

**RULES
OF
DEPARTMENT OF COMMUNITY HEALTH**

**111-2
HEALTH PLANNING**

**111-2-3
PATIENT'S RIGHT TO INDEPENDENT REVIEW**

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111-2-3-.01 Applicability. These Rules shall apply to the applicants for certification as independent review organizations, and all attendant procedures thereto; any and all independent review organizations certified by the State Health Planning Agency, or its successor Agency, the Department of Community Health, pursuant to the authority granted by O.C.G.A. § 33-20A-30, which article shall be known and cited as the "Patient's Right to Independent Review Act", and the procedures for the request for independent review; and the procedures for independent review of services previously rendered as well as concurrent or prospective services by a managed care entity to an eligible enrollee as those terms are defined herein. Any independent

review organization that has been certified by an independent national accrediting organization that has developed standards for the purpose of bestowing certification or accreditation upon entities of this type, and that can provide documentation to the Department of such certification or accreditation, shall be deemed certified by the Department and shall not have to apply for certification as an independent review organization in Georgia in order to be added to the Department's list of certified independent review organizations.

Authority O.C.G.A. § 31-6 *et seq.*

111-2-3-.02 Definitions.

(1) "Act" means O.C.G.A. § 33-20A-30 *et seq.*, which shall be known and cited as the "Patient's Right to Independent Review Act."

(2) "Adverse Outcome" means a decision issued by a managed care entity to an eligible enrollee after the grievance procedure provided for in O.C.G.A. § 33-20A-5, which was a denial of the claim in whole or in part of the eligible enrollee or a refusal to pay for a treatment sought.

(3) "Affiliate" means a person who directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with the person specified.

(4) "Applicant" means a party that seeks approval from the Department to be certified as an independent review organization, or to have a previous certification renewed.

(5) "Commissioner" means the Commissioner of the Georgia Department of Insurance.

(6) "Dental Plan" means an insurance policy or health benefit plan, including a policy written by a company subject to the provisions of O.C.G.A. § 33-20A-1 *et seq.* that provides coverage for expenses for dental services.

(7) "Dentist" means a licensed doctor of dentistry holding either a D.D.S. or a D.M.D. degree.

(8) "Department" means the Department of Community Health created pursuant to O.C.G.A. § 31-5A-4.

(9) "Eligible Enrollee" means a person who:

(a) Is an enrollee or an eligible dependent of an enrollee of a managed care plan or was an enrollee or an eligible dependent of an enrollee of such plan at the time of the request for treatment and,

(b) Seeks a treatment which reasonably appears to be a covered service or benefit under the enrollee's evidence of coverage; provided, however, that this subparagraph shall not apply if the notice from a managed care plan of the outcome of the grievance procedure was that a treatment is experimental.

(10) "Emergency Services" or "Emergency Care" means those health care services that are provided for a condition of recent onset and sufficient severity, including but not limited to severe pain, that would lead a prudent layperson, possessing an average knowledge of medicine and health, to believe that his or her condition, sickness, or injury is of such a nature that failure to obtain immediate medical care could result in:

(a) Placing the patient's health in serious jeopardy;

(b) Serious impairment to bodily functions; or

(c) Serious dysfunction of any bodily organ or part.

(11) "Expert reviewer" means a person assigned by the independent review organization to review a request, and whose qualifications are consistent with the criteria as set forth in the Act and/or this Rule.

(12) "Grievance Procedure" means the internal grievance procedure of a managed care entity established for that entity pursuant to O.C.G.A. § 33-20A-5.

(13) "Health Benefit Plan" means a plan of benefits that defines the coverage provisions for health care offered or provided by any organization, public or private, other than health insurance.

(14) "Health Care Provider" or "provider" means any physician, dentist, podiatrist, pharmacist, optometrist, psychologist, clinical social worker, advance practice nurse, registered optician, licensed professional counselor, physical therapist, marriage and family therapist, chiropractor, occupational therapist, speech language pathologist, audiologist, dietician, or physician's assistant.

(15) "Health Insurance Policy" means an insurance policy, including a policy subject to the provisions of O.C.G.A. § 33-20A et seq., that provides coverage for medical or surgical expenses incurred as a result of accident or sickness.

(16) "Independent Review" means a system of administrative appeal an eligible enrollee is entitled to receive when any of the conditions set forth in Rule 111-2-3-.04 have been met.

(17) "Independent Review Organization" means any organization certified as such by the State Health Planning Agency or its successor Agency, the Department of Community Health, pursuant to O.C.G.A. § 33-20A-39.

(18) "Independent Review Plan" means the screening criteria and review procedures of an independent review organization.

(19) "Managed Care Entity" includes an insurance company, hospital or medical service plan, hospital, health care provider network, physician hospital organization, health care provider, health maintenance organization, health care corporation, employer or employee organization, or managed care contractor that offers a managed care plan.

(20) "Managed Care Plan" means a major medical, hospitalization, or dental plan that provides for the financing and delivery of health care services to persons enrolled in such plan through:

- (a) Arrangements with selected providers to furnish health care services;
- (b) Explicit standards for the selection of participating providers and,
- (c) Cost savings for persons enrolled in the plan to use the participating providers and procedures provided for by the plan; provided, however, that the term "managed care plan" does not apply to Chapter 9 of Title 34, relating to workers' compensation.

(21) "Medical and Scientific Evidence" means:

- (a) 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;
- (b) 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 Index Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS data base or Health Services Technology Assessment Research (HSTAR);
- (c) Medical journals recognized by the United States Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act;
- (d) The following standard reference compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluation, the American Dental Association Accepted Dental Therapeutics, and the United States Pharmacopoeia-Drug Information; or
- (e) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the Federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of

Sciences, Health Care Financing Administration, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.

(22) "Medical Necessity", "Medically Necessary Care", or "Medically Necessary and Appropriate" means care based upon generally accepted medical practices in light of conditions at the time of treatment which is:

(a) Appropriate and consistent with the diagnosis and the omission of which could adversely affect or fail to improve the eligible enrollee's condition;

(b) Compatible with the standards of acceptable medical practice in the United States;

(c) Provided in a safe and appropriate setting given the nature of the diagnosis and the severity of the symptoms;

(d) Not provided solely for the convenience of the eligible enrollee or the convenience of the health care provider or hospital; and

(e) Not primarily custodial care, unless custodial care is a covered service or benefit under the eligible enrollee's evidence of coverage.

(23) "Nurse" means a registered nurse.

(24) "Open Records Act" means the provisions codified in O.C.G.A. § 50-18-70 et seq., including those provisions to be effective on July 1, 1999.

(25) "Out of Network" or "Point of Service" refers to health care items or services provided to an eligible enrollee by providers who do not belong to the provider network in the managed care plan.

(26) "Patient" means a person who seeks or receives health care services under a managed care plan.

(27) "Person" means an individual, corporation, partnership, association, joint stock company, trust, unincorporated

organization, any similar entity, or any combination of the foregoing acting in concert.

(28) "Physician" means a licensed doctor of medicine or a doctor of osteopathy.

(29) Reserved.

(30) "Provider of Record" means the physician or other health care provider that has primary responsibility for the care, treatment, and services requested on behalf of the patient and includes any health care facility when treatment is rendered on an inpatient or outpatient basis.

(31) "Receipt" means the date of the taking of actual physical possession of an item sent, or the date evidencing such possession by the normal and customary confirmation available for facsimile transmissions, other computer assisted electronic transmissions, courier delivery services, private delivery services, and the U.S. Mail service.

(32) "Screening Criteria" means the written policies, medical protocols, or guidelines used by the independent review organization as part of the independent review process.

(33) "Treatment" means a medical service, diagnosis, procedure, therapy, drug, or device.

(34) "Working Day" means a weekday, excluding any officially designated State holiday.

Authority O.C.G.A. § 31-6 *et seq.*

111-2-3-.03 Standards.

(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 Community Health, Division of Health Planning, at the following address: 2 Peachtree Street,

N.W., Atlanta, Georgia, 30303-3142. The certification fee must be in the form of a certified bank check, certified cashiers check, or certified money order, and made payable to the State of Georgia. The application must consist of an original and three copies. 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 Community Health, Division of Health Planning at 2 Peachtree Street, N.W., Atlanta, Georgia, 30303-3142.

(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; and

(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 Administrative Procedure Act, codified at O.C.G.A. § 50-13 et seq.

(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. § 31-6 *et seq.*

111-2-3-.04 Request for Independent Review. An eligible enrollee shall be entitled to appeal to an independent review organization when:

(1) The eligible enrollee has received notice of an adverse outcome pursuant to a grievance procedure or the managed care entity has not complied with the requirements of Code Section 33-20A-5 with regard to such procedures; or

(2) A managed care entity determines that a proposed treatment is excluded as experimental under the managed care plan, and all of the following criteria are met:

(a) The eligible enrollee has a terminal condition that, according to the treating physician, has a substantial probability of causing death within two years from the date of the request for independent review or the eligible enrollee's ability to regain or maintain maximum function, as determined by the treating physician, would be impaired by withholding the experimental treatment;

(b) After exhaustion of standard treatment as provided by the evidence of coverage or a finding that such treatment would be of substantially lesser or of no benefit, the eligible enrollee's treating physician certifies that the eligible enrollee has a condition for which standard treatment would not be medically indicated for the eligible enrollee or for which there is no standard treatment available under the evidence of coverage of the eligible enrollee more beneficial than the treatment proposed;

(c) The eligible enrollee's treating physician has recommended and certified in writing treatment which is likely to be more beneficial to the eligible enrollee than any available standard treatment;

(d) The eligible enrollee has requested a treatment as to which the eligible enrollee's treating physician, who is a licensed, board certified or board eligible physician qualified to practice in the area of medicine appropriate to treat the eligible enrollee's condition, has certified in writing that scientifically valid studies using accepted protocols, such as control group or double-blind testing, published in peer reviewed literature, demonstrate that

the proposed treatment is likely to be more beneficial for the eligible enrollee than available standard treatment; and

(e) A specific treatment recommended would otherwise be included within the eligible enrollee's certificate of coverage, except for the determination by the managed care entity that such treatment is experimental for a particular condition.

(3) The Department shall determine that an eligible enrollee is entitled to independent review because of the managed care entity's failure to comply with the requirements of Code Section 33-20A-5 if the managed care entity has failed to grant appropriate relief without delay after a determination favorable to the eligible enrollee; has failed to provide notice meeting the requirements of the Code Section to the eligible enrollee of the outcome of the grievance procedure within 60 days from the date of the grievance request, or 30 days where the grievance involves a case where the requested care or service has not been rendered, or in the case of an eligible enrollee who meets the requirements of Rule 111-2-3-.06(8) [Code Section 33-20A-37(c)], the managed care entity has failed to notify the eligible enrollee of the outcome of the grievance procedure within 72 hours from the date of the grievance request; or has otherwise failed to comply with the Code Section in question.

(4) The following additional criteria, in accordance with the Act, shall be required for independent review:

(a) Except where required pursuant to Code Section 51-1-49, a proposed treatment must require the expenditure of a minimum of \$500.00 to qualify for independent review, provided that the minimum \$500.00 expenditure shall include the full cost during the course of treatment of the items and services furnished by all providers and shall include the cost to the managed care entity and/or any provider at risk for the cost and any cost sharing by the eligible enrollee.

(b) The parent or guardian of a minor who is an eligible enrollee may act on behalf of the minor in requesting independent review. The legal guardian or representative of an incapacitated

eligible enrollee shall be authorized to act on behalf of the eligible enrollee in requesting independent review. Except as provided in Code Section 51-1-49, independent review may not be requested by persons other than the eligible enrollee or a person acting on behalf of the eligible enrollee as provided in these Rules in accordance with the Act.

(c) A managed care entity shall be required to pay the full cost of applying for and obtaining the independent review, including the flat fee rate plus any ancillary costs as outlined in these Rules.

(d) The eligible enrollee and the managed care entity shall cooperate with the independent review organization to provide the information and documentation, including executing necessary releases for medical records, which are necessary for the independent review organization to make a determination of the claim.

Authority O.C.G.A. § 31-6 *et seq.*

111-2-3-.05 Procedure for Request for Independent Review.

(1) In the event that the outcome of the grievance procedure under Code Section 33-20A-5 is adverse to the eligible enrollee, the managed care entity shall include with the written notice of the outcome of the grievance procedure a statement specifying that any request for independent review must be made to the Department on forms made available by the Department in accordance with this Rule, and such forms must be included with the notification. Such statement shall be in simple, clear language in boldface type, which is larger and bolder than any other typeface that is in the notice and in at least 14-point typeface.

(2) An eligible enrollee must submit the written request for independent review to the Department. This request need not be in any required format, but may be a simple written request for an independent review of an adverse outcome of a grievance procedure of a managed care entity. The request must include the name and address of the eligible enrollee, and/or the name

and address of the eligible enrollee's guardian in the case of a minor, the eligible enrollee's legal guardian in the case of an eligible enrollee's incapacity, and/or the eligible enrollee's representative. The written request must also include a copy of the notification to the eligible enrollee, or the eligible enrollee's applicable representative, of the adverse outcome determination of the grievance procedure of the managed care entity involved.

(3) Upon receipt of a written request by an eligible enrollee or the eligible enrollee's applicable representative made in accordance with these Rules as outlined above, the Department shall, no later than three (3) working days after receipt, notify the eligible enrollee, or the eligible enrollee's applicable representative, of receipt of the request and assign the request to an independent review organization on a rotating basis according to the date the request was received in accordance with these Rules as outlined below.

(4) Upon assignment of a request for independent review to an independent review organization, the Department shall provide written notification of the name and address of the assigned organization to both the requesting eligible enrollee, or the eligible enrollee's applicable representative, and the managed care entity.

Authority O.C.G.A. § 31-6 *et seq.*

111-2-3-.06 The Conduct of the Review by the Independent Review Organization.

(1) Within three working days of receipt of notice from the Department of assignment of the request for independent review, the managed care entity shall submit to that organization the following:

(a) Any information submitted to the managed care entity by the eligible enrollee or his/her provider in support of the eligible enrollee's grievance procedure filing;

(b) A copy of the contract provisions or evidence of coverage of the managed care plan, including the entire contract or policy; and

(c) Any other relevant documents or information used by the managed care entity in determining the outcome of the eligible enrollee's grievance.

(2) Upon request, the managed care entity shall provide a copy of all documents required by these Rules, except for any proprietary or privileged information, to the eligible enrollee, or the eligible enrollee's applicable representative. The eligible enrollee, or the eligible enrollee's applicable representative, may provide the independent review organization with any additional information the eligible enrollee may deem relevant. Proprietary or privileged information shall not include screening criteria or any procedure, studies, documents, communications, or any other information used by the managed care entity in making a determination in the eligible enrollee's case.

(3) The independent review organization shall request any additional information required for the review from the managed care entity and the eligible enrollee, or the eligible enrollee's applicable representative, within five working days of receipt of the documentation required under these Rules as outlined above. Any additional information requested by the independent review organization shall be submitted within five working days of receipt of the request, or an explanation of why the additional information is not being submitted shall be provided. In no case shall a managed care entity or an eligible enrollee, or an eligible enrollee's applicable representative, receive any more than an extension of ten working days to submit the required additional information. It shall not be grounds for a managed care entity to refuse to supply or to delay submission to the independent review organization any medical record based on an assertion by the managed care entity, or a provider or facility with which the managed care entity has a contract, that said records are then incomplete or un-reviewed.

(4) Additional information obtained from the eligible enrollee, or the eligible enrollee's applicable representative, shall be transmitted to the managed care entity, which may determine that such additional information justifies a reconsideration of the outcome of the grievance procedure. A decision by the managed care entity to cover fully the treatment in question upon reconsideration using such additional information shall terminate independent review. The managed care entity shall notify the eligible enrollee, or the eligible enrollee's representative, the Department, and the independent review organization when such a decision is made. Upon such notification, the independent review organization shall not terminate its review until it has determined that the managed care entity's decision constitutes full coverage of the treatment in question. If the independent review organization determines that the managed care entity's decision does not constitute full coverage of the treatment in question, the eligible enrollee shall not be required to make a new request for independent review, and the managed care entity shall be bound by the entire independent review process both before and after any decision it made to offer coverage.

(5) The expert reviewer of the independent review organization shall make a determination within 15 working days after expiration of all additional information time limits set forth in these Rules, but such time limits may be extended or shortened by mutual agreement between the eligible enrollee, or the eligible enrollee's applicable representative, and the managed care entity subject to the provisions outlined above. The determination by the expert reviewer of the independent review organization shall be in writing and shall state the basis of the reviewer's decision. The determination shall contain the specific findings of fact, regulation, and policy, the basis and reasons thereof, and copies of the documents, studies, and all other information utilized and relied upon by the expert reviewer and the independent review organization in reaching its determination. A copy of the decision shall be delivered to the managed care entity, the eligible enrollee, the eligible enrollee's

applicable representative, and the Department by Certified Mail, Return Receipt Requested.

(6) The independent review organization's decision shall be based upon a review of the information and documentation submitted to it.

(7) Information required or authorized to be provided pursuant to these Rules may be provided by facsimile transmission, and/or electronic mail if feasible for both sender and receiver. For purpose of any time deadline for the receipt of information in accordance with these Rules and the Act, the date of receipt by mail shall be the postmark date on the item(s) being sent, however this provision with regard to mailing does not supersede any applicable time deadline heretofore specified in the Act or these Rules.

(8) In the event that, in the judgment of the treating health care provider, the health condition of the eligible enrollee is such that following the procedure provisions outlined herein would jeopardize the life or health of the eligible enrollee or the eligible enrollee's ability to regain maximum function, as determined by the treating health care provider, an expedited review shall be available. The expedited review process shall encompass all applicable provisions outlined in these Rules, provided, however, that a decision by the expert reviewer shall be rendered within 72 hours (three calendar days) after the expert reviewer's receipt of all available requested documentation.

Authority O.C.G.A. § 31-6 *et seq.*

111-2-3-.07 Independent Review Organization Decision.

(1) The expert reviewer of the independent review organization shall make a determination as to whether a treatment is experimental based upon the following criteria:

(a) Whether such treatment has been approved by the federal Food and Drug Administration; or

(b) Whether medical and scientific evidence demonstrates that the expected benefits of the proposed treatment would be greater than the benefits of any available standard treatment and that the adverse risks of the proposed treatment will not be substantially increased over those of standard treatments.

(c) For either determination, the expert reviewer shall apply prudent professional practices and shall assure that at least two documents of medical and scientific evidence support the decision. The expert reviewer shall take into account evidence and opinions of practitioners in the field who are experts in the treatment proposed to be offered.

(2) In making a decision as to whether a treatment is medically necessary or appropriate, the expert reviewer shall use the definition of medical necessity, medically necessary care, and medically necessary and appropriate, as defined in these Rules and the Act. Criteria must be objective, clinically valid, compatible with established principles of health care, and flexible enough to allow deviations from the norms when justified on a case-by-case basis.

Authority O.C.G.A. § 31-6 *et seq.*

111-2-3-.08 Independent Review Organization Telephone Access.

(1) An independent review organization shall have appropriate personnel reasonably available by telephone, in accordance with Eastern Standard or Eastern Daylight time, whichever is applicable, at least forty (40) hours per week during normal business hours, to discuss eligible enrollee's care and to allow response to telephone questions. The independent review organization must also allow reasonable telephone access on evenings and weekends.

(2) An independent review organization must have a telephone system capable of accepting or recording or providing instructions to incoming calls during other than normal business

hours and shall respond to such calls not later than two working days of the later of the date on which the call was received or the date the details necessary to respond have been received from the caller. The independent review organization shall request the specific information needed from the caller not later than two working days after initial receipt of the call in question. In the event of an emergency, the independent review organization shall respond within the time appropriate to circumstances relating to the delivery of the services and the condition of the eligible enrollee.

Authority O.C.G.A. § 31-6 *et seq.*

111-2-3-.09 Independent Review Organization Confidentiality Provisions.

(1) An independent review organization, and all agents, contractors, and employees thereof, shall preserve the confidentiality of individual medical records and personal information to the extent required by law and by the doctor-patient relationship.

(2) An independent review organization may not disclose or publish individual medical records or other confidential information about an eligible enrollee without the prior written consent of the eligible enrollee or as otherwise required by law. An independent review organization may provide confidential information to a third party under contract or affiliated with the independent review organization for the sole purpose of performing or assisting with independent review. Information provided to third parties shall remain confidential.

(3) The independent review organization may not publish data which identifies a particular physician or health care provider, or particular health benefit plan or managed care entity, including any quality review studies or performance tracking data, without prior written notice to the involved provider, plan, or entity. This

prohibition does not apply to internal systems or reports used by the independent review organization.

(4) All patient, physician, health care provider, and health benefit plan data shall be maintained by the independent review organization in a confidential manner which prevents unauthorized disclosure to third parties. Nothing in this chapter shall be construed to allow an independent review organization to take actions that violate a state or federal statute or regulation concerning confidentiality of eligible enrollee records.

(5) To assure confidentiality, an independent review organization must, when contacting a physician's or provider's office, or hospital, provide its certification number and the caller's name and professional qualifications to the provider or the provider's named independent review representative.

(6) The independent review organization's procedures shall specify that specific information exchanged for the purpose of conducting review will be considered confidential, be used by the independent review organization solely for the purposes of independent review, and be shared by the independent review organization with only those third parties who have authority to receive such information. The independent review organization's plan shall specify the procedures that are in place to assure confidentiality and that the independent review organization agrees to abide by any federal and state laws governing the issue of confidentiality. Summary data that does not provide sufficient information to allow identification of individual eligible enrollees, providers, or health benefit plans need not be considered confidential.

(7) Medical records and eligible enrollee-specific information shall be maintained by the independent review organization in a secure area with access limited to essential personnel only.

(8) Destruction of documents in the custody of the independent review organization that contain confidential eligible enrollee information or physician or health care provider financial data shall be by a method which ensures complete destruction

of the information, when the organization determines that the information is no longer needed.

Authority O.C.G.A. § 31-6 *et seq.*

111-2-3-.10 Complaints and Inquiries Regarding Conduct of Independent Review Organizations.

(1) Complaints to the Department. Within a reasonable time period, upon receipt of a written complaint alleging a violation of these Rules or the Act by an independent review organization from an eligible enrollee's health care provider, a person acting on behalf of the eligible enrollee, the eligible enrollee, or a managed care entity, the Department shall investigate the complaint and furnish a written response to the complainant and the independent review organization named.

(2) Authority of the Department to make inquiries. In addition to the authority of the Department to respond to complaints described in subsection (a) of this section, the Department is authorized to address inquiries to any independent review organization in relation to the organization's business condition or any matter connected with its transactions which the Department may deem necessary for the public good or for a proper discharge of its duties. It shall be the duty of the independent review organization to promptly answer such inquiries in writing, and in all cases within thirty days of the request for response.

Authority O.C.G.A. § 31-6 *et seq.*

111-2-3-.11 On-Site Inspections by the Department.

(1) The Department is authorized to make examinations concerning the quality, availability, accessibility, and performance of independent review services as often as is deemed necessary.

(2) A representative of the Department is authorized to visit the administrative offices or any branch office of each independent review organization annually, or as frequently as necessary, during normal business hours, to review the books and operations of the independent review organization.

(3) The independent review organization must make available during such on-site visits the following documents:

(a) the minutes of the applicant's organizational meetings, indicating the time of each meeting and the date;

(b) a list of and information regarding physicians and other providers to be used by the independent review organization as follows:

(i) for physicians, indicate:

(A) medical specialty;

(B) board certification, if any;

(C) state license number;

(D) business address; and

(E) any professional association or other medical group with whom physicians are affiliated;

(ii) for other providers, indicate:

(A) address; and

(B) license or certification, if applicable;

(c) any other records concerning the operation of the independent review organization.

Authority O.C.G.A. § 31-6 *et seq.*

111-2-3-.12 Violations by Independent Review Organizations.

(1) If the Department believes that any person conducting independent review is in violation of the Act, or these Rules, the Department shall notify the independent review organization of the alleged violation and may compel the production of any and all documents or other information as necessary to determine whether or not such violation has taken place.

(2) The Department may initiate appropriate proceedings in accordance with the Act and these Rules. Notification to the independent review organization shall be in accordance with the Georgia Administrative Procedure Act, O.C.G.A. § 50-13 et seq.

(3) Proceedings under this article are a contested case for the purpose of O.C.G.A. § 50-13-13. The Department of Community Health shall be the party bringing any action pursuant to these Rules.

(4) If the independent Hearing Officer appointed, pursuant to the Georgia Administrative Procedure Act, determines that the independent review organization has violated or is violating any provision of the Act or these Rules, the Hearing Officer may:

(a) impose sanctions with regard to the assignment of review requests to the independent review organization;

(b) require the independent review organization to cease and desist from the action(s) found to be in violation of the Act or these Rules; and/or

(c) revoke or suspend the certification of an independent review organization.

(5) The commission of fraudulent or deceptive acts or omissions in obtaining, attempting to obtain, or use of certification or designation

Authority O.C.G.A. § 31-6 *et seq.*

111-2-3-.13 Fees for Independent Review.

(1) Any reviews which involve either a Medical Doctor or a Doctor of Osteopathy will be tier-one reviews with a flat fee of \$ 1,500.

(2) All other type of reviews shall be tier-two reviews with a flat fee of \$ 1,000.

(3) The fees referenced above shall be the flat rate for the applicable type of review, and the independent review organizations may also bill the managed care entities for their costs incurred in the review. Such costs are intended to include such items as photocopying, facsimile, postage, package delivery, and courier costs.

(4) Independent review organizations shall bill the managed care entity directly for the fees and costs of independent review.

(5) Managed Care Entities shall pay independent review organizations directly within 30 days of receipt of an invoice.

(6) Failure to Pay Invoice. Failure by a managed care entity to pay invoices from independent review organization within 30 days of receipt shall constitute a violation subject to the penalty referenced under the Act, and codified at O.C.G.A. § 33-20A-35.

Authority O.C.G.A. § 31-6 *et seq.*

111-2-3-.14 Assignment of Requests for Independent Review.

(1) The Department shall assign each request for independent review to an independent review organization.

(2) Independent review organizations shall be added to the list from which assignments for independent review are made in order of the date of certification by the Department.

(3) Assignment shall be made chronologically from the list of independent review organizations with ultimate assignment being to the first in line with no apparent conflicts of interest.

(4) Non-selection for presence of conflicts of interest does not move the independent review organization to the bottom of the list. Such independent review organization retains its chronological position until selected for independent review.

Authority O.C.G.A. § 31-6 *et seq.*