

ACT 230

S.B. NO. 1274

A Bill for an Act Relating to Health Insurance.

Be It Enacted by the Legislature of the State of Hawaii:

SECTION 1. The legislature finds that the purpose of this Act is to comply with the requirements of the Patient Protection and Affordable Care Act of 2010, Public Law No. 111-148, and its implementing regulations by updating Hawaii's Patients' Bill of Rights and Responsibilities Act, chapter 432E, Hawaii Revised Statutes, to conform to the requirements of the federal law.

SECTION 2. Chapter 432E, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

**“PART . EXTERNAL REVIEW OF HEALTH
INSURANCE DETERMINATIONS**

§432E-A Applicability and scope. (a) Except as provided in subsection (b), this part shall apply to all health carriers.

(b) This part shall not apply to a policy or certificate that provides coverage only for a specified disease, specified accident or accident-only coverage,

credit, dental, disability income, hospital indemnity, long-term care insurance, vision care, or any other limited supplemental benefit; to a medicare supplemental policy of insurance, coverage under a plan through medicare, medicaid, or the federal employees health benefits program, any federal medical and dental care coverage issued under chapter 55 of Title 10 United States Code and any coverage issued as supplemental to that coverage; any coverage issued as supplemental to liability insurance, workers' compensation, or similar insurance; automobile medical-payment insurance; any insurance under which benefits are payable with or without regard to fault, whether written on a group blanket or individual basis; or the employer union health benefits trust fund so long as it is self-funded.

§432E-B Notice of right to external review. Notice of the right to external review issued pursuant to this part shall set forth the options available to the enrollee under this part. The commissioner may specify the form and content of notice of external review.

§432E-C Request for external review. (a) All requests for external review of a health carrier's adverse action shall be made in writing to the commissioner and shall include:

- (1) A copy of the final internal determination of the health carrier, unless exempted pursuant to subsection (b);
- (2) A signed authorization by or on behalf of the enrollee for release of the enrollee's medical records relevant to the external review;
- (3) A disclosure for conflict of interests evaluation, as provided in section 432E-M; and
- (4) A filing fee of \$15, which shall be deposited into the compliance resolution fund established pursuant to section 26-9(o); provided that the filing fee shall be refunded if the adverse determination or final internal adverse determination is reversed through external review.

The commissioner shall waive the filing fee required by this subsection if the commissioner determines that payment of the fee would impose an undue financial hardship to the enrollee. The annual aggregate limit on filing fees for any enrollee within a single plan year shall not exceed \$60.

(b) The internal appeals process of a health carrier shall be completed before an external review request shall be submitted to the commissioner except in the following circumstances:

- (1) The health carrier has waived the requirement of exhaustion of the internal appeals process;
- (2) The enrollee has applied for an expedited external review at the same time that the enrollee applied for an expedited internal appeal; provided that the enrollee is eligible for an expedited external review; or
- (3) The health carrier has substantially failed to comply with its internal appeals process.

§432E-D Standard external review. (a) An enrollee or the enrollee's appointed representative may file a request for an external review with the commissioner within one hundred thirty days of receipt of notice of an adverse action. Within three business days after the receipt of a request for external review pursuant to this section, the commissioner shall send a copy of the request to the health carrier.

(b) Within five business days following the date of receipt of the copy of the external review request from the commissioner pursuant to subsection (a), the health carrier shall determine whether:

- (1) The individual is or was an enrollee in the health benefit plan at the time the health care service was requested or, in the case of a retrospective review, was an enrollee in the health benefit plan at the time the health care service was provided;
- (2) The health care service that is the subject of the adverse determination or the final adverse determination would be a covered service under the enrollee's health benefit plan but for a determination by the health carrier that the health care service does not meet the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness;
- (3) The enrollee has exhausted the health carrier's internal appeals process or the enrollee is not required to exhaust the health carrier's internal appeals process pursuant to section 432E-C(b); and
- (4) The enrollee has provided all the information and forms required to process an external review, including a completed release form and disclosure form as required by section 432E-C(a).

(c) Within three business days after a determination of an enrollee's eligibility for external review pursuant to subsection (b), the health carrier shall notify the commissioner, the enrollee, and the enrollee's appointed representative in writing as to whether the request is complete and whether the enrollee is eligible for external review.

If the request for external review submitted pursuant to this section is not complete, the health carrier shall inform the commissioner, the enrollee, and the enrollee's appointed representative in writing that the request is incomplete and shall specify the information or materials required to complete the request.

If the enrollee is not eligible for external review pursuant to subsection (b), the health carrier shall inform the commissioner, the enrollee, and the enrollee's appointed representative in writing that the enrollee is not eligible for external review and the reasons for ineligibility.

Notice of ineligibility for external review pursuant to this section shall include a statement informing the enrollee and the enrollee's appointed representative that a health carrier's initial determination that the external review request is ineligible for review may be appealed to the commissioner by submission of a request to the commissioner.

(d) Upon receipt of a request for appeal pursuant to subsection (c), the commissioner shall review the request for external review submitted by the enrollee pursuant to subsection (a), determine whether an enrollee is eligible for external review and, if eligible, shall refer the enrollee to external review. The commissioner's determination of eligibility for external review shall be made in accordance with the terms of the enrollee's health benefit plan and all applicable provisions of this part. If an enrollee is not eligible for external review, the commissioner shall notify the enrollee, the enrollee's appointed representative, and the health carrier within three business days of the reason for ineligibility.

(e) When the commissioner receives notice pursuant to subsection (c) or makes a determination pursuant to subsection (d) that an enrollee is eligible for external review, within three business days after receipt of the notice or determination of eligibility, the commissioner shall:

- (1) Randomly assign an independent review organization from the list of approved independent review organizations qualified to conduct the external review, based on the nature of the health care service that is the subject of the adverse action and other factors deter-

mined by the commissioner including conflicts of interest pursuant to section 432E-M, compiled and maintained by the commissioner to conduct the external review and notify the health carrier of the name of the assigned independent review organization; and

- (2) Notify the enrollee and the enrollee's appointed representative, in writing, of the enrollee's eligibility and acceptance for external review.

(f) An enrollee or an enrollee's appointed representative may submit additional information in writing to the assigned independent review organization for consideration in its external review. The independent review organization shall consider information submitted within five business days following the date of the enrollee's receipt of the notice provided pursuant to subsection (e). The independent review organization may accept and consider additional information submitted by an enrollee or an enrollee's appointed representative after five business days.

(g) Within five business days after the date of receipt of notice pursuant to subsection (e), the health carrier or its designated utilization review organization shall provide to the assigned independent review organization all documents and information it considered in issuing the adverse action that is the subject of external review. Failure by the health carrier or its utilization review organization to provide the documents and information within five business days shall not delay the conduct of the external review; provided that the assigned independent review organization may terminate the external review and reverse the adverse action that is the subject of the external review. The independent review organization shall notify the enrollee, the enrollee's appointed representative, the health carrier, and the commissioner within three business days of the termination of an external review and reversal of an adverse action pursuant to this subsection.

(h) The assigned independent review organization shall, within one business day of receipt by the independent review organization, forward all information received from the enrollee pursuant to subsection (f) to the health carrier. Upon receipt of information forwarded to it pursuant to this subsection, a health carrier may reconsider the adverse action that is the subject of the external review; provided that reconsideration by the health carrier shall not delay or terminate an external review unless the health carrier reverses its adverse action and provides coverage or payment for the health care service that is the subject of the adverse action. The health carrier shall notify the enrollee, the enrollee's appointed representative, the assigned independent review organization, and the commissioner in writing of its decision to reverse its adverse action within three business days of making its decision to reverse the adverse action and provide coverage. The assigned independent review organization shall terminate its external review upon receipt of notice pursuant to this subsection from the health carrier.

(i) In addition to the documents and information provided pursuant to subsections (f) and (g), the assigned independent review organization shall consider the following in reaching a decision:

- (1) The enrollee's medical records;
- (2) The attending health care professional's recommendation;
- (3) Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, enrollee, enrollee's appointed representatives, or enrollee's treating provider;
- (4) The application of medical necessity as defined in section 432E-1;
- (5) The most appropriate practice guidelines, which shall include applicable evidence-based standards and may include any practice

- guidelines developed by the federal government or national or professional medical societies, boards, and associations;
- (6) Any applicable clinical review criteria developed and used by the health carrier or its designated utilization review organization; and
 - (7) The opinion of the independent review organization's clinical reviewer or reviewers pertaining to the information enumerated in paragraphs (1) through (5) to the extent the information or documents are available and the clinical reviewer or reviewers consider appropriate.

In reaching a decision, the assigned independent review organization shall not be bound by any decisions or conclusions reached during the health carrier's utilization review or internal appeals process; provided that the independent review organization's decision shall not contradict the terms of the enrollee's health benefit plan or this part.

(j) Within forty-five days after it receives a request for an external review pursuant to subsection (e), the assigned independent review organization shall notify the enrollee, the enrollee's appointed representative, the health carrier, and the commissioner of its decision to uphold or reverse the adverse action that is the subject of the internal review. The independent review organization shall include in the notice of its decision:

- (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 the decision was issued; and
- (5) The basis for the independent review organization's decision, including its reasoning, rationale, and the supporting evidence or documentation, including evidence-based standards, that the independent review organization considered in reaching its decision.

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

§432E-E Expedited external review. (a) Except as provided in subsection (i), an enrollee or the enrollee's appointed representative may request an expedited external review with the commissioner if the enrollee receives:

- (1) An adverse determination that involves a medical condition of the enrollee for which the timeframe for completion of an expedited internal appeal would seriously jeopardize the enrollee's life, health, or ability to gain maximum functioning or would subject the enrollee to severe pain that cannot be adequately managed without the care or treatment that is the subject of the adverse determination;
- (2) A final adverse determination if the enrollee has a medical condition where the timeframe for completion of a standard external review would seriously jeopardize the enrollee's ability to gain maximum functioning, or would subject the enrollee to severe pain that cannot be adequately managed without the care or treatment that is the subject of the adverse determination; or
- (3) A final adverse determination if the final adverse determination concerns an admission, availability of care, continued stay, or health care service for which the enrollee received emergency services; provided that the enrollee has not been discharged from a facility for health care services related to the emergency services.

(b) Upon receipt of a request for an expedited external review, the commissioner shall immediately send a copy of the request to the health carrier. Immediately upon receipt of the request, the health carrier shall determine whether the request meets the reviewability requirements set forth in subsection (a). The health carrier shall immediately notify the enrollee or the enrollee's appointed representative of its determination of the enrollee's eligibility for expedited external review.

Notice of ineligibility for expedited external review shall include a statement informing the enrollee and the enrollee's appointed representative that a health carrier's initial determination that an external review request that is ineligible for review may be appealed to the commissioner by submission of a request to the commissioner.

(c) Upon receipt of a request for appeal pursuant to subsection (b), the commissioner shall review the request for expedited external review submitted pursuant to subsection (a) and, if eligible, shall refer the enrollee for external review. The commissioner's determination of eligibility for expedited external review shall be made in accordance with the terms of the enrollee's health benefit plan and all applicable provisions of this part. If an enrollee is not eligible for expedited external review, the commissioner shall immediately notify the enrollee, the enrollee's appointed representative, and the health carrier of the reasons for ineligibility.

(d) If the commissioner determines that an enrollee is eligible for expedited external review even though the enrollee has not exhausted the health carrier's internal review process, the health carrier shall not be required to proceed with its internal review process. The health carrier may elect to proceed with its internal review process even though the request is determined by the commissioner to be eligible for expedited external review; provided that the internal review process shall not delay or terminate an expedited external review unless the health carrier decides to reverse its adverse determination and provide coverage or payment for the health care service that is the subject of the adverse determination. Immediately after making a decision to reverse its adverse determination, the health carrier shall notify the enrollee, the enrollee's authorized representative, the independent review organization assigned pursuant to subsection (c), and the commissioner in the writing of its decision. The assigned independent review organization shall terminate the expedited external review upon receipt of notice from the health carrier pursuant to this subsection.

(e) Upon receipt of the notice pursuant to subsection (a) or a determination of the commissioner pursuant to subsection (c) that the enrollee meets the eligibility requirements for expedited external review, the commissioner shall immediately randomly assign an independent review organization to conduct the expedited external review from the list of approved independent review organizations qualified to conduct the external review, based on the nature of the health care service that is the subject of the adverse action and other factors determined by the commissioner including conflicts of interest pursuant to section 432E-M, compiled and maintained by the commissioner to conduct the external review and immediately notify the health carrier of the name of the assigned independent review organization.

(f) Upon receipt of the notice from the commissioner of the name of the independent review organization assigned to conduct the expedited external review, the health carrier or its designee utilization review organization shall provide or transmit all documents and information it considered in making the adverse action that is the subject of the expedited external review to the assigned independent review organization electronically or by telephone, facsimile, or any other available expeditious method.

(g) In addition to the documents and information provided or transmitted pursuant to subsection (f), the assigned independent review organization shall consider the following in reaching a decision:

- (1) The enrollee's pertinent medical records;
- (2) The attending health care professional's recommendation;
- (3) Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, enrollee, the enrollee's appointed representative, or the enrollee's treating provider;
- (4) The application of medical necessity criteria as defined in section 432E-1;
- (5) The most appropriate practice guidelines, which shall include evidence-based standards, and may include any other practice guidelines developed by the federal government, national or professional medical societies, boards, and associations;
- (6) Any applicable clinical review criteria developed and used by the health carrier or its designee utilization review organization in making adverse determinations; and
- (7) The opinion of the independent review organization's clinical reviewer or reviewers pertaining to the information enumerated in paragraphs (1) through (5) to the extent the information and documents are available and the clinical reviewer or reviewers consider appropriate.

In reaching a decision, the assigned independent review organization shall not be bound by any decisions or conclusions reached during the health carrier's utilization review or internal appeals process; provided that the independent review organization's decision shall not contradict the terms of the enrollee's health benefit plan or this part.

(h) As expeditiously as the enrollee's medical condition or circumstances requires, but in no event more than seventy-two hours after the date of receipt of the request for an expedited external review that meets the reviewability requirements set forth in subsection (a), the assigned independent review organization shall:

- (1) Make a decision to uphold or reverse the adverse action; and
- (2) Notify the enrollee, the enrollee's appointed representative, the health carrier, and the commissioner of the decision.

If the notice provided pursuant to this subsection was not in writing, within forty-eight hours after the date of providing that notice, the assigned independent review organization shall provide written confirmation of the decision to the enrollee, the enrollee's appointed representative, the health carrier, and the commissioner that includes the information provided in section 432E-G.

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

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

§432E-F External review of experimental or investigational treatment adverse determinations. (a) An enrollee or an enrollee's appointed representative may file a request for an external review with the commissioner within one hundred thirty days of receipt of notice of an adverse action that involves a denial of coverage based on a determination that the health care service or treatment recommended or requested is experimental or investigational.

(b) An enrollee or the enrollee's appointed representative may make an oral request for an expedited external review of the adverse action if the en-

rollee's treating physician certifies, in writing, that the health care service or treatment that is the subject of the request would be significantly less effective if not promptly initiated. A written request for an expedited external review pursuant to this subsection shall include, and oral request shall be promptly followed by, a certification signed by the enrollee's treating physician and the authorization for release and disclosures required by section 432E-C. Upon receipt of all items required by this subsection, the commissioner shall immediately notify the health carrier.

(c) Upon notice of the request for expedited external review, the health carrier shall immediately determine whether the request meets the requirements of subsection (b). The health carrier shall immediately notify the commissioner, the enrollee, and the enrollee's appointed representative of its eligibility determination.

Notice of eligibility for expedited external review pursuant to this subsection shall include a statement informing the enrollee and, if applicable, the enrollee's appointed representative that a health carrier's initial determination that the external review request is ineligible for review may be appealed to the commissioner.

(d) Upon receipt of a request for appeal pursuant to subsection (c), the commissioner shall review the request for external review submitted by the enrollee pursuant to subsection (a), determine whether an enrollee is eligible for external review and, if eligible, shall refer the enrollee to external review. The commissioner's determination of eligibility for external review shall be made in accordance with the terms of the enrollee's health benefit plan and all applicable provisions of this part. If an enrollee is not eligible for external review, the commissioner shall notify the enrollee, the enrollee's appointed representative, and the health carrier of the reason for ineligibility within three business days.

(e) Upon receipt of the notice pursuant to subsection (a) or a determination of the commissioner pursuant to subsection (d) that the enrollee meets the eligibility requirements for expedited external review, the commissioner shall immediately randomly assign an independent review organization to conduct the expedited external review from the list of approved independent review organizations qualified to conduct the external review, based on the nature of the health care service that is the subject of the adverse action and other factors determined by the commissioner including conflicts of interest pursuant to section 432E-M, compiled and maintained by the commissioner to conduct the external review and immediately notify the health carrier of the name of the assigned independent review organization.

(f) Upon receipt of the notice from the commissioner of the name of the independent review organization assigned to conduct the expedited external review, the health carrier or its designee utilization review organization shall provide or transmit all documents and information it considered in making the adverse action that is the subject of the expedited external review to the assigned independent review organization electronically or by telephone, facsimile, or any other available expeditious method.

(g) Except for a request for an expedited external review made pursuant to subsection (b), within three business days after the date of receipt of the request, the commissioner shall notify the health carrier that the enrollee has requested an expedited external review pursuant to this section. Within five business days following the date of receipt of notice, the health carrier shall determine whether:

- (1) The individual is or was an enrollee in the health benefit plan at the time the health care service or treatment was recommended or requested or, in the case of a retrospective review, was an enrollee

- in the health benefit plan at the time the health care service or treatment was provided;
- (2) The recommended or requested health care service or treatment that is the subject of the adverse action:
 - (A) Would be a covered benefit under the enrollee's health benefit plan but for the health carrier's determination that the service or treatment is experimental or investigational for the enrollee's particular medical condition; and
 - (B) Is not explicitly listed as an excluded benefit under the enrollee's health benefit plan;
 - (3) The enrollee's treating physician has certified in writing that:
 - (A) Standard health care services or treatments have not been effective in improving the condition of the enrollee;
 - (B) Standard health care services or treatments are not medically appropriate for the enrollee; or
 - (C) There is no available standard health care service or treatment covered by the health carrier that is more beneficial than the health care service or treatment that is the subject of the adverse action;
 - (4) The enrollee's treating physician:
 - (A) Has recommended a health care service or treatment that the physician certifies, in writing, is likely to be more beneficial to the enrollee, in the physician's opinion, than any available standard health care services or treatments; or
 - (B) Who is a licensed, board certified or board eligible physician qualified to practice in the area of medicine appropriate to treat the enrollee's condition, has certified in writing that scientifically valid studies using accepted protocols demonstrate that the health care service or treatment that is the subject of the adverse action is likely to be more beneficial to the enrollee than any available standard health care services or treatments;
 - (5) The enrollee has exhausted the health carrier's internal appeals process or the enrollee is not required to exhaust the health carrier's internal appeals process pursuant to section 432E-C(b); and
 - (6) The enrollee has provided all the information and forms required by the commissioner that are necessary to process an external review, including the release form and disclosure of conflict of interest information as provided under section 432E-5.
 - (h) Within three business days after determining the enrollee's eligibility for external review pursuant to subsection (g), the health carrier shall notify the commissioner, the enrollee, and the enrollee's appointed representative in writing as to whether the request is complete and eligible for external review.

If the request is not complete, the health carrier shall inform the commissioner, the enrollee, and the enrollee's appointed representative in writing of the information or materials needed to complete the request.

If the enrollee is not eligible for external review pursuant to subsection (g), the health carrier shall inform the commissioner, the enrollee, and the enrollee's appointed representative in writing of the ineligibility and the reasons for ineligibility.

Notice of ineligibility pursuant to this subsection shall include a statement informing the enrollee and the enrollee's appointed representative that a health carrier's initial determination that the external review request is ineligible for review may be appealed to the commissioner by submitting a request to the commissioner.

If a request for external review is determined eligible for external review, the health carrier shall notify the commissioner and the enrollee and, if applicable, the enrollee's appointed representative.

(i) Upon receipt of a request for appeal pursuant to subsection (h), the commissioner shall review the request for external review submitted pursuant to subsection (a) and, if eligible, shall refer the enrollee for external review. The commissioner's determination of eligibility for expedited external review shall be made in accordance with the terms of the enrollee's health benefit plan and all applicable provisions of this part. If an enrollee is not eligible for external review, the commissioner shall notify the enrollee, the enrollee's appointed representative, and the health carrier of the reasons for ineligibility within three business days.

(j) When the commissioner receives notice pursuant to subsection (h) or makes a determination pursuant to subsection (i) that an enrollee is eligible for external review, within three business days after receipt of the notice or determination of eligibility, the commissioner shall:

- (1) Randomly assign an independent review organization from the list of approved independent review organizations qualified to conduct the external review, based on the nature of the health care service that is the subject of the adverse action and other factors determined by the commissioner including conflicts of interest pursuant to section 432E-M, compiled and maintained by the commissioner pursuant to conduct the external review and notify the health carrier of the name of the assigned independent review organization; and
- (2) Notify the enrollee and the enrollee's appointed representative, in writing, of the enrollee's eligibility and acceptance for external review.

(k) An enrollee or an enrollee's appointed representative may submit additional information in writing to the assigned independent review organization for consideration in its external review. The independent review organization shall consider information submitted within five business days following the date of the enrollee's receipt of the notice provided pursuant to subsection (j). The independent review organization may accept and consider additional information submitted by an enrollee after five business days.

(l) Within five business days after the date of receipt of notice pursuant to subsection (j), the health carrier or its designated utilization review organization shall provide to the assigned independent review organization all documents and information it considered in issuing the adverse action that is the subject of external review. Failure by the health carrier or its utilization review organization to provide the documents and information within five business days shall not delay the conduct of the external review; provided that the assigned independent review organization may terminate the external review and reverse the adverse action that is the subject of the external review. The independent review organization shall notify the enrollee, the enrollee's appointed representative, the health carrier, and the commissioner within three business days of the termination of an external review and reversal of an adverse action pursuant to this subsection.

(m) Within three business days after the receipt of the notice of assignment to conduct the external review pursuant to subsection (j), the assigned independent review organization shall:

- (1) Select one or more clinical reviewers who each shall be a physician or other health care professional who meets the minimum qualifications described in section 432E-I and, through clinical experience in

the past three years, is an expert in the treatment of the enrollee's condition and knowledgeable about the recommended or requested health care service or treatment to conduct the external review; provided that neither the enrollee, the enrollee's appointed representative, nor the health carrier shall choose or control the choice of the physicians or other health care professionals to be selected to conduct the external review; and

- (2) Based on the written opinion of the clinical reviewer, or opinions if more than one clinical reviewer has been selected, to the assigned independent review organization on whether the recommended or requested health care service or treatment should be covered, make a determination to uphold or reverse the adverse action.

In reaching an opinion, the clinical reviewers are not bound by any decisions or conclusions reached during the health carrier's utilization review process or internal appeals process.

Each clinical reviewer selected pursuant to this subsection shall review all of the information and documents received pursuant to subsection (l) and any other information submitted in writing by the enrollee or the enrollee's authorized representative pursuant to this subsection.

(n) The assigned independent review organization, within one business day of receipt by the independent review organization, shall forward all information received from the enrollee pursuant to subsection (k) to the health carrier. Upon receipt of information forwarded to it pursuant to this subsection, a health carrier may reconsider the adverse action that is the subject of the external review; provided that reconsideration by the health carrier shall not delay or terminate an external review unless the health carrier reverses its adverse action and provides coverage or payment for the health care service that is the subject of the adverse action. The health carrier shall notify the enrollee, the enrollee's appointed representative, the assigned independent review organization, and the commissioner in writing of its decision to reverse its adverse action and within three business days of making its decision to reverse the adverse action and provide coverage. The assigned independent review organization shall terminate its external review upon receipt of notice pursuant to this subsection from the health carrier.

(o) Except as provided in subsection (p), within twenty days after being selected to conduct the external review, a clinical reviewer shall provide an opinion to the assigned independent review organization pursuant to subsection (q) regarding whether the recommended or requested health care service or treatment subject to an appeal pursuant to this section shall be covered.

The clinical reviewers' opinion shall be in writing and shall include:

- (1) A description of the enrollee'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 more likely than not to be more beneficial to the enrollee than any available standard health care services or treatments and whether 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, as that term is defined in section 432E-1.4, considered in reaching the opinion;
- (4) A description and analysis of any medical necessity criteria defined in section 432E-1; and

- (5) Information on whether the reviewer's rationale for the opinion is based on approval of the health care service or treatment by the federal Food and Drug Administration for the condition or medical or scientific evidence or evidence-based standards that demonstrate that the expected benefits of the recommended or requested health care service or treatment is likely to be more beneficial to the enrollee than any available standard health care services or treatments 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.

(p) Notwithstanding the requirements of subsection (o), in an expedited external review, the clinical reviewer shall provide an opinion orally or in writing to the assigned independent review organization as expeditiously as the enrollee's medical condition or circumstances require, but in no event more than five calendar days after being selected in accordance with subsection (m).

If the opinion provided pursuant to this subsection 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 the information required under subsection (o).

(q) In addition to the documents and information provided pursuant to subsection (b) or (l), a clinical reviewer may consider the following in reaching an opinion pursuant to subsection (o):

- (1) The enrollee's pertinent medical records;
- (2) The attending physician's or health care professional's recommendation;
- (3) Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, enrollee, the enrollee's appointed representative, or the enrollee's treating physician or health care professional; and
- (4) Whether:
 - (A) The recommended health care service or treatment has been approved by the federal Food and Drug Administration, if applicable, for the condition; or
 - (B) Medical or scientific evidence or evidence-based standards demonstrate that the expected benefits of the recommended or requested health care service or treatment is more likely than not to be beneficial to the enrollee 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;

provided that the independent review organization's decision shall not contradict the terms of the enrollee's health benefit plan or the provisions of this chapter.

(r) Except as provided in subsection (s), within twenty days after the date it receives the opinion of the clinical reviewer pursuant to subsection (o), the assigned independent review organization, in accordance with subsection (t), shall determine whether the health care service at issue in an external review pursuant to this section shall be a covered benefit and shall notify the enrollee, the enrollee's appointed representative, the health carrier, and the commissioner of its determination. The independent review organization shall include in the notice of its decision:

- (1) A general description of the reason for the request for 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 external review;
- (4) The date the external review was conducted;
- (5) The date the decision was issued;
- (6) The principal reason or reasons for its decision; and
- (7) The rationale for its decision.

Upon receipt of a notice of a decision reversing the adverse action, the health carrier immediately shall approve coverage of the recommended or requested health care service or treatment that was the subject of the adverse action.

(s) For an expedited external review, within forty-eight hours after the date it receives the opinion of each clinical reviewer, the assigned independent review organization, in accordance with subsection (t), shall make a decision and provide notice of the decision orally or in writing to the enrollee, the enrollee's appointed representative, the health carrier, and the commissioner.

If the notice provided was not in writing, within forty-eight hours after the date of providing that notice, the assigned independent review organization shall provide written confirmation of the decision to the enrollee, the enrollee's appointed representative, the health carrier, and the commissioner.

(t) If a majority of the clinical reviewers recommends 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.

If a majority of the clinical reviewers recommends 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.

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

§432E-G Binding nature of external review decision. (a) An external review decision shall be binding on the health carrier and the enrollee except to the extent that the health carrier or the enrollee has other remedies available under applicable federal or state law.

(b) An enrollee or the enrollee's appointed representative shall not file a subsequent request for external review involving the same adverse action for which the enrollee has already received an external review decision pursuant to this part.

§432E-H Approval of independent review organizations. (a) An independent review organization shall be approved by the commissioner in order to be eligible to be assigned to conduct external reviews under this part.

(b) To be eligible for approval by the commissioner to conduct external reviews under this part an independent review organization shall:

- (1) Submit an application on a form required by the commissioner and include all documentation and information necessary for the commissioner to determine if the independent review organization satisfies the minimum qualifications established under this part; and
- (2) Except as otherwise provided in subsection (c), shall be accredited by a nationally-recognized private accrediting entity that the commissioner has determined has independent review organization accreditation standards that are equivalent to or exceed the minimum standards established by this section and section 432E-I.

(c) 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.

(d) The commissioner may charge an application fee that the independent review organizations shall submit to the commissioner with an application for approval and re-approval.

(e) Approval pursuant to this section is effective for two years, unless the commissioner determines before its expiration that the independent review organization does not meet the minimum qualifications established under this part. If the commissioner determines that an independent review organization has lost its accreditation or no longer satisfies the minimum requirements of this part, the commissioner shall terminate the approval of the independent review organization and remove the independent review organization from the list of independent review organizations approved to conduct external reviews maintained by the commissioner.

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

§432E-I Minimum qualifications for independent review organizations.

(a) To be eligible for approval under this part to conduct external reviews, 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 set forth in this part that include, at minimum:

- (1) A quality assurance mechanism in place that ensures:
 - (A) That external reviews are conducted within the specified time frames of this part and required notices are provided in a timely manner;
 - (B) 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; provided that an independent review organization shall employ or contract with an adequate number of clinical reviewers to meet this objective;
 - (C) Confidentiality of medical and treatment records and clinical review criteria; and
 - (D) That any person employed by or under contract with the independent review organization complies with the requirements of this part;
- (2) Toll-free telephone, facsimile, and email capabilities to receive information related to external reviews twenty-four hours a day, seven days per week that are capable of accepting, recording, or providing

appropriate instruction to incoming telephone callers during other than normal business hours and facilitating necessary communication under this part; and

(3) An agreement to maintain and provide to the commissioner the information required by this part.

(b) Each clinical reviewer assigned by an independent review organization to conduct an external review shall be a physician or other appropriate health care provider who:

(1) Is an expert in the treatment of the medical condition that is the subject of the external review;

(2) Is knowledgeable about the recommended health care service and treatment through recent or current actual clinical experience treating patients with the same or similar medical condition at issue in the external review;

(3) Holds a non-restricted 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; and

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

(c) 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 over a health carrier, 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.

(d) To be eligible to conduct an external review of a specified case, neither the independent review organization selected to conduct the external review nor any clinical reviewer assigned by the independent review organization to conduct the external review shall have a material professional, familial, or financial conflict of interest with any of the following:

(1) The health carrier that is the subject of the external review;

(2) The enrollee whose treatment is the subject of the external review, the enrollee's appointed representative, or the enrollee's immediate family;

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

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

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

(6) The developer or manufacturer of the principal drug, device, procedure, or other therapy recommended for the enrollee whose treatment is the subject of the external review; or

(7) The health benefit plan that is the subject of the external review, the plan administrator, or any fiduciary or employee of the plan.

The commissioner may determine that no material professional, familial, or financial conflict of interest exists based on the specific characteristics of a particular relationship or connection that creates an apparent professional, familial, or financial conflict of interest.

(e) 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 this section to be eligible for approval under this part.

The commissioner shall review, initially upon approval of an accredited independent review organization and periodically during the time that the independent review organization remains approved pursuant to this section, the accreditation standards of the nationally-recognized private accrediting entity to determine whether the entity's standards are, and continue to be equivalent to, or exceed the minimum qualifications established under this section; provided that a review conducted by the National Association of Insurance Commissioners shall satisfy the requirements of this section.

Upon request of the commissioner, a nationally-recognized private accrediting entity shall make its current independent review organization accreditation standards available to the commissioner or the National Association of Insurance Commissioners in order for the commissioner to determine if the entity's standards are equivalent to or exceed the minimum qualifications established under this section. The commissioner may exclude any private accrediting entity that is not reviewed by the National Association of Insurance Commissioners.

(f) An independent review organization shall establish and maintain written procedures to ensure that it is unbiased in addition to any other procedures required under this section.

§432E-J Hold harmless for independent review organizations. No independent review organization or clinical reviewer working on behalf of an independent review organization or an employee, agent, or contractor of an independent review organization shall be liable in damages to any person for any opinions rendered or acts or omissions performed within the scope of the organization's or person's duties under the law during or upon completion of an external review conducted pursuant to this part, unless the opinion was rendered or the act or omission was performed in bad faith or involved gross negligence.

§432E-K External review reporting requirements. (a) An independent review organization assigned pursuant to this part to conduct an external review shall maintain written records in the aggregate by state and by health carrier on all requests for external review for which it conducted an external review during a calendar year and upon request shall submit a report to the commissioner, as required under subsection (b).

(b) Each independent review organization required to maintain written records on all requests for external review pursuant to subsection (a) for which it was assigned to conduct an external review 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 for each health carrier:

- (1) The total number of requests for external review;
- (2) The number of requests for external review resolved and, of those resolved, the number resolved upholding the adverse action and the number resolved reversing the adverse action;
- (3) The average length of time for resolution;
- (4) The summary of the types of coverages or cases for which an external review was sought, as provided in the format required by the commissioner;

- (5) The number of external reviews that were terminated as the result of a reconsideration by the health carrier of its adverse action after the receipt of additional information from the enrollee or the enrollee's appointed representative; and
- (6) Any other information the commissioner may request or require.

The independent review organization shall retain the written records required pursuant to this subsection for at least three years.

(c) Each health carrier shall maintain written records in the aggregate, by state and for each type of health benefit plan offered by the health carrier on all requests for external review that the health carrier receives notice of from the commissioner pursuant to this part.

Each health carrier required to maintain written records on all requests for external review shall submit to the commissioner, upon request, a report in the format specified by the commissioner that includes in the aggregate, by state, and by type of health benefit plan:

- (1) The total number of requests for external review;
- (2) From the total number of requests for external review reported, the number of requests determined eligible for a full external review; and
- (3) Any other information the commissioner may request or require.

The health carrier shall retain the written records required pursuant to this subsection for at least three years.

§432E-L Funding 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 cost of the independent review organization for conducting the external review. There shall be no recourse against the commissioner for the cost of conducting the external review and the selection of an independent review organization shall not be subject to chapter 103D; provided that the commissioner may initially approve up to three independent review organizations to serve beginning on the effective date of this part until the initial procurement process is completed; provided further that in any year in which procurement subject to chapter 103D does not produce at least three independent review organizations eligible for selection under section 432E-I, the commissioner may approve up to three independent review organizations notwithstanding the requirements of chapter 103D.

§432E-M Disclosure requirements. (a) Each health carrier shall include a description of the external review procedures in or attached to the policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to enrollees.

(b) Disclosure shall be in a format prescribed by the commissioner and shall include a statement informing the enrollee of the right of the enrollee to file a request for an external review of an adverse action with the commissioner. The statement may explain that external review is available when the adverse action 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.

(c) In addition to the requirements of subsection (b), the statement shall inform the enrollee that, when filing a request for an external review, the enrollee or the enrollee's appointed representative shall be required to authorize the release of any medical records of the enrollee that may be required to be reviewed for the purpose of reaching a decision on the external review and shall be required to provide written disclosures to permit the commissioner to perform a

conflict of interest evaluation for selection of an appropriate independent review organization.

(d) Each health carrier shall have available on its website and provide upon request to any enrollee, forms for the purpose of requesting an external review, which shall include an authorization release form that complies with the federal Health Insurance Portability and Accountability Act as well as a disclosure form for conflict of interest evaluation purposes that shall include the name of the enrollee, any authorized representative acting on behalf of the enrollee, the enrollee's immediate family members, the health carrier that is the subject of the external review, the health benefit plan, the plan administrator, plan fiduciaries and plan employees if the enrollee is in a group health benefits plan, the health care providers treating the enrollee for purposes of the condition that is the subject of the external review and the providers' medical groups, the health care provider and facility at which the requested health care service or treatment would be provided, and the developer or manufacturer of the principal drug, device, procedure, or other therapy that is the subject of the external review request.

(e) Each health carrier doing business in Hawaii shall file with the commissioner by the effective date of this part, information to permit the commissioner to perform a conflict of interest evaluation for selection of an appropriate independent review organization in the event of a request for external review involving the health carrier. A filing pursuant to this section shall include the name of the health carrier, its officers, directors, and management employees. The health carrier shall promptly amend its filing with the commissioner when there is any change of officers, directors, or managing employees.

(f) The commissioner may prescribe the form or format to use for the release authorization required by subsection (d) and the conflict of interest disclosures required by subsections (d) and (e).

(g) No disclosure required for purposes of this part shall include lawyer-client privileged communications protected pursuant to the Hawaii Rules of Evidence Rule 503.

§432E-N Rules. The insurance commissioner shall adopt rules pursuant to chapter 91 to effectuate the purpose of this part including requirements for forms to request external review and expedited external review, to request approval by independent review organizations, and for disclosure of conflicts of interest by enrollees and health carriers."

SECTION 3. Chapter 432E, Hawaii Revised Statutes, is amended by designating sections 432E-1 through 432E-2 as part I, entitled "General Provisions".

SECTION 4. Chapter 432E, Hawaii Revised Statutes, is amended by designating sections 432E-3 through 432E-8 as part II, entitled "General Policies".

SECTION 5. Chapter 432E, Hawaii Revised Statutes, is amended by designating sections 432E-9 through 432E-13 as part III, entitled "Reporting and Other Provisions".

SECTION 6. Section 432E-1, Hawaii Revised Statutes, is amended to read as follows:

"§432E-1 Definitions. As used in this chapter, unless the context otherwise requires:

“Adverse action” means an adverse determination or a final adverse determination.

“Adverse determination” means a determination by a health carrier or its designated utilization review organization that an admission, availability of care, continued stay, or other health care service that is a covered benefit has been reviewed and, based 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.

“Ambulatory review” means a utilization review of health care services performed or provided in an outpatient setting.

“Appeal” means a request from an enrollee to change a previous decision made by the ~~[managed care plan.]~~ health carrier.

“Appointed representative” means a person who is expressly permitted by the enrollee or who has the power under Hawaii law to make health care decisions on behalf of the enrollee, including:

- (1) A person to whom an enrollee has given express written consent to represent the enrollee in an external review;
- (2) A person authorized by law to provide substituted consent for an enrollee;
- (3) A family member of the enrollee or the enrollee’s treating health care professional, only when the enrollee is unable to provide consent;
- ~~(4)~~ (4) A court-appointed legal guardian;
- ~~(2)~~ (5) A person who has a durable power of attorney for health care;
or
- ~~(3)~~ (6) A person who is designated in a written advance directive[-];
provided that an appointed representative shall include an “authorized representative” as used in the federal Patient Protection and Affordable Care Act.

“Best evidence” means evidence based on:

- (1) Randomized clinical trials;
- (2) If randomized clinical trials are not available, cohort studies or case-control studies;
- (3) If the trials in paragraphs (1) and (2) are not available, case-series;
or
- (4) If the sources of information in paragraphs (1), (2), and (3) are not available, expert opinion.

“Case management” means a coordinated set of activities conducted for individual patient management of serious, complicated, protracted, or other health conditions.

“Case-control study” means a prospective evaluation of two groups of patients with different outcomes to determine which specific interventions the patients received.

“Case-series” means an evaluation of patients with a particular outcome, without the use of a control group.

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

“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.

“Cohort study” means a prospective evaluation of two groups of patients with only one group of patients receiving a specific intervention.

“Commissioner” means the insurance commissioner.

“Complaint” means an expression of dissatisfaction, either oral or written.

“Concurrent review” means a utilization review conducted during a patient’s hospital stay or course of treatment.

“Covered benefits” or “benefits” means those health care services to which an enrollee is entitled under the terms of a health benefit plan.

“Discharge planning” means the formal process for determining, prior to discharge from a facility, the coordination and management of the care that an enrollee receives following discharge from a facility.

“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.

“Emergency services” means services provided to an enrollee when the enrollee has symptoms of sufficient severity that a layperson could reasonably expect, in the absence of medical treatment, to result in placing the enrollee’s health or condition in serious jeopardy, serious impairment of bodily functions, serious dysfunction of any bodily organ or part, or death.

“Enrollee” means a person who enters into a contractual relationship under or who is provided with health care services or benefits through a [managed care plan.] health benefit plan.

~~“Expedited appeal” means the internal review of a complaint or an external review of the final internal determination of an enrollee’s complaint, which is completed within seventy-two hours after receipt of the request for expedited appeal.~~

~~“External review” means an administrative review requested by an enrollee under section 432E-6 of a managed care plan’s final internal determination of an enrollee’s complaint.]~~

“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.

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

“External review” means a review of an adverse determination (including a final adverse determination) conducted by an independent review organization pursuant to this chapter.

“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.

“Final adverse determination” means an adverse determination involving a covered benefit that has been upheld by a health carrier or its designated utilization review organization at the completion of the health carrier’s internal grievance process procedures, or an adverse determination with respect to which the internal appeals process is deemed to have been exhausted under section 432E-C(b).

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

“Health care [provider²²] professional” means an individual licensed, accredited, or certified to provide or perform specified health care services in the

ordinary course of business or practice of a profession[~~]~~ consistent with state law.

“Health care provider” or “provider” means a health care professional.

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

“Health carrier” means an entity subject to the insurance laws and rules of this State, or subject to the jurisdiction of the commissioner, that contracts or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health maintenance organization, a mutual benefit society, a nonprofit hospital and health service corporation, or any other entity providing a plan of health insurance, health benefits or health care services.

“Health maintenance organization” means a health maintenance organization as defined in section 432D-1.

“Independent review organization” means an independent entity [that:

- (1) Is unbiased and able to make independent decisions;
- (2) Engages adequate numbers of practitioners with the appropriate level and type of clinical knowledge and expertise;
- (3) Applies evidence-based decisionmaking;
- (4) Demonstrates an effective process to screen external reviews for eligibility;
- (5) Protects the enrollee’s identity from unnecessary disclosure; and
- (6) Has effective systems in place to conduct a review.]

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

“Internal review” means the review under section 432E-5 of an enrollee’s complaint by a [managed care plan] health carrier.

“Managed care plan” means any plan, policy, contract, certificate, or agreement, regardless of form, offered or administered by any person or entity, including but not limited to an insurer governed by chapter 431, a mutual benefit society governed by chapter 432, a health maintenance organization governed by chapter 432D, a preferred provider organization, a point of service organization, a health insurance issuer, a fiscal intermediary, a payor, a prepaid health care plan, and any other mixed model, that provides for the financing or delivery of health care services or benefits to enrollees through:

- (1) Arrangements with selected providers or provider networks to furnish health care services or benefits; and
- (2) Financial incentives for enrollees to use participating providers and procedures provided by a plan;

provided[;] that for the purposes of this chapter, an employee benefit plan shall not be deemed a managed care plan with respect to any provision of this chapter or to any requirement or rule imposed or permitted by this chapter [which] that is superseded or preempted by federal law.

“Medical director” means the person who is authorized under a [managed care plan] health carrier and who makes decisions for the [plan] health carrier denying or allowing payment for medical treatments, services, or supplies based on medical necessity or other appropriate medical or health plan benefit standards.

“Medical necessity” means a health intervention [as defined] that meets the criteria enumerated in section 432E-1.4.

“Medical or scientific evidence” means evidence found in the following sources:

- (1) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally-recognized re-

- quirements for scientific manuscripts and that submit most of their published articles for review by experts, who are not part of the editorial staff;
- (2) 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 and Elsevier Science Ltd. for indexing in Excerpta Medicas;
 - (3) Medical journals recognized by the United States Secretary of Health and Human Services under Section 1861(t)(2) of the federal Social Security Act;
 - (4) The following standard reference compendia:
 - (A) The American Hospital Formulary Service-Drug Information;
 - (B) Drug Facts and Comparisons;
 - (C) The American Dental Association Accepted Dental Therapeutics; and
 - (D) The United States Pharmacopeia Drug Information;
 - (5) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally-recognized federal research institutes, including:
 - (A) The federal Agency for Healthcare Research and Quality;
 - (B) The National Institutes of Health;
 - (C) The National Cancer Institute;
 - (D) The National Academy of Sciences;
 - (E) The Centers for Medicare and Medicaid Services;
 - (F) The federal Food and Drug Administration; and
 - (G) Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services; or
 - (6) Any other medical or scientific evidence that is comparable to the sources listed in paragraphs (1) through (5).

"Participating provider" means a licensed or certified provider of health care services or benefits, including mental health services and health care supplies, [that] who has entered into an agreement with a [managed-care-plan] health carrier to provide those services or supplies to enrollees.

"Prospective review" means utilization review conducted prior to an admission or a course of treatment.

"Protected health information" means health information as defined in the federal Health Insurance Portability and Accountability Act and related federal rules.

"Randomized clinical trial" means a controlled, prospective study of patients who 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.

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

"Reviewer" means an independent reviewer with clinical expertise either employed by or contracted by an independent review organization to perform external reviews.

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

“Specifically excluded” means that the coverage provisions of the health care plan, when read together, clearly and specifically exclude coverage for a health care service.

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

“Utilization review organization” means an entity that conducts utilization review other than a health carrier performing a review for its own health benefit plans.”

SECTION 7. Section 432E-5, Hawaii Revised Statutes, is amended to read as follows:

“§432E-5 Complaints and appeals procedure for enrollees. (a) A ~~[managed care plan]~~ health carrier with enrollees in this State shall establish and maintain a procedure to provide for the resolution of an enrollee’s complaints and internal appeals. The procedure shall provide for expedited internal appeals under section 432E-6.5. The definition of medical necessity in section 432E-1.4 shall apply in a ~~[managed care plan’s]~~ health carrier’s complaints and internal appeals procedures.

(b) The ~~[managed care plan]~~ health carrier shall at all times make available its complaints and internal appeals procedures. The complaints and internal appeals procedures shall be reasonably understandable to the average layperson and shall be provided in a language other than English upon request.

(c) A ~~[managed care plan]~~ health carrier shall decide any expedited internal appeal as soon as possible after receipt of the complaint, taking into account the medical exigencies of the case, but not later than seventy-two hours after receipt of the request for expedited appeal.

(d) A ~~[managed care plan]~~ health carrier shall send notice of its final internal determination within sixty days of the submission of the complaint to the enrollee, the enrollee’s appointed representative, if applicable, the enrollee’s treating provider, and the commissioner. The notice shall include the following information regarding the enrollee’s rights and procedures:

- (1) The enrollee’s right to request an external review;
- (2) The ~~[sixty-day]~~ one hundred thirty day deadline for requesting an external review;
- (3) Instructions on how to request an external review; and
- (4) Where to submit the request for an external review.

In addition to these general requirements, the notice shall conform to the requirements of section 432E-E.”

SECTION 8. Section 432E-6.5, Hawaii Revised Statutes, is amended by amending its title to read as follows:

“§432E-6.5 Expedited internal appeal, when authorized; standard for decision.”

SECTION 9. Section 432E-6.5, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

“(a) An enrollee may request that the ~~[following]~~ internal appeal under section 432E-5 be conducted as an expedited ~~[appeal:~~

- (1) ~~The internal review under section 432E-5 of the enrollee’s complaint; or~~
- (2) ~~The external review under section 432E-6 of the managed care plan’s final internal determination.]~~ appeal.

If a request for expedited appeal is approved by the ~~[managed care plan or the commissioner,]~~ health carrier, the appropriate ~~[review]~~ internal appeal shall be completed within seventy-two hours of receipt of the request for expedited appeal.”

SECTION 10. Section 432E-6, Hawaii Revised Statutes, is repealed.

SECTION 11. The insurance commissioner shall submit a report to the legislature no later than twenty days prior to the convening of the 2012 regular session on the implementation of this Act including the names of all independent review organizations contracted by the State pursuant to section 432E-L, Hawaii Revised Statutes, and data on the number of requests for external review and outcomes of external reviews as maintained by each independent review organization pursuant to section 432E-K(b), Hawaii Revised Statutes.

SECTION 12. The insurance commissioner shall assist the department of human services and the Hawaii employer-union health benefits trust fund in compiling data relating to each entity’s own administrative review process comparable to that maintained by independent review organizations pursuant to section 432E-K(b), Hawaii Revised Statutes, and submitting a report of the data and findings to the legislature no later than twenty days prior to the convening of the 2012 regular session. The report submitted pursuant to this section shall include a comparison between outcomes in the review processes maintained by the department of human services and Hawaii employer-union health benefits trust fund, respectively, and outcomes of the review processes of independent review organizations, as well as an analysis of whether or not consumers would have achieved better access to health care services under a review process maintained by an independent review organization.

SECTION 13. If any provision of this Act, or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act, which can be given effect without the invalid provision or application, and to this end the provisions of this Act are severable.

SECTION 14. This Act shall be construed at all times in conformity with the federal Patient Protection and Affordable Care Act, Public Law No. 111-148. If any provision of this part is interpreted to violate the Patient Protection and Affordable Care Act, the commissioner is authorized to adopt by emergency rule-making procedures, any rules as necessary to conform the provisions and procedures of this part with the Patient Protection and Affordable Care Act.

SECTION 15. In codifying the new sections added by section 2 of this Act, the revisor of statutes shall substitute appropriate section numbers for the letters used in designating the new sections in this Act.

SECTION 16. Statutory material to be repealed is bracketed and stricken.² New statutory material is underscored.

SECTION 17. This Act shall take effect on June 30, 2011; provided that if the United States Department of Health and Human Services by rule or other written guidance extends the time period for the State's existing external review process under section 432E-6, Hawaii Revised Statutes, to any later date during 2011, then the effective date of this Act shall be the sooner of the end date of the transition period or January 1, 2012; provided further that if the external review requirements of the federal Patient Protection and Affordable Care Act of 2010 are held unconstitutional by the United States Supreme Court, this Act shall be repealed as of the date that the United States Supreme Court issues its opinion and chapter 432E, Hawaii Revised Statutes, shall be reenacted in the form in which it existed as of the day before the United States Supreme Court issued its decision.

(Approved July 12, 2011.)

Notes

1. Prior to amendment "the" appeared here. "An" should be underscored.
2. Edited pursuant to HRS §23G-16.5.