SUBSTITUTE FOR

SENATE BILL NO. 247

A bill to amend 1956 PA 218, entitled

"The insurance code of 1956,"

by amending section 2212c (MCL 500.2212c), as added by 2013 PA 30, 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 a policy, certificate, or contract~~ **if a health benefit plan** 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~~ **5 business day** 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 a policy, certificate, or contract~~ **if a health benefit plan** 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 a policy, certificate, or contract~~ **if a health benefit plan** 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) "Health benefit plan" means that term as defined in section 2212e.

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

(*i*) An insurer issuing ~~an expense-incurred hospital, medical, or surgical policy or certificate.~~**or administering a health benefit plan.**

(*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.

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

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

(e) ~~(d)~~ "Prescription drug benefit" means the right to have a payment made by an insurer ~~pursuant to prescription drug~~ **for a prescription drug listed on the applicable formulary in accordance with** coverage contained within a ~~policy, certificate, or contract~~ **health benefit plan** delivered, issued for delivery, or renewed in this state.

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

Sec. 2212e. (1) For an insurer that delivers, issues for delivery, renews, or administers a health benefit plan in this state, if the health benefit plan requires a prior authorization with respect to any benefit, the insurer or its designee utilization review organization shall, by January 1, 2023, 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 January 1, 2023, an insurer described in this subsection or its designee utilization review organization and the health professional shall perform a prior authorization utilizing only a standard electronic prior authorization transaction process, which allows the transmission of clinical information, 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 and written in easily understandable language. An insurer described in this subsection or its designee utilization review organization shall make any current prior authorization requirements and restrictions, including the written clinical review criteria, readily accessible and conspicuously posted on its website to insureds, enrollees, health care professionals, and health care providers. Content published by a third party and licensed for use by an insurer described in this subsection or its designee utilization review organization may be made available through the insurer or its designee utilization review organization's secure, password-protected website if the access requirements of the website do not unreasonably restrict access to the content. 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) Unless the criteria are developed as described in subdivision (g), 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 receive direct payments based on the outcome of the clinical care decision.

(*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 sufficiently flexible to allow deviations from norms when justified on a case-by-case basis.

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

(g) For coverage other than prescription drug benefit coverage, before establishing, or substantially or materially altering, its own written clinical review criteria, an insurer or its designee utilization review organization must obtain input from actively practicing licensed physicians representing major areas of the specialty. For coverage of a prescription drug benefit, before establishing, or substantially or materially altering, its own clinical review criteria, an insurer or its designee utilization review organization must obtain input from actively practicing licensed pharmacists or actively practicing licensed physicians. 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.

(2) An insurer described in subsection (1) shall make available on the insurer's public website in a readily accessible format a list of all benefits that are subject to a prior authorization under the health benefit plan.

(3) If an insurer described in subsection (1) implements a new prior authorization requirement or restriction, or amends an existing requirement or restriction, with respect to any benefit under a health benefit plan, the insurer shall ensure that the new or amended requirement or restriction is posted on the insurer's public website before its implementation. For a benefit that does not involve coverage of a prescription drug, 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. For coverage of a prescription drug, an insurer shall make available on the insurer's public website or notify contracted health care providers via the insurer's provider portal of the new or amended requirement or restriction not less than 45 days before the requirement or restriction is implemented unless any of the following apply:

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

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

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

(*iii*) Issued any drug safety-related labeling changes.

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

(b) The drug receives a new United States Food and Drug Administration approval and has become available.

(c) The United States Food and Drug Administration has approved expanded use of the drug.

(4) The initial review of information submitted in support of a request for prior authorization may be conducted and approved by a health professional.

(5) For an adverse determination regarding a request for prior authorization for a benefit other than a prescription drug, the adverse determination must be made by a licensed physician. For an adverse determination of a health care service provided by a health professional that is not a licensed physician, a licensed physician may consider input from a health professional who is in the same profession as the health professional providing the health care service. The licensed physician shall make the adverse determination under this subsection under the general direction of the insurer's medical director who oversees the utilization management program. 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.

(6) For an adverse determination regarding a request for prior authorization for a prescription drug, the adverse determination must be made by a licensed pharmacist or licensed physician. The licensed pharmacist or licensed physician shall make the adverse determination under this subsection under the general direction of the insurer's medical director who oversees the utilization management program. 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.

(7) If an insurer described in subsection (1) denies a prior authorization, the insurer or its designee utilization review organization shall, on issuing a benefit denial, notify the health professional and insured or enrollee of all of the following:

(a) The reasons for the denial and related evidence-based criteria.

(b) The right to appeal the adverse determination.

(c) Instructions on how to file the appeal.

(d) Additional documentation necessary to support the appeal.

(8) Subject to subsection (9) an appeal of the denial under subsection (7) must be reviewed by a health professional to which all of the following apply:

(a) The health professional does not have a direct financial stake in the outcome of the appeal.

(b) The health professional has not been involved in making the adverse determination.

(c) The health professional 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.

(d) The health professional may consider input from a health professional who is licensed in the same profession as the health professional providing the health care service or a licensed pharmacist if the adverse decision is regarding a prescription drug.

(9) An insurer or its designee utilization review organization shall not affirm the denial of an appeal under subsection (8) unless the appeal is reviewed by a licensed physician who 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. However, if an insurer or its designee utilization review organization cannot identify a licensed physician who meets the requirements described in this subsection without exceeding the applicable time limits imposed under subsection (10), the insurer or its designee utilization review organization may utilize a licensed physician in a similar specialty as considered appropriate, as determined by the insurer or its designee utilization review organization.

(10) Beginning January 1, 2023 through December 31, 2023, a prior authorization request under this section that has not been certified as urgent by the health care provider is considered granted by the insurer or its designee utilization review

organization if the insurer or its designee utilization review organization fails to grant the request, deny the request, or require additional information of the health care provider within 9 calendar days after the date and time of submission of the prior authorization. After December 31, 2023, a prior authorization request under this section that has not been certified as urgent by the health care provider is considered granted by the insurer or its designee utilization review organization if the insurer or its designee utilization review organization fails to grant the request, deny the request, or require additional information of the health care provider within 7 calendar days after the date and time of submission of the prior authorization. Beginning January 1, 2023 through December 31, 2023, if additional information is requested by an insurer or its designee utilization review organization, the prior authorization request is considered to have been granted by the insurer or its designee utilization review organization if the insurer or its designee utilization review organization fails to grant the request, deny the request, or otherwise respond to the request of the health care provider within 9 calendar days after the date and time of the submission of additional information. After December 31, 2023, if additional information is requested by an insurer or its designee utilization review organization, the prior authorization request is considered to have been granted by the insurer or its designee utilization review organization if the insurer or its designee utilization review organization fails to grant the request, deny the request, or otherwise respond to the request of the health care provider within 7 calendar days after the date and time of the submission of additional information.

(11) Beginning January 1, 2023, a prior authorization request

under this section that has been certified as urgent by the health care provider is considered granted by the insurer or its designee utilization review organization if the insurer or its designee utilization review organization fails to grant the request, deny the request, or require additional information of the health care provider within 72 hours after the date and time of submission of the prior authorization request. If additional information is requested by an insurer or its designee utilization review organization, the prior authorization request is considered to have been granted by the insurer or its designee utilization review organization if the insurer or its designee utilization review organization fails to grant the request, deny the request, or otherwise respond to the request of the health care provider within 72 hours after the date and time of the submission of additional information.

(12) A prior authorization request granted under this section is valid for not less than 60 calendar days or for a duration that is clinically appropriate, whichever is later.

(13) By June 1, 2022, and each June 1 after that date, an insurer shall report to the department the following aggregated trend data related to the insurer's prior authorization practices and experience for the prior plan year:

(a) The number of prior authorization requests.

(b) The number of prior authorization requests denied.

(c) The number of appeals received.

(d) The number of adverse determinations reversed on appeal.

(e) Of the total number of prior authorization requests, the number of prior authorization requests that were not submitted electronically.

(f) The top 10 services that were denied.

(g) The top 10 reasons prior authorization requests were denied.

(14) By October 1, 2022, and each October 1 after that date, the department shall aggregate and deidentify the data collected under subsection (13) into a standard report and shall not identify the name of the insurer that submitted the data. The report must be written in easily understandable language and posted on the department's public internet website.

(15) All of the following apply to any data, documents, materials, or other information described in subsection (13) that has not been aggregated, deidentified, and otherwise compiled into the standard report described in subsection (14):

(a) The data, documents, materials, or other information is considered proprietary and to contain trade secrets.

(b) The data, documents, materials, or other information is confidential and privileged and is not subject to disclosure under the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246.

(16) An insurer described in subsection (1) shall adopt a program, developed in consultation with health care providers participating with the insurer, that promotes the modification of prior authorization requirements of certain prescription drugs, medical care, or related benefits, based on any of the following:

(a) The performance of health care providers with respect to adherence to nationally recognized evidence-based medical guidelines, appropriateness, efficiency, and other quality criteria.

(b) Involvement of contracted health care providers with an insurer described in subsection (1) to participate in a financial

risk-sharing payment plan, that includes downside risk.

(c) Health provider specialty, experience, or other factors.

(17) As used in this section:

(a) "Adverse determination" means that term as defined in section 2213.

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

(c) "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.

(d) "Health benefit plan" means an individual or group health insurance policy, an individual or group health maintenance organization contract, or a self-funded plan established or maintained by this state or a local unit of government for its employees. Health benefit plan includes prescription drug benefits.

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

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

(*ii*) A health professional.

(f) "Health professional" means an individual licensed, registered, or otherwise authorized to engage in a health profession under article 15 of the public health code, 1978 PA 368, MCL 333.16101 to 333.18838, or under the laws of another state to engage in a health profession.

(g) "Insurer" means that term as defined in section 2212c.

(h) "Licensed pharmacist" means either of the following:

(*i*) A pharmacist licensed to engage in the practice of pharmacy under part 177 of the public health code, 1978 PA 368, MCL 333.17701 to 333.17780.

(*ii*) A pharmacist licensed in another state.

(i) "Licensed physician" means any of the following:

(*i*) 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.

(*ii*) A physician licensed to engage in the practice of osteopathic medicine and surgery under part 175 of the public health code, 1978 PA 368, MCL 333.17501 to 333.17556.

(*iii*) A physician licensed in another state.

(j) "Peer-reviewed" means the clinical review criteria that is approved by a committee comprised of clinicians, including licensed physicians or licensed pharmacists, or both, that meets at regularly-scheduled intervals and evaluates, among other things, pharmaceutical literature or medical literature, or both, and scientific evidence to develop criteria that promotes appropriate, safe, and cost-effective drug utilization.

(k) "Prescription drug" means that term as defined in section 2212c.

(*l*) "Prescription drug benefit" means that term as defined in section 2212c.

(m) "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.

(n) "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. The process must allow health care providers to supply clinical information under the standardized electronic prior authorization process. Standard electronic prior authorization transaction process does not include a facsimile.

(o) "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.

(p) "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.