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

*In the Matter of*:

**CAREMARK, LLC**
**CAREMARKPCS HEALTH, LLC**

Administrative Proceeding No. 25-IC-179343

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER ADOPTING REPORT OF MARKET CONDUCT EXAMINATION

NOW COMES, Allan L. McVey, Insurance Commissioner of the State of West Virginia (hereinafter, "Commissioner"), who, after consideration of the *Report of Market Conduct Examination* (hereinafter, the "*Examination Report*") of Caremark, LLC and CaremarkPCS Health, LLC (hereinafter, "Caremark") for the examination period ending December 31, 2023, made the following findings of fact and conclusions of law and order.

FINDINGS OF FACT

1. The market conduct examination was conducted pursuant to W.Va. Code §§ 33-2-9, 33-51-8, 33-51-10, and W.Va. Code R. § 114-99-7. The examination focused on Caremark's compliance with West Virginia statutes and rules related to the company's operation as a pharmacy benefits manager ("PBM") in West Virginia. The examination was conducted by examiners appointed by the Commissioner and covered the period of January 1, 2022 through December 31, 2023.

2. On or about December 18, 2024, the examiner filed with the Commissioner, pursuant to W. Va. Code §33-2-9, the *Examination Report*.

3. A true copy of the *Examination Report* was provided to Caremark and Caremark was notified, pursuant to W.Va. Code § 33-2-9(j)(2), that it had twenty (20) days after receipt of the *Examination Report* to file a submission or rebuttals with the Commissioner. Caremark timely filed a lengthy submission/rebuttal to the *Examination Report*. On February 25, 2025 at 4:49 PM Caremark filed a supplemental response to the *Examination Report*.

4. As set forth in the *Examination Report*, the examination focused on the methods used by Caremark to manage its operations for each of the areas examined, including whether and how Caremark complies with federal and state law regarding its operation as a PBM.

5. The examination focused on the following: company operations and management, network adequacy, provider/pharmacy relations, PBM pricing, pharmacy audits, complaint handling, consumer appeals, pharmacy claims, drug utilization review, and formulary design and drug placement.

6. The Commissioner reviewed the *Examination Report* and considered Caremark's submissions/rebuttals, including the supplemental response, prior to entering this Order.

## CONCLUSIONS OF LAW

1. The Commissioner has jurisdiction over the subject matter and the parties to this proceeding.

2. This proceeding is conducted pursuant to and in accordance with W. Va. Code § 33-2-9.

3. The Commissioner is charged with the responsibility of verifying Caremark's continued compliance with West Virginia law. Caremark was found to be non-compliant with certain provisions of West Virginia law as detailed in the attached *Examination Report*.

4. Although Caremark was found to be non-compliant with certain provisions of West Virginia law as detailed in the *Examination Report*, the Commissioner is not adopting Findings 8, 9, 10, 11, 12, 13, 14, 15, 16, and 25 of the *Examination Report*, as violations against Caremark. The Commissioner does note that Findings 8, 9, 10, 11, 12, 13, 14, 15, 16, and 25 of the *Examination Report* appear to show violations of West Virginia law and the Commissioner reserves the right to take administrative action against the insurer or insurers responsible for the violations found in Findings 8, 9, 10, 11, 12, 13, 14, 15, 16, and 25 of the *Examination Report*.

5. As detailed in the *Examination Report*, Caremark failed to comply with certain provisions of West Virginia law. A summary of the applicable violations is set forth below.

- PBM Pricing: Caremark did not comply with W.Va. Code § 33-51-9(f) when it reimbursed itself or an affiliate pharmacy more for a prescription drug than other pharmacies within the PBM network. Caremark did not comply with W.Va. Code § 33-51-9(e) when it failed to reimburse pharmacies at least the national average drug acquisition cost (NADAC) plus a professional dispensing fee of $10.49, or the wholesale acquisition cost plus a professional dispensing fee of $10.49 if NADAC was not available at the time a drug was administered or dispensed. Caremark did not comply with W.Va. Code § 33-51-9(k) when it failed to pass through administrative fees associated with manufacturer rebates to a health plan and its members at the point of sale. Further, Caremark failed to properly apply the definition of "rebate" when withholding rebate payments and fees from the health plan.
- Pharmacy Audits: Caremark did not comply with W.Va. Code § 33-51-4(a)(14) because it used more stringent criteria than required by the statute for what is considered acceptable records or documents for prescriptions during an audit. Caremark did not comply with W.Va. Code § 33-51-4(a)(9)(B) by exceeding the maximum quantity of prescriptions covered in a pharmacy audit. Further, contracts and communications delivered to providers

described fees associated with the cost of pharmacy audits in excess of those allowed by W.Va. Code § 33-51-4(a)(13) and Caremark recouped funds from pharmacy claims in excess of actual financial harm associated with the dispensed product.

- Company operations: Caremark did not comply with W.Va. Code § 33-2-9 when it failed to provide unredacted and/or timely responses to the Commissioner's examiners which resulted in delays and inefficiencies in the examination and provided inaccurate and contradictory data on multiple occasions. Caremark failed to comply with W.Va. Code §§ 33-51-11(a)(5), 33-51-11(a)(10) and 33-51-11(e) when it imposed a monetary advantage or penalty under a health benefit plan that affected the member's choice among pharmacies. Further, Caremark did not comply with W.Va. Code § 33-51-11(a)(10) when it prohibited members from filling 90-day supplies of prescription drugs from a retail pharmacy and inappropriately steered members to a mail order pharmacy.
- Formulary and drug placement: Caremark did not comply with W.Va. Code §§ 33-51-11(a)(7) and 33-51-11(a)(8) when it limited access to prescription medications by unreasonably designating 65 covered prescription medications as specialty medications.
- Pharmacy/Provider relations: Caremark did not comply with W.Va. Code § 33-51-11(a)(3) when it required independent pharmacies to pay a $1,200 pharmacy enrollment application fee in order to participate in a health benefit plan network.

## ORDER

Pursuant to W.Va. Code § 33-2-9(j)(3)(A), following the review of the *Examination Report*, the examination work papers, and Caremark's response thereto, it is **ORDERED** as follows:

1. The referenced and attached *Examination Report* is hereby **ADOPTED** and **APPROVED** with the following modification; Findings 8, 9, 10, 11, 12, 13, 14, 15, 16, and 25 shall not be found to be violations against Caremark, but rather, are Findings that are applicable to the relevant insurer or insurers with whom Caremark contracted to provide PBM services, and with this modification, the *Examination Report* is incorporated herein and made a part hereof. The Commissioner does reserve the right to take administrative action against the insurer or insurers responsible for the violations found in Findings 8, 9, 10, 11, 12, 13, 14, 15, 16, and 25 of the *Examination Report.*

2. Caremark shall comply with the recommendations contained in the *Examination Report* regarding each Finding that was adopted by this Order.

3. Caremark shall continue to monitor its compliance with applicable West Virginia law.

4. Caremark shall specifically cure the violations and deficiencies identified in the *Examination Report* so as to bring itself into compliance and conformity with West Virginia law, as set forth hereinabove, to the extent such has not already been completed and/or accomplished.

5. Pursuant to W.Va. Code § 33-2-9(*l*)(3) and W.Va. Code R. § 114-99-8.1, additional regulatory action against Caremark will be taken by the Commissioner based upon the findings in the *Examination Report.*

6. Pursuant to W.Va. Code § 33-2-9(j)(4) within 30 days of the date this Order is entered, Caremark shall file affidavits executed by each of its directors stating under oath that they have received a copy of the adopted *Examination Report* and this Order.

7. Pursuant to W.Va. Code § 33-2-9(j)(4), this Order shall be considered a final administrative decision and may be appealed pursuant to W.Va. Code § 33-2-14. Pursuant to W.Va. Code § 51-11-4(b)(4), Orders of an agency entered after June 30, 2022, heretofore appealable to the Circuit Court of Kanawha County by code (i.e., W.Va. Code § 33-2-14), are appealable to the Intermediate Court of Appeals.

Entered this 26th day of February, 2025.

Allan L. McVey
CPCU, ARM, AAI, AAM, AIS
Insurance Commissioner

# WEST VIRGINIA OFFICES OF THE INSURANCE COMMISSIONER

# REPORT OF MARKET CONDUCT EXAMINATION

# OF

# CAREMARK, LLC
# CAREMARKPCS HEALTH, LLC

# AS OF SEPTEMBER 19, 2024

# MARKET CONDUCT EXAMINATION REPORT

| | |
|---|---|
| DATE OF EXAMINATION: | June 22, 2023, through September 19, 2024 |
| EXAMINATION OF: | CAREMARK, LLC<br>CAREMARKPCS HEALTH, LLC |
| LOCATION: | 9501 E. Shea Blvd., MC024<br>Scottsdale, AZ 85260 |
| PERIOD COVERED: | January 1, 2022, to December 31, 2023 |
| EXAMINERS: | June Coleman<br>George Lentini<br>Donna Lee Williams<br>Katie Dublinski<br>Wyatt Qualls<br>Tony Taylor<br>Steven Gloc<br>Calista Williams<br>Tyler Young<br>Trevor Strenchock<br>Matthew Sankey<br>Amanda Brandis, Examiner-in-Charge<br>Shelly Schuman, Supervisory Insurance Examiner |

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SALUTATION

September 19, 2024

The Honorable Allan L. McVey, CPCU, ARM, AAI, AAM, AIS
West Virginia Insurance Commissioner
900 Pennsylvania Ave.
Charleston, West Virginia 25302

Pursuant to the authority vested in the West Virginia Offices of the Insurance Commissioner, through W. Va. Code §§33-2-9 and 33-51-8, and W. Va. Code R. §114-99-7, a market conduct examination has been made of:

Caremark, LLC
CaremarkPCS Health, LLC

9501 E. Shea Blvd., MC024
Scottsdale, AZ 85260

The following examination report is respectfully submitted.

## I. IMPACTS

### A. FAILURE TO FACILITATE/LACK OF COOPERATION

1. Vertical integration has allowed the large healthcare companies to control many steps of the pharmaceutical supply chain. The pharmacy benefits manager ("PBM") has ownership or affiliation through its parent company with health plans, rebate aggregators/group purchasing organizations ("GPO"), mail order pharmacies, specialty pharmacies, retail pharmacies, and wellness programs. The complexity of these models has created a challenge for regulatory authorities attempting to understand and employ regulatory oversight. Caremark, LLC and CaremarkPCS Health, LLC ("Company") obstructed access to books and records and utilized delays, redactions, mandatory disclosure of materials in an onsite setting, refusal to provide books and records in an electronic form and other evasive measures (i.e. vague and partial responses) throughout the examination.

2. The data provided by the Company was often incomplete, inaccurate, or absent. The Company would often deflect and often claim the questions were out of scope for the examination. As a result of inaccurate data, the West Virginia Offices of the Insurance Commissioner ("WVOIC") and the examiners escalated the priority of all information requests to interrogatories which required the Company and its legal representative to sign off on all responses and provide notarization when returning information to the examination team.

3. The Company was required to submit pharmacy claims data multiple times due to inaccuracies. The examiners questioned the integrity of data being provided throughout the examination due to the Company's inability to initially provide accurate information.

### B. CONSUMER RELATED IMPACT

1. The Company provided educational materials to the health plan for distribution to members. The documents outlined that members must utilize select pharmacies in order to obtain coverage or incentives for maintenance medications. These educational materials are not compliant with the West Virginia ("W. Va.") code and may not be made to distribute to members enrolled in health plans in the state of W. Va.

2. The Company provided pharmacy benefits to members that did not allow a prescription to be filled at a retail pharmacy for more than a 30-day supply. If the member wanted to fill a prescription for a higher quantity of medication, they would be directed to the Company owned mail order facility. The Company coded specific health plans to not allow members to fill 90-day supplies at retail pharmacies. One of the plans affected by the coding error was the student health plan provided to the West Virginia University enrollees. The coding error was recognized by the Company in 2024, but not communicated to the WVOIC.

3. Formulary changes were made prior to the start of plan year 2022. One of the main formulary changes made by CVS Caremark was the exclusion of Eliquis, a blood thinner. Members that were stable on Eliquis were denied coverage and were told to try and fail Xarelto prior to approval of Eliquis. Although the patient was stable, and the physician determined medical necessity via prior authorization, the Company denied coverage. The

Company's Pharmacy and Therapeutics ("P & T") Committee discussed safety concerns when switching patients to Xarelto. They also mentioned concerns of increased bleeding risks with the use of Xarelto versus Eliquis. The Company did not appropriately approve step therapy processes and ignored the safety of patients on lifesaving medication. Furthermore, the Journal of the American Medical Association published an article in 2021 that confirms the committee members' concerns of an increased bleeding risk with the use of Xarelto versus Eliquis.

4. The Company reimbursed itself more for prescription drugs than other pharmacies in the state of W. Va. Because of this, consumers had higher copays and/or costs when utilizing the Company's mail order pharmacy facilities to fill prescription drugs.

5. The Company limited access to substance use disorder medications through prospective utilization management requirements. The use of step therapy, prior authorizations, and quantity limits placed a barrier on treatment of members with a substance use disorder.

6. The Company withheld administrative fees from the rebates passed through to the health plan/member during the examination period. The administrative fee was equal to 4% in most cases. The Company retained $47,000 in administrative fees from rebates in the second quarter of 2022 and $43,000 in the second quarter of 2023. All discounts and fees indirectly and directly collected are considered a rebate and must be passed through to the health plan or consumer to help lower drug costs and/or premiums.

7. The Company imposed quantity limitations on mental health and substance use disorder medications that resulted in mental health parity violations. The quantity limitations implemented within a policy on members' prescription drug benefits placed a barrier to access on quantities of specific medications used to treat substance use or mental health disorders.

C. PHARMACY RELATED IMPACTS

1. The pharmacies in W. Va. were not paid according to the W. Va. Code §33-51-9. The state mandate is to reimburse pharmacies at the national average drug acquisition cost ("NADAC") plus ("+") a professional dispensing fee of $10.49, or the wholesale acquisition cost ("WAC") when NADAC is unavailable. The Company failed to pay the pharmacies at the mandated pricing which led to the under reimbursement of prescription drugs.

2. The Company required independent pharmacies to pay a $1200 dollar pharmacy enrollment application fee in order to participate in a health benefit plan. The fee is assessed and non-refundable regardless of denial or approval of the application. The application fee imposed on independent pharmacies is more stringent than legislative rules of the Board of Pharmacy and not in compliance with W. Va. Code §33-51-11(a)(3). Additionally, an individual chain pharmacy was not required to pay the application fee prior to joining the network.

3. The Company implemented pharmacy audit procedures that are not in compliance with W. Va. Code §33-51-4. The W. Va. code outlines specific procedures that may not be more

stringent when conducting a pharmacy audit. Below are key areas in which the Company overstepped its authority during a pharmacy audit.

a. The Company did not allow specific documentation for prescription drug claims to be used during a pharmacy audit. The documentation criteria did not align with the W. Va. code and imposed restrictive guidelines on pharmacies during an audit.
b. The Company was found reviewing prescriptions in excess of the state allowable maximum amount. By reviewing more prescriptions than allowable, the Company placed an additional burden on an independent pharmacy.
c. The Company provided communications to the pharmacy during an audit that utilized language that was not allowed. The language discussed fees associated with pharmacy audits in excess of what is permitted in the W. Va. code.
d. The Company sent communications to pharmacies that failed to follow the timelines allowed to recoup and withhold funds as a result of a pharmacy audit. After conducting a pharmacy audit, the Company required a pharmacy to sign and agree to the withholding of any amounts determined to be overpayments. The pharmacy must be able to utilize an appeal process before any funds are withheld. The language used by the Company is predatory, and the timeline is not compliant with the W. Va. code.

4. The Company recouped funds as a result of pharmacy audits that were in excess of the actual financial harm associated with the dispensed product. The Company overstepped its authority when conducting pharmacy audits and recouped funds from pharmacies on high priced medications. The Company utilized proprietary software to target mistakes made when submitting claims for high priced prescription drugs. The Company used these mistakes as areas of concern during the audit process. Some of the prescription errors that resulted in recoupments had no financial harm to the consumer or the Company and is not compliant with the W. Va. code.

5. The Company did not allow a member to fill a prescription at a retail pharmacy for more than a 30-day supply. If the member wanted to fill a prescription for a higher quantity of medication, they would be directed to the Company owned mail order facility. The Company coded specific health plans to not allow retail pharmacies to fill 90-day supplies of prescription drugs. One of the plans affected by the coding error was the student health plan provided to the West Virginia University enrollees. The coding error was recognized by the Company in 2024, but not communicated to the WVOIC.

6. The Company collected transaction fees from pharmacies in W. Va. The Company indicated this practice ended after January 2022. The pharmacy was charged 0.30 per transaction and multiplied by how many times the claim was reversed and resubmitted. The transaction fee varied based on pharmacy contracts. Larger transaction fees were charged to smaller pharmacies. The larger chain pharmacies were able to negotiate smaller transaction fees with the Company. In some instances, as much as a 100% increase in transaction fees for smaller independent pharmacies (0.15 to 0.30). This issue was amended by the Company through a renewal project.

D. HEALTH CARE PAYOR IMPACTS

1. The W. Va. code highlights that a PBM shall offer pass-through pricing to all health plans that are provided pharmacy benefit management services. In all instances, the Company reported that all health care payors opted for pass through pricing in 2023. The Company was compliant with the W. Va. code, as there were no instances where spread pricing reimbursement models were being utilized for health plans.

2. The Company withheld administrative fees from the rebates passed through to the health plan/member during the examination period. The administrative fee was equal to 4% in most cases. The Company retained $47,000 in administrative fees from rebates in the second quarter of 2022 and $43,000 in the second quarter of 2023. All discounts and fees indirectly and directly collected are considered a rebate and must be passed through to the health plan or consumer to help lower drug costs and/or premiums. This administrative fee collection by the Company is not compliant with the W. Va. code.

3. Health care plans are routinely audited through market conduct examinations and held responsible for findings associated with formulary design. The PBMs use their own P & T Committee and rebate negotiations to determine formulary design. Any changes made to the Company's template formulary produced additional costs to the health plan. The PBM's formulary design resulted in multiple violations of state rules and regulations. The non-compliant formulary designs cause the health plan to incur most of the financial risk when violations present through market conduct examinations.

E. OTHER

1. The rebate aggregator/GPO, Zinc Health, administers rebate negotiation on behalf of the Company. Pharmacy benefit management defined in the W. Va. code includes administering rebate contracts. The GPO operates as a PBM, but it is not licensed as a PBM in the state of W. Va.

2. As defined in W. Va. Code §33-51-3, "rebate" means "any and all payments that accrue to a pharmacy benefits manager or its health 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 plan client."

   The Company collected rebates for certain medications delivered to W. Va. covered persons. In some instances, the rebate was as high as 81% of the drug list price. In addition, there were fees, which meet the definition of rebate in W. Va. code, that were collected as high as 8% of drug list price.

   a. The chart below depicts a single 30-day supply of four separate medications, and the rebates associated with each:

| Example | Indication | List Price | Rebate | Admin Fee (to PBM) | Portal Fee (to GPO) | Other Discount (to GPO) | Total Rebate Defined in W.Va. Code |
|---|---|---|---|---|---|---|---|
| Drug A | Growth Hormone | $1465.39 | $1047.75<br>71.5% | $58.62<br>4% | $7.33<br>0.5% | $29.30<br>2% | $1,143.00<br>78% |
| Drug B | Autoimmune | $6272.80 | $3826.41<br>61% | $250.91<br>4% | $62.73<br>1% | $141.13<br>2.25% | $4,281.18<br>68.25% |
| Drug C | Diabetes | $570.60 | $399.42<br>70% | $22.82<br>4% | $5.76<br>1% | $17.28<br>3% | $445.06<br>78% |
| Drug D | Respiratory Inhaler | $331.70 | $245.79<br>74.1% | $13.27<br>4% | $3.31<br>1% | $9.93<br>3% | $272.32<br>82.1% |

b. The complexities of the rebate negotiation process are illustrated using an example from the chart above. Drug C is a specific medication used to treat diabetes and has a list price of $570.60 for a 30-day supply. In rebate negotiations the Company will negotiate rebates off the list price based on formulary design. Listing the medication on the formulary as non-preferred would be a 37% rebate. If placed as preferred and if a competitor's medication is excluded from the formulary, the rebate would be 61%. Furthermore, if two products manufactured by competitors are excluded from the formulary, the rebate would be 70%. Additionally, if you add another 8% of fees as outlined in the chart above, the total rebate of the medication, as defined in W. Va. code, would amount to 78% of the list price of the 30-day supply of diabetic medication which equals $445.06. The use of formulary exclusion and step therapy utilization increases total rebates for the Company. The contracts outline which medications are considered "competitors" to fulfill rebate criteria.

c. The Company failed to pass through all rebates as defined in the W. Va. code. The Company reported that they failed to pass through administrative fees to health plans/members. Furthermore, the Company failed to pass through other fees and discounts associated with rebate negotiations with its affiliated rebate aggregator/GPO. The chart above in section 2a shows the discounts and fees that were omitted during the pass-through process. The table only shows the rebate associated with a 30-day supply of medication. Each time this medication is dispensed or provided to members, the PBM/GPO collects these fees.

## II. SCOPE OF THE EXAMINATION

The WVOIC has the authority to conduct an examination pursuant to, but not limited to, W. Va. Code §§33-2-9 and 33-51-8, and W. Va. Code R. §114-99-7. This is a market conduct examination report ("Report") of the Company. The examination was conducted at authorized offsite locations.

The purpose of the examination was to determine if the Company complied with the W. Va. code and federal statutes, rules, and regulations, and to consider whether the Company's operations are consistent with the public interest. The examination period covered by this review was January 1, 2022, to December 31, 2023, unless otherwise noted. Errors outside of this time discovered during the examination, however, may also be included in the Report.

The examiners cited errors made by the Company. Statutory citations were as of the examination period. However, failure to criticize specific practices, procedures or files does not constitute approval thereof by the WVOIC.

The examination involved the lines of business of fully insured commercial group and individual health insurance in this examination.

The scope of this examination focused on a review including the following areas: company operations and management, network adequacy, provider/pharmacy relations, PBM pricing, pharmacy audits, complaint handling, consumer appeals, pharmacy claims, drug utilization review, and formulary design and drug placement.

In performing this examination, the examiners reviewed a sample of the Company's practices, procedures, products, and files. Therefore, some noncompliant events may not have been discovered. As such, this Report may not fully reflect all the practices and procedures of the Company. As indicated previously, failure to identify or criticize improper or noncompliant business practices in this state or other jurisdictions does not constitute acceptance of such practices.

## III. SUMMARY OF FINDINGS

The following table represents general findings with specific details in each section of the Report.

| TABLE OF TOTAL VIOLATIONS | | | |
|---|---|---|---|
| Finding | Finding # | Statute/Rule | Description of Violation |
| Company Operations and Management-Failure to Facilitate | 2 | W. Va. Code §§33-51-8(e) and 33-2-9(i) | Failed to provide unredacted and/or timely responses to the information requested in the Coordinator Handbook and to information requests. Failed to facilitate and provide the requested information in a manner that examiners could readily verify the Company's compliance with W. Va. insurance code and rules. This resulted in substantial delays and inefficiencies in the examination. |
| Pharmacy Audits-Audit Documentation | 3 | W. Va. Code §33-51-4a(14)(A)(B) | The Company had more stringent criteria than the W. Va. code on what is acceptable records or documentation for prescriptions during an audit. Disallowed a pharmacy provider to use any valid prescription and verifiable statements or records when a pharmacy audit is performed. |
| Pharmacy Audits-Audit Fees | 4 | W. Va. Code §33-51-4a(13) | Contracts and communications delivered to providers describes fees associated with the cost of pharmacy audits in excess of those allowed per the W. Va. code. |
| Pharmacy Audits-Auditing Prescription Restrictions | 5 | W. Va. Code §33-51-4a(9)(B) | Failed to comply with the maximum number of prescriptions reviewed during an audit. |
| Pharmacy Audits-Withholding Funds | 6 | W. Va. Code §33-51-4b(6) | Communications delivered to providers following a pharmacy audit failed to comply with the timeline allowed to recoup or collect funds. |
| Complaint Handling-WVOIC | 7 | W. Va. Code R. §114-14-5.2 | Failed to respond to a WVOIC complaint within fifteen (15) working days of the date appearing on the inquiry. |
| Formulary Design and Drug Placement Information-Pharmacy Formulary | 8 | W. Va. Code §§33-16-3ff(c) and 33-25A-8u(c) | Implemented an exclusion of all naloxone formulations from mail order delivery on policies used by a health plan. |
| Formulary Design and Drug Placement Information-Pharmacy Formulary | 9 | W. Va. Code §§33-16-3ff(c) and 33-25A-8u(c) | Imposed more restrictive quantity limitations on Narcan and generic naloxone nasal spray on the formularies utilized by a health plan. |
| Formulary Design and Drug Placement Information-Pharmacy Formulary | 10 | W. Va. Code §§33-16-3cc(k) and 33-25A-8r(k) | Imposed quantity limitations, a prospective utilization management requirement, in its benefit design utilized by a health plan on all strengths of buprenorphine tablets. |
| Formulary Design and Drug Placement Information-Pharmacy Formulary | 11 | W. Va. Code §§33-16-3ff(c) and 33-25A-8u(c) | Imposed more restrictive quantity limitations on desvenlafaxine on all formularies utilized by a health plan. |
| Formulary Design and Drug Placement Information-Pharmacy Formulary | 12 | W. Va. Code §§33-16-3cc(k) and 33-25A-8r(k) | Limited access to substance use disorder treatment when placing Lucemyra as non-formulary on all formularies utilized by a health plan. |

| TABLE OF TOTAL VIOLATIONS | | | |
|---|---|---|---|
| Finding | Finding # | Statute/Rule | Description of Violation |
| Formulary Design and Drug Placement Information-Pharmacy Formulary | 13 | W. Va. Code §§33-16-3cc(k) and 33-25A-8r(k) | Imposed quantity limitations, a prospective utilization management requirement, on all smoking cessation medications on the formularies utilized by a health plan. |
| Formulary Design and Drug Placement Information-Pharmacy Formulary | 14 | W. Va. Code §§33-16-3cc(k) and 33-25A-8r(k) | Limited access to substance use disorder treatment when placing Suboxone as non-formulary on all formularies used by a health plan. |
| Formulary Design and Drug Placement Information-Pharmacy Formulary | 15 | W. Va. Code §§33-16-3cc(k) and 33-25A-8r(k) | Imposed quantity limitations, a prospective utilization management requirement, on all strengths of buprenorphine/naloxone products. |
| Formulary Design and Drug Placement Information-Pharmacy Formulary | 16 | W. Va. Code §§33-16-3cc(k) and 33-25A-8r(k) | Imposed quantity limitations, a prospective utilization management requirement, on Narcan, generic naloxone nasal spray, and Kloxxado on formularies utilized by a health plan. |
| PBM Pricing-Rebate Processing Procedures | 18 | W. Va. Code §§33-51-9(k) and 33-51-3 | Failed to pass through administrative fees associated with manufacturer rebates to a health plan and its members at the point of sale. |
| Company Operations and Management-Advertisements | 19 | W. Va. Code §§33-51-11(a)(5), 33-51-11(a)(10), and 33-51-11(e) | Imposed a monetary advantage or penalty under a health benefit plan that affected the member's choice among pharmacies. |
| PBM Pricing-Rebate Processing Procedures | 20 | W. Va. Code §§33-51-3 and 33-51-9(k) | Failed to properly apply the definition of "rebate" when withholding rebate payments and fees from the health plan. |
| Formulary and Drug Placement Information-Pharmacy Formulary | 21 | W. Va. Code §§33-51-11 and 33-51-3 | Limited access to prescription medications by unreasonably designating covered prescription medications as specialty medications on formularies utilized by a health plan. |
| Pharmacy Audits-Recoupments | 22 | W. Va. Code §33-51-4(a)(13) | Recouped funds from pharmacy claims in excess of the actual financial harm associated with the dispensed product or portion of the dispensed product. |
| PBM Pricing-Pharmacy Reimbursement | 23 | W. Va. Code §33-51-9(f) | Reimbursed itself or an affiliate pharmacy more for a prescription drug than other pharmacies within the PBM network. |
| PBM Pricing-Pharmacy Reimbursement | 24 | W. Va. Code §33-51-9(f) | Reimbursed itself (mail order and specialty pharmacies) more for a prescription drug than non-affiliated pharmacies within the PBM network. |
| Drug Utilization Review-Step Therapy Requirements | 25 | W. Va. Code §§33-16-3aa and 33-25A-8o | Failed to approve a medical/surgical medication (Eliquis) once step therapy requirements were met. |
| Company Operations and Management-Data Integrity | 26 | W. Va. Code §33-2-9(l)(4) and W. Va. Code R. §114-15-4.4.a.3 | Provided inaccurate and contradictory data on multiple occasions, demonstrating the Company's inability to exercise due diligence in ensuring data integrity. |
| Pharmacy Provider Relations-Pharmacy Provider Onboarding and Enrollment | 27 | W. Va. Code §33-51-11(a)(3) | Required independent pharmacies to pay a $1,200 pharmacy enrollment application fee in order to participate in a health benefit plan network. |

| TABLE OF TOTAL VIOLATIONS | | | |
|---|---|---|---|
| Finding | Finding # | Statute/Rule | Description of Violation |
| PBM Pricing-Pharmacy Reimbursement | 28 | W. Va. Code §33-51-9(e) | Failed to reimburse W. Va. pharmacies at the NADAC + a professional dispensing fee of $10.49 or the WAC + $10.49 dispensing fee, if NADAC pricing is not available at the time a drug is administered or dispensed. |
| Pharmacy Claims-Denials | 29 | W. Va. Code §33-51-11(a)(10) | Prohibited members from filling 90-day supplies of prescription drugs from a retail pharmacy. |

## IV. COMPANY BACKGROUND

CaremarkPCS Health, L.L.C. was formed as ADVP Operations, LP., a Delaware limited partnership, on May 31, 2000. The entity then went through the following changes:

- ADVP Operations, L.P. changed its name to AdvancePCS, L.P. in March 2001;
- AdvancePCS, LP. changed its name to AdvancePCS Health, L.P. in June 2001;
- AdvancePCS Health, L.P. changed its name to CaremarkPCS Health, LP. In September 2005; and
- CaremarkPCS Health, LP. converted to a Delaware limited liability company in January 2009, and is now known as CaremarkPCS Health, L.L.C., a Delaware limited liability company.

The entity has no physical location in W. Va., but it is licensed as a prescription benefit management company wherever such licensing is required throughout the country.

## V. METHODOLOGY

This market conduct examination placed emphasis on a PBM's systems, procedures, and contractual agreements used in operation with health care payors, pharmacies, members and other affiliated entities. The commercial group and individual health insurance lines of business were reviewed in this examination. Self-funded or Medicare/Medicaid plans were not reviewed.

The scope of the examination will include, but is not limited to, the following market conduct areas:

- Operations and Management
- Network Adequacy
- Pharmacy Provider Relations
- PBM Pricing
- Pharmacy Audits
- Complaint Handling
- Consumer Appeals
- Pharmacy Claims
- Drug Utilization Review
- Formulary Design and Drug Placement Information

The review of these categories was accomplished through examination of material related to the business functions, as well as interviews with various Company personnel and Company responses to the coordinator's handbook, information requests, interrogatories, and findings. Each of the categories listed above was examined for compliance with W. Va. code and federal statutes, rules, and regulations.

Sample selection was completed in accordance with the NAIC market regulation handbook.

Operations and Management

A review was conducted of the Company's privacy and antifraud policies and procedures, contracts with pharmacies, health care payors and third-party vendors, third-party monitoring (audits), voluntary accreditation programs, internal audits, source data, and advertisements. These documents were reviewed for compliance with W. Va. codes, rules, and regulations. Exceptions are noted in the Report.

Network Adequacy

The Company was requested to provide lists of all networks offered and of all pharmacies requesting access to any pharmacy network, identification of underserved areas, notification to pharmacies of new plans, and policies and procedures demonstrating pharmacy network adequacy and online directory updates. These documents and responses to information requests were received and reviewed for compliance with W. Va. codes, rules, and regulations. No exceptions are noted in the Report.

Pharmacy Provider Relations

The Company was requested to provide policies and procedures or other documentation demonstrating its procedures for new pharmacy onboarding, credentialing and re-credentialing, provider relations projects/logs, a list of all pharmacies terminated during the examination period, all provider manuals and policies and procedures for provider manual development. These

documents, files, and responses to information requests and interrogatories were received and reviewed for compliance with the W. Va. codes, rules, and regulations. Exceptions are noted in the Report.

PBM Pricing

The Company was requested to provide a list of all charges, fees, or other revenue collected from health care payors and pharmacy providers. The request also included specific details related to pharmacy claim reimbursement, rate guarantees and other pricing methodology. To facilitate a review of the rebate process, the Company was requested to provide policies and procedures related to rebate processing, rebate crediting at the point of sale, as well as other affiliated entities that may administer rebate negotiations on behalf of the Company. These documents, files, and responses to information requests and interrogatories were received and reviewed for compliance with the W. Va. codes, rules, and regulations. Exceptions are noted in the Report.

Pharmacy Audits

The Company was requested to provide policies and procedures utilized for conducting pharmacy audits, a list of all pharmacy onsite and desk audits with results, a list of pharmacy appeals to an audit, and, if a third-party entity conducted audits, a copy of the auditing entity registration. The Company also provided all work papers associated with any pharmacy audit that resulted in a recoupment of funds from the pharmacy following an audit. These documents, files, and responses to information requests and interrogatories were received and reviewed for compliance with the W. Va. codes, rules, and regulations. Exceptions are noted in the Report.

Complaint Handling

The Company was requested to provide all clients for which it maintains responsibility for responding to complaints and policies and procedures related to complaint handling and communication. The Company was also requested to identify direct consumer complaints, WVOIC complaints, and complaints from the health care payors. These documents, files, and responses to information requests were received and reviewed for compliance with the W. Va. codes, rules, and regulations. Exceptions are noted in the Report.

Consumer Appeals

The Company was requested to provide policies, procedures and other documentation demonstrating that the Company establishes and maintains consumer appeals procedures, expedited appeals procedures, and communication of appeals procedures and adverse determinations to covered persons as well as a list of consumer appeals. These documents were received and reviewed for compliance with the W. Va. codes, rules, and regulations. No exceptions are noted in the Report.

Pharmacy Claims

The Company was requested to provide policies and procedures related to pharmacy claims processing, cost sharing requirements for preventive services, and pricing methodology related to pharmacy claims. The Company was also requested to provide a list of all paid and rejected claims and claims recoupment data. The paid claims data included all W. Va. retail pharmacies along with all company owned mail order and specialty pharmacies. These documents, files, interviews with the Company, and responses to information requests and interrogatories were received and reviewed for compliance with the W. Va. codes, rules, and regulations. Exceptions are noted in the Report.

Drug Utilization Review

The Company was requested to provide policies and procedures demonstrating that it establishes and maintains a drug utilization program (DUR) program, provides written notice of adverse determination, monitors activities of third-party DUR organizations, and peer review requests. It was also asked to provide a list of medications for which blanket pre-authorizations are required, utilization management and/or drug utilization review committee meeting minutes, and other DUR data. These documents, interviews with the Company, and responses to information requests were received and reviewed for compliance with the W. Va. codes, rules, and regulations. Exceptions are noted in the Report.

Formulary Design and Drug Placement Information

The Company was requested to provide all formularies used by the health plans, P & T committee meeting minutes, a list of any other committees that make drug placement suggestions/determinations, details of mail order medications and of 90-day supply medications, financial incentives, and compliance reward programs. The data provided included policies and procedures utilized by the Company when determining quantity limits, prior authorization, step therapy, and other prospective utilization management techniques. The Company provided information related to rebate operations associated with the GPO, Zinc Health, as well as contracts, agreements, and invoices with pharmaceutical manufacturers. These documents, files, and responses to information requests and interrogatories were received and reviewed for compliance with the W. Va. codes, rules, and regulations. Exceptions are noted in the Report.

## VI. FINDINGS

### A. OPERATIONS AND MANAGEMENT

1. Delay of Response/Failure to Facilitate
   Finding #2 - The Company did not comply with W. Va. Code §33-51-8(e) and W. Va. Code §33-2-9 when the Company failed to provide unredacted and/or timely responses to the information requested in the Coordinator Handbook and to information requests. The Company failed to facilitate and provide the requested information in such a manner that examiners could readily verify the Company's compliance with W. Va. insurance code and rules. This resulted in substantial delays and inefficiencies in the examination.

2. Advertisements
   Finding #19 - The Company did not comply with W. Va. Code §§33-51-11(a)(5), 33-51-11(a)(10), and 33-51-11(e) by imposing a monetary advantage or penalty under a health benefit plan that affected the member's choice among pharmacies. The Company provided educational/marketing materials to its W. Va. clients that promoted either an incentivized, mandatory, opt-out mandatory, or voluntary Maintenance Choice Program. The mandatory program required members to fill prescriptions for maintenance medications in 90-day supplies at a select participating pharmacy that is affiliated with the Company, and if members refilled at another pharmacy, or in 30-day supplies, the medications would not be covered, and the member would pay the full cost. The opt-out mandatory program had the same requirements as the mandatory program but required the member to call to opt out of the program. The incentivized and the voluntary programs steered members to use select participating pharmacies to fill their medications in 90-day supplies to "enjoy extra savings".

3. Data Integrity
   Finding #26 – The Company did not comply with W. Va. Code §33-2-9(l)(4) and W. Va. Code R. §114-15-4.4.a.3 when it provided inaccurate and contradictory data on multiple occasions, demonstrating the Company's inability to exercise due diligence in ensuring data integrity. The issues are as follows:
   a. The original claims files had multiple data fields in several columns that were blank or contained "—" or "Not Available". A data dictionary was not provided to determine the reason for the blank and/or "Not Available" responses.
   b. The Company noted coding errors and re-ran the paid claims reports. The number of claims in the original paid claims reports did not match the number of claims in the updated paid claims reports.
   c. The paid claims reports were completed with data from the client side, not the pharmacy side.
   d. The paid claims files did not support the data provided in paid claims reports.
   e. The examiner chosen remittance advice samples provided in Interrogatory 03.2 did not support the data provided in paid claims reports.
   f. The Company's responses to two questions on an interrogatory about fraud, waste, and abuse (FWA) were contradictory.
   g. The Company's response to a question on an interrogatory about FWA was exactly the same as the Company's response to a similar, yet different,

question on an information request about FWA from an examination for another state.

B. NETWORK ADEQUACY

There were no findings in the review of network adequacy.

C. PHARMACY PROVIDER RELATIONS

1. Pharmacy Provider Onboarding and Enrollment
   Finding #27 - The Company did not comply with W. Va. Code §33-51-11(a)(3) when requiring independent pharmacies to pay a $1,200 pharmacy enrollment application fee in order to participate in a health benefit plan network. During a call on May 23, 2024, the Company representative discussed that every new independent pharmacy applicant is liable to pay $1,200 during the application process. This fee is incurred regardless of denial or approval of participation in the Company's health benefit plan network. Furthermore, the Company requires the pharmacy to reapply and pay an additional $1,200 if there is any change in ownership. When discussing the enrollment application fee, the Company representative stated that a chain pharmacy has a separate enrollment process and is not responsible for the application fee. The enrollment application fee imposed upon independent pharmacies as a condition of participation in the health benefit plan network is inconsistent with and more stringent than legislative rules of the Board of Pharmacy and not in compliance with W. Va. Code §33-51-11(a)(3).

D. PBM PRICING

1. Rebate Processing Procedures
   a. Finding #18 - The Company did not comply with W. Va. Code §33-51-9(k) when it failed to pass invoice rebate manufacturer administrative fees through to Aetna or Aetna members at the point of sale until September 1, 2023, as stated in the Company's response to Interrogatory 03.3. Failure of the Company to pass fees incurred in connection with the dispensing or administration of a prescription drug through to Aetna or Aetna members could prevent the health plan from reducing premiums.

   b. Finding #20 - The Company did not comply with W. Va. Code §§33-51-3 and 33-51-9(k) by failing to properly apply the definition of "rebate" when withholding rebate payments through its GPO.

      W. Va. code defines "rebate" as "any and all payments that accrue to a pharmacy benefits manager or its health 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 plan client." The Company's GPO, Zinc Health, assessed an enterprise payment and manufacturer portal fee to drug manufacturers that was not passed through to clients and/or members. The Company stated in the Zinc Health executed contract provided in Information Request 11.1 that:

"Enterprise Payments" means the enterprise payments received by GPO from pharmaceutical companies that are attributable to the overall size of GPO's prescription benefit book of business and that constitute an additional discount paid by pharmaceutical companies to the Company.

"Manufacturer Portal Fees" means the fees received by GPO from pharmaceutical companies for providing data portal and related services provided under the Manufacturer Rebate agreements.

The Company detailed that portal fees and enterprise payments were retained by the GPO based on an interview with Zinc Health and CVS Caremark representatives on March 20, 2024. The discounts and fees were indirectly associated with claims administered on behalf of a healthcare payor plan client. The WVOIC consistently applies W. Va. Code §§33-51-3 and 33-51-9(k) to all PBMs and their clients.

2. Pharmacy Reimbursement
   a. Finding #23 - The Company did not comply with W. Va. Code §33-51-9(f) when reimbursing itself or an affiliate pharmacy more for a prescription drug than other pharmacies within the PBM network. The Company presented the WVOIC and examiners with the reimbursement model utilized in W. Va. on March 25, 2024. The Company stated that "lower of logic" is used between the pharmacy's reimbursement of either Usual and Customary or NADAC + $10.49. When reviewing claims, pharmacies that were paid at Usual and Customary were reimbursed less than an affiliate pharmacy.

   b. Finding #24 - The Company did not comply with W. Va. Code §33-51-9(f) when reimbursing itself more for a prescription drug than non-affiliated pharmacies within the PBM network. When reviewing claims, the Company used a separate source other than NADAC + $10.49 for reimbursement to its own mail order pharmacy. Retail pharmacies in W. Va. were reimbursed in an amount less than the pharmacy benefit manager reimbursed itself. Furthermore, the Company owned pharmacy reimbursement model resulted in higher health payor buy amounts and/or higher consumer copays.

   c. Finding #28 - The Company did not comply with W. Va. Code §33-51-9(e) when failing to reimburse W. Va. pharmacies at the NADAC + a professional dispensing fee of $10.49 or the WAC + $10.49 dispensing fee, if NADAC pricing is not available at the time a drug is administered or dispensed. The Company failed to pay W. Va. pharmacies the state mandated reimbursement for prescription drugs or pharmacy services resulting in negative financial impacts for plan year 2022 and 2023.

E. PHARMACY AUDITS

1. Audit Documentation

   Finding #3 - The Company did not comply with W. Va. Code §33-51-4a(14)(A)(B) which allows a pharmacy provider to use any use valid prescription and verifiable statements or records when a pharmacy audit is performed. In response to Information Request 018, the Company presented the audited pharmacies with a document titled Appeals Process Documentation Guidelines. It describes the process for which the pharmacy must respond to any discrepancies uncovered during the audit. The guidelines mandate that any statements from prescribers must be on prescriber letterhead or prescription pad, and that documentation such as telephone prescriptions, computer generated labels or documents without all the required information will not be accepted, and "all documentation submitted must adhere to these guidelines exactly." The letter addressed to the pharmacy supervisor/owner also explains, "if the documentation is rejected, you will NOT be able to send further documentation." These guidelines set forth by the Company are more restrictive than outlined in the W. Va. code, therefore the Company is non-compliant.

2. Audit Fees

   Finding #4 - The Company did not comply with W. Va. Code §33-51-4a(13) by implementing fees associated with the cost of pharmacy audits in addition to those allowed per the W. Va. code. In response to the Coordinator Handbook Section F.1-Pharmacy Audit Procedures, the Company provided files NTPERF-072220_2021 and NTPERF-072220_2022 which outline financial adjustments made during audits. These documents explained how the Company implements financial withholdings and audit fees on pharmacy providers for the cost of the audit. Furthermore, audit reports provided by the Company illustrated a 20% fee for the cost of the audit if the discrepant amount exceeded the threshold of $10,000. The W. Va. code notates that any fee, charge-back, recoupment, or other adjustment is limited to the actual financial harm associated with the dispensed product, portion of the dispensed product, or the actual underpayment or overpayment.

3. Auditing Prescription Restrictions

   Finding #5 –The Company did not comply with W. Va. Code §33-51-4a(9)(B) regarding the quantity of prescriptions covered during an audit. The code sets a maximum quantity of 250 prescriptions that can be covered in an audit. The Company provided results from five audits of non-CVS branded pharmacies in 2022 and results from 37 pharmacy audits in 2023. In one instance, the Company reviewed 1,131 prescriptions rather than the maximum reviewable amount of 250 prescriptions.

4. Withholding Funds

   Finding #6 - The Company did not comply with W. Va. Code §33-51-4b(6) regarding the timeline allowed to recoup or collect funds following a pharmacy audit. Upon completion of the onsite audit, the pharmacy provider is required to sign a pharmacy audit acknowledgement form created by the Company. The acknowledgement form states, "CVS Caremark will withhold any amounts determined to be overpayments." At this point, the pharmacy provider has not had a chance to respond to the preliminary report or appeal the final decision. In addition, the final audit report given to the pharmacy provider states, "Caremark may begin withholding funds from future claims payments." The W. Va. code

explains that an auditing entity conducting a pharmacy audit or person acting on behalf of the entity may not charge-back, recoup, or collect penalties from a pharmacy until the time to file an appeal of a final pharmacy audit report has passed or the appeals process has been exhausted, whichever is later.

5. Recoupments

Finding #22 - The Company did not comply with W. Va. Code §33-51-4(a)(13) when recouping funds from pharmacy claims in excess of the actual financial harm associated with the dispensed product or portion of the dispensed product. Despite incorrect directions on the prescription label at the time of dispensing, the member would still utilize the quantity of medication dispensed to take the proper dose. Financial harm would be limited to the quantities dispensed that exceeded the prescribed amount. The Company is not compliant with the W. Va. code because the Company's recoupments of pharmacy claims were not a result of financial harm to the consumer, pharmacy, or insurer.

The table below provides instances where the funds recouped did not result in financial harm.

| Date of Fill | Medication | Final Discrepant Amount/Original Paid Claim Amount |
|---|---|---|
| 8/18/2022 | Ozempic inj. 2mg/1.5ml | $2,391.73/$2,456.73 |
| 11/7/2022 | Ozempic inj. 2mg/1.5ml | $2,231.16/$2,296.16 |
| 1/6/2023 | Brimonidine Sol 0.15% OP | $232.54/$233.99 |
| 2/16/2023 | Estradiol Vag Cream 0.01% | $111.99/$126.99 |
| 8/5/2022 | Premarin Vag Cream 0.625mg | $401.18/$443.58 |
| 1/27/2023 | Estradiol Vag Cream 0.01% | $92.13/$102.23 |
| 7/23/2023 | Estradiol Vag Cream 0.01% | $148.00/$158.00 |
| 8/11/2023 | Premarin Vag Cream 0.625mg | $326.78/$397.54 |
| 5/23/2023 | Estradiol Vag Cream 0.01% | $86.99/$126.99 |
| 6/7/2023 | Estradiol Vag Cream 0.01% | $104.49/$126.99 |
| 4/21/2023 | Ozempic.25/.5 Pen 2mg/3ml | $806.07/$841.12 |
| 5/15/2023 | Ozempic.25/.5 Pen 2mg/3ml | $806.07/$841.12 |

F. COMPLAINT HANDLING

1. Offices of Insurance Commissioner Complaints

Finding #7 – The Company did not comply with W. Va. Code R. §114-14-5.2 when it failed to respond to a WVOIC complaint within fifteen (15) working days of the date appearing on the inquiry. Sample 11-147362: the Company received the complaint from the WVOIC on May 3, 2022, and did not respond until May 27, 2022, which was nineteen (19) working days later.

2. Direct Consumer Complaints

There were no findings in the review of direct consumer complaints.

3. Health Care Payor Complaints

   The Company reported no health care payor complaints within the scope of the examination.

G. CONSUMER APPEALS

The Company reported no consumer appeals within the scope of the examination.

H. PHARMACY CLAIMS

1. Pharmacy Denials
   Finding #29 - The Company did not comply with W. Va. Code §33-51-11(a)(10) when prohibiting members from filling 90-day supplies of prescription drugs from a retail pharmacy. The Company did not allow health plan members enrolled in specific policies to fill 90-day supplies at retail pharmacies and inappropriately steered members to mail order pharmacy.

I. DRUG UTILIZATION REVIEW

1. Step Therapy
   Finding #25 – DUR The Company did not comply with W. Va. Code §§33-16-3aa(b)(c)(2)(E) and 33-25A-8o(b)(c)(2)(E) by failing to approve a medication once step therapy requirements were met. Eliquis is a medication used to reduce the risk of stroke or other clotting disorders. The Company failed to approve step therapy exceptions despite patient stability on a prescription drug (Eliquis) selected by their health care provider for the medical condition under consideration.

   The Company removed Eliquis from its formularies in 2022 and required the trial and failure of Xarelto and warfarin prior to approval. Patients that established stability on Eliquis prior to the formulary change must have the ability to continue therapy as directed by their prescriber. The Journal of the American Medical Association released a study in December of 2021 that concluded that treatment with Xarelto compared with Eliquis was associated with a significantly increased risk of major ischemic or hemorrhagic events. Despite the clinical evidence shown to not switch patients to Xarelto, the Company proceeded to remove Eliquis from the formularies for plan year 2022.

J. FORMULARY DESIGN AND DRUG PLACEMENT INFORMATION

1. Pharmacy Formulary
   a. Finding #8 - The Company did not comply with W. Va. Code §33-16-3ff(c) and §33-25A-8u(c) by implementing an exclusion of all naloxone formulations from mail order delivery on policies used by a health plan. Naloxone is indicated for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system (CNS) depression. The medication is intended for immediate administration as emergency therapy in settings where opioids may be present. A medical/surgical medication comparably used in an emergency is epinephrine.

Epinephrine is indicated for treatment of allergic reactions including anaphylactic reactions. There is no mail order delivery exclusion on this medication during the examination period.

The Company implemented a limitation utilized by a health plan that imposed a more restrictive non-quantitative treatment limitation on naloxone, a medication used in emergencies of suspected opioid overdose. The formulary design prohibited a member from receiving any naloxone product through mail order services. The Company may not impose a non-quantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the non-quantitative treatment limitation to substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical/surgical benefits.

b. Finding #9 – The Company did not comply with W. Va. Code §33-16-3ff(c) and §33-25A-8u(c) by imposing more restrictive quantity limitations on Narcan and generic naloxone nasal spray on the formularies utilized by a health plan from January 1, 2022, to October 1, 2022. Naloxone is indicated for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system (CNS) depression. The medication is intended for immediate administration as emergency therapy in settings where opioids may be present. A medical/surgical medication comparably used in an emergency is epinephrine. Epinephrine is indicated for treatment of allergic reactions including anaphylactic reactions.

   The Company imposed quantity limitations on Narcan nasal spray and the generic formulation, naloxone, to four sprays or two packages per 180 days on the formularies utilized by a health plan from January 1, 2022, to October 1, 2022. The Company's formulary design imposed a quantity limit of four injections or two packages of epinephrine every 25 days. The Company did not apply the same processes, strategies, evidentiary standards, or other factors to substance used disorder overdose treatment medications compared to the same processes, strategies, evidentiary standards, or other factors both as written and in operation to medical/surgical emergency treatment medications.

c. Finding #10 – The Company did not comply with W. Va. Code §33-16-3cc(k) and §33-25A-8r(k) when imposing quantity limitations, a prospective utilization management requirement, in its benefit design utilized by a health plan on all strengths of buprenorphine tablets. Buprenorphine is indicated for treatment of opioid dependence. The policy creates a barrier to treatment when a member is prescribed above label dosing on these medications for fentanyl abuse or other high dose opioid abuse. Requiring a doctor to authorize a quantity limitation on buprenorphine sublingual tablets for above label dosing when clinically appropriate is a prior authorization and is prohibited in accordance with W. Va. Code §33-16-3cc(k) and §33-25A-8r(k).

d. Finding #11 – The Company did not comply with W. Va. Code §33-16-3ff(c) and §33-25A-8u(c) by imposing more restrictive quantity limitations on desvenlafaxine on all formularies utilized by a health plan. The Company limited members to one tablet daily on all strengths of Pristiq, Khedezla and desvenlafaxine ER tablets. These products are indicated for the treatment of major depressive disorder (MDD) and are commercially available in strengths of 25mg, 50mg, and 100mg per tablet. The FDA approved maximum dose of desvenlafaxine is 400mg/day for MDD. As a result of this quantity limitation, a provider would be required to submit a prior authorization to obtain a dose over 100mg/day, thus creating barriers of access to mental health medications. The quantity limitation of desvenlafaxine did not allow patients to obtain its FDA approved maximum dosing for a mental health indication (MDD) without their healthcare professional's override. There were no comparable medical/surgical medications with the restrictive quantity limits.

   The Company did not apply the same processes, strategies, evidentiary standards, or other factors to a mental health medication compared to the same processes, strategies, evidentiary standards, or other factors both as written and in operation to medical/surgical medications.

e. Finding #12 – The Company did not comply with W. Va. Code §33-16-3cc(k) and §33-25A-8r(k) by limiting access to substance use disorder treatment when placing Lucemyra as non-formulary on all formularies utilized by a health plan. A member would be required to obtain a prior authorization/non-formulary coverage exception for approval of the medication. Lucemyra is indicated for the mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults. The American Society of Addiction Medicine (ASAM) discusses its role in treatment of managing opioid withdrawal in patients with substance use disorders. Lucemyra may be used for withdrawal management in an outpatient setting, where monitoring of blood pressure and management of hypotension is more difficult.

f. Finding #13 – The Company did not comply with W. Va. Code §33-16-3cc(k) and §33-25A-8r(k) when imposing quantity limitations, a prospective utilization management requirement, on all smoking cessation medications on the formularies utilized by a health plan. The medications, bupropion SR, all Nicotine Replacement Therapy (NRT), Nicotrol, and Chantix had yearly quantity limitations. In order for a patient to obtain coverage, a physician would need to submit a prior authorization. Eliminating this barrier would improve overall adherence to treatment. Any provider involvement after the initial prescribing process can interrupt the course of therapy. A prior authorization from the member's provider for smoking cessation treatment is prohibited according to W. Va. Code §33-16-3cc(k) and §33-25A-8r(k).

g. Finding #14 – The Company did not comply with W. Va. Code §33-16-3cc(k) and §33-25A-8r(k) by limiting access to substance use disorder treatment when placing Suboxone as non-formulary on all formularies used by a health plan. A member would be required to obtain a prior authorization/non-formulary coverage exception, a prospective utilization management requirement, for approval of the medication. The medication is determined to be medically necessary when the prescriber indicates "Brand Medically Necessary" on the prescription. By denying a member coverage of

medically necessary medication the Company was not compliant with the W. Va. code on the on the formularies utilized by Aetna Health. Suboxone is indicated for the treatment of opioid dependence. The coverage restriction creates a barrier for consumers and providers in the overall treatment plan of a patient diagnosed with substance use disorder.

h. Finding #15 – The Company did not comply with W. Va. Code §33-16-3cc(k) and §33-25A-8r(k) when imposing quantity limitations, a prospective utilization management requirement, on all strengths of buprenorphine/naloxone products. Suboxone, Zubsolv, and buprenorphine/naloxone tablets/films all had quantity limits implemented within policies utilized by a health plan. The medications had restrictive hard-limit quantity limitations. The buprenorphine/naloxone products are indicated for treatment of opioid dependence. This policy creates a barrier to treatment when a member is prescribed above label dosing on these medications for fentanyl abuse or other high dose opioid abuse. Requiring a doctor to authorize a quantity limitation on prescribed a buprenorphine/naloxone combination product for above label dosing when clinically appropriate is a prior authorization and is prohibited.

i. Finding #16 – The Company did not comply with W. Va. Code §33-16-3cc(k) and §33-25A-8r(k) when imposing quantity limitations, a prospective utilization management requirement, on Narcan, generic naloxone nasal spray, and Kloxxado on formularies utilized by a health plan. Naloxone is indicated for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system (CNS). The medication is intended for immediate administration as emergency therapy in settings where opioids may be present. The policy creates a barrier to emergency treatment for patients and does not follow current American Society for Addiction Medications (ASAM) guidelines. The ASAM guidelines recommend naloxone should be provided to patients being treated for, or with a history of opioid use disorder and both patients and family members/significant others should be trained in the use of naloxone in case of unexpected overdose. ASAM supports broadened accessibility to naloxone for individuals commonly in a position to initiate early response to evidence of opioid overdose. The individuals include family members, significant others, companions of people who use or are prescribed opioids, and people who use or are prescribed opioids. The Company implemented quantity limits on substance use disorder medications, when clinically appropriate, is prohibited.

j. Finding #21 – The Company did not comply with W. Va. Code §33-51-11(a)(7)(8) when limiting access to prescription medications by unreasonably designating 65 covered prescription medications as specialty medications on formularies utilized by a health plan. The W. Va. code defines a specialty medication 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 Company's definition of a specialty medication does not align with the definition in the W. Va. code. There are some medications that have certain characteristics of a specialty medication. However, none of them fulfill all the requirements as defined in the W. Va. code. While most of these medications are used in the treatment of chronic

and complex or rare conditions, they do not require special handling or administration, provider care coordination, or patient education that cannot be provided by a non-specialty pharmacy or pharmacist. The list contains several brand name medications to which the generic is not classified as a specialty medication. Classifying a brand medication as specialty, but not its generic, could indicate the reasoning for the classification is due to cost and not the criteria in the definition provided in the W. Va. code.

## VII. SUMMARY OF EXAMINATION RECOMMENDATIONS

1. The Company needs to provide requested items unredacted by the due dates and in a manner that examiners could readily verify the Company's compliance with W. Va. Code §§33-16-3aa and 33-25A-8o.

2. The Company needs to perform audits to ensure its advertisements and educational materials that may be distributed to W. Va. consumers are in compliance with W. Va. Code §§33-51-11(a)(5), 33-51-11(a)(10), and 33-51-11(e).

3. The Company needs to ensure it provides accurate examination data and it needs to perform audits to ensure it is compliant with W. Va. Code §33-2-9(l)(4) and W. Va. Code R. §114-15-4.4.a.3.

4. The Company needs to review its enrollment process for independent pharmacies in order to be compliant with W. Va. Code §33-51-11(a)(3).

5. The Company needs to issue refunds to members as it admits it failed to reduce the price used to calculate a covered individual's defined cost sharing at the point of sale by the amount of manufacturer administrative fees until September 1, 2023.

6. The Company needs to ensure it passes through rebates to health plans and apply the correct definition of rebates in all transactions to ensure its compliance with W. Va. Code §§33-51-3 and 33-51-9(k).

7. The Company must ensure reimbursement of prescription drugs to pharmacies in compliance with W. Va. Code §33-51-9(f).

8. The Company must ensure reimbursement of prescription drugs to pharmacies is in compliance with W. Va. Code §33-51-9(f).

9. The Company must reimburse pharmacies in compliance with W. Va. Code §33-51-9(e) when paying pharmacies for prescription drugs in the state of W. Va.

10. The Company must allow pharmacy providers to use prescriptions and documentation as outlined in W. Va. Code §33-51-4a(14)(A)(B) during pharmacy audits to ensure compliance.

11. The Company needs to remove any language associated with fees charged to audited pharmacies in communications and contracts that are not compliant with W. Va. Code §33-51-4a(13).

12. The Company may only recoup funds that are limited to actual financial harm or overpayments from audited pharmacies to be in compliance with W. Va. Code §33-51-4(a)(13).

13. The Company needs to implement audit procedures that do not exceed the maximum number of prescriptions (250) reviewed during a pharmacy audit to be compliant with W. Va. Code §33-51-4a(9)(B).

14. The Company may not charge-back, recoup, or collect penalties from a pharmacy until the time to file an appeal of a final pharmacy audit report has passed or the appeals process has been exhausted, whichever is later. The language on communications sent to the provider must be changed to be compliant with W. Va. Code §33-51-4b(6).

15. The Company is advised to notify the WVOIC within 15 working days if it receives a WVOIC complaint in which it is not the PBM of record to ensure compliance with W. Va. Code R. §114-14-5.2.

16. The Company may not limit a member to a number of days of a drug supply for which reimbursement will be allowed based on the type of pharmacy to ensure compliance with W. Va. Code §33-51-11(a)(10).

17. The Company must adhere to W. Va. Code §§33-16-3aa and 33-25A-8o when approving/denying step therapy requirements, regardless of the Company's formulary or non-formulary designation. The Company may not require a patient to try another medication after the patient has established stability on their current treatment.

18. The Company needs to remove the exclusion of all naloxone products from mail order delivery used by a health plan. to ensure compliance with W. Va. Code §§33-16-3ff(c) and 33-25A-8u(c).

19. The quantity limitation on Narcan and generic naloxone nasal spray was removed on October 1, 2022.

20. The Company needs to remove the quantity limitations imposed on desvenlafaxine that restricted a member's the ability to obtain the FDA maximum approved dose to ensure compliance with W. Va. Code §§33-16-3ff(c) and 33-25A-8u(c).

21. The Company needs to remove prospective utilization management requirements (quantity limitations) on all strengths of buprenorphine tablets in its benefit design utilized by health plan to ensure compliance with W. Va. Code §§33-16-3cc(k) and 33-25A-8r(k).

22. The Company needs to include Lucemyra on formularies utilized by a health plan to prevent the need for prior authorization/coverage exception for substance use disorder treatment to ensure compliance with W. Va. Code §§33-16-3cc(k) and 33-25A-8r(k).

23. The Company needs to remove quantity limitations on all smoking cessation medications on the formularies utilized by a health plan to ensure compliance with W. Va. Code §§33-16-3cc(k) and 33-25A-8r(k).

24. The Company needs to provide coverage for brand name Suboxone when medically necessary without prospective utilization management requirements on its formularies utilized by a health plan to ensure compliance with W. Va. Code §§33-16-3cc(k) and 33-25A-8r(k).

25. The Company needs to remove quantity limitations on all strengths of buprenorphine/naloxone products (Suboxone, Zubsolv, and buprenorphine/naloxone tablets/films) in the policies utilized by a health plan to ensure compliance with W. Va. Code §§33-16-3cc(k) and 33-25A-8r(k).

26. The Company needs to remove quantity limitations on all naloxone products (Narcan, generic naloxone nasal spray, and Kloxxado) on the formularies utilized by a health plan to ensure compliance with W. Va. Code §§33-16-3cc(k) and 33-25A-8r(k).

27. The Company may not limit access to medications that do not meet W. Va.'s definition of "specialty medication" from the specialty designation on the formularies to ensure compliance with W. Va. Code §33-51-11(a)(7)(8).

## EXAMINATION DRAFT REPORT SUBMISSION

The courtesy and cooperation of the officers and employees of the Company during the examination are acknowledged and appreciated.

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Respectfully submitted,

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