514J.109 External review of experimental or investigational treatment adverse determinations.

1. Within four months after the date of receipt of a notice of an adverse determination or final adverse determination that involves a denial of coverage based on a determination that the health care service or treatment recommended or requested is experimental or investigational, a covered person or the covered person's authorized representative may file a request for external review with the commissioner.

2. Within one business day after the date of receipt of the request, the commissioner shall notify the health carrier of the request.

3. Within five business days following the date of receipt of notice of a request for external review pursuant to this section, the health carrier shall complete a preliminary review of the request to determine whether:

a. The individual is or was a covered person under the health benefit plan at the time the health care service or treatment was recommended or requested.

b. The recommended or requested health care service or treatment that is the subject of the adverse determination or final adverse determination meets the following conditions:

(1) Is 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.

(2) Is not explicitly listed as an excluded benefit under the covered person's health benefit plan with the health carrier.

c. The covered person's treating physician has certified that one of the following situations is applicable:

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

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

(3) 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 sought.

d. The covered person's treating physician has certified in writing one of the following:

(1) That the recommended or requested health care service or treatment that is the subject of the adverse determination or final adverse determination is likely to be more beneficial to the covered person, in the physician's opinion, than any available standard health care services or treatments.

(2) The physician 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, and that scientifically valid studies using accepted protocols demonstrate that the health care service or treatment recommended or requested 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. The covered person or the covered person's authorized representative has exhausted the health carrier's internal grievance process, unless the covered person or the covered person's authorized representative is not required to exhaust the health carrier's internal grievance process pursuant to section 514J.106 or 514J.108.

f. The covered person or the covered person's authorized representative has provided all the information and forms required by the commissioner that are necessary to process an external review request pursuant to this section.

4. Within one business day after completion of the preliminary review pursuant to subsection 3, the health carrier shall notify the commissioner and the covered person or the covered person's authorized representative in writing whether the request is complete and whether the request is eligible for external review pursuant to this section. If the request is not complete, the health carrier shall notify the commissioner and the covered person or the covered person's authorized representative in writing and include in the notice what information or materials are needed to make the request complete. If the request is not eligible for external review, the health carrier shall notify the covered person or the covered

person's authorized representative and the commissioner in writing and include in the notice the reasons for its ineligibility.

5. The commissioner may specify by rule the form required for the health carrier's notice of initial determination and any supporting information to be included in the notice. The notice of initial determination shall include a statement informing the covered person or the covered person's authorized representative that a health carrier's initial determination that the external review request is ineligible for review may be appealed to the commissioner.

6. The commissioner may determine that a request is eligible for external review pursuant to this section, notwithstanding a health carrier's initial determination that the request is ineligible, and require that it be referred for external review. In making this determination, the commissioner's decision shall be made in accordance with the terms of the covered person's health benefit plan and shall be subject to all applicable provisions of this chapter.

7. Within one business day after receipt of the notice from the health carrier that the external review request is eligible for external review or upon a determination by the commissioner that a request is eligible for external review, the commissioner shall do all of the following:

a. Assign an independent review organization from the list of approved independent review organizations maintained by the commissioner and notify the health carrier of the name of the assigned independent review organization.

b. Notify the covered person or the covered person's authorized representative in writing of the request's eligibility and acceptance for external review and the name of the assigned independent review organization and that the covered person or the covered person's authorized representative may submit in writing to the independent review organization, within five business days following the date of receipt of such notice, additional information that the independent review organization shall consider when conducting the external review. The independent review organization may, in the organization's discretion, accept and consider additional information submitted by the covered person or the covered person's authorized representative after five business days.

8. Within one business day after receipt of the notice of assignment to conduct the external review, the assigned independent review organization shall select one or more clinical reviewers, as it determines is appropriate pursuant to subsection 9 to conduct the external review.

9. In selecting clinical reviewers, the independent review organization shall select physicians or other health care professionals who meet the minimum qualifications described in this chapter and, through clinical experience in the past three years, are experts in the treatment of the covered person's condition and knowledgeable about the recommended or requested health care service or treatment that is the subject of the adverse determination or the final adverse determination. Neither the covered person or the covered person's authorized representative nor the health carrier shall choose or control the choice of the clinical reviewers selected to conduct the external review.

10. Each clinical reviewer selected shall provide a written opinion to the independent review organization regarding whether the recommended or requested health care service or treatment should be covered. Each clinical reviewer shall review all of the information and documents received and any other information submitted in writing by the covered person or the covered person's authorized representative. In reaching an opinion, a clinical reviewer is not bound by any decisions or conclusions reached during the health carrier's internal grievance process.

11. Within five business days after receipt of notice of the assignment of the independent review organization, the health carrier shall provide to the independent review organization the documents and any information considered in making the adverse determination or the final adverse determination. Failure by the health carrier to provide the documents and information within the time specified shall not delay the conduct of the external review.

12. If the health carrier fails to provide the documents and information within the time specified, the independent review organization may terminate the external review and make a decision to reverse the adverse determination or final adverse determination. Within one

business day after making such a decision, the independent review organization shall notify the covered person or the covered person's authorized representative, the health carrier, and the commissioner.

13. Within one business day after the receipt of any information submitted by the covered person or the covered person's authorized representative, the independent review organization shall forward the information to the health carrier. Upon receipt of the forwarded information, the health carrier may reconsider its adverse determination or final adverse determination that is the subject of the external review.

a. Reconsideration by the health carrier of its adverse determination or final adverse determination shall not delay or terminate the external review. The external review shall only be terminated if the health carrier decides, upon completion of its reconsideration, to reverse its determination and provide coverage or payment for the recommended or requested health care service or treatment that is the subject of the determination.

b. Within one business day after making a decision to reverse its determination, the health carrier shall notify the covered person or the covered person's authorized representative, the independent review organization, and the commissioner in writing of its decision. The independent review organization shall terminate the external review upon receipt of such notice from the health carrier.

14. *a.* Within twenty days after being selected to conduct the external review, each clinical reviewer shall provide an opinion to the assigned independent review organization regarding whether the recommended or requested health care service or treatment should be covered pursuant to this section.

b. Each clinical reviewer's opinion shall be in writing and include the following information:

(1) A description of the covered person's medical condition.

(2) A description of the indicators relevant to determining whether there is sufficient evidence to demonstrate that the recommended or requested health care service or treatment is likely to be more beneficial to the covered person than any available standard health care services or treatments and that 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.

(3) A description and analysis of any medical or scientific evidence considered in reaching the opinion.

(4) A description and analysis of any applicable evidence-based standards.

(5) Information on whether the reviewer's rationale for the opinion is based on either of the factors described in subsection 15, paragraph *"e"*.

15. In addition to the documents and information provided, each clinical reviewer, to the extent the information or documents are available and the reviewer considers them appropriate, shall consider all of the following in reaching an opinion:

a. The covered person's pertinent medical records.

b. The treating physician's recommendation or request.

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

d. The terms of coverage under the covered person's health benefit plan with the health carrier to ensure that, but for the health carrier's determination that the recommended or requested health care service or treatment that is the subject of the opinion is experimental or investigational, the reviewer's opinion is not contrary to the terms of coverage under the covered person's health benefit plan with the health carrier.

e. Whether either of the following factors is applicable:

(1) The recommended or requested health care service or treatment has been approved by the federal food and drug administration, if applicable, for the condition.

(2) Medical or scientific evidence or evidence-based standards demonstrate that the expected benefits of the recommended or requested health care service or treatment is likely to be more beneficial to the covered person than 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. *a.* If a majority of the clinical reviewers opine that the recommended or requested health care service or treatment should be covered, the independent review organization shall make a decision to reverse the health carrier's adverse determination or final adverse determination.

b. If a majority of the clinical reviewers opine that the recommended or requested health care service or treatment should not be covered, the independent review organization shall make a decision to uphold the health carrier's adverse determination or final adverse determination.

c. If the clinical reviewers are evenly split as to whether the recommended or requested health care service or treatment should be covered, the independent review organization shall obtain the opinion of an additional clinical reviewer in order for the independent review organization to make a decision based on the opinions of a majority of the clinical reviewers.

d. The additional clinical reviewer selected shall use the same information to reach an opinion as the clinical reviewers who have already submitted their opinions.

e. The selection of an additional clinical reviewer under this subsection shall not extend the time within which the assigned independent review organization is required to make a decision based on the opinions of the clinical reviewers for the external review.

17. Within twenty days after it receives the opinion of each clinical reviewer, the assigned independent review organization shall make a decision based on the opinions of the clinical reviewer or reviewers, to uphold or reverse the adverse determination or final adverse determination of the health carrier and provide written notice of the decision to the covered person or the covered person's authorized representative, the health carrier, and the commissioner.

18. *a.* A covered person or the covered person's authorized representative may make a written or oral request to the commissioner for an expedited external review of the adverse determination or final adverse determination pursuant to this subsection if the covered person's treating physician certifies, in writing, that the recommended or requested health care service or treatment that is the subject of the request would be significantly less effective if not promptly initiated.

(1) Upon receipt of a request for an expedited external review pursuant to this subsection, the commissioner shall immediately notify the health carrier.

(2) Upon receipt of notice of the request for expedited external review, the health carrier shall immediately determine whether the request is eligible for external review as provided in subsection 3, paragraphs "*a*" through "*f*", and shall immediately issue a notice of initial determination informing the commissioner and the covered person or the covered person's authorized representative of its eligibility determination. The notice of initial determination of eligibility issued by a health carrier shall include a statement informing the covered person or the covered person's authorized representative that the health carrier's initial determination that the external review request is ineligible for expedited external review may be appealed to the commissioner.

(3) The commissioner may determine that a request is eligible for external review, notwithstanding a health carrier's initial determination that the request is not eligible, and refer the request for external review. In making this determination, the commissioner's decision shall be made in accordance with the terms of the covered person's health benefit plan and shall be subject to all applicable provisions of this chapter.

b. (1) Upon receipt of the notice of initial determination that the request is eligible for expedited external review or upon a determination by the commissioner that the request is eligible for expedited external review, the commissioner shall immediately assign an independent review organization to conduct the expedited external review, from the list of approved independent review organizations maintained by the commissioner, and notify the health carrier of the name of the assigned independent review organization.

(2) Upon receipt of notice of the independent review organization assigned to conduct an expedited external review, the health carrier shall provide or transmit all necessary documents and information considered in making the adverse determination or final adverse

determination to the independent review organization electronically or by telephone or facsimile or any other available expeditious method.

(3) A clinical reviewer or clinical reviewers shall be selected immediately by the independent review organization and shall provide an opinion orally or in writing to the assigned independent review organization as expeditiously as the covered person's medical condition or circumstances require, but in no event more than five calendar days after being selected. If the opinion provided was not in writing, within forty-eight hours following the date the opinion was provided, the clinical reviewer shall provide written confirmation of the opinion to the assigned independent review organization and include all required information in support of the opinion.

c. Within forty-eight hours after the date of receipt of the opinion of each clinical reviewer, the assigned independent review organization shall make a decision based on the opinions of the clinical reviewer or reviewers as to whether to reverse or uphold the adverse determination or final adverse determination and provide notice of the decision orally or in writing to the covered person or the covered person's authorized representative, the health carrier, and the commissioner. If the notice was provided orally, within forty-eight hours after the date of providing that notice, the independent review organization shall provide written confirmation of the decision to the covered person or the covered person's authorized representative, the health carrier, and the commissioner.

d. The independent review organization shall include in the notice of its decision all of the following:

(1) A general description of the reason for the request for an expedited external review.

(2) The written opinion of each clinical reviewer, including the recommendation of each clinical reviewer as to whether the recommended or requested health care service or treatment should be covered and the rationale for the reviewer's recommendation.

(3) The date the independent review organization was assigned by the commissioner to conduct the expedited external review.

(4) The date the expedited external review was conducted.

(5) The date of its decision.

(6) The principal reason or reasons for its decision.

(7) The rationale for its decision.

19. Upon receipt of notice of a decision of the independent review organization reversing an adverse determination or final adverse determination, the health carrier shall immediately approve coverage of the recommended or requested health care service or treatment that was the subject of the determination.

2011 Acts, ch 101, §9; 2011 Acts, ch 131, §71, 158
Referred to in §514J.104, 514J.106