House File 597 - Introduced

HOUSE FILE 597
BY COMMITTEE ON COMMERCE

(SUCCESSOR TO HSB 200)

A BILL FOR

An Act creating new procedures for external review of health care coverage decisions by health carriers and including transition and applicability provisions.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. NEW SECTION. **514J.101 Purpose — applicability.**

The purpose of this chapter is to provide uniform standards for the establishment and maintenance of external review procedures to assure that covered persons have the opportunity for an independent review of an adverse determination or final adverse determination made by a health carrier as required by the federal Patient Protection and Affordable Care Act, Pub. L. No. 111-148, as amended by the federal Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, which amends the Public Health Service Act and adopts, in part, new 42 U.S.C. § 300gg-19, and to address issues which are unique to the external review process in this state.

Sec. 2. NEW SECTION. **514J.102 Definitions.**

As used in this chapter, unless the context otherwise requires:

1. *"Adverse determination"* means a determination by a health carrier that an admission, availability of care, continued stay, or other health care service that is a covered benefit has been reviewed and, based upon 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. *"Adverse determination"* does not include a denial of coverage for a service or treatment specifically listed in plan or evidence of coverage documents as excluded from coverage, or a denial of coverage for a service or treatment that has already been received and for which the covered person has no financial liability.

2. *"Authorized representative"* means any of the following:

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

b. A person authorized by law to provide substituted consent for a covered person.

c. A family member of the covered person when the covered person is unable to provide consent.

d. The covered person's treating health care professional when the covered person is unable to provide consent.

3. *"Best evidence"* means evidence based on randomized clinical trials. If randomized clinical trials are not available, *"best evidence"* means evidence based on cohort studies or case-control studies. If randomized clinical trials, cohort studies, or case-control studies are not available, *"best evidence"* means evidence based on case-series studies. If none of these are available, *"best evidence"* means evidence based on expert opinion.

4. *"Case-control study"* means a retrospective evaluation of two groups of patients with different outcomes to determine which specific interventions the patients received.

5. *"Case-series study"* means an evaluation of a series of patients with a particular outcome, without the use of a control group.

6. *"Certification"* means a determination by a health carrier 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.

7. *"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.

8. *"Cohort study"* means a prospective evaluation of two groups of patients with only one group of patients receiving a specific intervention.

9. *"Commissioner"* means the commissioner of insurance.

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

11. *"Covered person"* means a policyholder, subscriber, enrollee, or other individual participating in a health benefit plan.

12. *"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.

13. *"Emergency medical condition"* means the sudden and, at the time, unexpected onset of a health condition or illness that requires immediate medical attention, where failure to provide medical attention would result in a serious impairment to bodily functions, serious dysfunction of a bodily organ or part, or would place the person's health in serious jeopardy.

14. *"Emergency services"* means health care items and services furnished or required to evaluate and treat an emergency medical condition.

15. *"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.

16. *"Expert opinion"* means a belief or an interpretation by specialists with experience in a specific area about the scientific evidence pertaining to a particular service, intervention, or therapy.

17. *"Facility"* means an institution providing health care services or a health care setting, including but not limited to hospitals and other licensed inpatient centers, ambulatory surgical or treatment centers, skilled nursing centers, residential treatment centers, diagnostic, laboratory and imaging centers, and rehabilitation and other therapeutic health settings.

18. *"Final adverse determination"* means an adverse determination involving a covered benefit that has been upheld by a health carrier at the completion of the health carrier's internal grievance process.

19. *"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 health care services.

20. *"Health care professional"* means a physician or other health care practitioner licensed, accredited, registered, or certified to perform specified health care services consistent with state law.

21. *"Health care provider"* or *"provider"* means a health care professional or a facility.

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

23. *"Health carrier"* means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, including an insurance company offering sickness and accident plans, a health maintenance organization, a nonprofit health service corporation, a plan established pursuant to chapter 509A for public employees, or any other entity providing a plan of health insurance, health care benefits, or health care services. *"Health carrier"* includes, for purposes of this chapter, an organized delivery system.

24. *"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 any of the following:

a. The past, present, or future physical, mental, or behavioral health or condition of a covered person or a member of the covered person's family.

b. The provision of health care services to a covered person.

c. Payment to a health care provider for the provision of health care services to a covered person.

25. *"Independent review organization"* means an entity that

conducts independent external reviews of adverse determinations and final adverse determinations.

26. *"Medical or scientific evidence"* means evidence found in any of the following sources:

a. 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.

b. 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 national library of medicine for indexing in index medicus or medline, or of elsevier science ltd. for indexing in excerpta medicus or embase.

c. Medical journals recognized by the United States secretary of health and human services under section 1861(t)(2) of the federal Social Security Act.

d. The following standard reference compendia:

(1) American hospital formulary service drug information.

(2) Drug facts and comparisons.

(3) American dental association accepted dental therapeutics.

(4) United States pharmacopoeia drug information.

e. Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including any of the following:

(1) Federal agency for health care research and quality.

(2) National institutes of health.

(3) National cancer institute.

(4) National academy of sciences.

(5) Centers for Medicare and Medicaid services.

(6) Federal food and drug administration.

(7) Any national board recognized by the national institutes of health for the purpose of evaluating the medical value of health care services.

f. Any other medical or scientific evidence that is comparable to the sources listed in paragraphs *"a"* through *"e"*.

27. *"NAIC"* means the national association of insurance commissioners.

28. *"Organized delivery system"* means an entity system authorized under 1993 Iowa Acts, ch. 158, and licensed by the director of public health, and performing utilization review.

29. *"Person"* means an individual, a corporation, a partnership, an association, a joint venture, a joint stock company, a trust, an unincorporated organization, any similar entity, or any combination of the foregoing.

30. *"Protected health information"* means health information that meets either of the following descriptions:

a. Health information that identifies a covered person who is the subject of the information.

b. Health information with respect to which there is a reasonable basis to believe that the information could be used to identify a covered person.

31. *"Randomized clinical trial"* means a controlled, prospective study of patients that have been randomized into an experimental group and a control group at the beginning of the study with only the experimental group of patients receiving a specific intervention, which includes study of the groups for variables and anticipated outcomes over time.

Sec. 3. NEW SECTION. **514J.103 Applicability and scope.**

1. Except as provided in subsection 2, this chapter shall apply to all health carriers.

2. This chapter shall not apply to any of the following:

a. A policy or certificate that provides coverage only for a specified disease, specified accident or accident-only, credit, disability income, hospital indemnity, long-term care, dental care, vision care, or any other limited supplemental benefit.

b. A Medicare supplement policy of insurance, as defined by the commissioner by rule.

c. Coverage under a plan through Medicare, Medicaid, or the federal employees health benefits program, any coverage issued under 10 U.S.C. ch. 55, and any coverage issued as supplemental to that coverage.

d. Any coverage issued as supplemental to liability insurance.

e. Workers' compensation or similar insurance.

f. 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.

Sec. 4. NEW SECTION. **514J.104 Notice of right to external review.**

1. A health carrier shall notify a covered person or the covered person's authorized representative, if known, in writing of the covered person's right to request an external review and include the appropriate statements and information set forth in this chapter at the time the health carrier sends written notice of a final adverse determination.

2. *a.* The notice shall include the following, or substantially equivalent, language:

We have denied your request for the provision of or payment for a health care service or course of treatment. You may have the right to have our decision reviewed by health care professionals who have no association with us if our decision involved making a judgment as to the medical necessity, appropriateness, health care setting, level of care, or effectiveness of the health care service or treatment you requested by submitting a request for external review to the commissioner of insurance.

b. The notice shall include the current address and contact information for the commissioner as specified in administrative rule.

3. The health carrier shall include in the notice a

statement informing the covered person or the covered person's authorized representative, if known, of the following:

a. If the covered person has a medical condition pursuant to which the time frame for completion of a standard external review would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function, the covered person or the covered person's authorized representative may file a request for an expedited external review.

b. If the final adverse determination concerns an admission, availability of care, continued stay, or health care service for which the covered person received emergency services, but has not been discharged from a facility, the covered person or the covered person's authorized representative may request an expedited external review.

c. If the final adverse determination concerns a denial of coverage based on a determination that the recommended or requested health care service or treatment is experimental or investigational as provided in section 514J.109, and the covered person's treating health care professional certifies in writing that the recommended or requested health care service or treatment that is the subject of the recommendation or request would be significantly less effective if not promptly initiated, the covered person or the covered person's authorized representative may request an expedited external review.

4. The health carrier shall include with the notice a copy of the descriptions of both the standard and expedited external review procedures the health carrier is required to provide pursuant to section 514J.116, 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.

5. The health carrier shall also include with the notice

an authorization form, or other document approved by the commissioner that complies with the requirements of 45 C.F.R. § 164.508 and with Tit. I of the federal Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881, by which the covered person or the covered person's authorized representative authorizes the health carrier and the covered person's treating health care provider to disclose protected health information, including medical records, concerning the covered person that is pertinent to the external review.

Sec. 5. NEW SECTION. **514J.105 Request for external review.**

A covered person or the covered person's authorized representative may make a request for an external review of a final adverse determination. Except for a request for an expedited external review, all requests for external review shall be made in writing to the commissioner. The commissioner may prescribe by rule the form and content of external review requests.

Sec. 6. NEW SECTION. **514J.106 Exhaustion of internal grievance process —— exceptions —— expedited external review request.**

1. Except as otherwise provided in this section, a request for an external review shall not be made until the covered person or the covered person's authorized representative has exhausted the health carrier's internal grievance process and received a final adverse determination.

2. A covered person or the covered person's authorized representative shall be considered to have exhausted the health carrier's internal grievance process if the covered person or the covered person's authorized representative has filed a grievance involving an adverse determination and, except to the extent the covered person or the covered person's authorized representative requested or agreed to a delay, has not received a written decision on the grievance from the health carrier within thirty days following the date the covered person or the

covered person's authorized representative filed the grievance with the health carrier.

3. A covered person or the covered person's authorized representative may file a request for an expedited external review of an adverse determination without exhausting the health carrier's internal grievance process under either of the following circumstances:

a. The covered person has a medical condition pursuant to which the time frame for completion of an internal review of the grievance involving an adverse determination would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function as provided in section 514J.108.

b. The adverse determination involves a denial of coverage based on a determination that the recommended or requested health care service or treatment is experimental or investigational and 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 adverse determination would be significantly less effective if not promptly initiated as provided in section 514J.109.

4. A request for an external review of an adverse determination may be made before the covered person or the covered person's authorized representative has exhausted the health carrier's internal grievance procedures whenever the health carrier agrees to waive the exhaustion requirement. If the requirement to exhaust the health carrier's internal grievance procedures is waived, the covered person or the covered person's authorized representative may file a request with the commissioner in writing for a standard external review.

Sec. 7. NEW SECTION. **514J.107 External review — standard.**

1. A covered person or the covered person's authorized representative may file a written request for an external review with the commissioner within four months after any of

the following events:

a. The date of receipt of a final adverse determination.

b. The failure of a health carrier to issue a written decision within thirty days following the date the covered person or the covered person's authorized representative filed a grievance involving an adverse determination as provided in section 514J.106, subsection 2.

c. The agreement of the health carrier to waive the requirement that the covered person or the covered person's authorized representative exhaust the health carrier's internal grievance procedures before filing a request for external review of an adverse determination as provided in section 514J.106, subsection 4.

2. Within one business day after the date of receipt of a request for external review, the commissioner shall send a copy of the request to the health carrier.

3. Within five business days following the date of receipt of the external review request from the commissioner, 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 was recommended or requested.

b. The health care service that is the subject of the adverse determination or of the final adverse determination, is a covered service under the covered person's health benefit plan, but for a determination by the health carrier that the health care service is not covered because it does not meet the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness.

c. 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 this section.

d. The covered person or the covered person's authorized representative has provided all the information and forms required to process an external review request.

4. Within one business day after completion of a 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.

a. If the health carrier determines that the request is not complete, the health carrier shall notify the covered person or the covered person's authorized representative and the commissioner in writing that the request is not complete and what information or materials are needed to make the request complete.

b. If the health carrier determines that the request is not eligible for external review, the health carrier shall issue a notice of initial determination in writing informing the covered person or the covered person's authorized representative and the commissioner of that determination and the reasons the request is not eligible for review. The health carrier shall also include a statement in the notice informing the covered person or the covered person's authorized representative that the health carrier's initial determination of ineligibility may be appealed to the commissioner.

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.

6. 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.

7. Within one business day after receipt of notice from a health carrier that a request for external review 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. The assignment of an independent review organization shall be done on a random basis among those approved independent review organizations qualified to conduct the particular external review based on the nature of the health care service that is the subject of the adverse determination or final adverse determination and other circumstances, including conflict of interest concerns.

b. Notify the covered person or the covered person's authorized representative in writing that the request is eligible and has been accepted for external review including 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 receipt of such notice from the commissioner, 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 five business days after receipt of notice from the commissioner pursuant to subsection 7, the health carrier shall provide to the independent review organization the documents and any information considered in making the adverse

determination or 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.

9. 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 of its decision.

10. The independent review organization shall review all of the information and documents received pursuant to subsection 8 and any other information submitted in writing to the independent review organization by the covered person or the covered person's authorized representative pursuant to subsection 7, paragraph *"b"*. Upon receipt of any information submitted by the covered person or the covered person's authorized representative, the independent review organization shall, within one business day, forward the information to the health carrier. In reaching a decision the independent review organization is not bound by any decisions or conclusions reached during the health carrier's internal grievance process.

11. Upon receipt of information forwarded pursuant to subsection 10, a 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 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 health care service that is the subject of the adverse

determination or final adverse determination.

b. Within one business day after making a decision to reverse its adverse determination or final adverse 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 notice of the health carrier's decision to reverse its adverse determination or final adverse determination.

12. In addition to the documents and information provided to the independent review organization pursuant to this section, the independent review organization shall, to the extent the information or documents are available and the independent review organization considers them appropriate, consider the following in reaching a decision:

a. The covered person's pertinent medical records.

b. The treating health care professional's recommendation.

c. Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, covered person, 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 the independent review organization's decision is not contrary to the terms of coverage under the covered person's health benefit plan with the health carrier.

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

f. Any applicable clinical review criteria developed and used by the health carrier.

g. The opinion of the independent review organization's

clinical reviewer after considering the information or documents described in paragraphs *"a"* through *"f"* to the extent the information or documents are available and the clinical reviewer considers them relevant.

13. *a.* Within forty-five days after the date of receipt of a request for an external review, the independent review organization shall provide written notice of its decision to uphold or reverse the adverse determination or final adverse determination of the health carrier to the covered person or the covered person's authorized representative, the health carrier, and the commissioner.

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

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

(2) The date the independent review organization received the assignment from the commissioner to conduct the external review.

(3) The date the external review was conducted.

(4) The date of the decision.

(5) The principal reason or reasons for its decision, including what applicable evidence-based standards, if any, were a basis for its decision.

(6) The rationale for its decision.

(7) References to evidence or documentation, including evidence-based standards, considered in reaching its decision.

14. Upon receipt of notice of a decision reversing the adverse determination or final adverse determination of the health carrier, the health carrier shall immediately approve the coverage that was the subject of the determination.

Sec. 8. NEW SECTION. **514J.108 External review — expedited.**

1. Notwithstanding section 514J.107, a covered person or the covered person's authorized representative may make an oral or written request to the commissioner for an expedited external review at the time the covered person or the covered

person's authorized representative receives any of the following:

a. An adverse determination that involves a medical condition of the covered person for which the time frame for completion of an internal review of a grievance involving an adverse determination would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function.

b. A final adverse determination that involves a medical condition where the time frame for completion of a standard external review would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function.

c. A final adverse determination that concerns an admission, availability of care, continued stay, or health care service for which the covered person received emergency services, and has not been discharged from a facility.

2. *a.* Upon receipt of a request for an expedited external review, the commissioner shall immediately send written notice of the request to the health carrier.

b. Immediately upon receipt of notice of a request for expedited external review, the health carrier shall complete a preliminary review of the request to determine whether the request meets the eligibility requirements for external review set forth in section 514J.107, subsection 3, and this section.

c. The health carrier shall then 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 including a statement informing the covered person or the covered person's authorized representative of the right to appeal that determination to the commissioner.

d. 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.

3. The commissioner may determine that a request is eligible for expedited external review, notwithstanding a health carrier's initial determination that the request is not eligible. In making a 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. The commissioner shall make a determination pursuant to this subsection as expeditiously as possible.

4. *a.* Upon receipt of notice from a health carrier that a request is eligible for expedited external review or upon a determination by the commissioner that a request is eligible for expedited external review, the commissioner shall immediately assign an independent review organization from the list of approved independent review organizations maintained by the commissioner to conduct the expedited external review. The commissioner shall then immediately notify the health carrier and the covered person or the covered person's authorized representative of the name of the assigned independent review organization.

b. The assignment of an independent review organization shall be done on a random basis among those approved independent review organizations qualified to conduct the particular external review based on the nature of the health care service that is the subject of the adverse determination or final adverse determination and other circumstances, including conflict of interest concerns.

5. Upon receiving notice of the independent review organization assigned to conduct the 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.

6. The independent review organization is not bound

by any decisions or conclusions reached during the health carrier's internal grievance process. The independent review organization shall consider the documents and information provided by the health carrier, and to the extent the information or documents are available and the independent review organization considers them appropriate, shall consider the following in reaching a decision:

a. The covered person's pertinent medical records.

b. The treating health care professional's recommendation.

c. Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, 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 the independent review organization's decision is not contrary to the terms of coverage under the covered person's health benefit plan with the health carrier.

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

f. Any applicable clinical review criteria developed and used by the health carrier.

g. The opinion of the independent review organization's clinical reviewer after considering the information or documents described in paragraphs "*a*" through "*f*" to the extent the information or documents are available and the clinical reviewer considers them relevant.

7. *a.* As expeditiously as the covered person's medical condition or circumstances require, but in no event more than seventy-two hours after the date of receipt of an eligible request for expedited external review, the assigned independent

review organization shall do all of the following:

(1) Make a decision to uphold or reverse the adverse determination or final adverse determination of the health carrier.

(2) Notify the covered person or the covered person's authorized representative, the health carrier, and the commissioner of its decision.

b. If the notice given by the independent review organization pursuant to paragraph *"a"* was not in writing, within forty-eight hours after 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 that includes the information set forth in section 514J.107, subsection 13, paragraph *"b"*.

c. Upon receipt of the notice of decision by an independent review organization pursuant to paragraph *"a"* reversing the adverse determination or final adverse determination, the health carrier shall immediately approve the coverage that was the subject of the adverse determination or final adverse determination.

Sec. 9. NEW SECTION. **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 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.

Sec. 10. NEW SECTION. **514J.110 Effect of external review decision.**

1. An external review decision pursuant to this chapter is binding on the health carrier except to the extent the health carrier has other remedies available under applicable Iowa law. The external review process shall not be considered a contested case under chapter 17A.

2. *a.* A covered person or the covered person's authorized representative may appeal the external review decision made by an independent review organization by filing a petition for judicial review either in Polk county district court or in the district court in the county in which the covered person resides. The petition for judicial review must be filed within fifteen business days after the issuance of the review decision. The petition shall name the covered person or the covered person's authorized representative, or the person's health care provider as the petitioner. The respondent shall be the health carrier. The petition shall not name the independent review organization as a party.

b. The commissioner shall not be named as a respondent unless the petitioner alleges action or inaction by the commissioner under the standards articulated in section 17A.19, subsection 10. Allegations against the commissioner under section 17A.19, subsection 10, shall be stated with particularity. The commissioner may, upon motion, intervene in the judicial review proceeding. The findings of fact by the independent review organization conducting the external review are conclusive and binding on appeal.

3. The health carrier shall follow and comply with the

decision of the court on appeal. The health carrier or treating health care provider shall not be subject to any penalties, sanctions, or award of damages for following and complying in good faith with the external review decision of the independent review organization or the decision of the court on appeal.

4. The covered person or the covered person's authorized representative may bring an action in Polk county district court or in the district court in the county in which the covered person resides to enforce the external review decision of the independent review organization or the decision of the court on appeal.

5. A covered person or the covered person's authorized representative shall not file a subsequent request for external review involving any determination for which the covered person or the covered person's authorized representative has already received an external review decision.

6. If a covered person dies before the completion of the external review process, the process shall continue to completion if there is potential liability of a health carrier to the estate of the covered person.

7. *a.* If a covered person who has already received health care services under a health benefit plan requests external review of the plan's adverse determination or final adverse determination and changes to another health benefit plan before the external review process is completed, the health carrier whose coverage was in effect at the time the health care service was received is responsible for completing the external review process.

b. If a covered person who has not yet received health care services requests external review of a health benefit plan's adverse determination or final adverse determination and then changes to another plan prior to receipt of the health care services and completion of the external review process, the external review process shall begin anew with the

covered person's current health carrier. In this instance, the external review process shall be conducted as an expedited external review.

Sec. 11. NEW SECTION. **514J.111 Approval of independent review organizations.**

1. The commissioner shall approve applications submitted by independent review organizations to conduct external reviews under this chapter. The commissioner may retain an outside expert to perform reviews of such applications.

2. In order to be eligible for approval by the commissioner to conduct external reviews, an independent review organization shall meet all of the following requirements:

a. Be accredited by a nationally recognized private accrediting entity that the commissioner determines has independent review organization accreditation standards that are equivalent to or exceed the minimum qualifications for independent review organizations established in this chapter.

b. Submit an application in a form and format as directed by the commissioner.

c. Meet the minimum qualifications contained in section 514J.112.

3. The commissioner may approve independent review organizations that are not accredited by a nationally recognized private accrediting entity if there are no acceptable nationally recognized private accrediting entities providing independent review organization accreditation.

4. The commissioner shall develop an application form for initially approving and for reapproving independent review organizations to conduct external reviews.

5. The commissioner may charge an initial application fee and a renewal fee as specified by rule.

6. The approval of an independent review organization to conduct external reviews by the commissioner pursuant to this chapter is effective for two years, unless the commissioner determines that the independent review organization is not

satisfying the minimum qualifications of this chapter. If the commissioner determines that an independent review organization has lost its accreditation or no longer satisfies the minimum requirements established under this chapter, the commissioner shall terminate approval of the independent review organization to conduct external reviews and remove the independent review organization from the list of independent review organizations approved to conduct external reviews that is maintained by the commissioner.

7. The commissioner shall maintain a list of currently approved independent review organizations.

Sec. 12. NEW SECTION. **514J.112 Minimum qualifications for independent review organizations.**

1. To be approved to conduct external reviews pursuant to this chapter, an independent review organization shall have and maintain written policies and procedures that govern all aspects of both the standard external review process and the expedited external review process and that include, at a minimum, all of the following:

a. A quality assurance mechanism that does all of the following:

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

(2) Ensures the selection of qualified and impartial clinical reviewers to conduct external reviews on behalf of the independent review organization and suitable matching of reviewers to specific cases and that the independent review organization employs or contracts with an adequate number of clinical reviewers to meet this objective.

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

(4) Establishes and maintains written procedures to ensure that the independent review organization is unbiased in addition to any other procedures required under this section.

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

b. A toll-free telephone service to receive information related to external reviews twenty-four hours a day, seven days a week, that is capable of accepting, recording, or providing appropriate instruction to incoming telephone callers outside normal business hours.

c. An agreement and a system to maintain required records and provide access to those records by the commissioner.

2. Each clinical reviewer assigned by an independent review organization to conduct external reviews shall 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 or requested health care service or treatment through recent or current actual clinical experience treating patients with the same or similar medical condition as the covered person.

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 reviewer's physical, mental, or professional competence or moral character.

3. An independent review organization shall 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. Neither the independent review organization selected to conduct an external review nor any clinical reviewer assigned by the independent organization to conduct an external review shall 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 health care service or 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 professional or the health care professional'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 health care service treatment is the subject of the external review.

5. In determining whether an independent review organization or a clinical reviewer of the independent review organization has a material professional, familial, or financial conflict of interest as provided in subsection 4, the commissioner shall take into consideration situations where the independent review organization to be assigned to conduct an external review of a specified case or a clinical 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 the

characteristics of that relationship or connection are such that they do not constitute a material professional, familial, or financial conflict of interest that would prohibit selection of the independent review organization or the clinical reviewer to conduct the external review.

6. *a.* An independent review organization that is accredited by a nationally recognized private accrediting entity that has independent review accreditation standards that the commissioner has determined are equivalent to or exceed the minimum qualifications of this section shall be presumed to be in compliance with the requirements of this section.

b. The commissioner shall initially and periodically review the standards of each nationally recognized private accrediting entity that provides accreditation to independent review organizations to determine whether the accrediting entity's standards are, and continue to be, equivalent to or exceed the minimum qualifications established under this section. The commissioner may accept a review of those standards conducted by the national association of insurance commissioners for the purpose of making a determination under this subsection.

c. Upon request, a nationally recognized private accrediting entity shall make its current independent review organization accreditation standards available to the commissioner or to the national association of insurance commissioners in order for the commissioner to determine if the accrediting entity's standards are equivalent to or exceed the minimum qualifications established under this section. The commissioner may exclude consideration of accreditation of independent review organizations by any private accrediting entity whose standards have not been reviewed by the national association of insurance commissioners.

Sec. 13. NEW SECTION. **514J.113 Immunity for independent review organizations.**

An independent review organization, a clinical reviewer working on behalf of an independent review organization, or

an employee, agent, or contractor of an independent review organization shall not be liable in damages to any person for any opinions rendered or acts or omissions performed within the scope of the duties of the organization, the clinical reviewer, or an employee, agent, or contractor of the organization under this chapter during, or upon completion of, an external review conducted pursuant to this chapter, unless the opinion was rendered or the act or omission was performed in bad faith or involved gross negligence.

Sec. 14. NEW SECTION. **514J.114 External review reporting requirements.**

1. *a.* An independent review organization assigned to conduct an external review shall maintain written records in the aggregate by state and by health carrier of all requests for external review for which it conducted an external review during a calendar year.

b. Each independent review organization required to maintain written records pursuant to this section shall submit to the commissioner, upon request, a report in the format specified by the commissioner. The report shall include in the aggregate by state and by health carrier all of the following:

(1) The total number of requests for external review assigned to the independent review organization.

(2) The average length of time for resolution of each request for external review assigned to the independent review organization.

(3) A summary of the types of coverages or cases for which an external review was requested, in the format required by the commissioner by rule.

(4) Any other information required by the commissioner.

c. The independent review organization shall retain the written records for at least three years.

2. *a.* Each health carrier shall maintain written records in the aggregate by state and by type of health benefit plan offered by the health carrier of all requests for external

review that the health carrier receives notice of from the commissioner pursuant to this chapter.

b. Each health carrier required to maintain written records of requests for external review pursuant to this subsection shall submit to the commissioner, upon request, a report in the format specified by the commissioner. The report shall include in the aggregate by state and by type of health benefit plan offered all of the following:

(1) The total number of requests for external review of the health carrier's adverse determinations and final adverse determinations.

(2) Of the total number of requests for external review, the number of requests determined eligible for external review.

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

(4) The number of external reviews 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.

(5) Any other information the commissioner may request or require.

c. The health carrier shall retain the written records for at least three years.

Sec. 15. NEW SECTION. **514J.115 Expenses of external review.**

The health carrier against which a request for a standard external review or an expedited external review is filed shall pay the costs of retaining an independent review organization to conduct the external review.

Sec. 16. NEW SECTION. **514J.116 Disclosure requirements.**

1. Each health carrier shall include a description of

the external review procedures contained in this chapter in or attached to any policy, certificate, membership booklet, outline of coverage, or other evidence of coverage that is provided to a covered person. The description shall be in a format prescribed by the commissioner by rule.

2. The description required by subsection 1 shall include a statement that informs the covered person of the right of the covered person to file a request for an external review of an adverse determination or final adverse determination of the health carrier with the commissioner. The statement shall explain that external review is available when the adverse determination or final adverse determination involves an issue of medical necessity, appropriateness, health care setting, level of care, or effectiveness. The statement shall include the telephone number and address of the commissioner. The statement shall also inform the covered person that when filing a request for external review, the covered person will be required to authorize the release of any medical records of the covered person that may be required to be reviewed for the purpose of reaching a decision on the request for external review.

Sec. 17. NEW SECTION. **514J.117 Rulemaking authority.**

The commissioner may adopt rules pursuant to chapter 17A to carry out the provisions of this chapter.

Sec. 18. NEW SECTION. **514J.118 Severability.**

If any provision of this chapter, or the application of the provision to any person or circumstance is held invalid, the remainder of the chapter, and the application of the provision to persons or circumstances other than those to which it is held invalid, shall not be affected.

Sec. 19. NEW SECTION. **514J.119 Penalties.**

A person who fails to comply with the provisions of this chapter or the rules adopted pursuant to this chapter is subject to the penalties provided under chapter 507B.

Sec. 20. NEW SECTION. **514J.120 Applicability.**

1. This chapter applies to all requests for external review filed on or after July 1, 2011.

2. Section 514J.116 applies to all health benefit plans delivered, issued for delivery, continued, or renewed in this state on or after July 1, 2011.

Sec. 21. REPEAL. Sections 514J.1 through 514J.15, Code 2011, are repealed.

Sec. 22. TRANSITION PROVISION —— APPLICABILITY TO PRIOR REQUESTS. Sections 514J.1 through 514J.15, Code 2011, are applicable to all requests for external review filed prior to July 1, 2011.

EXPLANATION

This bill adds new provisions in Code chapter 514J, which provides procedures for external review of adverse determinations made by health carriers, as required by the federal Patient Protection and Affordable Care Act, as amended by the federal Health Care and Education Reconciliation Act of 2010, which amends the Public Health Service Act. The new provisions apply to all requests for external review filed on or after July 1, 2011. The bill repeals the current provisions in Code chapter 514J relating to the external review of health care coverage decisions.

An "adverse determination" is a determination by a health carrier that payment for a health care service that is a covered benefit under a health benefit plan is being denied, reduced, or terminated because the health care service does not meet the carrier's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness. A "final adverse determination" is an adverse determination involving a covered benefit that has been upheld by a health carrier at the completion of the health carrier's internal grievance process.

The bill allows a covered person under a health benefit plan or the covered person's authorized representative to request an external review of the health carrier's determination after

receiving a final adverse determination or sooner, after receiving an adverse determination, if the covered person has a medical condition where the time frame for completion of that internal review would jeopardize the person's life or health or ability to regain maximum function, or the adverse determination is that the requested health care service is experimental or investigational and the effectiveness of the treatment will be significantly less effective if not promptly initiated. The bill provides procedures for a standard external review or an expedited external review.

Pursuant to a request for standard external review, the health carrier must complete a preliminary review to determine if the request is eligible for external review as specified in the bill and report to the commissioner of insurance and the covered person. Even if the health carrier determines that the request is ineligible, the commissioner of insurance may determine that the request is eligible for review.

Once a request is determined to be eligible for review, the commissioner is required to assign an independent review organization to conduct the external review of the adverse or final adverse determination of the health carrier. During the review, the carrier may reconsider its adverse or final adverse determination and provide the coverage requested. If this does not occur, the independent review organization selects clinical reviewers to consider all pertinent information and within 45 days of receiving the request for external review, the independent review organization must provide written notice of its decision to uphold or reverse the adverse or final adverse determination of the carrier. Upon receipt of a decision of reversal, the carrier must approve the coverage that was the subject of the adverse or final adverse determination.

The bill also provides a similar procedure for expedited external review of an adverse or final adverse determination that involves a medical condition of the covered person for which the time frame for completion of the internal review

by the health carrier or a standard external review would seriously jeopardize the life or health or the ability to regain maximum function of the covered person. The expedited external review procedures provide that a request for expedited external review can be made by a covered person orally, and shortens the required time frames for action by the health carrier, the commissioner, and the independent review organization in responding to the request and reaching a decision.

The bill provides separate procedures for standard and expedited external reviews of adverse determinations or final adverse determinations involving experimental or investigational treatment. In a standard external review, if an independent review organization selects multiple clinical reviewers to review the request, the organization must make a decision to uphold or reverse an adverse or final adverse determination of a health carrier based on the opinion of a majority of the clinical reviewers.

The bill allows a covered person or the covered person's authorized representative to appeal the external review decision made by an independent review organization by filing a petition for judicial review in Polk county district court or in the district court in the county where the covered person resides. Findings of fact made by an independent review organization are conclusive and binding on appeal. A covered person or the covered person's authorized representative may also bring an action in district court to enforce an external review decision against a carrier.

The bill includes requirements for the qualifications of an independent review organization to be listed as eligible for selection by the commissioner to conduct an external review.

The bill provides that independent review organizations and clinical reviewers are not liable in damages for any opinions rendered in furtherance of their duties under this new division unless rendered in bad faith or with gross negligence.

Independent review organizations and health carriers are required to keep specified records about external review requests involving them. The expense of retaining an independent review organization to conduct an external review is assessed against the health carrier whose adverse or final adverse determination is being reviewed.

External review procedures must be disclosed by health carriers by including or attaching them to the policies, certificates, membership booklets, outline of coverage, or other evidence of coverage that is provided to covered persons. This disclosure requirement applies to all health benefit plans delivered, issued for delivery, continued, or renewed on or after July 1, 2011.

The commissioner of insurance has the authority to adopt rules to carry out the provisions of the new division and the provisions of the new division are severable if held invalid.