

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland



CENTER FOR MEDICARE

September 04, 2024

Warning Letter

Contract ID: H1016

Parent Organization Name: Sentara Health Care (SHC)

Legal Entity Name: AVMED, INC.

Janet Green
Medicare Compliance Officer
1300 Sentara Way
Virginia Beach, VA 23462

VIA EMAIL: jlgree13@sentara.com

RE: Warning Letter for Failure to Incorporate Pharmacy Price Concessions at Point of Sale

Dear Janet Green:

The Centers for Medicare & Medicaid Services (CMS) is issuing this warning letter to AVMED, INC., which operates the Medicare Part D contract H1016 listed above, regarding your organization's failure to incorporate all pharmacy price concessions in pharmacies' negotiated prices at the Point of Sale ("POS") from January 1, 2024, through June 13, 2024. We are issuing a warning letter because this error impacted all or most retail pharmacy claims received by your organization for almost six months and because your actions directly contradicted explicit instructions provided by CMS.

In April 2022, CMS amended 42 CFR Part 423 to include all pharmacy price concessions in a pharmacy's negotiated price at the POS.[1] That amendment revised the definition of "negotiated price" at 42 CFR § 423.100 for covered Part D drugs to be the price that:

1. "The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug;"
2. That meets all the following criteria:
 - a. "Includes all price concessions (as defined in [42 CFR § 423.100]) from network pharmacies or other network providers;"
 - b. "Includes any dispensing fees;" and
 - c. "Excludes additional contingent amounts, such as incentive fees, if these amounts

increase prices;” and

3. “Is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D sponsor passes through to Part D enrollees at the point of sale.”

This requirement was made effective January 1, 2024, [2] after which the negotiated price Part D sponsors are required to give their Part D enrollees access to pursuant to 42 CFR § 423.104(g)(1) would need to comply with the revised definition. In preparing for implementation of the new policy, CMS issued an HPMS memo entitled *Reminder of Regulatory Requirements for Pharmacy Price Concessions* on June 2, 2023, to remind Part D sponsors of their obligations under the revised regulation by restating the answers provided to questions received from various parties during the CMS Office of the Actuary’s Actuarial User Group Calls.[3] One of the questions answered was specifically related to pharmacy contributions to a pool of money that would be used to make post-POS payments to pharmacies based on pharmacy performance. CMS instructed sponsors in its answer that “the pharmacy’s contribution to the plan’s pool, even when not assessed on a per claim basis, is considered a price concession that must be applied at the point of sale to reduce the negotiated price.”

In January 2024, CMS began receiving complaints on behalf of pharmacies that your organization’s pharmacy benefit manager (“PBM”), Express Scripts, Inc. (“ESI”) was assessing a pharmacy network bonus pool fee on retail pharmacy claims from network pharmacies, but that the fee was not reflected in the negotiated price provided to the pharmacy at the POS. Complainants reported that the adjustment was showing up only in bulk (not claim-by-claim) on remittance advice with an Adjustment Reason Code of “CS” and a Reference ID of “32 BBNP”.

ESI confirmed to CMS that the complaints were accurate. ESI explained that the network bonus pool arrangement would award the highest performing pharmacies (based on ESI’s pharmacy performance measures) more money than they paid into the pool and that the lowest performing pharmacies would receive none of the money back that they paid into the pool. The remaining pharmacies would receive back what they paid in. ESI claimed that they thought their network bonus pool arrangement, whereby all the money withheld would ultimately be distributed to pharmacies based on performance, did not need to be reflected in the negotiated price because neither ESI nor the Part D sponsors would retain any of the money paid in network bonus pool fees. CMS informed ESI that its understanding was incorrect based on the plain language of the regulation and the guidance CMS provided specifically related to performance incentives.

On April 3, 2024, CMS instructed ESI that sponsors would either need to resubmit correct prescription drug event (“PDEs”) records to reflect the network bonus pool fees in the negotiated price or refund the bonus pool fees in their entirety to the pharmacies that paid them. ESI informed CMS that it and/or its clients would refund the fees to the pharmacies. ESI informed affected retail pharmacies of this decision on June 11, 2024. ESI reported to CMS that it stopped charging pharmacies the fees on June 13, 2024, and that refunds would be finalized by the end of September 2024.

Your organization was identified as one of the Part D sponsors participating in the ESI network bonus pool arrangement. Therefore, your organization was out of compliance with Part D requirements from January 1 through June 13, 2024, because it failed to ensure that all price concessions were incorporated into the negotiated price provided to network pharmacies submitting Part D claims at POS.

Please be aware that this letter will be included in the record of your organization’s past Medicare contract performance, which CMS will consider as part of our review of any application for new or expanded Medicare contracts your organization may submit. CMS deems this instance of non-compliance a Part D issue. CMS notes that we are issuing this compliance notice based exclusively on information that we obtained from sources other than the sponsor’s own self-disclosure.

If you have any questions regarding this notice, please contact Arianne Spaccarelli at arianne.spaccarelli@cms.hhs.gov. Please copy your account manager on all communications.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Anders".

Linda Anders, Division Director
Division of Benefit Purchasing and Monitoring
Medicare Drug Benefit and C&D Data Group

CC via email:

SCOTT BEACH, CMS

Arianne Spaccarelli, CMS

[1] "Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs," (CMF-4192-F) 87 Fed. Reg. 27704, May 9, 2022, available at <https://www.govinfo.gov/content/pkg/FR-2022-05-09/pdf/2022-09375.pdf>.

[2] Id.

[3] <https://www.cms.gov/files/document/pharmacydirreminder508g.pdf>