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 provide for the regulation of pharmacy auditing entities and pharmacy benefit managers and to provide licensing, reporting and activity standards for pharmacy benefit managers. The rule also provides registration requirements for pharmacy auditing entities.

1.2. Authority. -- W. Va. Code §§33-51-8, 33-51-9, 33-51-10, 33-51-12 and 33-2-10.

1.3. Filing Date. – March 29, 2023

1.4. Effective Date. – April 1, 2023.

1.5. Sunset provision. -- This rule shall terminate and have no further force or effect upon August 1, 2028.

1.6. Applicability. -- This rule applies to pharmacy benefit managers (PBMs) and persons or companies that perform pharmacy audits, as provided in Article 51, Chapter 33 of the West Virginia Code. Certain regulatory sections of this rule may not apply to Medicare Part D plans or Medicare Advantage plans that offer prescription drug coverage because 42 U.S.C. §1395w–26(b)(3) and 42 U.S.C. §1395w–112(g) provide that standards established under 42 U.S.C. §1395w-101 *et seq*. and 42 U.S.C. §1395w-21 *et seq*. shall supersede any state law or regulation, other than state licensing laws or state laws relating to plan solvency. PBMs that perform pharmacy benefits management for Medicare Part D plans and Medicare Advantage plans in this state must be appropriately licensed. Additionally, certain sections of this rule may not be applicable to health benefit plans that are subject to the Employee Retirement Income Security Act of 1974 ("ERISA") if the subject provision of the rule is preempted by ERISA because it regulates a key facet or essential part of plan administration or design. However, certain sections of this rule that only affect costs, pricing or alter incentives for ERISA plans are not preempted by ERISA and may be applicable to PBMs providing pharmacy benefits management for ERISA plans. This section does not limit the applicability of other sections to PBMs providing pharmacy benefits management for ERISA plans should federal statutory or common law afford the state authority to regulate. PBMs that perform pharmacy benefits management for ERISA plans in this state must be appropriately licensed. This rule applies to PBMs that manage prescription drug coverage for workers' compensation insurers and employers who are self-insured for workers' compensation in this state because workers' compensation insurers and self-insured employers are "healthcare payors."

§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. "Affiliate" means a pharmacy, pharmacist or pharmacy technician which, either directly or indirectly through one or more intermediaries:

2.2.1. Has an investment or ownership interest in a PBM;

2.2.2. Shares common ownership with a PBM; or

2.2.3. Has an investor or ownership interest holder which is a PBM.

2.3. "Auditing entity" means a person or company that performs a pharmacy audit, including a PBM, managed care organization, or third-party administrator.

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

2.5. "Defined cost sharing" means a deductible payment or coinsurance amount imposed on an enrollee for a covered prescription drug under the enrollee's health benefit plan but does not include copayments.

2.6. "Health benefit plan" means a policy, contract, certificate or agreement entered into, offered, or issued by a health care payor to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services.

2.7. "Health care payor" or "payor" means a health insurance company; a health maintenance organization; a hospital, medical, or dental corporation; a health care corporation; an entity that provides, administers, or manages a self-funded health benefit plan, including a governmental plan; or any other payor that provides prescription drug coverages, including a workers' compensation insurer. Health care payor does not include an insurer that provides coverage under a policy of casualty or property insurance.

2.8. "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.

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

2.10. "National average drug acquisition cost" or "NADAC price" means the monthly survey of retail pharmacies conducted by the federal Centers for Medicare and Medicaid Services ("CMS") to determine average acquisition cost for Medicaid covered outpatient drugs.

2.11. "Network" means a pharmacy or group of pharmacies that agree to provide prescription services to covered individuals on behalf of a health benefit plan in exchange for payment for its services by a PBM 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.

2.12. "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.

2.13. "Pass-through pricing" means the model of prescription drug pricing wherein a PBM charges the health benefit plan the same price for a prescription drug that it pays the pharmacy for the same prescription drug.

2.14. "Pharmacist" means an individual licensed by the West Virginia Board of Pharmacy to engage in the practice of pharmacy.

2.15. "Pharmacy" means any place within this state where drugs are dispensed and pharmacist care is provided.

2.16. "Pharmacy audit" means an audit, conducted 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.

2.17. "Pharmacy benefits management" means the performance of any of the following:

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

2.17.2. The administration or management of prescription drug benefits provided by health benefit plan for the benefit of covered individuals; or

2.17.3. The administration of pharmacy benefits, including:

2.17.3.a. Operating a mail-service pharmacy;

2.17.3.b. Claims processing;

2.17.3.c. Managing a retail pharmacy network;

2.17.3.d. Paying claims to a pharmacy for prescription drugs dispensed to covered individuals via retail or mail-order pharmacy;

2.17.3.e. Developing and managing a clinical formulary including utilization management and quality assurance programs;

2.17.3.f. Rebate contracting administration; and

2.17.3.g. Managing a patient compliance, therapeutic intervention, and generic substitution program.

2.18. "Pharmacy benefits manager" or "PBM" means a person, business, or other entity that performs pharmacy benefits management for health benefit plans.

2.19. "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.

2.20. "Pharmacy services administration organization" means any entity that contracts with a pharmacy to assist with payor interactions and that may provide a variety of other administrative services, including contracting with PBMs on behalf of pharmacies and managing pharmacies' claims payments from payors.

2.21. "Point-of-sale fee" means all or a portion of a drug reimbursement to a pharmacy or other dispenser withheld at the time of adjudication of a claim for any reason.

2.22. "Rebate" means any and all payments that accrue to a PBM or its health benefit plan client, directly or indirectly, from a pharmaceutical manufacturer, including, but not limited to, discounts, administration fees, credits, incentives, or penalties associated directly or indirectly in any way with claims administered on behalf of a health benefit plan client. The term "rebate" does not include any discount or payment that may be provided to or made to any 340B entity through such program.

2.23. "Retroactive fee" means all or a portion of a drug reimbursement to a pharmacy or other dispenser recouped or reduced following adjudication of a claim for any reason.

2.24. "Specialty drug" means a drug used to treat rare or chronic and complex medical conditions and requiring special handling or administration, provider care coordination, or patient education that cannot be provided by a non-specialty pharmacy or pharmacist.

2.25. "Spread pricing" means the model of prescription drug pricing in which the PBM charges a health benefit plan a contracted price for prescription drugs although the contracted price may differ with the amount the PBM pays the pharmacist or pharmacy.

§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:

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

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

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

3.2.4. A nonrefundable filing fee sufficient to fund the Commissioner's regulatory duties in relation to Article 51, Chapter 33 of the West Virginia Code and this rule, 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 Article 51, Chapter 33 of the West Virginia Code and this rule, 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 Article 51, Chapter 33 of the West Virginia Code and this rule, 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 section 3.2 of this rule.

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

4.1. A person or organization may not establish or operate as a PBM in this state without first obtaining a license from the Commissioner.

4.1.1. A PBM shall apply for a license on a form and in a manner prescribed by the Commissioner.

4.1.2. 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:

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

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

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

4.2.4. A nonrefundable filing fee sufficient to fund the Commissioner's regulatory duties in relation to Article 51, Chapter 33 of the West Virginia Code and this rule, not to exceed $10,000, which shall be set annually by the Commissioner via Bulletin or Notice on or before July 1;

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

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

4.2.5.b. An irrevocable letter of credit;

4.2.5.c. Securities with a minimum value of $1 million;

4.2.5.d. A written parental guarantee; or

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

4.2.6. Proof of registration with the West Virginia Secretary of State;

4.2.7. 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;

4.2.8. 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;

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

4.2.10. 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 health benefit plans, for the purpose of ensuring that such contracts comply with W. Va. Code §33-51-9. If a PBM leases or otherwise uses, or anticipates using, a network from another

PBM or health benefit plan, the PBM seeking licensure must submit a copy of the contract that it has, or anticipates having, with the other licensed PBM or health benefit plan;

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

4.2.12. 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 health benefit plans 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 health benefit plan;

4.2.13. A network report describing the PBM's network service areas by county in this state for a health benefit plan and the PBM's pharmacy provider directory list for a health benefit plan, including a detailed description of any separate, sub-networks for specialty drugs. The detailed description should include a statement as to whether the PBM has restricted distribution of specialty drugs to mail-order specialty pharmacies or affiliate pharmacies, and further provide the names and addresses of any specialty pharmacies in the PBM's network that are not solely mail-order pharmacies or affiliate pharmacies and are located in West Virginia, or in an out-of-state county that is adjacent to West Virginia;

4.2.14. If the PBM is engaged in spread pricing for a health benefit plan, an explanation regarding whether or not the PBM is assuming risk for the covered benefit;

4.2.15. 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, penalized or entered into a monetary settlement for any reason by or with any state or federal entity, including but not limited to another state's department of insurance, department of health and human services or Medicaid program, attorney general's office, board of pharmacy or other similar regulatory agency;

4.2.16. 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;

4.2.17. Any and all methodologies utilized by a PBM in connection with reimbursement shall be filed at initial licensure and all reimbursement methodologies must comply with the requirements set forth in Article 51, Chapter 33 of the West Virginia Code. If a PBM was initially licensed prior to the time methodologies were required to be filed, a PBM shall file any and all methodologies utilized by a PBM in connection with reimbursement at its first renewal after January 1, 2022. All filed methodologies shall comply with the provisions of W. Va. Code §33-51-9(e) and a PBM shall not enter into a contract with a pharmacy that provides for reimbursement methodology not permissible under the provisions of W. Va. Code §33-51-9(e). The methodologies are confidential and exempt from disclosure under the *West Virginia Freedom of Information Act*, W. Va. Code §29B-1-4(a)(1);

4.2.18. An attestation that the PBM has offered all health benefit plans for which the PBM provides pharmacy benefits management the option of pass-through pricing as required by W. Va. Code §33-51-9(k) and, if applicable, an attestation that the PBM is charging a health benefit plan administered by or on behalf of the state or a political subdivision of the state, the same price for a prescription drug as it pays a pharmacy for the prescription drug, i.e. pass-through pricing. With the attestation, the PBM shall provide the Commissioner with a copy of the PBM's standard, generic template or form for correspondence making the mandatory offer of pass-through pricing to a health benefit plan; and

4.2.19. Any other information which is deemed necessary by the Commissioner in evaluating the

application to comply with Article 51, Chapter 33 of the West Virginia Code 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 section 4.2 of this rule, the Commissioner shall review the application and within 90 days:

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

4.3.2. 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

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

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

4.3.3.b. 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.

4.4.1. A renewal application shall be accompanied by the following:

4.4.1.a. A renewal filing fee sufficient to fund the Commissioner's regulatory duties in relation to Article 51, Chapter 33 of the West Virginia Code and this rule, not to exceed $10,000, which shall be set annually by the Commissioner via Bulletin or Notice on or before July 1;

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

4.4.1.c. Evidence of financial responsibility in the amount of $1 million as stated in subsection 4.2.5 of this rule;

4.4.1.d. An updated attestation that the PBM has offered all health benefit plans for which the PBM provides pharmacy benefits management the option of pass-through pricing as required by W. Va. Code §33-51-9(k) and, if applicable, an attestation that the PBM is charging a health benefit plan administered by or on behalf of the state or a political subdivision of the state, the same price for a prescription drug as it pays a pharmacy for the prescription drug, *i.e.* pass-through pricing. With the attestation, the PBM shall provide the Commissioner with a copy of the PBM's standard, generic template or form for correspondence making the mandatory offer of pass-through pricing to a health benefit plan;

4.4.1.e. Any changes made to the items in section 4.2 of this rule from the date of its most recent licensure, including but not limited to any changes in methodologies utilized in connection with reimbursement made at any time since initial licensure, updated information regarding the projected number of covered individuals in this state who have pharmacy benefit management services administered by the PBM on an annual basis for all health benefit plans with whom the PBM has contracted, and an updated

network report as described in subsection 4.2.13. of this rule; and

4.4.1.f. 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.

4.4.2. 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.

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

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

4.4.3.b. 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.

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

4.5.1.a. 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 subsection 4.2.5 of this rule;

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

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

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

4.5.2. 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 subsection 4.2.5 of this rule 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 subsection 4.2.5 of this rule 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. Responsibilities and 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:

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

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

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

5.2.4. 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 section 5.2 of this rule.

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 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. For purposes of this section, the term "other adjustment" includes placing any additional requirements, restrictions or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other pharmacies that do not participate in the 340B program, including affiliate pharmacies of the PBM, and further includes but is not limited to requiring a claim for a drug to include a modifier or be reprocessed or resubmitted to indicate that the drug is a 340B drug. Nothing in section 5.6 of this rule shall be construed to prohibit the Medicaid program or a Medicaid managed care organization ("MCO") as described in 42 U.S.C. §1396b(m) from preventing duplicate discounts as described in 42 U.S.C. §256b(a)(5)(A)(i). The provisions of section 5.6 of this rule are applicable to the West Virginia Public Employees Insurance Agency ("PEIA").

5.7. With respect to a patient eligible to receive drugs subject to an agreement under 42 U.S.C. §256b, a PBM 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. This section does not apply to 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. This section does apply to a Medicaid-managed care organization as described in 42 U.S.C. §1396b(m). For purposes of this section, it shall be considered a discriminatory practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity if a PBM places additional requirements, restrictions or unnecessary burdens upon a 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other pharmacies that do not participate in the 340B program, including affiliate pharmacies of the PBM, and further includes but is not limited to requiring a claim for a drug to include a modifier or be reprocessed or resubmitted to indicate that the drug is a 340B drug. Nothing in section 5.7 of this rule shall be construed to prohibit the Medicaid program or a Medicaid MCO as described in 42 U.S.C. §1396b(m) from preventing duplicate discounts as described in 42 U.S.C. §256b(a)(5)(A)(i). The provisions of section 5.7 of this rule are applicable to PEIA.

5.8. A PBM may not reimburse a pharmacy or pharmacist for a prescription drug or pharmacy service in an amount less than the NADAC price for the prescription drug or pharmacy service at the time the drug is administered or dispensed plus a dispensing fee of $10.49. If the NADAC price is not available at the time a drug is administered or dispensed, a PBM may not reimburse in an amount that is less than the wholesale acquisition cost of the drug as defined in 42 U.S.C. §1395w-3a(c)(6)(B) plus a dispensing fee of $10.49.

5.9. Payment Parity. -- A PBM may not reimburse a pharmacy or pharmacist for a prescription drug or pharmacy service in an amount less than the amount the PBM reimburses itself or one of its affiliates for the same prescription drug or pharmacy service.

5.10. A PBM shall utilize the most recently published NADAC price as a point of reference for the ingredient drug product component of a pharmacy's reimbursement for drugs appearing on the national average drug acquisition cost list.

5.11. A PBM shall not discriminate in reimbursement, assess any fees or adjustments, or exclude a pharmacy from the PBM's network on the basis that the pharmacy dispenses drugs subject to an agreement under 42 U.S.C. §256b.

5.12. A PBM shall not engage in any practice that:

5.12.1. Bases reimbursement for a drug on patient outcomes, scores, or metrics. This prohibition does not apply to reimbursement for pharmacy care, including dispensing fees, from being based on patient outcomes, scores or metrics so long as the terms are disclosed and agreed to by the pharmacy in advance;

5.12.2. Imposes a point-of-sale fee or retroactive fee; or

5.12.3. Derives any revenue from a pharmacy or insured in connection with performing pharmacy benefits management services. This prohibition shall not prohibit a PBM from processing coinsurance, deductibles or co-payments that have been approved by a covered individual's health benefit plan.

5.13. A PBM shall offer a health benefit plan the option of pass-through pricing and file with the Commissioner an attestation that such offer has been made to each health benefit plan that the PBM provides pharmacy benefit management services for as described in subsection 4.2.18 of this rule. However, pass-through pricing is required in regard to a PBM that contracts with a health benefit plan administered by or on behalf of the state or a political subdivision of the state.

5.14. A covered individual's defined cost sharing for each prescription drug shall be calculated at the point-of-sale based on a price that is reduced by an amount equal to at least 100% of all applicable rebates received, or to be received, in connection with the dispensing or administration of the prescription drug up

to the amount of a covered individual's defined cost sharing.

5.14.1. All rebates should be calculated by the PBM or third-party based upon the actual rebate amount negotiated between the PBM or health benefit plan and the manufacturer and provided, or to be provided, by the manufacturer to the PBM or health benefit plan.

5.14.2. Any price reduction based upon a rebate received, or to be received, must be completely reflected in the price of the prescription drug at the time the pharmacy dispenses it to the patient.

5.14.3. Any rebate that is calculated by the PBM or third-party to be over and above, or in excess of, a covered individual's defined cost sharing may not be retained by the PBM but must be passed on to the health benefit plan and must be used by the health benefit plan to reduce the cost of premiums.

5.14.4. The Commissioner may request information deemed necessary by the Commissioner from the pharmacy, PBM, third-party or health benefit plan to determine compliance with these point-of-sale rebating requirements as needed to investigate complaints and as set forth in the annual reporting requirements in section 6 of this rule.

5.14.5. Nothing precludes an insurer from decreasing a covered individual's defined cost sharing by an amount greater than that set forth in section 5.14. of this rule.

5.14.6. A PBM shall be responsible for calculating a covered individual's defined cost sharing for each prescription drug. No PBM shall charge or deduct from a pharmacist or pharmacy any fee, recoupment, charge back, or other monetary penalty, amount or adjustment due to the PBM's miscalculation of a rebate or defined cost sharing amount.

5.15. 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 Article 51, Chapter 33 of the West Virginia Code.

5.16. 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. Network adequacy and prohibition against required use of mail-order pharmacy.

6.1.1. A PBM shall maintain a reasonably 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.

6.1.1.a. Pursuant to W. Va. Code §§33-16-3q, 33-24-7h, 33-25-8f and 33-25A-8g, an insurer issuing a group accident and sickness policy, a hospital, medical, dental or health service corporation, a health care corporation, or a health maintenance organization may not require any covered individual to obtain prescription drugs from a mail-order pharmacy in order to obtain prescription drug benefits, and may not violate this prohibition by using an agent, contractor or administrator that requires the covered person to obtain prescription drugs from a mail-order pharmacy. An insurer, hospital, medical, dental or health service corporation, a health care corporation, or a health maintenance organization that violates W. Va. Code §§33-16-3q, 33-24-7h, 33-25-8f and 33-25A-8g through the use of a PBM may be subject to

regulatory action as permitted under Chapter 33 of the West Virginia Code.

6.1.2. A PBM shall, upon licensure and upon further 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 and shall include a detailed description of any separate, sub-networks for specialty drugs. The detailed description should include a statement as to whether the PBM has restricted distribution of specialty drugs to mail-order specialty pharmacies or affiliate pharmacies, and if so, the reasons therefore, and further provide the names and addresses of any specialty pharmacies in the PBM's network that are not solely mail-order pharmacies or affiliate pharmacies and are located in West Virginia, or in an out-of-state county that is adjacent to West Virginia. This statement shall also include a list of all specialty drugs currently on restricted distribution to specialty pharmacies or affiliate pharmacies. Failure to provide a report may result in the suspension or revocation of a PBM's license by the Commissioner.

6.1.3. Health benefit plans using PBMs for administration of pharmacy management benefits shall, upon request, provide the Commissioner with the number of pharmacists, pharmacies and pharmacy services administration organizations that have either terminated their network participation with the health benefit plan or have had their network participation terminated by the health benefit plan.

6.1.4. A PBM using a leased network must ensure that the leased network is reasonably adequate and accessible as provided in subsection 6.1.1 of this rule and the PBM using the leased network must be able to provide the reports described in subsections 6.1.2 and 6.1.3 of this rule upon request by the Commissioner.

6.2. Annual Reports.

6.2.1. A PBM shall report to the Commissioner on or before March 1 of each year, or more often as the Commissioner deems necessary, for each health benefit plan the following information:

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

6.2.1.b. The aggregate amount of rebates distributed to the health benefit plan;

6.2.1.c. The aggregate amount of rebates used at the point-of-sale to reduce a covered individual's defined cost sharing in accordance with section 5.14. of this rule;

6.2.1.d. The individual and aggregate amount paid by the health benefit plan to the PBM for pharmacist services itemized by pharmacy, by product, and by goods and services; and

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

6.2.2. In regard to a PBM that contracts with a health benefit plan, the PBM shall annually report in the aggregate to the Commissioner and to the health benefit plan the difference between the amount the PBM reimbursed a pharmacy and the amount the PBM charged the health benefit plan. The annual report required by this subsection may be referred to as the "spread pricing report" and shall be due on or before March 1 of each year.

6.2.3. A health benefit plan shall annually report to the Commissioner the aggregate amount of credits, rebates, discounts, or other such payments received by the health benefit plan from a PBM or drug manufacturer and disclose whether or not those credits, rebates, discounts or other such payments were passed on to reduce insurance premiums or rates. The Commissioner will use the information obtained in these reports when reviewing premium rates charged for individual and group accident and health insurance as set forth in W. Va. Code §§33-6-9(e), 33-24-6(c) and 33-25A-8. The annual report required by this

subsection shall be due on or before March 1 of each year.

6.3. Quarterly Report.

6.3.1. A PBM shall produce a quarterly report to the Commissioner of:

6.3.1.a. All drugs appearing on the national average drug acquisition cost list reimbursed 10% and below the national average drug acquisition cost; and

6.3.1.b. All drugs appearing on the national average drug acquisition cost list reimbursed 10% and above the national average drug acquisition cost.

6.3.2. For each drug listed in the quarterly report, a PBM shall include:

6.3.2.a. The month the drug was dispensed;

6.3.2.b. The quantity of the drug dispensed;

6.3.2.c. The amount the pharmacy was reimbursed;

6.3.2.d. Whether the dispensing pharmacy was an affiliate of the PBM;

6.3.2.e. Whether the drug was dispensed pursuant to a government health benefit plan; and

6.3.2.f. The average national drug acquisition cost for the month the drug was dispensed.

6.3.3. The quarterly report shall exclude drugs dispensed pursuant to 42 U.S.C. §256b.

6.3.4. A copy of the quarterly report shall be published on the PBM's publicly available website for a period of at least 24 months.

6.3.5. The quarterly report is exempt from the confidentiality provisions of section 6.5 of this rule.

6.3.6. The quarterly report required by this section shall be filed on or before May 15, August 15, November 15 and March 1 of each year; the final quarterly report being submitted with the annual report(s) required in section 6.2 of this rule.

6.4. The reports required by this section shall be filed electronically by the PBM or health benefit plan via the portal made available on the Commissioner's website.

6.5. With the exception of the quarterly report noted in section 6.3 of this rule, the information and data submitted by a PBM, health benefit plan under this section shall be considered proprietary and confidential by law and privileged, 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 Article 51, Chapter 33 of the West Virginia Code or the 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 Article 51, Chapter 33 of the West Virginia Code or the 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, 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 and Reimbursement.

8.1. If the Commissioner finds that a licensed PBM has violated any provisions of this rule or Article 51, Chapter 33 of the West Virginia Code that are applicable to the PBM, 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. This section shall not affect the right of a PBM to make a written demand for a hearing before the Commissioner pursuant to the provisions of W. Va. Code §33-2-13 or the right of any party to request judicial review of an order of the Commissioner.

8.2. If the Commissioner finds that a registered auditing entity has violated any provisions of this rule or any provisions of Article 51, Chapter 33 of the West Virginia Code, 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. This section shall not affect the right of an auditing entity to make a written demand for a hearing before the Commissioner pursuant to the provisions of W. Va. Code §33-2-13 or the right of any party to request judicial review of an order of the Commissioner.

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:

8.3.1. 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;

8.3.2. 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; and

8.3.3. This section shall not affect the right of a PBM to make a written demand for a hearing before the Commissioner pursuant to the provisions of W. Va. Code §33-2-13 or the right of any party to request judicial review of an order of the Commissioner.

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:

8.4.1. 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;

8.4.2. 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; and

8.4.3. This section shall not affect the right of an auditing entity to make a written demand for a hearing before the Commissioner pursuant to the provisions of W. Va. Code §33-2-13 or the right of any party to request judicial review of an order of the Commissioner.

8.5. The Commissioner may order reimbursement to an insured, pharmacy, or dispenser who has incurred a monetary loss as a result of a violation of Article 51, Chapter 33 of the West Virginia Code or the provisions of this rule by a PBM.

8.5.1. To seek reimbursement, an insured, pharmacy or dispenser should file a complaint with the Commissioner within one year following the actual or implied discovery of the violation.

8.5.2. The complaint should be filed on a form provided by the Commissioner and state with specificity the following:

8.5.2.a. The statutory provision, if known, which was allegedly violated;

8.5.2.b. The facts and circumstances giving rise to the alleged violation;

8.5.2.c. The name of any individual or other entity involved in the alleged violation;

8.5.2.d. Reference to specific contract language that is relevant to the alleged violation, if known; and

8.5.2.e. Any other information the commissioner may require.

8.5.3. Upon receipt of a sufficiently complete complaint, the Commissioner shall provide a copy to the PBM.

8.5.4. Within 15 working days after receiving a complaint, the PBM must advise the Commissioner in writing of the status of negotiations with the insured, pharmacy or dispenser to resolve the complaint for reimbursement unless the complaint has already been resolved. If the PBM intends to take no action to resolve the complaint, the PBM shall advise the Commissioner accordingly, in writing, and provide the Commissioner with a substantive response to the allegations in the complaint.

8.5.5. After receiving a written response to the complaint from a PBM, the Commissioner shall determine whether to:

8.5.5.a. Close the complaint and take no further action;

8.5.5.b. Order reimbursement be made from the PBM to the insured, pharmacy or dispenser; or

8.5.5.c. Set the matter for administrative hearing and further determination as to whether the allegations in the complaint are meritorious and reimbursement should be ordered.

8.5.6. An insured, pharmacy or dispenser has the right to contest the Commissioner's decision to close a complaint, without hearing, and take no further action thereon to award reimbursement. A PBM has the right to contest the Commissioner's decision to award reimbursement from the PBM to the insured, pharmacy, or dispenser without hearing thereon. This subsection shall not affect the right of a PBM, insured, pharmacy or dispenser to make a written demand for a hearing pursuant to the provisions of W. Va. Code §33-2-13 or the right of any party to request judicial review of an order of the Commissioner.

8.5.7. A hearing on a complaint shall be scheduled to be held within 90 days from the date of filing the complaint by the insured, pharmacy or dispenser unless continued by agreement of all parties or by the Commissioner for good cause. Good cause includes but is not limited to a determination by the Commissioner that additional investigation is necessary.

8.5.8. The Commissioner shall assign a time and place for a hearing and shall mail written notice of the hearing to the parties at least 10 days in advance thereof.

8.5.9. To the extent such provisions are not in conflict with this rule, hearings shall be conducted in accordance with the procedures set forth in 114CSR13.

8.5.10. The Commissioner may add interest to an award of reimbursement to an insured, pharmacy or dispenser who has incurred a monetary loss as a result of a violation of Article 51, Chapter 33 of the West Virginia Code or the provisions of this rule by a PBM. If an award of interest is made, it shall be calculated from the date the payment to the insured, pharmacy or dispenser was initially due or should have been made and shall be calculated using the U.S. Prime Rate.

§114-99-9. Consumer Choice for Pharmacy Benefits.

9.1. Applicability.

9.1.1. Section 9 of this rule applies to all PBMs and health benefit plans providing pharmaceutical services or pharmacy benefits, including but not limited to prescription drugs, to any resident of West Virginia.

9.1.2. Section 9 of this rule does not apply to any entity that has its own facility, employs or contracts with physicians, pharmacists, nurses and other health care personnel, and that dispenses prescription drugs from its own pharmacy to its employees and dependents enrolled in its health benefit plan.

9.1.3. Section 9 of this rule applies to an entity otherwise excluded under subsection 9.1.2 of this rule that contracts with an outside pharmacy or group of pharmacies to provide prescription drugs and services.

9.2. Prohibitions.

9.2.1. A PBM or health benefit plan may not:

9.2.1.a. Prohibit or limit any covered individual from selecting a pharmacy or pharmacist of his or her choice who has agreed to participate in the health benefit plan's network according to the terms offered by the health benefit plan;

9.2.1.b. Deny a pharmacy or pharmacist the right to participate as a contract provider under

the health insurance policy or health benefit plan's network if the pharmacy or pharmacist agrees to provide pharmacy services or benefits, including but not limited to prescription drugs, that meet the terms and requirements set forth by the insurer or health benefit plan under the health insurance policy or health benefit plan's network and agrees to the terms of reimbursement set forth by the insurer or health benefit plan;

9.2.1.c. Impose upon a pharmacy or pharmacist, as a condition of participation in a health benefit plan's network, any course of study, accreditation, certification, or credentialing that is inconsistent with, more stringent than, or in addition to state requirements for licensure or certification as provided for in W. Va. Code §30-5-1 *et seq.* and legislative rules of the Board of Pharmacy.

9.2.1.d. Impose upon a beneficiary of pharmacy services under a health benefit plan any co-payment, fee or condition that is not equally imposed upon all beneficiaries in the same benefit category, class or co-payment level under the health benefit plan's network when receiving services from a contract provider;

9.2.1.e. Impose a monetary advantage or penalty under a health benefit plan that would affect a beneficiary's choice among those pharmacies or pharmacists who have agreed to participate in the health benefit plan's network according to the terms offered by the insurer or health benefit plan. For purposes of this subdivision, "monetary advantage or penalty" includes higher co-payment, a reduction in reimbursement for services or the promotion of one participating pharmacy over another by these methods;

9.2.1.f. Reduce allowable reimbursement for pharmacy services to a beneficiary under a health benefit plan because the beneficiary selects a pharmacy of his or her choice, so long as that pharmacy has enrolled as a network provider with the health benefit plan under the terms offered to all pharmacies in the plan coverage area;

9.2.1.g. Prohibit or otherwise limit a beneficiary's access to prescription drugs from a pharmacy or pharmacist enrolled with the health benefit plan under the terms offered to all pharmacies in the plan coverage area by unreasonably designating the covered prescription drug as a specialty drug. Any beneficiary or pharmacy impacted by an alleged violation of this subsection may file a complaint with the Commissioner, who shall, in consultation with the West Virginia Board of Pharmacy, make a determination as to whether the covered prescription drug meets the definition of a specialty drug;

9.2.1.h. Limit a beneficiary's access to specialty drugs;

9.2.1.i. Require a beneficiary, as a condition of payment or reimbursement, to purchase pharmacy services, including but not limited to prescription drugs, exclusively through a mail-order pharmacy; or

9.2.1.j. Impose upon a beneficiary any co-payment, amount of reimbursement, restriction upon the number of days of a drug supply for which reimbursement will be allowed, or any other payment or condition relating to purchasing pharmacy services from any pharmacy, including but not limited to prescription drugs, that is more costly or more restrictive to the beneficiary than that which would be imposed upon the beneficiary if such services were purchased from a mail-order pharmacy or any other pharmacy that is willing to provide the same services or products for the same cost and copayment as any mail-order service.

9.3. Notification.

9.3.1. If a health benefit plan restricts pharmacy participation through a network, the health benefit plan shall notify, in writing, all pharmacies within the geographic coverage area of the health benefit plan and offer those pharmacies the opportunity to participate in the health benefit plan's network. Notification

shall be provided at least 60 days prior to the effective date of the health benefit plan, or, if the plan is in effect at the time this rule becomes effective, at least 60 days prior to the plan's renewal.

9.3.2. All pharmacies in the coverage area shall be eligible to participate in the network under identical reimbursement terms for providing pharmacy services, including prescription drugs.

9.3.3. Participating pharmacies shall be entitled to 30 business days effective date notice for any subsequent contract amendment or provider manual change by a health benefit plan or a PBM.

9.3.4. A health benefit plan shall inform the beneficiaries of the plan of the names and locations of pharmacies that are participating in the health benefit plan's network. Notification to beneficiaries should be provided through reasonable means, on a timely basis and at regular intervals. For purposes of this subsection, "reasonable means" may include written or electronic communications to beneficiaries by a health benefit plan, as well as publication on the health benefit plan's publicly available website. For purposes of this subsection, "regular intervals" should include notification to beneficiaries during a health benefit plan's open enrollment period and at least on a quarterly basis.

9.3.5. Participating pharmacies shall be entitled to announce their participation in a health benefit plan's network to their customers through a means acceptable to the pharmacy and the health benefit plan.

9.3.6. The notification provisions of this section shall not apply when an individual or group is enrolled in a health benefit plan, but when the health benefit plan enters a new county of the state.

9.4. Injunctive relief.

9.4.1. Any covered individual or pharmacy injured by a violation of section 9 of this rule may maintain a cause of action against a PBM or health benefit plan to enjoin the continuance of any such violation by filing a complaint in the Circuit Court of Kanawha County, or in any county in which the PBM or health benefit plan has committed the violation.

9.4.2. The Commissioner does not need to be made party to any complaint for injunctive relief filed against a PBM or health benefit plan, but may intervene in the lawsuit if he or she deems intervention necessary to enforce the provisions of this rule or of Article 51, Chapter 33 of the West Virginia Code.

9.4.3. The covered individual or pharmacy filing for injunctive relief shall provide a courtesy copy of the lawsuit to the Commissioner in order for the Commissioner to make a decision on intervention and to ensure administrative enforcement of this rule or of Article 51, Chapter 33 of the West Virginia Code.

9.4.4. The filing of an injunction against a health benefit plan for alleged violations of Article 51, Chapter 33 of the West Virginia Code or this rule does not alone affect any license or Certificate of Authority held by an insurer otherwise duly licensed in this state without separate regulatory action undertaken by the Commissioner.

§114-99-10. Specialty Drug Complaints.

10.1. A covered individual, beneficiary, pharmacy or pharmacist may file a specialty drug complaint with the Commissioner alleging that a PBM or health benefit plan has prohibited or otherwise limited access to a covered prescription drug from a pharmacy or pharmacist enrolled with the health benefit plan by unreasonably designating the drug as a "specialty drug," as that term is defined in W. Va. Code §33-51-3 and section 2.24 of this rule.

10.2. The specialty drug complaint should be filed on a form provided by the Commissioner and state with specificity the following:

10.2.1. The name and dosage of the prescription drug that has been designated as a specialty drug;

10.2.2. The name of the PBM;

10.2.3. The name of the health benefit plan or insurer, if known;

10.2.4. The name and group number of the health benefit plan, specifically including any separate group number for the health benefit plan's pharmacy plan;

10.2.5. The name of the covered individual or beneficiary of the health benefit plan, and the covered individual's or beneficiary's plan identification number;

10.2.6. The RxBIN for the health benefit plan or pharmacy plan;

10.2.7. The name of any individual or other entity involved in the alleged unreasonable designation of the drug as a specialty drug; and

10.2.8. Any other information the Commissioner may require.

10.3. Upon receipt of a sufficiently complete specialty drug complaint, the Commissioner shall provide a copy to the PBM and health benefit plan. The PBM shall have 15 working days to respond. A separate response may also be required of the health benefit plan. The Commissioner will advise a health benefit plan if it is required to respond separately from the PBM. A health benefit plan required to respond shall also have 15 working days to respond.

10.4. If the specialty drug complaint is resolved before the time period for a response expires, the PBM and/or health benefit plan must advise the Commissioner in writing that the specialty drug complaint has been resolved and specifically advise the Commissioner of what steps or actions were taken to resolve the complaint. If the PBM and/or health benefit plan intends to take no action to resolve the complaint, the PBM and/or health benefit plan shall advise the Commissioner accordingly, in writing, and provide the Commissioner with a substantive response to the allegations in the specialty drug complaint. Nothing in this section in any way limits the authority of the Commissioner to investigate and take action against a PBM which the Commissioner has reason to believe has unreasonably designated a covered prescription drug as a specialty drug or limited a beneficiary's access to a specialty drug in violation of the provisions of W.Va. Code §33-51-11(a)(7) or (8) or subdivisions 9.2.1.g or 9.2.1.h of this rule, but thereafter has consistently resolved each specialty drug complaint prior to the final resolution thereof by the Commissioner in accordance with section 10.8 of this rule.

10.5. If the specialty drug complaint remains unresolved, the Commissioner shall send a copy of the specialty drug complaint, and the response(s) thereto, to the Board of Pharmacy to make a determination as to whether the covered prescription drug meets the definition of specialty drug, as that term is defined in W. Va. Code §33-51-3 and section 2.24 of this rule.

10.6. The West Virginia Board of Pharmacy will review the complaint, and the response(s) thereto, and may refer the matter to a committee for determination as to whether there are valid clinical and/or therapeutical reasons for the covered prescription drug to be designated as a specialty drug. The Board of Pharmacy will consider whether the covered prescription drug is used to treat rare or chronic and complex medical conditions, and whether it requires special handling, administration, provider care coordination, or patient education that cannot be provided otherwise by a non-specialty pharmacy.

10.7. The Commissioner may also obtain additional information from the PBM and/or health benefit plan regarding the circumstances surrounding the designation of the covered prescription drug as a specialty

drug and whether access to a covered prescription drug is being limited in violation of W. Va. Code §33-51-11(7) and (8). Additional information may include, but is not limited to, an assessment of network adequacy and the availability or convenience of access for West Virginia residents to obtain the covered prescription drug, the number of mail-order pharmacies and physical pharmacies located in West Virginia that are permitted to dispense the covered prescription drug, the special handling, administration and/or provider care options or necessities that the PBM's specialty pharmacies offer that is not otherwise available at non-specialty pharmacies, and the circumstances surrounding the designation of the covered prescription drug as a specialty drug.

10.8. Upon completion of the review by the Commissioner and the Board of Pharmacy, the Commissioner will, in consultation with the Board of Pharmacy, make a determination as to whether the covered prescription drug meets the definition of specialty drug and whether a beneficiary's access is being prohibited or limited in violation of W. Va. Code §33-51-11(7) and (8). The Commissioner may then undertake the following actions:

10.8.1. Close the specialty drug complaint and take no further action by finding that the covered prescription drug meets the definition of specialty drug and that a beneficiary's access is not being prohibited or limited in violation of W. Va. Code §33-51-11(7) and (8);

10.8.2. Find that the subject prescription drug does not meet the definition of specialty drug and that a beneficiary's access is being prohibited or limited in violation of W. Va. Code §33-51-11(7) and (8), and further order that the covered prescription drug be removed from the PBM and/or health benefit plan's specialty drug list; or

10.8.3. Set the matter for administrative hearing and further determination as to whether the covered prescription drug meets the definition of specialty drug and whether a beneficiary's access is being prohibited or limited in violation of W. Va. Code §33-51-11(7) and (8).

10.9. Any party to an administrative proceeding regarding a specialty drug complaint has the right to contest the decision made pursuant to section 10.8 of this rule. If a decision is made pursuant to subsection 10.8.1 or 10.8.2 of this rule without hearing, any party may make a written demand for a hearing pursuant to the provisions of W. Va. Code §33-2-13. A hearing on a specialty drug complaint shall be scheduled to be held within 45 days from the date of the hearing request, unless continued by agreement of all parties or by the Commissioner and Board of Pharmacy for good cause. Good cause includes, but is not limited to, a determination by the Commissioner and Board of Pharmacy that additional investigation is necessary.

10.10. The Commissioner shall assign a time and place for a hearing and shall mail written notice of the hearing to the parties at least 10 days in advance thereof.

10.11. To the extent such provisions are not in conflict with this rule, hearings shall be conducted in accordance with the procedures set forth in 114CSR13.

10.12. An order entered by the Commissioner and Board of Pharmacy after a hearing conducted pursuant to subsection 10.8.3 or section 10.9 of this rule, or an order entered denying a party's request for a hearing, is subject to judicial review.