DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

PROGRAM COMPLIANCE AND OVERSIGHT GROUP

December 14, 2012

VIA:
EMAIL (cms admin@healthsun.com)
AND FACSIMILE (305-444-9148)

Alexander Fuster
President and Chief Executive Officer
HealthSun Health Plans, Inc.
3250 Mary Street, Suite 300
Coconut Grove, FL 33133
Phone: 305-234-9292

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage - Prescription Drug Plan Contract Number: H5431

Dear Mr. Fuster:

Pursuant to 42 C.F.R. §§ 422.752(c)(1) and 423.752(c)(1), the Centers for Medicare & Medicaid Services (CMS) is providing notice to HealthSun Health Plans, Inc. (HealthSun) that CMS has made a determination to impose a civil money penalty (CMP) in the amount of $50,000 for the following Medicare Advantage-Prescription Drug Plan (MA-PD) Contract Number: H5431.

CMS has determined that HealthSun failed to provide its enrollees with services and benefits in accordance with CMS requirements. A MA-PD sponsor's central mission is to provide Medicare enrollees with medical services and prescription medications within a framework of Medicare requirements that provide enrollees with a number of protections.

Summary of Noncompliance

CMS conducted an audit at HealthSun's Coconut Grove, Florida offices from July 23, 2012 through July 27, 2012. During the audit, CMS conducted reviews of HealthSun's operational areas to determine if HealthSun is following CMS regulations and guidelines. CMS reviewed HealthSun's prescription drug claims, data systems, and operations and discovered that HealthSun inappropriately rejected claims for its enrollees. These inappropriate claim rejections resulted in enrollees experiencing a delay in obtaining their prescription drugs, or not receiving

their drugs at all. After conducting an extensive review of HealthSun's rejected claims data, the CMS auditors concluded that HealthSun failed to provide its enrollees with prescription drug coverage as required by its CMS-approved formularies. HealthSun's failures violate the Medicare Part D program requirements contained at § 1860D-4(b)(3)(G) of the Social Security Act and 42 C.F.R. §§ 423.120(b)(2)(iv), 423.120(b)(3), 423.505(b)(17) and 423.272. Each violation has directly adversely affected (or has the substantial likelihood of adversely affecting) HealthSun's enrollees by delaying or denying enrollee access to vital medications.

Prescription Drug Program 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 a contract 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, including any 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), including the use of prior authorization or step therapy 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

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 prescribed 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.

Step therapy is another utilization management technique used by Part D sponsors (as well as commercial and other health insurers) 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.

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, another management technique Part D sponsors use are high cost edits. When used appropriately, high cost edits are implemented by health plans to prevent inadvertent claims overbilling. These high cost edits are intended to be utilized as a simple alert to the pharmacist and are required to be resolved at the point of sale after pharmacist confirmation. Routinely, pharmacists resolve these edits at the pharmacy counter and beneficiaries leave with their medication without significant delay.

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

Part D sponsors are ***not*** allowed to require prior authorization or step therapy for enrollees stabilized on drugs that have been designated as "protected class drugs." Protected class drugs are drugs that are typically critical to the health and safety of the population for whom the drugs prescribed. There are six classes of drugs to which Medicare enrollees must have ***uninterrupted access*** to all of the drugs in that class. 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 Formulary and Benefit Administration

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

- Improperly applied a quantity limit that was not approved by CMS, resulting in the inappropriate denial or delay of Part D drugs to beneficiaries. This is in violation of 42 C.F.R. § 423.104(a) and § 423.120(b)(2); see also Medicare Prescription Drug Benefit Manual, Pub. 100-18, ch. 6 § 30.2.; ch. 7 § 60.6.

- Improperly utilized a high dollar cost edit that was not resolvable at the point-of-sale, resulting in the inappropriate denial or delay of Part D drugs (including protected class medications) to beneficiaries. This is in violation of 42 C.F.R. §§ 423.104(a), 423.505(b)(17), and § 1860D-4(b)(3)(G) of the Social Security Act; see also Health Plan Management System (HPMS) Memo, CMS Part D Utilization Management Policies and Requirements Memo, October 22, 2010.

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. §§ 422.752(c) and 423.752(c), CMS has determined that HealthSun's violations of Part D requirements are significant enough to warrant the imposition of a CMP. In violating multiple Part D requirements, HealthSun failed substantially to carry out the terms of its MA-PD contract with CMS and failed to carry out its contract 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).

Right to Request a Hearing

HealthSun 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. HealthSun 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 February 13, 2013. 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 HealthSun disagrees. HealthSun 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 HealthSun 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 February 14, 2013. HealthSun 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 HealthSun 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 HealthSun has any questions about this notice, please call or email the enforcement contact provided in the email notification.

Sincerely,

/s/

Gerard J. Mulcahy
Acting Director
Program Compliance and Oversight Group

cc: Ms. Colleen Carpenter, CMS/CMHPO/Region IV
Ms. Teresa Kries, CMS/ CMHPO/Region IV
Mr. Michael Taylor, CMS/CMHPO/Region IV