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

PROGRAM COMPLIANCE AND OVERSIGHT GROUP

October 9, 2012

VIA:
EMAIL (srawlings@ahmpr.com)
AND FACSIMILE (787-620-0939)

Susan Rawlings
Chief Executive Officer
Triple-S Salud, Inc.
1441 Franklin D. Roosevelt Avenue
San Juan, PR 00920
Phone: 787-600-9101

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug Plan and/or Prescription Drug Plan Contract Numbers: Triple-S Salud (H4005, H4012, H5732, S5907)

Dear Ms. Rawlings:

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 Triple-S Salud, Inc. (Triple-S) that CMS has made a determination to impose a civil money penalty (CMP) in the amount of $350,000 for the following Medicare Advantage-Prescription Drug Plan (MA-PD) and Prescription Drug Plan (PDP) Contracts: Triple-S Salud H4005, H4012, H5732, S5907.

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

Summary of Noncompliance

CMS conducted an audit at Triple-S's San Juan, Puerto Rico offices from April 30, 2012 through May 4, 2012. During the audit, CMS conducted reviews of Triple-S's operational areas to determine if Triple-S is following CMS rules, regulations and guidelines. CMS reviewed Triple-S's prescription drug claims, data systems, and operations and determined that Triple-S inappropriately rejected claims for its enrollees. These inappropriate claim rejections resulted in

enrollees experiencing either a delay in obtaining their prescription drugs, or not receiving their drugs at all. After conducting an extensive review of Triple-S's rejected claims data, the CMS auditors concluded that Triple-S failed to provide its enrollee's prescription drug coverage as required by its CMS approved formularies and enrollee plan benefit packages. Triple-S'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. §§ 423.104(a); 423.120(a); 423.120(b)(2)(iv); 423.120(b)(3); and 423.505(b)(17). Each violation has directly adversely affected (or had the substantial likelihood of adversely affecting) Triple-S's enrollees across the four (4) contracts to which the penalty applies, by delaying or denying enrollee access to vital and sometimes life-sustaining medications.

Prescription Drug Program Requirements

Medicare Part D Prescription Drug Program requirements apply both to stand-alone Prescription Drug Plan sponsors and to Part C 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) and423.120(b)(4)-(6); and 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 PDP. 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 must obtain prior CMS approval and must notify its enrollees of any changes, including any changes in cost-sharing amounts for formulary drugs. CMS' formulary review and approval process includes a review of the MA-PD/PDP's proposed use of 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) and IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, section 30.2.

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 prior approval from the plan 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 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 the most cost-effective and safest drug, 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.

Protected Class Drugs
§ 1860D-4(b)(3)(G)(i) of the Social Security Act; 42 C.F.R. § 423.120(b)(2)(v) and 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 they are prescribed. There are six classes of drugs for 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.

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 non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) in order to accommodate the immediate needs of an enrollee, as well as to allow the sponsor and/or the enrollee sufficient time to work out with the prescriber 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.

Deficiencies Related to Formulary and Benefit Administration

CMS identified multiple, serious violations of Part D requirements in Triple-S's formulary and benefit administration operations. Triple-S's violations include:

- Failure to properly administer its CMS approved prescription drug benefit in violation of 42 C.F.R. §§ 423.104(a) and 423.120(b)(2)(iv) rejecting prescriptions for 90 day fills when the CMS approved benefit permitted 90 day fills;
- Failure to provide timely and appropriate point-of-service claims adjudication in violation of 42 C.F.R. § 423.505(b)(17). More specifically:
    - An unresolvable inappropriate rejection of claims at the point-of-sale when valid prescriber identifiers, other than the National Provider Identifier (NPI), were used. *see* IOM Medicare Prescription Drug Benefit Manual, Pub. 100-18, chapter 5, section 90.2; and
    - An improper implementation of a high cost dollar edit, which was not resolvable at the point of sale; Specifically, Triple-S utilized a high cost dollar edit that rejected claims for Part D protected class drugs and other vital medications whose cost exceeded $500.
- Failure to follow CMS requirements regarding transition supplies of prescription drugs in violation of 42 C.F.R. § 423.120(b)(3), including failing to provide for the appropriate transition of new and existing enrollees prescribed Part D drugs that are not on Triple-S's formulary;
- Failure to properly administer its CMS approved formulary by applying unapproved step therapy, prior authorization, and quantity limits (including those for protected class drugs) in violation of 42 C.F.R. §§ 423.104(a) and 423.120(b)(2); *see also* IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, chapter 6, section 30.2.; chapter 7, section 60.6;
- Failure to maintain a network for limited access drugs in violation of 42 C.F.R. § 423.120(a); *see also* IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, chapter 5, section 50.3; and
- Failure to provide coverage for protected class drugs in violation of § 1860D-4(b)(3)(G) of the Social Security Act.

Violation of Disenrollment Requirements

In addition to the penalties based on violations found during the audit, CMS is imposing a penalty on Triple-S for violations of Medicare disenrollment requirements at 42 C.F.R. §§ 422.74 and 423.44. In March 2012, CMS noticed a spike in enrollee complaints related to non-payment of premiums for two Triple-S plans, including contract number H4005. CMS initiated an investigation where it discovered that Triple-S moved enrollees in plan H4005-004 who failed to pay their premium to H4005-001, a MA only plan that did not have a premium without the enrollees' request or permission. Part D sponsors are required notify its members of possible disenrollment due to non-payment and, if payment is not made in full by the end of the grace period, to disenroll an individual who fails to timely pay his/her monthly premium. Instead of

disenrolling members, Triple-S moved the affected members from plans H4005-004, which covered Part D benefits, to a plan with no Part D coverage. When questioned about this practice, Triple-S indicated that it had been "downgrading" its enrollees for several years. Downgrading, however, is a practice permitted for supplemental benefits only and it does not apply to Part D coverage, since the prescription drug coverage included under a MA-PD plan is not a supplemental benefit. Triple-S, therefore, could not "downgrade" the enrollees' coverage for non-payment of their Part D premium. Triple-S was required by Medicare rules to disenroll the member and provide them proper notice. This violation denied enrollees access to critical Prescription Drug coverage which resulted in enrollees incurring out of pocket costs and experiencing denials of access to vital medications.

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. §§ 422.752(c) and 423.752(c), CMS has determined that Triple-S's violations of Part D requirements are significant enough to warrant the imposition of a civil money penalty. In violating multiple Part D requirements, Triple-S 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).

Right to Request a Hearing

Triple-S may request a hearing to appeal a CMS determination in accordance with the procedures outlined in 42 C.F.R. Parts 422 and 423, Subpart T. Triple-S 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 December 10, 2012. 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 Triple-S disagrees. Triple-S 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 Triple-S 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 December 11, 2012. Triple-S 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 Triple-S 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. Parts 422 and 423, Subparts K and O.

If Triple-S 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: Mr. Jonathan Blum, CMS/CM
Mr. Timothy Love, CMS/CM
Mr. Paul Collura, CMS/CMHPO
Mr. Reginald Slaten, CMS/CMHPO/Region II
Ms. Rachel Walker, CMS/CMHPO/Region II
Mr. Mitchell Croll, CMS/CMHPO/Region II
Ms. Militza Flores, CMS/CMHPO/Region II