

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



MEDICARE PARTS C AND D OVERSIGHT AND ENFORCEMENT GROUP

April 1, 2025

Chris Boles
Vice President, Medicare
Aware Integrated Inc.
3400 Yankee Drive
Eagan, MN 55121

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug
Contract Numbers: H5959, H2425, and H2461

Dear Mr. Chris Boles:

Pursuant to 42 C.F.R. §§ 417.500, 422.752(c)(1), 422.760(c), 423.752(c)(1), and 423.760(c), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Aware Integrated Inc. (Aware) that CMS has made a determination to impose a civil money penalty (CMP) in the amount of **\$31,088** for Medicare Cost Plan Contract Number H2461¹ and Medicare Advantage-Prescription Drug (MA-PD) Contract Numbers H5959 and H2425.

An MA-PD organization's and Medicare Cost Plan's² primary responsibility is to provide Medicare enrollees with medical services and prescription drug benefits in accordance with Medicare requirements. CMS has determined that Aware failed to meet that responsibility.

Summary of Noncompliance

CMS conducted an audit of Aware operations from May 1, 2024, through May 28, 2024. In a program audit report issued on December 2, 2024, CMS auditors reported that Aware failed to comply with Medicare requirements related to Part D formulary and benefits administration in violation of 42 C.F.R. Part 423, Subpart C. One (1) failure was systemic and adversely affected, or had the substantial likelihood of adversely affecting, enrollees because the enrollees experienced delayed access to medications, paid out-of-pocket costs for medications, or never received the medications.

CMS reviews audit findings individually to determine if an enforceable violation has occurred warranting a CMP. CMPs are calculated and imposed when a finding of non-compliance

¹ Contract H2461 is a Medicare Cost Plan with a qualified prescription drug plan. Pursuant to 42 C.F.R. § 417.440(b)(2)(ii), a Medicare Cost Plan may elect to provide qualified prescription drug coverage (as defined in 42 C.F.R. § 423.104) as an optional supplemental service in accordance with the applicable requirements under 42 C.F.R. Part 423. Therefore, all Part D requirements in 42 C.F.R. Part 423 cited in this notice apply to H2461.

² Referenced collectively as "plan sponsor".

adversely affected or had a substantial likelihood of adversely affecting enrollees. The determination to impose a CMP on a specific finding does not correlate with the plan sponsor's overall audit performance.

Part D Formulary and Benefit Administration Relevant Requirements

Medicare Part D Prescription Drug Program requirements apply to stand-alone Prescription Drug Plan Sponsors and to Medicare Advantage organizations that offer Part D prescription drug benefits. Sponsors that offer these plans are required to enter into agreements with CMS by which the sponsors agree to comply with a number of statutory, regulatory, and sub-regulatory requirements.

Qualified Prescription Drug Coverage

(42 C.F.R. § 423.104; Chapter 5, Section 20.1 of the Medicare Prescription Drug Benefit Manual, (IOM Pub. 100-18))

A Part D sponsor must provide its enrollees with qualified prescription drug coverage. Qualified prescription drug coverage, which consists of either standard or alternative prescription drug coverage, may be provided directly by the Part D sponsor or through arrangements with other entities.

Violation Related to Part D Formulary and Benefit Administration

CMS determined that Aware inappropriately rejected formulary medications due to errors with enrollees' eligibility files. There were two causes for this failure. First, Aware made an error that prematurely terminated the enrollment of dual eligible special needs plan (D-SNP) enrollees when processing state eligibility files. Second, in some cases, when multiple enrollment eligibility files were sent to Aware's PBM, the PBM's system did not recognize the files in the correct order, which caused the enrollee's enrollment to incorrectly show as cancelled in its systems. As a result, enrollees were inappropriately denied coverage for medications at the point of sale, and there is a substantial likelihood that enrollees experienced delayed access to medication, paid for medications out-of-pocket, or never received their medication. Aware's failure to comply with Part D formulary and benefit administration requirements violates 42 C.F.R. § 423.104(a).

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. §§ 417.500(a), 422.752 (c)(1)(i) and 423.752(c)(1)(i), CMS may impose a CMP for any determination made under 42 C.F.R. §§422.510(a) and 423.509(a). Specifically, CMS may issue a CMP if a plan sponsor has failed substantially to carry out its contract. Pursuant to 42 C.F.R. §§ 422.760(b)(2) and 423.760(b)(2), a penalty may be imposed for each enrollee directly adversely affected (or with the substantial likelihood of being adversely affected) by the deficiency.

CMS has determined that Aware failed substantially to carry out the terms of its contract with CMS (42 C.F.R. § 423.509(a)(1)) because it substantially failed to comply with requirements related to the administration of the Part D prescription benefit at 42 C.F.R. § 423.104(a). Aware's violations of Part D requirements directly adversely affected (or had the substantial

likelihood of adversely affecting) enrollees and warrants the imposition of a CMP.

Right to Request a Hearing

Aware may request a hearing to appeal CMS's determination in accordance with the procedures outlined in 42 C.F.R. Parts 422 and 423, Subpart T. Aware must send a request for a hearing to the Departmental Appeals Board (DAB) office listed below by June 2, 2025³. The request for hearing must identify the specific issues and the findings of fact or conclusions of law with which Aware disagrees. Aware must also specify the basis for each contention that the finding or conclusion of law is incorrect.

The request should be filed through the DAB E-File System (<https://dab.efile.hhs.gov>) unless the party is not able to file the documents electronically. If a party is unable to use DAB E-File, it must send appeal-related documents to the Civil Remedies Division using a postal or commercial delivery service at the following address:

Civil Remedies Division
Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6132
330 Independence Ave., S.W.
Cohen Building Room G-644
Washington, D.C. 20201

Please see https://dab.efile.hhs.gov/appeals/to_crd_instructions for additional guidance on filing the appeal.

A copy of the hearing request should also be emailed to CMS at the following address:

Kevin Stansbury
Director
Division of Compliance Enforcement
Centers for Medicare & Medicaid Services
Email: kevin.stansbury@cms.hhs.gov

If Aware does not request an appeal in the manner and timeframe described above, the initial determination by CMS to impose a CMP will become final and due on June 3, 2025. Aware may choose to have the penalty deducted from its monthly payment or transfer the funds electronically.

To notify CMS of your intent to make payment and for instructions on how to make payment, please email the enforcement contact provided in the email notification.

³ Pursuant to 42 C.F.R. §§ 422.1020(a)(2) and 423.1020(a)(2), the organization must file an appeal within 60 calendar days of receiving the CMP notice. The 60th day falls on a weekend or holiday, therefore the date reflected in the notice is the next regular business day for you to submit your request.

Impact of CMP

Further failures by Aware to provide its enrollees with Medicare benefits in accordance with CMS requirements may result in CMS imposing additional remedies available under law, including contract termination, intermediate sanctions, penalties, or other enforcement actions as described in 42 C.F.R. Parts 422 and 423, Subparts K and O.

If Aware has any questions about this notice, please call or email the enforcement contact provided in the email notification.

Sincerely,

/s/

John A. Scott
Director
Medicare Parts C and D Oversight and Enforcement Group

cc: Kevin Stansbury, CMS/CM/MOEG/DCE
Ashley Hashem, CMS/OPOLE
Michael Taylor, CMS/OPOLE
Anthony Jordan, CMS/OPOLE
Verna Hicks, CMS/OPOLE