F I S C A L I M P A C T R E P O R T

SPONSOR SCORC **ORIGINAL DATE** 2/01/18 **LAST UPDATED** 2/13/18 **HB**

SHORT TITLE Guidelines for Step Therapy for Drug Coverage **SB** CS/CS/11/SPACS/SCORC /aHFl#1

ANALYST Chilton

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY18	FY19	FY20	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total	NFI	Up to $7,500.0	Up to $7,500.0	Up to $15,000.0	Recurring	General Fund

(Parenthesis ( ) Indicate Expenditure Decreases)

Duplicates House Bill 42 (prior to committee substitutions and amendment)
Similar to 2017 Senate Bill 179 and House Bill 244

SOURCES OF INFORMATION
LFC Files

Responses Received From
Public School Insurance Authority (PSIA)
Retiree Health Care Authority (RHCA)(to identical House Bill 42)
Human Services Department (HSD)
General Services Department (GSD)
Responses received from these four agencies before committee substitutions; received also from HSD after committee substitutions but before the floor amendment.

Response Not Received From
Department of Health (DOH)

SUMMARY

Synopsis of HFl#1 Amendment

The House Floor #1 amendment adds identical language to each section of the bill that serves to define the term "not in the best interest of the patient," which term is one of the reasons for which an exception (from step therapy) request could be made. A drug "not in the best interest of the patient" is defined as one that would

- Cause a significant barrier to the patient's adherence or compliance with the patient's plan of care, or
- Worsen another medical condition the patient had, or

- Decrease the patient's ability to maintain activities of daily living.

Synopsis of Original Bill

Step therapy involves the requirement by health insurers that their enrollees be treated with a more effective and/or less expensive drug or device before moving to a more expensive one if the lower-cost therapy proves ineffective. It is used to attempt to reduce the cost of care, and is sometimes disparagingly referred to as "Fail First therapy." The Senate Corporations and Transportation Committee Substitute for the Senate Public Affairs Committee Substitute for Senate Bill 11 would regulate the use of step therapy and establish review procedures both before an insurer would institute step therapy for a given disorder, and to resolve complaints by insured patients subject to step therapy.

Insurers would have to base their step therapy protocols on recommendations of "an interdisciplinary panel of experts," which would use analytical and methodological experts to help with data analysis and interpretation of high-quality research studies in recommending the steps patients would be required to take. Articles published in peer-reviewed journals could form the basis of the step therapy, or, if published guidelines were not available, expert opinion could be used. Patients and prescribers would have access to a clear method to request an exception to a given step therapy determination (based on "medical necessity," a term defined below and on a "clinically valid explanation" from the prescriber), and insurers would have to respond within 72 hours, or 24 hours in an urgent situation and in accordance with medical necessity (defined below) and an explanation from the prescriber. Exceptions would be mandated in the following cases:

- The drug indicated in the step therapy protocol is contraindicated in that patient's case or could cause physical or mental harm in that patient.
- The patient's particular circumstances make it appear the indicated step therapy drug will be ineffective in that given patient.
- The patient has used the drug or a similar product before (under coverage from the same or a previous insurer), and found it either ineffective or causing an adverse effect.
- The drug indicated in the step therapy protocol is "not in the best interest of the patient, based on "medical necessity" (defined as concerning a drug that "is appropriate or necessary according to any applicable, generally accepted principles and practices of good medical care, practice guidelines developed by the federal government or professional medical groups, or applicable clinical protocols developed by the health plan "consistent with federal, national and professional guidelines.")

Patients could appeal the insurer's decisions through the Patient Protection Act. Health plans would be required to authorize continuing coverage of a prescription drug subject to an exception request until final adjudication of the request, including the appeal.

Plans could still require the use of a generic version of a patented drug. Medical practitioners would not be prevented from prescribing medications that they had determined to be "medically necessary."

Separate sections of Senate Bill 11 make the same requirements of a number of insurer types as indicated in the table below:

Section of Senate Bill 11	Type of insurance affected
1	Group health plans
2	Medical assistance plans
3	Individual health insurance policies, health care plans or certificates of insurance
4	Group or blanket health insurance policies, health care plans or certificates of health insurance
5	Individual or group health maintenance organizations
6	Individual or group nonprofit health care plans

According to the National Conference of State Legislatures, the states of West Virginia, Iowa, and Colorado enacted legislation during 2017 restricting the use of step therapy in various ways.

FISCAL IMPLICATIONS

PSIA states, "This bill would have a significant fiscal impact on the PSIA self-insured Rx Plan. Currently, there are step therapy rules in place that save PSIA approx. $1.3 annually based on the current formulary and prescription drugs currently out on the market today. The "up to $1.3 million" in the yearly financial impact is an estimate and is subject to change. Without the current step therapy rules in place, members would no longer be required to try using lower cost drugs that have proven to be effective (before using a more costly drug).

Similarly, RHCA (in its response to identical House Bill 42) notes, "For FY17, the savings associated with Step-Therapy Programs administered by NMRHCA totaled $1,731,590."

The RHCA continues, however, to state that "the bill does not propose to eliminate Step Therapy program. Rather it establishes the criteria for approval of exceptions to the program and timelines for the approval and response process."

HSD initially expressed concern over the possibility that this bill might result in large increases to the medication expenses of Medicaid managed care organizations. These concerns have decreased with the substitution, but remain in part:

> The bill provides protections for Medicaid enrollees; it lists the reasons for a Medicaid enrollee to be granted an exception from the first step of the step therapy process. The exception criteria regarding a Medicaid enrollee who is already stabilized on a medication is particularly important for treating some diseases such as heart disease, epilepsy, diabetes and several other chronic conditions. For behavioral health, HSD does not allow step therapy for psychotropic medications.
>
> The primary impact to HSD would be on the Medicaid Managed Care Organizations, the entities which primarily use step therapy in administering the state's Medicaid managed care program.

Changes to developing step therapy protocols could have a significant financial impact for HSD. HSD has calculated that a shift of just 1% of generic drug items to brand name items, due to ending some step therapy protocols or by exempting individuals from step therapy, would cost HSD approximately $10 million annually (combined state and federal funds).

The bill may delay new step therapy protocols from being applied to brand name drugs as they become available. Such delays in implementing new protocols or removing existing protocols would have a significant financial impact to the department.

Currently, the Medicaid Managed Care Organizations (MCOs) have protocols for a step therapy exception process that is developed and managed by their Pharmacy and Therapeutics (P&T) committees. The initial step therapy medication must be filled first or the member must fail the medication in order to allow the subsequent medication to proceed. With documented clinical notes, an exception is to be granted if:

- The treatment has been ineffective in the treatment of the medical condition in the past;
- The drug in question is likely to be ineffective based on the patient's physical or mental characteristics and the known characteristics of the drug;
- The preferred treatment will likely cause an adverse reaction or physical harm;
- The drug regimen is not in the best interest of the patient based on medical necessity;
- A provider certifies medical necessity in writing by noting "Brand Medically Necessary" and supporting documentation is charted indicating why a generic or alternative drug does not meet therapeutic needs.

If an enrollee is new to the MCO, a request for an exception must be initially submitted with clinical notes indicating that the patient has tried and failed the step therapy or failed the first drug to obtain an exception for the drug requested. Provisions of SCORCS/SB 11 bill would require similar exception criteria.

Additionally, in section 4.10.2.10.5 of the Medicaid MCO contracts, the MCOs are required to have an open formulary for all psychotropic medications and not able to apply step therapy or fail first criteria. Furthermore, if the prescriber certifies medical necessity by noting "brand medically necessary" or "brand necessary" on the prescription, and maintains supporting documentation in the member's medical record indicating that a generic or alternative medication does not meet the therapeutic needs of the member, then prior authorization is not necessary for use of a brand psychotropic drug.

SCORCS/SB 11 also includes requirements for how step therapy protocols are to be implemented: Most significantly, Section 2, A. (2) (a) of the bill [prescribes] that the interdisciplinary panel manage conflicts of interest among the members of the panel of experts by "requiring members to disclose any potential conflicts of interest with health care plans, medical assistance plans, health maintenance organizations, pharmaceutical manufacturers, pharmacy benefits managers and other entities" and requiring members to recuse themselves if there is a conflict of interest. . ."

If each medical assistance plan were to convene its own panel, this requirement could potentially prohibit a medical director or any other health professional employed or contracted by the Medical Assistance Program, including a Medicaid MCO, from participating in any part of the process to determine step therapy protocols that will be implemented within their own entity.

It could also remove the participation of the organization's "Pharmacy and Therapeutics Committee" which is the standard body within a MCO that typically considers preferred drug lists, prior authorization requirements, and step pharmacy through a multi-disciplinary panel charged with this responsibility. It could also potentially exclude any participation by a health professional employed by a Pharmacy Benefits Manager who may have expertise and experience derived from other states and other lines of business.

Other aspects of the requirements, such as the involvement of appropriate medical experts is beneficial because of the very complex nature of drug treatments, particularly in specialized medical fields. But otherwise, the requirements of the bill completely separate the management of step therapy from the managed care organizations' operations and responsibility.

In the bill, there is also no allowance for economy in selecting the step therapy drug items. In reality, the difference in cost between an older but very reliable and well-established drug and very new drug therapy may be drastically different. The bill does not seem to recognize that there may be significant economic reasons for trying the less expensive drug first in a step therapy protocol.

The consideration of "economy" within the Medical Assistance Programs is a primary tenet of the federal regulations that created the Medicaid programs and is still applicable.

Use of long established drug therapy may even provide some protections to the enrollee by requiring the use of more known standard therapies before using very expensive, newly marketed drugs.

Staff at Blue Cross Blue Shield of New Mexico, asked to estimate the cost to the state of the proposed legislation, gave the following response:

The bill(s) in question will result in the following higher drug costs for the state, health plans, and New Mexico citizens:

- State employees **$6.4 million** over three years according to a 2017 NM bill FIR
- BCBS-NM private employers and employees **$6 million** annually
- BCBS-NM Medicaid recipients and taxpayers **$1.1 million** annually
- These costs could ultimately be passed on to New Mexico citizens via higher premiums or higher out-of-pocket medicine costs…

Some details on the methodology that was used to develop the above numbers:

- Standard quarterly and yearly industry pharmacy utilization reports for BCBSNM were used.
- The numbers include savings from both combined step therapy and prior authorization programs as it would be difficult to tease out the individual program cost savings, and it is also not clear how the bill is written how it might affect both step therapy and prior authorization programs.
- The $1.1M estimate is for BCBS NM Centennial recipients only. Based on current relative Centennial membership the total cost to the Medicaid program could be three to four times higher.
- The assumption was made that the savings from those programs would be completely nullified, as the bill would require automatic approvals in many circumstances, including instances where patients were provided samples.

Representatives of HSD indicate that roughly one half of all exemption requests made by members of Medicaid managed care organizations are approved using current mechanisms. If this holds true for exemption requests made through all of the types of medical insurance plans, then the possible cost of the implementation of SCORCS/SB 11 would be likely to be less than one half of the amount indicated in the Blue Cross assessment above.

In summary, the fiscal impact of SCORCS/SB 11 depends on the extent to which step therapy would be circumvented. If the eventual outcome of the bill is only to regulate the means by which therapy protocols are generated and to speed up the process of step therapy exemption granting or denial, the resulting increase in medication costs for state medical benefit programs and for Medicaid would be small. If, on the other hand, fewer step therapy protocols were to be generated and exemptions from step therapy were to be much more frequent, the resulting increase in cost could be much greater. It should be clear that SCORCS/SB 11 does not intend to eliminate step therapy, only to regulate it.

SIGNIFICANT ISSUES

In the 2017 Legislature, two identical bills (House Bill 244 and Senate Bill 179) similar to SCORCS/SB 11 were introduced. An amendment eliminated clinical review criteria in the bill, eliminated application of the Patient Protection Act, and eliminated the 24- and 72-hour time limitations for reviews of exception requests, replacing them with “expeditious”. These changes are not included in SCORCS/SB 11.

The definition of “medical necessity” has been extensively revised in the current committee substitute to be more congruent with the term as used by the Superintendent of Insurance.

HSD raises the issue that the conflicts of interest provisions in the bill may be restrictive and “seem to include anyone working within the MCO, such as the Medical Director, from having any input when selecting the step therapies process.” HSD continues, “The bill does not seem to recognize that significant economic reasons may exist for trying the less expensive drug first in a step therapy protocol.”

HSD also discusses the new language in the amendment requiring plans to authorize continued use of a drug until the determination of the applicability of the step therapy protocol is made:

- Federal requirements regarding a continuation of a disputed benefit, which HSD has implemented, currently exist. When the recipient is receiving a service, such as a drug item that is going to be discontinued by the medical plan, the recipient has the right to request the continued use of the drug and the medical plan cannot deny that request.

- The federal rules specifically state that a recipient request for "a continuation of benefits" must be a separate request from the exception request. This is because the federally required timeframe for requesting continuing benefits are different from that of filling an appeal or for a fair hearing. It is also important that a recipient separately request a continued use of the drug item because if the recipient does not prevail in the appeal or final fair hearing decision, the recipient may be responsible for paying for the continued use of that drug item during the appeal and administrative hearing process as allowed under federal and current state rules.

- The bill is also in conflict with federal rules in that, when a recipient requests a continuation of a benefit such as a drug item, the benefit does not end with the decision on the exception request but continues through the full appeals and fair hearing process.

In Subsection I-2 of each section, practitioners are not prevented from prescribing a "prescription drug the provider has determined to be medically necessary," but it is not clear in that instance whether the insurer would be required to pay for that medication.

The American Medical Association (AMA) states, in a policy statement entitled "Prior Authorization and Utilization Management Reform Principles" that "Utilization management programs, such as prior authorization and step therapy, can create significant barriers for patients by delaying the start or continuation of necessary treatment and negatively affecting patient health outcomes. The very manual, time-consuming processes used in these programs burden providers (physician practices, pharmacies and hospitals) and divert valuable resources away from direct patient care." The AMA proposes 21 "principles" which it states should govern the use of step therapy and other forms of utilization management, as follows:

1. Any utilization management program applied to a service, device or drug should be based on accurate and up-to-date clinical criteria and never cost alone. The referenced clinical information should be readily available to the prescribing/ordering provider and the public.
2. Utilization management programs should allow for flexibility, including the timely overriding of step therapy requirements and appeal of prior authorization denials.
3. Utilization review entities should offer an appeals system for their utilization management programs that allows a prescribing/ordering provider direct access, such as a toll-free number, to a provider of the same training and specialty/subspecialty for discussion of medical necessity issues.
4. Utilization review entities should offer a minimum of a 60-day grace period for any step therapy or prior authorization protocols for patients who are already stabilized on

a particular treatment upon enrollment in the plan. During this period, any medical treatment or drug regimen should not be interrupted while the utilization management requirements (e.g., prior authorization, step therapy overrides, formulary exceptions, etc.) are addressed.

5. A drug or medical service that is removed from a plan's formulary or is subject to new coverage restrictions after the beneficiary enrollment period has ended should be covered without restrictions for the duration of the benefit year.
6. A prior authorization approval should be valid for the duration of the prescribed/ordered course of treatment.
7. No utilization review entity should require patients to repeat step therapy protocols or retry therapies failed under other benefit plans before qualifying for coverage of a current effective therapy.
8. Utilization review entities should publically disclose, in a searchable electronic format, patient-specific utilization management requirements, including prior authorization, step therapy, and formulary restrictions with patient cost-sharing information, applied to individual drugs and medical services. Such information should be accurate and current and include an effective date in order to be relied upon by providers and patients, including prospective patients engaged in the enrollment process. Additionally, utilization review entities should clearly communicate to prescribing/ordering providers what supporting documentation is needed to complete every prior authorization and step therapy override request.
9. Utilization review entities should provide, and vendors should display, accurate, patient specific, and up-to-date formularies that include prior authorization and step therapy requirements in electronic health record (EHR) systems for purposes that include e-prescribing.
10. Utilization review entities should make statistics regarding prior authorization approval and denial rates available on their website (or another publically available website) in a readily accessible format. The statistics shall include but are not limited to the following categories related to prior authorization requests:
    a. Health care provider type/specialty;
    b. Medication, diagnostic test or procedure;
    c. Indication;
    d. Total annual prior authorization requests, approvals and denials;
    e. Reasons for denial such as, but not limited to, medical necessity or incomplete prior authorization submission; and
    f. Denials overturned upon appeal. These data should inform efforts to refine and improve utilization management programs.
11. Utilization review entities should provide detailed explanations for prior authorization or step therapy override denials, including an indication of any missing information. All utilization review denials should include the clinical rationale for the adverse determination (e.g., national medical specialty society guidelines, peer-reviewed clinical literature, etc.), provide the plan's covered alternative treatment and detail the provider's appeal rights.
12. A utilization review entity requiring health care providers to adhere to prior authorization protocols should accept and respond to prior authorization and step-therapy override requests exclusively through secure electronic transmissions using the standard electronic transactions for pharmacy and medical services benefits. Facsimile, proprietary payer web-based portals, telephone discussions and nonstandard electronic forms shall not be considered electronic transmissions.

13. Eligibility and all other medical policy coverage determinations should be performed as part of the prior authorization process. Patients and physicians should be able to rely on an authorization as a commitment to coverage and payment of the corresponding claim.
14. In order to allow sufficient time for care delivery, a utilization review entity should not revoke, limit, condition or restrict coverage for authorized care provided within 45 business days from the date authorization was received.
15. If a utilization review entity requires prior authorization for non-urgent care, the entity should make a determination and notify the provider within 48 hours of obtaining all necessary information. For urgent care, the determination should be made within 24 hours of obtaining all necessary information.
16. Should a provider determine the need for an expedited appeal, a decision on such an appeal should be communicated by the utilization review entity to the provider and patient within 24 hours. Providers and patients should be notified of decisions on all other appeals within 10 calendar days. All appeal decisions should be made by a provider who (a) is of the same specialty, and subspecialty, whenever possible, as the prescribing/ordering provider and (b) was not involved in the initial adverse determination.
17. Prior authorization should never be required for emergency care.
18. Utilization review entities are encouraged to standardize criteria across the industry to promote uniformity and reduce administrative burdens.
19. Health plans should restrict utilization management programs to "outlier" providers whose prescribing or ordering patterns differ significantly from their peers after adjusting for patient mix and other relevant factors.
20. Health plans should offer providers/practices at least one physician-driven, clinically based alternative to prior authorization, such as but not limited to "gold-card" or "preferred provider" programs or attestation of use of appropriate use criteria, clinical decision support systems or clinical pathways.
21. A provider that contracts with a health plan to participate in a financial risk-sharing payment plan should be exempt from prior authorization and step-therapy requirements for services covered under the plan's benefits.
    https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf

From the perspective of an insurance company chief medical officer, Dr. Eugene Sun of Blue Cross Blue Shield of New Mexico, wrote in the Albuquerque Journal on January 3, 2018, in a guest column entitled "Step therapy vital to appropriate care:"

> It's [step therapy is] critical to maintain affordable access to appropriate care and medications… Step therapy is a process that health insurance companies use selectively to ensure that existing, highly effective, and more cost-efficient medications are tried first before approving coverage for new high-cost medications. For many of the conditions that require specialty medications, there is at least one, and sometimes several, U.S. Food and Drug Administration (FDA)-approved medication that has been used successfully for years, if not decades, to treat the condition. All step therapy does is to ask if those drugs have been tried and were successful, or not, in treating a condition… In my opinion, a call for legislation to require a clear and timely appeals process for step therapy is unnecessary. There are already a number of regulatory and legislative requirements in

> place for health insurers to provide transparent and expeditious appeals rights for all of our members.
>
> All physicians, nurses and health care providers in the state work tirelessly to care for all New Mexicans. By maintaining step therapy processes, we are ensuring appropriate care for our patients and the community."
> https://www.abqjournal.com/1113883/step-therapy-vital-to-appropriate-care.html

In summary, patients and practitioners often dispute the necessity of step therapy, contending that it infringes on a practitioner's right and ability to determine the best therapy for a given patient. On the other hand, insurers, noting practitioners' vulnerability to pharmaceutical detailing and patients' vulnerability to direct-to-patient advertising, indicate the need to control costs by step therapy, which insists upon use of proven, less-expensive therapy before more expensive, often non-generic therapy is tried. Again, it must be emphasized that SCORCS/SB 11 does not advocate for ending step therapy.

DUPLICATION of House Bill 42 (prior to SCORCS/SB11), near duplication with 2017 HB 244 and SB 179.

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL.

Step therapy would be established by each medical insurance company as it deemed fit, and there would be no uniformity or specified limit to the time an exemption adjudication might take.

LAC/sb/jle/al