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 3, 2013

VIA:
EMAIL (vherbel@torchmarkcorp.com)
AND FACSIMILE (972-569-3680)

Vern D. Herbel
Chief Executive Officer
Torchmark Corporation
3700 S. Stonebridge Drive
McKinney, TX 75070
Phone: 972-569-3299

Re: Notice of Imposition of Civil Money Penalty for Prescription Drug Plan Contract Numbers: S5580 and S5755

Dear Mr. Herbel:

Pursuant to 42 C.F.R. § 423.752(c)(1), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Torchmark Corporation (Torchmark), that CMS has made a determination to impose a civil money penalty (CMP) in the amount of $150,000 for Prescription Drug Plan (PDP) contract numbers S5580 and S5755.

CMS has determined Torchmark failed to provide its enrollees with services and benefits in accordance with CMS requirements. A PDP sponsor's central mission is to provide Medicare enrollees with 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 Torchmark's McKinney, Texas office from December 3 through December 12, 2012. During the audit, CMS conducted reviews of Torchmark's operational areas to determine if Torchmark is following CMS rules, regulations, and guidelines. CMS found that Torchmark failed to comply with Medicare Part D requirements related to the processing of coverage determinations and improperly utilized quantity limit edits.

Additionally, Torchmark failed to process enrollment and disenrollment requests in accordance with CMS regulations, which can delay or prevent beneficiaries from enrollment and access to Part D services. Further, Torchmark made numerous premium billing errors based on a failure to correctly determine the late enrollment penalty (LEP) amount, resulting in LEP overcharges. These violations have directly adversely affected (or had the substantial likelihood of adversely affecting) Part D eligible individuals as well as Torchmark enrollees.

Part D Program Relevant Requirements

Sponsors are required to enter into a contract with CMS and agree to comply with a number of requirements based upon statute, regulations, and program instructions.

Grievance, Coverage Determination and Appeal Requirements

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

The enrollee, the enrollee's appointed representative, or the enrollee's prescribing physician or other prescriber may request a coverage determination, which is the first level of review and is conducted by the PDP sponsor. *See* 42 C.F.R. § 423.566(c). Coverage determinations must be made in accordance with each sponsor's CMS-approved prescription drug benefits. *See* 42 C.F.R. §423.104(a).

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 PDP sponsor maintains a drug formulary or list of prescription medications covered by the sponsor. A number of Medicare requirements govern how PDP sponsors create and manage their formularies. Each PDP sponsor is required to submit its formulary for review and approval by CMS on an annual basis. A PDP 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, including any changes in cost-sharing amounts for formulary drugs. The CMS formulary review and approval process includes a review of the PDP sponsor's proposed drug utilization management processes to adjudicate Medicare prescription drug claims (Part D claims), including the use of quantity limits requirements.

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 a utilization management technique used by PDP 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 help to contain costs.

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 Part D Grievances, Coverage Determinations, Appeals and Formulary and Benefit Administration

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

- Misclassifying coverage determinations as grievances (Contract #S5755 only). This is a violation of 42 C.F.R. § 423.564(b).

- Improperly applying quantity limits that were not approved by CMS resulting in point-of-sale denials and requiring beneficiaries to request unnecessary coverage re-determinations for protected class medications. This is a violation of 42 C.F.R. §§ 423.104(a), 423.505(b)(17), and §1860D-4(b)(3)(G) of the Social Security Act.

- Failure to properly administer its CMS approved prescription drug benefit by charging beneficiaries additional co-payments for their medications (Contract #S5755 only). This is a violation of 42 C.F.R. §§ 423.104(a) and 423.120(b)(2)(iv).

Enrollment & Disenrollment Relevant Requirements

Enrollment Requirements

A PDP sponsor must timely process an individual's enrollment request in accordance with CMS enrollment guidelines. *See* 42 C.F.R. §423.32(c). When an enrollment request is incomplete, the sponsor must document its efforts to obtain the information required to complete the enrollment request. *See* Medicare Prescription Drug Benefit Manual, Chapter 3 §40.2.2. The PDP sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS. *See* 42 C.F.R. §423.32(d).

Disenrollment Requirements

The PDP sponsor must submit a disenrollment transaction to CMS within timeframes CMS specifies; provide the enrollee with a notice of disenrollment as CMS determines and approves; and file and retain disenrollment requests for the period specified in CMS instructions. *See* 42 C.F.R. §423.36(b).

Deficiencies Related to Enrollment & Disenrollment

CMS identified violations of enrollment and disenrollment requirements in Torchmark's enrollment and disenrollment operations:

- Failure to submit beneficiaries' enrollment information to CMS in a timely manner. This is a violation of 42 C.F.R. §423.32(c).
- Failure to provide beneficiaries with prompt notice of denial of enrollment request. This is in violation of 42 C.F.R. §423.32(d).
- Failure to submit disenrollment transactions to CMS in a timely manner. This is a violation of 42 C.F.R. §423.36(b)(1).
- Failure to ensure enrollees received correct notices regarding disenrollment in a timely manner. This is a violation of 42 C.F.R. §423.36(b)(2).
- Failure to retain adequate documentation related to disenrollment requests. This is a violation of 42 C.F.R. §423.36(b)(3).

Premium Billing/Late Enrollment Penalty Relevant Requirements

Part D sponsors must charge enrollees a consolidated monthly Part D premium. *See* 42 C.F.R. § 423.293(a). The base beneficiary premium is increased by the late enrollment penalty (LEP) for a Part D enrollee who did not enroll when s/he was first eligible and had a break in creditable prescription drug coverage for a continuous period of at least 63 days or longer. *See* 42 C.F.R. §§ 423.286(d)(3) and 423.46(a).

Deficiencies Related to Premium Billing/LEP Determinations

Torchmark billed inaccurate premiums to beneficiaries based on a failure to correctly determine the number of uncovered months of creditable coverage which resulted in an incorrect LEP amount. This is a violation of 42 C.F.R. § 423.286(d)(3). A review of LEP data submitted by Torchmark between January and March 2013 revealed numerous premium billing errors by Torchmark. Torchmark's data showed errors affected approximately 23,000 enrollees or former enrollees. The total financial impact of these errors is still being determined.

Torchmark's premium billing/LEP errors resulted from the following deficiencies:

- Torchmark failed to update their premium bills to reflect CMS' notice of LEP adjustment. This does not comply with the Medicare Prescription Drug Benefit Manual, Chapter 4 §§ 40.2 and 40.3.
- Torchmark identified a number of overcharges but did not notify the beneficiary of the LEP refund owed and did not refund the LEP. This is inconsistent with Medicare Prescription Drug Benefit Manual, Chapter 4 §60.3.
- Torchmark failed to properly report to CMS information received on creditable prescription drug coverage months. This is a violation of 42 C.F.R. § 423.46(b).

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. § 423.752(c), CMS has determined that Torchmark's violations of Medicare Part D requirements are significant enough to warrant the imposition of a CMP. Torchmark 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

Torchmark may request a hearing to appeal CMS's determination in accordance with the procedures outlined in § 42 C.F.R. Part 423, Subpart T. Torchmark 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 Torchmark disagrees. Torchmark 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
FAX: 410-786-6301

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

Please note that any further failures by Torchmark 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 Torchmark 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. Julie Kennedy, CMS/CMHPO/Region VI
Mr. Arthur Pagan, CMS/CMHPO/Region VI
Ms. Sandra Mason, CMS/CMHPO/Region V