HOUSE BILL NO. 5339

November 14, 2023, Introduced by Reps. McFall, Arbit, Price, Morgan, Rheingans, Hope, Hood, Edwards, Weiss, Brixie, Tsernoglou, Aiyash, Hoskins, Brenda Carter and Wegela and referred to the Committee on Insurance and Financial Services.

A bill to amend 1956 PA 218, entitled

"The insurance code of 1956,"

by amending section 3406t (MCL 500.3406t), as added by 2016 PA 38.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 3406t. (1) An insurer that delivers, issues for delivery, or renews in this state ~~an expense-incurred hospital, medical, or surgical group or individual~~ **a health insurance** policy ~~or certificate~~ that provides prescription drug coverage ~~, or a health maintenance organization that offers a group or individual contract that provides prescription drug coverage,~~ shall provide a program for synchronizing multiple maintenance prescription drugs for an

insured or enrollee if both of the following are met:

(a) The insured or enrollee, the insured's or enrollee's physician, and a pharmacist agree that synchronizing the insured's or enrollee's multiple maintenance prescription drugs for the treatment of a chronic long-term care condition is in the best interests of the insured or enrollee for the management or treatment of a chronic long-term care condition.

(b) The insured's or enrollee's multiple maintenance prescription drugs meet all of the following requirements:

(*i*) Are covered by the **health insurance** policy ~~, certificate, or contract~~ described in this section.

(*ii*) Are used for the management and treatment of a chronic long-term care condition and have authorized refills that remain available to the insured or enrollee.

(*iii*) Except as otherwise provided in this subparagraph, are not controlled substances included in schedules 2 to 5 under sections 7214, 7216, 7218, and 7220 of the public health code, 1978 PA 368, MCL 333.7214, 333.7216, 333.7218, and 333.7220. This subparagraph does not apply to anti-epileptic prescription drugs.

(*iv*) Meet all prior authorization requirements specific to the maintenance prescription drugs at the time of the request to synchronize the insured's or enrollee's multiple maintenance prescription drugs.

(*v*) Are of a formulation that can be effectively split over required short fill periods to achieve synchronization.

(*vi*) Do not have quantity limits or dose optimization criteria or requirements that will be violated when synchronizing the insured's or enrollee's multiple maintenance prescription drugs.

(2) An insurer ~~or health maintenance organization~~ described in

subsection (1) shall apply a prorated daily cost-sharing rate for maintenance prescription drugs that are dispensed by an in-network pharmacy for the purpose of synchronizing the insured's or enrollee's multiple maintenance prescription drugs.

(3) An insurer ~~or health maintenance organization~~ described in subsection (1) shall not reimburse or pay any dispensing fee that is prorated. The insurer ~~or health maintenance organization~~ shall only pay or reimburse a dispensing fee that is based on each maintenance prescription drug dispensed.

(4) If an insurer described in subsection (1) or a utilization review organization implements a step therapy protocol, an insurer or utilization review organization shall do both of the following:

(a) Implement protocol via clinical review criteria that are based on clinical practice guidelines to which all of the following apply:

(*i*) The guidelines recommend that the prescription drugs be taken in the specific sequence required by the step therapy protocol.

(*ii*) Subject to subparagraph (*vi*), the guidelines are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups by doing all of the following:

(A) Requiring members to disclose any potential conflict of interests with entities, including insurers, health plans, and pharmaceutical manufacturers and recuse themselves from voting if they have a conflict of interest.

(B) Using a methodologist to work with writing groups to provide objectivity in data analysis and ranking evidence through the preparation of evidence tables and facilitating consensus.

(C) Offering opportunities for public review and comments.

(*iii*) The guidelines are based on high-quality studies, research, and medical practice.

(*iv*) The guidelines are created by an explicit and transparent process that does all of the following:

(A) Minimizes biases and conflicts of interest.

(B) Explains the relationship between treatment options and outcomes.

(C) Rates the quality of the evidence supporting recommendations.

(D) Considers relevant patient subgroups and preferences.

(*v*) The guidelines are continually updated through a review of new evidence, research, and newly developed treatments.

(*vi*) If there are no clinical guidelines that meet the requirements in subparagraph (*ii*), peer-reviewed publications may be substituted.

(b) Take into account the needs of an atypical patient population and diagnosis when establishing clinical review criteria.

(5) An insurer described in subsection (1) or utilization review organization shall do both of the following:

(a) On written request, provide in writing all specific clinical review criteria relating to the particular condition or disease including clinical review criteria relating to a step therapy protocol override determination.

(b) Make available the clinical review criteria and other clinical information on its internet site and to a health care professional on behalf of an insured on written request.

(6) Subsection (4) does not require an insurer to set up a new

entity to develop clinical review criteria for step therapy protocols.

(7) If coverage of a prescription drug for the treatment of a medical condition is restricted for use by an insurer described in subsection (1) or utilization review organization through the use of a step therapy protocol, the insurer or utilization review organization shall provide the prescribing health care provider access to a clear, easily accessible, and convenient process to request a step therapy exception on behalf of a covered individual. An insurer or utilization review organization may use its existing medical exceptions process to satisfy this requirement. The process must be made easily accessible on the insurer's or utilization review organization's website. An insurer or utilization review organization must disclose all rules and criteria related to the step therapy protocol on request to all prescribing practitioners, including the specific information and documentation that must be submitted by a prescribing practitioner or patient to be considered a complete exception request.

(8) A step therapy exception must be expeditiously granted if any of the following conditions are met:

(a) The required prescription drug is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the patient.

(b) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen.

(c) The patient has tried the required prescription drug while under the patient's current or a previous health insurance or

health benefit plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and the prescription drug was discontinued because of lack of efficacy or effectiveness, diminished effect, or an adverse event.

(d) The required prescription drug is not in the best interest of the patient, based on medical necessity.

(e) The patient is stable on a prescription drug selected by the patient's health care provider for the medical condition under consideration while on a current or previous health benefit plan.

(9) On the granting of a step therapy exception under subsection (8), the insurer described in subsection (1) or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient's treating health care provider.

(10) The insurer or utilization review organization shall grant or deny a step therapy exception request or an appeal within 72 hours after receipt. If exigent circumstances exist, an insurer or utilization review organization must grant or deny a step therapy exception request or an appeal within 24 hours after receipt. If a request for a step therapy override exception is incomplete or additional clinically relevant information is required, the insurer or utilization review organization shall notify the prescribing practitioner within 72 hours after submission, or 24 hours in exigent circumstances, what additional or clinically relevant information is required to approve or deny the step therapy exception request or appeal in accordance with the criteria disclosed in subsection (4). Once the requested information is submitted, the applicable time period to grant or deny a step therapy exception request or appeal applies. If a

determination or request for incomplete or clinically relevant information by an insurer or utilization review organization is not received by the prescribing practitioner within the time allotted, the exception or appeal is considered granted. In the event of a denial, the insurer or utilization review organization must inform the patient of a potential appeal process.

(11) This section does not prevent any of the following:

(a) An insurer described in subsection (1) or utilization review organization from requiring a patient to try an AB-rated generic equivalent or interchangeable biological product, unless the requirement meets any of the conditions under subsection (8) in accordance with a step therapy exception request submitted under subsection (7), before providing coverage for the equivalent branded prescription drug.

(b) An insurer or utilization review organization from requiring a pharmacist to effect substitutions of prescription drugs consistently with section 17755 of the public health code, 1978 PA 368, MCL 333.17755.

(c) A health care provider from prescribing a prescription drug that is determined to be medically appropriate.

(12) Annually, an insurer described in subsection (1) or utilization review organization shall report to the director, in a format prescribed by the director, all of the following information:

(a) The number of step therapy exception requests received by exception as provided under subsection (8).

(b) The type of health care providers or the medical specialties of the health care providers submitting step therapy exception requests.

(c) The number of step therapy exception requests by exception, as provided under subsection (8), that were denied and the reasons for the denials.

(d) The number of step therapy exception requests by exception, as provided under subsection (8), that were approved.

(e) The number of step therapy exception requests by exception, as provided under subsection (8), that were initially denied and then appealed.

(f) The number of step therapy exception requests by exception, as provided under subsection (8), that were initially denied and then subsequently reversed by internal appeals or external reviews.

(g) The medical conditions for which patients are granted exceptions because of the likelihood that switching from the prescription drug will likely cause an adverse reaction by or physical or mental harm to the insured.

(13) As used in this section:

(a) "Clinical practice guidelines" means a systematically developed statement to assist decision making by health care providers and patient decisions about appropriate health care for specific clinical circumstances and conditions.

(b) "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols, and practice guidelines used by an insurer or utilization review organization to determine the medical necessity and appropriateness of health care services.

(c) "Medical necessity" means that health services or supplies are, under the applicable standard of care, any of the following:

(*i*) Appropriate to improve or preserve health, life, or

function.

(*ii*) Appropriate to slow the deterioration of health, life, or function.

(*iii*) Appropriate for the early screening, prevention, evaluation, diagnosis, or treatment of a disease, condition, illness, or injury.

(d) "Step therapy protocol" means a protocol, policy, or program that establishes the specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular patient are covered by an insurer or health plan.

(e) "Step therapy exception" means an overriding step therapy protocol in favor of immediate coverage of the health care provider's selected prescription drug.

(f) "Utilization review organization" means an entity that conducts utilization review, other than an insurer or health plan performing utilization review for its own health benefit plans.