Ohio Legislative Service Commission

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Fiscal Note & Local Impact Statement

Bill: H.B. 248 of the 131st G.A. (LSC 131 0237-11)

Date: April 27, 2016

Status: In House Health and Aging

Sponsor: Reps. Sprague and Antonio

Local Impact Statement Procedure Required: Yes

Contents: To provide access to abuse-deterrent opioid analgesic drug products

State Fiscal Highlights

- The bill requires that the same utilization review requirements be applied to all opioid analgesic drug products. According to the Ohio Department of Medicaid (ODM), this is not current practice. As a result, prescribers may be more likely to prescribe abuse-deterrent opioids (ADOs). The increase in cost cannot be determined since it will depend on the number of prescriptions substituted.
- The bill requires ODM to apply prior authorization requirements or utilization review measures as conditions of providing coverage of opioid analgesic drug products, including ADO analgesic drug products prescribed for the treatment of chronic pain, except under certain circumstances. As a result, there could be a decrease in Medicaid prescription drug costs if the prior authorizations result in fewer prescriptions of opioid analgesics filled. There could also be an increase in administrative costs to ODM to process additional prior authorizations received.
- The requirement that health insurers apply prior authorization requirements or utilization review measures as conditions of providing opioid analgesic drug products could similarly decrease the costs for the state to provide health benefits to workers and their dependents. A Department of Administrative Services official reports that the state plan does not currently employ prior authorization or utilization review for such drug products.
- The bill's requirements overall may either increase or decrease expenditures for the state self-insured health benefit plans beginning in either FY 2017 or FY 2018. LSC economists could not determine the magnitude of the fiscal impact. Any increase or decrease in costs associated with the state health benefit plans would be paid from the Health Benefit Fund (Fund 8080).

Local Fiscal Highlights

- The provisions related to health insurers, including public employee benefit plans, may increase costs to local governments to provide health benefits to employees and their dependents, beginning in CY 2017. However, any political subdivision that already complies with the requirements under the bill would experience no cost increase.

Detailed Fiscal Analysis

Medicaid Program

The bill requires the Medicaid Program provide access to abuse-deterrent opioid (ADO) analgesic drug products in its formularies or list of covered drugs.

The bill also requires the Ohio Department of Medicaid (ODM) to apply prior authorization requirements or utilization review measures as conditions of providing coverage of opioid analgesic drug products, including ADO analgesic drug products prescribed for the treatment of chronic pain, except when the opioid analgesic drug product is prescribed for or personally furnished (1) to a hospice patient in a hospice care program, (2) to any other patient diagnosed with a terminal condition, or (3) to treat cancer or another condition associated with cancer.

The bill specifies that any prior authorization requirements or utilization review measures under the Medicaid Program and any coverage denials made related to those requirements or measures, must not (1) be any more restrictive for ADO analgesic drug products than for non-ADO analgesic drugs, and (2) require treatment with an opioid analgesic drug product that is not an ADO analgesic drug product in order to access an ADO analgesic drug.[1]

Fiscal effect

As stated above, the bill requires the Medicaid Program provide access to ADO analgesic drug products in its formularies or list of covered drugs. According to ODM, access is currently provided to any drug that has received federal Food and Drug Administration approval. Thus, this provision would have no fiscal effect.

The bill also requires ODM to apply prior authorization requirements or utilization review measures as conditions of providing coverage of opioid analgesic drug products, including ADO analgesic drug products prescribed for the treatment of

[1] The bill specifies that the requirements under this bill must not be construed to prevent ODM from applying utilization review requirements to ADO analgesic drug products, including prior authorization or non-opioid analgesic drug step therapy, provided that the same requirements are applied to all opioid analgesic drug products.

chronic pain, except under certain circumstances.[2] There could be a decrease in Medicaid prescription drug costs if the prior authorizations result in fewer prescriptions of opioid analgesics filled. There could also be an increase in administrative costs to ODM to process additional prior authorizations received.

The bill also requires that the same utilization review requirements be applied to all opioid analgesic drug products. According to ODM, this is not current practice. As a result, prescribers may be more likely to substitute ADOs for non-ADOs. LSC calculates that for every 10% of ADO prescriptions that are substituted for non-ADO prescriptions, annual Medicaid costs would increase by an estimated $2.8 million. However, the actual increase in cost cannot be determined since it will depend on the number of prescriptions substituted.

Data and methodology

ODM provided the Legislative Service Commission (LSC) with calendar year (CY) 2015 data showing the number of prescriptions and net payments for commonly prescribed extended release non-ADOs and ADOs. To calculate the potential fiscal impact, LSC compared the number of prescriptions for extended release non-ADOs and ADOs and the associated payments. For CY 2015, Medicaid payments for extended release opioid analgesic drug products, including non-ADOs (66,009 prescriptions) and ADOs (22,828 prescriptions), totaled approximately $18.9 million. Payments for extended release non-ADOs and extended release ADOs were $6.9 million and $12.0 million, respectively. Based on these payment totals, the average cost per prescription was $104.74 for non-ADOs and $523.83 for ADOs. Therefore, for every 10%[3] of ADO prescriptions that are substituted for non-ADO prescriptions, annual Medicaid costs would increase by an estimated $2.8 million.[4] The calculation is the difference in average cost per prescription ($523.83 - $104.74 = $419.09) multiplied by the number of non-ADO prescriptions (66,009) multiplied by 10%.

Health insurers

The bill would require health insurers that provide prescription drug coverage for opioid analgesic drug products to provide access to ADO analgesic drug products in the drug formulary or other list of covered drugs that applies under their policy,

[2] According to ODM, there is one extended release opioid analgesic, Morphine Sulfate, which does not currently require prior authorization. This is the most commonly prescribed extended release opioid analgesic (54,723 prescriptions in CY 2015).

[3] 10% was chosen for illustration purposes only.

[4] For those enrolled in traditional Medicaid, LSC assumes the standard federal reimbursement rate of 64% would apply. For those enrolled in Group VIII (i.e., Medicaid expansion), LSC assumes the federal reimbursement rate would be 95% in CY 2017, 94% in CY 2018, 93% in CY 2019, and 90% in CY 2020 and thereafter.

contract, or agreement.[5] "Health insurers" in the bill include health insuring corporations (HICs), sickness and accident insurance policies for an individual or group, public employee benefit plans, and multiple employer welfare arrangements. The bill applies to policies, contracts, agreements, or plans issued, delivered, established, or modified in Ohio on or after January 1, 2017.

The bill specifies that any prior authorization requirements or utilization review measures contained in a policy, contract, or agreement for opioid analgesic drugs, and any coverage denials made related to those requirements or measures, must not (1) be any more restrictive for ADO analgesic drug products than for non-ADO opioid analgesic drugs, or (2) require treatment with an opioid analgesic drug product that is not an ADO analgesic drug product in order to access an ADO analgesic drug.[6]

The bill requires insurers to apply prior authorization requirements or utilization review measures as conditions of providing coverage of opioid analgesic drug products, including ADO analgesic drug products prescribed for the treatment of chronic pain, except when the opioid analgesic drug product is prescribed for or personally furnished (1) to a hospice patient in a hospice care program, (2) to any other patient diagnosed with a terminal condition, or (3) to treat cancer or another condition associated with cancer. When implementing prior authorization requirements or utilization review measures, the bill requires insurers to consider all of the treatment requirements as specified under the bill.

The bill also specifies that the Superintendent of Insurance is not required to determine the impact of the mandated health benefits under this bill. Under existing law, no mandated health benefits legislation enacted by the General Assembly may be applied to sickness and accident insurers or other health benefits policies, plans, or other arrangements until the Superintendent of Insurance determines that the provision can be applied fully and equally in all respects to employee benefit plans subject to regulation by the federal Employee Retirement Income Security Act of 1974 (ERISA) and employee benefit plans established or modified by the state or any political subdivision of the state.

Fiscal effect

According to a document entitled *Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse*, published on the U.S. FDA website,[7] there are four prescription drugs (Oxycontin, Embeda, Hysingla ER, and

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[5] The bill defines an "abuse-deterrent opioid analgesic drug" as a brand or generic opioid analgesic drug product that is approved by the United States Food and Drug Administration (FDA) and that has labeling claims that indicate that the drug product is expected to deter or reduce its abuse.

[6] The bill specifies that its requirements must not be construed to prevent insurers from applying utilization review requirements to ADO analgesic drug products, provided that the same requirements are applied to all opioid analgesic drug products.

[7] The U.S. FDA website is located at www.fda.gov, visited October 5, 2015.

Targiniq ER) that are currently approved by the FDA and labeled as having abuse-deterrent properties. According to a Department of Administrative Services (DAS) official, the state's self-insured health benefit plans are currently providing coverage for the first three drugs while the fourth is not yet available on the market.

According to a DAS official, the state plan does not currently employ prior authorization or utilization review measures for opioid analgesic drug products. Thus, the bill's requirement to do so could reduce the state's costs of providing health benefits to employees and their dependents. Some of the restrictions that the bill would place on prior authorization requirements and utilization review measures may increase costs to the state's plans. LSC economists could not determine the magnitude of the fiscal impact in either case. Any increase or decrease in costs to the state plan would be 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.[8] In FY 2015, actual expenditures from Fund 8080 were $632.3 million.

Currently, the state plans impose copayments of $25 for Oxycontin and Embeda and $50 for Hysingla ER.[9] The state plan's spending related to opioid drugs in FY 2015 was about $2.2 million, for a total of 62,437 prescriptions. Of the total spending, approximately $461,000 was for 948 prescriptions for Oxycontin, Embeda, and Hysingla ER. In contrast, the lowest drug copayment for a 30-day supply of generic opioid drug without abuse-deterrent properties is $10.[10]

The requirements under this bill may increase costs to local governments to provide health benefits to employees and their dependents. However, any political subdivision that already provides the specified prescriptions, and complies with the bill's requirements, would experience no cost increase. LSC staff is not able to estimate the bill's fiscal impact on local governments due to data limitations on specific prescription benefits provided by local governments' health benefits plans.

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[8] Currently, full-time state employees pay 15% of the premium cost, while state agencies pay the remaining amount.

[9] Based on the state plans' prescription data in FY 2015, the total cost (amounts paid by members and plans) for the three drugs were: Oxycontin – between $142.15 and $2,567.07, Embeda – between $171.34 and $801.85, and Hysingla ER – $368.89. LSC staff do not have information related to discounts or rebates associated with these three drugs.

[10] Based on the state plans' prescription data in FY 2015, the average costs paid by a member for an opioids prescription (with or without abuse-deterrent properties) ranged between $2.39 and $50.

Synopsis of Fiscal Effect Changes

Medicaid

Updated estimate

The Fiscal Note has been updated to reflect both the changes in the substitute bill and new data that LSC received after the As Introduced version of the Fiscal Note was issued. The fiscal impact provided in the As Introduced Fiscal Note was based on total opioid expenditures and the differential between the per pill cost of non-ADOs and ADOs. The fiscal impact of the substitute bill is based on the average cost per prescription for each opioid drug and uses data specific to extended release opioids.

The substitute bill requires that the same utilization review requirements be applied to all opioid analgesic drug products. According to ODM, this is not current practice. As a result, prescribers may be more likely to prescribe ADOs. The actual fiscal impact cannot be determined since it will depend on the number of prescriptions substituted. However, LSC calculates that for every 10%[11] of ADO prescriptions that are substituted for non-ADO prescriptions, annual Medicaid costs would increase by an estimated $2.8 million (state and federal shares).

Substitute bill changes

Overall, the estimated costs to the Medicaid Program under the substitute bill (LSC 131 0237-11) would likely be less than the estimated costs under the As Introduced version. The reasons are stated below.

The As Introduced version of the bill specified that any cost-sharing requirements cannot exceed the lowest cost-sharing requirements applied to opioid analgesic drugs without abuse-deterrent properties. This provision could have resulted in more ADOs being prescribed and thus higher Medicaid costs. The substitute bill removes this provision.

The substitute bill requires the Medicaid Program provide access to ADO analgesic drug products in its formularies or list of covered drugs. According to ODM, access is currently provided to any drug that has received federal Food and Drug Administration approval. Thus, this provision in the substitute bill would have no fiscal effect. The substitute bill adds the requirement that ODM apply prior authorization requirements or utilization review measures as conditions of providing coverage of opioid analgesic drug products, including opioid analgesic drug products prescribed for the treatment of chronic pain, except when the drug product is prescribed under any of the following circumstances: (1) to a hospice patient in a hospice care program, (2) to any other patient diagnosed with a terminal condition, or (3) to treat cancer or another condition associated with cancer. There could be a decrease in Medicaid prescription drug costs if the prior authorizations result in fewer prescriptions of opioid analgesics

[11] 10% was chosen for illustration purposes only.

filled. There could also be an increase in administrative costs to ODM to process additional prior authorizations received.

The As Introduced version provided that any prior authorization requirements or utilization review measures that ODM applies to opioid analgesic drugs, and any coverage denials made pursuant to them, cannot require treatment failure of non-ADO analgesic drug products in order to access ADO analgesic drugs. The substitute bill specifies that these requirements or measures, and any coverage denials made pursuant to them, cannot be any more restrictive for ADO analgesic products than for opioid analgesic products that are not abuse-deterrent. The substitute bill may provide easier access to ADOs. If so, Medicaid costs related to this provision could increase under the substitute bill.

Health insurers

The substitute bill (LSC 131 0237-11) removes the cost-sharing and reimbursement requirements related to abuse deterrent opioid analgesic drugs that were in the As Introduced version, but requires that insurers provide access to abuse-deterrent opioid analgesic drugs in their formularies or lists of covered drugs. It requires health insurers to apply prior authorization requirements or utilization review measures as conditions of providing coverage of opioid analgesic drug products. The substitute bill specifies that any prior authorization requirements or utilization review measures contained in a policy, contract, or agreement for opioid analgesic drugs, and any coverage denials made related to those requirements or measures, must not (1) be any more restrictive for abuse-deterrent opioid analgesic drug products than for nonabuse deterrent opioid analgesic drugs, or (2) require treatment with an opioid analgesic drug product that is not an abuse-deterrent opioid analgesic drug product in order to access an abuse-deterrent opioid analgesic drug. As a result, the estimated costs to the state and local government health benefit plans would likely be less than the estimated costs under the As Introduced version. Currently, the state plan does not employ prior authorization or utilization review of opioid analgesic drugs, the requirement to do so could potentially lead to savings for the state.

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