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 5, 2022

Ms. Elena McFann President Medicare Programs Anthem Inc. 220 Virginia Avenue Indianapolis, IN 46204

Mr. Matthew All President and CEO Blue Cross Blue Shield of Kansas 1133 SW Topeka Blvd. Topeka, KS 66629

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug, Prescription Drug Plan, and Medicare-Medicaid Plan Contract Numbers: H0544, H1607, H1894, H2593, H3240, H3342, H3447, H3536, H3655, H4036, H4346, H4909, H5422, H5471, H5746, H5854, H7728, H8432, H8552, H8786, H9065, H9525, R4487, R5941, S5596, S5726, and S8182

Dear Ms. McFann and Mr. All

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 Anthem Inc. (Anthem), that CMS has made a determination to impose a civil money penalty (CMP) in the amount of \$19,186 for Medicare Advantage-Prescription Drug (MA-PD), Prescription Drug Plan (PDP), and Medicare-Medicaid Plan (MMP) Contract Numbers H0544, H1607, H1894, H2593, H3240, H3342, H3447, H3536, H3655, H4036, H4346, H4909, H5422, H5471, H5746, H5854, H7728, H8432, H8552, H8786, H9065, H9525, R4487, R5941, S5596, S5726, and S8182.

An MA-PD, PDP, and MMP 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 Anthem failed to meet that responsibility.

Summary of Noncompliance

During July of 2020, Anthem failed to notify enrollees of its decision on Part D appeals timely due to an appeals system migration issue that caused delays with notification on Part D appeals.

¹ Referenced collectively as "plan sponsor"

Anthem informed CMS of this issue, however, in 2021 CMS found that Anthem did not forward these untimely appeals to the Independent Review Entity (IRE) for an independent review of Anthem's decisions on the appeals. Anthem's failure in this area was systemic and adversely affected (or had the substantial likelihood of adversely affecting) enrollees because they did not receive an independent review of Anthem's decisions to uphold denials of coverage requests as required.

Part D Coverage Determination, Appeal, and Grievance Requirements (42 C.F.R. Part 423, Subpart M)

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. If the coverage determination is adverse (i.e., not in favor of the enrollee), the enrollee has the right to file an appeal. The first level of appeal, called a redetermination, is handled by the plan sponsor and must be conducted by a person who was not involved in the coverage determination decision. There are different decision-making timeframes for the review of redeterminations. Plan sponsors are required to notify the enrollee of its determination on the redeterminations as expeditiously as the enrollee's health condition requires, but no later than seven (7) days after receiving the request for a standard redetermination or no later than seventy-two (72) hours after receiving the request for an expedited redetermination.

The second level of appeal is made to an independent review entity (IRE) that contracts with CMS. If the plan sponsor fails to provide the enrollee or the prescribing physician or other prescriber, as appropriate, with the results of its redetermination within the required timeframes, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe. If the plan sponsor does not send the case to the IRE then the enrollee does not receive an independent review of the plan sponsor's determination. This is especially concerning when the decision is to uphold the initial denial of the coverage determination.

Violation Related to Part D Coverage Determinations, Appeals, and Grievances

CMS determined that Anthem failed to notify enrollees of its decisions within the required timeframes for standard and expedited Part D redeterminations and then failed to send the redeterminations to the IRE. As a result, in the cases where Anthem upheld denials for medications, enrollees did not receive their denial notice timely and then did not receive an independent review of the denial. This failure violates 42 C.F.R. § 423.590.

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. § 422.752(c)(1), § 422.760(b), § 423.752(c)(1), and § 423.760(b), CMS may impose a CMP for any determination made under §§ 422.510 and 423.509. Specifically, CMS may issue a CMP if a plan sponsor has failed substantially to follow Medicare requirements according to its contract. Pursuant to §§ 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 Anthem failed substantially to carry out the terms of its contract (42 C.F.R. § 423.509(a)(1)). Additionally, CMS determined that Anthem failed substantially to comply with requirements in Subpart M relating to grievances and appeals (42 C.F.R. § 423.509(a)(4)(ii)). Anthem'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

Anthem 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. Anthem must send a request for a hearing to the Departmental Appeals Board (DAB) office listed below by June 6, 2022.² The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which Anthem disagrees. Anthem 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 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

² 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 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.

If Anthem 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 7, 2022. Anthem 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 instructions on how to make payment, please call or email the enforcement contact provided in the email notification.

Impact of CMP

Further failures by Anthem 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 Anthem 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: Judith Flynn, CMS/OPOLE
Raymond Swisher, CMS/OPOLE
Laura Coleman, CMS/ OPOLE
Michael Moore, CMS/OPOLE
Timothy Lape, CMS/OPOLE
April Forsythe, CMS/OPOLE
Joseph Sanchez CMS/OPOLE
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