

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

July 16, 2014

Mr. James B. Wilson
President and CEO
Blue Cross and Blue Shield of North Carolina
1830 Chapel Hill Blvd.
Chapel Hill, NC 27517

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug and Prescription Drug Plan Contract Numbers: H3404, H3449, S5540

Dear Mr. Wilson,

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 Blue Cross and Blue Shield of North Carolina (BCBSNC), that CMS has made a determination to impose a civil money penalty (CMP) in the total amount of **\$290,250** for Medicare Advantage-Prescription Drug and Prescription Drug Plan Contract Numbers: H3404, H3449, S5540.

CMS has determined that BCBSNC failed to provide its enrollees with Medicare benefits in accordance with CMS requirements. A Medicare Advantage organization'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 of BCBSNC's Medicare operations from August 5, 2013 through August 16, 2013. CMS auditors reported in the Medicare Advantage & Prescription Drug Program Audit report issued February 10, 2014, that BCBSNC failed to comply with Medicare requirements related to Part D formulary and benefit administration, Part C and Part D organization/coverage determinations, appeals, and grievances in violation of 42 C.F.R. Part 422, Subpart M and 42 C.F.R. Part 423, Subparts C and M. BCBSNC's failures in these areas were systemic and resulted in enrollees experiencing inappropriate delays or denials in receiving covered benefits and increased out-of-pocket costs.

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 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)

Prior authorization is a utilization management technique used by Part D sponsors (as well as commercial and other health insurers) that requires enrollees to obtain approval from the sponsor for coverage of certain prescriptions prior to being dispensed the medication. Part D enrollees can find out if prior authorization is required for a prescription by asking their physician or checking their plan's formulary (which is available online). Prior authorization guidelines are determined on a drug-by-drug basis and may be based on Food and Drug Administration (FDA) and manufacturer guidelines, medical literature, safety, appropriate use, and benefit design.

Quantity limits are another 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 for dosage optimization, which helps to contain costs.

In addition, Part D sponsors (as well as commercial and other health insurers) use step therapy to ensure that when enrollees begin drug therapy for a medical condition, the first drug chosen is cost-effective and safe and other more costly or risky drugs are only prescribed if they prove to be clinically necessary. The goal of step therapy is to control costs and minimize clinical risks.

Transition of Coverage

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

Additionally, a Part D sponsor must provide for an appropriate transition process for enrollees prescribed any Part D drugs that are not on its formulary in certain designated situations. A Part

D Sponsor's transition process must address situations in which an individual brings a prescription for a drug that is not on the formulary to a participating pharmacy. This may be particularly true for full-benefit dual eligible (i.e., Medicare and Medicaid) enrollees who are auto-enrolled in a plan and do not make an affirmative choice based on review of a plan's benefit relative to their existing medication needs. Part D sponsors must have systems capabilities that allow them to provide a one-time, temporary supply of a non-formulary Part D drug (including Part D drugs that are on a sponsor's formulary but require prior authorization or quantity limits under a sponsor's utilization management rules). In the long-term care setting, the temporary supply of non-formulary Part D drugs must be for at least 91 days, and may be up to at least 98 days, consistent with the dispensing increment, with refills provided, if needed. The transition process is designed to accommodate the immediate needs of an enrollee, as well as to allow the sponsor and/or the enrollee sufficient time to work out an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.

Violations Related to Formulary & Benefit Administration

CMS identified serious violations of Part D formulary and benefit administration requirements that resulted in BCBSNC's enrollees experiencing inappropriate delays or denials accessing their prescribed medication. BCBSNC's violations include:

- Failure to properly administer its CMS-approved formulary by rejecting formulary medications as non-formulary. This is in violation of 42 CFR § 423.120(b)(2); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.3.3.1.
- Failure to properly administer its CMS-approved formulary by applying unapproved quantity limits. This is in violation of 42 CFR § 423.120(b)(2); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.2., 30.2.2.1, and Chapter 7, Section 60.6.
- Failure to properly administer the CMS transition policy. This is in violation of 42 CFR § 423.120(b)(3); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2.
- Failure to have processes to promptly determine drug coverage under Part B versus Part D. This is in violation of §1927(k)(2)(A) and §1927(k)(3) of the Social Security Act; and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 6, Section 20.2.2.
- Failure to provide new beneficiaries a transition supply of a medication with a CMS-approved prior authorization requirement. This is in violation of 42 CFR § 423.120(b)(3); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.4.1 and 30.4.5.

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; IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18; IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13)

Medicare enrollees have the right to contact their plan 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. Sponsors are required to classify general complaints about services, benefits, or the sponsor's operations or activities as grievances. Sponsors are required to classify complaints about coverage for drugs or services as organization determinations (Part C – medical services) or coverage determinations (Part D – drug benefits). It is critical for a sponsor to properly classify each complaint as a grievance or an organization/coverage determination or both. Improper classification of an organization or coverage determination denies an enrollee the applicable 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 representative, or the enrollee's treating physician or prescriber may make a request for an organization determination or coverage determination. The first level of review is the organization determination or coverage determination, which is conducted by the plan sponsor, and the point at which beneficiaries or their physicians submit justification for the service or benefit.

If the organization or coverage determination is adverse (not in favor of the beneficiary), the beneficiary has the right to file an appeal. The first level of the appeal – called a reconsideration (Part C) or redetermination (Part D) – is handled by the plan sponsor and must be conducted by a physician who was not involved in the organization determination or coverage determination decision. The second level of appeal is made to an independent review entity (IRE) contracted by CMS.

There are different decision making timeframes for the review of organization determinations, coverage determinations, and appeals. CMS has a beneficiary protection process in place that requires plans to forward organization determinations, coverage determinations, and appeals to the IRE when the plan has missed the applicable adjudication timeframe.

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

CMS identified serious violations of Part C and Part D organization/coverage determination, appeal, and grievance requirements that resulted in BCBSNC's enrollees being delayed in processing of their coverage request and delayed or denied access to needed medication. BCBSNC's violations include:

- Failure to properly effectuate a prior authorization or exception request. This is in violation of 42 C.F.R. § 423.578(c)(3); § 423.578(c)(4); IOM Pub. 100-18 Medicare

Prescription Drug Benefit Manual, Chapter 18, Sections 30.2 and 130; CMS Part D Utilization Management Policies and Requirements Memo, HPMS, October 22, 2010.

- Failure to appropriately auto-forward coverage determinations to the IRE within CMS timeframes. This is in violation of 42 C.F.R. § 423.568(h); § 423.572(d); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 40.4, 50.6, 70.30, and 70.40.
- Failure to effectuate decisions and notify beneficiaries (or prescribers as appropriate) of its determination within CMS required timeframes for standard and expedited coverage determination requests. This is in violation of 42 CFR § 423.568(b); § 423.572(a) and (b); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 40.2, 40.3.3, 40.3.4, 40.3.5, 50.4, and 130.1.
- Failure to demonstrate sufficient outreach to the prescriber or beneficiary to obtain additional information necessary to make an appropriate clinical decision. This is in violation of 42 CFR § 423.564(a); § 423.566(a); § 423.586; and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 10.2, 20.3, 30.2.1.3, 30.2.2.3, 70.5, and 70.7.
- Failure to appropriately consider clinical information when rendering a decision. This is in violation of 42 CFR § 423.578 (a) and (b); § 423.586; and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 18, Sections 10.2, 30.1, 30.1.2.1, 30.1.2.1.4, 30.2.2.1, 30.1.2.2.4, 50.2.1, 70, and 70.5.
- Failure of the Medical Director to oversee Part D coverage determinations and appeals and to ensure clinical accuracy of coverage determinations and redeterminations involving medical necessity. This is in violation of 42 CFR § 423.562(a)(5).
- Failure to notify the beneficiary or the provider, as appropriate, of its decision within 14 calendar days of receipt of a standard organization determination request. This is in violation of 42 CFR § 423.568(b); and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 40.1, Paragraph 1.
- Misclassifying organization determination or reconsideration requests as grievances. This is in violation of 42 CFR § 422.564(b) and §422.566(b); and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Sections 10.2 and 20.2.

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 has determined that BCBSNC's violations of Parts C and D requirements directly adversely affected (or had the substantial likelihood of adversely affecting) enrollees and warrants the imposition of a CMP. BCBSNC 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)(7));
- To comply with the requirements in Subpart M relating to grievances and appeals (42 C.F.R. § 422.510(a)(5) and § 423.509(a)(5)).

Right to Request a Hearing

BCBSNC 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. BCBSNC 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 September 15, 2014. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which BCBSNC disagrees. BCBSNC 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:

Michael DiBella
Director, Division of Compliance Enforcement
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Mail Stop: C1-22-06
Email: Michael.Dibella@cms.hhs.gov

If BCBSNC 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 September 16, 2014. BCBSNC may choose to have the penalty deducted from its monthly payment, transfer the funds electronically, or mail a check to CMS.

Please note that further failures by BCBSNC may result in additional applicable remedies available under law, up to and including contract termination, the imposition of intermediate sanctions, penalties, or other enforcement actions as described in 42 C.F.R. Parts 422 and 423, Subparts K and O.

If BCBSNC 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: Gloria Parker, CMS/CMHPO/Region IV
Colleen Carpenter, CMS/CMHPO/Region IV
Estavan Carter III, CMS/CMHPO/Region IV