SUBSTITUTE FOR

SENATE BILL NO. 612

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 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, 2022, 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, 2022, 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 includes 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. 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 (h), 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 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) 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 review organization must obtain input from actively practicing licensed pharmacists. 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) Except as otherwise provided in subsection (4), an insurer described in subsection (1) or its designee utilization review organization shall ensure that an adverse determination, other than an adverse determination of prescription drug coverage, is 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, the 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 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.

(4) An insurer described in subsection (1) or its designee utilization review organization shall ensure that an adverse determination of a prescription drug benefit is made by a licensed pharmacist 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.

(5) 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. For a medical benefit that is not a prescription drug benefit, 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 a prescription drug benefit, 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 30 days before the requirement or restriction is implemented.

(6) If an insurer described in subsection (1) denies a prior authorization, the insurer or its designee utilization review organization shall, on issuing a medical benefit denial, notify the health professional and insured or enrollee of the reasons for the denial and related evidence-based criteria. Subject to subsection (7), an appeal of the denial under this subsection must be reviewed by a licensed health professional to which all of the following apply:

(a) The licensed health professional is knowledgeable of, and has the same or similar experience providing, the health care services under appeal.

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

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

(d) The licensed 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.

(7) An insurer or its designee review organization shall not affirm the denial of an appeal under subsection (5) unless the appeal is reviewed by a licensed physician.

(8) 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 5 business days after the date and time of submission of the prior authorization. If additional information is requested by an insurer or its designee utilization review organization, the prior authorization request is not considered granted if the health care provider fails to submit the additional information within 2 business days after the date and time of the request for additional information. 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 5 days after the date and time of the submission of additional information.

(9) 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 2 business days 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 not considered granted if the health care provider fails to submit the additional information within 1 business day after the date and time after the request for additional information. 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 2 days after the date and time of the submission of additional information.

(10) A prior authorization request granted under this section is valid for not less than 60 calendar days.

(11) 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 that term as defined in section 2006.

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

(h) "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.

(i) "Peer-reviewed" means the clinical review criteria that is approved by a committee comprised of clinicians, including licensed physicians or 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.

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

(k) "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.

(*l*) "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 require 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.

(m) "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.

(n) "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.