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

April 23, 2014

VIA EMAIL: (christopher.booth@excellus.com)

Christopher G. Booth
Chief Executive Officer
Lifetime Healthcare, Inc.
165 Court Street
Rochester, NY 14647
Phone: 585-453-6359

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug and Prescription Drug Plan Contract Numbers: H3335, H3351, and S3521

Dear Mr. Booth:

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 Lifetime Healthcare, Inc. (Lifetime), that CMS has made a determination to impose a civil money penalty (CMP) in the total amount of **$447,450** for violations found in the following Medicare Advantage-Prescription Drug (MA-PD) and Prescription Drug Plan (PDP) Contracts: H3335, H3351, and S3521.

CMS has determined that Lifetime failed to provide its enrollees with benefits in accordance with CMS requirements. A Medicare Advantage organization or Prescription Drug Plan sponsors' central mission is to provide Medicare beneficiaries with medical services and prescription drug benefits within a framework of Medicare requirements that provide plan enrollees with a number of protections.

Summary of Noncompliance

CMS conducted an audit of Lifetime's Medicare Part C and Part D operations from February 25, 2013 through March 8, 2013. During the audit, CMS conducted reviews of Lifetime's operational areas to determine if Lifetime was following CMS rules, regulations, and guidelines. CMS auditors reported that Lifetime failed to comply with Medicare requirements related to Part D formulary and benefit administration and Part D coverage determinations, appeals, and grievances in violation of 42 C.F.R. Part 423, Subparts C and M. CMS found that Lifetime's failures in these areas were widespread and systemic, and resulted in enrollees experiencing inappropriate delays or denials in receiving prescription drugs and/or increased out of pocket

costs. These violations directly adversely affected (or had the substantial likelihood of adversely affecting) Lifetime's enrollees.

Part D Formulary & 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 it 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 and Transition of Coverage

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

- Failure to properly administer its CMS-approved formulary by incorrectly rejecting formulary medications as non-formulary. This is in violation 42 C.F.R. §423.120(b)(2); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.2 and 30.3.3.1.

- Failure to properly effectuate its CMS-approved quantity limits by imposing a daily dose limit rather than quantity over time limitations. 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, Sections 30.2.2.1 and 30.2, and Chapter 7, Section 60.6.

- Failure to properly administer its CMS-approved formulary by applying unapproved quantity limits below CMS approved quantity limits and below FDA maximum labeled doses. This is in violation of 42 C.F.R. § 423.120(b)(2)(iv); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 6, Sections 30.2 and 30.2.2.1, and Chapter 7, Section 60.6.

- 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 (b), 423.120(a)(10); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.10.

- Failure to provide new beneficiaries with a transition supply of medication when there was a CMS-approved quantity limit, prior authorization or step therapy requirement, or when the medication was a non-formulary medication. 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 and 30.4.8.

Part D Grievance, Coverage Determination and Appeal Relevant Requirements
(42 C.F.R. Part 423, Subpart M; IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 18)

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 to which the enrollee believes he or she is entitled. Sponsors are required to classify general complaints about benefits or the sponsor's operations or activities as grievances. Sponsors are required to classify complaints about coverage for drugs as coverage determinations. It is critical for a sponsor to properly classify each complaint as a grievance or a coverage determination or both. Improper classification of a 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 drugs.

The enrollee, the enrollee's appointed representative, or the enrollee's prescribing physician or other prescriber may make a request for a coverage determination. The first level review is the 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 coverage determination is adverse (not in favor of the enrollee), the enrollee has the right to file an appeal. The first level of appeal - called a redetermination – is handled by the plan sponsor and must be conducted by a physician who was not involved in the 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 coverage determinations and appeals. CMS has a beneficiary protection in place that requires plans to forward coverage determinations and appeals to the IRE when the plan has missed the applicable adjudication timeframe.

Violations Related to Part D Coverage Determinations and Appeals

CMS identified serious violations of Part D requirements in the processing of grievances, coverage determinations, and appeals. Lifetime'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)(3) and § 423.590(c) and (e); and IOM 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 40.4, 50.6, and 70.7.1.

- Failure to timely and correctly effectuate plan coverage determinations on standard and expedited requests. This is in violation of 42 C.F.R. § 423.568(b), § 423.572(a); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 50.4 and 130.1.

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. § 422.752(c) and 423.752(c), CMS has determined that Lifetime's violations of Part D requirements are significant enough to warrant the imposition of a CMP. In violating Part D requirements, Lifetime failed substantially to carry out the terms of its MA-PD and PDP contracts with CMS and failed to carry out its contracts with CMS in a manner consistent with the effective and efficient implementation of the program. 42 C.F.R § 422.510(a)(1) and (2) and § 423.509(a)(1) and (2). Lifetime's violations directly adversely affected (or had the substantial likelihood of adversely affecting) enrollees. 42 C.F.R § 422.760(b) and § 423.760(b).

Right to Request a Hearing

Lifetime may request a hearing to appeal CMS's determination in accordance with the procedures outlined in 42 C.F.R. § 423, Subpart T. Lifetime 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 23, 2014. 42 C.F.R. § 422.1006, § 423.1006, § 422.1020, and § 423.1020. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which Lifetime disagrees. Lifetime 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 Lifetime 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 24, 2014. Lifetime 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 Lifetime 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 Lifetime 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: Mr. Reginald Slaten CMS/CMHPO/Region II
Mr. Mitchell Croll CMS/CMHPO/Region II
Mr. Dudley Lamming CMS/CMHPO/Region II