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

September 11, 2014

Mr. Scott King
Senior Vice President
Transamerica Corporation
100 Light Street, Floor B1
Baltimore, MD 21201

Re: Notice of Imposition of Civil Money Penalty for Prescription Drug Plan Contract Number: S9579

Dear Mr. King,

Pursuant to 42 C.F.R. § 423.752(c)(1) and § 423.760(b), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Stonebridge Life Insurance Company (Stonebridge) that CMS has made a determination to impose a civil money penalty (CMP) in the total amount of **$370,400** for Prescription Drug Plan Contract Number: S9579.

CMS has determined that Stonebridge failed to provide its enrollees with Medicare benefits in accordance with CMS requirements. A Medicare Prescription Drug Plan sponsors' central mission is to provide Medicare beneficiaries with 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 Stonebridge's Medicare operations from April 28, 2014 through May 9, 2014. CMS auditors reported in the Medicare Advantage & Prescription Drug Program Audit report issued September 4, 2014, that Stonebridge failed to comply with Medicare requirements related to Part D formulary and benefit administration, coverage determinations, appeals, and grievances in violation of 42 C.F.R. Part 423, Subparts C and M. Stonebridge'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.

Violations Related to Formulary & Benefit Administration

CMS identified serious violations of Part D formulary and benefit administration requirements that resulted in Stonebridge's enrollees being inappropriately delayed or denied medications. Stonebridge's violations include:

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

2. Failure to properly administer the 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, Sections 30.2, 30.2.2.1, and 60.6.

3. Failure to resolve claims with pharmacies that rejected for invalid National Provider Identifier (NPI) within 1 business day. This is in violation of 42 C.F.R. § 423.120(c)(5); and Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes, Federal Register 77:71 (April 12, 2012) p 22146; Revised Reporting Requirements for Prescriber Identifiers and Other Prescription Drug Event Fields Memo, HPMS, October 1, 2012; and, Announcement of Prescriber NPI Project and Website Release Memo, HPMS, December 4, 2012.

4. Failure to properly effectuate a prior authorization or exception request. This is in violation of 42 C.F.R. § 423.120(b)(2); IOM 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2.2; and CMS Part D Utilization Management Policies and Requirements Memo, HPMS, October 22, 2010, page 2.

Part D Coverage Determination, Appeal, and Grievance 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, Appeals, and Grievances

CMS identified the following violation of Part D coverage determination, appeal, and grievance requirements that resulted in Stonebridge's enrollees being inappropriately delayed or denied access to care and/or medications. Stonebridge's violations include:

5. Failure to follow required procedures after receiving an oral coverage determination and/or expedited determination request. This is in violation of 42 CFR § 423.568(a); 42 CFR § 423.570(b); 42 CFR § 423.570(c)(1-2) and IOM 100-18 Medicare Prescription Drug Benefit Manual, Sections 40.1 and 50.1.

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. § 423.752(c)(1) and § 423.760(b), CMS has determined that Stonebridge's violations of Part D requirements directly adversely affected (or had the substantial likelihood of adversely affecting) enrollees and warrants the imposition of a CMP. Stonebridge failed substantially:

- To carry out the terms of its contract with CMS (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));

Right to Request a Hearing

Stonebridge 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. Stonebridge 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 November 11, 2014. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which Stonebridge disagrees. Stonebridge 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 Stonebridge 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 November 12, 2014. Stonebridge may choose to have the penalty deducted from its monthly payment, transfer the funds electronically, or mail a check to CMS. To notify CMS of your intent to make payment and for instructions on how to make payment, please call or email the enforcement contact provided in the email notification.

Please note that further failures by Stonebridge 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 Stonebridge 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. James McCaslin, Associate Regional Administrator, CMS/ CMHPO/Region III
Mr. Jeremy Willard, Branch Manager, CMS/ CMHPO/Region III
Mr. Matthew Febbo, Account Manager, CMS/ CMHPO/Region III