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. Mark B. Ganz
Chief Executive Officer
Cambia Health Solutions, Inc.
100 SW Market Street, M/S E15A
Portland, OR 97201

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug and Prescription Drug Plan Contract Numbers: H1304, H3817, H4605, H5009, H5010, S5609, and S5916

Dear Mr. Ganz,

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 Cambia Health Solutions, Inc. (Cambia), that CMS has made a determination to impose a civil money penalty (CMP) in the total amount of **$254,000** for Medicare Advantage-Prescription Drug and Prescription Drug Plan Contract Numbers: H1304, H3817, H4605, H5009, H5010, S5609, and S5916.

CMS has determined that Cambia 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 Cambia's Medicare operations from November 4, 2013 through November 15, 2013. CMS auditors reported in the Medicare Advantage & Prescription Drug Program Audit report issued February 18, 2014, that Cambia 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. Cambia'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)

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.

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 Cambia's enrollees being delayed or denied access to necessary medications. Cambia's violations include:

- Failure to properly administer its CMS approved formulary by applying unapproved quantity limits. 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, 30.2.2.1 and Chapter 7, Section 60.6.

- Failure to provide new beneficiaries a transition supply of a medication when there was a CMS approved quantity limit. 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, Section 30.4.1 and 30.4.8.

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)

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 Cambia's enrollees being delayed or denied access to medications and medical services. Additionally, there was substantial likelihood enrollees experienced financial harm. Cambia's violations include:

- Failure to forward untimely coverage determinations and redeterminations to the Independent Review Entity (IRE) within the required timeframes. This is in violation of 42 C.F.R. § 423.568(h); 423.572(d); 423.590(c); and 423.590(e); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 40.4, 50.6, 70.30, 70.40, 70.7.1, 70.8.2, and 70.10.

- Failure to notify enrollees or prescribers of its decision within the CMS required timeframes for standard and expedited coverage determinations. This is in violation of 42 C.F.R. § 423.572(a) - (b) and 423.568(b); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 50.4, 40.2, 40.3.3, 40.3.4, and 40.3.5.

- Failure to demonstrate sufficient outreach to enrollees or prescribers 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, Section 10.2, 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 C.F.R. § 422.566; and IOM Pub.100-16 Medicare Managed Care Manual, Chapter 13, Section 70.5, Paragraph 2.

- Failure to notify non-contracted providers of their applicable appeal rights when denying requests for payment. This is in violation of 42 C.F.R. § 422.520; and IOM Pub.100-16 Medicare Managed Care Manual, Chapter 13, Section 40.2.3.

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 Cambia'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. Cambia 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

Cambia 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. Cambia 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 Cambia disagrees. Cambia 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 Cambia 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. Cambia 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 Cambia 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 Cambia 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: Brenda Suiter, CMS/CMHPO/Region X
Roya Rezai, CMS/CMHPO/Region X
Janice Snyder, CMS/CMHPO/Region X