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

SPONSOR Thomson **ORIGINAL DATE** 2/07/17 **LAST UPDATED** 3/13/17 **HB** 244/aSCORC

SHORT TITLE Prescription Drug Coverage Step Therapy **SB**

ANALYST Chilton

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY17	FY18	FY19	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total	Indeterminate*	Indeterminate*	Indeterminate*	Indeterminate*	Recurring	Various

(Parenthesis ( ) Indicate Expenditure Decreases) *But see fiscal implications below.

Duplicates Senate Bill 179

SOURCES OF INFORMATION
LFC Files

Responses Received From
Public School Insurance Authority (PSIA)
Retiree Health Care Authority (RHCA)
Human Services Department (HSD)
Department of Health (DOH)
General Services Department (GSD)

SUMMARY

Synopsis of Amendment

The Senate Corporations and Transportation Committee amendment substitutes language in each section of the bill (applying to different types of insurance as noted in the table below). In each case, the effects of the amendment are to

- Eliminates the clinical review criteria requirements for step therapy protocols previously specified at some length in each section of the bill,
- Eliminates application of the Patient Protection Act to exception requests to step therapy, and
- Eliminates a time limit for the approval of exceptions requests, replacing it with the term “expeditious.”

Synopsis of Bill

Step therapy involves the requirement by health insurers that their enrollees be treated with a 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. House Bill 244 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. Transparency of the process would be required, and opportunities for public input would be available. If published guidelines were not available, expert opinion could be used. Patients and prescribers would have access to a method to request an exception to a given step therapy determination, and insurers would have to respond within 72 hours, or 24 hours in an urgent situation. 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 patients particular circumstances make it appear the indicated step therapy drug will be ineffective in the given patient.
- The patient has used the drug before (under the same or a previous insurer), and found it either ineffective or causing an adverse effect.
- The patient is stable on the desired medication, whether it is currently covered by the insurer or by a previous insurer.

Patients could appeal the insurer's decisions through the Patient Protection Act.

Plans could still require the use of a generic version of a patented drug.

Separate sections of House Bill 244 makes the same requirements in a number of insurer types as indicated in the table below:

Section of House Bill 139	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

FISCAL IMPLICATIONS

GSD's Risk Management Division reported that step therapy management saved the group benefits fund $1.7 million in FY16 and without the benefit of step therapy management, prescription drug costs would increase by at least $6.4 million over the next three years. GSD went on to further explain that its plan participants already have the right to get prescription drugs paid for "as written" once their provider provides the appropriate medical justification.

Other responding agencies indicated that there would probably be little change in expenditures resulting from this legislation, although OSI noted that its staffing needs might increase if required to handle complaints or investigate insurers' compliance with the provisions of the bill. PSIA and HSD both indicated the possibility that medication costs might go up if there were many exceptions requested and granted.

HSD also noted that

> 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 Texas Medication Algorithm Project attempted something similar which was focused on behavioral health prescribing. The Texas behavioral health authority collaborated with UT Southwestern to develop a system of clinical practice guidelines which made recommendations regarding first line medications and subsequent steps. The whole endeavor was comprehensive but required a fair amount of funding to make it work. They received funding from a variety of sources - NIH, foundations, the VA, and a number of pharmaceutical companies. Although the pharmaceutical companies were not authors on the final guidelines, there has been some controversy that the guidelines were overly influenced by the pharmaceutical companies and when there were gray areas in the decision making process, expensive, newer generation medications were emphasized.

HB 244 might have a major impact on prescription costs if step therapy protocols were to be too easily circumvented. Step therapy programs require that patients try less expensive medications first before "stepping up" to drugs that cost more. These programs are in place to hold down drug costs for insurance plans and out-of-pocket costs for consumers. Insurance plans with transparent step therapy programs provide a clear appeals process for providers who feel the standard treatment is contraindicated or will not help their patients. There are some insurance plans that do not have transparent step therapy programs, making it quite difficult to make the case that a given patient should go immediately to a higher "rung" on the "step ladder." Some insurance companies will not honor a patient's previous insurance company's step therapy program after the patient has switched companies, requiring again that the patient start at the "lowest step." Because some drugs are extremely costly, starting with a less expensive drug may provide a patient with adequate therapy at a lower cost to the insurer and/or to the patient. Making it too easy to circumvent step therapy protocols may increase costs for plans and consumers alike.

SIGNIFICANT ISSUES

In each section, there appears to be a discrepancy between subsection A2, which mandates an "interdisciplinary panel of experts" to develop step therapy protocols, and subsection D, stating that no new entities are required in order to develop review criteria. In addition, it seems difficult to imagine one group being knowledgeable about all the possible step therapy protocols (e.g., drugs for gastro-esophageal reflux and drugs for psychosis).

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

Step therapy would continue to be unregulated, with some insurers having difficult appeals processes – difficult for patients and for prescribers.

LAC/jle/sb

VIEWPOINT

Step Therapy—Clinical Algorithms, Legislation, and Optimal Prescribing

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Increasing prescription drug costs impose economic burdens for patients and payers and are reflected in substantial increases in insurance premiums for individuals and employers and budget stress for public programs. One widely used approach to control prescription costs is "step therapy": requiring patients to try a less expensive drug for a given condition before a more expensive option can be approved. Authorization of the second-line agent may require attestation by the prescriber that the patient took the initial medication and had adverse effects or inadequate clinical benefit. Such clinical algorithms are often sensible and evidence based and can improve the quality of care. But sometimes they are not, because of limited evidence, inadequate attention to the underlying evidence, or an emphasis on cost containment rather than patient outcomes. The economic stakes can be high, because manufacturers' promotion to both prescribers and patients is usually aimed at encouraging use of more costly second-line agents.

Step therapy requirements have been criticized by advocacy groups, citing the experiences of individual patients who could not have prescriptions covered because of these policies. In response, several state legislatures (including California, Indiana, Missouri, New York, West Virginia) have passed laws limiting insurers' ability to require step therapy. Important questions persist about whether such legislation can successfully address either the problems that motivate step therapy policies or the problems that result from such policies.

Motivation for Step Therapy

Many prescribing choices are needlessly expensive, with patients given an expensive drug when a less costly one would be an equal or better choice. For example, a recent study showed that more than one-third of patients starting treatment for diabetes did not receive metformin, an inexpensive option that is the first step in all major guidelines.[1] Ideally, payers seeking to contain drug costs will identify situations in which the less costly medication option is also the best evidence-based choice for most patients, with a process in place to allow for exceptions based on emerging information about pharmacogenetic differences in drug response or idiosyncratic adverse effects that individual patients may experience.

Categories of Step Therapy Implementation

Preferred Agent Within a Therapeutic Class

Many drug classes include multiple agents with similar effects, some of which may be available as lower-cost generics. Insurers may require patients to try 1 or more generic agents in a given class before approving any others. In practice, this approach is similar to reference pricing, in which insurers reimburse only the cost of a single lower-priced agent within a class, regardless of which medication is actually prescribed. A systematic review showed that reference pricing can contain medication costs without adverse clinical consequences.[2]

Closely Related Medication Classes for a Condition

Some medications from different classes may have similar mechanisms of action and could be equally reasonable options for most patients. In these situations, insurers may require patients to try the lower-cost class of medication before considering the more expensive class. The reasonableness of such policies varies with the substitutability of the medication classes and the policy details. Prior research has demonstrated that such policies can shift medication use in the directed manner, but the extent of such changes was the same whether or not the policies used evidence-based criteria, raising concerns about the appropriateness of some of the policy-driven prescribing changes.[3,4]

Range of Medications Within a Disease Category

For some conditions, guidelines recommend prescribing a specific sequence of medication classes. For example, for many inflammatory diseases the initial therapeutic approach may be methotrexate or another nonbiologic agent, after which patients with poor response may be prescribed a more costly biologic agent instead.[5] Although the limited amount of adequate comparative effectiveness data makes it difficult to assess claims of superiority or equivalence between these agents, specialty medications are among the most important drivers of increasing prescription costs. Payers seeking to control costs have begun to advocate publicly for narrower coverage to control costs.[6] Advocacy activities, often based on anecdotal reports of patients who felt they were adversely affected by step therapy, have been influential in leading several states to pass laws restricting step therapy. This in turn raises concerns about the generalizability of single-case anecdotal information, as well as the fact that many of the patient groups opposing step-care requirements are heavily funded by the pharmaceutical industry.[7]

Potential Problematic Aspects of Step Therapy

When conceived and implemented intelligently, step therapy can use evidence-based criteria, with clinically reasonable provisions for exceptions, to encourage more rational prescribing and help control medication costs, while ensuring that patients are receiving the most data-driven regimens. However, if based on poor evidence or implemented inflexibly, the approach can cause clinical problems, especially for patients forced

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to return to a medication class that was previously ineffective. But all policies that require patients to change medications risk negative consequences. Even switches between pharmacologically identical generic versions of the same medication can decrease adherence if the medication appearances differ.[8]

The most concerning and preventable instance of how step therapy can interrupt a preferred regimen is change in insurance status resulting from change in job or employer-provided coverage. Changes in formulary, even for patients with stable insurance, can also adversely affect treatment. In these circumstances, patients for whom one regimen has truly failed may unexpectedly be subjected to new step therapy requirements, forcing them to switch from their current medication to whatever agent is the "first step" in their new plan. Paradoxically, medication decisions and costs are often managed in a different "silo" from other decisions, outcomes, and costs for which a physician is responsible, as when drug costs are "carved out" by a Medicare Part D drug benefit that is decoupled from the rest of a given patient's coverage.

Can Legislation Address These Problems?

Increasing legislative pressure to limit or prohibit step therapy raises concern over whether such laws are the best means to address the problems that poorly implemented step therapy may cause. Done well, step therapy can be a sensible and clinically appropriate means of containing increases in medication expenses, increases usually passed on to patients and taxpayers in the form of higher insurance costs. It is unlikely that legislators, by pulling one available lever in a complex system, can improve the rationality and affordability of prescribing. It will be difficult to implement such policies through laws and still respect the clinical and economic nuances that should ideally be driving optimal prescribing.

What Is Needed?

Simplistic legislation restricting step therapy fails to address the fundamental problems facing patients trying to obtain effective and affordable treatment for their medical conditions. Several policy approaches may help patients acquire drugs at affordable prices. First, insurers should be allowed to enact reasonable evidence-based policies to avoid needless expenses incurred by suboptimal prescribing practices, often driven by intense marketing to prescribers and patients (and now, to legislators). Second, insurers should be required to implement policies in a transparent fashion, so that criteria for covering a given medication are clear to patients and prescribers, and the process for submitting information is user-friendly, ideally as part of electronic prescribing systems.

Third, any step therapy requirements should make provision for prescribers to obtain permission to override the standard clinical algorithm for plausibly documented reasons, such as a patient's intolerance of or poor response to first-step treatments. Increased interoperability of information systems across insurers could eventually make this straightforward if prior use of the medication occurred when a different insurer covered the patient. Fourth, it is preferable to educate physicians about the relative efficacy and cost-effectiveness of drugs to help them make more rational initial choices, rather than having poor decisions second-guessed later by an algorithm. Several health care systems have implemented proactive programs of educational outreach to prescribers ("academic detailing") to achieve this goal.[9]

Fifth, more attention must be paid to medication adherence—one of the most concerning challenges of poorly implemented step therapy policies. Changes in medication regimens will continue to occur for multiple reasons, including step therapy requirements; clinicians need resources such as feedback on actual medication filling rates and pharmacy-based interventions to help with simplification and synchronization of drug regimens to support patients and ensure that policy changes do not compromise medication adherence. Sixth, insurers should be accountable for the overall health of the patients they cover, aligning incentives so that medication costs are part of the same organizational system as the rest of a patient's health care. Doing so could help ensure that inappropriately restricting coverage of needed medications would have consequences for insurers as well as for patients.

Prescription drug therapy remains the cornerstone of treatment for many diseases. Sensible policies to ensure the quality and affordability of prescribing are an increasingly central element of managing health care utilization. Laws to restrict the use of a single cost-containment approach only add complexity to an already Byzantine system, without clearly addressing the real problems with prescribing. Perhaps the debate over such laws can lead all stakeholders to engage in the more productive work of developing systems and interventions capable of truly improving rational prescribing and patient outcomes.

ARTICLE INFORMATION

Published Online: February 6, 2017. doi:10.1001/jama.2016.20619

Conflict of Interest Disclosures: The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Fischer reported serving as a clinical consultant for Alosa Health. Dr Avorn reported no disclosures.

REFERENCES

1. Desai NR, Shrank WH, Fischer MA, et al. Patterns of medication initiation in newly diagnosed diabetes mellitus: quality and cost implications. *Am J Med*. 2012;125(3):302e1-302e7.

2. Lee JL-Y, Fischer MA, Shrank WH, Polinski JM, Choudhry NK. A systematic review of reference pricing: implications for US prescription drug spending. *Am J Manag Care*. 2012;18(11):e429-e437.

3. Fischer MA, Choudhry NK, Winkelmayer WC. Impact of Medicaid prior authorization on angiotensin-receptor blockers: can policy promote rational prescribing? *Health Aff (Millwood)*. 2007;26(3):800-807.

4. Fischer MA, Schneeweiss S, Avorn J, Solomon DH. Medicaid prior-authorization programs and the use of cyclooxygenase-2 inhibitors. *N Engl J Med*. 2004;351(21):2187-2194.

5. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken)*. 2016;68(1):1-25.

6. Thomas K. A push to lower drug prices that hit insurers and employers the hardest. *New York Times*. September 8, 2016. https://www.nytimes.com/2016/09/09/business/express-scripts-urges-narrower-coverage-of-anti-inflammatory-drugs.html. Accessed November 1, 2016.

7. Thomas K. Furor over drug prices puts patient advocacy groups in bind. *New York Times*. September 27, 2016. https://www.nytimes.com/2016/09/28/business/furor-over-drug-prices-puts-patient-advocacy-groups-in-bind.html. Accessed November 1, 2016.

8. Kesselheim AS, Misono AS, Shrank WH, et al. Variations in pill appearance of antiepileptic drugs and the risk of nonadherence. *JAMA Intern Med*. 2013;173(3):202-208.

9. Avorn J. Academic detailing: "marketing" the best evidence to clinicians. *JAMA*. 2017;317(4):361-362.

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