

STATE OF VERMONT
Department of ~~Banking, Financial Regulation~~

Insurance, ~~Securities~~
~~And Health Care Administration~~

~~Division of Health Care Administration~~

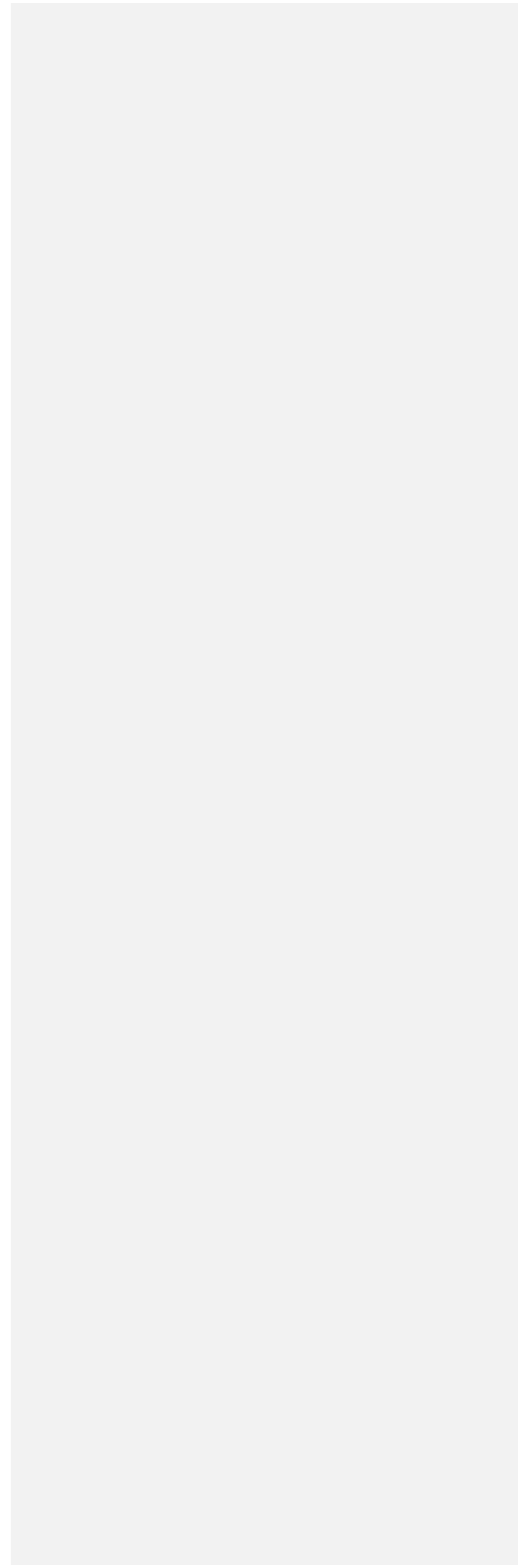
RULE H-2011-02 (Revised)

INDEPENDENT EXTERNAL REVIEW OF HEALTH CARE SERVICE DECISIONS

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INDEPENDENT EXTERNAL REVIEW OF HEALTH CARE SERVICE DECISIONS

SECTION 1. PURPOSE

The purpose of this rule is to establish a process for independent external reviews of adverse benefit determinations regarding health benefits that are eligible for independent external review by law.

SECTION 2. AUTHORITY

The Commissioner of ~~Banking, Insurance, Securities and Health Care Administration~~Financial Regulation has the authority to issue this rule under 8 V.S.A. §§ 15, 4089a and 4089f.

SECTION 3. APPLICABILITY AND SCOPE

- (A) This rule shall apply to every comprehensive major medical health benefit plan subject to the Department's jurisdiction, and the definitions of "medically necessary care", "experimental or investigational", and "medically appropriate off-label use of a drug" in the contracts, policies, certificates and other forms related to such plans shall be as defined in this rule.
- (B) This rule shall not apply to any health benefit plan that is not a comprehensive major medical health benefit plan subject to the Department's jurisdiction and shall not apply to one 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, Medicare supplement, Medicare Advantage, coverage provided by the Vermont Medicaid program or Medicaid benefits provided through a contracted health plan, or to health care services provided to inmates by the Department of Corrections.
- (C) Health Benefit Plans not subject to the Department's jurisdiction may voluntarily agree to utilize the independent external review process, however, the definitions of "medically necessary care", "experimental or investigational", and "medically appropriate off-label use of a drug" as defined in this rule, shall not apply to these plans.
- (D) If any provisions of any such contract, policy, certificate or other forms conflict with provisions of this rule, the Department and the independent review organization shall use whichever provision is more beneficial to the insured.

SECTION 4. DEFINITIONS

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- (A) “Adverse benefit determination” means a denial, reduction, modification or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit, including but not limited to:
1. a denial, reduction, termination or failure to provide or make payment that is based on a determination of a participant’s or beneficiary’s eligibility to participate in a health benefit plan;
 2. a denial, reduction, modification or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit resulting from the application of any utilization review;
 3. a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate; and
- (B) “Appealable decision” means an adverse benefit determination made by a health insurer to deny, reduce or terminate health care coverage, payment or a preferred level of payment for a health care service; where; the insured has exhausted all internal grievances required by law relating to the decision; and the decision is based on one of the following reasons:
1. The health care service is a covered benefit that the health insurer has determined to be not medically necessary.
 2. A limitation is placed on the selection of a health care provider that is claimed by the insured to be inconsistent with limits imposed by the health benefit plan and any applicable laws and regulations.
 3. The health care treatment has been determined to be experimental or investigational or an off-label use of a drug.
 4. The health care service involves a medically-based decision that a condition is preexisting.
 5. The decision involves an adverse determination related to surprise medical billing, as established under Section 2799A-1 or 2799A-2 of the Public Health Service Act, including with respect to whether an item or service that is the subject of the adverse determination is an item or service to which Section 2799A-1 or 2799A-2 of the Public Health Service Act, or both, applies.
- (C) “Commissioner” means the Commissioner of ~~the Department of Banking, Insurance, Securities and Health Care Administration~~Financial Regulation or his or her designee.
- (D) “Conflict of interest” means a material professional, familial or financial relationship with any of the following persons:

1. The insured (and any related parties to the insured) who has filed the independent external review.
2. Any health care provider responsible for the experimental or investigational treatment.
3. The health insurer, mental health review agent, administrator of the health benefit plan or any other person or entity that issued the decision that is the subject of the independent external review.
4. Any officer, director, or management employee of the health benefit plan or any other person or entity that issued the decision that is the subject of the independent external review.
5. The insured's treating provider or the provider's medical group (and any related parties to the treating provider or members of the medical group) recommending the health care service or treatment that is the subject of the independent external review.
6. The health care provider, facility or other entity at or by which the service or treatment that is the subject of the independent external review would be provided.
7. Entities involved in the development or manufacture of the principal drug, device, procedure or other therapy that is the subject of the independent external review.

(E) "Department" means the Department of ~~Banking, Insurance, Securities and Health Care Administration~~ Financial Regulation.

~~(F) "Emergency medical condition" means the sudden and, at the time, unexpected onset of an illness or medical condition that manifests itself by symptoms of sufficient severity, including severe pain, that the absence of immediate medical attention could reasonably be expected by the prudent layperson, who possesses an average knowledge of health and medicine, to result in:~~

- ~~1. placing the member's physical or mental health in serious jeopardy; or~~
- ~~2. serious impairment to bodily functions; or~~
- ~~3. serious dysfunction of any bodily organ or part.~~

~~(F) "Emergency medical condition" shall have the same meaning as in 42 U.S.C. § 300gg-111(a)(3)(B).~~

~~(G) "Emergency services" means health care items and services furnished or required to evaluate and treat an emergency medical condition, shall have the same meaning as in 42 U.S.C. § 300gg-111(a)(3)(C).~~

(H) "Experimental or investigational services" means health care items or services that are:

1. not generally accepted by informed health care providers in the United States as effective in treating the condition, illness or diagnosis for which their use is proposed, or are;
 2. not proven by medical or scientific evidence to be effective in treating the condition, illness or diagnosis for which their use is proposed.
- (I) “Health benefit plan” means a policy, contract, certificate or agreement entered into, offered or issued by a health insurer to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services.
- (J) “Health care provider” means a person, partnership, corporation or other legal business entity licensed or certified or authorized by law to provide professional health care services to an individual during that individual's health care, treatment or confinement.
- (K) “Health care services” or “services” means items or services for the diagnosis, prevention, treatment, cure or relief of a health condition, illness, injury or disease.
- (L) “Health insurer” or “insurer” ~~means any health insurance company, nonprofit hospital service corporation, nonprofit medical service corporation, managed care organization and, to the extent permitted under federal law, any administrator of an insured or self-insured health benefit plan or any self-funded plan offered by public and private entities shall have the same meaning as in~~ the same meaning as in 18 V.S.A. § 9402(8). For purposes of this rule, “health insurer” or “insurer” also means a mental health review agent or any other agent or delegate of a health benefit plan that makes or issues appealable decisions as defined by this rule.
- (M) “Independent review organization” or “IRO” means an organization under contract with the Department under Section 8 of this rule to undertake independent external reviews of appealable decisions pursuant to 8 V.S.A. § 4089f.
- (N) “Insured” means the beneficiary of a health benefit plan subject to this Rule, including the subscriber and all others covered under the plan. For purposes of this Rule, “insured” shall include any provider or other person acting on behalf of an insured with the insured’s HIPAA compliant authorization.
- (O) “Medical or scientific evidence” means the following sources:
1. 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.
 2. Peer-reviewed literature, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in, Excerpta Medica (EMBASE), Medline, Pubmed Medline, resources from the Cochrane Library, HSTAT, and the National Guideline Clearinghouse.

3. Medical journals recognized by the federal Secretary of Health and Human Services, under Section 1861(t)(2) of the federal Social Security Act.
4. The following standard reference compendia: the American Hospital Formulary Service- Drug Information (AHFS Drug Information), the American Dental Association Accepted Dental Therapeutics and Monograph Series on Dental Materials and Therapeutics, The United States Pharmacopeia, The National Formulary and the USP-DI.
5. Findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including the Agency for Health Care Research and Quality, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Centers for Medicare and Medicaid Services, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.
6. Peer-reviewed abstracts accepted for presentation at major medical association meetings.

(P) “Medically appropriate off-label use of a drug” means the use of a drug, pursuant to a valid prescription by a health care provider, for other than the particular condition(s) for which approval was given by the U.S. Food and Drug Administration in circumstances in which the medically appropriate off-label use is reasonably calculated to restore or maintain the member’s health, prevent deterioration of or palliate the member’s condition, prevent the reasonably likely onset of a health problem or detect an incipient problem; and that is informed by generally accepted medical or scientific evidence and consistent with generally accepted practice parameters as recognized by health care professions in the same specialties as typically provide the procedure or treatment, or diagnose or manage the medical condition.

(Q) “Medically-necessary care” means health care services, including diagnostic testing, preventive services and aftercare that are appropriate, in terms of type, amount, frequency, level, setting, and duration to the member’s diagnosis or condition. Medically-necessary care must be informed by generally accepted medical or scientific evidence and consistent with generally accepted practice parameters as recognized by health care professions in the same specialties as typically provide the procedure or treatment, or diagnose or manage the medical condition, and must be informed by the unique needs of each individual patient and each presenting situation, and

1. help restore or maintain the member’s health; or
2. prevent deterioration of or palliate the member’s condition; or
3. prevent the reasonably likely onset of a health problem or detect an incipient problem.

- (R) “Off-label use of a drug” means use of a drug for other than the particular condition for which approval was given by the U.S. Food and Drug Administration.
- (S) “Relevant document, record or other information” means, for the purposes of Section (5)(H)a. of this Rule that a document, record or other information shall be considered relevant if such document, record or other information was relied upon in making the benefit determination or the determination of a grievance, or was submitted, considered or generated in the course of making the benefit determination or the determination of a grievance, without regard to whether such document, record or other information was relied upon in making the benefit determination or the determination of a grievance.
- (T) “Urgent care” means those health care services that are necessary to treat a condition or illness of an individual that if not provided promptly (within twenty-four (24) hours or a time frame consistent with the medical exigencies of the case) presents a serious risk of harm.

SECTION 5. REQUESTS FOR INDEPENDENT EXTERNAL REVIEW

- (A) An insured may obtain independent external review of an appealable decision using the procedures established in this section. Exhaustion of the internal grievance process is not required when the insurer has waived the internal grievance process or has been deemed to have waived the internal grievance process by failing to adhere to grievance process time requirements. The right to independent external review is contingent on the insured’s exhaustion of the health insurer’s first level internal grievance process. The health insurer shall provide insureds with a Department-approved notice of Vermont appeal rights with each notification of adverse benefit determination.
- (B) To the extent that Insurers prepare any of the following documents: summary plan description, policy, certificate, and/or membership booklet, Insurers shall include a description of the external review process.
- (C) Neither the right to obtain independent external review nor any resulting decision by an [independent review organization IRO](#) shall be construed to change the terms of coverage under a health benefit plan.
- (D) To initiate an independent external review, the insured shall file a written request on a form specified by the Department, which shall include a release executed by the insured for all medical records pertinent to the independent external review, identification of the insurer by whom the insured is covered and which made the decision at issue, and a copy of the notice of the final grievance decision. The written request must be made within one hundred twenty (120) days or 4 months whichever is longer from any of the following to occur:
 1. receipt of written documentation of the health benefits plan’s final grievance decision and notice of appeal rights,
 2. the insurer having waived the required grievance process, or

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3. the insurer is deemed to have waived the grievance process by failing to adhere to grievance process time requirements.

- (E) A request for independent external review shall be considered timely if the Department has received an oral or written inquiry complaint or request for review pertaining to the matter in dispute at any time prior to the deadline and the request for independent external review is confirmed in writing on the Department-approved form within ten (10) working days.
- (F) An insured may initiate an expedited independent external review simultaneously when applying for an urgent internal grievance. The request for an expedited independent external review and the request for an urgent internal grievance must be filed within the time frames for requesting an urgent internal grievance set forth in [regulation rule H-2009-03](#). The written request must include the information required in Section 5 (D) with the exception of a copy of the notice of the final grievance decision.
- (G) An insured shall be entitled to assistance from the Department if the insured is unable to file a written request for review under this section. The Department shall not refuse to accept ~~ana~~ request for an independent external review or determine that an independent external review has not met the requirements of this rule for the sole reason that the request for an independent external review is not on the Department-approved form.
- (H) The application fee is twenty-five (\$25.00) dollars for independent external review of an appealable decision. The annual limit on filing fees for any insured shall not exceed seventy-five (\$75.00) dollars. Upon determination of financial hardship, the Commissioner may in his or her discretion reduce or waive the fee. In determining whether financial hardship is present, the Commissioner shall take into consideration the reasons for the insured's request. The Commissioner shall ~~automatically~~ waive or reduce the fee for persons who demonstrate they are eligible for a state- or federally-based assistance program such as food stamps, TANF (Temporary Aid to Needy Families), General Assistance, Medicaid, SSI, fuel assistance or unemployment assistance. Upon the appealable decision being overturned by the [independent review organizationIRO](#), the \$25.00 fee if paid shall be refunded to the insured.
- (I) Within five (5) business days of receiving the request, the Department shall [accept the request for an independent external review if it determines that:](#)
1. ~~accept the request for an independent external review if it determines that:~~
 1. ~~a.~~ the individual is or was an insured of the health insurer;
 2. ~~b.~~ the service that is the subject of the independent external review reasonably appears to be a covered service under the benefits provided by contract to the insured;
 3. ~~c.~~ the independent external review involves an appealable decision (as defined in this rule);

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4. ~~d.~~ —the insured has exhausted the health insurer’s required internal grievance process as required by law; and

5. ~~e.~~ —the insured has provided all information required by the Department to ensure compliance with this Rule.

~~2. —select an independent review organization on a rotating basis and determine whether it is able to accept the assignment. If the organization has a conflict of interest, does not have a reviewer available who is knowledgeable about the procedure or treatment, or is otherwise not able to accept the assignment, the Department shall assign the independent external review to the next independent review organization on the list without a conflict that is able to accept the assignment.~~

~~3. —notify the insured and the insurer of the specialty of the reviewer who has been assigned by the independent review organization.~~

(J) If the materials submitted by the insured are not complete, the Department shall notify the insured of what materials are incomplete and the time within which they must be submitted.

(K) Upon completion of its review, the Department shall notify the insured and the health insurer and, if applicable, the mental health review agent whether the application for independent external review has been accepted. If the application for independent external review is accepted, the Department shall also notify the parties of their opportunity to submit information and supporting documentation for consideration by the applicable ~~independent review organization~~IRO. Such information and documentation shall include:

1. Documentation to be submitted by the health insurer and, if applicable, the mental health review agent: All relevant documents, records or other information in its possession or control, including the review criteria used in making the decision being appealed under this rule, copies of any applicable policies or procedures, and copies of all medical records considered by the insurer in making its initial decision and its decisions pursuant to the internal grievance process. The health insurer and, if applicable, the mental health review agent, shall consecutively number the pages in its documentation and identify the total number of pages.
2. Documentation to be submitted by the insured: All medical records and any additional information that the insured would like to have considered by the ~~independent review organization~~IRO, which may include at the insured’s discretion written statements by either the insured and/or his or her health care providers, or both, relating to the subject of the independent external review.

(L) The information and supporting documentation required under Section 5(H) must be submitted to the Department within ten (10) days from the date the notice sent under that section was received, except as follows:

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1. health insurers and mental health review agents, if applicable may request an extension of up to ten (10) days in which to submit the information; and documentation, which shall be granted by the Department only for good cause shown.
2. insureds may request an extension within which to submit their information and supporting documentation for any reason, except that the Department may set a final deadline for submission if the insured has not submitted his or her information after having been granted multiple extensions.

(M) The Department shall provide copies of the information and supporting documentation filed by the insured and the health insurer to the other and to the [independent review organization IRO](#). Each shall have three (3) business days from receipt of the copies to file responsive information or documentation with the Department. The Department may grant extensions for filing responsive information on the same bases as set forth in paragraph (I) of this subsection. Upon receiving all supporting documentation filed by the insured and the health insurer, the Department shall:

1. select an IRO on a rotating basis and determine whether it is able to accept the assignment. If the organization has a conflict of interest, does not have a reviewer available who is knowledgeable about the procedure or treatment, or is otherwise not able to accept the assignment, the Department shall assign the independent external review to the next IRO on the list without a conflict that is able to accept the assignment.
2. notify the insured and the insurer of the specialty of the reviewer who has been assigned by the IRO.

(N) Within 10 business days of the date of receipt by the [independent review organization IRO](#) of the external appeal for review under Section 5(H), the insured or the health insurer may submit additional information or supporting materials to the Department. The additional information or supporting materials shall be sent by the Department to the other party, who shall have three (3) business days after receipt within which to file any additional responsive information or supporting materials. All such information shall then be sent by the Department to the [independent review organization IRO](#) for review as part of the independent external review.

(O) When submitting new information under Section 5 (K), the insured may request that the health insurer or mental health review agent, if applicable, reconsider the decision being appealed based on the additional information being provided. In addition, if the [independent review organization IRO](#) to whom the independent external review is assigned determines at any time that information it has received as part of the independent external review was not available or not made available to the health insurer or mental health review agent during its internal review process, it may also request the health insurer or mental health review agent to reconsider the decision based on the new information. Any such request by either the insured or the [independent review](#)

~~organizationIRO~~ shall stay the review by the ~~independent review organizationIRO~~ for no more than seven (7) days.

- (P) Failure by the health insurer or mental health review agent to submit information and documentation within the time periods required in this section or to participate in a telephone conference, if any, shall not delay independent external review and shall not impair the ability of the ~~independent review organizationIRO~~ to issue a binding decision that upholds, reverses or modifies the decision that was subject to independent external review.
- (Q) The Department in its sole discretion may toll any time frame to promote dispute resolution at the request of both parties.
- (R) Requests for expedited reviews shall follow the procedures contained in Section 7.

SECTION 6. REVIEW BY INDEPENDENT REVIEW ORGANIZATION

- (A) An ~~independent review organizationIRO~~ to which an independent external review has been assigned by the Department shall conduct a full review to determine whether:
 1. the health care service at issue is medically necessary;
 2. the health insurer has limited the insured's selection of a health care provider in a manner inconsistent with any limits imposed by the insurance contract and any applicable laws and rules;
 3. the proposed health care treatment is experimental or investigational or a medically- appropriate off-label use of a drug, as those terms are defined in this rule; and
 4. the service as to which coverage is being denied relates to a preexisting condition for which no coverage is available under the insurance contract.
- (B) The ~~independent review organizationIRO~~ shall review all of the materials included in the independent external review documentation provided by the Department or obtained as a result of a telephone conference, if any, including all pertinent medical records, consulting provider reports and other documents submitted by the parties, and any statement filed by the insured or his or her treating providers. ~~The independent review organization's~~The IRO's final decision shall be based on objective clinical evidence, and shall consider any applicable generally-accepted practice guidelines developed by the federal government, national or professional medical societies, boards and associations, and clinical protocols or practice guidelines developed by the health insurer or mental health review agent. The ~~independent review organizationIRO~~ is not bound by the insurer's or mental health review agent's clinical protocols or practice guidelines, and it shall give clinical data reported by the treating provider equal or greater weight than the protocols or practice guidelines used by the health insurer or mental health review agent.

- (C) In the course of reviewing the independent external review, the [independent review organizationIRO](#) may request that the Department obtain any additional information or approve the addition of a reviewer(s) with special expertise if the [independent review organizationIRO](#) and the Department agree that the information or additional reviewer is necessary or relevant to the independent external review. The Department will notify the insured and the insurer of any such request for additional information or the addition of another reviewer. Upon receipt of additional information, the Department shall provide copies to the insured and the insurer. Each shall have 3 business days from receipt of copies of the additional information to submit additional responsive information or to dispute the need for an additional reviewer.
- (D) If the insured has requested when filing the request for independent external review or materials to be considered during the independent external review, or the insurer has requested after notification of the request for an independent external review, the [independent review organizationIRO](#) shall meet by teleconference with the insured, the insured's representative and/or his or her treating provider, and a representative(s) of the health insurer, to review and discuss the clinical evidence in the independent external review.
- (E) Except as provided in Section 7(C) of this rule, the [independent review organizationIRO](#) shall complete its review and forward its determination to the Department as soon as possible in accordance with the medical exigencies of the case, which (except as provided in this subsection) shall not exceed thirty (30) days from receipt of all of the documentation. The decision shall be in writing and shall include the clinical rationale for the [independent review organization'sIRO's](#) determination. The [independent review organizationIRO](#) may request an extension of time from the Department within which to complete its review as may be necessary due to circumstances beyond its control, including but not limited to the receipt of additional information after the independent external review has been forwarded for review as set forth in Section 5(K), or the inability to timely schedule a telephone conference due to the unavailability of the applicant, the applicant's representative, any of the applicant's treating provider(s) or the insurer's representative(s).
- (F) Upon receipt of the [independent review organization'sIRO's](#) determination, the Department shall review it to ensure that it does not change the terms of coverage under the insured's health benefit plan, and then issue the determination to the health insurer, mental health review agent, if appropriate, and the insured. [The independent review organization'sIRO's](#) determination shall be binding on the insurer and the insured except to the extent either the insurer or insured has other remedies under applicable federal or Vermont laws.
- (G) If the Department finds that the [independent review organization'sIRO's](#) determination changes the terms of the insured's health benefit plan, it shall immediately return the determination to the [independent review organizationIRO](#) for revision.

- (H) The Department may use all enforcement powers granted to it under Titles 8 and 18 of the Vermont Statutes Annotated to ensure compliance by health insurers and mental health review agents with the requirements of this rule and any other applicable law or ~~rule~~rule.
- (I) No health insurer shall retaliate against an insured or provider for any activity related to independent external review.
- (J) The determinations of an ~~independent review organization~~IRO on individual cases shall have no precedential value as to any other independent external review filed with the Department.
- (K) The insured has the right to ask a health insurer to review a request for the same or similar services as to which an ~~independent review organization~~IRO has upheld an earlier denial if, since the ~~independent review organization's~~IRO's decision was made, the insured's medical condition has changed or the scientific or medical evidence as to the effectiveness of a proposed treatment has changed. The insured must exhaust the insurer's internal utilization management and grievance processes.

SECTION 7. EXPEDITED REVIEWS

- (A) Independent external reviews that the Department determines should be expedited, that have resulted from grievances that were required by law to be expedited, or that have been designated "emergency" or "urgent" by the insured or the insured's treating health care provider shall be expedited, as follows:
 1. Upon receipt of a request for independent external review that is the result of a grievance that has been designated as expedited, or that the Department in its sole discretion determines shall be expedited, and that meets the requirements for reviewability set forth in Section 5(F) of this ~~regulation~~rule, the Department shall immediately accept the ~~request~~ Oral request for reviews related to emergency or urgent services may be accepted if the insured completes and submits an application form and filing fee, if applicable, as soon thereafter as possible.
 2. Upon acceptance of the request for expedited independent external review, the Department will immediately notify the health insurer and the insured by the most expeditious means available, including telephone, fax or e-mail, of their right to submit information and supporting documentation under Section 5(H). Such information must be submitted to the Department in a time frame consistent with the medical exigencies of the case but in no event later than twenty-four (24) hours after the acceptance of the request.
 3. Immediately upon receipt of the supporting information and documentation from the insured and the insurer, but in no event more than twenty-four (24) hours after accepting the request for expedited review, the Department shall assign the independent external review to an ~~independent review organization~~IRO for clinical review as provided in Section 6 5(F) of this rule. ~~The independent review~~

~~organization~~The IRO shall complete its review and make a determination as soon as possible consistent with the medical exigencies of the case, but in no event more than three (3) days after receipt of the request for an independent external review, unless upon further review it determines that the appeal does not involve emergency or ~~urgently needed~~urgently needed services, in which case the deadline for review shall be as contained in 6(E).

4. If the expedited independent external review relates to services currently being provided to an insured in a health care facility or other previously approved course of treatment, and the request for expedited independent external review is made within twenty-four hours of the receipt by the insured of (i) the final grievance decision and (ii) the notice of appeal rights, whichever shall be later received, and the expedited external review is conducted in accordance with the time frames specified by law, the services shall be continued by the insurer without liability to the insured until:
 - a) the independent external review decision is issued, and
 - b) the insurer has authorized coverage for a medically safe and appropriate discharge or transition plan developed after consultation with the member's treating physician or the treating health care provider's designee.
5. When the expedited independent external review relates to services not currently being provided to an insured in a health care facility or other course of treatment and those services by contract require prior authorization from the insurer before being rendered, and the ~~independent review organization~~IRO reasonably believes that the delay caused by the review may cause significant harm to the insured and so notifies the Department, the Department shall order the health insurer to provide coverage for the contested services pending the final determination of the appeal independent external review. If the insurer's denial is upheld by the ~~independent review organization~~IRO, the insured will be responsible for reimbursing the insurer for the costs of such services paid for while the appeal was pending.
6. Health insurers and mental health review agents shall have qualified and informed personnel available twenty-four (24) hours a day, seven (7) days per week, who can respond to Department requests and assist the Department and/or ~~independent review organization~~IRO in assessing and processing potential cases and cases accepted for expedited review. Health insurers and mental health review agents shall provide the Department with updated contact information for such personnel annually and prior to any changes and shall ensure that all of their personnel are trained to facilitate such communication with the Department if requested.

SECTION 8. INDEPENDENT REVIEW ORGANIZATIONS

- (A) The Department shall from time to time enter into contracts with as many ~~independent review organizations~~IROs as it deems necessary to conduct the independent external review requests provided for in this Rule. The contracts shall set forth all terms that the Department deems necessary to ensure a full, fair and timely review of independent external reviews. Selection of the ~~independent review organizations~~IROs shall include review of proposals with regard to at least the following:
1. proposed scope of services;
 2. fee structure and total estimated costs of reviews;
 3. number and qualifications of reviewers, who shall include health care providers credentialed with respect to the health care service under review;
 4. procedures to ensure the confidentiality of the independent external reviews, including identifiable health care information used in reviewing the independent external reviews;
 5. procedures to ensure the neutrality of reviewers;
 6. administrative and operational policies and procedures; and
 7. procedures to ensure that no conflict of interest exists among the organization and its reviewers and the health insurer or insured whose case is under review.
 8. Evidence of accreditation by at least one nationally recognized private accrediting organization including, but not limited to, URAC or NCQA.

SECTION 9. EXTERNAL REVIEW REPORTING REQUIREMENTS

- (A) An ~~independent review organization~~IRO assigned pursuant to Section 6 or 7 of this rule to conduct an external review shall maintain written records in the aggregate for Vermont and by insurer on all requests for external review for which it conducted an external review during a calendar year and, upon request, submit a report to the Commissioner, as required under paragraph (B).
- (B) The report shall include in the aggregate for Vermont, and for each insurer:
1. the total number of requests for independent external review;
 2. the number of requests for independent external review resolved-;
 3. the number resolved upholding the adverse determination or final adverse determination and the number resolved reversing the adverse determination or final adverse determination;
 4. the average length of time for resolution;

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5. a summary of the types of coverages or cases for which an external review was sought, as provided in the format required by the Commissioner;
 6. the number of external reviews pursuant to Section 5 (L) of this rule that were terminated as the result of a reconsideration by the insurer of its adverse determination or final adverse determination after the receipt of additional information from the covered person or the covered person's authorized representative; and
 7. any other information the Commissioner may request or require.
- (C) The ~~independent review organization~~IRO shall retain the written records required pursuant to this subsection for at least three (3) years, and make item available at no cost to the Department.
- (D) Each insurer shall maintain at no cost to the Department, written records in the aggregate by State and for each type of health benefit plan offered by the insurer on all requests for independent external review that the insurer receives notices of from the Commissioner pursuant to this rule.
- (E) Each insurer required to maintain written records on all requests for external review pursuant to paragraph (1) shall submit to the Commissioner, upon request, a report in the format specified by the Commissioner.
- (F) The report shall include in the aggregate, for Vermont, 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 under subparagraph (1) of this paragraph, the number of requests determined eligible for a full external review; and
 3. any other information the Commissioner may request or require.
- (G) The insurer shall retain the written records required pursuant to this subsection for at least three (3) years.

SECTION 10. COSTS OF INDEPENDENT EXTERNAL REVIEWS

The Department shall notify the health insurer of the reasonable and necessary cost of an independent external review. The costs may vary depending on the type of review and the ~~independent review organization~~IRO assigned. The costs shall include but not be limited to the fees of the ~~independent review organization~~IRO, reasonable copying expenses, mail and delivery fees and any other expense related to the review by an ~~independent review organization's~~IRO's review. The insurer shall pay the costs of the independent external review to the Department within thirty (30) days of such notification.

SECTION 11. CONFIDENTIALITY

All documents and records relating to independent external reviews filed under this rule, including but not limited to independent external review forms, supporting information and documentation filed by the insured, by the health insurer, mental health review agent, or any materials prepared by the Department for the use of an ~~independent review organization, and the independent review organization's~~IRO, and the IRO's determination, are confidential and exempt from public disclosure under 1 V.S.A. § 316. Health insurers, mental health review agents and ~~independent review organizations~~IROs shall take appropriate measures to protect the confidentiality and security of all communications, records, procedures and meetings related to independent external reviews.

SECTION 12. SEVERABILITY

If a court holds any provision of this ~~regulation~~rule invalid in any circumstance, this shall not affect any other provision or circumstance.

SECTION 13. EFFECTIVE DATE

This ~~regulation~~revised rule shall take effect on ~~July~~January 1, ~~2011~~, ~~with the exception of the notice requirements of § 5-B which shall take effect one hundred and twenty (120) days after adoption~~2022.

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