

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

March 21, 2024

Dr. Tri Nguyen
Chairman of the Board & Chief Operating Officer
Astiva Health, Inc.
765 The City Drive South, Suite 200
Orange, CA 92868

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug
Contract Number: H1993

Dear Dr. Nguyen:

Pursuant to 42 C.F.R. §§ 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 Astiva Health, Inc. (Astiva), that CMS has made a determination to impose a civil money penalty (CMP) in the amount of **\$6,380** for Medicare Advantage-Prescription Drug (MA-PD) Contract Number H1993.

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

Summary of Noncompliance

CMS conducted an audit of Astiva's Medicare operations from June 12, 2023, through June 30, 2023. In a program audit report issued on September 12, 2023, CMS auditors reported that Astiva 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. The enrollees experienced, or likely experienced a delay in access to medications, paid out-of-pocket costs for medications, or never received 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 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 MA-PD'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 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 the 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 Astiva inappropriately rejected formulary medications. Specifically, Astiva failed to obtain the most current enrollment eligibility files directly from CMS and share them with its pharmacy benefit manager (PBM) timely. Therefore, enrollee files were not loaded into its PBM's system frequently enough resulting in enrollee Part D claims being rejected. As a result, enrollees were inappropriately denied coverage for medications at the point of sale and there is a substantial likelihood that enrollees experienced a delay in access to medication, paid for medications out-of-pocket, or never received their medication. This failure violates 42 C.F.R. § 423.104(a).

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. §§ 422.752(c)(1)(ii) and 423.752(c)(1)(ii), CMS may impose a CMP for any determination made under 42 C.F.R. §§ 422.510(a)(1) and 423.509(a)(1). Specifically, CMS may issue a CMP if an MA-PD has failed substantially to follow Medicare requirements according to 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 Astiva failed substantially to carry out the terms of its contract with CMS (42 C.F.R. §§ 422.510(a)(1) and 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). Astiva's violation 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

Astiva 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. Astiva must send a request for a hearing to the Departmental Appeals Board (DAB) office listed below by May 21, 2024.¹ The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which Astiva disagrees. Astiva 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
7500 Security Boulevard
Baltimore, MD 21244
Mail Stop: C1-22-06
Email: kevin.stansbury@cms.hhs.gov

If Astiva 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 May 22, 2024. Astiva 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.

¹ 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.

Impact of CMP

Further failures by Astiva 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 Astiva 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
Adrienne Carter, CMS/ OPOLE
Nyetta Patton, CMS/OPOLE
Ayanna Busby-Jackson, CMS/OPOLE
Cherry Castaneda, CMS/OPOLE