FISCAL IMPACT REPORT

SPONSOR	Thomson/Hernandez/Szczepanski/ Chasey/Jones	**LAST UPDATED**	
		ORIGINAL DATE	01/30/2024
SHORT TITLE	Step Therapy Guidelines	**BILL NUMBER**	Senate Bill 135
		ANALYST	Chilton/Rodriguez

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT*
(dollars in thousands)

Agency/Program	FY24	FY25	FY26	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
HCA personnel costs		$87.5	$87.5	$175.0	Recurring	General Fund
NMPSIA added cost		$1,400.0	$2,800.0	$4,200,000	Recurring	NMPSIA
RHCA added cost		$650.0	$650.0	$1,300.0	Recurring	RHCA
APS, GSD added cost		$1,000.0-$5,000.0	$1,000.0-$5,000.0	$2,000.0-$10,000.	Recurring	APS, GSD
Total		$3,137.5-$7,137.5	$5,537.5-$9,537.5	$8,675.0-$16,675.0	Recurring	

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

Duplicate of House Bill 185.

Sources of Information

LFC Files

Agency Analysis Received From
Office of the Superintendent of Insurance (OSI)
Public School Insurance Authority (PSIA)
Retiree Health Care Authority (RHCA)
General Services Department (GSD)
Health Care Authority (HCA)

Agency Analysis was Solicited but Not Received From
Department of Health (DOH)
Albuquerque Public Schools (APS)

SUMMARY

Synopsis of Senate Bill 135

Senate Bill 135 would amend the Health Care Purchasing and Public Assistance acts and other statutes to regulate the process by which insurers can require patients, and thus their prescribers,

to use preferred or less expensive medications before graduating to more expensive or non-preferred medications. It applies the same requirements to all forms of health insurance available in New Mexico in different sections of the bill, as indicated in the table below.

Health coverage providers would be required to establish review criteria for any step therapy protocol, as defined by peer-reviewed publications, a panel of qualified and disinterested experts, or both. Exceptions to the step therapy process may be requested by individuals, and the plan must rapidly review that request, with reasons given for a refusal to meet the request. If, on the other hand, the request for exception is granted, it remains in effect for that patient during that patient's lifetime.

Exceptions to this process would occur if the insurer required the use of a generic product rather than the brand-name equivalent, or if a prescriber determined that a given drug was medically necessary. "Medical necessity" may be defined by national guidelines or generally accepted principles.

The Office of Superintendent of Insurance is to establish protocols for enforcing these policies.

Section 4 of the bill amends Section 59A-22B-8 NMSA 1978, adding medical conditions for which step therapy could not be imposed before an insurance provider authored coverage (with the exception of requiring that a generic rather than the equivalent brand-name drug be used) to include an autoimmune disorder, a behavioral health condition, and cancer to the existing prohibition on a substance use disorder.

Sections of the Bill and their applications

Bill Section	Section of New Mexico Statutes NMSA 1978	Type of medical health coverage
1	Health Care Purchasing Act	Group health coverage
2	Public Assistance Act	Medical assistance plan care plan law
3	Section 59A-22	Individual health insurance policy, health care plan and certificate of health insurance
5	Section 59A-23	Group or blanket health insurance policy
6	Health Maintenance Organization Law	individual or group health maintenance organization contract
7	Nonprofit health care plan law	Individual or group nonprofit health care plan

Section 8 of the bill establishes exceptions to the provisions of the act for short-term health plans and the excepted benefits act. With those exceptions, the provisions apply to all health plans, group or individual, to be issued or renewed on or after January 1, 2025, and the Office of Superintendent of Insurance or a contractor to OSI is to monitor compliance with the act.

FISCAL IMPLICATIONS

There is no appropriation in Senate Bill 135.

Costs would be due to staff needed to implement the new requirements and the increased cost of pharmaceuticals to state employee and retiree health plans.

With regard to implementation costs, the Health Care Authority (HCA) indicates the following:

> 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.

As noted by the Public School Insurance Authority (PSIA) and Retiree Health Care Authority, removing prior authorization or step therapy for those covered by health insurance through those agencies would be expensive, with estimates of $2.8 million and $650 thousand, respectively. Albuquerque Public Schools and the General Services Department did not indicate costs to those agencies, but LFC estimates costs to the two of at least $1 million per year. PSIA notes that a large portion of the increased costs would result from prohibition on the use of the two cost-containment procedures for three categories of condition: autoimmune disorders, behavioral health conditions, and cancer.

Further, PSIA notes that a positive effect of prior authorization and step therapy protocols is that, "in addition to being a cost saving measure, prior authorizations are a means to maintain positive communication between providers and patients. It prompts conversations regarding a physician's treatment plan and promotes re-evaluation of that plan for the patient's benefit. This protocol also enacts a checks and balances of sorts for pharmaceutical companies who incentivize the prescription of certain brand name medications. Without proper a PA protocol, providers are not held accountable for prescribing brand name medications when there are more cost-effective option available."

SIGNIFICANT ISSUES

The requirements for prior authorization and for step therapy are confusing and frustrating for many patients and for their medical care providers. Making the process simpler for providers and patients may well improve their satisfaction with the medical care they receive but also have the potential to significantly increase the overall cost of medications.

In a 2018 National Academy of Science, Engineering and Medicine book titled *Making Medicines Affordable: A National Imperative*, the following recommendations are made to reduce the cost of medications:

> Recommendation A: Accelerate the market entry and the use of safe and effective generics as well as biosimilars, and foster competition to ensure the continued affordability and availability of these products.
>
> A-1. The U.S. Department of Justice and the Federal Trade Commission should vigorously deter manufacturers from paying other producers for the delayed entry of generics and biosimilars into the market.
>
> A-2. The U.S. Department of Justice and the Federal Trade Commission should expand the enforcement of policies that preclude mergers and acquisitions among companies possessing significant competing generics and biosimilars—either by preventing the mergers or acquisitions or by requiring divestiture of potentially competing drug products to independent entities.

A-3. The U.S. Patent and Trademark Office should identify specific means to reduce "evergreening" of drug exclusivity via new patents or extensions on existing drugs.

A-4. The U.S. Congress should authorize the U.S. Food and Drug Administration to seek reciprocal drug approval arrangements for generics and biosimilars between the regulatory agencies of the United States and the European Union, and such countries as Australia, Canada, Japan, and New Zealand.

A-5. The U.S. Congress and the U.S. Food and Drug Administration should actively seek to reduce barriers to generic market entry and promote the expeditious market entry of additional domestic and international providers of generics and biosimilars, particularly including those not marketed by the original patent holder.

A-6. State legislatures should develop policies to restrict the use of the "dispense as written" practice by prescribers that may unnecessarily impede the use of generics and biosimilars.

National Academies of Sciences, Engineering, and Medicine. 2018. Making Medicines Affordable: A National Imperative. Washington, DC: The National Academies Press. https://doi.org/10.17226/24946.

It would appear that there is tension between plans to simplify and decrease frustration for patients and providers and the desire to decrease the cost of medications overall and eventually to the individual patient.

CONFLICT

As noted by HCA, SB135 partially conflicts with existing law on prior authorizations:

> 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 timeframes 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.

DUPLICATION

This bill is a duplicate of House Bill 185, of the same name.

TECHNICAL ISSUES

As pointed out by PSIA:

> The bill does not appear to distinguish between existing utilizers and new utilizers. If a member is currently using an intermediary product (i.e., alternative medication that they are required to take under the step therapy protocol before they can access the medication prescribed by their provider) for treatment of one of the three specified condition categories, it is unclear whether they would be required to switch to the higher-cost product that was

originally prescribed."

The Office of Superintendent of Insurance states, "OSI performs compliance review of the operations of the health plans, as well as the insurance contracts issued and delivered in New Mexico. Therefore, OSI recommends that the audit requirement be removed."

OSI continues:

> As noted above, Section 4A states that coverage for medication approved by the federal food and drug administration that is prescribed for the treatment of an autoimmune disorder, a behavioral health condition, cancer or a substance use disorder, pursuant to a health care provider's medical necessity determination, shall not be subject to prior authorization, except in cases in which a generic version is available. This creates a conflict with the definition of medical necessity in the Prior Authorization Act, NMSA 1978, §59A-22B-2J, and throughout NMSA and NMAC, where medical necessity is defined as "determined by a health care provider, in consultation with the health insurer, to be appropriate or necessary according to…

OTHER SUBSTANTIVE ISSUES

PSIA points out that "SB 135 conflicts with the authority granted to the Board of Directors under 10-7C-5. Authority Created and 10-7C-6 Board created; membership; authority. 10-7C-7. Board; duties. for the New Mexico Retiree Health Care Authority, as it relates to administration of the Retiree Health Care Act Plan increases in cost share to NMRHCA will continue to apply financial pressure to the program related to deficit spending period and unfunded liabilities."

GSD points out the Risk Management Division's Employee Benefits Bureau will be part of the HCA beginning in FY25.

AMENDMENTS

OSI suggests the following:

- Indicate that Sections 3, 5, 6 and 7 amend existing language and are not new material.
- Add language requiring insurance companies to state in the insurance contract (policy or certificate) that they will accept step-therapy exceptions granted by another carrier. This will inform insureds of their rights and require insurance companies to accept exceptions when granted by prior carriers.
- Remove the audit requirement and add language requiring OSI to ensure compliance and take enforcement action when merited.

LC/JR/al/hg