LFC Requester:	Lance Chilton

AGENCY BILL ANALYSIS
2024 REGULAR SESSION

WITHIN 24 HOURS OF BILL POSTING, EMAIL ANALYSIS TO:

LFC@NMLEGIS.GOV

and

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{Include the bill no. in the email subject line, e.g., HB2, and only attach one bill analysis and related documentation per email message}

SECTION I: GENERAL INFORMATION
{Indicate if analysis is on an original bill, amendment, substitute or a correction of a previous bill}

Check all that apply:
Original X **Amendment** ____
Correction ___ **Substitute** ____

Date 1/26/24
Bill No: SB135

Sponsor: Sen. Stefanics
Short Title: STEP THERAPY GUIDELINES

Agency Name and Code Number: HCA-630
Person Writing Diana Moya (April Neri BRB)
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SECTION II: FISCAL IMPACT

APPROPRIATION (dollars in thousands)

Appropriation		Recurring or Nonrecurring	Fund Affected
FY24	**FY25**		
$0.0	$0.0	N/A	N/A

(Parenthesis ( ) Indicate Expenditure Decreases)

REVENUE (dollars in thousands)

Estimated Revenue			Recurring or Nonrecurring	Fund Affected
FY24	**FY25**	**FY26**		
$0.0	$0.0	$0.0	N/A	N/A

(Parenthesis ( ) Indicate Expenditure Decreases)

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY24	FY25	FY26	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total	$0.0	$87,494	$87,494	$174,988	Recurring	SGF

(Parenthesis ( ) Indicate Expenditure Decreases)

Duplicates/Conflicts with/Companion to/Relates to:
SB135 relates to HB185 CY2024

,
Duplicates/Relates to Appropriation in the General Appropriation Act

SECTION III: NARRATIVE

BILL SUMMARY

Synopsis:
Senate Bill 135 (SB135) would add a new section of the Health Care Purchasing Act; Public Assistance Act; the New Mexico Insurance Code (Chapter 59A, Article 22 & 23 NMSA 1978); the Health Maintenance Organization Law and the Nonprofit Health Care Plan Law to enact guidelines relating to step therapy for Prescription drug coverage.

Section 1 of SB135 would require an amendment to the Health Care Purchasing Act establishing guidelines and clinical review criteria for coverage of prescription drugs where step therapy protocols are required. The clinical review criteria are detailed based on clinical practice guidelines utilizing the specific sequences required by the step therapy protocols; developed and endorsed by an interdisciplinary panel of experts; will base decisions on research based studies and medical practices; created pursuant to explicit and transparent processes to minimize bias and conflicts of interest; explain relations between treatment options and outcomes taking into account the need of atypical patient populations and diagnosis. Peer-reviewed publications shall be substituted in the absence of clinical guidelines that meet the requirements of the guidelines.

Section 1 of SB135 continues to address when a group health plan restricts coverage of a prescription drug through the use of step therapy protocols, an enrollee and prescribing practitioner shall have a readily available process to expeditiously obtain an exception based on the medical necessity and a clinically valid explanation from the patient's practitioner including the details on why the formulary drug that is therapeutically equivalent to the prescribed drug should not be substituted for the prescribed drug.

Granting of a step therapy exception by a group health plan's protocol shall require the health plan's administrator to authorize continued coverage for the enrollee's life and need of the drug that is the subject to the exception request. The decision of the enrollee's exception request shall be provided with a response by the health plan within seventy-two hours of receipt and emergent requests shall require the health plan to respond in twenty-four hours from receipt of the request. If the health plan does not respond in the required time requested, the exception request shall be granted.

The provisions of this section shall not be construed to prevent a group health plan from requiring an enrollee to try a generic equivalent of the prescribed drug first before granting coverage of the brand-name equivalent or prevent a practitioner from prescribing the drug determined to be

medically necessary.

If enacted this section will only apply to a group health plan delivered, issued for delivery or renewed on or after January 1, 2025.

Section 1 also defines, "medical necessity" or "medically necessary" as it applies to health care services determined by a practitioner, in consultation with the insurer, to be appropriate or necessary according to:

1) the general accepted principles and practices of good medical care;
2) practice guidelines developed by the federal government or national or professional medical societies, boards, or associations; or
3) any applicable clinical protocols or practice guidelines developed by the group health plan consistent with federal, national, and professional practice guidelines. These standards shall be applied to decisions related to the diagnosis or direct care and treatment of a physical or behavioral health condition, illness, injury or disease."

Section 2 of SB135 would require amendments to the Public Assistance Act, which would have the Secretary of HCA require that clinical review criteria for step therapy protocols are established and included in any Medical Assistance plan (Medicaid and the Medicaid managed care organizations).

SB135 would require establishing clinical review criteria used to establish step therapy protocols for prescription drugs based on clinical practice guidelines and continually updated pursuant to reviews of new evidence, research and newly developed treatments.

SB135 also provides a list of potential conflicts of interest and will require members on the panel of experts to recuse themselves if such a conflict exists. Members on the panel shall develop guidelines based on high-quality studies, research, and medical practice with uniform member decisions. The public will also be offered opportunities for public review and comment. In the absence of clinical guidelines, peer-reviewed publications may be substituted to meet the requirements of Subsection A of the Public Assistance Act.

SB135 provides various conditions which, if met, would provide exceptions for a recipient from starting at the first step of the step therapy process.

SB135 would require that the enrollee and prescribing practitioner have access to a clear and convenient process to request an exception determination if coverage of medications for treatment of a medical condition is restricted for use by step therapy protocol requirements. Exception requests shall be granted promptly within seventy-two hours of receipt, and twenty-four hours in cases where urgent conditions exist. If the health plan does not respond within these time frames, the exception request shall be granted.

A denial of a request for a step therapy protocol exception will be subject to review and appeal pursuant to the Department’s rules.

Provisions of SB135 would not be construed to prevent certain actions as specified in the bill, such as requiring a recipient to try a generic equivalent of a brand name drug, or to prevent a practitioner from prescribing a medically necessary drug. Medically necessary is defined.

Beginning in July 2026, and annually thereafter, the office of superintendent of insurance or a

contracting party shall perform an audit to ensure compliance with the provisions of this 2024 act.

The provisions of this act apply to group health insurance policies, health care plans or certificates of health insurance, other than small group health plans, that are delivered, issued for delivery, or renewed in this state on or after January 1, 2025.

FISCAL IMPLICATIONS

Overall fiscal implications cannot be determined at this time. **Budgeting for additional staff at Medical Assistance Division to implement the Act and oversee MCO compliance will be needed. 1 FTE at a pay band 70 and a .5 of a Pharmacist II position at a pay band HL for a total of $87,494. (GF) for salary, fringe benefits, and operating costs each FY.** SB135 loosens the parameters health plans can utilize with step therapy to guide therapies towards generics first and ensure high-cost medications are utilized to treat only the individuals who meet the diagnosis criteria. Granting formulary exceptions can deter the ability of a health care entity to manage its formulary and decreases their ability to maintain clinically sound, and cost-effective medication therapy. Therefore, an increase in use of high cost clinically inappropriate medications will have a net increase in the over-all cost to the HCA.

SIGNIFICANT ISSUES

There are some provisions of the bill that are already in statute. In 2013, senate bill 296 passed the senate and the house and was signed by the governor, Chapter 170 April 4, 2013.

- It already has provisions for the standardization of the prior authorization form which was done and is in use. This bill states the process must be clear and implies that various entities may develop their own process. In fact, much about the process and form is already standardized in statute.

- The bill also has time frames which, following no response from the approving payer, the approval is considered granted. Both this bill and the legislation from 2013 already in effect have the same 24-hour and 72-hour time frames but in other details differ somewhat, with this bill providing more detail and definitions.

  Therefore, this partial overlap and duplication with existing law is confusing.

- SB135 calls for an interdisciplinary panel of experts to review the literature and develop guidelines for prescribing. Because of the cost and side effects of many of the newer drug items, as well as the very complex nature of the drug treatments, they emphasize the importance of including experts with familiarity of behavioral health, substance abuse disorder, autoimmune disorder, and oncology medications as well as all other categories of medications. Literature for all categories of medications can have confusing and contradictory evidence. For example, studies may demonstrate that a particular medication was superior for symptom reduction but not comment on quality of life or the presence of side effects.

PERFORMANCE IMPLICATIONS

None

ADMINISTRATIVE IMPLICATIONS
The bill would require significantly more time and work to implement and maintain a step therapy program than currently exists, including providing for public comment, the make-up of committees, etc. This level of effort may reduce the number of step therapy protocols that are implemented even though such protocols may be economically reasonable and may even provide some protections to the recipient by requiring the use of more known standard therapies before using very expensive newly marketed drugs.

The high level of effort without any additional funding to support such efforts may have unanticipated consequences.

The Pharmacy Benefit Management System (PBMS) would need to be updated to reflect any changes in the step therapy program. These changes would be part of maintenance and operations.

CONFLICT, DUPLICATION, COMPANIONSHIP, RELATIONSHIP

SB135 relates to HB185 and companion to SB179 from the 2017 session.

TECHNICAL ISSUES
None

OTHER SUBSTANTIVE ISSUES
None

ALTERNATIVES
None

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL
Status Quo

AMENDMENTS
None