



**WEST VIRGINIA SECRETARY OF STATE**

**MAC WARNER**

**ADMINISTRATIVE LAW DIVISION**

**eFILED**

9/18/2019 7:52:05 AM

Office of West Virginia  
Secretary Of State

**NOTICE OF PUBLIC COMMENT PERIOD**

AGENCY: Insurance Commission TITLE-SERIES: 114-99  
RULE TYPE: Legislative Amendment to Existing Rule: No Repeal of existing rule: No  
RULE NAME: Pharmacy Auditing Entities and Pharmacy Benefit Managers  
CITE STATUTORY AUTHORITY: W. Va. Code §33-51-10 and §33-2-10

COMMENTS LIMITED TO:

Written

DATE OF PUBLIC HEARING:

LOCATION OF PUBLIC HEARING:

DATE WRITTEN COMMENT PERIOD ENDS: 10/17/2019 5:00 PM

COMMENTS MAY BE MAILED OR EMAILED TO:

NAME: Victor Mullins  
ADDRESS: P.O. Box 50540  
Charleston, WV 25305-0540  
EMAIL: victor.a.mullins@wv.gov

PLEASE INDICATE IF THIS FILING INCLUDES:

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

INCORPORATED BY REFERENCE: No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

PROVIDE A BRIEF SUMMARY OF THE CONTENT OF THE RULE:

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 (PBMs) 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. The rule sets forth the information the Offices of the Insurance Commissioner (OIC) considers necessary and appropriate to establish the qualifications of PBMs and for the PBMs to receive a license as provided by Senate Bill 489 (2019), Pharmacy Audit Integrity Act (Act). The purpose of Senate Bill 489 was to provide for additional regulatory oversight of PBMs. The legislation requires PBMs to obtain a license from the OIC, as opposed to only being registered as previously required. The licensing and regulation of PBMs will require much greater regulatory oversight by the OIC.

The rule also sets forth licensing, fees, application, financial standards, and reporting requirements for PBMs, as well as the penalties or fines for violation of the Act for both PBMs and auditing entities. The Act requires that the application and renewal fees for PBMs and auditing entities be sufficient to fund the OICs duties in regard to its responsibilities under the Act.

SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN THE RULE AND A STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE:

The Insurance Commissioner is proposing a new rule relating to the licensing and regulation of Pharmacy Benefit Managers (PBMs) and registration of Pharmacy Auditing Entities, in response to Senate Bill 489 (2019), the Pharmacy Audit Integrity Act. The purpose of Senate Bill 489 was to provide for additional regulatory oversight of PBMs. The legislation requires PBMs to obtain a license from the Offices of the Insurance Commissioner (OIC), as opposed to only being registered as previously required. The licensing and regulation of PBMs will require much greater regulatory oversight by the OIC.

The OICs proposed rule sets forth the information the OIC considered necessary and appropriate to establish the qualifications of the PBM and for the PBM to receive a license, as required by the legislation. It also sets forth licensing, fees, application, financial standards, and reporting requirements for PBMs, as well as the penalties or fines for violation of the Act for both PBMs and auditing entities. The Act requires that the application and renewal fees for PBMs and auditing entities be sufficient to fund the OICs duties in regard to its responsibilities under the Act.

Senate Bill 489 became effective from passage. However, a PBM that was previously registered in this state may continue to do business in this state until the OIC has completed its legislative rule, provided that the PBM apply to be licensed within six months of completion of the final rule.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

The OIC estimates that enactment of SB489 would require the addition of 1 to 2 additional FTEs starting at a mid-point base salary of \$42,000. Benefits associated with the additional FTEs are calculated at 35.5%. Modest increases in the overall costs for the FTEs are included in the estimates for subsequent years to reflect potential increases in insurance, benefits, annual increment, salary advancements, etc

General overhead costs for space occupancy, education and training have been estimated at \$5000 annually per FTE. The purchase of computer equipment and general office furnishings and supplies have been estimated at \$3500 per FTE.

The Revenue estimate assumes that the licensing fees established are set at an adequate amount to offset the additional costs incurred.

The Fiscal Note Detail below assumes the OIC will need 2 FTEs.

**B. ECONOMIC IMPACT OF THE RULE ON THE STATE OR ITS RESIDENTS:**

Unknown.

**C. FISCAL NOTE DETAIL:**

<b>Effect of Proposal</b>	<b>Fiscal Year</b>		
	<b>2019 Increase/Decrease (use "-")</b>	<b>2020 Increase/Decrease (use "-")</b>	<b>Fiscal Year (Upon Full Implementation)</b>
<b>1. Estimated Total Cost</b>	N/A	130,820	136,511
<b>Personal Services</b>	N/A	113,820	119,511
<b>Current Expenses</b>	N/A	10,000	10,000
<b>Repairs and Alterations</b>	N/A	0	0
<b>Assets</b>	N/A	7,000	7,000
<b>Other</b>	N/A	130,820	136,511
<b>2. Estimated Total Revenues</b>	N/A	N/A	N/A

**D. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):**

This rule is being requested in response to SB489 (2019), which required the OIC to license and regulate PBMs.

SB 489 was designed to be revenue neutral, as the legislation mandates that the OIC establish fees necessary to offset the cost of increased regulation. However, the fees are capped at 10,000 per application and renewal for PBMs and 1,000 for application and renewal for auditing entities.

At present, we do not know how many PBMs and auditing entities will ultimately apply for licensure/registration. We have zero auditing entities registered currently because the entities that perform these services are separately registered as Third-Party Administrators and the law currently provides that they do not have to be registered as both. We have had 23 PBMs sign up for pre-licensing, which is enough to charge an application and renewal fee necessary to offset our costs. However, we have no guarantees that the PBMs who have been pre-licensed will ultimately apply for full licensure once the rule is passed or the fees are set.

The actual costs and revenues generated may vary significantly from the estimates made at the time of the filing of this fiscal note depending on how many PBMs we license and how many auditing entities we register.

**BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.**

**Yes**

**Allen R Prunty -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.**

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 §§33-51-10 and 33-2-10.

1.3. Filing Date. --

1.4. Effective Date. --

1.5. Sunset provision. -- This rule shall terminate and have no further force or effect upon the expiration of five years from its effective date.

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. "Healthcare insurer" means an accident and sickness insurance company, nonprofit hospital service corporation, medical service corporation, dental service organization, prepaid limited health service organization, health maintenance organization or any other entity required to be licensed by the Commissioner that may issue a health insurance policy.

2.6. "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.

2.7. “Insurance Commissioner” or “Commissioner” means the Insurance Commissioner of West Virginia.

2.8. “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.

2.9. “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.

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

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

2.12. “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.

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

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

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

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

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

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

2.14.c.2. Claims processing;

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

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

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

2.14.c.6. Rebate contracting administration; and

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

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

2.16. “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.

2.17. “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.

2.18. “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.

2.19. “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;

4.2.k. A copy of the most recent year-end audited financial statement of the PBM;

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 description of 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, or 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;

4.2.p. A description of whether the applicant had a business relationship with an insurance company terminated for any alleged 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 or to evaluate the financial condition of the PBM relative to the services it administers, or proposes to administer, for covered entities in this state.

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;

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 or to evaluate the financial condition of the PBM relative to the services it administers, or proposes to administer, for covered entities in this state.

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 relative to its financial condition and the services it administers, or proposes to administer for covered entities in this

state:

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; or

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.

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. To the extent possible, 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. A claim for pharmacist services shall not be retroactively denied or reduced after adjudication of the claim by a PBM acting as an auditing entity unless:

5.2.a. The original claim was submitted fraudulently;

5.2.b. The original claim payment was incorrect because the pharmacy or pharmacist had already been paid for the pharmacist services; or

5.2.c. The pharmacist services were not properly rendered by the pharmacy or pharmacist.

5.3. 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 the Pharmacy Audit Integrity Act or the regulation of PBMs thereunder, or for selling a lower cost alternative, if one is available, without using a health insurance policy.

5.4. 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.

5.5. 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:

5.5.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

5.5.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.

5.6. 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.

5.6.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).

5.7. 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.

5.8. 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 properly rendered.

5.9. Neither auditing entities nor PBMs shall not perform any act or acts that would be in violation of W. Va. Code §33-51-4 regarding the procedures for conducting pharmacy audits.

**§114-99-6. Duties of healthcare insurers.**

6.1. For healthcare insurers using PBMs for administration of pharmacy benefits of its health benefit plans, a healthcare insurer shall:

6.1.a. Reasonably ensure that the reimbursement or compensation of pharmacists or pharmacies does not adversely impact participation of pharmacists or pharmacies in its health benefit plans.

6.1.b. Develop a mechanism or system with its PBM to track or monitor, on an annual basis, the number of pharmacists or pharmacies which terminated their network participation with the healthcare insurer or PBM network due to reduction in compensation; and

6.1.c. Provide information related to the requirements of this section upon request of the Commissioner.

**§114-99-7. Network adequacy and reporting requirements.**

7.1. 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.

7.2. A PBM shall, upon request by the Commissioner, provide a network adequacy 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.

7.3. A PBM shall report to the Commissioner on a quarterly year basis for each healthcare insurer the following information:

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

7.3.b. The aggregate amount of rebates distributed to the appropriate healthcare insurer;

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

7.3.d. The individual and aggregate amount paid by the healthcare insurer to the PBM for pharmacist services itemized by pharmacy, by product, and by goods and services; and

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

7.4. To the extent possible, 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.

#### **§114-99-8. Examinations.**

8.1. 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. In addition, the Commissioner may examine the affairs of a healthcare insurer subject to the requirements of section 6 of this rule.

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

8.3. 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 or healthcare insurer, 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.

8.4. To the extent possible, 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.

**§114-99-9. Penalties.**

9.1. 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.

9.2. 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.

9.3. 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:

9.3.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

9.3.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.

9.4. 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:

9.4.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

9.4.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.