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

November 23, 2015

Ms. Patricia Richards
President and CEO
SelectHealth, Inc.
5381 S Green St
Murray, UT 84123

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug Contract Number: H1994

Dear Ms. Richards:

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 SelectHealth, Inc. (SelectHealth), that CMS has made a determination to impose a civil money penalty (CMP) in the total amount of **$174,800** for Medicare Advantage-Prescription Drug (MA-PD) Contract Number: H1994.

CMS has determined that SelectHealth 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 SelectHealth's Medicare operations from June 15, 2015 through June 26, 2015. In a program audit report issued on November 5, 2015, CMS auditors reported that SelectHealth failed to comply with Medicare requirements related to Part D formulary and benefit administration and coverage determinations, appeals, and grievances in violation of 42 C.F.R. Part 423, Subparts C and M. SelectHealth'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.

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 Part D Formulary & Benefit Administration

CMS identified violations of Part D formulary and benefit administration requirements that resulted in SelectHealth's enrollees experiencing inappropriate denials at point of sale. SelectHealth's violations include:

1. Failure to resolve claims that rejected for invalid National Provider Identifier (NPI) with pharmacies within one business day. As a result, enrollees experienced denials of coverage at the point of sale and were unable to obtain drugs within 24 hours. This is in violation of 42 C.F.R. § 423.120(c)(5).

2. Improperly effectuated prior authorizations or exception requests. As a result, enrollees experienced inappropriate denials of coverage 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)(2); Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2.

3. Failure to properly administer the CMS-approved formulary by applying unapproved prior authorization edits. As a result, enrollees experienced inappropriate denials of coverage at the point of sale and were delayed access to drugs, never received their prescribed 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)(2); Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2.

4. Failure to properly administer the CMS transition policy. As a result, enrollees experienced inappropriate denials of coverage 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); Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.4.

Part D Coverage Determination, Appeal, and Grievance Relevant Requirements
(42 C.F.R. Part 423, Subpart M; IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 18)

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 to which the enrollee believes he or she is entitled. Sponsors are required to classify general complaints about benefits or the sponsor's operations or activities as grievances. Sponsors are required to classify complaints about coverage for drugs as coverage determinations. It is critical for a sponsor to properly classify each complaint as a grievance or a coverage determination or both. Improper classification of a 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 drugs.

The enrollee, the enrollee's appointed representative, or the enrollee's prescribing physician or other prescriber may make a request for a coverage determination. The first level review is the coverage 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 coverage determination is adverse (not in favor of the enrollee), the enrollee has the right to file an appeal. The first level of appeal - called a redetermination – is handled by the plan sponsor and must be conducted by a physician who was not involved in the 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 coverage determinations and appeals. CMS has a beneficiary protection 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 D Coverage Determinations, Appeals, and Grievances

CMS identified violations of Part D coverage determination, appeal, and grievance requirements that resulted in SelectHealth's enrollees being inappropriately delayed or denied access to drugs or increased out-of-pocket costs. SelectHealth's violations include:

5. Failure to make payment decisions within 14 days after receipt of coverage determination requests. As a result, enrollees were delayed receiving reimbursement payments for drugs paid for out-of-pocket at the point of sale. This is in violation of 42 C.F.R. § 423.568(c); Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 40.2 and 130.1.

6. Misclassified coverage determination or redetermination 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); Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 20.2 and 30.4.

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 SelectHealth's violations of Part D requirements directly adversely affected (or had the substantial likelihood of adversely affecting) enrollees and warrants the imposition of a CMP. SelectHealth 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. § 423.509(a)(4)(ii)).

Right to Request a Hearing

SelectHealth 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. SelectHealth 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 January 25, 2016. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which SelectHealth disagrees. SelectHealth 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:

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

If SelectHealth 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 January 26, 2016. SelectHealth 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 SelectHealth 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 SelectHealth 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: Michael DiBella, CMS/CM/MOEG/DCE
Tod Anderson, CMS/ CMHPO/Region VII
Anne Kane, CMS/ CMHPO/Region VII
Christopher Bartling, CMS/ CMHPO/Region VII