OHIO LEGISLATIVE SERVICE COMMISSION

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Fiscal Note & Local Impact Statement

Bill: S.B. 265 of the 132nd G.A. **Status:** As Enacted

Sponsor: Sen. Dolan **Local Impact Statement Procedure Required:** No

Subject: To permit certain health insurers to provide payment or reimbursement for services lawfully provided by a pharmacist, to recognize pharmacist services in certain other laws, to allow the Medicaid Program to cover certain health care services provided by a pharmacist, and to adopt requirements related to step therapy protocols used by health plan issuers and the Department of Medicaid

State & Local Fiscal Highlights

- To the extent the bill results in restricting the use of step therapy methods it may increase prescription costs and lead to overall higher employee health costs to the state government and local governments in the short term. However, there is conflicting evidence in existing literature about 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 the bill are uncertain.
- 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 step therapy 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 state GRF, with expected federal reimbursement of approximately 63% 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.

- Provisions related to health plan issuers to provide payment or reimbursement for services provided by a pharmacist for covered patients and services are permissive and have no direct fiscal effect on the state or political subdivisions.

Detailed Fiscal Analysis

Health insurer payments to pharmacists

The bill would allow a health plan issuer to provide payment or reimbursement for services lawfully provided by a pharmacist for covered patients and services. Under the bill, a health plan issuer may provide payment or reimbursement if both of the following conditions are met: (1) the pharmacist provided a health care service to a patient in accordance with Chapter 4729. of the Revised Code, including managing an individual's drug therapy under a consult agreement with a physician, administering adult immunizations, or administering certain drugs by injection, and (2) the patient is covered by an individual or group policy, contract, or agreement offered by a health insurer that provides for payment or reimbursement of such services. The bill applies to health insuring corporations (HICs), sickness and accident insurers, public employee benefit plans, and multiple employer welfare arrangements that are delivered, issued for delivery, or renewed in Ohio on or after the bill's effective date.

The bill also would make other changes, including explicitly authorizing pharmacists to provide certain specified services, authorizing pharmacists to be hired by certain entities, and includes pharmacists and pharmacies in the definition of "provider" for the purposes of contracting entities and health care contracts.

These provisions of the bill are permissive. They would have no direct fiscal effect on the state or local governments unless an insurer is currently not permitted to reimburse a pharmacist for performing these services. If that is the case, it is possible that the bill could reduce insurers' costs of paying benefits for the services. That in turn might reduce the costs for the state and local governments to provide health benefits to employees and their beneficiaries.

Medicaid

Under the bill, the Medicaid Program may cover a health care service provided by a pharmacist to a Medicaid recipient. These services may include either of the following: managing drug therapy under a consult agreement with a physician or administering immunizations and injectable drugs in accordance with certain requirements. This provision is permissive, so any impact will depend on a number of factors including the following: whether the Ohio Department of Medicaid (ODM) chooses to cover these services, what services provided by a pharmacist are currently covered under Medicaid, and how many individuals utilize these services.

Step therapy

The bill specifies requirements for implementation in any step therapy protocol system to be utilized by a health plan issuer (including self-funded public plans) or the

Medicaid Program. A "step therapy protocol" is defined in the bill to be a protocol "that establishes a specific sequence in which prescription drugs that are for a specified medical condition and that are consistent with medical or scientific evidence for a particular patient are covered" under either a medical or prescription drug benefit by a health plan, including both self-administered and physician-administered drugs.

The bill requires that a step therapy protocol, if a health insurer uses one, be implemented through clinical review criteria that are based on clinical practice guidelines or medical or scientific evidence, though the bill specifies that it should 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. Health plan issuers must also take into account the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

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 to request a step therapy exemption on behalf of a covered individual. The bill allows a health plan issuer to use its existing medical exceptions process to satisfy this requirement. Exemptions or appeal must be granted in situations such as when (1) the drug required by step therapy procedures is contraindicated for that specific patient, pursuant to the drug's U.S. Food and Drug Administration (FDA) prescribing information, (2) the patient has tried the required prescription drug before and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, or (3) the patient is stable on a prescription drug selected by the patient's health care provider for the medical condition under consideration. The bill allows a health benefit plan to require a patient to try a pharmaceutical alternative, per the FDA's orange book, purple book, or their successors, prior to providing coverage for the prescribed drug. Exemption requests or appeals must be granted or denied 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. If the appeal does not resolve the disagreement the covered individual, or the covered individual's representative, may seek an external review under existing law. The bill allows the Superintendent of Insurance to adopt rules as necessary to enforce the requirements under this bill.

The bill's step therapy requirements apply to health benefit plans that are issued for delivery, modified, or renewed on or after January 1, 2020.

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. 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.

In general, S.B. 265 may lead to more exemptions from required drugs under step therapy procedures used by health plan issuers and the Medicaid Program. This may 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% 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, though the bill may reduce the use of drugs required by step therapy protocols, it would 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.

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 does not seem to be 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. Even if the existing body of research lacks consensus, 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 enforcement of the bill. Any 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.

In addition to the requirements regarding the implementation of step therapy protocols, the bill also requires the Medicaid Program to implement a process through which health care providers can request an exemption from the step therapy protocols on behalf of a Medicaid recipient. 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 63% 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.