

UTILIZATION MANAGEMENT

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House Bill 4358 as introduced
Sponsor: Rep. Abdullah Hammoud
Committee: Health Policy
Complete to 3-10-21

Analysis available at
<http://www.legislature.mi.gov>

SUMMARY:

House Bill 4358 would amend the Insurance Code to prohibit insurers that deliver, issue for delivery, or renew a health insurance policy that provides prescription drug coverage in Michigan ("specified insurers") from taking certain actions regarding that coverage.

Specifically, with the accommodation described below, a specified insurer could not **remove** a covered prescription drug from its list of prescription drugs or add utilization management restrictions to a formulary or **reclassify** a drug to a more restrictive drug tier or move a drug to a higher cost-sharing tier or a tier with a larger deductible, copayment, or coinsurance unless one of the following conditions applied:

- The U.S. Food and Drug Administration (FDA) has done any of the following:
 - Issued a statement that calls into question the clinical safety of the drug.
 - Required the manufacturers to conduct postmarket safety studies and clinical trials after the approval of the drug.
 - Issued any drug safety-related labeling changes.
 - Required the manufacturers to implement special risk management programs.
- The change is based on clinically accepted medical best practices.
- The change is a result of a newly approved drug with clinical advantage over existing drugs.
- A generic equivalent or biosimilar alternative of the drug has received FDA approval.
- The change is intended to reduce preventable drug harm caused by inappropriate use, such as unintentional overdose or inappropriate prescribing.
- The drug has changed from prescription to over-the-counter (OTC).
- The price of the drug has increased by at least 10% over the price in the previous plan year, or by at least 20% over the price in the previous three plan years.
- The insured is notified in writing 90 days before the drug is removed from the formulary. (Notice could be by electronic communication. If the drug is being removed, the notice would have to include a telephone number for the insured to call for information regarding alternative therapeutically equivalent medication options.)
- The insurer uses a pharmacy and therapeutics committee and the committee approves the change.
- The insurer grandfathers insured on the affected drug to maintain coverage with current cost sharing, deductible, copayment, or coinsurance for the remainder of the plan year.

Additionally, a specified insurer could **remove** a covered prescription drug from its list of prescription drugs or add utilization management restrictions to a formulary if any of the following conditions applied:

- The manufacturer of the drug has notified the Secretary of the U.S. Department of Health and Human Services of a manufacturing discontinuance of the drug under the Federal Food, Drug, and Cosmetic Act.
- The drug is being added to the formulary.
- The drug receives a new FDA approval and has become available.

Finally, a specified insurer could **reclassify** a drug to a more restrictive drug tier or move a drug to a higher cost-sharing tier or a tier with a larger deductible, copayment, or coinsurance if the drug receives a new FDA indication.

The bill would provide the following accommodation: during a qualified health plan year, if an insurer **removed** or added restrictions to a drug or **reclassified** or moved the drug to a more expensive tier, as described above, the insurer would have to treat the drug as if the drug had not been removed, restricted, reclassified, or moved.

The bill would not prohibit the addition of prescription drugs to a policy's list of covered drugs during the plan year. It also would not affect or limit a generic or biosimilar substitution. Additionally, it would not prohibit specified insurers from requiring a pharmacist to effect allowed generic substitutions of prescription drugs, which allow a pharmacist to substitute an interchangeable biological drug product for a prescribed biological drug product or to select a generic drug determined to be therapeutically equivalent by the FDA.

The bill's provisions would apply throughout the benefit period, from the beginning to the end of the qualified health plan's deductible year.

If any provision of the bill conflicted with a federal law, the federal law would prevail.

Proposed MCL 500.3406v

BACKGROUND:

The bill is a reintroduction of House Bill 5939 from the 2019-2020 session. It is identical to the H-1 substitute for HB 5939,¹ which was considered by the House Health Policy committee and referred to the House Ways and Means committee in September of 2020.

FISCAL IMPACT:

House Bill 4358 would have an indeterminate fiscal impact on the state and could have an impact on local units of government. Individuals violating provisions under the bill would be afforded an opportunity for a hearing before the director of the Department of Insurance

¹ <http://www.legislature.mi.gov/documents/2019-2020/billanalysis/House/pdf/2019-HLA-5939-102F5CB8.pdf>

and Financial Services. If the director finds that a violation has occurred, the director could order payment of a civil fine as well as suspension, limitation, or revocation of the individual's license or certificate of authority. Civil fine revenue received would be turned over to the state treasurer and credited to the general fund. The director could apply to the Court of Claims for an order of the court enjoining a violation. If this were to happen, local court systems would be impacted and costs would depend on the effect on court caseloads and related administrative costs. There is no practical way to determine the number of violations that will occur under provisions of the bill, so we cannot estimate the amount of costs to the state or to local units.

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■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.