

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**

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April 3, 2013

**VIA:**  
**EMAIL ([mfn@centene.com](mailto:mfn@centene.com))**  
**AND FACSIMILE (866-518-6034)**

Michael F. Neidorff  
Chief Executive Officer  
Centene Corporation  
7700 Forsyth Boulevard  
St. Louis, MO 63105  
Phone: 314-505-6331

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage - Prescription Drug Plan Contracts: Buckeye Community Health Plan, Inc. (H0908), Superior Health Plan, Inc. (H5294), Bridgeway Health Solutions (H5590), and Managed Health Services Wisconsin (H8189)

Dear Mr. Neidorff:

Pursuant to 42 C.F.R. § 423.752(c)(1), 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 total amount of \$100,000 for violations found in each of the above-referenced contracts.

CMS has determined that Centene failed to provide its enrollees with services and benefits in accordance with CMS requirements. An MA-PD sponsor's central mission is to provide Medicare enrollees with medical services and prescription drug benefits within a framework of Medicare requirements that provide enrollees with a number of protections.

**Summary of Noncompliance**

CMS conducted an audit at Centene's St. Louis, MO and Austin, TX offices from December 11, 2012 through December 14, 2012. During the audit, CMS conducted reviews of Centene's operational areas to determine if Centene is following CMS regulations and guidelines. CMS reviewed Centene's prescription drug claims, data systems, and operations and discovered that

Centene failed to comply with CMS requirements governing the processing of Part D coverage determinations and appeals; failed to administer prescription drug coverage as required by its CMS-approved formularies, and improperly utilized quantity limit and high dollar cost edits. Centene's failures violate CMS requirements contained at § 1860D-4(b)(3)(G) of the Social Security Act; 42 C.F.R. Part 423, Subparts C, K, and M. These violations directly adversely affected (or had the substantial likelihood of adversely affecting) Centene's enrollees.

### **Prescription Drug Program Relevant Requirements**

Medicare Part D Prescription Drug Program requirements apply to stand-alone Prescription Drug Plan sponsors and to Medicare Advantage sponsors that offer prescription drug benefits. Sponsors of these plans (Part D Sponsors) are required to enter into an agreement with CMS by which the sponsor agrees to comply with a number of requirements based upon statute, regulations, and program instructions.

#### Formulary

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

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. A Part D sponsor can change its formulary mid-year, but in order to do so must first obtain prior CMS approval, and then notify its enrollees of any changes, in addition to changes in cost-sharing amounts for formulary drugs. The CMS formulary review and approval process includes a review of the Part D sponsor's proposed drug utilization management processes to adjudicate Medicare prescription drug claims (Part D claims).

#### Utilization Management Techniques

*42 C.F.R. § 423.272(b)(2); IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2; Health Plan Management System (HPMS) Memo, CMS Part D Utilization Management Policies and Requirements Memo, October 22, 2010*

Quantity limits are one type of utilization management technique used by Part D sponsors. A sponsor may place a quantity limit on a drug for a number of reasons. A quantity limit may be placed on a medication as a safety edit based on FDA maximum daily dose limits. Quantity limits may also be placed on a drug to help detect data entry errors at the point-of-sale (POS), prevent unsafe quantities from being dispensed and to prevent fraud, waste and abuse. CMS expects that these types of edits can be overridden by the pharmacist once the correct quantity or dosage is confirmed with the prescribers and Part D sponsor. These high cost edits are intended to be utilized as a simple alert to the pharmacist and pharmacists routinely resolve these edits at the pharmacy counter and beneficiaries leave with their medication without significant delay. A

Part D sponsor must not, however, apply any additional types of clinical restrictions once the high cost edit is resolved for those drugs that do not otherwise require prior authorization. CMS expects sponsors to consider the usual and customary price of drugs when establishing a dollar threshold for the edits to reduce unnecessary burden associated with valid claims for drugs subject to high cost edits.

### Protected Class Drugs

*§ 1860D-4(b)(3)(G) of the Social Security Act; IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 6, Section 30.2.5*

Protected class drugs are drugs that are typically critical to the health and safety of the population for whom the drugs are prescribed. The six protected classes are:

- Anti-depressants (e.g., Fluoxetine, Venlafaxine, Sertraline) used for treating depression;
- Antipsychotics (e.g., Risperdal, Zyprexa, Seroquel) used for treating psychiatric disorders;
- Anticonvulsants (e.g., Divalproex, Lyrica, Carbamazepine) used for preventing or reducing seizures;
- Antiretrovirals used for the treatment of HIV and AIDS;
- Antineoplastics used for the treatment of cancers; and
- Immunosuppressants used to prevent the rejection of transplants.

### **Deficiencies Related to Formulary and Benefit Administration**

CMS identified multiple, serious violations of Part D requirements in Centene's formulary and benefit administration operations. Centene's violations include:

- Failure to properly administer its CMS-approved formulary by rejecting brand name drugs that were on Centene's formulary. This is in violation of 42 CFR § 423.104(a), 42 CFR § 423.120(b)(2)(iv). [Applicable to Centene contracts H8189, H5590, & H5294]
- Improperly applying a quantity limit that was not approved by CMS, resulting in the inappropriate denial of (or delay in obtaining) Part D drugs (including protected class medications) to beneficiaries. This is in violation of 42 C.F.R. §§ 423.104(a), 423.505(b)(17), and §1860D-4(b)(3)(G) of the Social Security Act. [Applicable to Centene contracts H5590, H0908, & H5294]
- Improperly utilized a hard, high cost edit that rejected any claims over \$ 500 (which is the PBM's standard script limit) and did not have a process in place to ensure that rejections were resolvable at the point-of-sale. In addition, Centene applied unapproved prior authorization criteria when evaluating requests to override the high cost edit and subjected the requests to a full clinical review thus resulting in the inappropriate denial of (or delay in obtaining Part D drugs (including protected class medications) to beneficiaries. This is in violation of 42 C.F.R. §§ 423.104(a), 423.505(b)(17), and

§ 1860D-4(b)(3)(G) of the Social Security Act. [Applicable to Centene contracts H8189, H5294, H5590 & H0908]

#### **Part D Coverage Determination and Appeal Relevant Requirements**

Medicare enrollees have the right to contact their sponsor to express general dissatisfaction with the operations, activities, or behavior of the plan sponsor or to make a specific complaint about the denial of coverage for drugs or services to which the enrollee believes he or she is entitled. Generally, sponsors are required to classify and process complaints about coverage for drugs as a request for a coverage determination. *See* 42 C.F.R. §§ 423.564(b) and 423.566(b). Improper processing of a coverage determination denies an enrollee their due process and appeal rights and may delay an enrollee's access to medically necessary or life-sustaining services or drugs.

The enrollee, the enrollee's appointed representative, or the enrollee's prescribing physician or prescriber may make a request for a coverage determination. *See* 42 C.F.R. § 423.566(c). The first level review is the coverage determination, which is conducted by the plan sponsor. *See* 42 C.F.R. § 423.566.

One type of coverage determination is called a formulary exception. The sponsor grants an exception whenever it determines that a non-preferred drug (usually includes a higher cost sharing amount incurred by the beneficiary for a drug that is not on the sponsor's approved formulary) for treatment of the enrollee's condition is medically necessary. *See* 42 C.F.R. § 423.578. When the sponsor approves an exception request for the non-preferred drug, the sponsor must continue to cover the drug for that beneficiary for the remainder of the plan year. *See* 42 C.F.R. § 423.578(c)(4)(i). If the sponsor fails to cover the drug for the remainder of the plan year, it will result in the sponsor's enrollees having to request multiple coverage determinations, which ultimately delays access to their medications.

#### **Deficiencies Related to Coverage Determinations and Appeals**

CMS identified serious violations of Part D requirements in Centene's processing of coverage determinations and appeals operations. Centene's violations discovered during the audit and through subsequent monitoring include:

- Failure to extend exceptions approvals through the end of the plan year. This is in violation of 42 C.F.R. § 423.578(c)(4). [Applicable to Centene contracts H8189, H5590, & H5294]

### **Basis for Civil Money Penalty**

Pursuant to 42 C.F.R. § 423.752(c), CMS has determined that Centene's violations of Medicare Part D requirements are significant enough to warrant the imposition of a CMP. Centene failed substantially to carry out the terms of its contract with CMS, and failed to carry out its contract with CMS in a manner that is consistent with the effective and efficient implementation of the program. 42 C.F.R. § 423.509(a)(1) and (2).

### **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. Part 423, Subpart T. Centene must send a written request for a hearing to the Departmental Appeals Board office listed below within 60 calendar days from receipt of this notice, or by June 3, 2013. 42 C.F.R. § 423.1020. The request for a 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 sent to:

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

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

Patricia Axt, Director, Division of Compliance Enforcement  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
MAIL STOP: C1-22-06  
Baltimore, MD 21244  
Email: [Trish.Axt@cms.hhs.gov](mailto:Trish.Axt@cms.hhs.gov)  
FAX: 410-786-6301

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 June 4, 2013. Centene may choose to have the penalty deducted from its monthly payment, transfer the funds electronically, or mail a check to CMS.

Mr. Michael F. Neidorff

April 3, 2013

Page 6 of 6

Please note that any further failures by Centene to comply with these or any other CMS requirements may subject your organization to other applicable remedies available under law, including the imposition of intermediate sanctions, penalties, or other enforcement actions as described in 42 C.F.R. Part 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/

Gerard J. Mulcahy

Director

Medicare Parts C and D Oversight and Enforcement Group

cc: Ms. Brenda Suiter, CMS/CMHPO/Region X  
Ms. Roya Rezai, CMS/CMHPO/Region X  
Ms. Jan Snyder, CMS/CMHPO/Region X