

TITLE 114
LEGISLATIVE RULE
INSURANCE COMMISSIONER

SERIES 99
PHARMACY AUDITING ENTITIES AND PHARMACY BENEFIT MANAGERS

§114-99-1. General.

1.1. Scope. -- The purpose of this rule is to implement the Pharmacy Audit Integrity Act and to provide licensing, reporting and activity standards for pharmacy benefit managers which provide claims processing services or other prescription drug or device services, or both, for health benefit plans. The rule also provides registration requirements for pharmacy auditing entities.

1.2. Authority. -- W. Va. Code §§ 33-51-8, 33-51-10 and 33-2-10.

1.3. Filing Date. -- February 27, 2020.

1.4. Effective Date. -- April 1, 2020.

1.5. Sunset provision. -- This rule shall terminate and have no further force or effect upon April 1, 2025.

1.6. Applicability. -- This rule applies to pharmacy benefit managers that perform pharmacy benefit management for covered entities and persons or companies that perform pharmacy audits, as provided by the Pharmacy Audit Integrity Act.

§114-99-2. Definitions.

2.1. "340B entity" means an entity participating in the federal 340B drug discount program, as described in 42 U.S.C. § 256b, including its pharmacy or pharmacies, or any pharmacy or pharmacies, contracted with the participating entity to dispense drugs purchased through such program.

2.2. "Auditing entity" means a person or company that performs a pharmacy audit, including a covered entity, pharmacy benefits manager, managed care organization, or third-party administrator.

2.3. "Covered entity" means a contract holder or policy holder providing pharmacy benefits to a covered individual under a health insurance policy pursuant to a contract administered by a pharmacy benefits manager.

2.4. "Covered individual" means a member, participant, enrollee, or beneficiary of a covered entity who is provided health coverage by a covered entity, including a dependent or other person provided health coverage through the policy or contract of a covered individual.

2.5. "Health insurance policy" means a policy, subscriber contract, certificate, or plan that provides prescription drug coverage. The term includes both comprehensive and limited benefit health insurance policies.

2.6. "Insurance Commissioner" or "Commissioner" means the Insurance Commissioner of West Virginia.

2.7. “Network” means a pharmacy or group of pharmacies that agree to provide prescription services to covered individuals on behalf of a covered entity or group of covered entities in exchange for payment for its services by a pharmacy benefits manager or pharmacy services administration organization. The term includes a pharmacy that generally dispenses outpatient prescriptions to covered individuals or dispenses particular types of prescriptions, provides pharmacy services to particular types of covered individuals or dispenses prescriptions in particular health care settings, including networks of specialty, institutional or long-term care facilities.

2.8. “Nonproprietary drug” means a drug containing any quantity of any controlled substance or any drug which is required by any applicable federal or state law to be dispensed only by prescription.

2.9. “Pharmacist” means an individual licensed by the West Virginia Board of Pharmacy to engage in the practice of pharmacy.

2.10. “Pharmacy” means any place within this state where drugs are dispensed and pharmacist care is provided.

2.11. “Pharmacy audit” means an audit, conducted on-site by or on behalf of an auditing entity of any records of a pharmacy for prescription or nonproprietary drugs dispensed by a pharmacy to a covered individual.

2.12. “Pharmacy Audit Integrity Act” means those provisions set forth in W. Va. Code §33-51-1 *et seq.*

2.13. “Pharmacy benefits management” means the performance of any of the following:

2.13.a. The procurement of prescription drugs at a negotiated contracted rate for dispensation within the State of West Virginia to covered individuals;

2.13.b. The administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals; or

2.13.c. The administration of pharmacy benefits, including:

2.13.c.1. Operating a mail-service pharmacy;

2.13.c.2. Claims processing;

2.13.c.3. Managing a retail pharmacy network;

2.13.c.4. Paying claims to a pharmacy for prescription drugs dispensed to covered individuals via retail or mail-order pharmacy;

2.13.c.5. Developing and managing a clinical formulary including utilization management and quality assurance programs;

2.13.c.6. Rebate contracting administration; and

2.13.c.7. Managing a patient compliance, therapeutic intervention, and generic substitution program.

2.14. “Pharmacy benefits manager” or “PBM” means a person, business, or other entity that performs pharmacy benefits management for covered entities.

2.15. "Pharmacy record" means any record stored electronically or as a hard copy by a pharmacy that relates to the provision of prescription or nonproprietary drugs or pharmacy services or other component of pharmacist care that is included in the practice of pharmacy.

2.16. "Pharmacy services administration organization" means any entity that contracts with a pharmacy to assist with third-party payer interactions and that may provide a variety of other administrative services, including contracting with pharmacy benefits managers on behalf of pharmacies and managing pharmacies' claims payments from third-party payers.

2.17. "Spread pricing" means the model of prescription drug pricing in which the pharmacy benefits manager charges a covered entity a contracted price for prescription drugs although the contracted price may differ with the amount the pharmacy benefits manager pays the pharmacist.

2.18. "Third party" means any insurer, health benefit plan for employees which provides a pharmacy benefits plan, a participating public agency which provides a system of health insurance for public employees, their dependents and retirees, or any other insurer or organization that provides health coverage, benefits, or coverage of prescription drugs as part of workers' compensation insurance in accordance with state or federal law. The term does not include an insurer that provides coverage under a policy of casualty or property insurance.

§114-99-3. Registration of Auditing Entities.

3.1. Prior to conducting business in this state, an auditing entity shall make an application on a form and in a manner prescribed by the Commissioner.

3.2. An initial registration application shall include the following:

3.2.a. The identity, address and telephone number of the applicant;

3.2.b. The name, business address and telephone number of the contact person for the applicant;

3.2.c. When applicable, the federal employer identification number for the applicant; and

3.2.d. A non-refundable filing fee sufficient to fund the Commissioner's regulatory duties in relation to the Pharmacy Audit Integrity Act, not to exceed \$1,000, which shall be set annually by the Commissioner via Bulletin or Notice on or before July 1.

3.3. A licensed insurer or other entity licensed by the Commissioner who conducts pharmacy audits shall comply with the standards and procedures of the Pharmacy Audit Integrity Act but is not required to separately register as an auditing entity.

3.4. The term of registration shall be two years. However, the Commissioner may, in his or her discretion, fix the date of expiration regarding the initial registration of an auditing entity in any manner as is considered by him or her to be advisable for an efficient distribution of the workload of his or her office, including fixing the date of expiration for the initial registration of an auditing entity for a period less than or more than two years.

3.5. An auditing entity's registration shall be renewed every two years on October 1 upon the submission of a renewal application and the payment of a renewal filing fee sufficient to fund the Commissioner's regulatory duties in relation to the Pharmacy Audit Integrity Act, not to exceed \$1,000, which shall be set annually by the Commissioner via Bulletin or Notice on or before July 1. The renewal application fee will be returned to the auditing entity if the renewal of the registration is not granted.

3.6. An auditing entity's renewal application shall be on the same form as the initial application and shall include the same information as required under subsection 3.2 of this section.

114-99-4. Licensure of Pharmacy Benefit Managers.

4.1. On or after the effective date of this rule, a PBM shall apply for a license on a form and in a manner prescribed by the Commissioner.

4.1.a. A PBM registered pursuant to W. Va. Code §33-5-7 at the time of the effective date of this rule and desires to continue to lawfully do business as a PBM in this state shall submit an application for licensure within six months of said effective date.

4.1.b. The term of licensure shall be two years. However, the Commissioner may, in his or her discretion, fix the date of expiration regarding the initial license of a PBM in any manner as is considered by him or her to be advisable for an efficient distribution of the workload of his or her office, including fixing the date of expiration for the initial license of a PBM for a period less than or more than two years.

4.2. An initial licensure application shall be verified by an officer or authorized representative of the applicant and shall include the following:

4.2.a. The identity, address, and telephone number of the applicant;

4.2.b. The name, business address, and telephone number of the contact person for the applicant;

4.2.c. When applicable, the federal employer identification number for the applicant;

4.2.d. A non-refundable filing fee sufficient to fund the Commissioner's regulatory duties in relation to the Pharmacy Audit Integrity Act, not to exceed \$10,000, which shall be set annually by the Commissioner via Bulletin or Notice on or before July 1;

4.2.e. Financial responsibility in an amount of \$1 million evidenced by one of the following:

4.2.e.1. A cash or surety bond issued by a corporate surety authorized to issue surety bonds in the State of West Virginia;

4.2.e.2. An irrevocable letter of credit;

4.2.e.3. Securities with a minimum value of \$1 million;

4.2.e.4. A written parental guarantee; or

4.2.e.5. One million dollars in working capital and/or surplus as reflected in audited financial statements submitted to the Commissioner;

4.2.f. Proof of registration with the West Virginia Secretary of State;

4.2.g. A list of the names, addresses and official positions of the persons who are to be responsible for the conduct of the affairs of the PBM applicant, including all members of the board of the directors, board of trustees, executive committee, or other governing board or committee, the principal officers in the case of a corporation, and the partners or members in the case of a partnership or association;

4.2.h. A copy of the basic organizational document of the PBM, such as the articles of incorporation, articles of association, partnership agreement, trust agreement or other applicable documents, and all

amendments thereto;

4.2.i. A copy of the bylaws, rules and regulations or similar document, if any, regulating the conduct of the internal affairs of the applicant;

4.2.j. A copy of the PBM's standard, generic contract template, provider manual or other appropriate items incorporated by reference which it uses for contracts entered into by the PBM with pharmacists, pharmacies or pharmacy services administrative organizations in this state in administration of pharmacy benefits for covered entities, for the purpose of ensuring that such contracts comply with W.Va. Code §33-51-9;

4.2.k. A copy of the most recent year-end audited financial statement of the PBM, which may be a consolidated audited financial statement if applicable;

4.2.l. A description of the projected population or numbers of covered individuals to be administered by the PBM in this state on an annual basis for all covered entities with whom the PBM has contracted, and, if applicable, the population or numbers of covered individuals administered by the PBM in the previous year for each covered entity;

4.2.m. A network report describing the PBM's network service areas by county in this state for a covered entity and the PBM's pharmacy provider directory list for a covered entity;

4.2.n. If the PBM is engaged in spread pricing for a covered entity, an explanation regarding whether or not the PBM is assuming risk for the covered benefit, and how, for payment of the covered prescription benefits of health insurance policies;

4.2.o. A statement of whether the applicant has been refused a registration, license or certification to act as (or provide the services of) a PBM or third party administrator, has any registration, license or certification to act as such been denied, suspended, revoked or non-renewed for any reason by any state or federal entity, or has been sanctioned, fined, or penalized for any reason by any state or federal entity;

4.2.p. A description of whether the applicant had a business relationship with an insurance company terminated for any legal finding or judgment of fraudulent or illegal activities in connection with the administration of a pharmacy benefits plan; and

4.2.q. Any other information which is deemed necessary by the Commissioner in evaluating the application to comply with the Pharmacy Audit Integrity Act or requirements of this rule or deemed necessary or appropriate by the Commissioner to establish the qualifications of the PBM to hold a license.

4.3. Review and Approval Process. -- For initial licensure applications, upon receipt of a complete application for items required under subsection 4.2 of this section, the Commissioner shall review the application and within 90 days:

4.3.a. Approve the application and issue the applicant a PBM license;

4.3.b. Notify the applicant in writing that the application is incomplete and that additional information is needed to complete the review of the application. If the missing or necessary information is not received within 30 days from the date of the notification, the Commissioner shall deny the application unless good cause is shown; or

4.3.c. Deny the application. If the Commissioner determines that the PBM applicant does not meet the requirements for licensure, the Commissioner shall:

4.3.c.1. Provide written notice to the PBM applicant that the application has been denied stating or explaining the basis of the denial; and

4.3.c.2. Advise the PBM applicant that a request for a hearing may be filed with the Commissioner in accordance with W. Va. Code §33-2-13.

4.4. Renewal. -- A PBM license shall be renewed every two years on October 1. A renewal application shall be deemed approved by the Commissioner after 45 days from the date of the receipt of the renewal application by the Commissioner, unless approved or denied by the Commissioner during that time period.

4.4.a. A renewal application shall be accompanied by the following:

4.4.a.1. A renewal filing fee sufficient to fund the Commissioner's regulatory duties in relation to the Pharmacy Audit Integrity Act, not to exceed \$10,000, which shall be set annually by the Commissioner via Bulletin or Notice on or before July 1;

4.4.a.2. A copy of the most recent year-end audited financial statement of the PBM, which may be a consolidated financial statement if applicable;

4.4.a.3. Evidence of financial responsibility in the amount of \$1 million as stated in subdivision 4.2.e of this section;

4.4.a.4. Any changes made to the items in subsection 4.2 of this section from the date of its most recent licensure; and

4.4.a.5. Any other information which is deemed necessary by the Commissioner in evaluating the renewal application to establish the continuing qualifications of the PBM to hold a license.

4.4.b. The Commissioner may require additional information or submissions from an applicant and may obtain any documents or information reasonably necessary to verify the information in the renewal application.

4.4.c. For disapprovals or denials of a renewal licensure by the Commissioner, the Commissioner shall:

4.4.c.1. Provide written notice to the renewal applicant that the licensure renewal was denied stating or explaining the basis of the denial; and

4.4.c.2. Advise the renewal applicant that a request for a hearing may be filed with the Commissioner in accordance with W. Va. Code §33-2-13.

4.5. Denial of Initial or Renewal Application.

4.5.a. The Commissioner shall deny an initial application for licensure or deny license renewal of a PBM for the following reasons:

4.5.a.1. The PBM operates, or proposes to operate, in a financially hazardous condition by failing to provide or maintain evidence of financial responsibility as noted under subdivision 4.2.e of this section;

4.5.a.2. The PBM has been determined by the Commissioner to be in violation or noncompliance with the requirements of this rule or West Virginia law;

4.5.a.3. The PBM has failed to timely submit information under subsection 4.2 of this section to complete a review of the initial application or has failed to submit a renewal application and information under subsection 4.4 of this section; or

4.5.a.4. The PBM fails to provide the Commissioner with its network report as required by W.Va. Code §33-51-8(d)(2) and (3).

4.5.b. In lieu of a denial of an initial licensure or renewal application, the Commissioner may permit the PBM to submit to the Commissioner an acceptable corrective action plan to cure or correct deficiencies.

4.6. Evidence of financial responsibility as noted under subdivision 4.2.e of this section shall be maintained at all times by the PBM during its licensure with the Commissioner, and the Commissioner shall have the right to confirm or verify the PBM's qualifications to hold a license and its financial responsibility at any time. The Commissioner may however reduce the amount of the financial responsibility requirement in subdivision 4.2.e of this section if the amount required is unreasonable relative to the size of the PBM's business operations in this state and would cause a significant financial hardship.

4.7. The information and data submitted by a PBM under this section shall be considered proprietary and confidential by law and privileged, and exempt from disclosure pursuant to Chapter 29B of the West Virginia Code as a "trade secret", is not open to public inspection, is not subject to subpoena, is not subject to discovery or admissible in evidence in any criminal, private civil or administrative action and is not subject to production pursuant to court order. The Commissioner is authorized to use the documents, materials or other information in the furtherance of any regulatory or legal action brought as part of the Commissioner's official duties.

§114-99-5. Prohibited acts.

5.1. A PBM shall not cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading.

5.2. An auditing entity conducting a pharmacy audit or person acting on behalf of the auditing entity may not seek any fee, charge-back, recoupment, or other adjustment for a dispensed product, or any portion of a dispensed product, unless one of the following has occurred:

5.2.a. Fraud or other intentional and willful misrepresentation as evidenced by a review of the claims data, statements, physical review, or other investigative methods;\

5.2.b. Dispensing in excess of the benefit design, as established by the plan sponsor;

5.2.c. Prescriptions not filled in accordance with the prescriber's order; or

5.2.d. Actual overpayment to the pharmacy.

5.3. Any fee, charge-back, recoupment, or other adjustment is limited to the actual financial harm associated with the dispensed product, or portion of the dispensed product, or the actual underpayment or overpayment as set forth in the criteria in subsection 5.2 of this section.

5.4. To assist healthcare consumers in making informed decisions, so called "gag clauses" in contracts between pharmacies and PBMs are prohibited. A pharmacy, pharmacist or pharmacy technician shall have the right to provide a consumer information relating to lower cost alternatives, and a pharmacy, pharmacist or pharmacy technician shall not be penalized by a PBM for discussing information in W.Va. Code §33-51-9 or the regulation of PBMs thereunder, or for selling a lower cost alternative, if one is available, without using a health insurance policy.

5.5. To prevent overcharges to consumers or insureds purchasing prescription drugs, so called “claw back” provisions in contracts between pharmacies and PBMs are prohibited and a PBM shall not collect from a pharmacy, a pharmacist, or a pharmacy technician a cost share or co-pay charged to a covered individual that exceeds the total submitted charges by the pharmacy or pharmacist to the PBM.

5.6. A PBM shall not directly or indirectly charge or hold a pharmacy, a pharmacist, or a pharmacy technician responsible for a fee related to the adjudication of a claim unless:

5.6.a. The total amount of the fee is identified, reported, and specifically explained for each line item on the remittance advice of the adjudicated claim; or

5.6.b. The total amount of the fee is apparent at the point of sale and not adjusted between the point of sale and the issuance of the remittance advice.

5.7. A PBM or any other third party that reimburses a 340B entity for drugs that are subject to an agreement under 42 U.S.C. §256b shall not reimburse the 340B entity for pharmacy-dispensed drugs at a rate lower than that paid for the same drug to pharmacies similar in prescription volume that are not 340B entities, and shall not assess any fee, charge-back, or other adjustment upon the 340B entity on the basis that the 340B entity participates in the program set forth in 42 U.S.C. §256b.

5.7.a. With respect to a patient eligible to receive drugs subject to an agreement under 42 U.S.C. § 256b, a PBM or any other third party that makes payment for such drugs, shall not discriminate against a 340B entity in a manner that prevents or interferes with the patient’s choice to receive such drugs from the 340B entity. For purposes of this subsection, “third party” does not include the state Medicaid program when Medicaid is providing reimbursement for covered outpatient drugs, as that term is defined in 42 U.S.C. § 1396r-8(k), on a fee-for-service basis; however, “third party” does include a Medicaid-managed care organization as described in 42 U.S.C. § 1396b(m).

5.8. A PBM’s contract with a participating pharmacist or pharmacy shall not prohibit, restrict, or limit disclosure of information to the Commissioner, law enforcement, or state and federal governmental officials investigating or examining a complaint or conducting a review of a PBM’s compliance with the requirements under this rule or the Pharmacy Audit Integrity Act.

5.9. Termination of a pharmacy or pharmacist from a PBM network shall not release the PBM from the obligation to make any payment due to the pharmacy or pharmacist for pharmacist services that are authorized for payment under the terms and conditions of the contract and rendered prior to the termination of the pharmacy or pharmacist from the PBM network.

§114-99-6. Network adequacy and reporting requirements.

6.1. A PBM shall maintain an adequate and accessible network for the provision of prescription drugs for a health benefit plan. The network shall provide for convenient patient access to pharmacies within a reasonable distance from a patient’s residence. A network shall not be comprised only of mail-order benefits but must have a mix of mail-order benefits and physical stores in this state.

6.2. A PBM shall, upon request by the Commissioner, provide a network report describing the PBM’s network and the mix of mail-order to physical stores in this state. Failure to provide a report may result in the suspension or revocation of a PBM’s license by the Commissioner.

6.3. Upon request, a PBM shall report to the Commissioner for each covered entity the following information:

6.3.a. The aggregate amount of rebates received by the PBM;

6.3.b. The aggregate amount of rebates distributed to the appropriate covered entity;

6.3.c. The aggregate amount of rebates passed on to the enrollees of each covered entity at the point of sale that reduced the enrollees applicable deductible, copayment, coinsurance, or other cost-sharing amount;

6.3.d. The individual and aggregate amount paid by the covered entity to the PBM for pharmacist services itemized by pharmacy, by product, and by goods and services; and

6.3.e. The individual and aggregate amount a PBM paid for pharmacist services itemized by pharmacy, by product, and by goods and services.

6.4. For covered entities using PBMs for administration of pharmacy benefits of its health benefit plans, the covered entity shall, upon request, provide the Commissioner with the number of pharmacists or pharmacies that have terminated their network participation with the covered entity.

6.5. The information and data submitted by a PBM under this section shall be considered proprietary and confidential by law and privileged, and exempt from disclosure pursuant to Chapter 29B of the West Virginia Code as a “trade secret”, is not open to public inspection, is not subject to subpoena, is not subject to discovery or admissible in evidence in any criminal, private civil or administrative action and is not subject to production pursuant to court order. The Commissioner is authorized to use the documents, materials or other information in the furtherance of any regulatory or legal action brought as part of the Commissioner’s official duties.

§114-99-7. Examinations.

7.1. The Commissioner may examine the affairs of a PBM for compliance with the requirements of the Pharmacy Audit Integrity Act or requirements of this rule.

7.2. Any examination permitted under this section shall follow the examination procedures and requirements applicable to covered entities under W. Va. Code §33-2-9, and the Commissioner may assess the costs of the examination or audit to the PBM.

7.3. A PBM shall not be regularly examined under the same time periods of insurers as required under W. Va. Code §33-2-9, however, the Commissioner may examine the PBM, pursuant to this section, at any time in which he or she believes it reasonably necessary to ensure compliance with the Pharmacy Audit Integrity Act or provisions of this rule.

7.4. The information and data obtained by the Commissioner from a PBM under this section shall be considered proprietary and confidential by law and privileged, and exempt from disclosure pursuant to Chapter 29B of the West Virginia Code as a “trade secret”, is not open to public inspection, is not subject to subpoena, is not subject to discovery or admissible in evidence in any criminal, private civil or administrative action and is not subject to production pursuant to court order. The Commissioner is authorized to use the documents, materials or other information in the furtherance of any regulatory or legal action brought as part of the Commissioner’s official duties.

§114-99-8. Penalties.

8.1. If the Commissioner finds that a licensed PBM has violated any provisions of this rule or any provisions of the Pharmacy Audit Integrity Act, the Commissioner may, in addition to or in lieu of a licensure suspension or revocation, order the PBM to pay a penalty in a sum not to exceed \$10,000 per violation. If

the PBM fails to pay the penalty within 30 days after notice of the penalty, the Commissioner may revoke or suspend the license of the PBM.

8.2. If the Commissioner finds that a registered auditing entity has violated any provisions of this rule or any provisions of the Pharmacy Audit Integrity Act, the Commissioner may, in addition to or in lieu of a registration suspension or revocation, order the auditing entity pay a penalty in a sum not to exceed \$2,500 per violation. If the auditing entity fails to pay the penalty within 30 days after notice of the penalty, the Commissioner may revoke or suspend the registration of the auditing entity.

8.3. With respect to any person or entity operating in this state as a PBM without a license, the Commissioner may do one or both of the following:

8.3.a. File a complaint in the Circuit Court of Kanawha County, or in any county in which a PBM has operated without a license, to enjoin the PBM from operating; and

8.3.b. After notice and hearing in accordance with W.Va. Code §33-2-13, assess restitution in an amount sufficient to reimburse any person adversely affected by the operation of the unlicensed PBM and, in addition to or in lieu of restitution, impose a fine in a sum not to exceed \$20,000 for each unauthorized act.

8.4. With respect to any person or entity operating in this state as an auditing entity without being registered or exempted from registration, the Commissioner may do one or both of the following:

8.4.a. File a complaint in the Circuit Court of Kanawha County, or in any county in which an auditing entity has operated without a license, to enjoin the auditing entity from operating; and

8.4.b. After notice and hearing in accordance with W.Va. Code §33-2-13, assess restitution in an amount sufficient to reimburse any person adversely affected by the operation of the unregistered auditing entity and, in addition to or in lieu of restitution, impose a fine in a sum not to exceed \$5,000 for each unauthorized act.