RULES AND REGULATIONS

FOR THE UTILIZATION REVIEW

OF HEALTH CARE SERVICES

(R23-17.12-~~1~~-UR)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Health
August 1993 (E)

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INTRODUCTION

These *Rules and Regulations for the Utilization Review of Health Care Services (R23-17.12-UR)* are promulgated pursuant to the authority conferred under Chapters 23-17.12 and 42-35 of the General Laws of Rhode Island, as amended, and are established for the purpose of defining minimum standards for the utilization review of health care services, and the delivery of health care in a cost effective manner.

In accordance with the provisions of section 42-35-3 (c) of the General Laws of Rhode Island, as amended, in the development of the regulations, consideration was given to: (1) alternative approaches to the regulations; (2) duplication or overlap with other state regulations; and (3) any significant economic impact on small business as defined in Chapter 42-35 of the General Laws. Based on the available information, no known alternative approach, duplication or overlap was identified. The health, safety, and welfare of the public overrides any economic impact which may be incurred from these proposed regulations.

These amended regulations shall supersede all previous *Rules and Regulations for the Utilization Review of Health Care Services (R23-17.12-UR)* promulgated by the Department of Health and filed with the Secretary of State.

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PART I **DEFINITIONS**

Section 1.0 ***Definitions***

Wherever used in these rules and regulations, the terms listed below shall be construed as follows:

1.1 ***"Act"*** refers to Chapter 23-17.12 of the General Laws of Rhode Island, as amended, entitled "Health Care Services - Utilization Review Act."

1.2 ***"Administrative cost***" means any charge by an external appeal agency for a determination excluding the appeal fee charged by the neutral physician or dentist.

1.3 ***"Adverse determination"*** means any decision by a review agent not to certify a health care service; provided, however, that a decision by a reviewing agent to certify a health care service in an alternative treatment setting, or to certify a modified extension of stay, or an alternative treatment, shall not constitute an adverse determination if the reviewing agent and the requesting provider are in agreement regarding the decision. Adverse determinations shall include decisions not to certify formulary and non-formulary medication with the exception of the circumstances defined in sections 1.33 and 1.35 herein.

1.4 ***"Attending provider"*** shall mean the same as "***ordering practitioner***" for the purposes of the rules and regulations herein.

1.5 ***"Business day"*** means a day during which the state government of Rhode Island conducts regular business.

1.6 ***"Certificate"*** means a certificate of registration granted by the Director to a utilization review agent.

1.7 ***"Claims review"*** means the assessment by or on behalf of the health plan of the health care services rendered and charges made, followed by either the authorization of payment or nonpayment.

1.8 ***"Concurrent assessment"*** means a review conducted during a patient's hospital stay or course of treatment. If the medical problem is ongoing, this assessment may include the review of services after they have been rendered and billed. This review does not mean the elective requests for clarification of coverage or claims review or a provider's internal quality assurance program except if it is associated with a health care financing mechanism.

1.9 ***"Conflict of interest"*** means the lack of objectivity which may be caused by, but is not limited to, financial incentives which base reimbursements received upon the numbers of adverse determinations rendered, or other action which prevents the proper discharge of duties between a reviewer and other affected persons.

1.10 ***"Department"*** means the Rhode Island Department of Health.

1.11 **"*Designee*"** means a qualified professional responsible for the treatment of the patient in the absence of the attending provider. The designee is selected and assigned to the patient by the attending provider.

1.12 ***"Director"*** means the Director of Health.

1.13 ***"Emergency"*** means the sudden onset of a medical or mental condition that the absence of immediate medical attention could reasonably be expected, by a prudent lay person, to result in placing the patient's health in serious jeopardy, serious impairment to bodily or mental functions, serious dysfunction of any bodily organ or part.

1.14 "***Emergent health care services"*** shall have the same meaning as that meaning contained in the rules and regulations promulgated pursuant to Chapter 12.3 of Title 42 of the Rhode Island General Laws, as amended, and shall include those resources provided in the event of the sudden onset of a medical, mental health or substance abuse, or other health care condition manifesting itself by acute symptoms of severity (e.g. acute pain) where the absence of immediate medical attention could reasonably be expected, by a prudent lay person, to result in placing the patient's health in serious jeopardy, serious impairment to bodily or mental functions, or serious dysfunction of any body part or organ.

1.15 ***"Expedited appeal"*** means a formal request to the utilization review agency or review agent to reconsider an adverse determination that is made prior to or during an ongoing service that has been determined by the attending provider to be of an emergency nature as defined in section 1.13 herein.

1.16 ***"External appeals agency"*** means an unrelated and objective appeal agency, selected by the Director to provide a binding decision in cases where a second level appeal by a certified utilization review agency or review agent has been unsuccessful.

1.17 "***Health care entity"*** means a licensed insurance company, or hospital, or dental or medical service plan or health maintenance organization, or a contractor that operates as a health plan certified according to Chapter 23-17.13 of the Rhode Island General Laws.

1.18 ***"Health care services"*** means and includes an admission, diagnostic procedure, therapeutic procedure, treatment, extension of stay, the ordering and/or filling of formulary or non-formulary medications, and any other services, activities or supplies which are covered by the patient's benefit plan.

1.19 ***"Internal appeal"*** means the procedure provided by the review agency in which either the patient or the provider of record may seek review of decisions not to certify an admission, procedure, service or extension of stay.

1.20 ***"Material modification"*** means any substantial systemic change to the certification information on file at the Department, which is deemed material by the Department pursuant to section 3.3 herein.

1.21 ***"Neutral physician or dentist"*** means an objective physician of allopathic or osteopathic medicine or a dentist, licensed to practice by a state or territorial licensing entity in the United States having no conflict of interest, who is selected in accordance with section 6.0 herein.

1.22 ***"Ordering practitioner"*** means any person licensed to provide or otherwise lawfully providing health care services, including, but not limited to, a physician, dentist, chiropractor, nurse, optometrist, podiatrist, physical therapist, clinical social worker, or psychologist who has been identified by the patient/family as having a significant role in the determination and delivery of the individual's medical care and who has requested the admission, health care service, procedure or extension of stay.

1.23 ***"Patient"*** means an enrollee or participant in a hospital or medical or dental plan, who is seeking health care services and treatment from a provider. A patient may designate a person(s) as his/her representative.

1.24 ***"Person"*** means any individual, trust or estate, partnership, corporation (including but not limited to associations, joint stock companies), limited liability companies, state or political subdivision or instrumentality of the state.

1.25 ***"Practitioner"*** means any person licensed to provide or otherwise lawfully providing health care services, including, but not limited to, a physician, dentist, nurse, optometrist, podiatrist, physical therapist, clinical social worker, or psychologist.

1.26 ***"Precertification"*** is the requirement that a patient or provider, as a condition of coverage for a specific benefit, obtain approval from a review agent prior to services being provided. This shall have the same meaning as preauthorization and prior authorization.

1.27 ***"Prospective assessment"*** means a review conducted prior to a patient's hospital stay or course of treatment.

1.28 ***"Provider"*** means any health care facility, as defined in section 23-17-12 of the General Laws, as amended, including any mental health and/or substance abuse treatment facility, physician, dentist or other licensed, registered or certified practitioners identified to the review agent as having responsibility for the care, treatment and services rendered to a patient.

1.29 ***"Provider of record"*** shall mean the same as "Provider" for the purposes of the rules and regulations herein.

1.30 ***"Request for authorizations"*** are those requests for health care services from an ordering practitioner where criteria is applied by a review agency in order to determine the medical necessity and appropriateness of the service and where an adverse determination may result.

1.31 ***"Retrospective review***" means assessment of the medical necessity and appropriateness of health care services that have been rendered. This shall not include reviews conducted when the review agency has been obtaining ongoing information.

1.32 ***"Review agent"*** or ***"review agency"*** means a person, entity or insurer performing utilization review that is either employed by, affiliated with, under contract with or acting on behalf of:

1.32.1 a business entity doing business in this state; or

1.32.2 a party that provides or administers health care benefits to citizens of this state, including, but not limited to, a health insurer, self-insured plan, non-profit health services plan, health insurance plan, health insurance service organization, preferred provider organization or health maintenance organization authorized to offer health insurance policies or contracts or pay for the delivery of health care services or treatment in this state; or

1.32.3 a provider.

1.33 ***"Therapeutic interchange"*** means the interchange or substitution of a drug with a dissimilar chemical structure within the same therapeutic or pharmacological class that can be expected to have similar outcomes and similar adverse reaction profiles when given in equivalent doses, in accordance with protocols approved by the president of the medical staff or medical director and the director of pharmacy.

1.34 ***"Urgent health care services"*** shall have the same meaning as that meaning contained in the rules and regulations promulgated pursuant to Chapter 12.3 of Title 42, as amended, and shall include those resources necessary to treat a symptomatic medical, mental health or substance abuse or other health care condition requiring treatment within a twenty-four (24) hour period of the onset of such a condition in order that the patient's health status not decline as a consequence. This does not include those conditions considered to be emergent health care services as defined herein.

1.35 ***"Utilization review"*** means the prospective, concurrent, or retrospective assessment of the medical necessity and appropriateness of the allocation of health care services of a provider, given or proposed to be given to a patient, or group of patients. Utilization review does not include:

1.35.1 elective requests for the clarification of coverage;

1.35.2 claims review that does not include the assessment of the medical necessity and appropriateness;

1.35.3 a provider's internal quality assurance program, except if it is associated with a health care financing mechanism;

1.35.4 the therapeutic interchange of drugs or devices by a pharmacy operating as part of a licensed inpatient health care facility; and

1.35.5 the assessment by a pharmacist licensed pursuant to the provisions of Chapter 19 of Title 5 and practicing in a pharmacy operating as part of a licensed inpatient health care facility in the interpretation, evaluation and implementation of medical orders, including assessments and/or comparisons involving formularies and medical orders.

1.36 ***"Utilization review plan"*** means a description, in such detail as may be required by the Director, of the standards governing utilization review activities performed by a private review agent.

PART II **CERTIFICATION AND WAIVER REQUIREMENTS**

Section 2.0 ***Utilization Review Agency General Requirements***

2.1 A review agent shall not conduct utilization review for health care services delivered or proposed to be delivered in the state of Rhode Island unless the Department has either granted the review agent a certificate or determined by application that the review agent has met the requirements of the waiver defined in section 4.0 herein.

2.2 To be certified by the state of Rhode Island as a utilization review agency, the agency must meet and maintain the minimum standards defined herein.

2.2.1 The Department shall issue a certificate to an applicant that has met the minimum standards established by the Act and the rules and regulations herein, including the payment of such fees and other applicable requirements.

2.2.2 Individuals shall not be required to hold separate certification under the Act when acting either as an employee of, an affiliate of, a contractor for, or otherwise acting on behalf of a certified review agency.

2.2.3 A certificate is not transferable. Transfer of fifty percent (50%) or more of the ownership of a review agency shall be deemed a transfer.

2.2.4 Certified utilization review agent shall adhere to any and all applicable state or federal laws.

Section 3.0 ***Requirements for the Certification of Utilization Review Agencies***

3.1 The submission of any application filed with the Department shall include:

3.1.1 a completed application form provided by the Director that is accompanied by supporting documents as required, which are verified and signed by the applicant;

3.1.2 a utilization review plan, including, but not limited to:

a) standards, criteria and guidelines to be utilized by any agent providing utilization review; The external appeals agency shall not disclose to any other third party those standards which are considered "trade secrets" by the review agent;

b) those circumstances, if any, under which utilization review may be delegated to any other utilization review program and evidence that such delegated agency is a certified utilization review agent pursuant to the requirements herein; and

c) a complaint resolution process, consistent with section 23-17.12-9 of the General Laws, whereby patients, physicians or other health care providers may seek prompt consideration or appeal of adverse determinations by the review agent as well as the resolution of other complaints regarding the review process.

3.1.3 the scope of services provided by the utilization review agency/agent;

3.1.4 the type and qualifications of personnel either employed by, affiliated with, contracted with or otherwise acting on behalf of the review agent to perform utilization review; including the requirement that only an appropriately licensed physician, dentist or other practitioner with the same licensure status as the ordering practitioner, or a physician or dentist be permitted to make adverse determinations;

3.1.5 the policies and procedures to ensure that all applicable state and federal laws to protect the confidentiality of medical records are followed;

3.1.6 policies and procedures to ensure that a representative of the review agent is reasonably accessible to patients and providers according to the following:

a) a minimum of five days a week during normal business in the state of Rhode Island and during the agency's review operations; and

b) if the agency performs concurrent review, there shall be an acceptable mechanism in place to conduct such review after the agency's normal business hours.

3.1.7 assurance that enrollees have been informed of the requirements under the health benefit plan for seeking utilization review or precertification and their rights under the Act, including information on appealing adverse determinations;

3.1.8 a copy of the materials designed to inform patients and providers of the requirements of the utilization review plan;

3.1.9 a list of the third party payors and business entities for which the review agent is performing utilization review in this state and a brief description of the services it is providing for each client;

3.1.10 a statement that the review agency has not entered into compensation agreements with its employees or contracts with its employees, individuals or other entities whereby the compensation is based upon a reduction of services or charges, the reduction of length of stay or the use of alternative treatment settings; provided, however, that capitation agreements and similar risk sharing arrangements are not prohibited;

3.1.11 evidence of liability insurance or of assets sufficient to cover potential liability; and

3.1.12 other information requested by the Department to evidence compliance with the rules and regulations herein.

3.2 The Department shall act upon the agency's completed application within ninety (90) days of receipt of a completed application for certification, recertification, or material modification.

3.3 The certified utilization review agency shall notify the Department prior to the implementation of any substantial systemic change in operations relative to the certification information on file with the Department. If the Department determines a change to be material, the certified agency shall submit an application for a material modification.

3.3.1 The information shall be filed no less than thirty (30) days prior to implementation of the change.

3.3.2 No implementation of any material modification shall be in effect without the prior approval of the Department.

3.3.3 If the Department does not disapprove of the modification within ninety (90) days of the receipt of all necessary information, it shall be deemed approved.

3.3.4 If a certified review agency terminates a contract to conduct utilization review for a health care entity, it shall conform to the following unless otherwise determined by the Department:

a) provide a sixty (60) day prior notice of termination to the Department;

b) assure a sixty (60) day prior notice of termination to the enrollees of each health care entity for which it is conducting utilization review; and

c) continue utilization review services delegated to the review agency by the health care entity during this sixty (60) day period.

3.4 The Department may review a certified review agent at any time.

3.4.1 Certified utilization review agents shall submit an application for recertification every two years.

3.4.2 Every review agency shall be given prompt notice by the Department of all deficiencies cited upon examination. A plan to correct all deficiencies shall be submitted to the Department by the agency within a twenty (20) calendar day period. If said plan is not acceptable to the Department, the Department may take action in accordance with section 9.0 herein.

3.5 The cost of the application process, certification, recertification, material modifications, agency reviews, and other activities directly related to obtaining and maintaining a utilization review agency's certification including, but not limited to, compliance with the rules and regulations herein shall be borne by the agency.

3.5.1 An application fee of five hundred dollars ($500) must accompany the application for certification. The cost of one hundred and fifty percent (150%) of the total salaries paid to the certifying personnel of the Department for the certification activities described in section 3.5 herein shall be paid by the agency. Such cost shall be in addition to the application fee and any other fee, fine or tax otherwise payable to the Department as a result of the enforcement of the rules and regulations herein.

3.5.2 Certified utilization review agencies shall have the opportunity to review documents to substantiate their costs as described in section 3.5.1 herein.

3.5.3 Payments for the costs of the application process, certification, recertification, material modifications and agency reviews shall be made payable to the General Treasurer, State of Rhode Island.

a) Payments for the costs of the application process, certification, recertification, material modification and agency reviews shall be billed monthly and payment by the review agency is due thirty (30) days following issuance of each bill.

b) Failure to make payment by the required due date will result in a fine determined by the Director. Failure to respond to the Department and remit fine within a ninety (90) day period will be subject to section 9.0 herein.

Section 4.0 ***Waiver of Certification Requirements***

4.1 Except for utilization review activities performed to determine the necessity and appropriateness of substance abuse and mental health care, treatment or services, and except for the rules and regulations to maintain compliance with sections 23-17.12-9, 23-17.12-12 and 23-17.12-14 of the Rhode Island General Laws, the Department shall determine the waiver of the requirements herein for a review agent that has received, maintains and provides evidence to the Department of accreditation from the Utilization Review Accreditation Commission (URAC), or other such agency as approved by the Director. The waiver shall be applicable only to those utilization services, which are included and reviewed under such accreditation.

4.1.1 The utilization review agency shall submit all its operational policies and procedures that apply to its utilization review activity in order for the Department to determine its waiver status.

4.1.2 The certified utilization review agent shall notify the accreditation agency of any formal action taken by the Department within fifteen (15) days of such action.

4.1.3 The certified utilization review agent shall notify the Department of any formal action taken by the accreditation agency within fifteen (15) days of such action.

4.2 The Department shall waive the certification requirements of the Act and these rules and regulations only when a direct conflict exists with the requirements of the Act and these rules and regulations herein and for those activities of a review agent that are conducted pursuant to contract with the state or federal government or those activities under other state or federal jurisdictions.

4.3 All utilization review agencies must apply for a waiver by submitting a completed application form provided by the Director.

4.4 The cost to obtain and maintain certification under this section shall be in accordance with section 3.5 herein.

4.5 All agencies shall be notified by the Department, in writing, as to their waiver status within sixty (60) days of the receipt of a completed application.

PART III **DETERMINATIONS AND APPEALS**

Section 5.0 ***Utilization Review Determinations and Internal Appeals Process for Adverse Determination*s**

5.1 A review agency must maintain and provide evidence of and adherence to operational policies and procedures for utilization review determinations, which have been approved by the Department or an accreditation agency acceptable to the Department and shall include policies and procedures for the following:

5.1.1 a utilization review plan that shall be provided, upon request, to patients and providers; this plan shall include a summary of the standards, procedures and methods to be used in evaluating proposed or delivered health care services; said plan shall be in compliance with sections 5.13 and 5.14 herein;

5.1.2 the clear documentation of the ordering providers' original requests and any negotiation/agreement to accept an alternative treatment or modified extension of stay as defined in section 1.3 herein;

5.1.3 assurance that the negotiation/agreement between the review agency and the ordering provider as defined in section 1.3 herein is not coerced by the review agency or its reviewers;

5.1.4 written screening criteria and review procedures used to determine the medical necessity and/or appropriateness of health care services which are periodically updated with documentation of consultation with appropriately qualified Rhode Island licensed physicians, including practicing physicians and other health care providers; said criteria and procedures shall be in compliance with sections 5.13 and 5.14 herein;

5.1.5 documentation that the utilization review agency or its review agents shall not impede the provision of health care services when the attending provider has determined the health care services to be an emergency as defined in section 1.13 herein;

a) the emergency nature of an admission or treatment shall be documented and signed by the appropriate provider;

b) this emergency admission may be subject to review by a review agency for the purpose of reimbursement or denial;

5.1.6 assurance that the utilization review agency and/or its review agents shall not engage in direct discussions and/or patient interview to assess the medical and/or mental health status of a patient;

a) all assessments shall be made through chart review and discussion with attending provider and/or his /her designee;

5.1.7 provisions that if a patient or provider does not release the necessary information to the utilization review agency in accordance with sections 5.10 and 5.12 herein, the utilization review agency may deny certification;

5.1.8 assurance that the review agency has a policy which states that the decision to provide treatment or service to a patient is the responsibility of the attending provider and his or her patient;

5.1.9 provisions that the determination of covered services and benefits is the responsibility of the hospital plan, medical plan, dental plan, health maintenance organization, designated claims administrator or other health care plan;

5.1.10 documentation that the review agency establish a quality assurance program structured to monitor and evaluate the implementation of its administrative and operational policies on an annual basis; and

5.1.11 a review agency is not permitted to retrospectively deny coverage for health care services provided to a covered person when prior approval (i.e. pre-certification) has been obtained from the review agent unless such approval was based upon inaccurate information material to the review; or the health care services were not consistent with the provider's submitted plan of care and/or any restrictions included in the prior approval granted by the review agent.

5.2 The review agency shall maintain an adverse determination process which shall meet the following standards:

5.2.1 Upon written request made by or on behalf of a patient, any adverse determination that health care rendered or to be rendered is inappropriate shall include a written evaluation and the findings of the reviewing practitioner except as defined in section 5.3.5 herein; provided, however, that the review agent is required to accept a verbal request made by or on behalf of a patient for such information where a provider or patient can demonstrate that a timely response is urgent.

a) the verbal request must be forwarded in writing to the review agency within seven (7) days;

b) the provider and the review agency shall adhere to state and federal confidentiality laws;

5.2.2 No prospective or concurrent adverse determination can be made, and no retrospective adverse determination for emergency health care services can be made, until there is evidence that an appropriately qualified and licensed practitioner with the same licensure status as the ordering practitioner, or physician or dentist, has spoken to, or otherwise provided for, an equivalent two-way direct communication with the patient's attending practitioner (or designee) concerning the health care services.

a) Such equivalent two-way direct communication shall include:

i) telephone conversations; and/or

ii) facsimile or electronic transmissions, if mutually agreed upon.

b) If, pursuant to these efforts, a patient's attending practitioner (or designee) is not reasonably available, an adverse determination may be made based on the information available to the review agency in accordance with section 5.3 herein.

c) The agency reviewer shall make no fewer than two documented attempts to communicate, consistent with the requirements of section 5.2.2 herein, with the attending provider (or designee), giving the provider sufficient time to respond after each attempt.

d) The designee shall be assigned only with the authority of the attending practitioner.

5.2.3 Documentation of the efforts to communicate, consistent with the requirements of section 5.2.2 herein, with the patient's attending practitioner (or designee) must be retained on file by the review agent.

5.2.4 No employee of or other individual rendering an adverse determination for a review agent may be compensated or paid bonus or receive any financial incentives based upon the number of denials or approvals made by such an employee.

5.2.5 No prospective or concurrent adverse determination can be made, and no retrospective adverse determination for emergency health care services shall be made on any question relating to health care services by any person other than an appropriately licensed physician, dentist or other practitioner with the same licensure status as the ordering practitioner, or a physician or dentist.

a) Prior to such determination, the decision shall be communicated, consistent with the requirements of section 5.2.2 herein, with the affected practitioner or qualified professional responsible for the treatment of the patient where such person is reasonably available.

b) The concurrent review process shall take into consideration, but not be limited to:

i) the transition of care of the patient;

ii) the time of day of discharge;

iii) the patient's transportation limitations; and

iv) the welfare and safety of the patient.

c) A review agency is not permitted to conduct a retrospective review of health care services that were in the process of a concurrent review even if those services were already rendered and/or billed.

5.3 The decision and notification process of the review agency shall conform to the following requirements:

5.3.1 Notification of a prospective adverse determination by the review agent shall be mailed or otherwise communicated to the provider of record and to the individual patient within one (1) business day of receipt of all information necessary to complete the review with the exception of the following:

a) non urgent and non emergency cases as defined in sections 1.13, 1.14 and 1.34 shall be communicated within seven (7) business days of receipt of all information necessary to complete the review or prior to the proposed date of service if more than seven (7) days.

5.3.2 Notification of a concurrent adverse determination shall be mailed or otherwise communicated to the patient and to the provider of record prior to the end of the current certified period with the exception and consideration of the following:

a) in cases where the financial arrangements between providers and payers determine that patients be held financially harmless, notice to the patients shall be provided within one (1) business day of the final determination; and

b) in the event that the attending provider (or designee) has not been reasonably available and the attending provider's input has been determined to be essential by the agency to assessing the medical necessity of the health care services, the review agency may delay such notification for a period of one (1) business day in order to attempt further contacts with the attending provider (or designee).

i) If contact with the attending provider (or designee) is made within this period of time and the agency chooses to authorize the requested health care services, no adverse determination has been made and therefore no notification is required.

ii) If contact is made with the attending provider (or designee) within this period of time and the agency chooses not to authorize the requested health care services, notification of the denial to the patient and provider shall be made by the end of the extended period of time as defined in section 5.3.2 b) herein.

iii) If contact with the attending provider (or designee) is unsuccessful, the agency shall make its determination based on the clinical information available and notification to the patient and provider shall be made by the end of the extended period of time as defined in section 5.3.2 b) herein.

5.3.3 Notification of a retrospective adverse determination shall be mailed or otherwise communicated to the patient and to the provider of record within thirty (30) business days of receipt of a request for payment with all supporting documentation for the covered benefit being reviewed.

5.3.4 Any notice of a prospective or concurrent adverse determination and any notice of a retrospective adverse determination for emergency health care services shall be mailed or otherwise communicated to the patient and provider of record, and shall include:

a) the principal reasons for adverse determination;

b) the procedures to initiate an appeal of the determination;

c) the telephone number of the person to contact with regard to an appeal; and

d) a reasonable period of time in which an appeal must be filed to be considered.

5.3.5 Any notice of a retrospective adverse determination with the exception noted in section 5.3.4 herein, shall be mailed or otherwise communicated to the patient and provider of record, and shall include:

a) documentation that the determination was based on the lack of medical necessity and/or appropriateness of the health care service; and

b) the telephone number of the person to contact with regard to initiating an appeal.

5.3.6 All initial concurrent and prospective adverse determinations and retrospective adverse determinations for emergency health care services that have been ordered by a practitioner shall be:

a) made by a licensed practitioner with the same licensure status as the ordering practitioner or a licensed physician or dentist, as appropriate;

b) signed by a licensed practitioner with the same licensure status as the ordering practitioner or a licensed physician or dentist as appropriate; and

c) documented by a licensed practitioner with the same licensure status as the ordering practitioner or a licensed physician or dentist, as appropriate.

5.3.7 All retrospective adverse determinations for non emergency health care services that have been ordered by a practitioner shall be:

a) made according to written guidelines which have been reviewed by local participating and practicing providers; and

b) any guidelines used to make the adverse determination must be signed by the appropriately qualified and licensed practitioner responsible for the implementation of the utilization review program.

5.4 The first level internal appeals process of the utilization review agent shall conform to the following:

5.4.1 The review agent shall give a reasonable period of time for an appeal to be filed in order to be considered and that period shall not be less than sixty (60) days from the date of notice of the adverse determination.

5.4.2 The review agent shall maintain and make available a written description of the internal appeal procedure by which the patient or the provider of record may seek review of determinations not to certify a health care service.

5.4.3 The review agent shall notify in writing the patient and provider of record of its decision on the first and second level appeal according to the following:

a) for concurrent and prospective reviews no later than fifteen (15) business days after receiving the required documentation of the appeal;

b) for retrospective reviews no later than thirty (30) business days after receiving the required documentation of the appeal; and

c) if verbal notice is given to the patient and provider of record within the timeframes set in sections 5.4.3 a) and b) herein, written notice may be given within six (6) business days following verbal notice.

5.4.4 First level appeal decisions not to certify a health care service that had been ordered by a provider shall be:

a) made by a licensed practitioner with the same licensure status as the ordering practitioner or a licensed physician or dentist, as appropriate;

b) signed by a licensed practitioner with the same licensure status as the ordering practitioner or a licensed physician or dentist, as appropriate;

c) documented by a licensed practitioner with the same licensure status as the ordering practitioner or a licensed physician or dentist, as appropriate; and

d) for retrospective adverse determinations for non emergency health care services, no first level appeal decision may be made until there is evidence that an appropriately qualified and licensed practitioner with the same licensure status as the ordering practitioner, or physician or dentist, has communicated with the patient's attending provider (or designee) concerning the health care services and the agency shall conform to the requirements set forth in section 5.2.2 herein.

5.5 The second level of the internal appeals process shall be offered in those cases where an initial appeal is unsuccessful.

5.5.1 All second level appeal decisions not to certify a health care service that had been ordered by a provider shall be:

a) made by a licensed practitioner with the same licensure status as the ordering practitioner or licensed physician or dentist in the same or similar specialty as typically manages the medical condition, procedure or treatment under review;

b) signed by a licensed practitioner with the same licensure status as the ordering practitioner or licensed physician or dentist in the same or similar specialty as typically manages the medical condition, procedure or treatment under review; and

c) documented by a licensed practitioner with the same licensure status as the ordering practitioner or licensed physician or dentist in the same or similar specialty as typically manages the medical condition, procedure or treatment under review.

5.5.2 Prior to reaching a final decision at the second level of appeal, the review agent shall afford the appealing party an opportunity to inspect the utilization review file and add information to the file. The review agent shall:

a) require the additional information to be forwarded in writing; and

b) comply with all state and federal laws to protect the confidentiality of individual medical records as described in sections 5.10 and 5.12 herein.

5.5.3 In cases where the second level of appeal is unsuccessful, the review agency shall inform the patient and provider filing the appeal of the external appeals process as described in section 6.0 herein.

5.6 An expedited review must be provided at the first and second level of internal appeals by the review agency for an appeal that has been deemed an emergency as defined in section 1.13 herein.

5.6.1 The review agent shall complete the adjudication of such expedited appeals within two (2) business days of the date the appeal is filed, provided that all information necessary to complete the appeal is received by the review agent.

5.7 No reviewer who has been involved in prior reviews either at the adverse determination or appeal level of the case under appeal may participate in subsequent reviews.

5.7.1 Provided, however, that if new information has been made available, the first level of appeal may be conducted by the same reviewer who made the adverse determination.

5.8 No reviewer who has participated in the direct care of the patient (who is the subject of the review), may participate as a reviewer in reviewing the case under appeal.

5.9 The review agent shall notify the patient and provider of record in writing of the second level appeal determination within the timeframes set in section 5.4.3 herein and shall include:

5.9.1 notice to those parties that the decision may be appealed to the state designated external appeals agencies;

5.9.2 the means by which such an external appeal may be initiated; and

5.9.3 the fee for completing such an external appeal.

5.10 A review agent is only entitled to review information or data which is reasonably relevant to the utilization review process. A review agent may not disclose or publish individual medical records or any confidential medical information obtained in the performance of utilization review activities as described in section 5.12 herein. A review agent shall be considered a third (3rd) party health insurer for the purposes of section 5-37.3-4 (b) (6) of the General Laws of Rhode Island and shall be required to maintain the security procedures mandated in section 5-37.3-4 (c) therein.

5.11 Pursuant to the provisions of section 23-17.12-9 (j) of the Rhode Island General Laws, as amended, the Department, in response to a written complaint, is authorized to review any internal appeals processes regarding adverse determinations, and may request written information of the review agent, provider or patient regarding the status, processing, outcome, and rationale regarding a decision on which the complaint is based.

5.12 That the review agency and its employees shall adhere to all applicable state and federal laws to protect the confidentiality of individual health care information, including, but not limited to, Chapter 5-37.3 ("Confidentiality of Health Care Information Act") and specifically section 5-37.3-4 (c) which requires limitation of the distribution of such information on a "need to know" basis and section 40.1-5-26 of Chapter 40-1-1 (Mental Health Law) of the Rhode Island General Laws, as amended.

5.13 Upon certification, re-certification, and material changes to review criteria and review policies and procedures all review agencies shall conform to the following:

5.13.1 a review agency shall establish and update criteria and review procedures with the appropriate consultation of health care providers in the same specialty as would typically order the services subject to the criteria;

5.13.2 the review agency shall seek consultation on the criteria and procedures from no fewer than five (5) Rhode Island licensed providers and when the screening criteria and review procedures are applicable to inpatient and/or outpatient services of a hospital, with the Medical Directors of each Rhode Island licensed hospital;

a) non-Rhode Island licensed providers may be utilized when the agency demonstrates that the review criteria and review procedures relate to services not provided in the state of Rhode Island;

5.13.3 for the purposes of 5.13.2 herein, consultation shall include, but not be limited to, the following:

a) the provision of the proposed criteria and review procedures to the required parties;

b) allowance of at least a thirty (30) day period for the parties to provide written comments and/or recommendations; and

c) evidence that the review agency has considered the consultants' comments and/or recommendations.

5.13.4 the review agents using review criteria and review procedures developed by other persons shall be considered in compliance with this section if it is demonstrated, to the satisfaction of the Department, that the requirements of section 5.13 herein have been met by these persons;

5.13.5 providers used to conduct the consultations noted in section 5.13.2 herein shall limit their financial relationship to the reimbursement for the provision of direct care to a patient and reasonable compensation for said consultative services;

5.13.6 documentation shall be maintained by the agency of the comments and/or recommendations submitted by the consultants noted in section 5.13.2 herein and any actions taken by the review agency to incorporate these comments and/or recommendations;

a) such documentation shall be submitted to the Department upon initial certification, re-certification and within thirty (30) days of receipt of the documentation by the agency when changes are made to the review criteria and review procedures;

b) upon request, review agents shall make such documentation available to health care providers at a nominal cost sufficient to cover the reviews agent's costs of copying and mailing; and

5.13.7 review agents with annualized data reported to the Department totaling less than five hundred (500) requests for authorizations may request a variance from sections 5.13 and 5.14, herein.

5.14 Utilization review agents shall provide its medically acceptable review criteria and utilization review procedures, in either electronic or paper format, to the Rhode Island licensed hospitals and the Rhode Island Medical Society as follows:

5.14.1 review agencies shall include this material in the application to the Department;

5.14.2 any changes in the material submitted shall be provided within thirty (30) days of implementing such a change.

Section 6.0 ***External Appeals***

6.1 In cases where a second level of internal appeal by the utilization review agency fails to reverse the original decision, the utilization review agent shall provide for an external appeal by an unrelated, objective agency designated by the Director.

6.1.1 Such provision with an external appeals agency will be manifested by a timely "Memorandum of Understanding" (MOU) signed by the external appeals agency and the certified review agent.

a) All MOU's shall be submitted to the Department by the external agency for approval prior to use.

i) MOU's shall include the obligations of both the external agencies and the certified review agents; and

ii) the content of the MOU shall be compliant with the rules and regulations herein.

6.1.2 To initiate an external appeal, the patient or provider of record shall file written notification of such appeal with the review agent that rendered the adverse decision. Such notice shall include a check payable to the external review agency for one half (½) the predetermined fee.

a) The predetermined fee includes all administrative costs and the cost of the reviewing physician or dentist.

b) An external appeal must be filed within sixty (60) days of receipt of notice that the second level appeal has been denied.

c) If the decision of the utilization review agent is overturned by the external appeal agency, the appealing party shall be reimbursed by the review agency within sixty (60) days of the notice of the overturn for their share of the appeal fee paid as defined herein.

6.1.3 Within five (5) business days of receipt of written notification, as described in section 6.1.2 herein, the review agent shall forward to the external appeals agency:

a) the complete file upon which the adverse decision was based, including the specific findings of the adverse determination;

b) the specific review agency criteria utilized in rendering the adverse determination; and

c) documentation that payment has been authorized for the pre-determined fee of the external review.

6.1.4 The external appeals agency shall not process any appeal without first receiving the total prepayment required from the appellant and the review agent and the information required in sections 6.1.2 and 6.1.3 herein.

6.1.5 For appeals determined to be an emergency as defined in sections 1.13 and 5.6 herein, an expedited external appeal shall be completed and a final determination shall be made within two (2) business days.

6.1.6 For all non-emergency appeals the external appeals agency shall complete its review and make a final determination within ten (10) business days.

6.1.7 The external review shall be based on the following:

a) the review criteria utilized by the review agent to make the denial;

b) the medical necessity for the care, treatment or service which was denied; and

c) the appropriateness of the service delivery which was denied.

6.1.8 The external review shall be performed by a licensed physician, dentist or other practitioner in the same or similar specialty as typically manages the health care service.

6.1.9 The external appeals agent must provide notice to the patient and provider of record of the outcome of the external appeal.

a) Such notice must include the rationale for determination.

6.1.10 Decisions rendered by the external appeals agency under the provisions of these rules and regulations shall be final and binding upon the review agent, except as provided for in section 6.1.12 herein, and shall be communicated by the external review agency to the review agent, the person who filed the appeal, and to the third party payor.

6.1.11 In no case shall the external appeals agent be required to authorize services in excess of those which are provided for in any contract, subscriber agreement or other arrangements between the patient and the party who retains the review agent.

6.1.12 Any party or person who has exhausted all administrative remedies available to him or her who is aggrieved by a final decision of the external appeals agency is entitled to judicial review pursuant to sections 42-35-15 and 42-35-16 of the Rhode Island General Laws, as amended.

6.2 The external appeals agency must comply with the following:

6.2.1 Selection for designation will include, but not be limited to, review of the agency's application with regard to the following:

a) proposed scope of services;

b) a fee structure not exceeding the maximum fees permitted by the Director;

c) utilization review plan;

d) ability to ensure the confidentiality of health care information in accordance with sections 5.10 and 5.12 herein;

e) ability to ensure the neutrality of the licensed physician or dentist or other practitioner reviewers;

f) the type and qualifications of the personnel authorized to perform the reviews;

g) hours of operation;

h) administrative and operational policies and procedures;

i) procedure for reporting intentions to compete for contracts or other arrangements or any other action by the designated external appeals agent which may result in the designated agency becoming a competitor of a certified or waived entity;

j) policy for ensuring that no conflict of interest exists among the designated external appeals agent and its reviewers and the certified utilization review agents; and

k) submission of all information requested by the Director.

6.2.2 In order to continue designation, the external appeals agency must comply with the following provisions:

a) Designated agencies must enter into a written agreement with the Department to ensure compliance with the provisions of Chapter 23-17.12 of the Rhode Island General Laws, as amended.

b) Changes in the ownership, operational and/or administrative status of the external appeals agency shall be reported to the Department no less than a minimum of forty-five (45) days prior to such a change.

i) If the Director determines that the proposed change(s) may negatively impact the effectiveness and/or objectivity of the designated external appeals agency, the Director reserves the right to revoke said designation.

c) The designated external appeals agency shall report all determinations to the Department within ten (10) business days.

d) The designated external appeals agency shall submit reports due within thirty (30) days of the end of each quarter of the calendar year detailing the following:

i) the number of appeals conducted and listed by clinical category;

ii) the outcome of each appeal; and

iii) the time required to complete each external appeal.

e) The designated external appeals agency shall inform the Department of its intention to compete for contracts or other arrangements which may result in the designated agency becoming a competitor of a certified or waived agency.

f) The designated agency shall annually submit a list of neutral physicians, dentists, and other practitioner reviewers.

i) This list shall be mutually agreed upon by the provider associations, insurers and the purchasers of health services.

6.2.3 The designation as an external appeals agency may be terminated without cause by either party to the designation agreement following a ninety (90) day written notice.

6.2.4 The designation of an external appeals agency may be terminated immediately if the Director determines that continuation of an existing designation may result in unfair, biased, or unreliable determinations which pose a threat to the public health;

a) written complaints against external appeals agencies may be submitted to the Department for a review of compliance to the rules and regulations herein.

Section 7.0 ***Reporting Requirements***

7.1 Utilization review agencies shall provide reports and information required on a form prescribed by the Director to determine if the utilization review agencies are in compliance with provisions of Chapter 23-17.12 of the Rhode Island General Laws, as amended, and the rules and regulations herein.

7.1.1 The Department shall provide the certified review agents with a twenty (20) day comment period after issuing changes in the reporting requirements;

a) Certified review agents shall have a period of ninety (90) days after the comment period to comply with this section given changes in the reporting requirements.

7.1.2 Submission of reports shall be made quarterly, due sixty (60) days after each quarter of the calendar year.

7.1.3 The quarterly reports shall be signed by an authorized representative of the review agency and shall include a statement that the reports submitted are complete and accurate to the best of their knowledge.

7.1.4 Failure to report in accordance with the timeframe set forth in section 7.1.2 herein, will result in a fine determined by the Director.

PART IV **RENEWAL, DENIAL AND SUSPENSION OF CERTIFICATES AND WAIVERS**

Section 8.0 ***Renewal of Certificate and/or Waiver***

8.1 A certificate or waiver shall expire on the second anniversary of its effective date unless it is renewed for a two (2) year term as provided in this section.

8.2 Before a certificate or waiver expires, it may be renewed for an additional two (2) year term if the applicant:

8.2.1 submits a renewal application to the Director on a form supplied by the Director, and provides satisfactory evidence of compliance with any requirements for certification or waiver status. This application must be submitted sixty (60) days prior to the expiration of the certificate or waiver;

8.2.2 is otherwise entitled to the certificate or waiver; and

8.2.3 pays to the Director the certification or waiver renewal fee set by the Director.

8.3 A certificate or waiver may be continued until a renewal determination is made, if a completed application is being processed.

Section 9.0 ***Denial, Suspension or Revocation of Certificate and/or Waiver***

9.1 The Department may deny an application for certification or waiver, if it finds that the applicant proposing to conduct utilization review does not meet one or more of the requirements of the Act and the rules and regulations herein.

9.2 The Department may revoke, suspend or restrict a certificate or waiver and/or impose reasonable monetary penalties not to exceed five thousand dollars ($5,000) per violation in any case in which the review agent fails to:

9.2.1 comply substantially with the Act and the requirements of the rules and regulations herein;

9.2.2 comply with the policies set forth in its application for certification or waiver; and

9.2.3 permit examination by the Director to determine compliance to the Act and to the rules and regulations herein.

a) Such examination shall be subject to the confidentiality and "need to know" provisions described in sections 5.10 and 5.12 herein.

9.3 Any applicant or certificate holder aggrieved by a decision to deny, revoke, suspend, limit or restrict a certificate may, within thirty (30) days after notice of the decision, make a written request to the Department for a hearing therein pursuant to section 42-35-15 of the Rhode Island General Laws, as amended.

9.4 The procedure governing hearings authorized by this section shall be in accordance with sections 42-35-9 through 42-35-13 of the General Laws and the *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Rhode Island Department of Health and Access to Public Records of the Department of Health* (R42-35-PP).

9.5 Any person who has exhausted all administrative remedies available to him/her within the Department and who is aggrieved by a final decision of the Department is entitled to judicial review pursuant to sections 42-35-15 and 42-35-16 of the Rhode Island General Laws.

Section 10.0 ***Penalties***

10.1 A person who substantially violates any provision of the Act or any regulation adopted under the Act or who submits any false information in an application required by the Act is guilty of a misdemeanor and on conviction is subject to a penalty not exceeding five thousand dollars ($5,000).

Section 11.0 ***Severability***

11.1 If any provision of the Act or the application thereof to any person or circumstances shall be held invalid, such invalidity shall not affect the provisions of application of the Act which can be given effect without the invalid provision or application, and to this end the provisions of the Act and the rules and regulations herein are declared to be severable.

Section 12.0 ***Variance Procedure***

12.1 The Department may grant a variance upon its own motion or upon request of the utilization review agency from a provision defined herein in a specific case if it finds that a literal enforcement of such provision will result in unnecessary hardship to the utilization review agency and that such a variance will be consistent with the overall intent and purpose of this Act and will not be contrary to the public interest, public health, and/or health and safety of enrollees.

12.2 A request for a variance shall be filed by an applicant in writing, setting forth in detail the basis upon which the request is made.

12.2.1 Upon filing of each request for variance with the Department, and within a reasonable period of time thereafter, the Department shall notify the review agency of its approval or in the case of a denial, a hearing date, time and place may be scheduled if the review agency appeals the denial. All hearings and reviews shall be in accordance with the provisions of Chapter 42-35 of the Rhode Island General Laws and the *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health (R42-35-PP).*