OHIO LEGISLATIVE SERVICE COMMISSION

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Fiscal Note & Local Impact Statement

Bill: S.B. 56 of the 132nd G.A. (L_132_0728-4)

Status: In Senate Health, Human Services, & Medicaid

Sponsor: Sens. Lehner and Tavares

Local Impact Statement Procedure Required: Yes

Subject: Adopts requirements related to step therapy protocols used by health plan issuers and the Department of Medicaid

State & Local Fiscal Highlights

- It is likely that the bill would increase prescription costs and lead to overall higher employee health costs in the short term to the state government and local governments. However, there is conflicting evidence in existing literature on the monetary effect of step therapy programs in the long run. Some studies of step therapy procedures have found an increase in nonprescription medical expenditures (e.g., hospital visits) that accompanies the savings on prescriptions. Therefore, the long-term health cost effects of this bill, which in general would restrict the use of step therapy methods, are more ambiguous.
- The state's costs to provide health benefits to employees and their dependents are paid from the Health Benefit Fund (Fund 8080). Fund 8080 receives funding through state employee payroll deductions and state agency contributions toward their employees' health benefits, which come out of the GRF and various other state funds.
- Similarly, the bill's requirements for the Medicaid Program could result in higher prescription drug costs to the program. The extent is unknown, but some Medicaid managed care plans that were surveyed commented that it could be as high as tens of millions of dollars each year if all prescription drugs currently subject to step therapy were to be exempt. Such Medicaid costs would be paid by the GRF, with expected federal reimbursement of approximately 64% of the costs.
- There could be a wide range of fiscal outcomes for local public entities based on the health coverage provided to their employees, the current use of step therapy methods by the respective plan issuers, and the uneven distribution of medical patient case mix. Some local municipalities may experience virtually no change if they do not currently offer employee prescription benefits, or if their plan issuers do not currently use step therapy methods.

Detailed Fiscal Analysis

Step therapy

The bill specifies requirements for implementation in any step therapy protocol[1] system to be utilized by a health plan issuer (including self-funded public plans) or the Medicaid Program. The protocol must be implemented through clinical review criteria that are based on clinical practice guidelines or medical or scientific evidence. The bill requires health plan issuers or utilization review organizations to certify, annually in rate filing documents submitted to the Superintendent of Insurance, that the clinical review criteria used to implement a step therapy protocol for prescription drugs meet the bill's requirements.

The bill requires that any health plan issuer (including Medicaid) that uses step therapy procedures must also provide the prescribing health care provider access to a "clear, easily accessible, and convenient" process with which a patient can be exempted from the step therapy. The bill allows a health plan issuer to use its existing medical exceptions process to satisfy the requirement related to the step therapy exemption. The bill requires a health plan issuer to make available, to all health care providers, a list of all drugs covered by the issuer that are subject to a step therapy protocol; this list must also be available on the issuer's website or provider portal. Exemptions must be granted in situations such as when the drug required by step therapy procedures has been ineffective for the patient in the past, or when the prescribing health care provider (e.g., doctor) determines it is not in the best interest of the patient based on medical necessity. Exemption requests or appeals must be responded to by a health plan issuer or utilization review organization within 48 hours of receipt if the requests are related to urgent care services or ten calendar days for all other requests. Any rejected appeal must be considered an adverse benefit determination, and the covered individual, or the covered individual's representative, may seek an external review under existing law.[2]

The bill specifies that it must not be construed as requiring either a health plan issuer or the state to set up a new entity to develop clinical review criteria for step therapy protocols. The bill allows the Superintendent to adopt rules as necessary to enforce the bill's requirements.

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[1] The bill defines a "step therapy protocol" as a protocol or program that establishes a specific sequence in which prescription drugs that are for a specified medical condition and that are medically necessary for a particular patient are covered, under either a medical or prescription drug benefit, by a health benefit plan, including both self-administered and physician-administered drugs.

[2] Under Chapter 3922. of the Revised Code.

Fiscal effect

Step therapy (often called "fail first" by opponents) protocols are programs developed by health plan issuers to limit prescription drug costs. These types of programs have increased in use over the last decade. The growing popularity of the programs is one piece of evidence that the programs save money for health plan issuers, at least in the short term. There is a growing body of research on the policy that seems to confirm this. A study of step therapy methods used for antipsychotic medications in the Georgia Medicaid Program found a decrease in prescription expenditures of $19.62 per member per month over the 11-month policy period.[3] A separate study of step therapy methods used for antihypertensive medications (prescribed for high blood pressure) using a nationwide dataset found an initial 3.1% decrease in medication costs.[4]

In general, S.B. 56 would likely lead to more exemptions from required drugs under step therapy procedures used by health plan issuers and the Medicaid Program. This would likely increase prescription costs to state and local governments. The magnitude of the increase would depend on the health benefit plan used for public employees in a given municipality. About 24%[5] of local public health insurance plans are fully insured by outside health plan issuers and would be susceptible to resulting rises in premiums to cover additional prescription costs. The remaining 76% of local plans, in addition to the state employee plan, are self-funded. The costs of these plans will be affected differently based on the current level of prescription coverage and use of step therapy methods. The self-funded state of Ohio employee plan uses step therapy programs for many different types of medication including prescriptions in the therapeutic categories of cardiovascular, diabetes, inflammatory bowel disease, and respiratory.

Therefore, the state plan, and any similar local public employee plan which covers prescriptions and currently uses step therapy methods, will be affected by the bill. However, the bill is likely only to reduce the use of drugs required by step therapy protocols, not eliminate it. The magnitude of the reduction (from additional exemptions granted or the deterrence of use of step therapy procedures by health plans) is unknown, but will ultimately determine the increase in prescription costs. Current individual prescription usage and overall health of the employees under each local plan will also determine the costs to each locality.

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[3] Farley, J. et al., "Retrospective assessment of Medicaid step-therapy prior authorization policy for atypical antipsychotic medications," *Clinical Therapeutics*, 30: 1524-1539, 2008.

[4] Mark, Tami L. et al., "The effects of antihypertensive step-therapy protocols on pharmaceutical and medical utilization and expenditures," *The American Journal of Managed Care*, Vol. 15, No. 2: 123-131, 2009.

[5] According to the State Employee Relations Board 2017 Annual Report on the Cost of Health Insurance in Ohio's Public Sector.

However, the existing body of research is inconclusive about the overall cost effects of the step therapy programs in the long term. The Georgia Medicaid study of antipsychotic medications cited above found an increase of outpatient expenditures in the group impacted by step therapy methods. The outpatient cost increase was $31.59 per member per month, which would more than offset the cost savings from prescriptions. The nationwide study on antihypertensive medications, also cited above, found an increase in spending of $33 per month on inpatient admissions and emergency room visits within the step therapy group. These studies were narrow in scope (focused on specific types of drugs, etc.) and the existing body of research is far from settled on the issue of overall health costs related to step therapy procedures. However, there is some evidence that suggests step therapy programs may not actually decrease overall health costs in the long run. Therefore it is at least possible that the reduction of its use in Ohio through an enhanced exemption process may not increase overall health costs either. As stated, the existing body of research lacks consensus, but even if this is true, the net fiscal effect of step therapy protocols to public health plans would be based on how these different types of health costs (prescriptions, outpatient visits, etc.) are covered by each respective plan.

Regardless of the long-term fiscal effects related to health outcomes, there would likely be substantial administrative costs involved with the implementation of the bill. Plan administrators will need to handle new exemption requests, respond to requests and appeals within 48 hours for urgent care services or ten calendar days for other services. New administrative costs would likely result in increased fees paid to third-party administrators by public entities with fully funded plans, and increased premiums paid by public entities which have employee health plans that are fully insured. The Department of Insurance could also have new administrative costs related to step therapy criteria approval required by the bill. Any new administrative costs would be paid from the Department of Insurance Operating Fund (Fund 5540).

The costs of providing health benefits to state employees and their dependents are paid from the Health Benefit Fund (Fund 8080). Fund 8080 receives funding through state employee payroll deductions and state agency contributions toward their employees' health benefits, which come out of the GRF and various other state funds.

Medicaid

In addition to the requirements regarding the implementation of step therapy protocols, the bill requires the Medicaid Program to implement a process through which patients and health care providers can request an exemption from the step therapy protocols. The Ohio Department of Medicaid (ODM) uses prior authorization along with step therapy, in conjunction with a preferred drug list, to encourage the prescribing of the most clinically appropriate and cost-effective drug within a specific therapeutic drug category. Ohio Medicaid currently has step therapy requirements for a variety of drugs, including drugs in the following categories: analgesic, cardiovascular, central nervous system, endocrine, genitourinary, ophthalmic, and respiratory.

Fiscal impact

According to ODM, the potential fiscal impact of the step therapy exemption process is difficult to determine. There are currently some exemptions from step therapy protocols under the Medicaid Program. ODM surveyed the Medicaid managed care plans (MCPs) and some of them reported that the cost to the Medicaid Program could be in the tens of millions of dollars each year if all prescription drugs currently subject to step therapy were to be exempt. The potential cost impact would also apply to prescription drugs provided through Medicaid fee-for-service. Such Medicaid costs would be paid by the GRF, with expected federal reimbursement of approximately 64% of the costs.

There are two delivery systems for Ohio Medicaid: fee-for-service and managed care. Both delivery systems provide medically necessary primary care, specialty and emergency care services, and preventive services. Although Medicaid MCPs offer prescription drugs listed on the Ohio Medicaid list of covered drugs, they may have ODM-approved preferred drug lists or prior authorization requirements that are different from fee-for-service.

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