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

CORRECTION: THE ORIGINAL NOTICE ISSUED ON DECEMBER 29, 2015 HAS BEEN RESCINDED AND REPLACED BY THIS NOTICE

June 2, 2016

Mr. James P. O'Drobinak
Chief Executive Officer
Medical Card System, Inc.
MCS Plaza
255 Ponce de Leon Avenue, Second Floor
San Juan, PR 00918

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug
Contract Number: H5577

Dear Mr. O'Drobinak:

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 Medical Card System, Inc. (MCS), that CMS has made a determination to impose a civil money penalty (CMP) in the total amount of **$652,650** for Medicare Advantage-Prescription Drug (MA-PD) Contract Number: H5577.

CMS has determined that MCS 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 MCS' Medicare operations from June 1, 2015 through June 11, 2015. In a program audit report issued on November 6, 2015, CMS auditors reported that MCS failed to comply with Medicare requirements related to Part D formulary and benefit administration, Part C and Part D organization/coverage determinations, appeals, and grievances, and Part C records management in violation of 42 C.F.R. Part 422, Subparts K and M and 42 C.F.R. Part 423, Subparts C and M. MCS' failures in these areas were systemic and resulted in enrollees experiencing inappropriate delays or denials in receiving covered benefits or 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).

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 a non-formulary Part D drug (including Part D drugs that are on a sponsor's formulary but require prior authorization or quantity limits under a sponsor's utilization management rules). In the long-term care setting, the temporary supply of non-formulary Part D drugs must be for at least 91 days, and may be up to at least 98 days, consistent with the dispensing increment, with refills provided, if needed. The transition process is designed to accommodate the immediate needs of an enrollee, as well as to allow the sponsor and/or the enrollee sufficient time to work out 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.

Violations Related to Formulary & Benefit Administration

CMS identified a violation of Part D formulary and benefit administration requirements that resulted in MCS' enrollees being delayed and/or denied access to transition-eligible drugs, or having to pay unnecessary out-of-pocket expenses. MCS' violation includes:

1. Failure to provide enrollees transition supplies of medications. As a result, enrollees experienced inappropriate denials of coverage for transition-eligible drugs at the point of sale and were delayed access to drugs, never received the drugs, or incurred increased out-of-pocket costs in order to receive the drugs. This is in violation of 42 C.F.R. § 423.120(b)(3); and IOM Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.4.1 and 30.4.5.

Part C and Part D Organization/Coverage Determination, Appeal, and Grievance Relevant Requirements
(42 C.F.R. Part 422, Subparts M and K; 42 C.F.R. Part 423, Subpart M; IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18; 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 drugs or services as organization determinations (Part C – medical services) or coverage determinations (Part D – drug benefits). It is critical for a sponsor to properly classify each complaint as a grievance or an organization/coverage determination or both. Improper classification of an organization or 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 services or drugs.

The enrollee, the enrollee's representative, or the enrollee's treating physician or prescriber may make a request for an organization determination or coverage determination. The first level of review is the organization determination or coverage determination, which is conducted by the plan sponsor, and the point at which enrollees or their physicians submit justification for the benefit.

If the organization or coverage determination is adverse (not in favor of the enrollee), the enrollee has the right to file an appeal. The first level of the appeal – called a reconsideration (Part C) or redetermination (Part D) – is handled by the plan sponsor and must be conducted by a physician who was not involved in the organization determination or 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 organization determinations, coverage determinations, and appeals. CMS has an enrollee protection process 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 C and Part D Organization/Coverage Determinations, Appeals and Grievances

CMS identified violations of Part C and Part D organization/coverage determination, appeal, and grievance requirements that resulted in MCS' enrollees being delayed or denied access to medical services and/or drugs. MCS' violations include:

2. Failure to notify enrollees, or their prescribers, of decisions within 72 hours of receipt of expedited redetermination requests. As a result, enrollees experienced unnecessary delays in receiving coverage decisions for drugs that required expedited reviews. This is in violation of 42 C.F.R. § 423.590(d); and IOM Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 70.9.3, 70.9.4, and 70.8.1.

3. Failure to notify enrollees, or their prescribers, of decisions within 7 days after receipt of standard redetermination requests. As a result, enrollees experienced unnecessary delays in receiving coverage decisions after filing an appeal. This is in violation of 42 C.F.R. §§ 423.590(a) and 590(b); and IOM Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 70.7, 70.9.1, and 70.9.2.

4. Failure to effectuate exception approvals through the end of the plan year. As a result, enrollees had the substantial likelihood of being denied coverage at the point of sale and would have to obtain new prior authorizations or exception approvals to get their drugs. This is in violation of 42 C.F.R. §§ 423.578(c)(3) and 578(c)(4); and IOM Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 30.2 and 130.

5. Failure of the Medical Director to ensure the clinical accuracy of coverage decisions in instances where the contracted providers were routinely unresponsive to requests for additional information. As a result, enrollee requests for coverage decisions had the substantial likelihood of being inappropriately denied because contracted providers were unresponsive to requests for additional information needed to process the case. This is in violation of 42 C.F.R. § 423.562(a)(5).

6. Misclassified coverage determination or appeals requests as grievances and/or customer service inquiries. As a result, enrollee requests were not processed with the correct adjudicatory time requirements and appeal rights, which likely resulted in delays in receiving a coverage decision or the inability to appeal adverse decisions.

This is in violation of 42 C.F.R. § 423.564(b); and IOM Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 20.2.4.1, 20.2.4.2, and 30.4.

7. Failure to notify enrollees, or their providers, of decisions within 14 calendar days of receipt of standard organization determination requests. As a result, enrollees experienced unnecessary delays in receiving coverage decisions for medical services that required pre-service approval. This is in violation of 42 C.F.R. § 422.568(b); and IOM Pub. 100-16, Medicare Managed Care Manual, Chapter 13, Section 40.1, Paragraph 1.

8. Failure to notify enrollees, or their providers, of decisions within 72 hours after receipt of expedited reconsideration requests. As a result, enrollees experienced unnecessary delays in receiving coverage decisions for pre-service appeals for medical services that required expedited review. This is in violation of 42 C.F.R. § 422.590(d)(1); and IOM Pub. 100-16, Medicare Managed Care Manual, Chapter 13, Section 80.1, Paragraph 3.

9. Failure to correctly identify enrollee complaints as either grievances, organization determinations or appeals. As a result, enrollee requests were not processed with the correct adjudicatory time requirements and appeal rights, which likely resulted in delays in receiving a coverage decision or the inability to appeal a denied medical service. This is in violation of 42 CFR § 422.564(b); 42 CFR § 422.566(b); and IOM Pub. 100-16, Medicare Managed Care Manual, Chapter 13, Sections 10.2 and 20.2.

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.

CMS identified violations of Part C record maintenance, access to facilities and records, and disclosure of information requirements that resulted in MCS' enrollees being substantially likely to experience inappropriate delays and/or denials of medical care or devices. MCS' violations include:

10. 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 decisions for standard pre-service reconsiderations; (2) the timeliness of enrollee notification for standard pre-service reconsiderations; and (3) appropriate autoforwarding of adverse decisions to the Independent Review Entity (IRE). This is in violation of 42 C.F.R. § 422.504(e)(1)(i).

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 MCS' 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. MCS 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) and § 423.509(a)(4)(ii)); and
- To comply with the requirements in Subpart K relating to record maintenance, access to facilities and records, and disclosure of information (42 C.F.R. § 422.510(a)(4)(ix) and § 423.509(a)(4)(viii).

Right to Request a Hearing

MCS may request a hearing to appeal CMS' determination in accordance with the procedures outlined in 42 C.F.R. Parts 422 and 423, Subpart T. MCS 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 August 2, 2016. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which MCS disagrees. MCS 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:

John Scott
Director, Division of Compliance Enforcement
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Mail Stop: C1-23-17
Email: john.scott@cms.hhs.gov

If MCS 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 August 3, 2016. MCS 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 MCS 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 MCS 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: John Scott, CMS/CM/MOEG/DCE
Kevin Stansbury, CMS/CM/MOEG/DCE
Stephanie S. Brown, CMS/CM/MOEG/DCE
Reginald G. Slaten, CMS/ CMHPO/Region II
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