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

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICARE

MEDICARE PARTS C AND D OVERSIGHT AND ENFORCEMENT GROUP

March 22, 2022

Mr. Richard Fisher
VP, Medicare CFO
Centene Corporation
8735 Henderson Road
Tampa, FL 33634

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug, Prescription Drug, and Medicare-Medicaid Plan Contract Numbers: H0022, H0111, H0174, H0351, H0480, H0562, H0913, H1032, H1112, H1664, H1723, H2491, H2775, H2915, H3237, H3561, H4506, H4868, H5087, H5439, H5590, H6080, H6550, H6815, H6870, H9630, and S4802

Dear Mr. Fisher:

Pursuant to Section 5.3.13 of the Cal MediConnect (California) contract, Section 5.3.14 of the Healthy Connections Prime (South Carolina) contract, Section 5.3.14 of the Medicare-Medicaid Alignment Initiative (Illinois) contract, Section 5.3.14 of the Michigan MI Health Link contract, Section 5.3.14 of the MyCare Ohio contract, Section 5.3.17 of the Texas Dual Eligible Integrated Care Demonstration Project contract, and 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 Centene Corporation (Centene), that CMS has made a determination to impose a civil money penalty (CMP) in the amount of **$88,192** for Medicare Advantage-Prescription Drug (MA-PD), Prescription Drug Plan (PDP), and Medicare-Medicaid Plan (MMP) Contract Numbers H0022, H0111, H0174, H0351, H0480, H0562, H0913, H1032, H1112, H1664, H1723, H2491, H2775, H2915, H3237, H3561, H4506, H4868, H5087, H5439, H5590, H6080, H6550, H6815, H6870, H9630, and S4802.

An MA-PD, PDP, and MMP organization's[1] primary responsibility is to provide Medicare enrollees with medical services and prescription drug benefits in accordance with Medicare requirements. CMS has determined that Centene failed to meet that responsibility.

Summary of Noncompliance

CMS conducted an audit of Centene's Medicare operations from June 7, 2021 through June 25, 2021. In a program audit report issued on November 4, 2021, CMS auditors reported that

[1] Referenced collectively as "plan sponsor"

Centene failed to comply with Medicare requirements related to Part D formulary and benefit administration in violation of 42 C.F.R. Part 423 Subpart C; Part C and Part D organization/coverage determinations, appeals, and grievances in violation of 42 C.F.R. Parts 422 and 423, Subpart M; and Medicare-Medicaid service authorization requests, appeals, and grievances in violation of Sections 2.11.5.6.2 and 2.11.5.6.1 of the Cal MediConnect (California) contract; Section 2.8.3 of the Healthy Connections Prime (South Carolina) contract; Section 2.9.4 of the Medicare-Medicaid Alignment Initiative (Illinois) contract; Sections 2.8.3.6.2 and 2.8.3.6.1 of the Michigan MI Health Link contract, Sections 2.8.4.5.2 and 2.8.4.5.1 of the MyCare Ohio contract, Sections 2.8.3.7.2 and 2.8.3.7.1 of the Texas Dual Eligible Integrated Care Demonstration Project contract. Four (4) 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 a plan sponsor's overall audit performance.

Part D Formulary and Benefit Administration 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. Plan sponsors that offer these plans are required to enter into agreements with CMS by which the plan sponsors agree to comply with a number of statutory, regulatory, and sub-regulatory requirements.

Formulary
(42 C.F.R. §§ 423.120(b)(2)(iv) and 423.120(b)(4)-(6); Chapter 6, Section 30.3 of the Medicare Prescription Drug Benefit Manual, (IOM Pub. 100-18))

Each Part D sponsor maintains a drug formulary or list of prescription medications covered by the sponsor. A number of Medicare requirements govern how Part D sponsors create and manage their formularies. Each Part D sponsor is required to submit its formulary for review and approval by CMS on an annual basis. The formulary review and approval process includes reviewing the Part D sponsor's proposed drug utilization management processes to adjudicate Medicare Part D prescription drug claims. Once CMS approves a sponsor's formulary, the sponsor cannot change the formulary unless it obtains CMS approval and subsequently notifies its enrollees of the changes.

Transition of Coverage
(42 C.F.R. § 423.120(b)(3); Chapter 6, Section 30.4 of the Medicare Prescription Drug Benefit Manual (IOM Pub.100-18))

A Part D sponsor must provide for an appropriate transition process for enrollees who are prescribed non-formulary Part D drugs in certain situations. This may be particularly true for

full-benefit dual eligible (i.e., Medicare and Medicaid) enrollees who are auto-enrolled in a plan. Part D sponsors must have processes in place to provide an enrollee in transition with a one-time, temporary supply of a non-formulary Part D drug (including Part D drugs that are on a sponsor's formulary but are subject to prior authorization or quantity limits). The transition process is designed to accommodate the immediate needs of an enrollee, and to allow the sponsor and/or enrollee sufficient time to switch to a therapeutically equivalent medication or request an exception to maintain coverage of an existing drug.

Violation Related to Part D Formulary and Benefit Administration

CMS determined that Centene failed to properly administer the CMS transition policy. As a result, enrollees experienced inappropriate denials of coverage at the point of sale, which impeded their access to prescription drugs. Enrollees may have experienced delayed access to their medications, never received medications, or incurred increased out of pocket costs in order to receive their medications. This failure violates 42 C.F.R. § 423.120(b)(3).

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. 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.

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

CMS determined that Centene 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).

Part C Organization Determination, Appeal, and Grievance Requirements
(42 C.F.R. Part 422, Subpart M)

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 an MA organization. If the organization determination is adverse (i.e., not in favor of the enrollee or provider), the enrollee or provider has the right to file an appeal. The first level of the appeal, called a reconsideration, is handled by the MA organization. There are different decision-making timeframes for the review of reconsiderations. MA organizations are required to notify the enrollee of its determination on the reconsideration as expeditiously as the enrollee's health condition requires, but no later than thirty (30) calendar days after receiving the request for a standard reconsideration or no later than seventy-two (72) hours after receiving the request for an expedited reconsideration.

The second level of appeal is made to an independent review entity (IRE) that contracts with CMS. If the sponsor does not issue the reconsideration decision timely, the decision is considered to be unfavorable to the enrollee and must be automatically sent to the IRE contracted by CMS no later than thirty (30) calendar days from the date it receives the request for a standard reconsideration or within twenty-four (24) hours of expiration of the timeframe for an expedited reconsideration.

Violation Related to Part C Organization Determinations, Appeals and Grievances

CMS determined that Centene failed to notify enrollees of its decisions within the required timeframes for standard and expedited Part C reconsiderations and then failed to send the reconsiderations to the IRE within the applicable timeframes. As a result, enrollees may have been delayed access to approved services, or if their appeals were denied, the enrollees were not notified of their appeal rights timely. In some cases, enrollees were not notified at all of the denial and then the case was not forwarded to the IRE for an independent review of the denial as required. This failure violates 42 C.F.R. §§ 422.590(a) and (e).

Medicare-Medicaid Service Authorization Requests, Appeals, and Grievances Requirements
(*Sections 2.11.5.6.2 and 2.11.5.6.1 of the Cal MediConnect (California), Section 2.8.3 of the Healthy Connections Prime (South Carolina), Section 2.9.4 of the Medicare-Medicaid Alignment Initiative (Illinois), Sections 2.8.3.6.2 and 2.8.3.6.1 of the Michigan MI Health Link, Sections 2.8.4.5.2 and 2.8.4.5.1 of the MyCare Ohio, Sections 2.8.3.7.2 and 2.8.3.7.1 of the Texas Dual Eligible Integrated Care Demonstration Project*)

A service authorization request is when an enrollee, provider, or legal representative of a deceased enrollee requests coverage for an item or service with a Medicare-Medicaid Plan (MMP). There are different decision-making timeframes for the review of service authorization requests. For standard service authorization requests, the MMP must provide notice of the decision no later than fourteen (14) calendar days after receipt of the request for service. If requests are expedited, an MMP is required to notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving

the request for an expedited service authorization request. Failure to provide enrollees and/or their providers notice within the required timeframes, can result in enrollees failing to receive the approved services, or delays with accessing services and/or appeal rights.

Violation related to Medicare-Medicaid Service Authorization Requests, Appeals, and Grievances

CMS determined that Centene failed to notify enrollees of its decisions within the required timeframes for standard and expedited service authorization requests. As a result, there is a substantial likelihood that those enrollees with approved services were impeded from obtaining medically necessary services while others with denied services were delayed timely appeal rights. This failure violates Sections 2.11.5.6.2 and 2.11.5.6.1 of the Cal MediConnect (California), Section 2.8.3 of the Healthy Connections Prime (South Carolina), Section 2.9.4 of the Medicare-Medicaid Alignment Initiative (Illinois), Sections 2.8.3.6.2 and 2.8.3.6.1 of the Michigan MI Health Link, Sections 2.8.4.5.2 and 2.8.4.5.1 of the MyCare Ohio, Sections 2.8.3.7.2 and 2.8.3.7.1 of the Texas Dual Eligible Integrated Care Demonstration Project.

Basis for Civil Money Penalty

Pursuant to Cal MediConnect contract, Section 5.3.13.2.1; Healthy Connections Prime (South Carolina), Section 5.3.14.4.1; Medicare-Medicaid Alignment Initiative (Illinois), Section 5.3.14.2.1; Michigan MI Health Link contract, Section 5.3.14.4.1; MyCare Ohio contract, Section 5.3.14.2.2; Texas Dual Eligible Integrated Care Demonstration Project contract, Section 5.3.17.4.1; and 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 plan sponsor 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 Centene failed substantially:

- To carry out the terms of its contract with CMS (42 C.F.R. § 422.510(a)(1) and 42 C.F.R. § 423.509(a)(1));
- To comply with the Part D service access requirements in § 423.120 (42 C.F.R. § 423.509(a)(4)(iv));
- To comply with the requirements in Subpart M relating to grievances and appeals (42 C.F.R. § 422.510(a)(4)(ii) and § 423.509(a)(4)(ii));
- To comply with federal regulatory requirements related to Cal MediConnect (California) contract with CMS (Section 5.3.13.1.6);
- To comply with federal regulatory requirements related to Healthy Connections Prime (South Carolina) contract with CMS (Section 5.3.14.3.6);
- To comply with federal regulatory requirements related to Medicare-Medicaid Alignment Initiative (Illinois) contract with CMS (Section 5.3.14.1.6);
- To comply with federal regulatory requirements related to Michigan MI Health Link contract with CMS (Section 5.3.14.3.6);

- To comply with federal regulatory requirements related to MyCare Ohio contract with CMS (Section 5.3.14.1.6); and
- To comply with federal regulatory requirements related to Texas Dual Eligible Integrated Care Demonstration Project contract with CMS (Section 5.3.17.3.6).

Centene'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

Centene 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. Centene must send a request for a hearing to the Departmental Appeals Board (DAB) office listed below by May 23, 2022.[2] The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which Centene disagrees. Centene 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 Centene 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. Centene 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 Centene 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 Centene 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: Laura Coleman, CMS/ OPOLE
Michael Moore, CMS/OPOLE
Doreen Gagliano, CMS/ OPOLE
April Forsythe, CMS/ OPOLE
Erica Dimes, CMS/OPOLE
Ayana Busby-Jackson, CMS/OPOLE
Toni Duplain, CMS/OPOLE
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Kevin Stansbury, CMS/CM/MOEG/DCE