TITLE 760 DEPARTMENT OF INSURANCE

Proposed Rule
LSA Document #22-287

DIGEST

Adds 760 IAC 5 to implement IC 27-1-24.5 concerning pharmacy benefit managers, and to set forth provisions for licensure and financial requirements; application and renewal fees; pharmacy claims audits; maximum allowable cost pricing; annual reporting; penalties for violations. Effective 30 days after filing with the Publisher.

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

760 IAC 5

SECTION 1. 760 IAC 5 IS ADDED TO READ AS FOLLOWS:

ARTICLE 5. PHARMACY BENEFIT MANAGER STANDARDS

Rule 1. Definitions

760 IAC 5-1-1 Applicability

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5

Sec. 1. The definitions in this rule apply throughout this article.

(Department of Insurance; 760 IAC 5-1-1)

760 IAC 5-1-2 "Auditor" defined

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5

Sec. 2. "Auditor" means:
(1) a pharmacy benefit manager; or
(2) an independent auditor.

(Department of Insurance; 760 IAC 5-1-2)

760 IAC 5-1-3 "Commissioner" defined

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5

Sec. 3. "Commissioner" means the commissioner of the Indiana department of insurance.

(Department of Insurance; 760 IAC 5-1-3)

760 IAC 5-1-4 "Covered individual" defined

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-1

Sec. 4. "Covered individual" has the meaning set forth in IC 27-1-24.5-1.

(Department of Insurance; 760 IAC 5-1-4)

760 IAC 5-1-5 "Department" defined

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5

Sec. 5. "Department" means the Indiana department of insurance.

(Department of Insurance; 760 IAC 5-1-5)

760 IAC 5-1-6 "Health plan" defined

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-5

Sec. 6. "Health plan" has the meaning set forth in IC 27-1-24.5-5.

(Department of Insurance; 760 IAC 5-1-6)

760 IAC 5-1-7 "Independent auditor" defined

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5

Sec. 7. "Independent auditor" means a person other than a:
(1) covered individual;
(2) health plan;
(3) pharmacist;
(4) pharmacy;
(5) pharmacy benefit manager; or
(6) pharmacy services administrative organization;
that conducts an onsite or remote audit on behalf of a pharmacy benefit manager.

(Department of Insurance; 760 IAC 5-1-7)

760 IAC 5-1-8 "Maximum allowable cost" defined

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-7

Sec. 8. "Maximum allowable cost" has the meaning set forth in IC 27-1-24.5-7.

(Department of Insurance; 760 IAC 5-1-8)

760 IAC 5-1-9 "Pharmacist" defined

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-9

Sec. 9. "Pharmacist" has the meaning set forth in IC 27-1-24.5-9.

(Department of Insurance; 760 IAC 5-1-9)

760 IAC 5-1-10 "Pharmacy" defined

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-11

Sec. 10. "Pharmacy" has the meaning set forth in IC 27-1-24.5-11.

(Department of Insurance; 760 IAC 5-1-10)

760 IAC 5-1-11 "Pharmacy benefit manager" defined

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-12

Sec. 11. "Pharmacy benefit manager" has the meaning set forth in IC 27-1-24.5-12.

(Department of Insurance; 760 IAC 5-1-11)

760 IAC 5-1-12 "Pharmacy services administrative organization" defined

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-15

Sec. 12. "Pharmacy services administrative organization" has the meaning set forth in IC 27-1-24.5-15.

(Department of Insurance; 760 IAC 5-1-12)

760 IAC 5-1-13 "Remote audit" defined

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5

Sec. 13. "Remote audit" means a pharmacy audit conducted partially or completely offsite.

(Department of Insurance; 760 IAC 5-1-13)

Rule 2. Licensure Requirements

760 IAC 5-2-1 Application

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-18; IC 27-1-24.5-22; IC 27-1-25-11.1

Sec. 1. A person must, before establishing or operating as a pharmacy benefit manager, apply to and obtain a license from the commissioner. The pharmacy benefit manager must submit an application on a form prescribed by the commissioner. The application must include the following information:

(1) The name or names under which the applicant conducts business.
(2) A copy of the applicant's articles of incorporation or other business organization documents.
(3) The following contact information:
(A) The address of the principal place of business of the applicant.
(B) The mailing address of the applicant.
(C) The address of each office the applicant maintains in Indiana.
(D) The primary licensing phone number of the applicant.
(E) The primary licensing electronic mail address of the applicant.
(4) The applicant's taxpayer or employer identification number.
(5) A list by jurisdiction of the names under which the applicant has operated in the preceding five (5) years, including:
(A) alternative names;
(B) names of predecessors; and
(C) if known, successor business entities.
(6) A detailed explanation of adverse regulatory actions taken by a state or federal regulatory law enforcement or regulatory agency, or other reportable actions, against the applicant or an owner, a partner, an officer or a director of the applicant, or a member or manager of a limited liability company according to the following:
(A) Except as provided in clause (C), an adverse regulatory action means a:
(i) criminal conviction;
(ii) regulatory fine;
(iii) cease and desist order;

(iv) prohibition order; or
(v) suspension, probation, or revocation of a license or registration.
(B) Except as provided in clause (C), a reportable action means a:
(i) lawsuit or arbitration proceeding involving allegations of fraud, misappropriation or conversion of funds, misrepresentation, or breach of fiduciary duty;
(ii) military offense;
(iii) judgment rendered for overdue monies;
(iv) bankruptcy proceeding;
(v) delinquent tax obligation; or
(vi) termination of a contract or other business relationship with an insurance company for alleged misconduct.
(C) The applicant may exclude juvenile adjudications and the following misdemeanor convictions:
(i) Traffic citations.
(ii) Driving under the influence or driving while intoxicated.
(iii) Driving without a license.
(iv) Reckless driving.
(v) Driving with a suspended or revoked license.
(D) The explanation must summarize the details of each incident and explain why the applicant believes the incident should not prevent the applicant from receiving a pharmacy benefit manager license. The applicant must submit copies of all relevant documents related to each incident. Additionally, when an incident involves:
(i) a felony conviction involving dishonesty or breach of trust, the applicant must:
(AA) disclose whether application was made for written consent to engage in the business of insurance in the applicant's home state as required by 18 U.S.C. 1033;
(BB) disclose whether the consent was granted; and
(CC) if granted, attach a copy of the consent approved by the applicant's home state;
(ii) administrative proceedings, the applicant must provide:
(AA) a written statement identifying the type of license, all parties involved (including their percentage of ownership, if any), and explaining the circumstances of the incident;
(BB) a copy of the notice of hearing or other document that states the charges and allegations; and
(CC) a copy of the official document which demonstrates the resolution of the charges or a final judgment;
(iii) bankruptcy, the applicant must submit a statement summarizing the details of the indebtedness and arrangements for repayment; or
(iv) a delinquent tax obligation, the jurisdiction or jurisdictions must be disclosed.
(7) A list identifying the following and indicating percentage of ownership, if applicable:
(A) Stockholders holding ten percent (10%) or more of the voting securities.
(B) Investors holding a ten percent (10%) or greater interest.
(C) Partners.
(D) Corporate officers and directors.
(E) Trustees.
(F) If an association, all of the members.
(G) Affiliates, together with a chart showing the relationship of the applicant to all affiliates. An affiliate that is an insurance company shall be identified as such.
(8) National Association of Insurance Commissioners (NAIC) biographical affidavits, as described in IC 27-1-25-11.1(b)(3), of all of the following:
(A) Officers.
(B) Directors.
(C) Stockholders holding ten percent (10%) or more voting securities.
(D) Investors holding ten percent (10%) or greater interest.
(E) Partners.
(F) Trustees.
(G) Members, if an association.
(9) A statement describing the applicant's business plan, including the following information:
(A) Staffing levels and activities proposed in Indiana and nationwide.
(B) Details concerning the applicant's capability for providing a sufficient number of experienced and qualified personnel in the areas of pharmacy contracting, prescription drug benefit administration, pharmacy claims processing, prescription drug formulary development, prior authorization determination, prescription drug rebate administration, establishing pharmacy networks, and record keeping.

(C) A list of all health plans for whom the applicant provides pharmacy benefit management services in this state and the date the applicant began providing pharmacy benefit management services to each health plan. The list must include the NAIC number of any insurance companies.

(10) A copy of the written policies and procedures which demonstrate that the applicant has compliant processes established to adhere to both of the following:

(A) The appeals and dispute resolution process as required by IC 27-1-24.5-22.

(B) The requirements for maximum allowable cost pricing set forth in IC 27-1-24.5-22.

(11) A list of states in which the applicant is currently licensed or registered as a pharmacy benefit manager, identifying the applicant's resident or home state, if applicable.

(12) A list of states in which the applicant is currently engaged in business as a pharmacy benefit manager but is not required to be licensed or registered as a pharmacy benefit manager, identifying the applicant's resident or home state, if applicable.

(13) A list of states where the applicant is currently applying for a license or registering as a pharmacy benefit manager.

(14) Other information required by the commissioner to determine compliance with IC 27-1-24.5 or requirements of this article.

(Department of Insurance; 760 IAC 5-2-1)

760 IAC 5-2-2 Financial statement

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-20

Sec. 2. (a) An application for issuance of a license or renewal of a license must be accompanied by an applicant's current audited annual financial statements prepared by an independent certified public accountant in accordance with generally accepted accounting principles reflecting a positive net worth, and additional information determined by the commissioner to be necessary for a review of the current financial condition of the applicant to determine compliance with IC 27-1-24.5 or requirements of this rule. Financial information and proprietary information submitted by an applicant to the department is confidential under IC 27-1-24.5-20.

(b) An applicant for a license or renewal of a license may make written application to the commissioner for approval to file audited consolidated or combined financial statements instead of separate annual audited financial statements. If an applicant makes written application to the commissioner under this subsection, the statement must include a columnar consolidating or combining worksheet that includes the amounts shown on the consolidated audited financial statement, separately reported on the worksheet for each entity included on the statement, and an explanation of consolidating and eliminating entries.

(Department of Insurance; 760 IAC 5-2-2)

760 IAC 5-2-3 License application and renewal application fees

Authority: IC 27-1-24.5-20
Affected: IC 27-1-3-28

Sec. 3. (a) A license application submitted under section 1 of this rule must be accompanied by a fee of five hundred dollars ($500).

(b) A renewal application submitted under this rule must be accompanied by a fee of five hundred dollars ($500).

(c) License application fees and renewal fees shall be deposited in the department of insurance fund established by IC 27-1-3-28.

(Department of Insurance; 760 IAC 5-2-3)

760 IAC 5-2-4 Material changes in application as filed

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-20

Sec. 4. A pharmacy benefit manager must keep current the information required to be disclosed in its application by timely reporting all material changes to the department. If there is a material change in the information required by the application, the licensee must provide updated information to the department within sixty (60) days of the change.

(Department of Insurance; 760 IAC 5-2-4)

760 IAC 5-2-5 Denial of initial application

Authority: IC 27-1-24.5-20
Affected: IC 4-21.5

Sec. 5. If an initial application is denied under this section, the applicant may appeal the denial under the terms of the provisions of IC 4-21.5. A hearing of the appeal must be conducted within forty-five (45) days from the date the petition for hearing is filed with the commissioner.

(Department of Insurance; 760 IAC 5-2-5)

760 IAC 5-2-6 Renewal of license

Authority: IC 27-1-24.5-20
Affected: IC 4-21.5

Sec. 6. (a) A license obtained under this rule is valid for one (1) year.

(b) A pharmacy benefit manager must complete a renewal application on a form prescribed by the commissioner. The pharmacy benefit manager must identify any change in the information provided with the pharmacy benefit manager's initial application for licensure.

(c) A renewal application must be accompanied by the renewal fee set forth in section 3(b) of this rule.

(d) A renewal application, with supporting documentation, as outlined in section 2 of this rule, must be received by the commissioner on or before thirty (30) days prior to the anniversary of the effective date of the pharmacy benefit manager's most recent license.

(e) A pharmacy benefit manager license remains in effect unless revoked or suspended, as long as the renewal fee set forth in subsection (c) is paid, the renewal application is received in accordance with subsection (d), and the annual reporting requirements set forth in 760 IAC 5-5-1 are met by the due date.

(f) If a renewal application is denied under this section, the applicant or licensee may appeal the denial under the terms of the provisions of IC 4-21.5. A hearing of the appeal must be conducted within forty-five (45) days from the date the petition for hearing is filed with the commissioner.

(Department of Insurance; 760 IAC 5-2-6)

Rule 3. Pharmacy Claims Audits

760 IAC 5-3-1 Scope

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-22

Sec. 1. This rule does not apply to an audit that involves probable or potential fraud or willful misrepresentation by a pharmacy or pharmacist. This rule does not:

(1) preclude an entity from instituting an action for fraud against a pharmacy;
(2) apply to an audit of pharmacy records when fraud or other intentional and willful misrepresentation is evidenced by physical review, review of claims data or statements, or other investigative methods; or
(3) apply to a state agency that is conducting audits or a person that has contracted with a state agency to conduct audits of pharmacy records.

(Department of Insurance; 760 IAC 5-3-1)

760 IAC 5-3-2 Applicability

Authority: IC 27-1-24.5-20
Affected: IC 12-15; IC 12-17.6; IC 27-1-24.5-22

Sec. 2. (a) An auditor auditing a pharmacy or pharmacist under contract with a pharmacy benefit manager must conduct the onsite or remote audit in accordance with this section.

(b) This rule does not apply to a pharmacy benefit manager when administering pharmacy benefits under:
(1) the state Medicaid program under IC 12-15;
(2) the federal Medicare program (42 U.S.C. 1395 et seq.);
(3) the children's health insurance program established by IC 12-17.6; or
(4) worker's compensation insurance.

(c) Nothing in this rule is intended or shall be construed to be in conflict with existing relevant federal law.

(Department of Insurance; 760 IAC 5-3-2)

760 IAC 5-3-3 Limitations

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-22

Sec. 3. (a) A pharmacy benefit manager may cause an onsite or remote audit to occur at a particular pharmacy location not more than one (1) time per calendar year. However, if the audit results in a finding of material noncompliance at the pharmacy, the pharmacy benefit manager or auditor may return within the calendar year to determine ongoing compliance.

(b) An independent auditor that conducts an onsite or remote audit on behalf of a pharmacy benefit manager may conduct an audit at a particular pharmacy location not more than one (1) time per calendar year for each pharmacy benefit manager. However, if the audit results in a finding of material noncompliance at the pharmacy, the auditor may return within the calendar year to determine ongoing compliance.

(Department of Insurance; 760 IAC 5-3-3)

760 IAC 5-3-4 Conduct of audit

Authority: IC 27-1-24.5-20
Affected: IC 25-26; IC 27-1-24.5-22

Sec. 4. (a) The contract under which an onsite or remote audit is performed must provide a description of audit procedures that will be followed.

(b) An auditor conducting an onsite or remote audit must comply with all of the following:
(1) The auditor must perform the audit in accordance with contract terms.
(2) The auditor must provide written notice to the pharmacy or pharmacist at least fourteen (14) calendar days before conducting the initial audit for each audit cycle.

(3) The auditor must not interfere with the delivery of pharmacist services to a patient, and must use every effort to minimize inconvenience and disruption to pharmacy operations during the audit. This subdivision does not prohibit audits during normal business hours of the pharmacy.
(4) If the audit requires use of clinical or professional judgment, the audit must be conducted by or in consultation with an individual licensed as a pharmacist under IC 25-26.
(5) The auditor must allow the use of written or otherwise transmitted hospital, physician, or other health practitioner records to validate a pharmacy record.
(6) The auditor must perform the audit according to the same standards and parameters that the auditor uses to audit all other similarly situated pharmacies.
(7) The period covered by the audit must not exceed twenty-four (24) months after the date on which a claim that is the subject of the audit was submitted to or adjudicated by the pharmacy benefit manager, unless a longer period is required under federal or state law. The pharmacy must be permitted to resubmit electronically any claims disputed by the audit. Audit procedures must provide for a period of at least thirty (30) calendar days during which the pharmacy may resubmit a disputed claim.
(8) The auditor must not schedule an audit to begin during the first seven (7) calendar days of a month without the voluntary consent of the pharmacy. The consent may not be mandated by a contract or other means.
(9) Payment to the auditor for conducting the audit must not be based on a percentage of the amount recovered as a result of the audit.
(10) Within twenty-four (24) hours of receiving the notice of an audit, a pharmacy may reschedule the audit to a date not more than fourteen (14) calendar days after the date proposed by the auditor. However, if the auditor is unable to reschedule within the fourteen (14) calendar day period, the auditor must select and reschedule the audit for a date after the fourteen (14) calendar day period.
(11) The auditor must allow a pharmacy or pharmacist to produce documentation to address a discrepancy found during the audit.

(Department of Insurance; 760 IAC 5-3-4)

760 IAC 5-3-5 Written audit reports

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-22

Sec. 5. Following an onsite or remote audit, an auditor must provide to the pharmacy written audit reports as follows:
(1) Deliver the preliminary audit report to the pharmacy or pharmacist not later than ninety (90) calendar days after the audit is concluded, with reasonable extensions allowed.
(2) Provide with the preliminary audit report a written appeal procedure for the pharmacy to follow if the pharmacy desires to appeal a finding contained in the preliminary audit report. The written appeal procedure must provide for a period of at least thirty (30) calendar days after the pharmacy receives the preliminary audit report, during which the pharmacy may file an appeal of findings contained in the preliminary audit report.
(3) Deliver a final audit report to the pharmacy or pharmacist not later than one hundred twenty (120) calendar days after:
(A) the preliminary audit report is received by the pharmacy; or
(B) if an appeal is filed, a final appeal determination is made;
whichever is later.

(Department of Insurance; 760 IAC 5-3-5)

760 IAC 5-3-6 Clerical errors; fraud; recoupment of payment

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-22

Sec. 6. (a) A clerical or record keeping error, such as a typographical error, scrivener's error, or computer error related to or contained in a document that is necessary to the conduct of an audit, does not constitute fraud without proof of intent to commit fraud.

(b) If a clerical error is identified during the course of an audit, the pharmacy must be allowed to obtain a prescription that corrects the clerical error from the prescriber.

(c) A clerical or record keeping error may not result in the recoupment of payment if the patient has received the drug for which the claim was submitted.

(Department of Insurance; 760 IAC 5-3-6)

760 IAC 5-3-7 Overpayment and underpayment audit findings

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-22

Sec. 7. An audit finding of an overpayment or underpayment of a claim:
(1) must be based on an actual overpayment or underpayment of an audited claim discovered to include a recoverable error;
(2) must not be based on a projection that is based on the number of:
(A) patients who:
(i) have similar diagnoses; and
(ii) are served by the pharmacy; or
(B) prescriptions for or refills of similar prescription drugs that are dispensed by the pharmacy; and
(3) must not include dispensing fees unless a prescription was not actually dispensed, the prescriber denied authorization, the prescription dispensed was a medication error by the pharmacy, or the identified overpayment is solely based on an extra dispensing fee.

(Department of Insurance; 760 IAC 5-3-7)

760 IAC 5-3-8 Audit report; distribution; interest accrual

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-22

Sec. 8. (a) Before recoupment of funds may be made based on an audit finding of overpayment or underpayment:
(1) a final audit report must be distributed; and
(2) except when an audit finds that fraud, willful misrepresentation, or alleged serious abuse has occurred, at least thirty (30) calendar days must elapse after the date on which the final audit report is distributed before the recoupment of funds exceeding ten thousand dollars ($10,000).

(b) A pharmacy benefit manager must remit all monies due to a pharmacy or pharmacist as a result of an underpayment of a claim within thirty (30) calendar days after the final audit report has been delivered to the pharmacy or pharmacist.

(c) Interest on funds described in this section does not accrue during the audit and appeal period.

(Department of Insurance; 760 IAC 5-3-8)

760 IAC 5-3-9 Prohibition on use of extrapolation for calculating recoupments or penalties

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-22

Sec. 9. Extrapolation, probability sampling, or other means of projection may not be used by an auditor as a basis for calculating overpayment or underpayment recoupments or penalties. Finding that a claim was incorrectly presented or paid must be based on identified transactions.

(Department of Insurance; 760 IAC 5-3-9)

760 IAC 5-3-10 Internal appeals process

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-22

Sec. 10. (a) An auditor must establish an internal appeals process under which a pharmacy or pharmacist may appeal a disputed claim in a preliminary audit report.

(b) Under the internal appeals process, an auditor must allow a pharmacy or pharmacist to request an internal appeal within thirty (30) calendar days after receipt of a preliminary audit report, with reasonable extensions allowed.

(c) An auditor must include in its preliminary audit report a written explanation of the internal appeals process, including the name, address, and telephone number of the person or entity to whom an internal appeal should be addressed.

(d) The decision of the auditor on an appeal of a disputed claim in a preliminary audit report by a pharmacy or pharmacist must be reflected in the final audit report.

(e) An auditor must deliver a final audit report to a pharmacy or pharmacist not later than one hundred twenty (120) calendar days after a final appeal determination is made. The final report must include a final accounting of all monies to be recovered or returned by the pharmacy benefit manager.

(Department of Insurance; 760 IAC 5-3-10)

760 IAC 5-3-11 Use of third party auditors

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-22

Sec. 11. The acts of an independent auditor are considered to be the acts of the pharmacy benefit manager on whose behalf the independent auditor is acting.

(Department of Insurance; 760 IAC 5-3-11)

Rule 4. Maximum Allowable Cost Pricing

760 IAC 5-4-1 Maximum allowable cost pricing

Authority: IC 27-1-24.5-20; IC 27-1-24.5-23
Affected: IC 27-1-24.5

Sec. 1. (a) In a contract between a pharmacy benefit manager and a pharmacy, or a pharmacy benefit manager and a pharmacy services administrative organization, the pharmacy or the pharmacy services administrative organization must be given the right to obtain from the pharmacy benefit manager, within ten (10) calendar days after a request, a current list of the sources used to determine maximum allowable cost pricing. The pharmacy benefit manager must update the maximum allowable cost list at least every seven (7) calendar days and provide a means by which contracted pharmacies and pharmacy services administrative organizations may promptly review maximum allowable cost list updates in a format that is readily available and accessible.

(b) A pharmacy benefit manager must maintain a procedure to eliminate products from the list of drugs subject to maximum allowable cost pricing in a timely manner in order to remain consistent with pricing changes in the marketplace.

(c) In order to place a prescription drug on a maximum allowable cost list, a pharmacy benefit manager must ensure that:

(1) the drug is listed as "A" or "B" rated in the most recent version of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, or has an "NR" or "NA" rating or similar rating by a nationally recognized reference; and

(2) the drug:

(A) is generally available for purchase by pharmacies in Indiana from a national or regional wholesaler licensed and operating in Indiana; and

(B) is not obsolete, temporarily unavailable, included on a drug shortage list, or unable to be lawfully substituted.

(Department of Insurance; 760 IAC 5-4-1)

760 IAC 5-4-2 Disputes

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-22

Sec. 2. A pharmacy benefit manager shall establish a process for contracted pharmacies, pharmacy services administrative organizations, and group purchasing organizations to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing that includes the following:

(1) The right to appeal a claim in accordance with IC 27-1-24.5-22(b)(1).

(2) A requirement that the appeal be investigated and resolved within thirty (30) calendar days after the appeal is received.

(3) A requirement that if an appeal is denied, the pharmacy benefit manager must do the following:

(A) Provide a reason for the appeal denial.

(B) Provide the appealing contracted pharmacy, pharmacy services administrative organization, or group purchasing organization with the national drug code of a prescription drug that is generally available for purchase by pharmacies in Indiana:

(i) from a national or regional wholesaler licensed and operating in Indiana; and

(ii) for a price at or below the maximum allowable cost price as determined by the pharmacy benefit manager.

(4) A requirement that if an appeal is approved, the pharmacy benefit manager must follow the procedures set forth in IC 27-1-24.5-22(b)(4).

(Department of Insurance; 760 IAC 5-4-2)

Rule 5. Annual Reporting

760 IAC 5-5-1 Annual reporting

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5-21

Sec. 1. A pharmacy benefit manager must file annually by June 1 a report containing data from the immediately preceding calendar year on a form provided by the commissioner. The report must contain the information set forth in IC 27-1-24.5-21(a).

(Department of Insurance; 760 IAC 5-5-1)

Rule 6. Violations

760 IAC 5-6-1 Violations

Authority: IC 27-1-24.5-28
Affected: IC 27-4-1-4

Sec. 1. Violations of this article constitute an unfair or deceptive act under IC 27-4-1-4. The penalties, actions, or orders, including, but not limited to, monetary fines, suspensions, or license revocations, as authorized under IC 27-4-1, shall apply to violations of this article.

(Department of Insurance; 760 IAC 5-6-1)

Rule 7. Separability

760 IAC 5-7-1 Separability

Authority: IC 27-1-24.5-20
Affected: IC 27-1-24.5

Sec. 1. If the provisions of this article, or the application thereof, to a person or circumstance is for a reason held to be invalid, the remainder of the article and the application of the provisions to other persons or circumstances shall not be affected.

(Department of Insurance; 760 IAC 5-7-1)

Notice of Public Hearing

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