HOUSE BILL NO. 5939

July 21, 2020, Introduced by Reps. Vaupel, Liberati and Tyrone Carter and referred to the Committee on Health Policy.

A bill to amend 1956 PA 218, entitled

"The insurance code of 1956,"

(MCL 500.100 to 500.8302) by adding section 3406v.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 3406v. (1) An insurer that delivers, issues for delivery, or renews in this state a health insurance policy that provides prescription drug coverage shall not do either of the following:

(a) During a qualified health plan year, remove a covered prescription drug from its list of prescription drugs or add utilization management restrictions to a formulary unless any of

the following apply:

(*i*) The United States Food and Drug Administration has done any of the following:

(A) Issued a statement that calls into question the clinical safety of the drug.

(B) Required the manufacturers to conduct postmarket safety studies and clinical trials after the approval of the drug.

(C) Issued any drug safety-related labeling changes.

(D) Required the manufacturers to implement special risk management programs.

(*ii*) The manufacturer of the drug has notified the Secretary of the United States Department of Health and Human Services of a manufacturing discontinuance or potential discontinuance of the drug under 21 USC 356c.

(*iii*) The drug has changed from prescription to over-the-counter.

(*iv*) The change is intended to reduce preventable drug harm caused by inappropriate use, such as unintentional overdose or inappropriate prescribing.

(*v*) 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 shall treat a drug that is removed or for which restrictions are added under this subparagraph as if the drug was not removed or the restrictions were not added.

(*vi*) The change is a result of a newly approved drug with clinical advantage over existing drugs.

(*vii*) The drug is being added to the formulary.

(*viii*) The drug receives a new United States Food and Drug

Administration approval and has become available.

(*ix*) A generic equivalent or biosimilar alternative of the drug has received United States Food and Drug Administration approval.

(*x*) The insurer notifies the insured in writing 60 days before the drug is removed from the formulary.

(b) 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 any of the following apply:

(*i*) The United States Food and Drug Administration has done any of the following:

(A) Issued a statement that calls into question the clinical safety of the drug.

(B) Required the manufacturers to conduct postmarket safety studies and clinical trials after the approval of the drug.

(C) Issued any drug safety-related labeling changes.

(D) Required the manufacturers to implement special risk management programs.

(*ii*) 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 shall treat a drug that is reclassified or moved under this subparagraph as if the drug was not reclassified or moved.

(*iii*) The change is a result of a newly approved drug with clinical advantage over existing drugs.

(*iv*) A generic equivalent or biosimilar alternative of the drug has received United States Food and Drug Administration approval and has become available.

(*v*) The change is intended to reduce preventable drug harm

caused by inappropriate use, such as unintentional overdose or inappropriate prescribing.

(*vi*) The drug has changed from prescription to over-the-counter.

(*vii*) The drug receives a new United States Food and Drug Administration indication.

(*viii*) The insurer uses a pharmacy and therapeutics committee and the committee approves the change.

(*ix*) 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.

(*x*) The insured is notified in writing 60 days before the drug is removed from the formulary.

(2) This section does not prohibit the addition of prescription drugs to a policy's list of covered drugs during the plan year. This section does not impact or limit a generic or biosimilar substitution.

(3) This section does not prohibit an insurer described in subsection (1), by contract, written policy or procedure, or any other agreement or course of conduct, from requiring a pharmacist to effect generic substitutions of prescription drugs consistent with part 177 of the public health code, 1978 PA 368, MCL 333.17701 to 333.17780, under which a pharmacist may do either of the following:

(a) Substitute an interchangeable biological drug product for a prescribed biological drug product.

(b) Select a generic drug determined to be therapeutically equivalent by the United States Food and Drug Administration.

(4) This section applies throughout the benefit period, from

the beginning of the qualified health plan's deductible year until the end of the deductible year.

(5) As used in this section:

(a) "Biological drug product" means that term as defined in section 17702 of the public health code, 1978 PA 368, MCL 333.17702.

(b) "Interchangeable biological drug product" means that term as defined in section 17704 of the public health code, 1978 PA 368, MCL 333.17704.

(c) "Qualified health plan" means that term as defined in section 1261.