

Proposed Filing - Coversheet

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the “Rule on Rulemaking” ([CVR 04-000-001](#)) adopted by the Office of the Secretary of State, this filing will be considered complete upon filing and acceptance of these forms and enclosures with the Office of the Secretary of State, and the Legislative Committee on Administrative Rules.

All forms shall be submitted to the Office of the Secretary of State, no later than 3:30 pm on the last scheduled day of the work week.

The data provided in text areas of Proposed Filing Coversheet will be used to generate a notice of rulemaking in the portal of “Proposed Rule Postings” online, and the newspapers of record. Publication of notices will be charged back to the promulgating agency.

**PLEASE REMOVE ANY COVERSHEET OR FORM NOT
REQUIRED WITH THE CURRENT FILING BEFORE DELIVERY!**

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801 (b) (11) for a definition), I approve the contents of this filing entitled:

**Independent External Review of Health Care Service
Decisions**

/s/ Kevin Gaffney _____, on 09/29/2022
(signature) (date)

Printed Name and Title:

Kevin Gaffney, Commissioner of Financial Regulation

RECEIVED BY: _____

- Coversheet
- Adopting Page
- Economic Impact Analysis
- Environmental Impact Analysis
- Strategy for Maximizing Public Input
- Scientific Information Statement (if applicable)
- Incorporated by Reference Statement (if applicable)
- Clean text of the rule (Amended text without annotation)
- Annotated text (Clearly marking changes from previous rule)
- ICAR Filing Confirmed

1. TITLE OF RULE FILING:

Independent External Review of Health Care Service Decisions

2. ADOPTING AGENCY:

Department of Financial Regulation

3. PRIMARY CONTACT PERSON:

(A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE).

Name: E. Sebastian Arduengo

Agency: Department of Financial Regulation

Mailing Address: 89 Main Street, Montpelier, VT 05620 - 3101

Telephone: (802) 828-4846 Fax: (802) 828-5593

E-Mail: Sebastian.Arduengo@vermont.gov

Web URL *(WHERE THE RULE WILL BE POSTED)*:

<https://dfr.vermont.gov/view/regbul>

4. SECONDARY CONTACT PERSON:

(A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON).

Name: Emily Kisicki

Agency: Department of Financial Regulation

Mailing Address: 89 Main Street, Montpelier, VT 05620 - 3101

Telephone: (802) 622-4305 Fax:

E-Mail: Emily.Kisicki@vermont.gov

5. RECORDS EXEMPTION INCLUDED WITHIN RULE:

(DOES THE RULE CONTAIN ANY PROVISION DESIGNATING INFORMATION AS CONFIDENTIAL; LIMITING ITS PUBLIC RELEASE; OR OTHERWISE, EXEMPTING IT FROM INSPECTION AND COPYING?) Yes

IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

1 V.S.A. § 317(c)(28).

PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:

Documents and records relating to independent external reviews filed under this rule may contain Protected Health Information (PHI) that is protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The proposed rule revisions do not expand or contract this statutory exemption.

6. LEGAL AUTHORITY / ENABLING LEGISLATION:

(THE SPECIFIC STATUTORY OR LEGAL CITATION FROM SESSION LAW INDICATING WHO THE ADOPTING ENTITY IS AND THUS WHO THE SIGNATORY SHOULD BE. THIS SHOULD BE A SPECIFIC CITATION NOT A CHAPTER CITATION).

8 V.S.A. §§ 15, 4089a, & 4089f.

7. EXPLANATION OF HOW THE RULE IS WITHIN THE AUTHORITY OF THE AGENCY:

Under 8 V.S.A. § 4089f, the Department of Financial Regulation is required to adopt rules necessary to ensure that an insured who has exhausted all applicable internal review procedures provided by a health benefit plan has the right to an independent external review of the plan's decision to deny, reduce or terminate health care coverage or to deny payment for a health care service.

8. CONCISE SUMMARY (150 WORDS OR LESS):

The Independent External Review of Health Care Services Decision (hereafter, the Rule) provides a process for individuals whose health insurance plan has denied, reduced or terminated their health insurance coverage or denied payment for a health care service, and who have exhausted all applicable internal review procedures provided by their health benefit plan, to obtain an independent external review of the plan's decision.

In addition to technical corrections, the proposed revisions to the Rule expands the scope of external review to any adverse benefit determination involving whether a claim is eligible for surprise billing and cost-sharing protections under the federal No Surprises Act.

9. EXPLANATION OF WHY THE RULE IS NECESSARY:

Under 45 C.F.R. § 147.136(c), states that do not have a process for external review of No Surprises Act compliance matters must direct insurers to a federally-administered process to meet the minimum standards for state external review.

Because a state-administered process is faster and more accessible than the federal process, it is necessary to amend the Independent External Review of Health Care Services Decision rule (hereinafter "Rule") to allow

for external review of No Surprises Act compliance matters.

10. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY AS DEFINED IN 3 V.S.A. § 801(b)(13)(A):

The proposed revisions to the Rule are not arbitrary in that they are necessary to conform the Rule to regulations at 45 C.F.R. § 147.136(c) specifying that plans and issuers subject to an applicable state external review process must provide for external review of No Surprises Act compliance matters.

11. LIST OF PEOPLE, ENTERPRISES AND GOVERNMENT ENTITIES AFFECTED BY THIS RULE:

Health Insurers

Department of Financial Regulation

Health Insurance Consumers

12. BRIEF SUMMARY OF ECONOMIC IMPACT (150 WORDS OR LESS):

The Department anticipates that the economic impact of the the proposed revisions to this Rule will be minimal. All Vermont-licensed health insurers already participate in the Department's external review program, and the Independent Review Organizations contracted with the Department have the capability to provide external review of No Surprises Act compliance matters. Because the vast majority of providers in Vermont are in-network with Vermont-licensed health insurers it is rare for patients to receive surprise bills, and therefore, the Department does not anticipate many reviews being generated from No Surprises Act compliance.

13. A HEARING WILL BE SCHEDULED.

IF A HEARING WILL NOT BE SCHEDULED, PLEASE EXPLAIN WHY.

14. HEARING INFORMATION

(THE FIRST HEARING SHALL BE NO SOONER THAN 30 DAYS FOLLOWING THE POSTING OF NOTICES ONLINE).

IF THIS FORM IS INSUFFICIENT TO LIST THE INFORMATION FOR EACH HEARING, PLEASE ATTACH A SEPARATE SHEET TO COMPLETE THE HEARING INFORMATION NEEDED FOR THE NOTICE OF RULEMAKING.

Date: 11/28/2022

Time: 09:00 AM

Street Address: 89 Main Street, Montpelier, VT

Zip Code: 05620 - 3101

Date:

Time: AM

Street Address:

Zip Code:

Date:

Time: AM

Street Address:

Zip Code:

Date:

Time: AM

Street Address:

Zip Code:

15. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING):

16. KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

No Surprises Act

Healthcare

Health Insurance

External Review

Health Benefit Plan

Adopting Page

Instructions:

This form must accompany each filing made during the rulemaking process:

Note: To satisfy the requirement for an annotated text, an agency must submit the entire rule in annotated form with proposed and final proposed filings. Filing an annotated paragraph or page of a larger rule is not sufficient. Annotation must clearly show the changes to the rule.

When possible, the agency shall file the annotated text, using the appropriate page or pages from the Code of Vermont Rules as a basis for the annotated version. New rules need not be accompanied by an annotated text.

1. TITLE OF RULE FILING:

Independent External Review of Health Care Service Decisions

2. ADOPTING AGENCY:

Department of Financial Regulation

3. TYPE OF FILING (*PLEASE CHOOSE THE TYPE OF FILING FROM THE DROPDOWN MENU BASED ON THE DEFINITIONS PROVIDED BELOW*):

- **AMENDMENT** - Any change to an already existing rule, even if it is a complete rewrite of the rule, it is considered an amendment if the rule is replaced with other text.
- **NEW RULE** - A rule that did not previously exist even under a different name.
- **REPEAL** - The removal of a rule in its entirety, without replacing it with other text.

This filing is **AN AMENDMENT OF AN EXISTING RULE** .

4. LAST ADOPTED (*PLEASE PROVIDE THE SOS LOG#, TITLE AND EFFECTIVE DATE OF THE LAST ADOPTION FOR THE EXISTING RULE*):

April 13, 2011 – SOS Log # 11P014

Economic Impact Analysis

Instructions:

In completing the economic impact analysis, an agency analyzes and evaluates the anticipated costs and benefits to be expected from adoption of the rule; estimates the costs and benefits for each category of people enterprises and government entities affected by the rule; compares alternatives to adopting the rule; and explains their analysis concluding that rulemaking is the most appropriate method of achieving the regulatory purpose. If no impacts are anticipated, please specify “No impact anticipated” in the field.

Rules affecting or regulating schools or school districts must include cost implications to local school districts and taxpayers in the impact statement, a clear statement of associated costs, and consideration of alternatives to the rule to reduce or ameliorate costs to local school districts while still achieving the objectives of the rule (see 3 V.S.A. § 832b for details).

Rules affecting small businesses (excluding impacts incidental to the purchase and payment of goods and services by the State or an agency thereof), must include ways that a business can reduce the cost or burden of compliance or an explanation of why the agency determines that such evaluation isn't appropriate, and an evaluation of creative, innovative or flexible methods of compliance that would not significantly impair the effectiveness of the rule or increase the risk to the health, safety, or welfare of the public or those affected by the rule.

1. TITLE OF RULE FILING:

**Independent External Review of Health Care Service
Decisions**

2. ADOPTING AGENCY:

Department of Financial Regulation

3. CATEGORY OF AFFECTED PARTIES:

LIST CATEGORIES OF PEOPLE, ENTERPRISES, AND GOVERNMENTAL ENTITIES POTENTIALLY AFFECTED BY THE ADOPTION OF THIS RULE AND THE ESTIMATED COSTS AND BENEFITS ANTICIPATED:

Health Insurers - All Vermont-licensed health insurers already participate in the Department's external review program. The cost of external review is ultimately billed to the health insurer that rendered the adverse benefit determination. Each appeal costs between \$650 and \$950, depending upon the complexity of the case and

whether the parties have requested a conference. Because the vast majority of providers in Vermont are in-network with Vermont-licensed health insurers it is rare for patients to receive surprise bills, and therefore, the Department does not anticipate many additional reviews being generated to determine whether a claim is eligible for surprise billing and cost-sharing protections under the federal No Surprises Act.

Department of Financial Regulation - The Independent Review Organizations (IROs) contracted with the Department have the capability to provide external review of No Surprises Act compliance matters at no additional cost to the State, since they had to build it out to service other governmental clients following enactment of the No Surprises Act.

Health Insurance Consumers - Under 8 V.S.A. § 4089f, consumers must pay a fee of \$25 to access external review. The Commissioner of Financial Regulation may waive this fee in cases of financial hardship, and has done so for all consumers for the duration of the COVID-19 public health emergency. The fee will not change as a result of the proposed revisions to this Rule.

4. IMPACT ON SCHOOLS:

INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON PUBLIC EDUCATION, PUBLIC SCHOOLS, LOCAL SCHOOL DISTRICTS AND/OR TAXPAYERS CLEARLY STATING ANY ASSOCIATED COSTS:

None anticipated.

5. ALTERNATIVES: CONSIDERATION OF ALTERNATIVES TO THE RULE TO REDUCE OR AMELIORATE COSTS TO LOCAL SCHOOL DISTRICTS WHILE STILL ACHIEVING THE OBJECTIVE OF THE RULE.

Because the Department does not anticipate any impact to local school districts, alternatives to the rule that could reduce or ameliorate costs to local school districts were not considered.

6. IMPACT ON SMALL BUSINESSES:

INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON SMALL BUSINESSES (EXCLUDING IMPACTS INCIDENTAL TO THE PURCHASE AND PAYMENT OF GOODS AND SERVICES BY THE STATE OR AN AGENCY THEREOF):

None anticipated.

7. SMALL BUSINESS COMPLIANCE: *EXPLAIN WAYS A BUSINESS CAN REDUCE THE COST/BURDEN OF COMPLIANCE OR AN EXPLANATION OF WHY THE AGENCY DETERMINES THAT SUCH EVALUATION ISN'T APPROPRIATE.*

Because the proposed revisions to this Rule will not impact small businesses, the Department did not consider ways that a business could reduce the cost/burden of compliance.

8. COMPARISON:

COMPARE THE IMPACT OF THE RULE WITH THE ECONOMIC IMPACT OF OTHER ALTERNATIVES TO THE RULE, INCLUDING NO RULE ON THE SUBJECT OR A RULE HAVING SEPARATE REQUIREMENTS FOR SMALL BUSINESS:

The economic impact of the proposed revisions to this Rule would be minimal compared to not revising the Rule. Under the current rule, the Department processed 23 external appeals in FY 2020 and 15 external appeals in FY 2021. Not revising the rule would require the Department to refer consumers seeking external review of an insurer determination related to the No Surprises Act to the federal government.

9. SUFFICIENCY: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*

Because the proposed revisions to this Rule only bring it into conformance with federal regulations and make technical corrections, the above economic analysis is sufficient. To conduct this analysis, the Department looked at external appeal filings for FY 2020 and FY 2021 in addition to current Independent Review Organization contracts.

Environmental Impact Analysis

Instructions:

In completing the environmental impact analysis, an agency analyzes and evaluates the anticipated environmental impacts (positive or negative) to be expected from adoption of the rule; compares alternatives to adopting the rule; explains the sufficiency of the environmental impact analysis. If no impacts are anticipated, please specify “No impact anticipated” in the field.

Examples of Environmental Impacts include but are not limited to:

- Impacts on the emission of greenhouse gases
- Impacts on the discharge of pollutants to water
- Impacts on the arability of land
- Impacts on the climate
- Impacts on the flow of water
- Impacts on recreation
- Or other environmental impacts

1. TITLE OF RULE FILING:

**Independent External Review of Health Care Service
Decisions**

2. ADOPTING AGENCY:

Department of Financial Regulation

3. GREENHOUSE GAS: *EXPLAIN HOW THE RULE IMPACTS THE EMISSION OF GREENHOUSE GASES (E.G. TRANSPORTATION OF PEOPLE OR GOODS; BUILDING INFRASTRUCTURE; LAND USE AND DEVELOPMENT, WASTE GENERATION, ETC.):*
None .

4. WATER: *EXPLAIN HOW THE RULE IMPACTS WATER (E.G. DISCHARGE / ELIMINATION OF POLLUTION INTO VERMONT WATERS, THE FLOW OF WATER IN THE STATE, WATER QUALITY ETC.):*
None .

5. LAND: *EXPLAIN HOW THE RULE IMPACTS LAND (E.G. IMPACTS ON FORESTRY, AGRICULTURE ETC.):*
None .

6. **RECREATION:** *EXPLAIN HOW THE RULE IMPACT RECREATION IN THE STATE:*

None.

7. **CLIMATE:** *EXPLAIN HOW THE RULE IMPACTS THE CLIMATE IN THE STATE:*

None.

8. **OTHER:** *EXPLAIN HOW THE RULE IMPACT OTHER ASPECTS OF VERMONT'S ENVIRONMENT:*

None.

9. **SUFFICIENCY:** *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*

The proposed revisions to this Rule are not expected to have any environmental impact. Therefore, this analysis is sufficient.

Public Input Maximization Plan

Instructions:

Agencies are encouraged to hold hearings as part of their strategy to maximize the involvement of the public in the development of rules. Please complete the form below by describing the agency's strategy for maximizing public input (what it did do, or will do to maximize the involvement of the public).

This form must accompany each filing made during the rulemaking process:

1. TITLE OF RULE FILING:

Independent External Review of Health Care Service Decisions

2. ADOPTING AGENCY:

Department of Financial Regulation

3. PLEASE DESCRIBE THE AGENCY'S STRATEGY TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE, LISTING THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:

The Department has been in communication with stakeholders, including the health insurers listed in response to question 4 and the Health Care Advocate about this Rule since the enactment of Act 137 of 2022, which gave the Commissioner of Financial Regulation authority to enforce the No Surprises Act to the extent permitted by federal law.

In addition, as part of the Department's mandate under Act 137, the Department has been working to educate health care providers about regulatory changes stemming from the No Surprises Act, including changes to external review.

The Rule will be posted on the Department's website. Additionally, the Department will ensure that all materials pertinent to this Rule will be available online and in paper form in the event that interested

Public Input

individuals do not have internet access.

Due to the ongoing COVID-19 pandemic, the rule's public hearing will be conducted via Microsoft Teams. Call-in information for the meeting is included in the APA forms and will be posted on the Department's website.

4. BEYOND GENERAL ADVERTISEMENTS, PLEASE LIST THE PEOPLE AND ORGANIZATIONS THAT HAVE BEEN OR WILL BE INVOLVED IN THE DEVELOPMENT OF THE PROPOSED RULE:

Blue Cross Blue Shield of Vermont

MVP Health Care

Cigna

Vermont Association of Hospitals and Health Systems

Vermont Medical Society

Office of the Health Care Advocate

STATE OF VERMONT
Department of Financial Regulation

Insurance Division

RULE H-2011-02 (Revised)

INDEPENDENT EXTERNAL REVIEW OF HEALTH CARE SERVICE DECISIONS

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STATE OF VERMONT
Department of Financial Regulation
Insurance Division

RULE H-2011-02 (Revised)

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 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

- (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 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 Financial Regulation.
- (F) "Emergency medical condition" shall have the same meaning as in 42 U.S.C. § 300gg-111(a)(3)(B).
- (G) "Emergency services" 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” shall have 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 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
 - 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 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 a 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 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 IRO, 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. the individual is or was an insured of the health insurer;
 2. 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. the independent external review involves an appealable decision (as defined in this rule);
 4. the insured has exhausted the health insurer's required internal grievance process as required by law; and
 5. the insured has provided all information required by the Department to ensure compliance with this Rule.
- (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 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 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:
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 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 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 IRO independent review organization 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 independent review organization.
- (N) Within 10 business days of the date of receipt by the 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 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 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 IRO shall stay the review by the IRO 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 IRO 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 IRO 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 IRO 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 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 IRO 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 IRO may request that the Department obtain any additional information or approve the addition of a reviewer(s) with special expertise if the IRO 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 IRO 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 IRO 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 IRO's determination. The IRO 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 IRO'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 IRO'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 IRO's determination changes the terms of the insured's health benefit plan, it shall immediately return the determination to the IRO 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.
- (I) No health insurer shall retaliate against an insured or provider for any activity related to independent external review.
- (J) The determinations of an 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 IRO has upheld an earlier denial if, since the 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 rule, the Department shall immediately accept the 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 IRO for clinical review as provided in Section 6 5(F) of this rule. 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 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 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 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 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 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 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 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;
 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 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 IRO assigned. The costs shall include but not be limited to the fees of the IRO, reasonable copying expenses, mail and delivery fees and any other expense related to the review by an 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 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 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 rule invalid in any circumstance, this shall not affect any other provision or circumstance.

SECTION 13. EFFECTIVE DATE

This revised rule shall take effect on January 1, 2022.

STATE OF VERMONT
Department of Financial Regulation

Insurance Division

RULE H-2011-02 (Revised)

INDEPENDENT EXTERNAL REVIEW OF HEALTH CARE SERVICE DECISIONS

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STATE OF VERMONT
Department of Financial Regulation
Insurance Division

RULE H-2011-02 (Revised)

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 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.

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SECTION 4. DEFINITIONS

- (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 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:

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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 Financial Regulation.

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

(G) "Emergency services" ~~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.

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Deleted: (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.

Deleted: means health care items and services furnished or required to evaluate and treat an emergency medical condition....

- (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” ~~shall have the same meaning as in~~ 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.

Deleted: 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.

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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 ~~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
 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 ~~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.

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(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 ~~a~~ 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.

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(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 ~~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 JRO, the \$25.00 fee if paid shall be refunded to the insured.

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(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. ~~the~~ individual is or was an insured of the health insurer;

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2. ~~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;

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3. ~~the~~ independent external review involves an appealable decision (as defined in this rule);

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

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

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(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.

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

(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 JRO. Such information and documentation shall include:

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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 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.

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(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:

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 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:

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1. select an IRO 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 IRO independent review organization 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 independent review organization.

(N) Within 10 business days of the date of receipt by the 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 IRO for review as part of the independent external review.

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(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 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 IRO shall stay the review by the IRO for no more than seven (7) days.

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(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 IRO to issue a binding decision that upholds, reverses or modifies the decision that was subject to independent external review.

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(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 IRO to which an independent external review has been assigned by the Department shall conduct a full review to determine whether:

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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 JRO 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 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 IRO 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.

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(C) In the course of reviewing the independent external review, the JRO may request that the Department obtain any additional information or approve the addition of a reviewer(s) with special expertise if the JRO 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.

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(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 JRO 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.

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(E) Except as provided in Section 7(C) of this rule, the JRO 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 JRO's determination. The IRO 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).

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(F) Upon receipt of the IRO'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 IRO'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.

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(G) If the Department finds that the IRO's determination changes the terms of the insured's health benefit plan, it shall immediately return the determination to the IRO for revision.

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(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.

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(I) No health insurer shall retaliate against an insured or provider for any activity related to independent external review.

(J) The determinations of an IRO on individual cases shall have no precedential value as to any other independent external review filed with the Department.

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(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 IRO has upheld an earlier denial if, since the 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.

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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 rule, the Department shall immediately accept the 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

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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 IRO for clinical review as provided in Section 6 5(F) of this rule. 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 services, in which case the deadline for review shall be as contained in 6(E).

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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 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 IRO, the insured will be responsible for reimbursing the insurer for the costs of such services paid for while the appeal was pending.

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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 IRO in assessing and processing potential cases and cases accepted for expedited review.

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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 JROs 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 JROs shall include review of proposals with regard to at least the following:

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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

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(A) An JRO 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).

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(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;

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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;
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 JRO 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.

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(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 JRO assigned. The costs shall include but not be limited to the fees of the JRO, reasonable copying expenses, mail and delivery fees and any other expense related to the review by an JRO's review.

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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 ~~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 ~~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 ~~rule~~ invalid in any circumstance, this shall not affect any other provision or circumstance.

SECTION 13. EFFECTIVE DATE

This ~~revised rule~~ shall take effect on ~~January 1, 2022~~.

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