

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**

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January 29, 2015

Mr. Wayne Lowell  
Chief Executive Officer  
Senior Whole Health Holdings, Inc.  
58 Charles Street, 2<sup>nd</sup> Floor  
Cambridge, MA 02141

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug  
Contract Numbers: H2224 and H5992

Dear Mr. Lowell,

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 Senior Whole Health Holdings, Inc. (SWH), that CMS has made a determination to impose a civil money penalty (CMP) in the total amount of **\$229,350** for Medicare Advantage-Prescription Drug Contract Numbers: H2224 and H5992.

CMS has determined that SWH failed to provide its enrollees with Medicare benefits in accordance with CMS requirements. A Medicare Advantage organization'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 SWH's Medicare operations from September 2, 2014 through September 17, 2014. CMS auditors reported in the Medicare Advantage & Prescription Drug Program Audit report issued December 5, 2014, that SWH 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 in violation of 42 C.F.R. Part 422, Subpart M and 42 C.F.R. Part 423, Subparts C and M. SWH'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 serious violations of Part D formulary and benefit administration requirements that resulted in SWH's enrollees being inappropriately delayed access to prescribed medications at the point of sale. SWH's violations include:

1. Failure to properly administer its CMS-approved formulary by applying unapproved quantity limits and utilization management practices. This is in violation of 42 CFR § 423.120(b)(2), § 423.104(a); IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2, 30.2.2.1, 30.2.5; and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 7, Section 20.4 and 60.6.

### **Part C and Part D Organization/Coverage Determination, Appeal, and Grievance Relevant Requirements**

*(42 C.F.R. Part 422, Subpart M; 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 beneficiaries or their physicians submit justification for the benefit.

If the organization or coverage 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 (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 a beneficiary 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 serious violations of Part C and Part D organization/coverage determination, appeal, and grievance requirements that resulted in SWH's enrollees being inappropriately delayed or denied access to medical services and medications. SWH's violations include:

2. Failure to forward untimely coverage determinations to the independent review entity (IRE) within the required timeframe. This is in violation of 42 CFR § 423.568(h), § 423.572(d); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 40.4, 50.6, 70.30 and 70.40.
3. Misclassified oral coverage determination requests as inquiries. This is in violation of 42 CFR § 423.564(b); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 20.2, 20.2.4.1, 20.2.4.2 and 30.4.
4. Failure to notify the beneficiary of its decision within 14 calendar days of receipt of standard organization determination requests. This is in violation 42 CFR § 422.568(b); and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 40.1, Paragraph 1.
5. Failure to demonstrate sufficient outreach to the provider or beneficiary to obtain additional information necessary to make appropriate clinical decisions. This is in violation of 42 CFR § 422.566(a); IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 4, Section 110.3; and IOM Pub 100-16 Medicare Managed Care Manual, Chapter 13, Section 70.7.1, Paragraph 2 and 70.7.2, Paragraph 1.

### **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 SWH'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. SWH 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 requirements in Subpart M relating to grievances and appeals (42 C.F.R. § 422.510 (a)(4)(ii) and § 423.509(a)(4)(ii)).

### **Right to Request a Hearing**

SWH 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. SWH 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 March 31, 2015. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which SWH disagrees. SWH 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 SWH 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 1, 2015. SWH 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 SWH 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 SWH 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: Douglas Edwards, CMS/ CMHPO/Region I

Adele Pietrantonio, CMS/ CMHPO/Region I  
Kelly Valente, CMS/ CMHPO/Region I