## 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 1 2 shall develop a standard prior authorization methodology for use by prescribers to request and receive prior authorization from an 3 insurer when a policy, certificate, or contract if a health benefit 4 plan requires prior authorization for prescription drug benefits. 5 6 The workgroup shall include in the standard prior authorization methodology the ability for the prescriber to designate the prior 7 authorization request for expedited review. In order to designate a 8





S01865'19 (S-3)

1 prior authorization request for expedited review, the prescriber 2 shall certify that applying the 15-day standard 5 business day 3 review period may seriously jeopardize the life or health of the 4 patient or the patient's ability to regain maximum function.

(2) A prescription drug prior authorization workgroup is 5 6 created. Within 30 days after the effective date of this section, 7 the The department of community health and human services and the 8 department of insurance and financial services shall work together 9 and appoint members to the workgroup. The workgroup must consist of 10 a member who represents the department of community health and 11 human services, a member who represents the department, of 12 insurance and financial services, and members who represent 13 insurers, prescribers, pharmacists, hospitals, and other 14 stakeholders as determined necessary by the department of community 15 health and human services and the department. of insurance and 16 financial services. The workgroup shall appoint a chairperson from 17 among its members. The chairperson of the workgroup shall schedule 18 workgroup meetings. The department of community health and human services and the department of insurance and financial services 19 20 shall organize the initial meeting of the workgroup and shall provide administrative support for the workgroup. 21

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

25 (a) Existing and potential technologies that could be used to26 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.



S01865'19 (S-3)

s 07627 12162020

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

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

6 (4) Beginning on the effective date of this section, March 14,
7 2014, an insurer may specify in writing the materials and
8 information necessary to constitute a properly completed standard
9 prior authorization request when a policy, certificate, or contract
10 if a health benefit plan requires prior authorization for
11 prescription drug benefits.

12 (5) If the workgroup develops a paper form as the standard 13 prior authorization methodology under subsection (1), the paper 14 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.

23 (ii) Information necessary for approval of the prior24 authorization request under plan criteria.

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

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(b) Be electronically available.

28 (c) Be electronically transmissible, including, but not29 limited to, transmission by facsimile or similar device.



S01865'19 (S-3)

s 07627 12162020

(6) Beginning July 1, 2016, if an insurer uses a prior 1 2 authorization methodology that utilizes an internet webpage, internet webpage portal, or similar electronic, internet, and web-3 based system, the prior authorization methodology described in 4 5 subsection (5) does not apply. Subsections Subsection (4)  $\tau$  (8), 6 and (9) apply and section 2212e apply to a prior authorization 7 methodology that utilizes an internet webpage, internet webpage 8 portal, or similar electronic, internet, and web-based system.

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

14 (8) Beginning January 1, 2016, a prior authorization request 15 that has not been certified for expedited review by the prescriber 16 is considered to have been granted by the insurer if the insurer 17 fails to grant the request, deny the request, or require additional information of the prescriber within 15 days after the date and 18 19 time of submission of a standard prior authorization request under 20 this section. If additional information is requested by an insurer, a prior authorization request under this subsection is not 21 considered granted if the prescriber fails to submit the additional 22 23 information within 15 days after the date and time of the original 24 submission of a properly completed standard prior authorization 25 request under this section. If additional information is requested by an insurer, a prior authorization request is considered to have 26 27 been granted by the insurer if the insurer fails to grant the request, deny the request, or otherwise respond to the request of 28 the prescriber within 15 days after the date and time of submission 29



s 07627 12162020

of the additional information. If additional information is 1 requested by an insurer, a prior authorization request under this 2 subsection is considered void if the prescriber fails to submit the 3 additional information within 21 days after the date and time of 4 the original submission of a properly completed standard prior 5 6 authorization request under this section. 7 (9) Beginning January 1, 2016, a prior authorization request 8 that has been certified for expedited review by the prescriber is 9 considered to have been granted by the insurer if the insurer fails 10 to grant the request, deny the request, or require additional information of the prescriber within 72 hours after the date and 11 time of submission of a standard prior authorization request under 12 this section. If additional information is requested by an insurer, 13 14 a prior authorization request under this subsection is not 15 considered granted if the prescriber fails to submit the additional 16 information within 72 hours after the date and time of the original 17 submission of a properly completed standard prior authorization request under this section. If additional information is requested 18 by an insurer, a prior authorization request is considered to have 19 20 been granted by the insurer if the insurer fails to grant the 21 request, deny the request, or otherwise respond to the request of the prescriber within 72 hours after the date and time of 22 submission of the additional information. If additional information 23 is requested by an insurer, a prior authorization request under 24 25 this subsection is considered void if the prescriber fails to submit the additional information within 5 days after the date and 26 27 time of the original submission of a properly completed standard prior authorization request under this section. 28 29 (8) (10) As used in this section:



s 07627 12162020

(a) "Health benefit plan" means that term as defined in
 section 2212e.

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

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

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(ii) A health maintenance organization.

8 (iii) A health care corporation operating pursuant to the
9 nonprofit health care corporation reform act, 1980 PA 350, MCL
10 550.1101 to 550.1704.

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

(c) (b)—"Prescriber" means that term as defined in section
13 17708 of the public health code, 1978 PA 368, MCL 333.17708.

14 (d) (c) "Prescription drug" means that term as defined in
15 section 17708 of the public health code, 1978 PA 368, MCL
16 333.17708.

(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.

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

25 Sec. 2212e. (1) For an insurer that delivers, issues for 26 delivery, renews, or administers a health benefit plan in this 27 state, if the health benefit plan requires a prior authorization 28 with respect to any benefit, the insurer or its designee 29 utilization review organization shall, by January 1, 2022, make



1 available a standardized electronic prior authorization request 2 transaction process utilizing an internet webpage, internet webpage 3 portal, or similar electronic, internet, and web-based system. Beginning January 1, 2022, an insurer described in this subsection 4 or its designee utilization review organization and the health 5 6 professional shall perform a prior authorization utilizing only a 7 standard electronic prior authorization transaction process, which 8 includes the transmission of clinical information, unless the 9 health professional is not able to use the standard electronic 10 prior authorization transaction process because of a temporary 11 technological or electrical failure. The current prior 12 authorization requirements must be described in detail and written 13 in easily understandable language. The prior authorization 14 requirements must be based on peer-reviewed clinical review 15 criteria. All of the following apply to clinical review criteria under this subsection: 16

17 (a) Unless the criteria are developed as described in
18 subdivision (h), the clinical review criteria must be criteria
19 developed by either of the following:

20 (*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 theoutcome of the clinical care decision.

26 ( $\ddot{u}$ ) A professional medical specialty society.

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

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(c) The clinical review criteria must ensure quality of care



S01865'19 (S-3)

s 07627 12162020

1 and access to needed health care services.

2 (d) The clinical review criteria must be evidence-based3 criteria.

4 (e) The clinical review criteria must be publicly available5 free of charge.

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

9 (g) The clinical review criteria must be evaluated and 10 updated, if necessary, at least annually.

11 (h) For coverage other than prescription drug benefit 12 coverage, before establishing, or substantially or materially 13 altering, its own written clinical review criteria, an insurer or 14 its designee utilization review organization must obtain input from 15 actively practicing licensed physicians representing major areas of 16 the specialty. For coverage of a prescription drug benefit, before 17 establishing, or substantially or materially altering, its own 18 clinical review criteria, an insurer or its designee review 19 organization must obtain input from actively practicing licensed 20 pharmacists. If criteria are developed for a health care service 21 provided by a health professional not licensed to engage in the 22 practice of medicine under part 170 of the public health code, 1978 23 PA 368, MCL 333.17001 to 333.17097, or osteopathic medicine and 24 surgery under part 175 of the public health code, 1978 PA 368, MCL 25 333.17501 to 333.17556, an insurer or designee utilization review 26 organization must also seek input from a health professional in the 27 same profession as the health professional providing the health 28 care service.

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(2) An insurer described in subsection (1) shall make



s 07627 12162020

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.

4 (3) Except as otherwise provided in subsection (4), an insurer 5 described in subsection (1) or its designee utilization review 6 organization shall ensure that an adverse determination, other than 7 an adverse determination of prescription drug coverage, is made by 8 a licensed physician. For an adverse determination of a health care 9 service provided by a health professional that is not a licensed 10 physician, the licensed physician may consider input from a health 11 professional who is in the same profession as the health 12 professional providing the health care service. The licensed 13 physician shall make the adverse determination under the clinical 14 direction of 1 of the insurer's medical directors who is 15 responsible for the provision of health care items and services provided to insureds or enrollees. Medical directors under this 16 17 subsection must be licensed to engage in the practice of medicine 18 under part 170 of the public health code, 1978 PA 368, MCL 333.17001 to 333.17097, or the practice of osteopathic medicine and 19 20 surgery under part 175 of the public health code, 1978 PA 368, MCL 333.17501 to 333.17556. 21

22 (4) An insurer described in subsection (1) or its designee 23 utilization review organization shall ensure that an adverse 24 determination of a prescription drug benefit is made by a licensed 25 pharmacist under the clinical direction of 1 of the insurer's 26 medical directors who is responsible for the provision of health 27 care items and services provided to insureds or enrollees. Medical 28 directors under this subsection must be licensed to engage in the 29 practice of medicine under part 170 of the public health code, 1978



s 07627 12162020

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 (5) If an insurer described in subsection (1) implements a new 5 prior authorization requirement or restriction, or amends an 6 existing requirement or restriction, the insurer shall ensure that 7 the new or amended requirement or restriction is posted on the 8 insurer's public website before its implementation. For a medical 9 benefit that is not a prescription drug benefit, an insurer shall 10 notify contracted health care providers via the insurer's provider 11 portal of the new or amended requirement or restriction not less than 60 days before the requirement or restriction is implemented. 12 13 For a prescription drug benefit, an insurer shall notify contracted 14 health care providers via the insurer's provider portal of the new 15 or amended requirement or restriction not less than 30 days before the requirement or restriction is implemented. 16

17 (6) If an insurer described in subsection (1) denies a prior 18 authorization, the insurer or its designee utilization review 19 organization shall, on issuing a medical benefit denial, notify the 20 health professional and insured or enrollee of the reasons for the 21 denial and related evidence-based criteria. Subject to subsection 22 (7), an appeal of the denial under this subsection must be reviewed 23 by a licensed health professional to which all of the following 24 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 directfinancial stake in the outcome of the appeal.



s 07627 12162020

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

3 (d) The licensed health professional considers all known
4 clinical aspects of the health care services under review,
5 including, but not limited to, a review of all pertinent medical
6 records provided to the insurer or designee utilization review
7 organization by the insured or enrollee's health care provider and
8 any relevant records provided to the insurer or designee
9 utilization review organization by a health care facility.

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

13 (8) A prior authorization request under this section that has 14 not been certified as urgent by the health care provider is 15 considered granted by the insurer or its designee utilization review organization if the insurer or its designee utilization 16 17 review organization fails to grant the request, deny the request, 18 or require additional information of the health care provider 19 within 5 business days after the date and time of submission of the 20 prior authorization. If additional information is requested by an 21 insurer or its designee utilization review organization, the prior 22 authorization request is not considered granted if the health care 23 provider fails to submit the additional information within 2 24 business days after the date and time of the request for additional 25 information. If additional information is requested by an insurer 26 or its designee utilization review organization, the prior 27 authorization request is considered to have been granted by the 28 insurer or its designee utilization review organization if the 29 insurer or its designee utilization review organization fails to



s 07627 12162020

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.

4 (9) A prior authorization request under this section that has 5 been certified as urgent by the health care provider is considered 6 granted by the insurer or its designee utilization review 7 organization if the insurer or its designee utilization review 8 organization fails to grant the request, deny the request, or 9 require additional information of the health care provider within 2 10 business days after the date and time of submission of the prior 11 authorization request. If additional information is requested by an 12 insurer or its designee utilization review organization, the prior 13 authorization request is not considered granted if the health care 14 provider fails to submit the additional information within 1 15 business day after the date and time after the request for additional information. If additional information is requested by 16 17 an insurer or its designee utilization review organization, the 18 prior authorization request is considered to have been granted by 19 the insurer or its designee utilization review organization if the 20 insurer or its designee utilization review organization fails to 21 grant the request, deny the request, or otherwise respond to the 22 request of the health care provider within 2 days after the date 23 and time of the submission of additional information.

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

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(11) As used in this section:

27 (a) "Adverse determination" means that term as defined in28 section 2213.

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(b) "Evidence-based criteria" means criteria developed using



1 evidence-based standards.

2 (c) "Evidence-based standard" means that term as defined in
3 section 3 of the patient's right to independent review act, 2000 PA
4 251, 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.

10 (e) "Health care provider" means any of the following:
11 (i) A health facility as that term is defined in section 2006.

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(ii) A health professional.

13 (f) "Health professional" means that term as defined in 14 section 2006.

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

16 (h) "Licensed physician" means any of the following:

17 (i) A physician licensed to engage in the practice of medicine
18 under part 170 of the public health code, 1978 PA 368, MCL
19 333.17001 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.

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(*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 regularlyscheduled intervals and evaluates, among other things,
pharmaceutical literature or medical literature, or both, and
scientific evidence to develop criteria that promotes appropriate,



s 07627 12162020

1 safe, and cost-effective drug utilization.

2 (j) "Prescription drug benefit" means that term as defined in3 section 2212c.

4 (k) "Prior authorization" means a determination by an insurer 5 or utilization review organization that a requested health care 6 benefit has been reviewed and, based on the information provided, 7 satisfies the insurer or utilization review organization 8 requirements for medical necessity and appropriateness.

9 (1) "Standardized electronic prior authorization transaction 10 process" means a standardized transmission process, identified by 11 the director and aligned with standards that are nationally 12 accepted, to enable prior authorization requests to be accessible, 13 submitted by health care providers, and accepted by insurers or 14 their designee utilization review organizations electronically 15 through secure electronic transmissions with the goal of maximizing 16 administrative simplification, efficiency, and timeliness. The 17 process must require health care providers to supply clinical 18 information under the standardized electronic prior authorization 19 process. Standard electronic prior authorization transaction 20 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.

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



S01865'19 (S-3)

s 07627 12162020