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**2024 LEGISLATIVE SESSION
AGENCY BILL ANALYSIS**

Section I: General

Chamber: Senate

Category: Bill

Number: 0135

Type: Introduced

Date (of **THIS** analysis): 1/29/2024

Sponsor(s): Elizabeth "Liz" Stefanics, Graig W. Brandt, Sia Correa Hemphill, Antonio Maestas, Daniel A. Ivey-Soto

Short Title: Step Therapy Guidelines

LFC Requester: Lance Chilton

Reviewing Agency: Agency 665 - Department of Health

Person Writing Analysis: Arya Lamb

Phone Number: 505 - 470 - 4141

e-Mail: arya.lamb@doh.nm.gov

Section II: Fiscal Impact

APPROPRIATION (dollars in thousands)

Appropriation Contained		Recurring or Nonrecurring	Fund Affected
FY 24	FY 25		
\$0	\$0	N/A	N/A

REVENUE (dollars in thousands)

Estimated Revenue			Recurring or Nonrecurring	Fund Affected
FY 24	FY 25	FY 26		
\$0	\$0	\$0	N/A	N/A

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY 24	FY 25	FY 26	3 Year Total Cost	Recurring or Non-recurring	Fund Affected
Total	\$0	\$0	\$0	\$0	N/A	N/A

Section III: Relationship to other legislation

Duplicates: HB 0185

Conflicts with: None

Companion to: None

Relates to: None

Duplicates/Relates to an Appropriation in the General Appropriation Act: HB 0185

Section IV: Narrative

1. BILL SUMMARY

a) Synopsis

Senate Bill 135 proposes to enact new sections of the Health Care Purchasing Act, the Public Assistance Act, the NM Insurance Code, the Health Maintenance Organization Law, and the Nonprofit Health Care Plan Act to establish guidelines for step therapy processes for prescription drug coverage and elimination of step therapy for certain health conditions.

It will require health insurance to establish clinical review criteria based on clinical practice guidelines for step therapy. The clinical guidelines will:

- Recommend the prescription drug in question be taken in a certain sequence,
- Be developed and endorsed by an interdisciplinary panel of experts. The panel of experts will manage conflicts of interest by disclosing any conflicts or removing themselves from the panel if there is one, and use of experts to provide objectivity through evidence tables and a facility consensus
- Be based high quality studies
- Be created in a transparent process that curtails bias, explains relationship between treatments and outcomes, rates the quality of evidence and recommendations, takes relevant patient subgroups and preferences into consideration along with consideration of atypical population needs and diagnoses.

When clinical guidelines are not available, peer-reviewed publications may be substituted.

When step therapy restricts a drug, the patient and the provider can access a clear, convenient and accessible process to request step therapy exceptions.

The insurer is to expeditiously grant an exception based on medical necessity and a clinically valid explanations from the patient's provider as to why the insurer's equivalent cannot be substituted if meeting the following criteria:

- Contraindicated
- Expected to not be effective based on the patient clinical characteristics and those of the treatment
- The patient has previously trialed the drug or another drug in the same pharmacologic class and has been discontinued for reduced or lack of efficacy or an adverse event
- The drug is not in the best interest of the patient if it can cause a barrier to adherence, worsen a comorbid condition, or decrease the patient's functional abilities for daily activities.

The insurer is to grant the exception for the life of the patient.

The insurer is to give a response on their decision for approval or denial within 72 hours, or 24 hours in time-sensitive cases where no response in the required time frame results in granting of the request.

The insurer administrator's denial will be available for review and appeal pursuant to the Patient Protection Act.

Once an exception is approved, the insurer is to authorize continued approval of the approved drug.

SB0135 will not prevent an insurer from requiring a patient to trial a generic equivalent prior to covering the request for exception or preventing a provider from prescribing a drug deemed medical necessary.

It would apply to a group health plan after January 1, 2025.

Section 59A-22B-8 NMSA 1978 Chapter 114, Section 13 will be amended from substance use disorder to Certain Conditions and include a health care provider's determination for medical necessity. It will include autoimmune disorder, a behavioral health condition, cancer, or a substance use disorder, pursuant to a health care provider's medical necessity determination.

This bill would not apply to short-term plans subject to the Short-term Health Plan and Excepted Benefit Act.

Is this an amendment or substitution? Yes No

Is there an emergency clause? Yes No

b) Significant Issues

Step therapy (also known as a “fail first requirement”) is a strategy used by insurers to contain drug expenditures: it requires that patients try the most cost-effective drugs for a condition prior to moving to more expensive or risky options. This strategy can be burdensome for patients and clinicians to manage, but it decreases spending on targeted therapies and may promote improved care when used to steer patients to evidence-based care or consensus treatment guidelines: in 2022, the National Library of Medicine stated about one-third of protocols aligned with clinical guidelines for specialty drugs. [Step Therapy's Balancing Act — Protecting Patients while Addressing High Drug Prices - PMC \(nih.gov\)](#)

As of July 2023, step therapy protections have been enacted in 36 states. [Step Therapy Legislation By State | Overview | Step Therapy](#)

Federal legislation has been introduced as the Safe Step Act which requires group health plans to establish exceptions to step therapy protocols in specified cases. [H.R.2630 - 118th Congress \(2023-2024\): Safe Step Act | Congress.gov | Library of Congress](#)

NMDOH clients would not be affected by step therapy protocols within our current operation as current CDC treatment guidelines are utilized for treatments given in the Local Public Health Offices for uninsured and underinsured patients with recommended treatments purchased by the specific NMDOH programs.

Similar legislation had been introduced as SB11 and HB42 from the 2018 legislative session and HB244 from the 2017 legislative session. These previous bills died during their respective sessions.

The superintendent of insurance would promulgate these rules for implementation and the office of the superintendent of insurance or a contracted party would need to perform annual audits for compliance.

2. PERFORMANCE IMPLICATIONS

- Does this bill impact the current delivery of NMDOH services or operations?
 Yes No
- Is this proposal related to the NMDOH Strategic Plan? Yes No
 - Goal 1:** We expand equitable access to services for all New Mexicans
 - Goal 2:** We ensure safety in New Mexico healthcare environments
 - Goal 3:** We improve health status for all New Mexicans
 - Goal 4:** We support each other by promoting an environment of mutual respect, trust, open communication, and needed resources for staff to serve New Mexicans and to grow and reach their professional goals

3. FISCAL IMPLICATIONS

- If there is an appropriation, is it included in the Executive Budget Request?
 Yes No N/A
- If there is an appropriation, is it included in the LFC Budget Request?
 Yes No N/A
- Does this bill have a fiscal impact on NMDOH? Yes No

Fiscal implications would result from the superintendent of insurance needing to publicize the rules for implementation, and for yearly auditing by the office of the superintendent of insurance or a contracted party.

4. ADMINISTRATIVE IMPLICATIONS

Will this bill have an administrative impact on NMDOH? Yes No

5. DUPLICATION, CONFLICT, COMPANIONSHIP OR RELATIONSHIP

HB0185 is a duplication of this bill.

6. TECHNICAL ISSUES

Are there technical issues with the bill? Yes No

Section 10, line 20, states small group health plans, but does not define a small group health plan in the bill.

7. LEGAL/REGULATORY ISSUES (OTHER SUBSTANTIVE ISSUES)

- Will administrative rules need to be updated or new rules written? Yes No
- Have there been changes in federal/state/local laws and regulations that make this legislation necessary (or unnecessary)? Yes No

- Does this bill conflict with federal grant requirements or associated regulations?
 Yes No
- Are there any legal problems or conflicts with existing laws, regulations, policies, or programs? Yes No

8. DISPARITIES ISSUES

- The American Community Survey documents 90.03% of the population in New Mexico have insurance. <https://usafacts.org/topics/health/state/new-mexico/> Individuals with insurance who require step therapy would be the population being served by this bill. The National Center for Health Statistics document that many people who have insurance continue to have difficulties in paying for medical bills. [National Health Statistics Reports, Number 180, January 18, 2023 \(cdc.gov\)](#)

- Individuals who are uninsured would not be directly affected by this process, although broader use of evidence-based or expert consensus on treatment protocols may occur as providers integrate step therapy approaches into their practice.

- Section 4 of the bill further limits the prohibition of step therapy only for insured patients who have been prescribed a treatment for an autoimmune disorder, a behavioral health condition, cancer or a substance use disorder.

9. HEALTH IMPACT(S)

- According to the Journal of Managed Care and Specialty Pharmacy, most of the prescribers surveyed believe that step therapy policies could improve the affordability of medication use and its clinical appropriateness. They also stated that step therapy policies have been implemented inefficiently and inflexibly, and more often patient specific information is not taken into consideration when requesting step therapy exceptions.

<https://www.jmcp.org/doi/full/10.18553/jmcp.2019.25.11.1210>

Clear and accessible established processes for requesting exceptions to step therapy guidelines for insurers can ease the process for a practitioner to have an exception approved.

- According to the National Organization for Rare Disorders, if step therapies are not implemented appropriately, necessary treatments can be delayed, leading to adverse reactions that will ultimately increase health care costs. <https://rarediseases.org/policy-issues/step-therapy/>

10. ALTERNATIVES

None

11. WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL?

If SB0135 is not enacted, then new sections of the Health Care Purchasing Act, the Public Assistance Act, the New Mexico Insurance Code, the Health Maintenance Organization Law and the Nonprofit Health Care Plan will not be created to establish guidelines related to step therapy for prescription drug coverage and will not eliminate step therapy requirements for autoimmune disorders, behavioral health conditions, cancer or substance abuse disorders.

12. AMENDMENTS

None