RULES AND REGULATIONS OF

THE INSURANCE COMMISSIONER

CHAPTER 120-2-111

PATIENT'S RIGHT TO INDEPENDENT REVIEW

TABLE OF CONTENTS

(1) Certification of Independent Review Organizations.

(a) Filing Information. An application for certification of an independent review organization and certification fee must be filed with the Department of Insurance, Administrative Procedure Division, electronically at the following email address: adminprocedure@oci.ga.gov. There shall be a fee for the application to become an independent review organization, and to renew the certification as an independent review organization, and the provisions governing such fees shall be as follows:

The Department shall establish, administer, and enforce the certification and renewal fees under this section, and the fee for initial application to receive certification as an independent review organization shall be $500; and the fee for annual certification renewal as an independent review organization shall be $250.00.

(b) How to Obtain Forms. The application must be submitted on a form which can be obtained from the Department of Insurance, Administrative Procedure Division at adminprocedure@oci.ga.gov.

(c) Certification Application Content. The applicant must provide information required by the Department, which includes, but is not limited to the following:

(i) a summary of the independent review plan which meets the requirements of this Rule as outlined below and must include:

(A) the screening criteria and review procedures to be used to determine medical necessity, medically necessary care, or medically necessary and appropriate care;

(B) a certification signed by an authorized representative that such screening criteria and review procedures to be applied in review determinations are established with input from appropriate health care providers, including physicians;

(C) procedures ensuring that the information regarding the reviewing physicians and providers is updated in accordance with this Rule as outlined below relating to Revisions During Review Process and relating to Renewal of Certificate of Registration to ensure the independence of each health care provider or physician making review determinations; and

(D) specific procedures which will be used to determine if a proposed treatment is experimental.

(ii) copies of policies and procedures which ensure that all applicable state and federal laws to protect the confidentiality of medical records and personal information are followed. These procedures must comply with this Rule as outlined below relating to Confidentiality; and the applicant shall also submit a certification signed by an authorized representative that the independent review organization will protect the confidentiality of medical records and personnel information and will comply with all applicable state and federal laws pertaining thereto.

(iii) a certification signed by an authorized representative that the independent review organization will comply with the provisions of the Act and these Rules;

(iv) a description of personnel and the accrediting policies and procedures of the applicant, and a completed profile for each expert reviewer and provider, in compliance with this Rule as outlined below relating to Personnel and Credentialing;

(v) a description of hours of operation, which must conform to Eastern Standard Time or Eastern Daylight Time, whichever is applicable, and how the independent review organization may be contacted during weekends and holidays, as set forth in this Rule as outlined below relating to Independent Review Organization's Telephone Access;

(vi) the organizational information, documents and all amendments, including:

(A) the bylaws, Rules and regulations, or operating agreement regulating the conduct of the internal affairs of the applicant with a notarized certification bearing the original signature of an officer or authorized representative of the applicant that they are true, accurate, and complete copies of the originals;

(B) for an applicant that is publicly held, the name of each stockholder or owner of more than five percent of any stock or options;

(C) a chart listing the internal organizational structure of the applicant's management and administrative staff;

(D) a chart showing contractual arrangements of the independent review system; and

(E) evidence of the applicant's authorization to conduct business in the state of Georgia.

(vii) the name of any holder of bonds or notes of the applicant that exceed $ 100,000;

(viii) the name and type of business of each corporation or other organization that the applicant controls or is affiliated with and the nature and extent of the affiliation or control and a chart or list clearly identifying the relationships between the applicant and any affiliates;

(ix) biographical information about officers, directors, and staff, including:

(A) the independent review organization must submit the name and biographical information for each director, officer, and executive of the applicant, any entity listed in this section of these Rules, and each expert reviewer conducting independent review, and a description of any relationship, including but not limited to, any past, present or known future professional, personal, familial, financial, fiduciary, or contractual relationship which the named individual has with:

(aa) a health benefit plan;

(bb) a health maintenance organization;

(cc) an insurer;

(dd) a nonprofit health corporation;

(ee) a payor;

(ff) a health care provider; or

(gg) a group representing any of the entities described by paragraphs (aa) through (gg) of this subsection;

(B) any relationship between the independent review organization and any affiliate or other organization in which a shareholder has 10 percent (10%) or more interest must be clearly identified;

(C) a list of any currently outstanding loans or contracts to provide services between the applicant and any of its affiliates or any officers of its affiliates;

(x) information related to out-of-state licensure, permit, certification or other similar business, and service of legal process. All applicants must furnish a copy of the certificate of registration, licensing, or other similar document from the domiciliary state's licensing authority. As a condition of being certified to conduct the business of independent review in this state, an independent review organization that maintains its principal offices or any portion of its books, records, or accounts outside this state must appoint and maintain a person in this state as attorney for service of process on whom all judicial and administrative process, notices, or demands may be served, and must notify the Department of any change of appointment or appointee's address immediately.

(xi) written disclosure of types of compensation arrangements made to physicians and providers in exchange for the provision of independent review, including any financial incentives for physicians and providers.

(xii) the percentage of the applicant's revenues that are anticipated to be derived from independent reviews conducted.

(xiii) the names of any predecessor affiliates and/or companies, including trade names.

(2) Independent Review Organization Conflict of Interest Criteria. Neither the independent review organization nor any expert reviewer of the independent review organization may have any material professional, familial, or financial conflict of interest with any of the following:

(a) A managed care plan or entity being reviewed;

(b) Any officer, director, or management employee of a managed care plan which is being reviewed;

(c) The physician, the physician's medical group, health care provider, or the independent practice association proposing a treatment under review;

(d) The institution at which a proposed treatment would be provided;

(e) The eligible enrollee or the eligible enrollee's representative; or

(f) The development or manufacture of the treatment proposed for the eligible enrollee whose treatment is under review.

(3) As used in subsection (iv) above, the term "conflict of interest" shall not be interpreted to include a contract under which an academic medical center or other similar medical research center provides health care services to eligible enrollees of a managed care plan, except as subject to the requirement of line item (D) of subsection (iv) above; nor affiliations which are limited to staff privileges at a health care facility; or an expert reviewer's participation as a contracting plan provider where the expert is affiliated with an academic medical center or other similar medical research center that is acting as an independent review organization under the Act. An agreement to provide independent review for an eligible enrollee or managed care entity is not a conflict of interest under subsection (iv) of these Rules.

(4) The independent review organization shall have and submit as a part of its application a written quality assurance mechanism in place that ensures the timeliness and quality of the reviews, the qualifications and independence of the expert reviewers, and the confidentiality of medical records and review materials.

(5) The Department shall provide upon the request of any interested person a copy of all information filed with it pursuant to these Rules. Screening criteria and other review procedures of the independent review organization shall not be considered proprietary and privileged information, and shall be subject to disclosure. The Department shall provide at least quarterly a

current list of certified independent review organizations to all managed care entities and to any interested persons.

(6) The expert reviewers assigned by the independent review organizations must be physicians or other appropriate providers who meet the following minimum requirements:

(a) Are experts in the treatment of the medical condition at issue and are knowledgeable about the recommended treatment through actual clinical experience;

(b) Hold a non-restricted license issued by a State of the United States and, for physicians, a current certification by a recognized American medical specialty board in the area or areas appropriate to the subject of review; and

(c) Have no history of disciplinary action or sanctions, including, but not limited to, loss of staff privileges or participation restriction, taken or pending by any hospital, government, or regulatory body.

(7) Department Review of Certification Application. The application process is as follows:

(a) Upon receipt of an original and three copies of the application, along with the correct application fee, the Department will have ten (10) working days to determine if the application contains all necessary information needed to deem the application complete. When the Department has determined that the application contains all necessary information for a decision on certification to be made, the Department shall deem the application to be complete.

(b) The Department will notify the applicant, no later than ten (10) working days after the application has been received, if there are any items or additional information necessary for the review for certification that need to be submitted to the Department. If the Department requests additional items or information, the applicant shall have no more than thirty (30) calendar days to provide the additional items or information. If the applicant does not provide the information requested within thirty (30) calendar days from the date of the Department's request, the application shall be deemed withdrawn, and the applicant will be required to submit an entirely new application.

(c) The Department shall notify the applicant of any omissions or deficiencies in the application no later than thirty (30) calendar days after the date on which the application has been deemed complete. The applicant shall have five (5) working days after the receipt of notification from the Department of any omissions or deficiencies to provide the Department with any additional, supplemental, or clarifying information.

(d) The Department shall issue a written decision to the applicant that either approves or denies the application for certification no later than sixty (60) calendar days after the date the Department deems the application complete for review. If the applicant is denied certification, the written notification to the applicant must state, with specificity, the reasons for denial. Either the Department or the applicant may request a thirty (30) calendar day extension of the sixty (60) day review period. In this case, the Department

may accept additional, supplemental, or clarifying information up to the 65th day of the review period. In no circumstances shall the certification review period be longer than ninety (90) calendar days from the date the application has been deemed complete for review.

(e) The Department shall maintain a master file that shall contain the application, and any and all written correspondence between the applicant and the Department during the certification review period, as well as any written comments on the application from other parties sent to the Department during the review period.

(f) If any of the information contained in the application should change during the review period, the applicant must provide the Department with the new information no later than thirty-five (35) days after the application has been deemed complete, or no later than the date for submission of additional or clarifying information requested by the Department as referenced above, or no later than the sixty-fifth (65th) day of the review period if the period is extended to ninety (90) days.

(8) On-Site Examinations. The Department may conduct an on-site examination of an applicant as a requirement of certification as an independent review organization. Documents must be available for inspection at the time of such examination at the administrative offices of the independent review organization as set forth in this Rule as outlined below relating to On-Site Review by the Department.

(9) Withdrawal of an Application.

(a) Upon written notice to the Department, an applicant may request withdrawal of an application from consideration.

(b) Upon the Department's receipt of a request to withdraw an application pursuant to this section, the application shall be withdrawn from consideration. Subsequent applications by the same applicant must be new submissions in their entirety.

(10) Renewal of Certificate of Registration.

(a) The Department shall designate annually each organization that meets the standards as an independent review organization.

(b) An independent review organization must apply for renewal of its certificate of registration every year, not later than ninety (90) days prior to the anniversary date of the issuance of the registration. A renewal form must be used for this purpose. The renewal form can be obtained from the address listed for the Department elsewhere in this Rule. The completed renewal form, the current screening criteria, renewal fee, and certification of no material changes not already filed with the Department must be submitted to the Department.

(c) An independent review organization may continue to operate under its certificate of registration after a completed renewal application form and the current screening criteria

has been timely received by the Department until the renewal is finally denied or issued by the Department.

(d) If a completed renewal form and the current screening criteria is not received no later than ninety (90) days prior to the anniversary date of the year in which the certificate of registration must be renewed, the certificate of registration will automatically be canceled and the independent review organization must complete and submit a new application for certificate of registration.

(e) A previously certified independent review organization shall report any material changes in the information contained in its original certification application within 30 days of any change, and all such new information must be reflected in any submissions by the independent review organization in its request for certification renewal. A material change shall be those changes listed in the Act at O.C.G.A. § 33-20A-39(a)(3).

(11) Appeal of Denial of Application or Renewal. If an application or renewal is initially denied under this subchapter, the applicant may appeal such denial pursuant to the provisions of the Georgia Insurance Code, codified at O.C.G.A. § 33-2-17 and Ga. R. & Regs. 120-2-2.

(12) Independent Review Plan. The independent review plan shall be adhered to by the designated expert reviewer and conducted in accordance with the screening criteria and procedures developed with input from appropriate health care providers, including physicians. The independent review plan shall include the following components:

(a) a description of the elements of review which the independent review organization provides, including but not limited to:

(i) prospective review;

(A) second opinion;

(B) hospital admission;

(C) procedures;

(D) courses of outpatient treatment;

(E) choice of provider;

(ii) concurrent review;

(A) second opinion;

(B) discharge planning;

(C) readmission review;

(D) continued stay authorization;

(iii) retrospective review; and

(iv) procedures for addressing experimental treatment.

(b) written procedures, in accordance with the Act for:

(i) notification of the independent review organization's decisions provided to the eligible enrollee or the eligible enrollee's representative, the managed care entity, and the Department.

(ii) review, including:

(A) any form used during the review process;

(B) time frames that shall be met during the review; and

(iii) contacting and receiving information from health care providers in accordance with this Rule relating to Independent Review Organization's Contact With and Receipt of Information from Health Care Providers.

(13) Screening Criteria. Each independent review organization shall utilize written medically acceptable screening criteria and review procedures which are established and periodically evaluated and updated with appropriate involvement from physicians, including practicing physicians, and other health care providers. All determinations of medical necessity shall be made by the designated expert reviewer of the independent review organization. Such written screening criteria and review procedures shall be available for review and inspection and copying as necessary by the Department in order for the Department to carry out the duties provided for under the Act.

(14) The personnel of an independent review organization must conform to the following criteria:

(a) Personnel employed by or under contract with the independent review organization to perform independent review shall be appropriately trained and qualified and, if applicable, currently licensed, registered, or certified. Personnel who obtain information directly from a physician, dentist, or other health care provider, either orally or in writing, and who are not physicians or dentists, shall be nurses, physician assistants, or health care providers qualified to provide the service requested by the provider. This provision shall not be interpreted to require such qualifications for clerical or administrative personnel who do not perform independent review.

(b) The independent review organization is required to provide to the Department the number, type, and minimum qualifications of the personnel either employed or under contract to perform the independent review. Independent review organizations shall be required to adopt written procedures used to determine whether physicians or other health care providers utilized by the independent review organization are licensed, qualified, and appropriately trained, and must maintain records on such. In addition, the independent review organization must maintain complete profiles of any designated expert reviewer. Such profiles must include all information required by these Rules as outlined below relating to Information Required, and must be kept current.

(c) Independent review conducted by an independent review organization shall be under the direction of an expert reviewer in accordance with these Rules as outlined.

(d) Dental plans shall be independently reviewed by an expert reviewer who is a dentist currently licensed by a state licensing agency in the United States, and who meets all the other requirements for an expert reviewer.

(e) The independent review organization is required to provide to the department a copy of the applicant's selection policies and procedures, including:

(i) a description of the categories and qualifications of persons employed or under contract to perform independent review;

(ii) copies of policies and procedures for orientation and training of persons who perform independent review, including any expert reviewers, and evidence that the applicant meets any applicable provisions of this chapter relating to the qualifications of independent review organizations or the performance of independent reviews, including section (xvii) of these Rules.

(15) Independent Review Organization Contact With and Receipt of Information from Health Care Providers and Patients.

(a) A health care provider may designate one or more individuals as the initial contact or contacts for independent review organizations seeking routine information or data. In no event shall the designation of such an individual or individuals preclude an independent review organization or the expert reviewer from contacting a health care provider or others in his or her employ where a review might otherwise be unreasonably delayed or where the designated individual is unable to provide the necessary information or data requested by the independent review organization.

(b) An independent review organization may not engage in unnecessary or unreasonably repetitive contacts with the health care provider or patient and shall base the frequency of contacts or reviews on the severity or complexity of the patient's condition or on necessary treatment and discharge planning activity.

(c) The managed care entity or the eligible enrollee or the eligible enrollee's representative shall be responsible for delivering to the independent review organization any written information required to conduct the independent review as provided for in a timely manner as specified in the Act and these Rules.

(d) When conducting independent review, the independent review organization shall collect any information necessary to review the adverse outcome not already provided by the managed care entity or the eligible enrollee or the eligible enrollee's representative. This information may include, but is not limited to, identifying information about the eligible enrollee, the benefit plan, the treating health care provider, and/or facilities rendering care. It may also include clinical information regarding the diagnoses of the eligible enrollee and the medical history of the eligible enrollee relevant to the diagnoses;

the eligible enrollee's prognosis; and/or the treatment plan prescribed by the treating health care provider along with the provider's justification for the treatment plan. Second opinion information may also be required when applicable. The burden of proof shall rest with the managed care entity in all questions before the independent review organization.

(e) The independent review organization should share all clinical and demographic information on individual eligible enrollees among its various divisions to avoid duplication of requests for information from eligible enrollees or providers.

Authority: O.C.G.A. Sections 33-2-9 & 33-20A-41.