Chapter 246-305 WAC
CERTIFICATION OF INDEPENDENT REVIEW ORGANIZATIONS (IROs)

WAC

WAC 246-305-001 Purpose and scope. (1) Purpose. These rules are adopted by the Washington state department of health to implement the provisions of RCW 43.70.235 regarding the certification of independent review organizations (IROs). Certified IROs are qualified to receive referrals from the insurance commissioner or designee under RCW 48.43.535 to make binding determinations related to health care coverage and payment disputes between health insurance carriers and their enrollees.

(2) Other applicable rules. Independent review is also subject to rules of the insurance commissioner implementing RCW 48.43.535.

(3) Applicability. These rules apply to independent review cases originating in Washington state under RCW 48.43.535, and to independent review organizations conducting these reviews.

[Statutory Authority: RCW 43.70.235 and 48.43.535. WSR 11-23-124, § 246-305-001, filed 11/21/11, effective 11/26/11; WSR 01-08-023, § 246-305-001, filed 3/28/01, effective 4/28/01.]

WAC 246-305-010 Definitions. The definitions in this section apply throughout the chapter unless the context clearly requires otherwise.

(1) "Adverse benefit determination" means a benefit is denied, reduced, or terminated. The basis for these actions or determinations may include:

(a) An enrollee's or applicant's eligibility to participate in a plan or group plan;

(b) Any utilization review; or

(c) Failure to cover an item or service for which benefits are otherwise provided because of a determination that the item or service is experimental, investigational, or not medically necessary or appropriate.

(2) "Applicant" means a person or entity seeking to become a Washington certified independent review organization (IRO).

(3) "Attending provider" includes "treating provider" or "ordering provider" as used in WAC 284-43-620 and 284-43-630.

(4) "Carrier" or "health carrier" has the same meaning in this chapter as in WAC 284-43-130.

(5) "Case" means a dispute relating to a carrier's decision to deny, modify, reduce, or terminate coverage of or payment for health care service for an enrollee, which has been referred to a specific IRO by the insurance commissioner under RCW 48.43.535.

(6) "Clinical peer" means a physician or other health professional who holds an unrestricted license or certification and is in the same or similar specialty as typically manages the medical condition, procedures, or treatment under review. Generally, as a peer in a similar specialty, the individual must be in the same profession, i.e., the same licensure category, as the attending provider. In a profession that has organized, board-certified specialties, a clinical peer generally will be in the same formal specialty.

(7) "Clinical reviewer" means a medical reviewer, as defined in this section.

(8) "Conflict of interest" means violation of any provision of WAC 246-305-030, including, but not limited to, material familial, professional and financial affiliations.

(9) "Contract specialist" means a reviewer who deals with interpretation of health plan coverage provisions. If a clinical reviewer is also interpreting health plan coverage provisions, that reviewer shall have the qualifications required of a contract specialist.

(10) "Department" means the Washington state department of health.

(11) "Enrollee" means an "appellant" as defined in WAC 284-43-130. "Enrollee" also means a person lawfully acting on behalf of the enrollee, including, but not limited to, a parent or guardian.

(12) "Evidence-based standard" means the conscientious, explicit, and judicious use of the current best evidence based on the overall systematic review of the research in making decisions about the care of individual patients.

(13) "Health care provider" or "provider" means a person practicing health care services consistent with Washington state law, or a person with valid credentials from another state for a similar scope of practice.

(14) "Independent review" means the process of review and determination of a case referred to an IRO under RCW 48.43.535.

(15) "Independent review organization" or "IRO" means an entity certified by the department under this chapter.

(16) "IRO," see independent review organization.

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

(18) "Material professional affiliation" includes, but is not limited to, any provider-patient relationship, any partnership or employment relationship, or a shareholder or similar ownership interest in a professional corporation.

(19) "Material financial affiliation" means any financial interest including employment, contract or consultation which generates more than five percent of total annual revenue or total annual income of an IRO or an individual director, officer, executive or reviewer of the IRO. This includes a consulting relationship with a manufacturer regarding technology or research support for a specific product.

(20) "Medical reviewer" means a physician or other health care provider who is assigned to an external review case by a certified IRO, consistent with this chapter.

(21) "Medical, scientific, and cost-effectiveness evidence" means published evidence on results of clinical practice of any health profession which complies with one or more of the following requirements:

(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 Institute of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS data base Health Services Technology Assessment Research (HSTAR);

(c) Medical journals recognized by the Secretary of Health and Human Services, under Section 1861 (t)(2) of the federal Social Security Act;

(d) 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;

(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 Healthcare Research and Quality, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Centers for Medicare and Medicaid Services, Congressional Office of Technology Assessment, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services;

(f) Clinical practice guidelines that meet Institute of Medicine criteria; or

(g) In conjunction with other evidence, peer-reviewed abstracts accepted for presentation at major scientific or clinical meetings.

(22) "Referral" means receipt by an IRO of notification from the insurance commissioner or designee that a case has been assigned to that IRO under provisions of RCW 48.43.-535.

(23) "Reviewer" or "expert reviewer" means a clinical reviewer or a contract specialist, as defined in this section.

[Statutory Authority: RCW 43.70.235 and 48.43.535. WSR 11-23-124, § 246-305-010, filed 11/21/11, effective 11/26/11; WSR 01-08-023, § 246-305-010, filed 3/28/01, effective 4/28/01.]

WAC 246-305-020 General requirements for certification. In order to qualify for certification, an IRO shall:

(1) Submit an application for certification to the department as described in WAC 246-305-080.

(2) Hold a current accreditation from a nationally recognized private accrediting organization acceptable to the federal Department of Health and Human Services or Department of Labor for the federal external review process.

(3) Demonstrate expertise and a history of reviewing health care in terms of medical necessity, appropriateness, and the application of other health plan coverage provisions.

(4) Demonstrate the ability to handle a full range of review cases occurring in Washington state. Certified IROs may contract with more specialized review organizations; however, the certified IRO shall ensure that each review conducted meets all the requirements of this chapter.

(5) Demonstrate capability to review administrative and contractual coverage issues, as well as medical necessity and effectiveness, and the appropriateness of experimental and investigational treatments.

(6) Comply with all conflict of interest provisions in WAC 246-305-030.

(7) Maintain and assign qualified expert reviewers in compliance with WAC 246-305-040.

(8) Conduct reviews, reach determinations and document determinations consistent with WAC 246-305-050 and 246-305-060.

(9) Maintain administrative processes and capabilities in compliance with WAC 246-305-070.

[Statutory Authority: RCW 43.70.235 and 48.43.535. WSR 11-23-124, § 246-305-020, filed 11/21/11, effective 11/26/11; WSR 01-08-023, § 246-305-020, filed 3/28/01, effective 4/28/01.]

WAC 246-305-030 Conflict of interest. (1) An IRO:

(a) Must not be a subsidiary of, or in any way owned or controlled by, a carrier or an association of health care providers or carriers;

(b) Shall provide information to the department on its own organizational affiliations and potential conflicts of interest at the time of application and when material changes occur;

(c) Shall immediately turn down a case referred by the insurance commissioner if accepting it would constitute an organizational conflict of interest; and

(d) Shall ensure that reviewers are free from any actual or potential conflict of interest in assigned cases.

(2) An IRO, as well as its reviewers, must not have any material familial, professional, or financial affiliation, as defined in WAC 246-305-010, with the health carrier, enrollee, enrollee's provider, that provider's medical or practice group, the facility at which the service would be provided, or the developer or manufacturer of a drug or device under review. An affiliation with any director, officer or executive of an IRO must be considered to be an affiliation with the IRO.

(3) The following do not constitute violations of this section:

(a) Staff affiliation with an academic medical center or National Cancer Institute-designated clinical cancer research center;

(b) Staff privileges at a health care facility;

(c) Maintaining a provider contract with a carrier which provides no more than five percent of the provider's or clinical group's annual revenue; or

(d) An IRO's receipt of a carrier's payment for independent reviews assigned by the insurance commissioner under RCW 48.43.535.

(4) Notwithstanding the provisions of subsection (3) of this section, a potential reviewer must be considered to have a conflict of interest with regard to a facility or health plan, regardless of revenue from that source, if the potential reviewer is a member of a standing committee of: The facility, the health plan, or a provider network that contracts with the health plan.

(5) A conflict of interest may be waived only if both the enrollee and the health plan agree in writing after receiving full disclosure of the conflict, and only if:

(a) The conflict involves a reviewer, and no alternate reviewer with necessary special expertise is available; or

(b) The conflict involves an IRO and the insurance commissioner determines that seeking a waiver of conflict is preferable to reassigning the review to a different IRO.

[Statutory Authority: RCW 43.70.235 and 48.43.535. WSR 11-23-124, § 246-305-030, filed 11/21/11, effective 11/26/11; WSR 01-08-023, § 246-305-030, filed 3/28/01, effective 4/28/01.]

WAC 246-305-040 Expert reviewers. (1) Each IRO shall maintain an adequate number and range of qualified expert reviewers in order to:

(a) Make determinations regarding the full range of independent review cases occurring in Washington state under RCW 48.43.535; and

(b) Meet timelines specified in WAC 246-305-050(3) including those for expedited review.

(2) All reviewers must be health care providers with the exception of contract specialists.

(3) IROs shall maintain policies and practices that assure that all clinical reviewers:

(a) Hold a current, unrestricted license, certification, or registration in Washington state, or current, unrestricted credentials from another state with substantially comparable requirements, as determined by the department and outlined in the May 2011 edition of the department of health publication, *Health Care Professional Credentialing Requirements*;

(b) Have at least five years of recent clinical experience;

(c) Are board-certified in the case of a medical doctor, a doctor of osteopathy, a podiatrist, or a member of another profession in which board certification exists as determined by the department of health; and

(d) Have the ability to apply scientific standards of evidence in judging research literature pertinent to review issues, as demonstrated through relevant training or professional experience.

(4) Contract specialists must be knowledgeable in health insurance contract law, as evidenced by training and experience, but do not need to be an attorney or have any state credential.

(5) Assignment of appropriate reviewers to a case.

(a) An IRO shall assign one or more expert reviewer to each case, as necessary to meet requirements of this subsection.

(b) Any reviewer assigned to a case shall comply with the conflict of interest provisions in WAC 246-305-030.

(c) The IRO shall assign one or more clinical reviewers to each case. All clinical reviewers assigned to a case shall each meet the following requirements:

(i) A clinical peer as defined in WAC 246-305-010(6);

(ii) An expert in the treatment of the enrollee's medical condition that is the subject of the external review;

(iii) Knowledgeable about the recommended health care service or treatment through five years of recent or current actual clinical experience treating patients with the same or similar medical condition of the enrollee. Exceptions may be made to this requirement in unusual situations when the only experts available for a highly specialized review are in academic or research life and do not meet the clinical experience requirement; and

(iv) Have the ability to evaluate alternatives to the proposed treatment.

(d) If contract interpretation issues must be addressed, a contract specialist must be assigned to the review.

(e) Each IRO shall have a policy specifying the number and qualifications of reviewers to be assigned to each case. The number of expert reviewers should be dictated by what it takes to meet the requirements of this subsection.

(i) The number of expert reviewers should reflect the complexity of the case, the goal of avoiding unnecessary cost, and the need to avoid tie votes.

(ii) The IRO may consider, but shall not be bound by, recommendations regarding complexity from the carrier or attending provider.

(iii) Special attention should be given to situations such as review of experimental and investigational treatments that may benefit from an expanded panel.

[Statutory Authority: RCW 43.70.235 and 48.43.535. WSR 11-23-124, § 246-305-040, filed 11/21/11, effective 11/26/11; WSR 01-08-023, § 246-305-040, filed 3/28/01, effective 4/28/01.]

WAC 246-305-050 Independent review process. (1) Information for review.

(a) IROs shall, as necessary, request, accept, and consider the following information as relevant to a case:

(i) Information that the carrier is required to submit to the IRO under WAC 284-43-630, including information identified in that section that is initially missing or incomplete as submitted by the carrier.

(ii) Other medical, scientific, and cost-effectiveness evidence which is relevant to the case. For the purposes of this section, medical, scientific, and cost-effectiveness evidence has the meaning defined in WAC 246-305-010.

(b) After referral of a case, an IRO shall accept additional information from the enrollee, the carrier, or a provider acting on behalf of the enrollee or at the enrollee's request, provided the information is submitted within five business days of the referral or, in the case of an expedited referral, within twenty-four hours. The additional information must be related to the case and relevant to statutory criteria.

(c) The IRO shall forward this information to the carrier within one business day of receipt of the information.

(2) Completion of reviews. Once the insurance commissioner or designee refers a review, the IRO shall proceed to final determination unless requested otherwise by both the

carrier and the enrollee or the carrier notifies the IRO it has reversed its adverse benefit determination.

(3) Time frames for reviews.

(a) An IRO shall make its determination within the following time limits:

(i) If the review is not expedited, within fifteen days after receiving necessary information, or within twenty days after receiving the referral, whichever is earlier. In exceptional circumstances where information is incomplete, the determination may be delayed until no later than twenty-five days after receiving the referral.

(ii) If the review is expedited, as defined in WAC 284-43-540, within seventy-two hours after receiving the referral. If information on whether a referral is expedited is not provided to the IRO, the IRO may presume that it is not an expedited review, but the IRO has the option to seek clarification from the insurance commissioner or designee.

(b) An IRO shall provide notice to enrollees and the carrier of the result and basis for the determination, consistent with subsection (5) of this section, within two business days of making a determination in regular cases and immediately in expedited cases.

(c) As used in this subsection, a day is a calendar day, except that if the period ends on a weekend or an official Washington state holiday, the time limit is extended to the next business day. A business day is any day other than Saturday, Sunday or an official Washington state holiday.

(4) Decision-making procedures.

(a) The independent review process is intended to be neutral and independent of influence by any affected party or by state government. The department may conduct investigations under the provisions of this chapter but the department has no involvement in the disposition of specific cases.

(b) Independent review is a paper review process. These rules do not establish a right to in-person participation or attendance by the enrollee, the health plan, or the attending provider nor to reconsideration of IRO determinations.

(c) An IRO shall present cases to reviewers in a way that maximizes the likelihood of a clear, unambiguous determination. This may involve stating or restating the questions for review in a clear and precise manner that encourages yes or no answers.

(d) If more than one reviewer is used, the IRO shall:

(i) Provide an opportunity for the reviewers to exchange ideas and opinions about the case with one another, if requested by a reviewer. This must be done in a manner that avoids pressure on reviewers to take a position with which they do not agree and preserves a dissenting reviewer's opportunity to document the rationale for dissent in the case file.

(ii) Accept the majority decision of the clinical reviewers in determining clinical issues.

(e) When a case requires an interpretation regarding the application of health plan coverage provisions, that determination must be made by a reviewer or reviewers who are qualified as contract specialists.

(f) An IRO may uphold an adverse benefit determination if the patient or any provider refuses to provide relevant medical records that are available and have been requested with reasonable opportunity to respond. An IRO may overturn an adverse benefit determination if the carrier refuses to provide relevant medical records that are available and have been requested with reasonable opportunity to respond.

(g) If reviewers are deadlocked, the IRO may add another reviewer if time allows.

(h) If all pertinent information has been disclosed and reviewers are unable to make a determination, the IRO shall decide in favor of the enrollee.

(5) Notification and documentation of determinations. An IRO shall notify the enrollee and the carrier of the result and rationale for the determination, including its clinical basis unless the decision is wholly based on application of coverage provisions, within the time frame in subsection (3)(b) of this section.

(a) Documentation of the basis for the determination shall include references to supporting evidence, and if applicable, the rationale for any interpretation regarding the application of health plan coverage provisions.

(b) If the determination overrides the health plan's medical necessity or appropriateness standards, the rationale shall document why the health plan's standards are unreasonable or inconsistent with sound, evidence-based medical practice.

(c) The written report shall include the qualifications of reviewers but shall not disclose the identity of the reviewers.

(d) Notification of the determination must be provided initially by telephone, e-mail, or facsimile, followed by a written report by mail. In the case of expedited reviews the initial notification must be immediate and by telephone.

[Statutory Authority: RCW 43.70.235 and 48.43.535. WSR 11-23-124, § 246-305-050, filed 11/21/11, effective 11/26/11; WSR 01-08-023, § 246-305-050, filed 3/28/01, effective 4/28/01.]

WAC 246-305-051 Additional requirements for experimental or investigational treatment reviews. (1) In addition to the qualifications listed in WAC 246-305-040 (3) and (5), at least part of the clinical reviewers' relevant, recent clinical experience must have been obtained in the past three years.

(2) Each clinical reviewer shall consider the following information, if appropriate and available, in reaching an opinion:

(a) The enrollee's pertinent medical records;

(b) The attending physician or health care provider's recommendation;

(c) Consulting reports from appropriate health care providers and other documents submitted by the carrier, enrollee, or enrollee's authorized representative, or the enrollee's treating physician or health care provider; and

(d) Whether:

(i) The terms of coverage under the enrollee's health benefit plan would have covered the treatment had the carrier not determined that the treatment was experimental or investigational;

(ii) The recommended or requested health care service or treatment has been approved by the federal Food and Drug Administration, if applicable, for the condition; or

(iii) Medical or scientific evidence or evidence-based standards demonstrate that the recommended or requested health care service or treatment is more likely than any available standard health care service or treatment to be beneficial to the enrollee and the adverse risks would not be substan-

tially increased over those of available standard health care services or treatments.

(3) Clinical reviewers shall include the following in their written opinions to the IRO:

(a) A description of the enrollee's medical condition;

(b) A description of the indicators relevant to determining whether there is sufficient evidence to demonstrate that the recommended or requested health care service or treatment is likely to be more beneficial to the enrollee than any available standard health care services or treatments and the adverse risks would not be substantially increased over those of available standard health care services or treatments;

(c) A description and analysis of any medical, scientific evidence, or cost-effectiveness evidence as defined in WAC 246-305-010(21);

(d) A description and analysis of any evidence-based standard as defined in WAC 246-305-010(12); and

(e) Information on whether the reviewer's rationale for the opinion is based on subsection (2)(e)(i) or (ii) of this section.

(4) IROs shall include the following in their notification of the results and rationale for the determination:

(a) A general description of the reason for the request for external review;

(b) The written opinion of each clinical reviewer, including whether the recommended or requested health care service or treatment should be covered and the rationale for each reviewer's recommendation;

(c) The date the review was requested;

(d) The date the review was conducted;

(e) The date of the IRO's decision;

(f) The principle reason or reasons for the IRO's decision; and

(g) The rationale for the IRO's decision.

[Statutory Authority: RCW 43.70.235 and 48.43.535. WSR 11-23-124, § 246-305-051, filed 11/21/11, effective 11/26/11.]

WAC 246-305-060 Criteria and considerations for independent review determinations. (1) General criteria and considerations.

(a) The determination must be consistent with the standards in RCW 43.70.235, 48.43.535, and chapter 246-305 WAC.

(b) The expert reviewers from a certified IRO will make determinations regarding the medical necessity or appropriateness of, and the application of health plan coverage provisions to, health care services for an enrollee.

(c) The IRO shall ensure that determinations are consistent with the scope of covered benefits as outlined in the medical coverage agreement.

(i) Clinical reviewers may override the health plan's medical necessity or appropriateness standards only if the standards are determined upon review to be unreasonable or inconsistent with sound, evidence-based medical practice, or experimental or investigational treatment protocols.

(ii) Reviewers may make determinations about the application of general health plan coverage provisions to specific issues concerning health care services for an enrollee. For example, whether a specific service is excluded by more general benefit exclusion language may require independent interpretation.

(2) Medical necessity and appropriateness - Criteria and considerations. Only clinical reviewers may determine whether a service, which is the subject of an adverse decision, is medically necessary and appropriate. These determinations must be based upon their expert clinical judgment, after consideration of relevant medical, scientific, and cost-effectiveness evidence, and medical standards of practice in Washington state.

(a) Medical standards of practice include the standards appropriately applied to physicians or other health care providers, as pertinent to the case.

(b) In considering medical standards of practice within Washington state:

(i) Clinical reviewers may use national standards of care, absent evidence presented by the health plan or enrollee that the Washington state standard of care is different.

(ii) A health care service or treatment should be considered part of the Washington state standard of practice if reviewers believe that failure to provide it would be inconsistent with that degree of care, skill and learning expected of a reasonably prudent health care provider acting in the same or similar circumstances.

(c) Medical necessity will be a factor in most cases referred to an IRO, but not necessarily in all. See WAC 246-305-060(3).

(3) Health plan coverage provisions - Criteria and considerations. The following requirements must be observed when a review requires making determinations about the application of health plan coverage provisions to issues concerning health care services for an enrollee.

(a) These determinations must be made by one or more contract specialists meeting the requirements of WAC 246-305-040(4), except that a clinical determination of medical necessity or appropriateness, by itself, is not an interpretation of the scope of covered benefits and does not require a contract specialist.

(b) If the full health plan coverage agreement has not already been provided by the carrier under WAC 284-43-630 (2)(f) of the insurance commissioner, the IRO shall request additional provisions from the health plan coverage agreement in effect during the relevant period of the enrollee's coverage, as necessary to have an adequate context for determinations.

(c) In general, the IRO and its contract specialists may assume that the contractual health plan coverage provisions themselves are consistent with the Washington Insurance Code (Title 48 RCW), absent information to the contrary. Primary responsibility for determining consistency with the insurance code, when at issue, rests with the insurance commissioner.

(4) No provision of this chapter should be interpreted to establish a standard of medical care, or to create or eliminate any cause of action.

[Statutory Authority: RCW 43.70.235 and 48.43.535. WSR 11-23-124, § 246-305-060, filed 11/21/11, effective 11/26/11; WSR 01-08-023, § 246-305-060, filed 3/28/01, effective 4/28/01.]

WAC 246-305-070 Administrative processes and capabilities of IROs. (1) An IRO shall maintain written policies and procedures covering all aspects of review.

(2) An IRO shall ensure the confidentiality of medical records and other personal health information received for use in independent reviews, in accordance with applicable federal and state laws.

(3) An IRO shall have a quality assurance program that ensures the timeliness, quality of review, and communication of determinations to enrollees and carriers. The quality assurance program must ensure the qualifications, impartiality, and freedom from conflict of interest of the organization, its staff, and expert reviewers.

(a) The quality assurance program must include a written plan addressing scope and objectives, program organization, monitoring and oversight mechanisms, and evaluation and organizational improvement of IRO activities.

(b) Quality of reviews includes use of appropriate methods to match the case, confidentiality, and systematic evaluation of complaints for patterns or trends. Complaints must be recorded on a log, including the nature of the complaint and the resolution. The department reserves the right to examine both the complaints and the log.

(c) Organizational improvement efforts must include the implementation of action plans to improve or correct identified problems, and communication of the results of action plans to staff and reviewers.

(4) An IRO shall maintain case logs and case files with full documentation of referrals, reviewers, questions posed, information considered (including sources of the information and citations of studies or criteria), determinations and their rationale, communication with parties in the dispute including notices given, and key dates in the process, for at least three years following the review.

(5) An IRO shall maintain a training program for staff and expert reviewers, addressing at least:

(a) Confidentiality;

(b) Neutrality and conflict of interest;

(c) Appropriate conduct of reviews;

(d) Documentation of evidence for determination; and

(e) In the case of contract specialists, principles of health contract law and any provisions of Washington state law determined to be essential.

(6) An IRO shall maintain business hours, methods of contact (including by telephone), procedures for after-hours requests, and other relevant procedures to ensure timely availability to conduct expedited as well as regular reviews.

(7) An IRO shall not disclose reviewers' identities. The department will not require reviewers' identities as part of the certification application process, but may examine identified information about reviewers as part of enforcement activities.

(8) An IRO shall promptly report any attempt at interference by any party, including a state agency, to the department.

(9) An IRO shall have a medical director who holds a current unrestricted license as a medical doctor or osteopathic physician and has had experience in direct patient care. The medical director shall provide guidance for clinical aspects of the independent review process and oversee the IRO's quality assurance and credentialing programs.

[Statutory Authority: RCW 43.70.235 and 48.43.535. WSR 11-23-124, § 246-305-070, filed 11/21/11, effective 11/26/11; WSR 01-08-023, § 246-305-070, filed 3/28/01, effective 4/28/01.]

WAC 246-305-080 Application for certification as an IRO. (1) To be certified as an IRO under this chapter, an organization shall submit to the department an application on the form required by the department. The application must include:

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

(b) The name of any holder of bonds or notes of the applicant that exceed one hundred thousand dollars;

(c) 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;

(d) The name and a biographical sketch of each director, officer, and executive of the applicant and any entity listed under (c) of this subsection and a description of any relationship the named individual has with:

(i) A carrier;

(ii) A utilization review agent;

(iii) A nonprofit or for-profit health corporation;

(iv) A health care provider;

(v) A drug or device manufacturer; or

(vi) A group representing any of the entities described by (d)(i) through (v) of this subsection;

(e) The percentage of the applicant's revenues that the applicant anticipates will be derived from reviews conducted under RCW 48.43.535;

(f) A description of the areas of expertise of the health care professionals and contract specialists making review determinations for the applicant, as well as the IRO's policies and standards addressing qualifications, training, and assignment of all types of reviewers;

(g) The procedures that the IRO will use in making review determinations regarding reviews conducted under RCW 48.43.535;

(h) Attestations that all requirements will be met;

(i) Evidence of current accreditation from a nationally recognized private accrediting organization acceptable to the federal Department of Health and Human Services or Department of Labor for the federal external review process.

(i) Applicants shall authorize release of information from primary sources, including full reports of site visits, inspections, and audits;

(ii) The department may require the applicant to indicate which documents demonstrate compliance with specific Washington state certification requirements under this chapter.

(j) Other documentation, including, but not limited to, legal and financial information, policies and procedures, and data that are pertinent to requirements of this chapter; and

(k) Any other reasonable application requirements demonstrating ability to meet all requirements for certification in Washington state.

(2) Department investigation and verification activities regarding the applicant may include, but are not limited to:

(a) Review of application and filings for completeness and compliance with standards;

(b) On-site survey or examination;

(c) Primary-source verification with accreditation or regulatory bodies of compliance with requirements which are

used to demonstrate compliance with certain standards in this chapter;

(d) Other means of determining regulatory and accreditation histories; and

(e) Exercising any power of the department under WAC 246-305-100.

[Statutory Authority: RCW 43.70.235 and 48.43.535. WSR 11-23-124, § 246-305-080, filed 11/21/11, effective 11/26/11; WSR 01-08-023, § 246-305-080, filed 3/28/01, effective 4/28/01.]

WAC 246-305-090 Ongoing requirements for IROs. A certified IRO shall:

(1) Comply with the provisions of RCW 43.70.235, 48.43.535(5), and this chapter;

(2) Cooperate with the department during investigations;

(3) Provide the department with information requested in a prompt manner;

(4) Conduct annual self-assessments of compliance with Washington certification requirements;

(5) Submit an annual statistical report with the department on a form specified by the department summarizing reviews conducted. The report shall include, but may not be limited to, volumes, types of cases, compliance with timelines for expedited and nonexpedited cases, determinations, number and nature of complaints, and compliance with the conflict of interest requirements described in WAC 246-305-030.

(6) Submit updated information to the department if at any time there is a material change in the information included in the application.

[Statutory Authority: RCW 43.70.235 and 48.43.535. WSR 11-23-124, § 246-305-090, filed 11/21/11, effective 11/26/11; WSR 01-08-023, § 246-305-090, filed 3/28/01, effective 4/28/01.]

WAC 246-305-100 Powers of the department. (1) The department may deny, suspend, revoke, or modify certification of an IRO if the department has reason to believe the applicant, certified IRO, its agents, officers, directors, or any person with any interest in the IRO has failed or refused to comply with the requirements established under this chapter.

(2) The department may conduct an on-site review, audit, and examine records to investigate complaints alleging that an applicant, certified IRO, or reviewer committed any conduct described in WAC 246-305-110.

[Statutory Authority: RCW 43.70.235 and 48.43.535. WSR 11-23-124, § 246-305-100, filed 11/21/11, effective 11/26/11; WSR 01-08-023, § 246-305-100, filed 3/28/01, effective 4/28/01.]

WAC 246-305-110 Grounds for action against an applicant or a certified IRO. (1) The department may deny an application for certification, or suspend, revoke, or modify certification if the applicant, certified IRO, its agents, officers, directors, or any person with any interest:

(a) Knowingly or with reason to know makes a misrepresentation of, false statement of, or fails to disclose, a material fact to the department. This applies to any data attached to any record requested or required by the department or matter under investigation or in a self-assessment;

(b) Obtains or attempts to obtain certification by fraudulent means or misrepresentation;

(c) Fails or refuses to comply with the requirements of RCW 43.70.235, 48.43.535(5), or this chapter;

(d) Conducts business or advertising in a misleading or fraudulent manner;

(e) Refuses to allow the department access to records, or fails to promptly produce for inspection any book, record, document, or item requested by the department, or willfully interferes with an investigation;

(f) Accepts referral of cases from the insurance commissioner under RCW 48.43.535 without certification, or with certification which has been terminated, or is subject to sanction;

(g) Was the holder of a license, certification, or contract issued by the department or by any competent authority in any state, federal, or foreign jurisdiction that was terminated for cause and never reissued, or sanctioned for cause and the terms of the sanction have not been fulfilled;

(h) Had accreditation from a recognized national or state IRO accrediting body that was terminated for cause and never reissued, or sanctioned for cause and the terms of the sanction have not been fulfilled;

(i) Willfully prevents, interferes with, or attempts to impede in any way the work of any representative of the department and the lawful enforcement of any provision of this chapter. This includes, but is not limited to: Willful misrepresentation of facts during an investigation, or administrative proceeding, or any other legal action; or use of threats or harassment against any patient, client, customer, or witness; or use of financial inducements to any patient, client, customer, or witness to prevent or attempt to prevent him or her from providing evidence during an investigation, in an administrative proceeding, or any other legal action involving the department;

(j) Willfully prevents or interferes with any department representative in the preservation of evidence;

(k) Misrepresented or was fraudulent in any aspect of the conduct of business;

(l) Within the last five years, has been found in a civil or criminal proceeding to have committed any act that reasonably relates to the person's fitness to establish, maintain, or administer an IRO;

(m) Violates any state or federal statute, or administrative rule regulating the IRO;

(n) Fails to comply with an order issued by the secretary of the department of health or designee;

(o) Uses interference, coercion, discrimination, reprisal, or retaliation against a patient, client, or customer exercising his or her rights;

(p) Offers, gives, or promises anything of value or benefit to any federal, state, or local employee or official for the purpose of influencing that employee or official to circumvent federal, state, or local laws, regulations, or ordinances governing the certification holder or applicant;

(2) A person, including, but not limited to, enrollees, carriers, and providers, may submit a written complaint to the department alleging that a certified IRO committed conduct described in this section.

(3) An applicant or certified IRO may contest a department decision or action according to the provisions of RCW 43.70.115, chapter 34.05 RCW, and chapter 246-10 WAC.

[Statutory Authority: RCW 43.70.235 and 48.43.535. WSR 11-23-124, § 246-305-110, filed 11/21/11, effective 11/26/11; WSR 01-08-023, § 246-305-110, filed 3/28/01, effective 4/28/01.]

WAC 246-305-990 Maximum fee schedule. This section sets the maximum fee schedule for independent reviews, and the process of review and determination of a case referred to an independent review organization (IRO).

(1) IROs may not charge more than the following amount for each review:

Category	Amount
Contract review, interpretation of health plan coverage provisions	$600
Standard medical review, straightforward review of medical necessity or adverse determination	$700
Highly specialized medical review of complex conditions or experimental or investigational treatment	$1000
Medical review with multiple reviewers	$1100
Surcharge for expedited review	$200

The fees in this section include all costs for time and materials associated with the review including, but not limited to:

(a) Record transmission expenses such as postage and facsimile costs; and

(b) Medical record handling and duplication.

(2) If the IRO and the health care plan agree in advance that the referral includes both a contract review and a medical review, the IRO may charge both fees.

(3) If an IRO charges more than the maximum fees allowed under this section, the department may take action as described in WAC 246-305-110.

[Statutory Authority: RCW 43.70.235 and 48.43.535. WSR 11-23-124, § 246-305-990, filed 11/21/11, effective 11/26/11. Statutory Authority: 2005 c 54. WSR 05-24-029, § 246-305-990, filed 11/30/05, effective 12/31/05.]