BEFORE ALLAN L. MCVEY, INSURANCE COMMISSIONER
OF THE STATE OF WEST VIRGINIA

ASHLEY HOUVOURAS and
VALLEY HEALTH PHARMACY,
Complainant,

v. Administrative Proceeding No. 24-IC-175889

PRIME THERAPEUTICS, LLC,
Respondent.

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER ASSESSING PENALTY

FINDINGS OF FACT

1. Allan L. McVey is the Insurance Commissioner of the State of West Virginia ("Commissioner") and is charged with enforcing the provisions of Chapter 33 of the West Virginia Code.

2. Prime Therapeutics, LLC (hereafter, "Prime"), a Delaware domiciled pharmacy benefit manager ("PBM"), is licensed to act as a PBM in the State of West Virginia, pursuant to W.Va. Code § 33-51-8.

3. On March 27, 2024, Ashley Hourvouras, on behalf of Valley Health Pharmacy (herein after referred to collectively as the "Complainant"), filed a complaint alleging that Prime denied a claim for a customer to fill a prescription for Epclusa (Sofosbuvir 400mg/velpatasvir 100mg tablets) at the Valley Health Pharmacy because Epclusa was designated as a specialty drug. The Complainant stated that, per its communication with Prime, the health benefit plan required prescriptions for specialty drugs to be filled at a specific pharmacy and, therefore, that prescription was unable to be filled at Valley Health Pharmacy.[1]

[1]Valley Health is a Federally Qualified Health Center ("FQHC") with 40 healthcare facilities in WV, including seven (7) pharmacies that participate in the federal 340B discount drug

4. The Commissioner forwarded the complaint to Prime for a response.

5. Prime filed a response to the complaint. Prime stated that Epclusa "is a specialty drug which is used to treat long-term and complex health issues."[2] Prime further stated that the self-funded health benefit plan from which the customer derived their prescription drug benefits required members "to fill a select list of non-limited distribution specialty medications" at a specific pharmacy. Finally, Prime stated that it processes claims based on the benefit specifications and accurately rejected the claim because Epclusa is considered a specialty drug and, per the plan, could not be filled at Valley Health Pharmacy.

6. The Commissioner reviewed Prime's response and found that additional information was required as permitted by W.Va. Code St. R. §114-99-1, *et seq*. The Commissioner sent a request for additional information to Prime, specifically requesting that the company "advise what clinical methodology you applied to list this as a specialty drug on your formulary in accordance with the definition of specialty drug under [W.Va. Code] 33-51-3."

7. Prime filed a response to the Commissioner's request for additional information. Prime set forth the following response:

> Formularies are determined by the plan and are part of plan benefit design. As part of pharmacy benefit management services, Prime does develop a list of recommended specialty drugs. Drugs are recommended as specialty drugs based on the following criteria:
> 1. High Cost / High Complexity (must meet at least 1 of the following):
> a. Cost > $950 per 30-day supply based on WAC prices (CMS specialty-tier cost threshold)
> b. Biotechnology products
> c. Orphan drug
> d. Drugs treating complex medical conditions

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program. *See* www.valleyhealth.org. Valley Health pharmacies regularly have Epclusa in stock and available for distribution.

[2]Epclusa is an antiviral treatment for individuals with for chronic Hepatitis C.

e. Limited distribution by the manufacturer and not available at retail pharmacies

2. High Touch (must meet at least 1 of the following):
a. Subject to restricted distribution by the US FDA (e.g., REMS program)
b. Specialty provider coordination
c. Special storage, handling/shipping requirements, and/or administration
d. Patient education/training, management, monitoring, and reporting that cannot be provided by a retail pharmacy
Prime's client, in this case Capital Blue Cross, which is the third-party administrator for this Pennsylvania-based employer plan, may add or remove drugs from the specialty drug list for the plan. Prime processes claims based on the plan approved list, according to the benefit specifications.

8. Prime later notified the Commissioner that it planned to update its specialty drug criteria to remove cost as a consideration and require the drug to have one of the remaining eight possible criteria to be considered a specialty drug.

9. Pursuant to W.Va. Code St. R. §114-99-10, the Commissioner referred the complaint to the West Virginia Board of Pharmacy ("WV BOP") to make a determination as to whether Epclusa met the definition of specialty drug as set forth in W.Va. Code §33-51-3 and W.Va. Code St. R. §114-99-2.24.

10. The WV BOP opined that Epclusa (Sofosbuvir 400mg/velpatasvir 100mg tablets) did not meet the statutory definition of a specialty drug.

11. In a letter addressed to the Commissioner (attached), the WV BOP acknowledged that Epclusa is used to treat chronic Hepatitis C.

12. The WV BOP considered that Epclusa was administered through either oral tablets or oral pellets and was required to be dispensed in the original container.

13. The WV BOP determined that the handling and administration of both dosage forms of Epclusa was within the scope of a non-specialty pharmacy or pharmacist.

14. Further, the WV BOP considered that Epclusa did not require a special registration program or care coordination, and, therefore, concluded that there was no special care coordination that could not be provided by a non-specialty pharmacy or pharmacist.

15. Finally, the WV BOP considered that Epclusa's side effects and drug interactions were common and not beyond the knowledge of a non-specialty pharmacist.

16. Accordingly, the WV BOP found that Epclusa did not require patient education that could not be provided by a non-specialty pharmacy or pharmacist.

CONCLUSIONS OF LAW

1. The Commissioner has jurisdiction over the subject matter and the parties to this proceeding pursuant to Chapter 33 of the West Virginia Code.

2. This proceeding is pursuant to and in accordance with W.Va. Code §§ 33-51-1, *et seq*, and W.Va. Code R. § 114-99-1, *et seq*. *See* W.Va. Code § 33-51-10 (granting the Commissioner authority to propose rules governing PBMs, including rules of procedure for specialty drug complaints).

3. Pursuant to W.Va. Code § 33-51-11(a)(7), a pharmacy benefit manager may not

> [p]rohibit 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 Insurance 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.

4. Further, W.Va. Code § 33-51-11(a)(8) provides that a pharmacy benefit manager may not "[l]imit a beneficiary's access to specialty drugs."

5. W.Va. Code § 33-51-3 defines "specialty drug" as "a drug used to treat chronic and complex, or rare 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."

6. In accordance with W.Va. Code R. § 114-99-10.1, individuals, beneficiaries, pharmacies and pharmacists may file specialty drug complaints 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 in the health benefit plan by unreasonably designating the drug as a "specialty drug."

7. Upon receipt of the complaint and a response from the PBM, 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." *See* W.Va. Code R. § 114-99-10.5.

8. Finally, 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 the beneficiary's access is being prohibited or limited in violation of W.Va. Code § 33-51-11(7) and (8)." W.Va. Code R. § 114-99-10.8

9. The Commissioner may then undertake one of 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. In this case, in conjunction with the Board of Pharmacy, the Commissioner has determined that Epclusa is not a specialty drug pursuant to the statutory definition set forth in W.Va. Code § 33-51-3.

11. Although Epclusa treats a chronic disease, it does not meet the statutory definition for a specialty drug because it does not require special handling or administration, does not require a provider care coordination component, and/or does not require special patient education.

12. Further, Prime's classification of Epclusa as a specialty drug has limited the beneficiary's access to this drug in violation of W.Va. Code § 33-51-11(7) and (8) because the beneficiary could not fill the prescription at the pharmacy of their choice.

13. Pursuant to W.Va. Code § 114-99-8.1,

> 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.

14. As Prime has classified Epclusa as a specialty drug when it does not meet the statutory definition to be classified as such, Prime has violated W.Va. Code § 33-51-11(7) and (8).

ORDER

It is accordingly ORDERED as follows:

1. It is ORDERED that Epclusa does not meet the statutory definition of specialty drug in West Virginia.

2. It is ORDERED that Prime will CEASE AND DESIST from failing to comply with the Statutes, Rules and Regulations of the State of West Virginia as set forth above.

3. Further, it is ORDERED that Prime shall ensure compliance with the West Virginia Code and the Code of State Rules.

4. Finally, it is ORDERED that Prime shall pay an administrative penalty to the State of West Virginia in the amount of Ten Thousand Dollars ($10,000.00) for noncompliance with the West Virginia Code as described herein. The payment of this administrative penalty is in lieu of any other regulatory penalty or remedy and is due within thirty days of receipt of this Order.

5. Upon the failure of Prime to pay the penalty set forth above as required, the Commissioner may take other action against Prime, pursuant to W.Va. Code R. § 114-99-8.1, including suspension or revocation of Prime's PBM license in West Virginia.

6. W.Va. Code R. § 114-99-10.9 states, "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."

ENTERED this 1ST day of November 2024.

Allan L. McVey
CPCU, ARM, AAI, AAM, AIS
Insurance Commissioner
State of West Virginia

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September 30, 2024

Michael Malone, Associate General Counsel
Health Policy Division
Offices of the Insurance Commissioner
900 Pennsylvania Avenue
Charleston, WV 25302

Dear Mr. Malone:

As provided for in W.Va. Code §33-51-11(a)(7) and WV §114 CSR 99-9.2.1. in relation to the consultation with the WV Board of Pharmacy regarding the determination as to whether the covered drug Epclusa® (sofosbuvir /velpatasvir) meets the definition of a "specialty drug." WV defines a specialty drug as a drug used to treat chronic and complex, or rare 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.

The WV Board of Pharmacy evaluated the sofosbuvir/velpatasvir in comparison with each individual section of the definition as stated in W.Va. Code §33-51-11(a)(7). The Epclusa® is a drug used to a treat chronic and complex or rare medical conditions as it is indicated for the treatment of adults and pediatric patients three years of age and older with chronic Hepatitis C virus genotype 1, 2, 3, 4, 5, or 6 infection (1) without cirrhosis or with compensated cirrhosis or (2) with decompensated cirrhosis for use in combination with ribavirin.

Epclusa® (sofosbuvir/velpatasvir) was then examined to determine considerations for special handling or administration, provider care coordination or patient education that could not be provided by a non-specialty pharmacy or pharmacist. Epclusa® is available as two dosage forms: oral tablets - 400 mg of sofosbuvir and 100 mg of velpatasvir; 200 mg of sofosbuvir and 50 mg of velpatasvir; and Oral pellets - 200 mg of sofosbuvir and 50 mg of velpatasvir; 150 mg of sofosbuvir and 37.5 mg of velpatasvir. The oral tablets are to be taken by mouth by the patient with or without food once daily. The oral pellets can be taken directly by mouth or sprinkled on non-acidic food like pudding, chocolate syrup, or ice cream to increase the palatability. It is to be dispensed in its original container. The handling and administration of both dosage forms of Epclusa® are well within the scope of a non-specialty pharmacy or pharmacist.

Some medications require special care coordination. This could include enrollment in programs with the manufacturer or the Food and Drug Administration to monitor the distribution and use of the medication. Other medications may require confirmation of certain lab work to be performed and the results attached to the prescription before the pharmacist is able to dispense the medication. None of these examples are required by Epclusa®. There is no special care coordination required that could not be provided by a non-specialty pharmacy or pharmacist.

Finally, the Board examined patient counseling required for the Epclusa®. Headache and tiredness are the most common side effects. Additionally, hepatitis B virus reactivation and bradycardia are the most serious side effects that a pharmacist would provide during patient education. While the medication does have certain drug interactions, these are commonplace and a professional expectation that a non-specialty pharmacist would work with prescribers to manage and counsel on every day. Therefore, there is no patient counseling with this medication education that cannot be provided by a non-specialty pharmacy or pharmacist.

Through thorough assessment of the medication at issue, the WV Board of Pharmacy has determined that the drug Epclusa® (sofosbuvir/velpatasvir) **does not** meet the definition provided in W.Va. Code §33-54 as a "specialty drug."

Thank you for the consultation and we look forward to being of assistance in the future.

Professionally,

Krista D. Capehart, PharmD, MS, BCACP, FAPhA
Director of Professional and Regulatory Affairs
WV Board of Pharmacy