PATIENT'S RIGHT TO INDEPENDENT REVIEW ACT Act 251 of 2000

AN ACT to provide review of certain health care coverage adverse determinations made by health carriers; to prescribe eligibility, powers, and duties of certain independent review organizations; to prescribe the powers and duties of certain health carriers; to prescribe the powers and duties of certain persons; to prescribe the powers and duties of certain state officials; to provide for the reporting of certain information; to provide fees; and to provide penalties for violations of this act.

History: 2000, Act 251, Eff. Oct. 1, 2000.

The People of the State of Michigan enact:

550.1901 Short title.

Sec. 1. This act shall be known and may be cited as the "patient's right to independent review act". **History:** 2000, Act 251, Eff. Oct. 1, 2000.

550.1903 Definitions.

Sec. 3. As used in this act:

(a) "Adverse determination" means a determination by a health carrier or its designee utilization review organization that an admission, availability of care, continued stay, or other health care service that is a covered benefit has been reviewed and, based on the information provided, does not meet the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness, and the requested service or payment for the service is therefore denied, reduced, or terminated. Failure to respond in a timely manner to a request for a determination is an adverse determination.

(b) "Ambulatory review" means utilization review of health care services performed or provided in an outpatient setting.

(c) "Authorized representative" means any of the following:

(*i*) A person to whom a covered person has given express written consent to represent the covered person in an external review.

(*ii*) A person authorized by law to provide substituted consent for a covered person.

(*iii*) If the covered person is unable to provide consent, a family member of the covered person or the covered person's treating health care professional.

(d) "Case management" means a coordinated set of activities conducted for individual patient management of serious, complicated, protracted, or other health conditions.

(e) "Certification" means a determination by a health carrier or its designee utilization review organization that an admission, availability of care, continued stay, or other health care service has been reviewed and, based on the information provided, satisfies the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care, and effectiveness.

(f) "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols, and practice guidelines used by a health carrier to determine the necessity and appropriateness of health care services.

(g) "Concurrent review" means utilization review conducted during a patient's hospital stay or course of treatment.

(h) "Covered benefits" or "benefits" means those health care services to which a covered person is entitled under the terms of a health benefit plan.

(i) "Covered person" means a policyholder, subscriber, member, enrollee, or other individual participating in a health benefit plan.

(j) "Department" means the department of insurance and financial services.

(k) "Director" means the director of the department.

(*l*) "Discharge planning" means the formal process for determining, before discharge from a facility, the coordination and management of the care that a patient receives following discharge from the facility.

(m) "Disclose" means to release, transfer, or otherwise divulge protected health information to any person other than the individual who is the subject of the protected health information.

(n) "Evidence-based standard" means the conscientious, explicit, and judicious use of the current best evidence based on the overall systematic review of the research in making decisions about the care of individual patients.

(o) "Expedited internal grievance" means an expedited grievance under section 2213(1)(l) of the insurance code of 1956, 1956 PA 218, MCL 500.2213, or section 404(4) of the nonprofit health care corporation reform

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act, 1980 PA 350, MCL 550.1404.

(p) "Facility" or "health facility" means:

(*i*) A facility or agency or a part of a facility or agency that is licensed or authorized under parts 201 to 217 of the public health code, 1978 PA 368, MCL 333.20101 to 333.21799e.

(*ii*) A psychiatric hospital, psychiatric unit, partial hospitalization psychiatric program, or center for persons with disabilities operated by the department of health and human services or certified or licensed under the mental health code, 1974 PA 258, MCL 330.1001 to 330.2106.

(iii) A facility providing outpatient physical therapy services, including speech pathology services.

(iv) A kidney disease treatment center, including a freestanding hemodialysis unit.

(*v*) An ambulatory health care facility.

(vi) A tertiary health care service facility.

(*vii*) A substance use disorder services program licensed under part 62 of the public health code, 1978 PA 368, MCL 333.6230 to 333.6251.

(viii) An outpatient psychiatric clinic.

(*ix*) A home health agency.

(q) "Final adverse determination" means an adverse determination involving a covered benefit that has been upheld by a health carrier, or its designee utilization review organization, at the completion of the health carrier's internal grievance process procedures as set forth in section 2213 of the insurance code of 1956, 1956 PA 218, MCL 500.2213, or sections 404 or 407 of the nonprofit health care corporation reform act, 1980 PA 350, MCL 550.1404 and MCL 550.1407.

(r) "Health benefit plan" means a policy, contract, certificate, or agreement offered or issued by a health carrier to provide, deliver, arrange for, pay for, or reimburse any of the costs of covered health care services.

(s) "Health care professional" means an individual licensed, certified, registered, or otherwise authorized to engage in a health profession under parts 161 to 183 of the public health code, 1978 PA 368, MCL 333.16101 to 333.18315.

(t) "Health care provider" or "provider" means a health care professional or a health facility.

(u) "Health care services" means services for the diagnosis, prevention, treatment, cure, or relief of a health condition, illness, injury, or disease.

(v) "Health carrier" means a person that is subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the director, that contracts or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health maintenance organization, a nonprofit health care corporation, a nonprofit dental care corporation operating under 1963 PA 125, MCL 550.351 to 550.373, or any other person providing a plan of health insurance, health benefits, or health services. Health carrier does not include a state department or agency administering a plan of medical assistance under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b.

(w) "Health information" means information or data, whether oral or recorded in any form or medium, and personal facts or information about events or relationships that relates to 1 or more of the following:

(*i*) The past, present, or future physical, mental, or behavioral health or condition of an individual or a member of the individual's family.

(*ii*) The provision of health care services to an individual.

(iii) Payment for the provision of health care services to an individual.

(x) "Independent review organization" means a person that conducts independent external reviews of adverse determinations.

(y) "Medical or scientific evidence" means evidence found in any of the following sources:

(*i*) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

(*ii*) Peer-reviewed medical literature, including literature relating to therapies reviewed and approved by a qualified institutional review board, biomedical compendia, and other medical literature that meet the criteria of the National Institutes of Health's United States National Library of Medicine for indexing in the former Index Medicus or its current online version, MEDLINE, and Elsevier B. V. for indexing in EMBASE.

(*iii*) Medical journals recognized by the secretary of the United States Department of Health and Human Services under 42 USC 1395x(t)(2)(B)(ii)(I).

(*iv*) The following standard reference compendia:

(A) The American Hospital Formulary Service drug information.

(B) Drug facts and comparisons.

(C) The American Dental Association's accepted dental therapeutics.

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(D) The United States Pharmacopoeia drug information.

(v) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including the following:

(A) The Agency for Healthcare Research and Quality.

(B) The National Institutes of Health.

(C) The National Cancer Institute.

(D) The National Academy of Sciences.

(E) The Centers for Medicare and Medicaid Services.

(F) The United States Food and Drug Administration.

(G) Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services.

(*vi*) Any other medical or scientific evidence that is comparable to the sources listed in subparagraphs (*i*) to (*v*).

(z) "Person" means an individual or a corporation, partnership, association, joint venture, joint stock company, trust, unincorporated organization, or similar entity, or any combination of these.

(aa) "Prospective review" means utilization review conducted before an admission or a course of treatment.

(bb) "Protected health information" means health information that identifies an individual who is the subject of the information or with respect to which there is a reasonable basis to believe that the information could be used to identify an individual.

(cc) "Retrospective review" means a review of medical necessity conducted after services have been provided to a patient, but does not include the review of a claim that is limited to an evaluation of reimbursement levels, veracity of documentation, accuracy of coding, or adjudication for payment.

(dd) "Second opinion" means an opportunity or requirement to obtain a clinical evaluation by a provider other than the one originally making a recommendation for a proposed health service to assess the clinical necessity and appropriateness of the initial proposed health service.

(ee) "Utilization review" means a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings. Techniques may include ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning, or retrospective review.

(ff) "Utilization review organization" means a person that conducts utilization review, other than a health carrier performing a review for its own health plans.

History: 2000, Act 251, Eff. Oct. 1, 2000;—Am. 2006, Act 542, Imd. Eff. Dec. 29, 2006;—Am. 2016, Act 274, Eff. Sept. 29, 2016.

550.1905 Scope.

Sec. 5. (1) Except as otherwise provided in subsection (2), this act applies to all health carriers.

(2) This act does not apply to a policy or certificate that provides coverage only for specified accident or accident-only coverage, credit, disability income, hospital indemnity, long-term care insurance, as that term is defined in section 3901 of the insurance code of 1956, 1956 PA 218, MCL 500.3901, or any other limited supplemental benefit other than specified disease, dental, vision care, or care provided pursuant to a system of health care delivery and financing operating under section 3573 of the insurance code of 1956, 1956 PA 218, MCL 500.3573, Medicare supplement policy of insurance, coverage under a plan through Medicare, or the federal employees health benefits program, any coverage issued under 10 USC 1071 to 1110b, and any coverage issued as supplement to that coverage, any coverage issued as supplemental to liability insurance, worker's disability compensation or similar insurance, automobile medical-payment insurance, or any insurance under which benefits are payable with or without regard to fault, whether written on a group blanket or individual basis.

History: 2000, Act 251, Eff. Oct. 1, 2000;-Am. 2016, Act 274, Eff. Sept. 29, 2016.

550.1907 Right to request external review for adverse determination; written notice.

Sec. 7. (1) A health carrier shall provide written notice to a covered person of the internal grievance and external review processes at the time the health carrier sends written notice of an adverse determination.

(2) Except as provided in subsection (3)(a), a request for an external review under section 11 or 13 must not be made until the covered person has exhausted the health carrier's internal grievance process provided for by law.

(3) The written notice of the right to request an external review for an adverse determination issued before the service is provided to a covered person must include all of the following:

(a) A statement informing the covered person of all of the following:

(*i*) If the covered person has a medical condition such that the time frame for completion of an expedited Rendered Friday, August 6, 2021 Page 3 Michigan Complete Through PA 64 of 2021 internal grievance would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function, as substantiated by a physician either orally or in writing, the covered person or the covered person's authorized representative may file a request for an expedited external review under section 13 at the same time the covered person or the covered person's authorized representative files a request for an expedited internal grievance subject to section 13(3). A covered person who files a request under this subparagraph is considered to have exhausted the health carrier's internal grievance process for purposes of subsection (2).

(*ii*) The covered person or the covered person's authorized representative may file a grievance under the health carrier's internal grievance process, but if the health carrier has not issued a written decision to the covered person or the covered person's authorized representative within the required time and without the covered person or the covered person's authorized representative may file a requesting or agreeing to a delay, the covered person or the covered person's authorized representative may file a request for external review under section 9 and is considered to have exhausted the health carrier's internal grievance process for purposes of subsection (2).

(*iii*) A health carrier may waive its internal grievance process and the requirement for a covered person to exhaust the process before filing a request for an external review or an expedited external review.

(*iv*) The covered person is considered to have exhausted a health carrier's internal grievance process if the health carrier has failed to comply with the requirements of the internal grievance process unless the failure or failures are based on de minimis violations that do not cause, and are not likely to cause, prejudice or harm to the covered person.

(b) A copy of the description of both the standard and expedited external review procedures the health carrier is required to provide under section 25, highlighting the provisions in the external review procedures that give the covered person or the covered person's authorized representative the opportunity to submit additional information and including any forms used to process an external review.

(c) As part of any forms provided under subdivision (b), an authorization form, or other document approved by the director, by which the covered person, for purposes of conducting an external review under this act, authorizes the health carrier and health care provider to disclose protected health information, including medical records, concerning the covered person that are pertinent to the external review.

(4) The written notice of the right to request an external review for an adverse determination issued after the service was provided to the covered person must include the standard external review procedures information required under subsection (3) and be provided to the covered person in the manner prescribed by the director.

History: 2000, Act 251, Eff. Oct. 1, 2000;-Am. 2016, Act 274, Eff. Sept. 29, 2016.

550.1909 Written request to director; manner; electronic communication.

Sec. 9. (1) Except for a request for an expedited external review under section 13, all requests for external review must be made in writing to the director.

(2) A written notice required to be provided under this act must be provided in a culturally and linguistically appropriate manner, as required under 45 CFR 147.136(b)(2)(ii)(E).

(3) A health carrier may satisfy a requirement for the delivery of a notice to a covered person under this act by complying with 29 CFR 2520.104b-1(c) with respect to the use of electronic communication.

History: 2000, Act 251, Eff. Oct. 1, 2000;-Am. 2016, Act 274, Eff. Sept. 29, 2016.

550.1911 Request for external review; commencement; preliminary review; notice of acceptance; duties of director; incomplete request; nonacceptance; assignment of independent review organization; duty of health carrier to provide documents; reconsideration by health carrier of its adverse determination; recommendation; considerations; review by director; notice of decision.

Sec. 11. (1) Not later than 60 days or, after December 31, 2016, 120 days after the date of receipt of a notice of an adverse determination or final adverse determination under section 7, a covered person or the covered person's authorized representative may file a request for an external review with the director. Upon receipt of a request for an external review, the director immediately shall notify and send a copy of the request to the health carrier that made the adverse determination or final adverse determination that is the subject of the request.

(2) Not later than 5 business days after the date of receipt of a request for an external review, the director shall complete a preliminary review of the request to determine all of the following:

(a) Whether the individual is or was a covered person in the health benefit plan at the time the health care service was requested or, for a retrospective review, was a covered person in the health benefit plan at the Rendered Friday, August 6, 2021 Page 4 Michigan Compiled Laws Complete Through PA 64 of 2021

time the health care service was provided.

(b) Whether the health care service that is the subject of the adverse determination or final adverse determination reasonably appears to be a covered service under the covered person's health benefit plan.

(c) Whether the covered person has exhausted the health carrier's internal grievance process, unless the covered person is not required to exhaust the health carrier's internal grievance process.

(d) Whether the covered person has provided all the information and forms required by the director that are necessary to process an external review, including the health information release form.

(e) Whether the health care service that is the subject of the adverse determination or final adverse determination appears to involve issues of medical necessity or clinical review criteria.

(3) If a request for an external review involves issues of experimental or investigational service or treatment, not later than 5 business days after the date of receipt of a request for an external review, the director shall complete a preliminary review of the request to determine all of the following:

(a) Whether the individual is or was a covered person in the health benefit plan at the time the health care service was requested or, for a retrospective review, was a covered person in the health benefit plan at the time the health care service was provided.

(b) Whether the recommended or requested health care service or treatment that is the subject of the adverse determination or final adverse determination is both of the following:

(*i*) A covered benefit under the covered person's health benefit plan except for the health carrier's determination that the service or treatment is experimental or investigational for a particular medical condition.

(*ii*) Not explicitly listed as an excluded benefit under the covered person's health benefit plan with the health carrier.

(c) Whether the covered person's treating provider with the authority to treat under the public health code, 1978 PA 368, MCL 333.1101 to 333.25211, has certified that 1 or more of the following situations are applicable:

(*i*) Standard health care services or treatments have not been effective in improving the condition of the covered person.

(ii) Standard health care services or treatments are not medically appropriate for the covered person.

(*iii*) There is no available standard health care service or treatment covered by the health carrier that is more beneficial than the recommended or requested health care service or treatment described in subdivision (d).

(d) Whether the covered person's treating provider with the authority to treat under the public health code, 1978 PA 368, MCL 333.1101 to 333.25211, has done either of the following:

(*i*) Recommended a health care service or treatment that the treating provider certifies, in writing, is likely to be more beneficial to the covered person, in the treating provider's opinion, than any available standard health care services or treatments.

(*ii*) If the treating provider is a licensed, board certified or board eligible physician qualified to practice in the area of medicine appropriate to treat the covered person's condition, certified in writing that scientifically valid studies using accepted protocols demonstrate that the health care service or treatment requested by the covered person that is the subject of the adverse determination or final adverse determination is likely to be more beneficial to the covered person than any available standard health care services or treatments.

(e) Whether the covered person has exhausted the health carrier's internal grievance process, unless the covered person is not required to exhaust the health carrier's internal grievance process under this act.

(f) Whether the covered person has provided all the information and forms required by the director that are necessary to process an external review, including the health information release form.

(4) Upon completion of a preliminary review under subsection (2) or (3), the director immediately shall provide a written notice to the covered person and, if applicable, the covered person's authorized representative as to whether the request is complete and whether it has been accepted for external review.

(5) On accepting a request for external review, the director shall do both of the following:

(a) Include in the written notice under subsection (4) a statement that the covered person or the covered person's authorized representative may submit to the director in writing within 7 business days following the date of the notice additional information and supporting documentation that the reviewing entity will consider when conducting the external review.

(b) Immediately notify the health carrier in writing of the acceptance of the request for external review.

(6) If a request is not accepted for external review because the request is not complete, the director shall inform the covered person and, if applicable, the covered person's authorized representative what information or materials are needed to make the request complete. The covered person or, if applicable, the covered person's authorized representative shall provide the information or materials identified by the director within Rendered Friday, August 6, 2021 Page 5 Michigan Compiled Laws Complete Through PA 64 of 2021

30 days after receiving the notification. If a request is not accepted for external review, the director shall provide written notice to the covered person, if applicable, the covered person's authorized representative, and the health carrier of the reasons for its nonacceptance.

(7) If a request is accepted for external review and appears to involve issues of medical necessity or clinical review criteria, the director shall assign an independent review organization at the time the request is accepted for external review. The assigned independent review organization must be approved under this act to conduct external reviews. The assigned independent review organization shall provide a written recommendation to the director on whether to uphold or reverse the adverse determination or the final adverse determination.

(8) If a request is accepted for external review, does not appear to involve issues of medical necessity or clinical review criteria, and appears to only involve purely contractual provisions of a health benefit plan, such as covered benefits or accuracy of coding, the director may keep the request and conduct his or her own external review or may assign an independent review organization as provided in subsection (7) at the time the request is accepted for external review. Except as otherwise provided in subsection (18), if the director keeps a request, he or she shall review the request and issue a decision upholding or reversing the adverse determination or final adverse determination within the same time limits and subject to all other requirements of this act for requests assigned to an independent review organization. If at any time during the director's review of a request it is determined that a request does appear to involve issues of medical necessity or clinical review criteria, the director shall immediately assign the request to an independent review organization approved under this act to conduct external reviews.

(9) In reaching a recommendation, the reviewing entity is not bound by any decisions or conclusions reached during the health carrier's utilization review process or the health carrier's internal grievance process.

(10) Not later than 7 business days after the date of the notice under subsection (5)(b), the health carrier or its designee utilization review organization shall provide to the reviewing entity the documents and any information considered in making the adverse determination or the final adverse determination. Except as provided in subsection (11), the reviewing entity shall not delay the external review because of failure by the health carrier or its designee utilization review organization to provide the documents and information within 7 business days.

(11) Upon receipt of a notice from the assigned independent review organization that the health carrier or its designee utilization review organization has failed to provide the documents and information within 7 business days, the director may terminate the external review and make a decision to reverse the adverse determination or final adverse determination and shall immediately notify the assigned independent review organization, the covered person, if applicable, the covered person's authorized representative, and the health carrier of his or her decision.

(12) The reviewing entity shall review all of the information and documents received under subsection (10) and any other information submitted in writing by the covered person or the covered person's authorized representative under subsection (5)(a) that has been forwarded by the director. Upon receipt of any information submitted by the covered person or the covered person's authorized representative under subsection (5)(a), at the same time the director forwards the information to the independent review organization, the director shall forward the information to the health carrier.

(13) The health carrier may reconsider its adverse determination or final adverse determination that is the subject of the external review. Reconsideration by the health carrier of its adverse determination or final adverse determination does not delay or terminate the external review. The external review may only be terminated if the health carrier decides, upon completion of its reconsideration, to reverse its adverse determination or final adverse determination and provide coverage or payment for the health care service that is the subject of the adverse determination or final adverse determination. Immediately upon making the decision to reverse its adverse determination or final adverse determination, the health carrier shall notify the covered person, if applicable the covered person's authorized representative, if applicable the assigned independent review organization, and the director in writing of its decision. The reviewing entity shall terminate the external review upon receipt of the notice from the health carrier.

(14) In addition to the documents and information provided under subsection (10), the reviewing entity, to the extent the information or documents are available and the reviewing entity considers them appropriate, shall consider the following in reaching a recommendation:

(a) The covered person's pertinent medical records.

(b) The attending health care professional's recommendation.

(c) Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, the covered person, the covered person's authorized representative, or the covered person's treating provider. Page 6

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(d) The terms of coverage under the covered person's health benefit plan with the health carrier.

(e) The most appropriate practice guidelines, which may include generally accepted practice guidelines, evidence-based practice guidelines, or any other practice guidelines developed by the federal government or national or professional medical societies, boards, and associations.

(f) Any applicable clinical review criteria developed and used by the health carrier or its designee utilization review organization.

(15) If a request for an external review involves issues of experimental or investigational service or treatment, in addition to the documents and information provided under subsections (10) and (14), the reviewing entity, in reaching a recommendation, shall consider whether either of the following applies:

(a) The recommended or requested health care service or treatment has been approved by the United States Food and Drug Administration, if applicable, for the condition.

(b) Medical or scientific evidence or evidence-based standards demonstrate that the expected benefits of the recommended or requested health care service or treatment are more likely than not to be more beneficial to the covered person than the benefits of any available standard health care service or treatment and the adverse risks of the recommended or requested health care service or treatment would not be substantially increased over those of available standard health care services or treatments.

(16) The assigned independent review organization shall provide its recommendation to the director within 14 days after the assignment by the director of the request for an external review. The independent review organization shall include in its recommendation all of the following:

(a) A general description of the reason for the request for external review.

(b) The date the independent review organization received the assignment from the director to conduct the chive a external review.

(c) The date the external review was conducted.

(d) The date of its recommendation.

(e) The principal reason or reasons for its recommendation.

(f) The rationale for its recommendation.

(g) References to the evidence or documentation, including the practice guidelines, considered in reaching its recommendation.

(17) Upon receipt of the assigned independent review organization's recommendation under subsection (16), the director immediately shall review the recommendation to ensure that it is not contrary to the terms of coverage under the covered person's health benefit plan with the health carrier.

(18) The director shall provide written notice to the covered person, if applicable the covered person's authorized representative, and the health carrier of the decision to uphold or reverse the adverse determination or the final adverse determination within 7 business days after the date of receipt of the selected independent review organization's recommendation. If the director has kept a request for review, the director shall provide written notice to the covered person, if applicable the covered person's authorized representative, and the health carrier of his or her decision within 14 days after the decision to keep the request. The director shall include in a notice under this subsection all of the following:

(a) The principal reason or reasons for the decision, including, as an attachment to the notice or in any other manner the director considers appropriate, the information provided as determined by the reviewing entity under subsection (16).

(b) If appropriate, the principal reason or reasons why the director did not follow the assigned independent review organization's recommendation.

(19) Upon receipt of a notice of a decision under subsection (18) reversing the adverse determination or final adverse determination, the health carrier immediately shall approve the coverage that was the subject of the adverse determination or final adverse determination.

History: 2000, Act 251, Eff. Oct. 1, 2000;—Am. 2000, Act 398, Imd. Eff. Jan. 8, 2001;—Am. 2016, Act 274, Eff. Sept. 29, 2016.

550.1913 Expedited external review.

Sec. 13. (1) Except as provided in subsection (12), a covered person or the covered person's authorized representative may make a request for an expedited external review with the director within 10 days after the covered person receives an adverse determination if both of the following apply:

(a) The adverse determination involves a medical condition of the covered person for which the time frame for completion of an expedited internal grievance would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function as substantiated by a physician either orally or in writing.

(b) The covered person or the covered person's authorized representative has filed a request for an expedited internal grievance.

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(2) When the director receives a request for an expedited external review, the director immediately shall notify and provide a copy of the request to the health carrier that made the adverse determination or final adverse determination. If the director determines the request meets the reviewability requirements under section 11(2) or (3), the director shall assign an independent review organization that has been approved under this act to conduct the expedited external review and to provide a written recommendation to the director on whether to uphold or reverse the adverse determination or final adverse determination.

(3) If a covered person has not completed the health carrier's expedited internal grievance process, the independent review organization shall determine immediately after receipt of the assignment to conduct the expedited external review whether the covered person will be required to complete the expedited internal grievance before conducting the expedited external review. If the independent review organization determines that the covered person must first complete the expedited internal grievance process, the independent review organization immediately shall notify the covered person and, if applicable, the covered person's authorized representative of this determination and that it will not proceed with the expedited external review until the covered person completes the expedited internal grievance.

(4) In reaching a recommendation, an assigned independent review organization is not bound by any decisions or conclusions reached during the health carrier's utilization review process or the health carrier's internal grievance process.

(5) Not later than 12 hours after a health carrier receives a notice under subsection (2), the health carrier or its designee utilization review organization shall provide or transmit all necessary documents and information considered in making the adverse determination or final adverse determination to the assigned independent review organization electronically or by telephone, facsimile, or any other available expeditious method.

(6) In addition to the documents and information provided or transmitted under subsection (5), the assigned independent review organization, to the extent the information or documents are available and the independent review organization considers them appropriate, shall consider the following in reaching a recommendation:

(a) The covered person's pertinent medical records.

(b) The attending health care professional's recommendation.

(c) Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, covered person, the covered person's authorized representative, or the covered person's treating provider.

(d) The terms of coverage under the covered person's health benefit plan with the health carrier.

(e) The most appropriate practice guidelines, which may include generally accepted practice guidelines, evidence-based practice guidelines, or any other practice guidelines developed by the federal government or national or professional medical societies, boards, and associations.

(f) Any applicable clinical review criteria developed and used by the health carrier or its designee utilization review organization in making adverse determinations.

(7) If a request for an external review involves issues of experimental or investigational service or treatment, in addition to the documents and information provided under subsections (5) and (6), the assigned independent review organization, in reaching a recommendation, shall consider whether either of the following applies:

(a) The recommended or requested health care service or treatment has been approved by the United States Food and Drug Administration, if applicable, for the condition.

(b) Medical or scientific evidence or evidence-based standards demonstrate that the expected benefits of the recommended or requested health care service or treatment are more likely than not to be more beneficial to the covered person than the benefits of any available standard health care service or treatment and the adverse risks of the recommended or requested health care service or treatment would not be substantially increased over those of available standard health care services or treatments.

(8) An assigned independent review organization shall provide its recommendation to the director as expeditiously as the covered person's medical condition or circumstances require, but not more than 36 hours after the date the director received the request for an expedited external review.

(9) Upon receipt of an assigned independent review organization's recommendation, the director immediately shall review the recommendation to ensure that it is not contrary to the terms of coverage under the covered person's health benefit plan with the health carrier.

(10) As expeditiously as the covered person's medical condition or circumstances require, but not more than 24 hours after receiving the recommendation of the assigned independent review organization, the director shall complete the review of the independent review organization's recommendation and notify the covered person, if applicable, the covered person's authorized representative, and the health carrier of the decision to uphold or reverse the adverse determination or final adverse determination. If the notice under this Rendered Friday, August 6, 2021 Page 8 Michigan Compiled Laws Complete Through PA 64 of 2021

subsection is not in writing, within 2 days after the date of providing the notice, the director shall provide written confirmation of the decision to the covered person, if applicable, the covered person's authorized representative, and the health carrier and include the information required in section 11(18).

(11) Upon receipt of a notice of a decision under subsection (10) reversing the adverse determination or final adverse determination, the health carrier immediately shall approve the coverage that was the subject of the adverse determination or final adverse determination.

(12) An expedited external review must not be provided for retrospective adverse determinations or retrospective final adverse determinations.

History: 2000, Act 251, Eff. Oct. 1, 2000;—Am. 2000, Act 398, Imd. Eff. Jan. 8, 2001;—Am. 2016, Act 274, Eff. Sept. 29, 2016.

550.1915 Decision as final administrative remedy; other remedies.

Sec. 15. (1) An external review decision and an expedited external review decision are the final administrative remedies available under this act. A person aggrieved by an external review decision or an expedited external review decision may seek judicial review no later than 60 days from the date of the decision in the circuit court for the county where the covered person resides or in the circuit court of Ingham county.

(2) Subsection (1) does not preclude a health carrier from seeking other remedies available under applicable state law.

(3) Subsection (1) does not preclude a covered person from seeking other remedies available under applicable federal or state law.

(4) A covered person or the covered person's authorized representative may not file a subsequent request for external review involving the same adverse determination or final adverse determination for which the covered person has already received an external review decision under this act.

History: 2000, Act 251, Eff. Oct. 1, 2000;—Am. 2000, Act 398, Imd. Eff. Jan. 8, 2001.

550.1917 Approved independent review organizations; application; form; fee; expiration; termination; updated list.

Sec. 17. (1) The director shall approve independent review organizations eligible to be assigned to conduct external reviews under this act to ensure that an independent review organization satisfies the minimum standards established under section 19.

(2) The director shall develop an application form for initially approving and for reapproving independent review organizations to conduct external reviews.

(3) Any independent review organization wishing to be approved to conduct external reviews under this act shall submit the application form developed under subsection (2) and include with the form all documentation and information necessary for the director to determine if the independent review organization satisfies the minimum qualifications established under section 19. The director may charge an application fee that independent review organizations shall submit to the director with an application for approval or reapproval.

(4) An approval under this section is effective for 2 years, unless the director determines before expiration of the approval that the independent review organization is not satisfying the minimum standards established under section 19. If the director determines that an independent review organization no longer satisfies the minimum standards established under section 19, the director shall terminate the approval of the independent review organization and remove the independent review organization from the list of independent review organizations approved to conduct external reviews under this act that is maintained by the director under subsection (5).

(5) The director shall maintain and periodically update a list of approved independent review organizations.

History: 2000, Act 251, Eff. Oct. 1, 2000;—Am. 2016, Act 274, Eff. Sept. 29, 2016.

550.1919 Approved independent review organization; requirements.

Sec. 19. (1) To be approved under section 17 to conduct external reviews, an independent review organization must do all of the following:

(a) Have and maintain written policies and procedures that govern all aspects of both the standard external review process and the expedited external review process under sections 11 and 13 that include, at a minimum, a quality assurance mechanism in place that does all of the following:

(i) Ensures that external reviews are conducted within the specified time frames and required notices are provided in a timely manner.

(ii) Ensures the selection of qualified and impartial clinical peer reviewers to conduct external reviews on Rendered Friday, August 6, 2021 Michigan Compiled Laws Complete Through PA 64 of 2021 Page 9 Courtesy of www.legislature.mi.gov C

behalf of the independent review organization and suitable matching of reviewers to specific cases.

(iii) Ensures the confidentiality of medical and treatment records and clinical review criteria.

(*iv*) Ensures that any person employed by or under contract with the independent review organization adheres to the requirements of this act.

(b) Agree to maintain and provide to the director the information required in section 23.

(c) Be accredited by a nationally recognized private accrediting organization approved by the director.

(2) A clinical peer reviewer assigned by an independent review organization to conduct external reviews must be a physician or other appropriate health care professional who meets all of the following minimum qualifications:

(a) Is an expert in the treatment of the covered person's medical condition that is the subject of the external review.

(b) Is knowledgeable about the recommended health care service or treatment because he or she devoted in the immediately preceding year a majority of his or her time in an active clinical practice within the medical specialty most relevant to the subject of the review.

(c) Holds a nonrestricted license in a state of the United States and, for physicians, a current certification by a recognized American medical specialty board in the area or areas appropriate to the subject of the external review.

(d) Has no history of disciplinary actions or sanctions, including loss of staff privileges or participation restrictions, that have been taken or are pending by any hospital, governmental agency or unit, or regulatory body that raise a substantial question as to the clinical peer reviewer's physical, mental, or professional competence or moral character.

(3) An independent review organization may not own or control, be a subsidiary of or in any way be owned or controlled by, or exercise control with a health benefit plan, a national, state, or local trade association of health benefit plans, or a national, state, or local trade association of health care providers.

(4) An independent review organization selected to conduct the external review and any clinical peer reviewer assigned by the independent organization to conduct the external review must not have a material professional, familial, or financial conflict of interest with any of the following:

(a) The health carrier that is the subject of the external review.

(b) The covered person whose treatment is the subject of the external review or the covered person's authorized representative.

(c) Any officer, director, or management employee of the health carrier that is the subject of the external review.

(d) The health care provider, the health care provider's medical group, or independent practice association recommending the health care service or treatment that is the subject of the external review.

(e) The facility at which the recommended health care service or treatment would be provided.

(f) The developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended for the covered person whose treatment is the subject of the external review.

(5) In determining whether an independent review organization or a clinical peer reviewer of the independent review organization has a material professional, familial, or financial conflict of interest for purposes of subsection (4), the director shall take into consideration situations in which the independent review organization to be assigned to conduct an external review of a specified case or a clinical peer reviewer to be assigned by the independent review organization to conduct an external review of a specified case or a clinical peer reviewer to be assigned by the independent review organization to conduct an external review of a specified case may have an apparent professional, familial, or financial relationship or connection with a person described in subsection (4), but that the characteristics of that relationship or connection are such that they are not a material professional, familial, or financial conflict of interest that results in the disapproval of the independent review organization or the clinical peer reviewer from conducting the external review.

History: 2000, Act 251, Eff. Oct. 1, 2000;—Am. 2016, Act 274, Eff. Sept. 29, 2016.

550.1921 Independent review organization; liability for damages.

Sec. 21. An independent review organization or clinical peer reviewer working on behalf of an independent review organization is not liable in damages to any person for any opinions rendered during or upon completion of an external review conducted under this act, unless the opinion was rendered in bad faith or involved gross negligence.

History: 2000, Act 251, Eff. Oct. 1, 2000.

550.1923 Maintenance of records; report to director.

Sec. 23. (1) An independent review organization assigned to conduct an external review under section 11 or 13 shall maintain for 3 years written records in the aggregate and by health carrier on all requests for Rendered Friday, August 6, 2021 Page 10 Michigan Compiled Laws Complete Through PA 64 of 2021

external review for which it conducted an external review during a calendar year. Each independent review organization required to maintain written records on all requests for external review for which it was assigned to conduct an external review shall submit to the director, at least annually, a report in the format specified by the director.

(2) The report to the director under subsection (1) must include in the aggregate and for each health carrier all of the following:

(a) The total number of requests for external review.

(b) The number of requests for external review resolved and, of those resolved, the number resolved upholding the adverse determination or final adverse determination and the number resolved reversing the adverse determination or final adverse determination.

(c) The average length of time for resolution.

(d) A summary of the types of coverages or cases for which an external review was sought, as provided in the format required by the director.

(e) The number of external reviews under section 11(13) that were terminated as the result of a reconsideration by the health carrier of its adverse determination or final adverse determination after the receipt of additional information from the covered person or the covered person's authorized representative.

(f) Any other information the director may request or require.

(3) A health carrier shall maintain for 3 years written records in the aggregate and for each type of health benefit plan offered by the health carrier on all requests for external review that are filed with the health carrier or that the health carrier receives notice of from the director under this act. A health carrier required to maintain written records on all requests for external review shall submit to the director, at least annually, a report in the format specified by the director.

(4) The report to the director under subsection (3) must include in the aggregate and by type of health benefit plan all of the following:

(a) The total number of requests for external review.(b) From the number of requests for external review that are filed directly with the health carrier, the number of requests accepted for a full external review.

(c) The number of requests for external review resolved and, of those resolved, the number resolved upholding the adverse determination or final adverse determination and the number resolved reversing the adverse determination or final adverse determination.

(d) The average length of time for resolution.

(e) A summary of the types of coverages or cases for which an external review was sought, as provided in the format required by the director.

(f) The number of external reviews under section 11(13) that were terminated as the result of a reconsideration by the health carrier of its adverse determination or final adverse determination after the receipt of additional information from the covered person or the covered person's authorized representative.

(g) Any other information the director may request or require.

History: 2000, Act 251, Eff. Oct. 1, 2000;-Am. 2000, Act 398, Imd. Eff. Jan. 8, 2001;-Am. 2016, Act 274, Eff. Sept. 29, 2016.

550.1925 Description of internal grievance and external review procedures; inclusion with materials provided to covered persons.

Sec. 25. (1) A health carrier shall include a description of the internal grievance and external review procedures in or attached to the policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to covered persons.

(2) The description under subsection (1) must include all of the following:

(a) A statement informing the covered person of his or her right to file a request for an internal grievance and external review of an adverse determination.

(b) The director's toll-free telephone number and address.

(c) A statement informing the covered person that, when filing a request for an external review, the covered person will be required to authorize the release of any medical records that may be required to be reviewed to reach a decision on the external review.

History: 2000, Act 251, Eff. Oct. 1, 2000;-Am. 2016, Act 274, Eff. Sept. 29, 2016.

550.1927 Rules.

Sec. 27. The director may promulgate rules under the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328, necessary to carry out this act.

History: 2000, Act 251, Eff. Oct. 1, 2000;-Am. 2016, Act 274, Eff. Sept. 29, 2016.

550.1929 Cease and desist order; additional orders; fines; hearing; injunction; creation of cancer clinical trials; disposition of funds.

Sec. 29. (1) If the commissioner finds that a violation of this act has occurred, the commissioner shall reduce the findings and decision to writing and shall issue and cause to be served upon the person charged with the violation a copy of the findings and an order requiring the person to cease and desist from the violation. In addition, the commissioner may order any of the following:

(a) Payment of a civil fine of not more than \$1,000.00 for each violation. However, if the person knew or reasonably should have known that he or she was in violation of this act, the commissioner may order the payment of a civil fine of not more than \$5,000.00 for each violation.

(b) The suspension, limitation, or revocation of the person's license or certificate of authority.

(2) If the commissioner finds that a health carrier has deliberately refused to pay for a covered benefit, the commissioner may order any of the following:

(a) For a first offense, payment of a civil fine of not more than \$25,000.00 and recovery of the cost of the investigation.

(b) For a second offense, payment of a civil fine of not more than \$50,000.00 and recovery of the cost of the investigation.

(c) For a third or subsequent offense or if the commissioner determines that the health carrier has deliberately engaged in a pattern of refusing to pay for a covered benefit, both of the following:

(*i*) The greater of the following:

(A) Payment of a civil fine of not more than \$280,000.00.

(B) Payment of a civil fine which shall be the amount of the health carrier's total liability for the covered benefits denied.

(*ii*) Recovery of the cost of the investigation.

(3) A fine collected under this section shall be placed in the cancer clinical trials fund created in subsection (7).

(4) A person who violates any provision of this act shall be afforded an opportunity for a hearing before the commissioner pursuant to the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328. After notice and opportunity for hearing, the commissioner may by order reopen and alter, modify, or set aside, in whole or in part, an order issued under this section if, in the commissioner's opinion, conditions of fact or law have changed to require that action or the public interest requires that action.

(5) If a person knowingly violates a cease and desist order under this section and has been given notice and an opportunity for a hearing held pursuant to the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328, the commissioner may order a civil fine of \$10,000.00 for each violation, or a suspension, limitation, or revocation of a person's license, or both.

(6) The commissioner may apply to the Ingham county circuit court for an order of the court enjoining a violation of this act.

(7) The cancer clinical trials fund is created as a separate fund in the state treasury. The money in the fund shall be used as provided in this subsection. The state treasurer shall credit to the cancer clinical trials fund all fines collected under this section. The state treasurer may invest money in the fund in any manner authorized by law for the investment of state money, and earnings shall be credited to the fund. Money may be appropriated from the fund to hospitals, outpatient oncology centers, and other facilities located in this state involved in national institutes of health phase III or IV cancer clinical trials that apply for fund money to partially defray costs of patient participation in cancer clinical trials not covered by pharmaceutical manufacturers or health carriers. Money may be appropriated from the fund in amounts that shall not exceed \$5,000.00 per facility per year. Money in the cancer clinical trials fund at the close of the fiscal year shall remain in the fund and shall not lapse to the general fund.

History: 2000, Act 251, Eff. Oct. 1, 2000.