TERRY E. BRANSTAD
GOVERNOR

OFFICE OF THE GOVERNOR

KIM REYNOLDS
LT. GOVERNOR

April 28, 2011

The Honorable Matthew Schultz
Secretary of State of Iowa
State Capitol Building
LOCAL

Dear Mr. Secretary:

I hereby transmit:

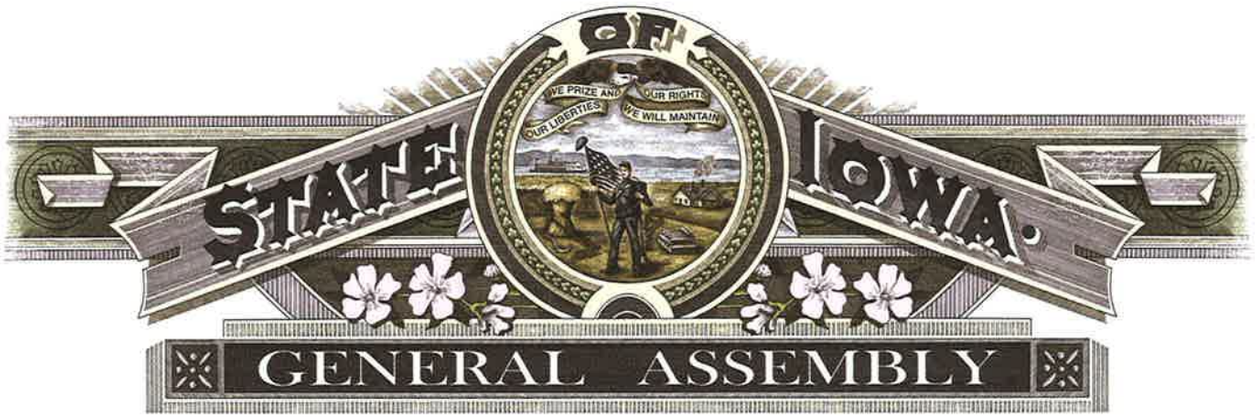
House File 597, an Act creating new procedures for external review of health care coverage decisions by health carriers and including transition and applicability provisions.

The above House File is hereby approved this date.

Sincerely,

Terry E. Branstad
Governor

cc: Secretary of the Senate
Clerk of the House



House File 597

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.

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, the covered person may file a request for external review pursuant to section 514J.109. In addition, if 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 pursuant to section 514J.109, subsection 18.

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