SUMMARY:

House Bill 5939 would add a section to the Insurance Code that would 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, during a qualified health plan year, 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. (However, if a patient’s health care prescriber determines that the drug is medically necessary, the insurer must treat a drug that is removed or moved or for which restrictions are added under the bill as if the drug were not removed or moved or the restrictions were not added.)
- 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 insured is notified in writing 60 days before the drug is removed from the formulary.

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 any of the following conditions applied:

- The drug receives a new FDA indication.
- The insurer uses a pharmacy and therapeutics committee and the committee approves the change.
- The insurer grandfathers insureds on the affected drug to maintain coverage with current cost-sharing, deductible, copayment, or coinsurance for the remainder of the plan year.

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.

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**FISCAL IMPACT:**

House Bill 5939 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 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.