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

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICARE

MEDICARE PARTS C AND D OVERSIGHT AND ENFORCEMENT GROUP

February 28, 2020

Ms. Madeline Hernandez-Urquiza
President
Triple-S Management Corporation
P.O. Box 363628
San Juan, PR 00936-3628

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug
Contract Numbers: H4005 and H5774

Dear Ms. Hernandez-Urquiza:

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 Triple-S Management Corporation (Triple-S), that CMS has made a determination to impose a civil money penalty (CMP) in the amount of **$329,872** for Medicare Advantage-Prescription Drug (MA-PD) Contract Numbers H4005 and H5774.

An MA-PD organization's primary responsibility is to provide Medicare enrollees with medical services and prescription drug benefits in accordance with Medicare requirements. CMS has determined that Triple-S failed to meet that responsibility.

Summary of Noncompliance

CMS conducted an audit of Triple-S's Medicare operations from July 29, 2019 through August 16, 2019. In a program audit report issued on November 6, 2019, CMS auditors reported that Triple-S failed to comply with Medicare requirements related to Part D formulary and benefit administration in violation of 42 C.F.R. Part 423, Subpart C and Part C organization determinations, appeals, and grievances in violation of 42 C.F.R. Part 422, Subpart M. Triple-S's failures in these areas were systemic and adversely affected, or had the substantial likelihood of adversely affecting, enrollees. The enrollees experienced, or likely experienced, delayed or denied access to covered benefits, increased out-of-pocket costs, and/or inadequate grievance or appeal rights.

Part D Formulary and Benefit Administration Relevant Requirements
(42 C.F.R. Part 423, Subpart C (§§423.104 and 423.120(b)); Chapter 5, Section 20.1 and Chapter 6, Section 30.3 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18))

Medicare Part D Prescription Drug Program requirements apply to stand-alone Prescription Drug Plan sponsors and to Medicare Advantage organizations that offer Part D prescription drug benefits. Sponsors that offer these plans are required to enter into agreements with CMS by which the sponsors agree to comply with a number of statutory, regulatory, and sub-regulatory requirements.

A Part D sponsor must provide its enrollees with qualified prescription drug coverage. Qualified prescription drug coverage, which consists of the either standard or alternative prescription drug coverage, may be provided directly by the Part D sponsor or through arrangements with other entities.

As part of the qualified prescription drug coverage, 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. The formulary review and approval process includes reviewing the Part D sponsor's proposed drug utilization management processes to adjudicate Medicare Part D prescription drug claims. Once CMS approves a sponsor's formulary, the sponsor cannot change the formulary unless it obtains CMS approval and subsequently notifies its enrollees of the changes.

Violations Related to Part D Formulary & Benefit Administration

CMS determined that Triple-S violated the following Part D formulary and benefit administration requirement(s):

1. Inappropriately rejected formulary medications due to errors with enrollees' eligibility files. As a result, enrollees were inappropriately denied coverage for medications at the point of sale and were either delayed access to medications, failed to receive medications, or paid out of pocket for medications. This failure violates 42 C.F.R. §§ 423.104(a) and 423.120(b).

Part C Organization Determination, Appeal, and Grievance Requirements
(42 C.F.R. Part 422, Subpart M; Part C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance)

Medicare enrollees have the right to contact their plan sponsors to express general dissatisfaction with the operations, activities, or behavior of the plan sponsors, or to make specific complaints about the denial of coverage for drugs or services to which the enrollees believe they are entitled. Sponsors are required to classify general complaints about services, benefits, or the sponsor's operations or activities as grievances. Sponsors are required to classify complaints about coverage for Part C services or reimbursements as organization determinations. It is critical for a sponsor to properly classify each complaint as a grievance, organization determination, or both.

If an organization determination is not properly classified, the enrollee's access to medically necessary or life-sustaining services may be delayed.

The first level of review is the organization determination, which is conducted by the plan sponsor. The enrollee, the enrollee's representative, or the enrollee's treating physician or prescriber may make a request for an organization determination. If the organization determination is adverse (i.e., not in favor of the enrollee), the enrollee has the right to file an appeal. The first level of the appeal, called a reconsideration, is handled by the plan sponsor. The second level of appeal is made to an independent review entity (IRE) that contracts with CMS. If the sponsor does not issue the reconsideration decision timely, the decision is considered to be unfavorable to the enrollee and must be automatically sent to the IRE.

There are different decision making timeframes for the review of organization determinations and appeals. For standard organization determinations, the sponsor must provide notice of the decision no later than fourteen (14) calendar days after receipt of the request for service. For organization determinations requesting reimbursement determinations, sponsor must pay or provide notice of the decision no later than sixty (60) days after the receipt of the request for reimbursement. Failure to provide enrollees and/or their providers notice within the required timeframes can result in enrollees failing to receive the approved services or reimbursements, or delays with accessing services and/or appeal rights.

Violations Related to Part C Organization Determinations, Appeals and Grievances

CMS determined that Triple-S violated the following Part C organization determination, appeal, and grievance requirement(s):

2. Failure to notify enrollees of its decisions within 14 calendar days of receipt of standard organization determination requests. As a result, there is a substantial likelihood that enrollees with approved services were impeded from obtaining medically necessary services while others with denied services were delayed timely appeal rights. This failure violates 42 C.F.R. § 422.568(b).

3. Failure to reimburse enrollees within 60 calendar days from the date it received a request for reimbursement. As a result, enrollees with approved reimbursements experienced substantial delays in receiving payment or never received payment. This failure violates 42 CFR § 422.520(a)(3) and 42 CFR § 422.590(b).

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. § 422.752(c)(1), § 422.760(b), § 423.752(c)(1), and § 423.760(b), CMS has determined that Triple-S's violations of Parts C and D requirements directly adversely affected (or had the substantial likelihood of adversely affecting) enrollees and warrants the imposition of a CMP. Triple-S failed substantially:

- To carry out the terms of its contract with CMS (42 C.F.R. § 422.510(a)(1) and 42 C.F.R. § 423.509(a)(1)); and

- To comply with the requirements in Subpart M relating to grievances and appeals (42 C.F.R. § 422.510(a)(4)(ii)).

Right to Request a Hearing

Triple-S 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. Triple-S must send a request for a hearing to the Departmental Appeals Board (DAB) office listed below by April 29, 2020. 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 filed through the DAB E-File System (https://dab.efile.hhs.gov) unless the party is not able to file the documents electronically. If a party is unable to use DAB E-File, it must send appeal-related documents to the Civil Remedies Division using a postal or commercial delivery service at the following address:

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

Please see https://dab.efile.hhs.gov/appeals/to_crd_instructions for additional guidance on filing the appeal.

A copy of the hearing request should also be sent to CMS at the following address:

Kevin Stansbury
Director, Division of Compliance Enforcement
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Mail Stop: C1-22-06
Email: kevin.stansbury@cms.hhs.gov

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 April 30, 2020. Triple-S 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.

Impact of CMP

Please note this action may factor into Triple-S's past performance evaluation.

Further failures by Triple-S to provide its enrollees with Medicare benefits in accordance with CMS requirements may result in CMS imposing additional remedies available under law, including contract termination, 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/

John A. Scott
Acting Director
Medicare Parts C and D Oversight and Enforcement Group

cc: Heather Lang, CMS/OPOLE
Douglas Edwards, CMS/OPOLE
Rachel Walker, CMS/OPOLE
Sandra Rosa, CMS/OPOLE
Kevin Stansbury, CMS/CM/MOEG/DCE