11 NYCRR 410.1

Preamble

=====Parallel Citations==========
Regulation 166

Insureds, and in the case of a retrospective adverse determination, an insured's health care provider shall have the right to request an external appeal of a final adverse determination which is made by a health care plan on the grounds that the health care service is not medically necessary or is experimental or investigational. This Part shall be applicable to health care plans as defined in subdivision d-5 of Section 4900 of the Insurance Law and to external appeal agents certified pursuant to Title II of Article 49 of the Insurance Law and Public Health Law and this Part and to applicants for certification as external appeal agents.

Statutory Authority - Insurance Law, §§ 201, 301, 1109, 3201, 3216, 3217, 3217-a, 3221, 4235, 4303, 4304, 4305, 4321, 4322, 4324, Article 47 and 49; ch. 586, L. 1998.

11 NYCRR 410.2

Definitions

=====Parallel Citations==========
Regulation 166

The following words or terms shall have the following meanings when used in this Part:

(a) *Attending physician* means, for the purpose of requesting an external appeal of an experimental or investigational treatment or service, a licensed, board-certified or board-eligible physician who is qualified to practice in the area of medicine or in the specialty appropriate to treat an insured's life-threatening or disabling condition or disease who has recommended a service or treatment that is the subject of a request for external appeal.

(b) *Commissioner* means the Commissioner of Health of the State of New York.

(c) *Confidential HIV related information* means any information in the possession of a person who provides one or more health or social services or who obtains the information pursuant to a release of confidential HIV related information, concerning whether an individual has been the subject of an HIV related test, or has HIV infection, HIV related illness or AIDS, or information which identifies or reasonably could identify an individual as having one or more of such conditions, including information pertaining to such individual's contacts.

(d) *Final adverse determination* means an adverse determination which has been upheld by a utilization review agent with respect to a proposed health care service following a standard appeal, or an expedited appeal where applicable, pursuant to section 4904 of the Insurance Law. If a health care plan offers two levels of internal appeals, a final adverse determination shall mean the adverse determination of the first level appeal.

(e) *Material familial affiliation* means any relationship as a spouse, child, parent, sibling, spouse's parent, spouse's child, child's parent, child's spouse, or sibling's spouse.

(f) *Material financial affiliation* means any financial interest of more than five percent of total annual revenue or total annual income of a certified external appeal agent or officer, director, or management employee thereof; or clinical peer reviewer employed or engaged thereby to conduct any external appeal. The term "material financial affiliation" shall not include revenue received from a health care plan by (a) a certified external appeal agent to conduct an external appeal pursuant to Section 4914 of Title II of Article 49 of the Insurance Law and Public Health Law, or (b) a clinical peer reviewer for health care services rendered to insureds.

(g) *Material professional affiliation* means any physician-patient relationship, any partnership or employment relationship, a shareholder or similar ownership interest in a professional corporation, or any independent contractor arrangement that constitutes a material financial affiliation with any expert or any officer or director of the independent organization.

(h) *Retrospective adverse determination* means a determination for which utilization review was initiated after health care services have been provided. Retrospective adverse determination does not mean an initial determination involving continued or extended health care services, or additional services for an insured undergoing a course of continued treatment prescribed by a health care provider pursuant to Section 4903(c) of the Insurance Law.

(i) *Utilization review* means the review to determine whether health care services that have been provided, are being provided or are proposed to be provided to a patient, whether undertaken prior to, concurrent with or subsequent to the delivery of such services, are medically necessary. A health care plan's denial of coverage of a health care service as defined in Section 4900(e)(2) of the Insurance Law, whether made initially or on appeal under Title I of Article 49 of the Insurance Law, on the basis that the health care service is experimental or investigational, is a determination that the health care service is not medically necessary, provided however, that such health care service would otherwise be a covered benefit.

Statutory Authority - Insurance Law, §§ 201, 301, 1109, 3201, 3216, 3217, 3217-a, 3221, 4235, 4303, 4304, 4305, 4321, 4322, 4324, Article 47 and 49; ch. 586, L. 1998.

11 NYCRR 410.3

Standard description of the external appeal process

=====Parallel Citations==========
Regulation 166

(a) Health care plans shall provide insureds, and upon request, health care providers, with a copy of the standard description of the external appeal process developed jointly by the superintendent and commissioner, including a form and instructions for insureds to request an external appeal. The standard description, request form and instructions for the external appeal process developed jointly by the superintendent and commissioner shall include, but not be limited to:

(1) a statement of the insured's right to an external appeal of health care services denied pursuant to a utilization review determination by the insured's health care plan on the basis that the services are not medically necessary or that the services are experimental or investigational;

(2) a description of the eligibility criteria for an external appeal pursuant to Section 4910 of the Insurance Law and Public Health Law and the following:

(i) Medicare cannot be the insured's only source of health services; and

(ii) Insureds receiving benefits under both Medicaid and Medicare are eligible for the external appeal process only for denials of benefits that are covered under Medicaid;

(3) notification that insureds receiving benefits under Medicaid may also file a complaint through the fair hearing process and that the determination in the fair hearing process will be the one that controls;

(4) notification of the timeframes within which the certified external appeal agent must make a determination on expedited and non-expedited external appeals;

(5) notification that insureds requesting an expedited external appeal or an external appeal of a health care plan's denial because the requested health care service is considered to be experimental

or investigational should forward the attending physician's attestation to the insured's attending physician to complete;

(6) notification that requests for an external appeal must be accompanied by the appropriate fee, as determined by the insured's health care plan, or a statement that a waiver of the fee has been requested, in order to be eligible for an external appeal;

(7) a description of the responsibility of the insured's health care plan to send the insured's medical and treatment records to the certified external appeal agent, provided that the certified external appeal agent may request additional information from the insured, the insured's health care provider or the insured's health care plan at any time;

(8) a description of the right of the insured and the insured's health care provider to submit information to the certified external appeal agent, regardless of whether the agent has requested any information, within 45 days from when the insured received notice that the health care plan made a final adverse determination or within 45 days from when the insured received a letter from the health care plan affirming that both the insured and the insured's health care plan jointly agreed to waive the internal appeal process, provided that the external appeal agent has not yet rendered a determination on the appeal;

(9) a description of the process for notifying the insured and the insured's health care plan of the certified external appeal agent's determination;

(10) instructions for submitting the request for external appeal to the superintendent;

(11) instructions for contacting the state if the insured or health care provider has questions;

(12) notification that an insured or a person authorized pursuant to law to consent to health care for the insured must sign the request and consent to the release of medical and treatment records for an insured to be eligible for an external appeal; and

(13) a signature line for the insured's consent to the release of his or her medical and treatment records, including HIV, mental health and alcohol and drug abuse records, to the certified external appeal agent assigned to review the insured's external appeal, and the expiration date of the authority to release the insured's medical and treatment records in accordance with Section 2782 of the Public Health Law for confidential HIV related information and Sections 33.13 and 33.16 of the Mental Hygiene Law for mental health related information.

(b) The superintendent and commissioner shall develop a separate form and instructions for an insured's health care provider to request an external appeal in connection with a retrospective adverse utilization review determination pursuant to Section 4904 of the Insurance Law. The form must include notification that an insured or a person authorized pursuant to law to consent to health care for the insured must sign the request and consent to the release of medical and treatment records for the health care provider to be eligible for an external appeal.

Statutory Authority - Insurance Law, §§ 201, 301, 1109, 3201, 3216, 3217, 3217-a, 3221, 4235, 4303, 4304, 4305, 4321, 4322, 4324, Article 47 and 49; ch. 586, L. 1998.

11 NYCRR 410.4

Certification of external appeal agents

=====Parallel Citations==========
Regulation 166

(a) External appeal agents shall be certified jointly by the superintendent and commissioner pursuant to Section 4912 of the Insurance Law, Section 4912 of the Public Health Law and the following:

(1) The applicant has demonstrated to the satisfaction of the superintendent and the commissioner that it has access to a pool of clinical peer reviewers sufficient to reasonably assure that appropriately qualified reviewers will be available on a timely basis for all appeals allowed by Section 4910 of the Insurance Law and Section 4910 of the Public Health Law and to avoid or minimize conflicts of interest pursuant to Section 410.6 of this Part; and

(2) the applicant has demonstrated its capability to comply with all applicable laws, rules, regulations, contractual terms, policies and standards as set forth in Section 4912 of the Insurance Law and Section 4912 of the Public Health Law and as required by the superintendent and commissioner.

(b) Applicants for certification as external appeal agents shall submit two originals and seven copies of the application to the commissioner in the form and manner prescribed jointly by the superintendent and commissioner. Upon receipt of the application for certification, the commissioner shall transmit copies of such application to the superintendent for review.

(c) No applicant shall be certified as an external appeal agent unless the applicant's proposed fees for external appeals are determined to be reasonable by the superintendent and commissioner.

(d) In order to be certified as an external appeal agent, an applicant shall consent to cooperate in court proceedings relevant to its role as a certified external appeal agent.

Statutory Authority - Insurance Law, §§ 201, 301, 1109, 3201, 3216, 3217, 3217-a, 3221, 4235, 4303, 4304, 4305, 4321, 4322, 4324, Article 47 and 49; ch. 586, L. 1998.

11 NYCRR 410.5

Certification requirements

=====Parallel Citations==========
Regulation 166

Applicants for certification as external appeal agents shall be required to submit a signed and notarized application to the commissioner, in the form and manner prescribed jointly by the superintendent and the commissioner. Such application shall include the requirements of Section 4912 of the Insurance Law and Public Health Law and the following:

(a) A description of the applicant's organizational structure and capability to operate a statewide external appeal program, including:

(1) certificate of incorporation, articles of organization and by-laws or operating agreement of the applicant and, as applicable, the applicant's holding company or parent company;

(2) the applicant's organizational chart; and

(3) any existing or proposed relationships between the applicant and any health care services entities, health care providers and management service organizations. A certified external appeal agent shall not delegate any management function related to external appeal activities pursuant to Title II of Article 49 of the Insurance Law and Public Health Law to a management service organization or any other entity.

(b) Identification of management staff and a description of such management staff's responsibilities. Each member of the management staff shall provide personal qualifying information, in the form and manner prescribed jointly by the superintendent and the commissioner.

(c) The chief executive officer of the external appeal agent shall complete an attestation, also described in Section 410.6(b) of this Part which affirms, under penalty of perjury, that:

(1) the applicant for certification as an external appeal agent does not own or control, is not owned or controlled by and does not exercise common control with any national, state or local illness, health benefit or public advocacy group, society or association of hospitals, physicians or other providers of health care services or association of health care plans; and

(2) the external appeal entity, including the medical director and all owners, officers, directors and management employees of such entity has no material professional affiliation, material familial affiliation, material financial affiliation or other affiliation proscribed by Section 410.6 of this Part with any health care plan, any owner, officer, director or management employee of any health care plan, any health care provider, physician's medical group, independent practice association or provider of pharmaceutical products or services or durable medical equipment, any health care facility, or any developer or manufacturer of health services, except as specifically listed in an attachment to the attestation.

(d) Information concerning the governing board of the applicant, including roles and responsibilities, identification of the board members and a description of their qualifications.

(e) A description of the clinical peer reviewer network, including an assessment of the network's adequacy to provide statewide external appeal services.

(f) The current financial condition of the applicant, including a certified financial statement, a statement of revenues and expenses, a balance sheet and methods to repay any indebtedness, sources of capitalization and documentation of accounts, assets, reserves and deposits.

(g) The process for ensuring that clinical peer reviewers, when making an external appeal determination concerning medical necessity, consider the clinical standards of the health care plan, the information provided concerning the insured, the attending physician's recommendation and applicable generally accepted practice guidelines developed by the federal government, national or professional medical societies, boards and associations.

(h) Policies and procedures for processing external appeals, including:

(1) a description and a chart or diagram of the sequence of steps through which an external appeal will move from receipt of the external appeal by the certified external appeal agent through notification to the insured and the insured's health care plan regarding the external appeal determination. Such description shall take into account the requirements of Section 4914 of the Insurance Law and Public Health Law and subdivisions (a) through (h) and (k) of Section 410.10 of this Part; and

(2) procedures for ensuring that no prohibited material affiliation exists with respect to the clinical peer reviewer(s) assigned to each external appeal, pursuant to Section 410.6 of this Part. Such procedures shall include, for each clinical peer reviewer assigned to review the external appeal, a requirement for a duly signed and notarized attestation which affirms, under penalty of perjury, that no prohibited material affiliation exists with respect to such clinical peer reviewer's participation in the review of the external appeal pursuant to subdivisions (e), (f) and (h) of Section 410.6 of this Part. Such attestation shall be in such form as prescribed by the superintendent and commissioner and must be maintained on file with the certified external appeal agent.

(i) A description of the fees which shall reflect the total amount that will be charged by the certified external appeal agent for external appeals, inclusive of indirect costs, administrative fees and incidental expenses, and a description of the methodology used to calculate the fees. Fees shall be approved for use for two years. Any proposed change in fees must be prior approved by the superintendent and the commissioner.

(j) A description of the certified external appeal agent's ability to accept requests for external appeals, provide requisite notifications, screen for material affiliations, respond to calls from the State and meet other requirements on a seven day per week basis.

Statutory Authority - Insurance Law, §§ 201, 301, 1109, 3201, 3216, 3217, 3217-a, 3221, 4235, 4303, 4304, 4305, 4321, 4322, 4324, Article 47 and 49; ch. 586, L. 1998.

11 NYCRR 410.6

Conflict of interest

=====Parallel Citations==========
Regulation 166

(a) No entity shall be qualified for certification as an external appeal agent if it owns or controls, is owned or controlled by, or exercises common control with any of the following:

(1) any national, state or local illness, health benefit or public advocacy group;

(2) any national, state or local society or association of hospitals, physicians, or other providers of health care services; or

(3) any national, state or local association of health care plans.

(b) An applicant for certification as an external appeal agent shall submit a sworn statement setting forth that none of the control affiliations proscribed in subdivision (a) above apply to the applicant, and that the applicant, its medical director and each of its owners, officers, directors and management employees, either:

(1) has no material familial, financial or professional affiliation, as those terms are defined in section 410.2(e)-(g) of this Part, with any person or entity listed in subparagraphs (2)(i)-(v) of this subdivision; or

(2) provides a list of those material familial, financial and professional affiliations, each of which may, upon certification, result in a prohibited conflict of interest in connection with an external appeal because of such affiliation with:

(i) any health care plan; or

(ii) any owner, officer, director, or management employee of any health care plan; or

(iii) any health care provider, physician's medical group, independent practice association, or provider of pharmaceutical products or services or durable medical equipment; or

(iv) any facility at which a health service would be provided; or

(v) any developer or manufacturer of a health service.

(c) Following certification:

(1) if an external appeal agent acquires ownership or control of, or becomes owned or controlled by, or acquires and begins to exercise common control with any entity described in paragraphs (1) through (3) of subdivision (a) of this section, the external appeal agent shall notify the Departments of Insurance and Health in writing within five business days of such acquisition or exercise of control. Such notice shall be sufficient basis for the revocation of certification without a hearing; and

(2) the sworn statement required by subdivision (b) of this section shall be amended and resubmitted to the Departments of Insurance and Health within five business days of the addition or deletion of any material affiliation as described in subparagraphs (i) through (v) of paragraph (2) of subdivision (b) of this section.

(d) The applicant shall submit a detailed written description of its policies, processes and procedures for ensuring, in accordance with the criteria set forth in subdivisions (b) and (c) and paragraphs (2) through (4) of subdivision (e) of this section and paragraph (2) of subdivision (h) of Section 410.5 of

this Part, that appeals will be conducted by impartial clinical peer reviewers, for the reporting and review of clinical peer reviewer conflicts of interest and for assigning or reassigning an appeal where a conflict or potential conflict is identified and further, that the applicant, its medical director and each of its owners, officers, directors, management employees and clinical peer reviewers have no material familial, financial or professional affiliation with the insured whose health care service is the subject of an appeal assigned to it subsequent to certification as an external appeal agent or with the insured's designee.

(e) Unavoidable conflicts; minimization. Notwithstanding any other provision of law and in accordance with Section 4913(b) of the Insurance Law and Section 4913.2 of the Public Health Law:

(1) If the superintendent determines in the course of assigning an external appeal that a conflict is unavoidable because all external appeal agents certified pursuant to this Part or their medical director, owners, officers, directors and/or management employees have a disqualifying material affiliation with one or more of the persons or entities listed in subparagraphs (i) through (v) of paragraph (2) of subdivision (b) of this section in relation to the appeal to be assigned, the superintendent shall make a random assignment of the appeal in accordance with Section 410.8 of this Part, provided, however, that the certified external appeal agent assigned shall, within two (2) business days of the assignment or for an expedited appeal, within 24 hours of the assignment, certify to the superintendent by sworn statement that the clinical peer reviewer(s) who will review the external appeal have been assigned in accordance with paragraph (2) of this subdivision and subdivision (f) of this section. When an appeal must be assigned pursuant to this paragraph, the superintendent shall notify the insured that all certified agents have a proscribed material affiliation(s), of the need to randomly assign the appeal to one of the external appeal agents certified by the state in order that a determination of the appeal be obtained and of the nature of the affiliation(s) involving the certified external appeal agent assigned to the appeal, and shall inform the insured that, in no event shall the agent's clinical peer reviewer(s) who reviews the appeal have any affiliation proscribed by this section.

(2) An agent assigned pursuant to this Part shall not assign an appeal to a clinical peer reviewer(s) which has a material affiliation with any of those persons listed in subparagraphs (i) through (v) of paragraph (2) of subdivision (b) of this section or to a clinical peer reviewer(s) which has a material familial, financial or professional affiliation with the insured whose health care service is the subject of the appeal, or with the insured's designee.

(3) Where a clinical peer reviewer has a material affiliation with a health maintenance organization or line of business thereof, such affiliation alone shall not constitute a disqualifying conflict with respect to an appeal involving an affiliated health maintenance organization or line of business with respect to which the clinical peer reviewer has no material affiliation.

(4) Where a clinical peer reviewer has a material affiliation with a hospital or other licensed provider which is an affiliate of a larger hospital or other provider system or network, such affiliation alone shall not constitute a disqualifying conflict with respect to an appeal involving another hospital or other provider affiliated with such hospital or provider system with respect to which the clinical peer reviewer has no material affiliation.

(f) No appeal shall be assigned to an external appeal agent or clinical peer reviewer that participated in or issued an internal utilization review decision or the final adverse utilization review determination which is the basis for an external appeal.

(g) Any appeal assigned to an external appeal agent or clinical peer reviewer which is subsequently determined to involve a disqualifying material affiliation, or prior involvement of the external appeal agent or clinical peer reviewer in the underlying internal utilization review decision or final adverse utilization review determination, shall be immediately returned for reassignment to the superintendent, or the external appeal agent, respectively. If the appeal is being returned to the superintendent, the certified external appeal agent shall also immediately notify the superintendent, by telephone or fax, that the appeal is being returned.

(h) Notwithstanding any other provision of this Part, a certified external appeal agent may assign an appeal to a clinical peer reviewer with unique expertise and experience with respect to a health care service which is relevant to an appeal for reasons which may include, but shall not necessarily be limited to:

(1) the development or participation in the development of a service, procedure or related equipment; and/or

(2) prior training and participation in the diagnosis or treatment of a condition rarely encountered or rarely encountered in the geographic area in which the insured resides, provided, however, that such clinical peer reviewer did not participate in the internal utilization review decision or the final adverse determination which is the basis for the external appeal.

Statutory Authority - Insurance Law, §§ 201, 301, 1109, 3201, 3216, 3217, 3217-a, 3221, 4235, 4303, 4304, 4305, 4321, 4322, 4324, Article 47 and 49; ch. 586, L. 1998.

11 NYCRR 410.7

Screening of requests for external appeal

=====Parallel Citations==========
Regulation 166

(a) Requests for external appeals shall be submitted to the superintendent. Upon receipt of such requests completed in the form and manner prescribed by the superintendent and commissioner, the requests shall be screened by the superintendent to determine eligibility for external appeal pursuant to the criteria detailed in Section 4910(b) of the Insurance Law and Section 4910.2 of the Public Health Law and the following:

(1) The insured submitting the request or on whose behalf a request for external appeal was submitted, or in the case of a retrospective adverse determination, on whose behalf a health care service is delivered, is not covered exclusively by Title XVIII of the federal Social Security Act; and

(2) if the insured submitting the request or on whose behalf a request for external appeal was submitted, or in the case of a retrospective adverse determination, on whose behalf a health care service is delivered, is receiving benefits under both Title XVIII and Title XIX of the federal Social Security Act, the health care service being requested is a covered benefit under Title XIX.

(3) The request is substantially complete as appropriate for the type of determination to be appealed and contains the following:

(i) a copy of the final adverse determination letter from the health care plan notifying the insured that their request for health care services was denied on appeal; or

(ii) a copy of a letter from the health care plan to the insured indicating a joint agreement to waive any internal appeal offered by the health care plan; or

(iii) in the case of a retrospective adverse determination, a copy of the final adverse determination letter from the health care plan;

(iv) payment of a fee, if applicable, or a statement that a waiver of the fee has been requested;

(v) the signature of the insured, or a person authorized pursuant to law to consent to health care for the insured, authorizing release of medical and treatment information; and

(vi) in the case of a retrospective adverse determination, if the insured's health care provider is requesting an external appeal, and the insured's acknowledgement of the external appeal request and consent for the release of the insured's medical records to a certified external appeal agent is

obtained at the time health care services are provided, a copy of a letter sent by the insured's health care provider to the insured notifying the insured that an external appeal of a retrospective adverse determination has been requested and that the insured's medical records will be released to a certified external appeal agent.

(4) As applicable, the insured's attending physician attestation is fully and appropriately completed by the attending physician in the form and manner prescribed by the superintendent and commissioner, or the insured has indicated that the attending physician attestation has been transmitted to the insured's attending physician. An application shall not be considered incomplete or untimely solely on the basis of failure by the attending physician to submit such documentation within the insured's 45 day timeframe for initiation of an external appeal request pursuant to Section 4914(b)(1) of the Insurance Law, provided however, the application will not be forwarded to an external appeal agent until the attestation is submitted.

(5) If the attending physician is recommending that the insured participate in a clinical trial, the attending physician attests that:

(i) the insured has a life-threatening or disabling condition or disease, as defined in subdivision (g-1) of Section 4900 of the Insurance Law;

(ii) the insured meets the eligibility criteria for the clinical trial;

(iii) the clinical trial is open to the insured; and

(iv) the insured has been or will likely be accepted into the clinical trial.

(6) The external appeal request was submitted, in the form and manner prescribed by the superintendent and commissioner, to the superintendent within 45 days from the date the insured or, for provider initiated retrospective appeals, the insured's health care provider, received notice that the health care plan made a final adverse determination or within 45 days from when the insured received a letter from the health care plan affirming that both the insured and the insured's health care plan jointly agreed to waive the internal appeal process. Unless otherwise demonstrated, it shall be presumed that the insured, or the insured's health care provider for provider initiated retrospective appeals, received the notice of final adverse determination or letter agreeing to waive the internal appeal process within eight days of the date on the notice of final adverse determination or the date on the letter agreeing to waive the internal appeal process.

(b) Screening of expedited appeals shall be initiated by the superintendent within 24 hours of receipt of the request. Screening of standard appeals shall be initiated by the superintendent within five business days of receipt of the request.

(c) In the event that additional information is required to process a request, the superintendent shall contact the initiator of the request, the insured's health care plan or the insured's attending physician, as appropriate, by the most efficient means available, to request the necessary information.

(d) A copy of appropriately completed requests for appeals of final adverse utilization review determinations made by entities certified under Article 44 of the Public Health Law that are determined to be eligible for external appeal shall be transmitted to the commissioner immediately after assignment to a certified external appeal agent.

(e) The superintendent shall notify the insured and the insured's health care plan if a request is determined to be eligible for external appeal within seven days of receipt of a complete request for a standard appeal and within 48 hours of receipt of a complete request for an expedited appeal. Such notification shall include:

(1) identification of the certified external appeal agent assigned to the appeal;

(2) notification to the insured of any unavoidable material affiliations concerning the certified external appeal agent assigned to the appeal, including a brief explanation of the nature of the material affiliation(s) pursuant to paragraph (1) of subdivision (e) of Section 410.6 of this Subpart;

(3) for purposes of notifying the insured's health care plan, a copy of the insured's signed release of medical and treatment information, completed in a manner as prescribed jointly by the superintendent and commissioner and in accordance with Section 2782 of the Public Health Law for confidential HIV related information and Sections 33.13 and 33.16 of the Mental Hygiene Law for mental health related information; and

(4) for purposes of notifying the insured's health care plan, as applicable, a copy of the attending physician's attestation.

(f) If a fee is submitted, and the health care plan's determination is upheld by the external appeal agent, the superintendent shall forward the fee to the health care plan within seven days of receipt of the external appeal agent's determination.

(g) If a fee is submitted, and the health care plan's determination is overturned in whole or in part by the external appeal agent, the superintendent shall return the fee to the insured or, in the case of a provider initiated retrospective appeal, the insured's health care provider, within seven days of receipt of the external appeal agent's determination.

(h) Those requests determined to be ineligible for external appeal shall be returned to the insured or, in the case of a provider initiated retrospective appeal, the insured's health care provider, by the superintendent, with notification to the insured's health care plan and attending physician, as appropriate, accompanied by an explanation as to why the request was determined to be ineligible for external appeal within seven days of receipt of a complete request for a standard appeal and within 48 hours of receipt of a complete request for an expedited appeal.

Statutory Authority - Insurance Law, §§ 201, 301, 1109, 3201, 3216, 3217, 3217-a, 3221, 4235, 4303, 4304, 4305, 4321, 4322, 4324, Article 47 and 49; ch. 586, L. 1998.

11 NYCRR 410.8

Random assignment of external appeals

=====Parallel Citations==========
Regulation 166

Requests for external appeals that have been determined to be eligible for external appeal shall be randomly assigned by the superintendent to a certified external appeal agent according to a process prescribed by the superintendent and commissioner. Such process must take into account conflicts of interest pursuant to Section 4913 of the Insurance Law and Public Health Law and Section 410.6 of this Part.

Statutory Authority - Insurance Law, §§ 201, 301, 1109, 3201, 3216, 3217, 3217-a, 3221, 4235, 4303, 4304, 4305, 4321, 4322, 4324, Article 47 and 49; ch. 586, L. 1998.

11 NYCRR 410.9

Responsibilities of health care plans

=====Parallel Citations==========
Regulation 166

Health care plans shall be responsible for compliance with all applicable requirements of Article 49 of the Insurance Law and with the following:

(a) Insured requests for experimental or investigational health care services that would otherwise be a covered benefit except for the health care plan's determination that the health care service is experimental or investigational shall be subject to utilization review pursuant to Title I of Article 49 of the Insurance Law.

(b) If a health care plan requires information necessary to conduct a standard internal appeal pursuant to Section 4904 of the Insurance Law, the health care plan shall notify the insured and the insured's health care provider, in writing, within fifteen (15) days of receipt of the appeal, to identify and request the necessary information. In the event that only a portion of such necessary information is received, the health care plan shall request the missing information, in writing, within five business days of receipt of the partial information. In the case of expedited appeals, the health care plan shall immediately notify the insured and the insured's health care provider by telephone or facsimile to identify and request the necessary information, followed by written notification. The period of time to make an appeal determination under Section 4904 of the Insurance Law begins upon a health care plan's receipt of necessary information.

(c) If a health care plan offers two levels of internal appeals, the health care plan may not require the insured to exhaust the second level of internal appeal to be eligible for an external appeal.

(d) Notices of final adverse determinations shall comply with all requirements of Article 49 of the Insurance Law and with all applicable federal laws and rules.

(e) Each notice of a final adverse determination of an expedited or standard utilization review appeal under Section 4904 of the Insurance Law shall be in writing, dated and include the following:

(1) a clear statement describing the basis and clinical rationale for the denial as applicable to the insured;

(2) a clear statement that the notice constitutes the final adverse determination;

(3) the health care plan's contact person and his or her telephone number;

(4) the insured's coverage type;

(5) the name and full address of the health care plan's utilization review agent;

(6) the utilization review agent's contact person and his or her telephone number;

(7) a description of the health care service that was denied, including, as applicable and available, the dates of service, the name of the facility and/or physician proposed to provide the treatment and the developer/manufacturer of the health care service;

(8) a statement that the insured may be eligible for an external appeal and the timeframes for requesting an appeal; and

(9) for health care plans that offer two levels of internal appeals, a clear statement written in bolded text that the 45 day time frame for requesting an external appeal begins upon receipt of the final adverse determination of the first level appeal, regardless of whether or not a second level appeal is requested, and that by choosing to request a second level internal appeal, the time may expire for the insured to request an external appeal.

(f) A written notice of final adverse determination concerning an expedited utilization review appeal under Section 4904 of the Insurance Law shall be transmitted to the insured within 24 hours of the rendering of such determination.

(g) If the insured and the health care plan have jointly agreed to waive the internal appeal process offered by the health care plan, the information required in subdivision (e) of this section must be provided to the insured simultaneously with the letter agreeing to such waiver. The letter agreeing

to such waiver and the information required in subdivision (e) of this section must be provided to the insured within 24 hours of the agreement to waive the health care plan's internal appeal process.

(h) Health care plans shall facilitate the prompt completion of external appeal requests, including but not limited to, the following:

(1) Health care plans shall provide the insured with a copy of the standard description of the external appeal process as developed jointly by the superintendent and commissioner, including a form and instructions for requesting an external appeal along with a description of the fee, if any, charged to insureds for an external appeal, criteria for determining eligibility for a waiver of such fees based on financial hardship, and the process for requesting a waiver of such fees based on financial hardship:

(i) simultaneous with a notice of a final adverse determination that a health care service is not medically necessary, including on the grounds that the health care service is experimental or investigational; or

(ii) simultaneous with the written confirmation of agreement between the health care plan and the insured to waive the health care plan's internal appeal process; and

(iii) within three business days of a request by an insured or an insured's designee;

(2) transmitting insured's medical and treatment records pursuant to an appropriately completed release or releases signed by the insured or by a person authorized pursuant to law to consent to health care for the insured and, in the case of medical necessity appeals, transmitting the clinical standards used to determine medical necessity for health care services within three business days of receiving notification of the external appeal from the certified external appeal agent to which the subject appeal is assigned, or in the case of an expedited appeal, within 24 hours of receiving notification of the external appeal from the certified external appeal agent to which the subject appeal is assigned;

(3) providing information requested by the assigned certified external appeal agent as soon as is reasonably possible, but in no event shall the health care plan take longer than two business days to provide the requested information for standard appeals. Requests for information relative to expedited appeals must be provided to the certified external appeal agent within 24 hours; and

(4) providing a form and instructions, developed jointly by the superintendent and commissioner, for an insured's health care provider to request an external appeal in connection with a retrospective adverse utilization review determination under Section 4904 of the Insurance Law, within three business days of a health care provider's request for a copy of the form. For retrospective adverse determinations, health care plans may charge the appealing health care provider up to $50 for each appeal, provided however, that no fee may be charged to an insured for a health care provider's external appeal of a retrospective adverse determination and provided further, that in the event a retrospective adverse determination is overturned on external appeal, the full amount of the fee shall be refunded to the appealing health care provider.

(i) In the event an adverse determination is overturned on external appeal, or in the event that the health care plan reverses a denial which is the subject of external appeal, the health care plan shall provide, arrange to provide or make payment for the health care service(s) which is the basis of the external appeal to the insured to the extent that such health care service(s) is provided while the insured has coverage with the health care plan.

Nothing herein shall be construed to require the health care plan to provide any health care services to an individual who is no longer insured by that health care plan at the time of an external appeal agent's reversal of a health care plan's utilization review denial.

(j) Health care plans shall establish the fee, if any, to be charged to insureds for an external appeal and shall have a methodology for determining an insured's eligibility for a waiver of the fee

requirement for an external appeal based on financial hardship pursuant to Section 4910(c) of the Insurance Law and Section 4910.3 of the Public Health Law.

(k) Nothing in this Part shall be construed to relieve the health care plan of financial responsibility for external appeals that have been assigned to a certified external appeal agent. In the case of a health care plan reversing a denial which is the subject of an external appeal after assignment of the appeal to a certified external appeal agent, but prior to assignment of clinical peer reviewer(s), the health care plan shall be assessed an administrative fee as prescribed by the superintendent and commissioner.

Statutory Authority - Insurance Law, §§ 201, 301, 1109, 3201, 3216, 3217, 3217-a, 3221, 4235, 4303, 4304, 4305, 4321, 4322, 4324, Article 47 and 49; ch. 586, L. 1998.

11 NYCRR 410.10

Responsibilities of certified external appeal agents

=====Parallel Citations==========
Regulation 166

(a) Within 24 hours of receiving assignment from the superintendent of a request for external appeal, certified external appeal agents shall send notification of such assignment to the insured requesting an external appeal or on whose behalf an external appeal is requested, the insured's health care plan, the attending physician, as applicable, and, in the case of a provider initiated appeal of a retrospective adverse determination, the insured's health care provider. The certified external appeal agent shall include in such notification:

(1) a request for any additional documentation that may be available to support the appeal;

(2) the address to which any required or additional documentation should be sent;

(3) whether the appeal is a standard or expedited appeal; and

(4) for purposes of notifying the insured's health care plan, as applicable, copies of the documents relied upon by the insured's attending physician to establish medical and scientific evidence that the recommended health care service is likely to be more beneficial to the insured than any covered standard health care service or procedure.

(b) Certified external appeal agents shall make a final determination on non-expedited external appeals within 30 days of receiving the request for external appeal from the superintendent, provided that, in the event that the certified external appeal agent requests additional documentation from the insured, the insured's health care plan, the insured's attending physician or health care provider, other than the documentation requested pursuant to subdivision (a) of this section, the certified external appeal agent shall have an additional five business days from receipt of the request for external appeal from the superintendent within which to make a final determination. Certified external appeal agents shall notify the superintendent if additional documentation has been requested.

(c) Certified external appeal agents shall make a final determination on expedited external appeals within 3 days of receiving the request for external appeal from the superintendent.

(d) In addition to the requirements in Section 4914(b)(4) of the Insurance Law and Section 4914.2(d) of the Public Health Law the external appeal agent shall consider any documentation submitted by the insured or the insured's designee, the insured's attending physician, the insured's health care plan or the insured's health care provider that is pertinent to the external appeal under review provided that such documentation is submitted by the earlier of:

(1) within 45 days from when the insured or, in the case of a provider initiated retrospective appeal, the insured's health care provider received notice that the health care plan made a final adverse determination or within 45 days of the date from when the insured received a letter from the health care plan affirming that both the insured and the insured's health care plan jointly agreed to waive the internal appeal process; or

(2) prior to the external review agent's final determination on the appeal.

A certified external appeal agent may not reconsider an appeal for which a final determination has been made based upon receipt of additional information subsequent to such final determination.

(e) The certified external appeal agent shall forward to the insured's health care plan any documentation received by the certified external appeal agent that is pertinent to an appeal that has been referred to the agent by the superintendent. Any such documentation that, in the opinion of the certified external appeal agent, constitutes a material change from the documentation upon which the utilization review agent based its adverse determination or upon which the health care plan based its denial shall be forwarded immediately, but no later than 24 hours after receipt of such documentation, to the insured's health care plan, with notification that such documentation represents a material change, for consideration pursuant to Section 4914(b)(1) of the Insurance Law and Section 4914.2(a) of the Public Health Law. In the event of receipt of such material documentation, for other than expedited appeals, the certified external appeal agent shall not issue a determination for up to three (3) business days or until the health care plan has considered such documentation and amended, reversed or confirmed the adverse determination, whichever is earlier.

(f) For each external appeal determination made by a certified external appeal agent, the medical director of the certified external appeal agent shall certify that:

(1) the certified external appeal agent and each clinical peer reviewer assigned to review the external appeal followed appropriate procedures as defined in Section 4914 of the Insurance Law and Public Health Law, Section 410.10 of this Part and the certified external appeal agent's application and, as applicable, conditions for certification; and

(2) all clinical peer reviewers met the criteria for conducting the external review pursuant to Section 4900(b) of the Insurance Law and Section 4900(2) of the Public Health Law; and

(3) for each clinical peer reviewer assigned to review the external appeal, a duly signed and notarized attestation which affirms, under penalty of perjury, that no prohibited material affiliation exists with respect to such clinical peer reviewer's participation in the review of the external appeal pursuant to subdivisions (e), (f) and (h) of Section 410.6 of this Part, is on file with the certified external appeal agent. Such attestation shall be in such form as prescribed by the superintendent and commissioner.

(g) Certified external appeal agents shall forward copies of appeal determination notification letters sent to health care plans and insureds pursuant to Section 4914(b)(2) and (3) of the Insurance Law and Section 4914.2(b) and (c) of the Public Health Law to the insured's health care provider, if applicable, and to the superintendent and commissioner. Such notification letters shall include:

(1) a clear statement of the health care plan's responsibility in regard to provision of the contested health care service to the insured;

(2) a statement attesting that no prohibited material affiliation existed with respect to the clinical peer reviewers; and

(3) with respect to a medical necessity appeal determination, the reasons for the determination, which shall include a discussion of the health care plan's clinical standards, the information provided concerning the patient, the attending physician's recommendation, and applicable and generally accepted practice guidelines developed by the federal government, national or professional medical societies, boards and associations which were used in making the determination; or

(4) with respect to an experimental or investigational treatment or service appeal determination, a statement as to whether the proposed health service or treatment is likely to be more beneficial than any standard treatment or treatments for the insured's life-threatening or disabling condition or disease; or

(5) with respect to a clinical trial appeal determination, a statement as to whether the clinical trial is likely to benefit the insured in the treatment of the insured's condition or disease.

(h) Certified external appeal agents shall enclose a request for payment with the copy of the appeal notification letter sent to the health care plan.

(i) Certified external appeal agents shall not be relieved of responsibility for making a determination with respect to an assigned external appeal on the basis that the insured no longer has coverage with the health care plan that denied the health care service(s) that is the subject of the appeal. However, a health care plan will not be required to pay the patient costs of any health service(s) or procedure(s) that is the subject of an external appeal for insureds who no longer have coverage with such health care plan unless, and to the extent that the health care service(s) was provided while the insured had coverage with the health care plan.

(j) In addition to the information required by Section 4916(b) of the Insurance Law and Section 4916.2 of the Public Health Law, certified external appeal agents shall include in the annual report a description of each external appeal assigned to such certified external appeal agent by the superintendent, including a summary of the clinical justification for the agent's determination, and any other information required by the superintendent and/or commissioner.

(k) In no event shall the certified external appeal agent provide the health care plan with a copy of the insured's application for an external appeal or divulge to the health care plan, the insured, the insured's attending physician or health care provider the names of the clinical peer reviewers assigned to the appeal. However, such information shall be made available upon request to and upon audit or examination by the superintendent and commissioner. Nothing herein is intended to preclude access to such information during court proceedings.

Statutory Authority - Insurance Law, §§ 201, 301, 1109, 3201, 3216, 3217, 3217-a, 3221, 4235, 4303, 4304, 4305, 4321, 4322, 4324, Article 47 and 49; ch. 586, L. 1998.

11 NYCRR 410.11

Insured rights and responsibilities

=====Parallel Citations==========
Regulation 166

(a) Insureds shall be responsible for:

(1) exhausting the health care plan's internal appeal process under Section 4904 of the Insurance Law, provided however, that if a health care plan has two levels of internal appeals, the insured must only exhaust the first level of appeal. In the alternative, the insured and the insured's health care plan may jointly agree to waive the internal appeal process;

(2) ensuring that requests for external appeals are filed and completed within the time frames provided for in subdivision (4) of this section, except in the case of transmittal of medical and treatment records, which shall be the responsibility of the insured's health care plan;

(3) as applicable, providing the attending physician with the documents necessary to complete the physician attestation component of the external appeal request, and, as necessary, providing evidence to the superintendent that such has occurred; and

(4) ensuring that, to the extent possible, all supporting documentation, including but not limited to diagnostic test results and medical literature, is submitted to the assigned certified external appeal agent within the earlier of:

(i) 45 days from the date of the insured's receipt of a final adverse determination notice or within 45 days of receiving a letter from the health care plan affirming that both the insured and the insured's health care plan jointly agreed to waive the internal appeal process; or

(ii) prior to the date the external appeal determination is finalized by the certified external appeal agent.

(5) responding to the superintendent's request for information concerning an incomplete external appeal request in a timely manner.

(b) Insureds whose health benefits are provided through both Title XVIII and XIX of the federal Social Security Act are eligible to request an external appeal only for those health care services covered through Title XIX.

(c) Insureds whose health benefits are provided through Title XIX of the federal Social Security Act and who request an external appeal pursuant to Title II of Article 49 of the Insurance Law or Public Health Law may additionally apply to the Department of Health for a fair hearing pursuant to the terms and within the time frames prescribed by Sections 22 and 364-j of the Social Services Law and applicable regulations. Pursuant to Section 4910(d) of the Insurance Law and Section 4910.4 of the Public Health Law, a fair hearing determination prevails over an external appeal determination; therefore, any appeal for which a determination has been made pursuant to the fair hearing process shall not be considered for external appeal.

(d) Insureds, except for those whose health benefits are provided through Title XIX of the federal Social Security Act and Title 1-A of Article 25 of the Public Health Law, are responsible for enclosing a fee with the request for an external appeal to the superintendent in accordance with the fee prescribed by the insured's health care plan. The insured is responsible for requesting a waiver of the fee requirement from the health care plan if such fee will pose a financial hardship for the insured. Insureds shall not be responsible for paying a fee for any external appeal requested by a health care provider relative to a retrospective adverse determination.

(e)(1) Upon requesting an external appeal, the insured, the insured's designee or the insured's health care provider shall acknowledge that the determination of the external appeal is binding on the plan and the insured, and shall agree not to commence any legal proceeding against an external appeal agent or clinical peer reviewer to review a determination made by such external appeal agent or clinical peer reviewer pursuant to Article 49 of the Insurance Law or Article 49 of the Public Health Law; provided, however, that the foregoing shall not limit any rights the insured, the insured's designee or the insured's health care provider may have with respect to bringing an action for damages for bad faith or gross negligence or with respect to bringing an action against the insured's health care plan.

(2) As specified in Insurance Law section 4914(c) and Public Health Law section 4914(3), no external appeal agent or clinical peer reviewer conducting an external appeal shall be liable in damages to any person for any opinions rendered by such external appeal agent or clinical peer reviewer upon completion of an external appeal conducted pursuant to Article 49 of the Insurance Law or Article 49 of the Public Health Law, unless such opinion was rendered in bad faith or involved gross negligence.

Statutory Authority - Insurance Law, §§ 201, 301, 1109, 3201, 3216, 3217, 3217-a, 3221, 4235, 4303, 4304, 4305, 4321, 4322, 4324, Article 47 and 49; ch. 586, L. 1998.

11 NYCRR 410.12

Confidentiality

=====Parallel Citations==========
Regulation 166

(a) No health care plan may share an insured's medical and treatment records or any other confidential information, including HIV related and mental health related information, with a certified external appeal agent or a clinical peer reviewer designated by such certified external appeal agent unless the insured, or a person authorized pursuant to law to consent to health care for the insured, has signed a specific release of information for HIV, mental health and drug and alcohol abuse or otherwise appropriate release in a manner and in such form as prescribed by the superintendent and commissioner in accordance with Section 2782 of the Public Health Law for confidential HIV related information and Sections 33.13 and 33.16 of the Mental Hygiene Law for mental health related information and as required by any applicable federal law or regulation.

(b) No certified external appeal agent or clinical peer reviewer designated by such certified external appeal agent shall, except as specifically authorized by an appropriate release signed by the insured or by a person authorized pursuant to law to consent to health care for the insured, divulge confidential medical and treatment information or other information obtained through the review of an external appeal to any individual or group except the certified external appeal agent to whom the appeal was assigned and, as necessary, the superintendent and commissioner.

Statutory Authority - Insurance Law, §§ 201, 301, 1109, 3201, 3216, 3217, 3217-a, 3221, 4235, 4303, 4304, 4305, 4321, 4322, 4324, Article 47 and 49; ch. 586, L. 1998.

11 NYCRR 410.13

Audits and examinations

=====Parallel Citations==========
Regulation 166

(a) The superintendent or commissioner or their representative(s) may examine at any time each certified external appeal agent, including any entities under contract with the certified external appeal agent for the purpose of carrying out the requirements of Title II of Article 49 of the Insurance Law or Title II of Article 49 of the Public Health Law and this Part, as to compliance with such requirements and the quality of services offered.

(b) All external appeal case records shall be subject to audit and examination for a period of six years from the date of the certified external appeal agent's final determination on the appeal. All documentation relating to the case shall be kept and maintained by the certified external appeal agent for no less than six years from the date of the certified external appeal agent's final determination on the appeal. Such documentation shall include, but not be limited to:

(1) procedures for credentialing clinical peer reviewers;

(2) procedures for selecting clinical peer reviewers for the case, including procedures for ensuring the absence of any prohibited material affiliation relative to clinical peer reviewers;

(3) insured's medical and treatment records;

(4) any other documentation received by the certified external appeal agent relative to the case;

(5) notes, comments and determinations of each clinical peer reviewer assigned to the case;

(6) written justification when more than three clinical peer reviewers are assigned to a particular case;

(7) letter of notification to the insured and the insured's health care plan and, as applicable, the insured's health care provider of the final determination;

(8) the names and qualifications of the clinical peer reviewer(s) that reviewed the external appeal; and

(9) a signed and notarized attestation from each clinical peer reviewer assigned to an external appeal that no prohibited material affiliation exists with respect to such external appeal.

(c) The superintendent or commissioner or their representative(s) may examine at any time each health care plan to determine compliance with the requirements of Title II of Article 49 of the Insurance Law or Title II of Article 49 of the Public Health Law and this Part.

(d) All external appeal case records shall be subject to audit and examination for a period of six years from the date of the certified external appeal agent's final determination on the appeal. All documentation relating to the case shall be kept and maintained by the health care plan for no less than six years from the date of the certified external appeal agent's final determination on the appeal. Such documentation shall include, but not be limited to:

(1) record of fees collected and waived;

(2) all correspondence and any other documentation received by and submitted to the certified external appeal agent assigned to the case;

(3) a copy of the notice provided by the health care plan to the insured or, as applicable, the insured's health care provider regarding the final utilization review adverse determination and the insured's right to request an external appeal; and

(4) a copy of the letter or other documentation of agreement between the health care plan and the insured to waive the health care plan's internal utilization review processes.

Statutory Authority - Insurance Law, §§ 201, 301, 1109, 3201, 3216, 3217, 3217-a, 3221, 4235, 4303, 4304, 4305, 4321, 4322, 4324, Article 47 and 49; ch. 586, L. 1998.