TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 1</td>
<td>Purpose</td>
<td>2</td>
</tr>
<tr>
<td>Section 2</td>
<td>Authority</td>
<td>2</td>
</tr>
<tr>
<td>Section 3</td>
<td>Definitions</td>
<td>2</td>
</tr>
<tr>
<td>Section 4</td>
<td>Applicability and Scope</td>
<td>6</td>
</tr>
<tr>
<td>Section 5</td>
<td>Requirements for Licensure</td>
<td>6</td>
</tr>
<tr>
<td>Section 6</td>
<td>License Application</td>
<td>7</td>
</tr>
<tr>
<td>Section 7</td>
<td>Requirements for Service Review</td>
<td>10</td>
</tr>
<tr>
<td>Section 8</td>
<td>Disclosing Essential Information</td>
<td>11</td>
</tr>
<tr>
<td>Section 9</td>
<td>Agreements</td>
<td>11</td>
</tr>
<tr>
<td>Section 10</td>
<td>Enforcement</td>
<td>12</td>
</tr>
<tr>
<td>Section 11</td>
<td>Severability</td>
<td>13</td>
</tr>
<tr>
<td>Section 12</td>
<td>Effective Date</td>
<td>13</td>
</tr>
</tbody>
</table>
SECTION 1. PURPOSE

The purpose of this regulation is to set forth the requirements and standards for the licensing of persons or entities that perform service review activities of mental health care services.

SECTION 2. AUTHORITY

This rule is issued pursuant to the authority vested in the Commissioner of the Department of Banking, Insurance, Securities and Health Care Administration by 8 V.S.A. §§ 15, 4089a, 4089b, and 4724 and 18 V.S.A. § 9414.

SECTION 3. 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; and

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.

(B) “Clinical review criteria” means the written screening procedures, clinical protocols, practice guidelines and utilization management and review guidelines used by the managed care organization to determine the necessity and appropriateness of health care services.

(C) “Commissioner” means the Commissioner of Banking, Insurance, Securities and Health Care Administration or his or her designee.

(D) “Concurrent review” means utilization review conducted during a member's stay in a hospital or other facility, or other ongoing course of treatment.

(E) “Contracted provider” means a provider employed by, under contract or subcontract with, in a network, designated as preferred or otherwise in an arrangement with a managed care organization for
the purpose of furnishing health care services to the members of the managed care organization, regardless of the specific terms of or the terminology applied by the managed care organization to its relationship with the provider.

(F) “De-identified” means there has been a redaction consistent with the requirements in federal privacy rules promulgated pursuant to the Health Insurance Portability and Accountability Act (HIPAA) such that the de-identified information does not identify an individual and there is no reasonable basis to believe that the information can be used to identify an individual.

(G) “Department” means the Department of Banking, Insurance, Securities and Health Care Administration.

(H) “Discharge plan” means the plan that results from the formal process for determining, before discharge from a health care facility, the coordination and management of the care that a member will receive following the discharge.

(I) “File”, where used in the context of information to be provided to the Department by a managed care organization, means to file an original document by delivering it, and any copies as requested by the Department, to the Department of Banking, Insurance, Securities and Health Care Administration and, if requested by the Department, to an organization designated by the Department under Section 6(D). The Department may also, at its discretion, permit documents to be filed electronically.

(J) “Grievance” means a complaint submitted by or on behalf of a member regarding the:

1. Adverse benefit determination;
2. Availability, delivery or quality of health care services;
3. Claims payment, handling or reimbursement for health care services; or
4. Matters relating to the contractual relationship between a member and a managed care organization or the health insurer offering the health benefit plan.

(K) “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.

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

(M) “Health insurer” means any health insurance company, nonprofit hospital service corporation and nonprofit medical service corporation, managed care organization, and, to the extent permitted under federal law, any administrator of an insured, self-insured, or publicly funded health care benefit plan offered by public and private entities.

(N) “License” means a review agent’s license granted by the Commissioner

(O) “Manage care organization” means any financing mechanism or system that manages health care delivery for its members or subscribers, including but not limited to health maintenance
organizations, preferred provider organizations, exclusive provider organizations and any other health care delivery system or organization that manages health care delivery for its members or subscribers, or that issues a health insurance policy, plan, or subscriber contract which operates to manage health care delivery. The term managed care organization includes a mental health review agent as defined in 8 V.S.A. § 4089a, a health insurer as defined in 18 V.S.A. § 9402, a managed care organization as defined in 18 V.S.A. § 9402, a delegate of a health insurer or managed care organization, and any person or entity that meets the definition of a managed care organization under law.

(P) “Manage health care delivery” means to apply any design or mechanism to a health benefit plan to affect access to or the quality, coordination or cost of the health care available to members under the health benefit plan, including but not limited to the use of any form of utilization management; pharmaceutical benefit management; networks, preferred providers or any other restrictions or incentives for members to use certain providers; and/or disease, care or case management.

(Q) “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, and PubMed Medline, and 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 USPDI.

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.

(R) “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; 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.

(S) “Member” means any individual who has entered into a contract with a health insurer or managed care organization for the provision of health care services, or on whose behalf such an arrangement has been made, as well as the individual’s dependents covered by the contract.

(T) “Mental health care services” means acts of diagnosis, treatment, evaluation or advice or any other acts permissible under the health care laws of Vermont, whether performed in an outpatient or an institutional setting, and includes alcohol and drug abuse treatment.

(U) “Person” means a natural person, partnership, unincorporated association, corporation, limited liability company, municipality, the state of Vermont or a department, agency or subdivision of the state, or other legal entity.

(V) “Practicing mental health care provider” means any person certified or licensed to provide mental health care services and currently providing such services, including but not limited to a physician, nurse with recognized psychiatric specialties, psychologist, clinical social worker, mental health counselor, or alcohol or drug abuse counselor.

(W) “Review agent” means a person or entity performing service review activities who is either affiliated with, under contract with, or acting on behalf of a business entity in this state; or a third party who provides or administers mental health care benefits to citizens of Vermont, who are members of health benefit plans subject to the Department’s jurisdiction, including a health insurer, nonprofit health service plan, health insurance service organization, health maintenance organization or preferred provider organization, including organizations that rely upon primary care physicians to coordinate delivery of services.

(X) “Review agent medical director” means a Vermont-licensed physician who is board-certified or board-eligible in his or her field of specialty as determined by the American Board of Medical Specialties (ABMS) or the American Osteopathic Association (AOA), and who is charged by a mental health review agent with responsibility for overseeing all clinical activities of the mental health review agent in Vermont, or his or her designee.

(Y) “Service review” means any system for reviewing the appropriate and efficient allocations of mental health care services given or proposed to be given to a member or group of members for the purpose of recommending or determining whether such services should be reimbursed, covered or provided by an insurer, plan or other entity or person and includes activities of utilization review and managed care, but does not include professional peer review which does not affect reimbursement for or provision of services.

(Z) “Treating mental health care provider” means any person, corporation, facility or institution certified or licensed to provide mental health care services that is providing treatment to a member of a health benefit plan, including but not limited to a physician, nurse with recognized psychiatric specialties, hospital or other health care facility, psychologist, clinical social worker, mental health counselor,
alcohol or drug abuse counselor, employee or agent of such provider acting in the course and scope of employment, or agency related to mental health care services.

(AA) “Utilization management” means the set of organizational functions and related policies, procedures, criteria, standards, protocols and measures used by a managed care organization or pharmaceutical benefit management program to ensure that it is appropriately managing access to and the quality and cost of health care services, including prescription drug benefits, provided to its members.

(BB) “Utilization review” means a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings, including prescription drugs.

SECTION 4. APPLICABILITY AND SCOPE

Any person or entity meeting the definition of review agent shall not conduct or arrange for service review in this state without a valid and current review agent's license. All parties to any contracts between a third party payor and any person or entity conducting service review activities, directly or indirectly, whether affiliated or not, are responsible for compliance with the requirements and standards of this rule and all other applicable state and federal laws and rules, including but not limited to Department Rules H-2009-03 and H-2011-02. A license is not transferable or assignable and is valid only for the person or entity named in the application.

SECTION 5. REQUIREMENTS FOR LICENSURE

(A) A review agent license or license renewal may be granted if the applicant demonstrates to the satisfaction of the Department, or its delegate(s), that it:

1. has a sufficient number of qualified licensed mental health care providers to conduct review services in a timely manner;

2. adheres to accepted professional and clinical standards and principles in the review of services;

3. does not agree to any arrangement with a payor or any other entity in which compensation to the review agent or a provider is affected by any incentive or contingent fee arrangement based on any reduction or limitation of covered and medically necessary mental health care services including but not limited to length of stay, treatment, treatment level or setting; or that contains any provision that might be construed to offer an inducement to a reviewer or provider to forgo providing covered and medically necessary mental health care services to a member. Nothing in this subsection shall prohibit capitation arrangements for reimbursement of mental health care services;

4. has a review agent medical director to review and oversee operations and the quality thereof, including the appropriateness of clinical review criteria and their application, and a sufficient number of other Vermont-licensed psychiatrists, who are either board-certified or board-eligible, to conduct reviews, grievances and appeals as required by law;

5. complies with all applicable state and federal confidentiality laws and rules, that would apply to a health benefit plan if it were conducting the service review, including but not limited to
Section 2.1 of Department Rule H-2009-03;

6. operates in compliance with this rule and all other state and federal laws and rules that would apply to a health benefit plan if it were conducting the service review and that are applicable to its own activities and to the health benefit plans for which the applicant conducts service review; and

7. maintains liability insurance coverage consistent with the operations it undertakes.

SECTION 6. LICENSE APPLICATION

(A) An application for an initial license as a review agent shall include, in a form prescribed by the Commissioner:

1. the applicant’s name, business address, contact name, telephone and email address, business website address, EIN;

2. the number of lives for whom the applicant is obligated to provide service reviews in each of the following categories:

   a. the number of lives proposed to be or currently covered by health benefit plans subject to the Department’s jurisdiction, and within each of those categories, the number of lives that reside in Vermont and the number of lives that do not reside in Vermont, if known;

   b. the number of Vermont lives proposed to be or currently covered by health benefit plans not subject to the Department’s jurisdiction;

   c. the total number of lives nationwide for which the review agent is responsible.

3. an organizational chart that identifies all positions within the organization, including the location within the organization of the position or positions responsible for supervising the service review staff, and the licensed physicians responsible for reviewing adverse benefit determinations prior to their issuance;

4. a list of officers and directors of the review agent, the person or persons with responsibility for supervising the service review staff and the names and license numbers of all physicians responsible for reviewing adverse benefit determinations;

5. a statement explaining any changes in name or acquisition of a majority equity interest by a single individual or entity of the review agent at any time during the previous two calendar years;

6. disclosure of all instances during the past five years in which the review agent and review agent medical director(s) have:

   a. had a license, permit, registration, accreditation or other certificate of authority denied, revoked, suspended, limited, conditioned or otherwise sanctioned by a licensing entity in any jurisdiction;
b. been subject to a cease and desist letter or order, or enjoined, either temporarily or permanently, in any judicial, administrative, regulatory, or disciplinary action, from violating any federal or state laws, or law of another country;

c. been subject to any non-confidential business-related administrative, civil or criminal investigations, regulatory actions, disciplinary actions, lawsuits, arbitrations or other proceedings, except for any such actions initiated by the Department.

Any such disclosures shall include a description of the matter, including dates; how the matter was resolved, if not a confidential settlement; and the subsequent history of the matter, including details of any settlement, restrictions, conditions, limitations and penalties.

7. information about the professions, licensure type and status, qualifications, compensation structure and number of personnel performing service review activities. Information about compensation structure shall not include information about salaries, but shall include information about any bonus or incentive structures, not to include amounts;

8. documentation of any URAC, NCQA or other accreditation, including level and duration of accreditation, and whether the business office(s) location of the review agent responsible for Vermont service reviews has specifically been accredited;

9. copies of all written policies, and procedures, and adverse benefit determination letter templates, used for initial service review, and grievance reviews, if applicable, or a detailed explanation of how such notices to members are handled if not by the review agent;

10. a list of the titles, sources and a brief description of all clinical review criteria, including those that are proprietary; any other resources used by service review staff, including interpretive guidelines for use with the criteria; and an attestation by the review agent medical director that the clinical review criteria:

a. are 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 condition; and

b. have been reviewed and updated at least annually, taking into account input from practicing mental health care providers, including providers under contract with the review agent, if any. This subsection shall not be construed to require review agents to make modifications to nationally-recognized guidelines. The Department reserves the right to review clinical review criteria at any time;

11. a detailed description of how the applicant will train and evaluate all service review staff at least annually to ensure consistent and clinically appropriate application of clinical review criteria and how it will assess accuracy and inter-reviewer reliability;

12. evidence of liability insurance coverage sufficient to ensure financial responsibility in the event of a claim, settlement or judgment against the review agent;

13. a description of the applicant’s business activities in the State of Vermont other than mental
Rule H-2011-01

9

health or substance abuse service review, if any, and evidence of registration and/or licensure if required for those activities; and if the applicant is not licensed as an insurer by the Department, an attestation that the applicant does not engage in the business of insurance in Vermont;

14. any other information requested by the Department; and

15. the license fee required by law and any additional expenses incurred by the Department to examine and investigate the application or amendment to the application.

(B) The review agent shall report any changes to the information described in Section 6A of this Rule and provided in its application or renewal applications to the Department at least 30 days prior to the anticipated implementation of the change and within 15 days of an unanticipated material change.

(C) A review agent shall apply annually for license renewal on September 15 or an alternative date specified by the Department. The renewal application shall include:

1. a completed renewal application in a form prescribed by the Commissioner;

2. disclosure of any changes in the information described in Section 6A of this Rule that have occurred since the latter of the initial license application or any renewal application, whether or not previously disclosed to the Department;

3. a de-identified summary of the information specified below for the prior calendar year, in the format specified by the Department, that includes:
   a. the number, results and a summary of all service reviews, if applicable and whether benefits were denied or reduced, including the number of members involved. The Department, in its sole discretion, may waive the requirement in this sub-paragraph for review agents that are subject to and in compliance with other rules that would require them to file the identical information with the Department;
   b. the number and results of any internal grievances, if applicable, including the number of members involved; and
   c. a summary of reasons for the internal grievances, if applicable.

4. current evidence of liability insurance coverage sufficient to ensure financial responsibility in the event of a claim, settlement or judgment against the review agent;

5. an updated attestation, verifying that:
   a. the clinical review criteria and standards have been reviewed within the last year, taking into account input from practicing licensed mental health care providers, including providers under contract with the review agent, if any. This subsection shall not be construed to require managed care organizations to make modifications to nationally-recognized guidelines based on input from practicing mental health care providers;
b. the clinical review criteria and standards and policy and procedure manuals have been updated, if necessary, and remain informed by generally accepted medical and scientific evidence and consistent with clinical practice parameters as recognized by health care professions in the same specialties as typically provide the procedure or treatment, or diagnose or manage the condition; and

c. the training required by subsection 6.A.14. of this Rule was conducted within the last year, including a summary of the evaluation of the service reviewer staff’s consistency, accuracy and inter-reviewer reliability;

6. current copies of adverse benefit determination letter templates used for initial service reviews, first level grievances and voluntary second level grievances;

7. any other information requested by the Department; and

8. the license renewal fee required by law, including any additional expenses incurred by the Department to examine and investigate the application or amendment to the application.

(D) The Department may, in its discretion, designate another organization to review initial license applications. Any such organization shall have a confidentiality code acceptable to the Department, or shall be subject to the Department’s confidentiality code.

SECTION 7. REQUIREMENTS FOR SERVICE REVIEW

(A) A review agent shall adopt and implement written policies and procedures to ensure that its service review practices:

1. comply with applicable state and federal law regarding service review, including but not limited to utilization review and grievance procedures, independent external review of adverse benefit determinations, if applicable, and related notice requirements. In the absence of specific other state law requirements for service review in health benefit plans subject to the Department’s jurisdiction, the service review procedures shall be consistent with or more favorable to the member than the utilization review and grievance requirements and procedures set forth in Sections 3.1, 3.2 and 3.3 of Rule H-2009-03 or any later amendment. In addition, the service review practice shall:

   a. provide that if the review agent medical director is not a psychiatrist, there must be at least one consulting psychiatrist with board certification in psychiatry who is licensed in the State of Vermont readily available to the clinical review staff;

   b. ensure that the treating mental health care provider or his or her designee has been notified and has been given an opportunity to participate before the review agent initiates contact with a member other than for routine outpatient utilization review purposes. Such notification and opportunity to participate shall be documented in the records of the review agent. Notice shall not be required when a member has a complaint about the treating mental health care provider or is receiving treatment at a non-participating facility.

   c. adopt and implement clinical review criteria to make service review decisions which
are established and evaluated at least annually and updated with appropriate involvement from practicing mental health care providers and which are the subject of the attestations required by subsections 6(A)(13) and 6(C)(5) of this rule. Such standards and criteria must be compatible with established principles and standards of mental health care;

d. limit review activities to those necessary to ensure the delivery of quality mental health care in a cost effective manner; and

e. retain all medical and service review records in the possession of the review agent for a period of six (6) years.

SECTION 8. DISCLOSING ESSENTIAL INFORMATION

(A) The review agent shall comply with the requirement set forth in Department Rule H-2009-03 Sections 3.2(G) and 3.3(P) regarding the disclosure of information to members for initial service review and grievance review determinations respectively; and

(B) The review agent shall provide members with a Department-approved notice of Vermont appeal rights with each notification of determination.

SECTION 9. AGREEMENTS

(A) A review agent shall not agree with any business entity or third-party payor that the payment to the review agent shall include an incentive or contingent fee arrangement based on the reduction of medically necessary care for mental health services.

(B) All agreements between a review agent and a business entity or person regarding the review of mental health care shall be in writing. If such entity or person is engaging in activity that meets the definition of “service review” under this Rule, it must be licensed under this Rule. In addition, any contracted business entity or person to whom the review agent delegates activities must meet the requirements of Section 1.3(F) of Department Rule H-2009-03.

(C) A review agent, that enters into a contract with a health insurer for the purpose of administering the health insurer’s mental health benefits shall COOPERATE with the health insurer to ensure that the portion of the health insurer’s premium rate attributable to the coverage of mental health benefits under Title 8 V.S.A. §§ 4062, 4513, 4584, or 5104 is not excessive, inadequate, unfairly discriminatory, unjust, unfair, inequitable, misleading or contrary to the laws of this State prior to implementation.

Premium rates submitted by a health insurer are subject to Department review and approval at least 90 days prior to the first intended use of that premium rate and shall include the following information obtained from the contract currently in effect between the health insurer and the mental health review agent as of the date the premium rate filing is submitted regarding the premium rate component attributable to coverage for mental health benefits administrated by a review agent:

1. the amount that the health insurer has agreed to pay a review agent for administering mental health benefits; and
2. an itemized detailed description of the benefits and administrative services to be financed and/or administered by the review agent or managed care organization;

3. the degree of insurance risk assumed by the review agent;

4. the period of time that the rates are designed to be effective;

5. the amount of the rate(s), variations by benefit level (if any), and any other variations that are contemplated;

6. for other than capitation agreements, the components of the proposed rates, including the expected claims cost, the cost of administration, the profit margin, and any other component not otherwise identified;

7. any other relevant information requested by the Department; and

8. a statement signed by a member of the American Academy of Actuaries attesting that the filing is consistent with actuarial standards of practice and meets the requirements of the Code of Professional Conduct of the American Academy of Actuaries.

(D) Nothing in this section shall prohibit capitation arrangements for reimbursement of mental health services.

SECTION 10. ENFORCEMENT

(A) The Commissioner may refuse to issue or renew a license if the Commissioner finds that the applicant or licensee does not satisfy any standard or requirement of this rule or of any provision of any other applicable state or federal law relating to the qualifications of review agents or the performance of service review.

(B) The Commissioner may suspend or revoke a license or permit continued licensure subject to such conditions as the Commissioner deems necessary to carry out the purposes of applicable law for a violation of this regulation or any provision of applicable state and federal law.

(C) A person who violates any provision of this rule is subject to the penalties provided in Chapters 3, 101, 107 and 129 of Title 8 and such other chapters of Titles 8 and 18 as may be applicable.

SECTION 11. SEVERABILITY

If any provision of this regulation or the application thereof to any person or circumstance is for any reason held to be invalid, the remainder of the regulation and the application of such provisions to other persons or circumstances shall be not affected thereby.

SECTION 12. EFFECTIVE DATE

This rule shall take effect ninety (90) days after adoption. The Department may, in its sole discretion and
upon good cause shown, permit a review agent to transition to full compliance with any component(s) of this rule over a period of time not to exceed six months from the date of adoption.