SUBSTITUTE FOR

SENATE BILL NO. 612

A bill to amend 1956 PA 218, entitled

"The insurance code of 1956,"

by amending sections 2212c and 3406t (MCL 500.2212c and 500.3406t), section 2212c as added by 2013 PA 30 and section 3406t as added by 2016 PA 38, and by adding section 2212e.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 2212c. (1) ~~On or before~~ **By** January 1, 2015, the workgroup shall develop a standard prior authorization methodology for use by prescribers to request and receive prior authorization from an insurer ~~when~~ **if** a **health insurance** policy ~~, certificate, or contract~~ requires prior authorization for prescription drug benefits. The workgroup shall include in the standard prior authorization methodology the ability for the prescriber to

designate the prior authorization request for expedited review. ~~In order to designate a prior authorization request for expedited review, the prescriber shall certify that applying the 15-day standard review period may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.~~

(2) A prescription drug prior authorization workgroup is created. ~~Within 30 days after the effective date of this section, the~~ **The** department of ~~community~~ health **and human services** and the department ~~of insurance and financial services~~ shall work together and appoint members to the workgroup. The workgroup must consist of a member who represents the department of ~~community~~ health **and human services**, a member who represents the department, ~~of insurance and financial services,~~ and members who represent insurers, prescribers, pharmacists, hospitals, and other stakeholders as determined necessary by the department of ~~community~~ health **and human services** and the department. ~~of insurance and financial services.~~ The workgroup shall appoint a chairperson from among its members. The chairperson of the workgroup shall schedule workgroup meetings. The department of ~~community~~ health **and human services** and the department ~~of insurance and financial services~~ shall organize the initial meeting of the workgroup and shall provide administrative support for the workgroup.

(3) In developing the standard prior authorization methodology under subsection (1), the workgroup shall consider all of the following:

(a) Existing and potential technologies that could be used to transmit a standard prior authorization request.

(b) The national standards pertaining to electronic prior authorization developed by the ~~national council for prescription~~

~~drug programs.~~**National Council for Prescription Drug Programs.**

(c) Any prior authorization forms and methodologies used in pilot programs in this state.

(d) Any prior authorization forms and methodologies developed by the federal ~~centers for medicare and medicaid services.~~**Centers for Medicare and Medicaid Services.**

(4) Beginning ~~on the effective date of this section,~~ **March 14, 2014,** an insurer may specify in writing the materials and information necessary to constitute a properly completed standard prior authorization request ~~when~~ **if** a **health insurance** policy ~~, certificate, or contract~~ requires prior authorization for prescription drug benefits.

(5) If the workgroup develops a paper form as the standard prior authorization methodology under subsection (1), the paper form ~~shall~~ **must** meet all of the following requirements:

(a) Consist of not more than 2 pages. However, an insurer may request and require additional information beyond the 2-page limitation of this subdivision, if that information is specified in writing by the insurer under subsection (4). As used in this subdivision, "additional information" includes, but is not limited to, any of the following:

(*i*) Patient clinical information including, but not limited to, diagnosis, chart notes, lab information, and genetic tests.

(*ii*) Information necessary for approval of the prior authorization request under plan criteria.

(*iii*) Drug specific information including, but not limited to, medication history, duration of therapy, and treatment use.

(b) Be electronically available.

(c) Be electronically transmissible, including, but not

limited to, transmission by facsimile or similar device.

(6) Beginning July 1, 2016, if an insurer uses a prior authorization methodology that utilizes an internet webpage, internet webpage portal, or similar electronic, internet, and web-based system, the prior authorization methodology described in subsection (5) does not apply. ~~Subsections~~ **Subsection** (4) ~~, (8), and (9) apply~~ **and section 2212e apply** to a prior authorization methodology that utilizes an internet webpage, internet webpage portal, or similar electronic, internet, and web-based system.

(7) Beginning July 1, 2016, except as otherwise provided in subsection (6), an insurer shall use the standard prior authorization methodology developed under subsection (1) ~~when~~ **if** a **health insurance** policy ~~, certificate, or contract~~ requires prior authorization for prescription drug benefits.

~~(8) Beginning January 1, 2016, a prior authorization request that has not been certified for expedited review by the prescriber is considered to have been granted by the insurer if the insurer fails to grant the request, deny the request, or require additional information of the prescriber within 15 days after the date and time of submission of a standard prior authorization request under this section. If additional information is requested by an insurer, a prior authorization request under this subsection is not considered granted if the prescriber fails to submit the additional information within 15 days after the date and time of the original submission of a properly completed standard prior authorization request under this section. If additional information is requested by an insurer, a prior authorization request is considered to have been granted by the insurer if the insurer fails to grant the request, deny the request, or otherwise respond to the request of~~

~~the prescriber within 15 days after the date and time of submission of the additional information. If additional information is requested by an insurer, a prior authorization request under this subsection is considered void if the prescriber fails to submit the additional information within 21 days after the date and time of the original submission of a properly completed standard prior authorization request under this section.~~

~~(9) Beginning January 1, 2016, a prior authorization request that has been certified for expedited review by the prescriber is considered to have been granted by the insurer if the insurer fails to grant the request, deny the request, or require additional information of the prescriber within 72 hours after the date and time of submission of a standard prior authorization request under this section. If additional information is requested by an insurer, a prior authorization request under this subsection is not considered granted if the prescriber fails to submit the additional information within 72 hours after the date and time of the original submission of a properly completed standard prior authorization request under this section. If additional information is requested by an insurer, a prior authorization request is considered to have been granted by the insurer if the insurer fails to grant the request, deny the request, or otherwise respond to the request of the prescriber within 72 hours after the date and time of submission of the additional information. If additional information is requested by an insurer, a prior authorization request under this subsection is considered void if the prescriber fails to submit the additional information within 5 days after the date and time of the original submission of a properly completed standard prior authorization request under this section.~~

(8) ~~(10)~~ As used in this section:

(a) "Insurer" means any of the following:

(*i*) An insurer issuing an expense-incurred hospital, medical, or surgical policy or certificate.

(*ii*) A health maintenance organization.

(*iii*) A health care corporation operating pursuant to the nonprofit health care corporation reform act, 1980 PA 350, MCL 550.1101 to 550.1704.

(*iv*) A third party administrator of prescription drug benefits.

(b) "Prescriber" means that term as defined in section 17708 of the public health code, 1978 PA 368, MCL 333.17708.

(c) "Prescription drug" means that term as defined in section 17708 of the public health code, 1978 PA 368, MCL 333.17708.

(d) "Prescription drug benefit" means the right to have a payment made by an insurer pursuant to prescription drug coverage contained within a policy, certificate, or contract delivered, issued for delivery, or renewed in this state.

(e) "Workgroup" means the prescription drug prior authorization workgroup created under subsection (2).

Sec. 2212e. (1) For an insurer that delivers, issues for delivery, or renews in this state a health insurance policy, if the health insurance policy requires a prior authorization with respect to any benefit, the insurer or its designee utilization review organization shall, by April 1, 2021, make available a standardized electronic prior authorization request transaction process utilizing an internet webpage, internet webpage portal, or similar electronic, internet, and web-based system. Beginning April 1, 2021, an insurer described in this subsection or its designee utilization review organization shall transact a prior

authorization request utilizing only a standard electronic prior authorization transaction process unless the health professional is not able to use the standard electronic prior authorization transaction process because of a temporary technological or electrical failure. The current prior authorization requirements must be described in detail, written in easily understandable language, and readily available to the health provider at the point of care. The prior authorization requirements must be based on peer-reviewed clinical review criteria. All of the following apply to clinical review criteria under this subsection:

(a) The clinical review criteria must be criteria developed by either of the following:

(*i*) An entity to which both of the following apply:

(A) The entity works directly with clinicians, either within the organization or outside the organization, to develop the clinical review criteria.

(B) The entity does not have a financial stake in the outcome of the clinical care decisions made using the criteria.

(*ii*) A professional medical specialty society.

(b) The clinical review criteria must take into account the needs of atypical patient populations and diagnoses.

(c) The clinical review criteria must ensure quality of care and access to needed health care services.

(d) The clinical review criteria must be evidence-based criteria.

(e) The clinical review criteria must be publicly available free of charge.

(f) The clinical review criteria must be sufficiently flexible to allow deviations from norms when justified on a case-by-case

basis.

(g) The clinical review criteria must be evaluated and updated, if necessary, at least annually.

(h) Before establishing, or substantially or materially altering, its own written clinical review criteria, an insurer or designee utilization review organization must obtain input from actively practicing physicians representing major areas of the specialty. The insurer or designee utilization review organization shall seek input from physicians who are not employees of the insurer or designee utilization review organization or consultants to the insurer or designee utilization review organization. If criteria are developed for a health care service provided by a health professional not licensed to engage in the practice of medicine under part 170 of the public health code, 1978 PA 368, MCL 333.17001 to 333.17097, or osteopathic medicine and surgery under part 175 of the public health code, 1978 PA 368, MCL 333.17501 to 333.17556, an insurer or designee utilization review organization must also seek input from a health professional in the same profession as the health professional providing the health care service. This subdivision does not apply to subdivision (a).

(2) At least annually, an insurer described in subsection (1) shall make statistics regarding prior authorization conspicuously posted and available on the insurer's public website in a readily accessible format. The categories must include all of the following information:

(a) A list of all benefits that are subject to a prior authorization requirement under the plan.

(b) The percentage of prior authorization requests approved during the previous plan year by the insurer with respect to each

benefit described in subdivision (a).

(c) The percentage of prior authorization requests denied during the previous plan year by the insurer with respect to each benefit described in subdivision (a) and the top 10 reasons for denial, which must include related evidence-based criteria, if applicable.

(d) The percentage of requests described in subdivision (c) that were appealed, and the percentage of the appealed requests that were overturned, with respect to the benefit.

(3) An insurer described in subsection (1) or its designee utilization review organization shall ensure that any adverse determination is made by a physician licensed to engage in the practice of medicine under part 170 of the public health code, 1978 PA 368, MCL 333.17001 to 333.17097, or the practice of osteopathic medicine and surgery under part 175 of the public health code, 1978 PA 368, MCL 333.17501 to 333.17556. For a health care service provided by a health professional not licensed to engage in the practice of medicine under part 170 of the public health code, 1978 PA 368, MCL 333.17001 to 333.17097, or osteopathic medicine and surgery under part 175 of the public health code, 1978 PA 368, MCL 333.17501 to 333.17556, the physician may consider input from a health professional who is in the same profession as the health professional providing the health care service. The physician shall make the adverse determination under the clinical direction of 1 of the insurer's medical directors who is responsible for the provision of health care items and services provided to insureds or enrollees. Medical directors under this subsection must be licensed to engage in the practice of medicine under part 170 of the public health code, 1978 PA 368, MCL 333.17001 to 333.17097, or the

practice of osteopathic medicine and surgery under part 175 of the public health code, 1978 PA 368, MCL 333.17501 to 333.17556. As used in this subsection, "adverse determination" means that term as defined in section 2213.

(4) If an insurer described in subsection (1) implements a new prior authorization requirement or restriction, or amends an existing requirement or restriction, the insurer shall ensure that the new or amended requirement or restriction is posted on the insurer's public website before its implementation. An insurer shall notify contracted health care providers via the insurer's provider portal of the new or amended requirement or restriction not less than 60 days before the requirement or restriction is implemented.

(5) If an insurer described in subsection (1) denies a prior authorization, the insurer or its designee utilization review organization shall, on issuing the denial, notify the health professional and insured or enrollee of the reasons for the denial and related evidence-based criteria. An appeal of the denial under this subsection must be reviewed by a physician to which all of the following apply:

(a) The physician is licensed to engage in the practice of medicine under part 170 of the public health code, 1978 PA 368, MCL 333.17001 to 333.17097, or the practice of osteopathic medicine and surgery under part 175 of the public health code, 1978 PA 368, MCL 333.17501 to 333.17556, or is licensed in another state.

(b) The physician is board certified or eligible in the same specialty as a health care provider who typically manages the medical condition or disease or provides the health care service.

(c) The physician is knowledgeable of, and has experience

providing, the health care services under appeal.

(d) The physician does not have any financial interest in the outcome of the appeal.

(e) The physician has not been involved in making the adverse determination.

(f) The physician considers all known clinical aspects of the health care services under review, including, but not limited to, a review of all pertinent medical records provided to the insurer or designee utilization review organization by the insured or enrollee's health care provider and any relevant records provided to the insurer or designee utilization review organization by a health care facility.

(g) The physician may consider input from a health professional who is licensed in the same profession as the health professional providing the health care service.

(6) A prior authorization request that has not been certified as urgent by the health care provider is considered to have been granted by the insurer or its designee utilization review organization if the insurer fails to grant the request, deny the request, or require additional information of the health care provider within 2 business days after the time of the submission. If additional information is requested by an insurer or its designee utilization review organization, a prior authorization request under this subsection is not considered granted if the health care provider fails to submit the additional information within 2 business days after the time of the original submission of a prior authorization request under this section. If all additional clinical information is requested and received by an insurer or its designee utilization review organization, a prior authorization

request is considered to have been granted by the insurer if the insurer fails to grant the request, deny the request, or otherwise respond to the request of the health care provider within 2 business days after the time of the submission of additional information not to exceed 7 calendar days after the receipt of the original request.

(7) A prior authorization request that has been certified as urgent by the health care provider is considered to have been granted by the insurer or its designee utilization review organization if the insurer fails to grant the request, deny the request, or require additional information of the health care provider within 1 business day after the time of the submission. If all additional clinical information is requested and received by an insurer or its designee utilization review organization, a prior authorization request is considered to have been granted by the insurer if the insurer fails to grant the request, deny the request, or otherwise respond to the request of the health care provider within 1 business day after the time of submission of additional information.

(8) A prior authorization request granted under this section is valid for not less than 60 calendar days and not more than 1 year depending on the clinical conditions of the care needed.

(9) As used in this section:

(a) "Evidence-based criteria" means criteria developed using evidence-based standards.

(b) "Evidence-based standard" means that term as defined in section 3 of the patient's right to independent review act, 2000 PA 251, MCL 550.1903.

(c) "Health care provider" means any of the following:

(*i*) A health facility as that term is defined in section 2006.

(*ii*) A health professional.

(d) "Health professional" means that term as defined in section 2006.

(e) "Prior authorization" means a determination by an insurer or utilization review organization that a requested health care benefit has been reviewed and, based on the information provided, satisfies the insurer or utilization review organization requirements for medical necessity and appropriateness and that payment will be made for that health care benefit.

(f) "Standardized electronic prior authorization transaction process" means a standardized transmission process, identified by the director and aligned with standards that are nationally accepted, to enable prior authorization requests to be accessible, submitted by health care providers, and accepted by insurers or their designee utilization review organizations electronically through secure electronic transmissions with the goal of maximizing administrative simplification, efficiency, and timeliness. Standard electronic prior authorization transaction process does not include a facsimile.

(g) "Urgent" means an insured or enrollee is suffering from a health condition that may seriously jeopardize the insured's life, health, or ability to regain maximum function or could subject the insured or enrollee to severe adverse health consequences that cannot be adequately managed without the care or treatment that is the subject of the prior authorization.

(h) "Utilization review organization" means that term as defined in section 3 of the patient's right to independent review act, 2000 PA 251, MCL 550.1903.

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) An insurer described in subsection (1) shall not do any of the following:

(a) Require the insured's or enrollee's physician to participate in a step therapy protocol if the physician considers that the step therapy protocol is not in the insured's or enrollee's best interest, including, but not limited to, any of the following:

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

(*ii*) The required prescription drug is not approved by the United States Food and Drug Administration.

(*iii*) 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.

(*iv*) 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 due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(*v*) 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 insurance or health benefit plan.

(b) Require the insured's or enrollee's physician to obtain a waiver, exception, or other override before the physician makes a determination under subdivision (a).

(c) Sanction the insured's or enrollee's physician for recommending or issuing a prescription, performing or recommending a procedure, or performing a test that may conflict with the insurer's step therapy protocol.

(5) An insurer described in subsection (1) shall adopt a transparent program, developed in consultation with health care providers participating with that insurer, that promotes the modification of prior authorization requirements based on the performance of the health care providers with respect to adherence to evidence-based medical guidelines and other quality criteria.

(6) As used in this section:

(a) "Health care provider" means that term as defined in section 2212e.

(b) "Prior authorization" means a determination by an insurer or utilization review organization that a requested health care benefit has been reviewed and, based on the information provided, satisfies the insurer or utilization review organization requirements for medical necessity and appropriateness and that payment will be made for that health care benefit. As used in this subdivision, "utilization review organization" means that term as defined in section 3 of the patient's right to independent review act, 2000 PA 251, MCL 550.1903.

(c) "Step therapy protocol" means a protocol or program of an insurer described in subsection (1) that establishes the specific sequence in which prescription drugs for a medical condition are medically appropriate.