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

May 28, 2014

Gary D. St. Hilaire
President & CEO
Capital Blue Cross
2500 Elmerton Avenue
Harrisburg, PA 17177

Re: Notice of Immediate Imposition of Intermediate Sanctions (Suspension of Enrollment and Marketing) for Medicare Advantage-Prescription Drug and Prescription Drug Plan Contract Numbers: H3923, H3962, and S8067

Dear Mr. St. Hilaire,

Pursuant to 42 C.F.R. § 422.756 and § 423.756, the Centers for Medicare & Medicaid Services (CMS) is providing notice to Capital Blue Cross (CBC) that CMS has made a determination to immediately impose intermediate sanctions on the following Medicare Advantage-Prescription Drug and Prescription Drug Plan Contract Numbers: H3923, H3962, and S8067.

These intermediate sanctions will consist of the suspension of enrollment of Medicare beneficiaries into CBC plans (42 C.F.R. § 422.750(a)(1) and § 423.750(a)(1)), and the suspension of all marketing activities to Medicare beneficiaries (42 C.F.R. § 422.750(a)(3) and § 423.750(a)(3)). CMS is imposing these intermediate sanctions immediately, effective May 28, 2014, at 11:59 p.m. EST, pursuant to 42 C.F.R. § 422.756(c)(2) and § 423.756(c)(2), because it has determined that CBC's conduct poses a serious threat to the health and safety of Medicare beneficiaries. Pursuant to 42 C.F.R. §422.756(c)(3) and § 423.756(c)(3), the intermediate marketing and enrollment sanctions will remain in effect until CMS is satisfied that the deficiencies upon which the determination was based have been corrected and are not likely to recur. CMS will provide CBC with detailed instructions regarding the marketing and enrollment suspensions in a separate communication.

CMS has determined that CBC failed to provide its enrollees with services and benefits in accordance with CMS requirements. A Medicare Advantage organization and Prescription Drug Plan 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 of CBC's Medicare operations from April 7, 2014 through April 18, 2014. During the audit, CMS conducted reviews of numerous operational areas to determine if CBC is following CMS rules, regulations, and guidelines. CMS auditors concluded that CBC substantially failed to comply with CMS requirements regarding Part C and Part D appeals and grievances, organization/coverage determinations, and Part D formulary and benefit administration in violation of 42 C.F.R. Part 422, Subparts C and M and 42 C.F.R. 423, Subparts C, J, and M. CMS found that CBC's failures in these areas were widespread and systemic. Violations resulted in enrollees experiencing delays or denials in receiving prescription drugs, and increased out of pocket costs for medical services and prescription drugs.

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. Coverage decisions must be made in accordance with Medicare coverage guidelines, Medicare covered benefits, and each sponsor's CMS-approved coverage policies and prescription drug benefits (see below for Part D Formulary and Benefit Administration Relevant Requirements).

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 multiple, serious violations of Part C and Part D organization/coverage determination, appeal, and grievance requirements that resulted in CBC's enrollees experiencing inappropriate denials or delays of medications at the point of sale and within enrollees' coverage determinations or appeals. Additionally, enrollees experienced inappropriate out of pocket cost for covered Medicare services and medications. These failures pose a serious threat to the health and safety of enrollees. Many of these issues stem from a complete ineffective monitoring and oversight of CBC's Pharmacy Benefit Manager (PBM), which is responsible for CBC's coverage determinations. Additionally, CBC's lack of internal controls and of consistent procedures resulted in a breakdown in other processes with Part D redeterminations, Part C organization determinations, Part C reconsiderations and grievances. CBC's violations include:

Part D

- Failure to properly effectuate prior authorization or exception requests. This is in violation of 42 C.F.R. § 423.120(b)(2); and IOM Pub. 100-18 Medicare Prescription Drug Manual, Chapter 6, Section 30.2.2 and Chapter 18, Section 130.

- Failure to properly administer its CMS-approved formulary by applying unapproved utilization management practices. This is in violation of 42 C.F.R. § 423.104(a) and § 423.120(b)(2); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.2 and 30.3.3.3 and Chapter 7, Section 20.4.

- Failure to process redetermination requests. This is in violation of 42 C.F.R. § 423.580, § 423.582(a), § 423.584(b), and § 423.590(a), (b), and (d); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 70.2, 70.7, 70.8 and 70.8.1.

- Inappropriate denials of medications when processing coverage determinations. This is in violation of 42 C.F.R. § 423.566(a) and (b); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 30.

- Failure to conduct sufficient outreach to the prescriber or beneficiary to obtain additional information necessary to make appropriate clinical decisions. This is in violation of 42 C.F.R. § 423.566(a) and § 423.586; and IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 18 , Sections 10.2, 30.2.1.3, 30.2.2.3, 70.5, and 70.7.

- Failure to implement a favorable decision by the Independent Review Entity (IRE) or other appeal entity for the beneficiary within CMS required timeframes. This is in

violation of 42 C.F.R. § 423.636(b); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 130.3.1, 130.3.2, and 130.3.3.

- Denial letters do not include an adequate rationale and/or contain incorrect information specific to the denial. This is in violation of 42 C.F.R. § 423.568(g), § 423.572(c)(2), and § 423.590(g); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 40.3.4, 50.5.1, and 70.9.1.

- Approval letters do not accurately or fully explain the conditions of approval. This is in violation of 42 C.F.R. § 423.568(e), § 423.572(c)(1), and § 423.590(h); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 40.3.5.

- Misclassifying coverage determinations and appeals as grievances. This in violation of 42 C.F.R. § 423.564(b); and IOM 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 20.2, 20.2.4.1, 20.2.4.2, and 30.4.

- Failure to take appropriate action, including a full investigation and/or appropriately addressing all issues identified in the grievance. This is in violation of 42 C.F.R. § 423.564(a); and IOM 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 20.3.

- Failure to resolve the grievances within CMS required timeframes. This is in violation of 42 C.F.R. § 423.564(e) and (f); and IOM 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 20.3.

- Failure to provide the beneficiary with written notice of his/her right to file with, and the contact information for, the Quality Improvement Organization (QIO). This is in violation of 42 C.F.R. § 423.564(c) and (e); and IOM 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 20.2.1.

- Failure to properly oversee CBC's delegated entity regarding guidance in 42 C.F.R. Part 423 Subpart M – Grievances, Coverage Determinations, Redeterminations, and Reconsiderations. This is in violation of 42 C.F.R. § 423.562(a)(4).

In addition to the above violations related to the Part D coverage determination, appeal and grievance requirements, CMS auditors discovered an additional failure while reviewing CBC's grievance logs. CBC failed to perform timely retroactive claims adjustments, in violation of 42 C.F.R. § 423.466(a); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 14, Section 50.14.3. As a result of this failure, over 3,000 enrollees were overcharged a total of $27,667 for their medications.

Part C

- Failure to hold the enrollee harmless when services were provided by a contracted plan provider or a provider referred by a contracted plan provider. This is in violation of 42

C.F.R. § 422.100(a) and § 422.105(a); and IOM 100-16 Medicare Managed Care Manual, Chapter 4, Section 170.

- Inappropriate denials of payment for emergency medical services. This is in violation of 42 C.F.R. § 422.113(b)(2) and (c)(2); and IOM 100-16 Medicare Managed Care Manual, Chapter 4, Section 20.2.

- Failure to state the specific reason for denial or provide a description of the appeal process in the remittance advice/notice when denying a request for payment from a non-contracted provider. This is in violation of IOM 100-16 Medicare Managed Care Manual, Chapter 13, Section 40.2.3.

- Denial letters do not include an adequate rationale, contain incorrect information specific to the denial, and/or are written in a manner not easily understandable to the beneficiary. This is in violation of 42 C.F.R. § 422.568(e) and § 422.572 (e); and IOM 100-16 Medicare Managed Care Manual, Chapter 13, Section 40.2.2.

- Failure to conduct sufficient outreach to the provider or beneficiary to obtain additional information necessary to make an appropriate clinical decision. This is in violation of 42 C.F.R. § 422.566(a) and § 422.586; and IOM 100-16 Medicare Managed Care Manual, Chapter 13, Sections 70.7.1 and 70.7.2.

- Misclassifying organization determinations or reconsiderations as grievances. This is in violation of 42 C.F.R. § 422.564(b); and IOM 100-16 Medicare Managed Care Manual, Chapter 13, Section 20.2.

- Failure to take appropriate action, including a full investigation and/or appropriately addressing all issues identified in the grievance. This is in violation of 42 C.F.R. § 422.564(a); and IOM 100-16 Medicare Managed Care Manual, Chapter 13, Section 20.3.

- Failure to recognize, investigate and appropriately act on, quality of care grievances contained within beneficiary complaints. This is in violation of 42 C.F.R. § 422.564(c); and IOM 100-16 Medicare Managed Care Manual, Chapter 13, Section 20.2.

- Failure to provide the beneficiary with written notice of his/her right to file with, and the contact information for, the Quality Improvement Organization. This is in violation of 42 C.F.R. § 422.564(e)(3)(iii); and IOM 100-16 Medicare Managed Care Manual, Chapter 13, Section

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 CBC's enrollees experiencing inappropriate denials or delays of medications at the point of sale and receiving incorrect transition notification letters. CBC's violations include:

- Failed to properly administer its CMS-approved formulary by applying unapproved step therapy edits and/or criteria. This is in violation of 42 C.F.R. § 423.120(b)(2); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2.2.1.

- Failure to properly administer the CMS transition policy by providing incorrect text in beneficiary transition notification letters for prior authorization instead of step therapy criteria. This is in violation of 42 C.F.R. § 423.120(b)(3); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.4.1, 30.4.10, and 30.4.4.2

Basis for Intermediate Sanctions

CMS has determined that CBC's deficiencies provide a sufficient basis for the immediate imposition of intermediate sanctions (42 C.F.R. § 422.752(b) and § 423.752(b)). CBC failed substantially:

- To carry out the terms of its contracts with CMS (42 C.F.R. § 422.510 (a)(1) and § 423.509(a)(1));

- To comply with the requirements in 42 C.F.R. Parts 422 and 423 Subpart M related to grievances and appeals (42 C.F.R. § 422.510 (a)(5) and § 423.509(a)(5));

CBC's Deficiencies Create a Serious Threat to Enrollee Health and Safety

CBC has experienced widespread and systemic failures impacting CBC's enrollees' ability to access prescription medications. Enrollee access to services and prescribed medications is the most fundamental aspect of the Part C and Part D programs because it most directly affects clinical care. CBC is denying enrollees access to drugs at the point of sale and within their appeals and coverage determinations process. The ineffective oversight of CBC's PBM, coupled with serious deficiencies with CBC's administration of its Part D coverage determinations, appeals, and grievances and Part D formulary, resulted in enrollees being denied access to the drugs that they are entitled to receive.

The nature of CBC's noncompliance provides sufficient basis for CMS to find the presence of a serious threat to enrollees' health and safety, supporting the immediate suspension of CBC's enrollment and marketing activities. Consequently, these sanctions are effective on May 28, 2014 at 11:59 p.m. EST, pursuant to the authority provided by 42 C.F.R. § 422.756(c)(2) and § 423.756(c)(2).

Opportunity to Correct

Pursuant to 42 C.F.R. § 422.756(c)(3) and § 423.756(c)(3), the sanctions will remain in effect until CMS is satisfied that the deficiencies that are the basis for the sanctions determination have been corrected and are not likely to recur. Attached to this notice is a Corrective Action Plan template with instructions for CBC to complete. CBC should submit its Corrective Action Plan to CMS within seven (7) calendar days from the date of receipt of this notice, or by June 5, 2014. If CBC needs additional time beyond seven (7) days to submit its Corrective Action Plan, contact your enforcement lead.

Once CBC has fully implemented its Corrective Action Plan, it must submit to CMS an attestation from CBC's Chief Executive Officer, or most senior official, stating that CBC has corrected the deficiencies that are the basis for the sanction and they are not likely to recur. Pursuant to 42 C.F.R. § 422.756(c)(3)(i) and § 423.756(c)(3)(i), once CBC submits its attestation, CMS will require CBC to hire an independent auditor to conduct validation in all operation areas cited in this notice and to provide a validation report to CMS. Upon completion of the validation, CMS will make a determination about whether the deficiencies that are the basis for the sanctions have been corrected and are not likely recur.

Pursuant to 42 C.F.R. § 422.506(b)(3), § 422.510(c), § 423.507(b)(3), and § 423.509(c), CBC is solely responsible for the identification, development, and implementation of its Corrective Action Plan, and for demonstrating to CMS that the underlying deficiencies have been corrected and are not likely to recur.

Opportunity to Respond to Notice

Pursuant to 42 C.F.R. § 422.756(a)(2) and § 423.756(a)(2), CBC has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or by June 9, 2014. Please note that CMS considers receipt as the day after the notice is sent by fax, email, or overnight mail, or

in this case, May 29, 2014. If you choose to submit a rebuttal, please send it to the attention of Michael DiBella at the address noted below. Note that the sanctions imposed pursuant to this letter are not stayed pending a rebuttal submission.

Right to Request a Hearing

CBC may also request a hearing before a CMS hearing officer in accordance with the procedures outlined in 42 C.F.R. § 422.660-684 and § 423.650-662. Pursuant to 42 C.F.R. § 422.756(b) and § 423.756(b), a written request for a hearing must be received by CMS within fifteen (15) calendar days of receipt of this notice, or by June 13, 2014.[1] Please note, however, a request for a hearing will not delay the date specified by CMS when the sanctions become effective. Your hearing request will be considered officially filed on the date that it is mailed; accordingly, we recommend using an overnight traceable mail carrier.

The request for a hearing must be sent to the CMS Hearing Office at the following address:

Benjamin Cohen
CMS Hearing Officer
Office of Hearings
ATTN: HEARING REQUEST
Centers for Medicare & Medicaid Services
2520 Lord Baltimore Drive
Suite L
Mail Stop: LB-01-22
Baltimore, MD 21244-2670
Phone: 410-786-3169
Email: Benjamin.Cohen@cms.hhs.gov

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

CMS will consider the date the Office of Hearings receives the email or the date it receives the fax or traceable mail document, whichever is earlier, as the date of receipt of the request. The request for a hearing must include the name, fax number, and e-mail address of the contact within CBC (or an attorney who has a letter of authorization to represent the organization) with whom CMS should communicate regarding the hearing request.

[1] If the 15th day falls on a weekend or federal holiday, you have until the next regular business day to submit your request.

Please note that we are closely monitoring your organization and CBC may also be subject to other applicable remedies available under law, including the imposition of additional sanctions, penalties, or other enforcement actions as described in 42 C.F.R. Parts 422 and 423, Subparts K and O. CMS will consider taking action to immediately terminate your contract if additional issues that pose a serious threat to the health and safety of Medicare beneficiaries are identified or left uncorrected.

If you have any questions about this notice, please call or email the enforcement contact provided in your email notification.

Sincerely,

/s/

Gerard J. Mulcahy
Director
Medicare Parts C and D Oversight and Enforcement Group

Enclosure:
Attachment A – Corrective Action Plan Template

cc: James McCaslin, CMS/CMHPO/Region III
Jeremy Willard, CMS/CMHPO/Region III
Joyce Bryant, CMS/CMHPO/Region III