~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.