The article heading of 3 AAC 23, Article 6, is changed:

**Article 6. License Renewal [GENERAL PROVISIONS].**

3 AAC 23 is amended by adding new sections to read:

**Article 7. Pharmacy Benefits Managers: Grievances and Appeals.**

**Section**



(((Publisher: Please keep 3 AAC 23.860 in Article 6 and assign 3 AAC 23.999 to new Article 8. Repealed 3 AAC 23.900 stays in Article 7 amidst the new sections.)))

**3 AAC 23.870. Grievance reporting; recordkeeping requirements.** (a) A pharmacy benefits manager shall maintain a written register for each grievance received in a calendar year. The register must be maintained in a manner that is reasonably clear and accessible to the director and must document the

(1) reason for the grievance, including a general description of the grievance and the name of the prescription drug;

(2) date the pharmacy benefits manager received the grievance;

(3) date of the grievance review;

(4) resolution of the grievance;

(5) date of the grievance resolution;

(6) name of the covered person for whom the grievance was filed;

(7) name of the covered person's health insurance company;

(8) name of the pharmacy who filed the grievance;

(9) pharmacy benefits manager's review of the grievance;

(10) notice or claim associated with the grievance;

(11) request for a review of a grievance involving an adverse pricing adjustment or claim denial, other than a denial of coverage under a patient's health plan; and

(12) evidence sufficient to establish compliance with this section.

(b) A pharmacy benefits manager, or the insurance company the pharmacy benefits manager performs services for under contract, shall make the register maintained under (a) of this section available to the following upon request:

(1) the pharmacy that filed the grievance;

(2) the director;

(3) an applicable federal oversight agency.

(c) A pharmacy benefits manager shall retain a calendar year register for six years or until the director adopts a final report of an examination that contains a review of the register for that calendar year, whichever is longer.

(d) A pharmacy benefits manager shall submit a calendar year annual report to the director, in a format approved by the director. The report must include, for each pharmacy benefits manager and for each insurance company the pharmacy benefits manager performs services for under contract,

(1) a certificate of compliance stating that the pharmacy benefits manager has established and maintains grievance procedures that comply with this section and 3 AAC 23.875;

(2) the number of covered lives in the state;

(3) the total number of grievances the pharmacy benefits manager received;

(4) the number of grievances resolved and the resolution of each resolved grievance;

(5) the number of grievances that were appealed to the director and of which the pharmacy benefits manager is aware;

(6) the number of grievances that were referred to alternative dispute resolution procedures or that resulted in litigation; and

(7) a synopsis of actions being taken by the pharmacy benefits manager to correct a problem identified by the pharmacy benefits manager or the division during a grievance. (Eff. ____/____/_____, Register _____)

**Authority:** AS 21.06.090 AS 21.27.953

**3 AAC 23.875. Review of a pharmacy benefits manager grievance.** (a) A pharmacy benefits manager shall make a description of the pharmacy benefits manager's grievance procedures and other grievance procedure documentation electronically available to a pharmacy and the division. The pharmacy benefits manager's description and other grievance procedure documentation must include a statement of a pharmacy's right to file a grievance and the pharmacy's option to contact the director for assistance at any time. The statement must include the division's current mailing address, electronic mail address, and telephone number.

(b) A pharmacy may file a grievance with a pharmacy benefits manager related to an adverse pricing adjustment or claim denial not later than 90 days after the pharmacy receives notice of the adjustment or denial.

(c) Upon receipt of a grievance filed under (b) of this section, a pharmacy benefits manager shall provide contact information for the person whom the pharmacy benefits manager designates to coordinate the grievance review on behalf of the pharmacy benefits manager to the pharmacy that filed the grievance, including the designee's

(1) full name;

(2) mailing address;

(3) electronic mail address; and

(4) direct telephone number.

(d) For a grievance review conducted under this section, a pharmacy benefits manager shall ensure the independence and impartiality of each individual involved in making the review decision.

(e) A pharmacy benefits manager may not use the likelihood that an individual who is involved in making a grievance review decision will support the adverse pricing adjustment or

claim denial as the basis for a decision related to that individual's

(1) hiring;

(2) compensation;

(3) termination;

(4) promotion; or

(5) other similar matter.

(f) In an adverse pricing adjustment or claim denial, a pharmacy benefits manager shall designate a panel to review the adjustment or denial made up of appropriate pharmacists, claims analysts, or clinical peers of the same or similar specialty that would typically manage the type of dispute under review. The panel of experts shall analyze relevant data, including national and local drug pricing, acquisition cost, formulary placements, and drug availability as well as relevant policies, clinical guidelines, and data utilized in establishing pricing. A pharmacy benefits manager may not designate a person who was involved in the initial adverse pricing adjustment or claim denial to participate in the review of the grievance.

(g) If more than one clinical peer is designated under (f) of this section, a pharmacy benefits manager shall ensure that a majority of designated panel members are health care professionals who have appropriate expertise.

(h) In conducting a review under this section, a reviewer shall consider each comment, document, record, or other piece of information regarding the request for services submitted by a pharmacy without regard to whether the information was submitted or considered in making the initial adverse pricing adjustment or claim denial.

(i) During a review under this section, a pharmacy does not have the right to attend the review, but may

(1) submit written comments, documents, records, or other materials relating to the grievance for consideration during the review; and

(2) receive reasonable access to and copies of each document, record, or other piece of information relevant to the grievance from the pharmacy benefits manager upon request and free of charge; in this paragraph, "relevant" means a document, record, or other information that

(A) was relied upon in making the benefit or pricing determination; or

(B) was submitted, considered, or generated in the course of making the adverse pricing adjustment or claim denial, without regard to whether the document, record, or other information was relied upon in making the adjustment or denial.

(j) A pharmacy benefits manager shall issue a review decision and notify the pharmacy not later than 10 working days after the pharmacy benefits manager receives the grievance under (b) of this section.

(k) The time period within which a pharmacy benefits manager is required to issue a review decision and provide notice under (j) of this section begins on the date when the pharmacy benefits manager receives the grievance. The time period begins to run regardless of whether complete information necessary to make the determination accompanies the filing.

(*l*) Before issuing a review decision under (j) of this section, a pharmacy benefits manager shall provide new or additional evidence relied upon in connection with the grievance free of charge to the pharmacy. The pharmacy benefits manager shall provide the new or additional evidence to the pharmacy sufficiently in advance of the decision deadline to permit the pharmacy a reasonable opportunity to respond to the new or additional evidence before that date.

(m) Before issuing a final pricing adjustment or claim denial under (j) of this section that is based on a new or additional rationale, a pharmacy benefits manager shall provide the new or additional rationale to the pharmacy free of charge and as soon as possible. The pharmacy benefits manager shall provide the new or additional rationale to the pharmacy sufficiently in advance of the final adjustment or denial decision deadline to permit a pharmacy a reasonable opportunity to respond before that date.

(n) Notice of a decision issued under (j) of this section must be written so that a person with average knowledge of the subject matter clearly understands the information and must include

(1) the name, title, and qualifying credentials of each person who participated as a reviewer in the review process;

(2) sufficient information to identify the adverse pricing adjustment or claim denial related to the subject of the grievance;

(3) a statement of the reviewers' understanding of the grievance;

(4) the reviewers' decision, including clear terms and a sufficiently detailed explanation for a pharmacy to respond further to the pharmacy benefits manager's position;

(5) a reference to the evidence or documentation used as the basis for the decision;

(6) for a decision issued under this subsection that upholds the adverse pricing adjustment or claim denial,

(A) the specific reason for upholding the adverse pricing adjustment or claim denial and the information the reviewers relied upon for the final adjustment or denial, including a

(i) denial code and the code's corresponding meaning, if applicable; in this sub-subparagraph, "denial code" means a health care insurer specific identifier indicating the reason why a claim is being denied; and

(ii) description of the standard the pharmacy benefits manager used in reaching the denial;

(B) a reference to the specific contract provisions upon which the determination was based;

(C) a statement that the pharmacy is entitled to receive reasonable access to and copies of each document, record, or other piece of information relevant to the adverse pricing adjustment or claim denial upon request and free of charge; in this subparagraph, "relevant" has the meaning given in (i)(2) of this section;

(D) for a decision based upon an internal rule, guideline, protocol, or other similar criterion,

(i) the specific rule, guideline, protocol, or other similar criterion; or

(ii) a statement that a copy of the rule, guideline, protocol, or other similar criterion was relied upon to make the final pricing adjustment or claim denial and that a copy of the rule, guideline, protocol, or other similar criterion will be provided free of charge to the pharmacy;

(E) if applicable, instructions for requesting a copy of the rule, guideline, protocol, or other similar criterion relied upon in making the final pricing adjustment or claim denial under (D) of this paragraph; and

(F) a statement describing the procedure for a pharmacy to obtain an

independent review of the adverse pricing adjustment or claim denial under 3 AAC 23.880 - 3 AAC 23.935; and

(G) a statement of a pharmacy's right to contact the director's office for assistance with respect to a claim, grievance, or appeal at any time; the statement must include the division's current mailing address, electronic mail address, and telephone number. (Eff. ____/____/_____, Register _____)

**Authority:** AS 21.06.090 AS 21.27.953

**3 AAC 23.880. Appeal to the director for independent review.** (a) A pharmacy may file a request for an independent review of an adverse pricing adjustment or claim denial with the director not later than 90 days after the pharmacy receives notice of a final grievance determination.

(b) Not later than one working day after the director receives a request for an independent review, the director shall send written notice of the request to the pharmacy benefits manager.

(c) Not later than five working days after the pharmacy benefits manager receives notice of an independent review request under (b) of this section, the pharmacy benefits manager shall complete a preliminary review of the request to determine whether the final determination of the grievance is complete and eligible for independent review. If the pharmacy benefits manager determines that the request is complete and eligible for independent review, the pharmacy benefits manager shall notify the pharmacy and the director.

(d) If the pharmacy benefits manager determines that the request is not complete, the pharmacy benefits manager shall notify the pharmacy and the director that the request is not complete and identify what information or material is needed to complete the request.

(e) Notwithstanding a pharmacy benefits manager's initial determination that a request is not eligible for independent review, the director may determine under (c) of this section that the request is eligible and refer the request for independent review.

(f) Not later than three working days after the director receives notice of an initial determination under (c) of this section from a pharmacy benefits manager that a request is eligible for independent review, or upon a determination by the director that a request is eligible for independent review, the director will

(1) assign an independent review organization to conduct the independent review from the list of approved independent review organizations maintained under 3 AAC 23.915(c); the director will assign the independent review organization by rotation among approved independent review organizations that are qualified to conduct an independent review of the adverse pricing adjustment or claim denial decision based on the nature of that decision; when considering qualifications, the director also will review conflict-of-interest concerns;

(2) notify the pharmacy benefits manager

(A) that the director has determined under (e) of this section that the request is eligible for independent review and that an independent review organization has been assigned, and provide the name of the assigned independent review organization; or

(B) if the pharmacy benefits manager has determined under (c) of this section that the request is eligible for independent review, that an independent review organization has been assigned, and provide the name of the assigned independent review organization; and

(3) notify the pharmacy in writing

(A) that the request was determined to be eligible for independent review;

(B) that the request was accepted for independent review of the adverse pricing adjustment or claim denial;

(C) that an independent review organization has been assigned, and provide the name of the assigned independent review organization; and

(D) that the pharmacy may submit additional information or documents to the assigned independent review organization, which the independent review organization shall consider when conducting the independent review of the adverse pricing adjustment or claim denial, subject to the following requirements:

(i) the additional information or documents must be in writing;

(ii) the pharmacy must submit the additional information or documents not later than five working days after the pharmacy receives notice that an independent review organization has been assigned;

(iii) the assigned independent review organization may not accept or consider additional information or documents that a pharmacy submits later than five working days after the pharmacy received notice that an independent review organization has been assigned.

(g) Not later than three working days after the pharmacy benefits manager receives notice that an independent review organization has been assigned, a pharmacy benefits manager shall provide necessary information or documents that the pharmacy benefits manager considered in making the adverse pricing adjustment or claim denial to the assigned independent review organization. Except under (h) of this section, a pharmacy benefits manager's failure to timely provide the information or documents may not delay the assigned independent review

organization's review of the adverse pricing adjustment or claim denial.

(h) If a pharmacy benefits manager fails to provide the information or documents during the time specified under (g) of this section, an assigned independent review organization may terminate the independent review, reverse the pharmacy benefits manager's determination, and provide an appropriate adjustment to the reimbursement to the pharmacy or reverse the determination of the claim. Not more than one working day after making a decision, the assigned independent review organization shall notify the pharmacy, the pharmacy benefits manager, and the director of the assigned independent review organization's decision.

(i) An assigned independent review organization shall review the information and documents received from a pharmacy under (f)(3)(D) of this section or from a pharmacy benefits manager under (g) of this section. If the assigned independent review organization receives information or documents from the pharmacy, the assigned independent review organization shall forward the pharmacy's information or documents to the pharmacy benefits manager not later than one working day after the assigned independent review organization receives the information or documents from the pharmacy.

(j) After a pharmacy benefits manager receives information or documents forwarded by an assigned independent review organization under (i) of this section, the pharmacy benefits manager may reconsider the adverse pricing adjustment or claim denial that is under independent review. The pharmacy benefits manager's reconsideration of the adverse pricing adjustment or claim denial under review may not delay or terminate the independent review. The independent review will only be terminated if the pharmacy benefits manager reconsiders and decides to reverse the adverse pricing adjustment or claim denial under review. If the pharmacy is not satisfied with the resolution offered by the pharmacy benefits manager, the pharmacy may

decline the proposed resolution and continue with the independent review until a final decision is issued by the assigned independent review organization.

(k) Not more than one working day after a pharmacy benefits manager decides to reverse the adverse pricing adjustment or claim denial under review, the pharmacy benefits manager shall notify the pharmacy, the assigned independent review organization, and the director of the pharmacy benefits manager's decision in writing. The assigned independent review organization shall terminate the review of the adverse pricing adjustment or claim denial upon receipt of the pharmacy benefits manager's notice of the decision.

(*l*) In addition to the information or documents provided to an assigned independent review organization under (g) of this section, the assigned independent review organization shall consider the following during independent review, to the extent the information or documents are available and the assigned independent review organization considers the information or documents appropriate:

(1) the price list on the date of service;

(2) the availability of the drug in the state where the prescription was filled;

(3) whether the pharmacy benefits manager considered AS 21.27.945(b);

(4) actual acquisition cost verified by pharmacy invoices.

(m) Not later than 10 working days after an assigned independent review organization receives a request for an independent review of an adverse pricing adjustment or claim denial, the assigned independent review organization shall issue a decision to uphold or reverse the adverse pricing adjustment or claim denial and notify the pharmacy benefits manager, the pharmacy, and the director of the decision in writing. In reaching a decision, the assigned independent review organization is not bound by a decision or conclusion reached during the

pharmacy benefits manager's internal grievance processes. If the assigned independent review organization reverses the pharmacy benefits manager's determination regarding an adverse pricing adjustment or claim denial, the assigned independent review organization's decision must include

(1) the appropriate adjustment amount for reimbursement to the pharmacy, if the assigned independent review organization revises an adverse pricing adjustment;

(2) a general description of the reason that the pharmacy requested an appeal of the adverse price adjustment or claim denial;

(3) the date the independent review organization received the assignment from the director to conduct the appeal of the adverse price adjustment or claim denial;

(4) the date the assigned independent review organization conducted the appeal of the adverse price adjustment or claim denial;

(5) the date of the assigned independent review organization's decision;

(6) each principal reason and source document utilized for the assigned independent review organization's decision, including applicable pricing lists the assigned independent review organization relied on, if any;

(7) the rationale for the assigned independent review organization's decision; and

(8) the credentials and professional licenses held by each reviewer.

(n) After a pharmacy benefits manager receives notice of an assigned independent review organization's decision under (m) of this section that reverses the claim denial or revises the adverse pricing determination, the pharmacy benefits manager shall make an adjustment to the claim under independent review within one working day. (Eff. ____/____/_____, Register _____)

**Authority:** AS 21.06.090 AS 21.27.953

**3 AAC 23.885. Declining an independent review assignment.** Not later than one working day after an independent review organization receives an assignment to conduct an independent review under 3 AAC 23.880, the independent review organization shall determine whether the independent review organization is able to perform the independent review and advise the director if the independent review organization is unable to perform the review due to a conflict of interest or a lack of expertise or qualification for the particular subject matter of the review. (Eff. ____/____/_____, Register _____)

**Authority:** AS 21.06.090 AS 21.27.953

(((Publisher: Please retain the existing language that repeals 3 AAC 23.900 (definitions).)))

3 AAC 23 is amended by adding new sections to read:

**3 AAC 23.905. Binding nature of an independent review decision.** (a) An independent review decision is binding on a pharmacy benefits manager except to the extent the pharmacy benefits manager has other remedies available under applicable state law.

(b) An independent review decision is binding on the pharmacy except to the extent the pharmacy has other remedies under applicable federal or state law.

(c) A pharmacy may not file a subsequent request for independent review that involves the same adverse pricing adjustment or claim denial for which the pharmacy has already received an independent review decision. (Eff. ____/____/_____, Register _____)

**Authority:** AS 21.06.090 AS 21.27.953

**3 AAC 23.910. Term of initial biennial independent review organization registration period; renewal.** (a) Except as provided in (b) of this section, an initial biennial independent review organization registration period includes the rest of the calendar year in which the registration is issued and all of the following calendar year.

(b) If the director issues an initial biennial independent review organization registration on or after October 1, the registration period includes the rest of the calendar year in which the registration is issued and all of the following two calendar years.

(c) An independent review organization is responsible for knowing the date that the independent review organization's biennial registration period ends. The independent review organization shall submit a biennial independent review organization registration renewal application not later than 30 days before the next biennial registration period begins. (Eff. ____/____/_____, Register _____)

**Authority:** AS 21.06.090 AS 21.27.953

**3 AAC 23.915. Approval of independent review organizations; registration.** (a) The director may assign an independent review organization to conduct an independent review in the state of a pharmacy benefits manager if the independent review organization

(1) has an approved registration application on file with the director;

(2) is currently in good standing in the state;

(3) is accredited by a nationally recognized private accrediting agency that the director determines has independent review organization accreditation standards that are equivalent to or exceed the minimum qualifications for an independent review organization under 3 AAC 23.925; and

(4) meets the minimum qualifications under 3 AAC 23.925.

(b) Notwithstanding (a)(3) of this section, the director may approve an independent review organization that is not accredited by a nationally recognized private accrediting entity if there is no acceptable nationally recognized private accrediting entity that accredits independent review organizations for pharmacy benefits manager reviews.

(c) The director will maintain and periodically update a list of approved independent review organizations. The director will remove an independent review organization from the list if the director determines the independent review organization no longer satisfies the requirements established under this section.

(d) An independent review organization application must include

(1) an independent review organization application form prescribed by the director that includes the applicant's

(A) state of domicile;

(B) organization name;

(C) "doing business as" name;

(D) complete physical address, mailing address, electronic mail address, telephone number, and facsimile transmission number for the

(i) principal place of business in the applicant's state of domicile; and

(ii) principal place of business in this state;

(E) primary electronic mail address for communication with the division;

(F) Internet website address;

(G) federal employer identification number;

(H) contact information for use on the division's website, including the applicant's

(i) company name;

(ii) contact person for inquiries on independent review questions;

(iii) mailing address;

(iv) electronic mail address;

(v) telephone number; and

(vi) facsimile transmission number;

(I) signed attestation and certification that

(i) verifies that the information provided by the applicant is truthful and complete;

(ii) acknowledges that payment of fees associated with independent reviews conducted under 3 AAC 23.880 - 3 AAC 23.935 are the sole responsibility of the pharmacy benefits manager;

(iii) acknowledges that the applicant has no recourse against the division or the state to the extent that a pharmacy benefits manager fails to pay fees associated with the independent review process; and

(iv) authorizes the director to verify applicant information with a federal, state, or local government agency, insurance company, or accrediting organization; and

(J) ultimate controlling owner or holding company name and mailing address, if applicable; in this subparagraph, "ultimate controlling owner" has the meaning given "ultimate controlling person" in 3 AAC 21.195;

(2) a copy of the state business license (AS 43.70) issued to the applicant;

(3) a list of states in which the applicant is approved to conduct independent reviews, including the types of reviews performed;

(4) if applicable, a list of states that have

(A) denied approval for the applicant to conduct independent reviews; or

(B) revoked the applicant's approval to conduct independent reviews;

(5) evidence of accreditation received from a nationally recognized accrediting entity that meets the requirements under (a) or (b) of this section;

(6) a copy of the applicant's written policies and procedures that include evidence of

(A) meeting the qualifications under 3 AAC 23.925(a)(1); and

(B) ensuring adherence to the requirements under 3 AAC 23.880 - 3 AAC 23.935 by a contractor, subcontractor, agent, or employee affiliated with the independent review organization;

(7) a list of the reviewers retained by the independent review organization, with a description of each reviewer's area of expertise and the types of cases each reviewer is qualified to review;

(8) the name, title, electronic mail address, and direct telephone number of the physician, pharmacist, or other health care provider responsible for the supervision and oversight of the independent review procedure; and

(9) a description of the fees to be charged to a pharmacy benefits manager by the independent review organization for independent reviews.

(e) The director may retain an outside expert to perform reviews of applications submitted under this section. (Eff. ____/____/_____, Register _____)

**Authority:** AS 21.06.090 AS 21.27.953

**3 AAC 23.920. Examination; suspension or revocation of registration.** (a) The director may examine an independent review organization's affairs, transactions, accounts, records, and documents to determine compliance with 3 AAC 23.880 - 3 AAC 23.935. The director may suspend or revoke an independent review organization registration after a hearing, for failure to meet the requirements under 3 AAC 23.915(a).

(b) The director may modify, rescind, or reverse a suspension issued under this section. An independent review organization's registration may be suspended

(1) for a fixed period of time as determined by the director; or

(2) until the independent review organization completes a remedial action that the director determines necessary to reinstate the independent review organization's registration.

(c) The director will not assign an independent review in the state to an independent review organization that is subject to a period of suspension under this section. The independent review organization may continue to conduct an independent review assigned before the suspension if the director determines that it is in the best interest of the public for the independent review organization to complete the assignment. (Eff. ____/____/_____, Register _____)

**Authority:** AS 21.06.090 AS 21.06.180 AS 21.27.953

**3 AAC 23.925. Minimum qualification for independent review organizations.** (a) An

independent review organization is eligible to conduct independent reviews under 3 AAC 23.880 - 3 AAC 23.935 if the independent review organization has and maintains written policies and procedures that govern the independent review process. The policies and procedures must include

(1) a quality assurance mechanism to

(A) ensure that an independent review is not conducted later than a specified time frame and that required notice is provided in a timely manner;

(B) select qualified and impartial auditors or clinical reviewers as appropriate who are suitable for the specific case to conduct an independent review on behalf of the independent review organization;

(C) employ or contract with an adequate number of auditors or clinical reviewers to meet the objectives under (B) of this paragraph;

(D) maintain the confidentiality of administrative, financial, medical, and treatment records and clinical review criteria;

(E) establish and maintain written procedures to ensure that the independent review organization is unbiased, in addition to other procedures required under this section; and

(F) ensure that a person employed by or under contract with the independent review organization adheres to the requirements under 3 AAC 23.880 - 3 AAC 23.935;

(2) a toll-free telephone service to receive information related to independent reviews; the service must be capable of accepting, recording, or providing appropriate instruction to incoming telephone callers; and

(3) an agreement and a system to maintain required records and to provide the director with access to those records; the agreement must include a provision that the independent review organization shall reply in writing not later than five working days after reviewing a records inquiry from the director.

(b) A reviewer that is assigned to conduct an independent review by an independent review organization for an adverse price adjustment or claim denial that requires clinical judgment must be a physician, pharmacist, or other appropriate health care provider who

(1) is an expert in the treatment of the medical condition that is the subject of the independent review;

(2) is knowledgeable about the recommended or requested health care service or treatment through recent or current actual clinical experience treating patients with the same or similar medical condition;

(3) holds a nonrestricted license in this or another state; a physician must also hold a current certification by a nationally recognized medical specialty board in the area appropriate to the subject of the independent review; and

(4) does not have a history of disciplinary actions or sanctions taken or pending by a hospital, governmental agency or unit, or regulatory body that raises a substantial question as to the clinical reviewer's physical, mental, or professional competence or moral character, including loss of staff privileges or participation restrictions.

(c) An independent review organization may not own or control, be a subsidiary of, be owned or controlled by, or exercise control with

(1) a pharmacy benefits manager;

(2) a national, state, or local trade association of pharmacy benefits managers; or

(3) a national, state, or local trade association of health care providers.

(d) An independent review organization selected to conduct an independent review or a clinical reviewer assigned by the independent review organization to conduct an independent review may not have a material professional, familial, or financial conflict of interest with

(1) the pharmacy benefits manager that is the subject of the independent review;

(2) the covered person whose health care service or treatment is the subject of the independent review, or the covered person's authorized representative;

(3) an officer, director, or management employee of the pharmacy benefits manager that is the subject of the independent review;

(4) the pharmacy, health care professional, or health care professional's medical group or independent practice association that recommended the health care service or treatment that is the subject of the independent review;

(5) the facility at which the recommended health care service or treatment would be provided; or

(6) the developer or manufacturer of the principal drug, device, procedure, or other therapy recommended for the covered person whose health care service or treatment is the subject of the independent review.

(e) The director will determine whether an independent review organization or a clinical reviewer assigned by the independent review organization has a material professional, familial, or financial conflict of interest under (d) of this section that would prohibit selection of the independent review organization or the clinical reviewer assigned by the independent organization to conduct the independent review. If an independent review organization or a clinical reviewer assigned by the independent review organization has an apparent conflict of

interest as set out in (d) of this section, the director will consider the characteristics of that relationship or connection to determine that the apparent conflict of interest

(1) is of a material professional, familial, or financial nature that would prohibit selection of the independent review organization or the clinical reviewer assigned by the independent organization to conduct the independent review; or

(2) does not constitute a material professional, familial, or financial conflict of interest and would not prohibit selection of the independent review organization or the clinical reviewer assigned by the independent organization to conduct the independent review.

(f) An independent review organization is presumed to be in compliance with the requirements of this section if the organization is accredited by a nationally recognized private accrediting entity that meets the requirements of this section.

(g) The director will initially and periodically review the standards of each nationally recognized private accrediting entity that accredits independent review organizations to determine whether the accrediting entity's standards meet the requirements of this section. The director may make the determination based on a National Association of Insurance Commissioners review of the standards.

(h) A nationally recognized private accrediting entity shall provide the entity's current independent review organization accreditation standards to the director or to the National Association of Insurance Commissioners upon request for the director to determine if the accrediting entity's standards meet the requirements of this section. (Eff. ____/____/_____, Register _____)

**Authority:** AS 21.06.090 AS 21.27.953

**3 AAC 23.930. Funding of independent review.** A pharmacy benefits manager shall pay the cost of an independent review organization to conduct the independent review that is filed against the pharmacy benefits manager. (Eff. ____/____/_____, Register _____)

**Authority:** AS 21.06.090 AS 21.27.953

**3 AAC 23.935. Disclosure requirements.** (a) A pharmacy benefits manager shall include a description of the independent review procedures set out under 3 AAC 23.880 - 3 AAC 23.935 in each contract with a pharmacy and in each written denial. The description must include

(1) a statement of the pharmacy's right to file a request for an independent review of an adverse determination with the director; the statement must include the division's current mailing address, electronic mail address, and telephone number;

(2) a statement that the pharmacy must comply with P.L. 104-191 (Health Insurance Portability and Accountability Act) when filing a request for an independent review that involves clinical review of medical records or other protected health information about the covered person for the purpose of reaching a decision on the independent review;

(3) a brief description of the independent review process, including process timelines; and

(4) a statement of the pharmacy's right to provide additional information or otherwise participate in the independent review process as described in 3 AAC 23.880.

(b) In this section,

(1) "health information" means data or information, whether oral or recorded in any form or medium, and personal facts or information about events or relationships that relates to the following:

(A) the past, present, or future physical, mental, or behavioral health or condition of an individual or a member of the individual's family;

(B) the provision of health care services or treatments to an individual;

(C) payment for the provision of health care services or treatments to an individual;

(2) "protected health information" means health information

(A) that identifies an individual who is the subject of the information; or

(B) with respect to which there is a reasonable basis to believe that the information could be used to identify an individual. (Eff. ____/____/_____, Register _____)

**Authority:** AS 21.06.090 AS 21.27.953

**3 AAC 23.939. Definitions.** In 3 AAC 23.870 - 3 AAC 23.939, unless the context requires otherwise,

(1) "claim denial" includes the following whole or partial actions:

(A) an adverse claim determination related to formulary requirements;

(B) medication-prescribing limitations, restrictions, or substitutions that a pharmacy benefits manager directly establishes and implements;

(2) "director" means the director of insurance;

(3) "division" means the Division of Insurance;

(4) "grievance" includes the failure of an adverse pricing adjustment, claim denial, or other adverse determination to meet requirements under state law;

(5) "health care professional" means a physician or other health care practitioner

licensed, accredited, or certified to perform specified health care services consistent with state law;

(6) "health care services" means services for the diagnosis, prevention, treatment, cure, or relief of a health condition, illness, injury, or disease;

(7) "independent review organization" means an entity that conducts independent reviews of a pharmacy benefits manager's adverse pricing adjustment or claim denial;

(8) "pharmacy benefits manager" has the meaning given in AS 21.27.975;

(9) "working day" has the meaning given in AS 21.97.900. (Eff. ____/____/_____, Register _____)

**Authority:** AS 21.06.090 AS 21.27.953 AS 21.27.975