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 22, 2022

Ms. Aparna Abburi President, Medicare Advantage CIGNA 500 Great Circle Road Nashville, TN 37228

Ms. Jennie Knisley Vice President - Express Scripts PDP CIGNA One Express Way St Louis, MO 63121

Re: Notice of Imposition of Civil Money Penalty for Medicare-Medicaid Plan Contract Numbers: H0354, H0439, H0672, H1415, H2108, H3949, H4407, H4513, H5410, H7020, H7787, H7849, H9460, H9725, S5617, and S5660

Dear Mses. Abburi and Knisley:

Pursuant to 42 C.F.R. §§ 422.752(c)(1), 422.760(b), 423.752(c)(1), and 423.760(b), the Centers for Medicare & Medicaid Services (CMS) is providing notice to CIGNA that CMS has made a determination to impose a civil money penalty (CMP) in the amount of **\$85,436** for Medicare Advantage-Prescription Drug (MA-PD) and Prescription Drug Plan (PDP) Contract Numbers H0354, H0439, H0672, H1415, H2108, H3949, H4407, H4513, H5410, H7020, H7787, H7849, H9460, H9725, S5617, and S5660.

An MA-PD and PDP organization's<sup>1</sup> primary responsibility is to provide Medicare enrollees with medical services and/or prescription drug benefits in accordance with Medicare requirements. CMS has determined that CIGNA failed to meet that responsibility

### **Summary of Noncompliance**

CMS conducted an audit of CIGNA's Medicare operations from June 7, 2021 through June 25, 2021. In a program audit report issued on November 3, 2021, CMS auditors reported that CIGNA failed to comply with Medicare requirements related to Part C and Part D organization/coverage determinations, appeals, and grievances in violation of 42 C.F.R. Part 422,

<sup>&</sup>lt;sup>1</sup> Referenced collectively as "plan sponsor"

Subpart M, and Part 423, Subpart M. Three (3) failures were systemic and adversely affected, or had the substantial likelihood of adversely affecting, enrollees. The enrollees experienced, or likely experienced, delayed or denied access to covered benefits, increased out-of-pocket costs, and/or untimely appeal rights.

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 plan sponsor's overall audit performance.

#### Part C and Part D Organization/Coverage Determination, Appeal, and Grievance Relevant Requirements

(42 C.F.R. Part 422, Subpart M; 42 C.F.R. Part 423, Subpart M))

A Medicare enrollee has the right to contact his or her plan sponsor to express general dissatisfaction with the plan sponsor's operations, activities, or behavior, or to make a specific complaint about the denial of coverage for Part C medical services or Part D drugs to which the enrollee believes he or she is entitled to receive. Plan sponsors are required to classify general complaints about benefits or the plan sponsor's operations or activities as grievances. Plan sponsors are required to classify complaints about coverage for drugs and payment as Part D coverage determinations and classify complaints about coverage for Part C medical services or reimbursements as Part C organization determinations. It is critical for a plan sponsor to properly classify each complaint as a grievance, coverage/organization determination, or both. Improper classification may result in enrollees not receiving the required level of review, and/or experiencing delayed access to medically necessary or life-sustaining drugs or medical services.

A Part D coverage determination is any determination made by the plan sponsor, or its delegated entity, with respect to a decision about whether to provide or pay for a drug that an enrollee believes may be covered by the plan sponsor, including a decision related to a Part D drug that is not on the plan's formulary, determined not to be medically necessary, furnished by an out-of-network pharmacy, or otherwise excluded under § 1862(a) of the Act if applied to Medicare Part D. The plan sponsor must employ a medical director who is responsible for ensuring the clinical accuracy of all coverage determinations and appeals involving medical necessity. If the plan sponsor expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the Part D coverage determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise. If the plan sponsor inappropriately denies the coverage determination, then enrollees may be denied or delayed access to medications, or may pay unnecessary costs to access medications.

A Part C organization determination is when an enrollee, provider, or legal representative of a deceased enrollee requests coverage or payment for an item or service with a plan sponsor. Part C medical coverage decisions must be made within the required timeframes and in accordance with Medicare coverage guidelines, Medicare covered benefits, each sponsor's CMS-approved coverage, and contracts with providers. This can be made by furnishing the benefits directly or through arrangements, or by paying for the benefits. If the plan sponsor incorrectly denies or

delays coverage decisions, then enrollees may be inappropriately denied or delayed access to services, or may be held financially liable for services already received.

Additionally, if a contracted provider refers an enrollee to a non-contracted provider for a service that is covered by the plan sponsor upon referral, the enrollee is financially liable for only the applicable cost-sharing for that service. This is known as plan directed care and must be taken into consideration when the plan sponsor makes coverage decisions to pay for services furnished by non-contracted providers. If the plan sponsor inappropriately denies plan directed care, then enrollees may incur inappropriate out-of-pocket expenses for medical services.

# Violations Related to Part C and Part D Organization/Coverage Determinations, Appeals and Grievances

CMS determined that CIGNA violated the following Part C and Part D organization/coverage determination, appeal, and grievance requirements:

- 1. CIGNA failed to hold enrollees harmless for Part C items or medical services provided by contract providers or providers referred by contract providers. As a result, enrollees either incurred or may have incurred inappropriate cost-sharing for Part C items and medical services. This failure violates 42 C.F.R. § 422.105(a).
- 2. CIGNA failed to appropriately initiate Part D coverage determination or appeal requests. As a result, enrollees either did not receive their Part D medications or cost-sharing exceptions timely (if their request was approved) or did not receive their appeal rights timely (if their request was denied). This failure violates 42 C.F.R. § 423.564(b).
- 3. CIGNA failed to appropriately consider clinical information when rendering decisions for Part D drugs based on medical necessity. As a result, enrollees were inappropriately denied coverage for medications and experienced delayed access to their medications, never received the medications, or may have incurred increased out-of-pocket costs in order to receive the medications. This failure violates 42 C.F.R. §§ 423.562(a)(5), 423.566(d) and 423.590(f).

## **Basis for Civil Money Penalty**

Pursuant to 42 C.F.R. §§ 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)(1) and 423.509(a)(1). Specifically, CMS may issue a CMP if a Medicare Advantage - Prescription Drug Plan 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 CIGNA failed substantially to carry out the terms of its contract (42C.F.R. §§ 422.510(a)(1) and 423.509(a)(1)). Additionally, CMS determined that CIGNA failed substantially to comply with requirements in Subpart M relating to grievances and appeals (42 C.F.R. §§ 422.510(a)(4)(ii) and 423.509(a)(4)(ii)). CIGNA's violations of Part C and 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**

CIGNA 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. CIGNA must send a request for a hearing to the Departmental Appeals Board (DAB) office listed below by May 23, 2022<sup>2</sup>. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which CIGNA disagrees. CIGNA 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 (<u>https://dab.efile.hhs.gov</u>) 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 <u>https://dab.efile.hhs.gov/appeals/to\_crd\_instructions</u> for additional guidance on filing the appeal.

A copy of the hearing request should also be sent 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 CIGNA 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 24, 2022. CIGNA may choose to have the penalty deducted from its monthly payment, transfer the funds electronically, or mail a check to CMS. To notify CMS of your intent to make payment and for

<sup>&</sup>lt;sup>2</sup> Pursuant to 42 C.F.R. §§ 422.1020(a)(2) and 423.1020(a)(2), the plan sponsor must file an appeal within 60 calendar days of receiving the CMP notice. The  $60^{th}$  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.

instructions on how to make payment, please call or email the enforcement contact provided in the email notification.

### Impact of CMP

Further failures by CIGNA 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 CIGNA 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 Heather Lang, CMS/OPOLE Douglas Edwards, CMS/OPOLE Yvette Banks, CMS/OPOLE Ericka Williams, CMS/OPOLE