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

February 29, 2016

Matt Cowley
Chief Executive Officer
Tenet Healthcare Corporation
7878 N. 16th Street,
Suite 105
Phoenix, AZ 85020

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug Contract Numbers: H5985, H7960, and H8554

Dear Mr. Cowley:

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 Tenet Healthcare Corporation (Tenet), that CMS has made a determination to impose a civil money penalty (CMP) in the total amount of **$127,200** for Medicare Advantage-Prescription Drug (MA-PD) Contract Numbers: H5985, H7960, and H8554.

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

Summary of Noncompliance

CMS conducted an audit of Tenet's Medicare operations from October 26, 2015 through November 6, 2015. In a program audit report issued on February 5, 2016, CMS auditors reported that Tenet 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, Part C access to facilities and records and Part C organization determinations, appeals, and grievances in violation of 42 C.F.R. Part 422, Subparts M and K. Tenet'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 a violation of Part D formulary and benefit administration requirements that resulted in Tenet's enrollees not receiving their requested medication(s) or experiencing unnecessary delays after receiving a rejected claim. Tenet's violation includes:

1. Failure to properly administer its CMS-approved formulary by applying unapproved prior authorization edits. As a result, enrollees experienced inappropriate denials of coverage at the point of sale that impeded their access to prescription drugs. Enrollees may have experienced delays, paid out-of-pocket, or never received the prescription drugs at all. This is in violation of 42 C.F.R. § 423.120(b)(2); Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2.

Part C Organization Determination, Appeal, and Grievance Relevant Requirements
(42 C.F.R. Part 422, Subpart M; IOM Pub. 100-16, Medicare Managed Care Manual, Chapter 13)

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 or services to which the enrollee believes he or she is 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 services as organization determinations. It is critical for a sponsor to properly classify each complaint as a grievance or an organization determination or both. Improper classification of an organization denies an enrollee the applicable due process and appeal rights and may delay an enrollee's access to medically necessary or life-sustaining services.

The enrollee, the enrollee's representative or the enrollee's treating physician or prescriber may make a request for an organization determination. The first level of review is the organization 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 organization determination is adverse (not in favor of the beneficiary), the beneficiary has the right to file an appeal. The first level of the appeal, called a reconsideration, is handled by the plan sponsor and must be conducted by a physician who was not involved in the organization determination. 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 organization determinations and appeals. CMS has a beneficiary protection process in place that requires plans to forward appeals to the IRE when the plan has missed the applicable adjudication timeframe.

Violations Related to Part C Organization Determinations, Appeals and Grievances

CMS identified violations of Part C organization determination, appeal, and grievance requirements that resulted in Tenet's enrollees being inappropriately delayed or denied their access to services and/or organization determinations and appeals. Tenet's violations include:

2. Failure to correctly classify and process enrollee requests as grievances, organization determinations or appeals. As a result, enrollees may have experienced delays or inappropriate denials of medical services. This is in violation of 42 C.F.R. §§ 422.564(b) and 422.566(b); Medicare Managed Care Manual, Chapter 13, Sections 10.2 and 20.2.

3. Failure to conduct sufficient outreach to providers or beneficiaries to obtain additional information necessary to make appropriate clinical decisions. As a result, enrollees experienced inappropriate delays or denials of medical services. This is in violation of Medicare Managed Care Manual, Chapter 13, Section 70.7.1, Paragraph 2, Section 70.7.2, Paragraph 1, and Chapter 4, Section 110.4.

4. Failure to follow CMS guidelines when making pre-service organization determinations. As a result, enrollees experienced inappropriate delays or denials of medical services. This is in violation of 42 C.F.R. §§ 422.101(a) and (b); Medicare Managed Care Manual, Chapter 13, Sections 10.2 and 10.4.1.

Part C Record Maintenance, Access to Facilities and Records, and Disclosure of Information Relevant Requirements
(42 C.F.R §§ 422.504(d)(1)(ii), 422.504(e)(1)(i),422.504(f)(2)(v) and 422.504(f)(2)(vii))

Part C Sponsors must adhere to certain record maintenance, facility access and disclosure requirements in order to participate in the Medicare Advantage Program. These requirements are necessary for CMS to effectively evaluate sponsors' compliance with applicable statutes, regulations and program instructions. For instance, Part C Sponsors must maintain records of organization determinations, appeals and grievances for at least 10 years that are sufficiently detailed and complete in order to enable CMS auditors to evaluate the quality, appropriateness and timeliness of services performed under the contract. In furtherance of that objective, sponsors are also required to provide CMS with access to their facilities and records.

Finally, sponsors are required to disclose to CMS all information that may be necessary for CMS to administer and evaluate the program, including but not limited to, information about enrollee appeals and their dispositions. Failure to produce accurate and timely universes related to Part C organization determinations, appeals and grievances constitutes a violation of these requirements, as CMS is unable to evaluate the quality, appropriateness and timeliness of services performed under the contract. Additionally, the failure to produce accurate and timely universes demonstrates that sponsors' are not adequately monitoring their operations to ensure compliance with CMS requirements. As a result, sponsors are not able to readily identify and

remediate issues of program noncompliance that have adversely affected (or have the substantial likelihood of adversely affecting) enrollees.

Violations Related to Part C Record Maintenance, Access to Facilities and Records, and Disclosure of Information

CMS identified a violation of Part C record maintenance, access to facilities and records, and disclosure of information requirements that resulted in Sponsor's enrollees experiencing a substantial likelihood of being delayed or denied access to medical services. Sponsor's violation includes:

5. Failure to produce sufficient records for CMS to evaluate the quality, appropriateness, and timeliness of services furnished to Medicare enrollees. As a result, auditors were unable to test the following areas for compliance: (1) the timeliness of processing standard and expedited organization determinations, claims, and requests for payment reconsiderations; and (2) the timeliness of processing pre-service Independent Review Entity (IRE) cases requiring effectuation. This is in violation of 42 C.F.R §§ 422.504(d)(1)(ii), 422.504(e)(1)(i),422.504(f)(2)(v) and 422.504(f)(2)(vii).

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 Tenet'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. Tenet 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));
- To comply with the Part D service access requirements in § 423.120 (42 C.F.R. § 423.509(a)(4)(iv));
- 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

Tenet 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. Tenet 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 April 29, 2016. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which Tenet disagrees. Tenet 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:

Vikki Ahern
Acting Director, Division of Compliance Enforcement
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Mail Stop: C1-22-07
Email: Vikki.Ahern@cms.hhs.gov

If Tenet 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 May 2, 2016. Tenet 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 Tenet 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 Tenet 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: Vikki Ahern, CMS/CM/MOEG/DCE
Kevin Stansbury, CMS/CM/MOEG/DCE
Julie Kennedy, CMS/ CMHPO/Region VI
Arthur Pagan, CMS/ CMHPO/Region VI
Toni Duplain, CMS/ CMHPO/Region VI