

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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June 12, 2014

Mr. Brit Pim  
Chief Executive Officer  
Express Scripts Medicare™  
One Express Way  
St. Louis, MO 63121

Re: Notice of Imposition of Civil Money Penalty for Prescription Drug Plan Contract  
Numbers: S5660, S5983, S7950

Dear Mr. Pim,

Pursuant to 42 C.F.R. § 423.752(c)(1) and § 423.760(b), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Express Scripts Medicare™ (Express Scripts) that CMS has made a determination to impose a civil money penalty (CMP) in the total amount of **\$334,300** for Prescription Drug Plan Contract Numbers: S5660, S5983 and S7950.

CMS has determined that Express Scripts failed to provide its enrollees with Medicare benefits in accordance with CMS requirements. A Medicare Prescription Drug Plan sponsors' central mission is to provide Medicare beneficiaries with prescription drug benefits within a framework of Medicare requirements that provide plan enrollees with a number of protections.

**Summary of Noncompliance**

CMS conducted an audit of Express Scripts' Medicare operations from June 17, 2013 through June 28, 2013. CMS auditors reported in the Medicare Prescription Drug Program Audit report issued January 10, 2014 that Express Scripts failed to comply with Medicare requirements related to Part D formulary and benefit administration, coverage determinations, appeals, and grievances in violation of 42 C.F.R. Part 423, Subparts C and M. Express Scripts' 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 Formulary & Benefit Administration**

CMS identified serious violations of Part D formulary and benefit administration requirements that resulted in Express Scripts' enrollees being inappropriately delayed or denied access to their medications. Express Scripts' violations include:

- Failure to properly administer its CMS approved formulary by applying unapproved prior authorization edits. This is in violation of 42 C.F.R. § 423.120(b)(2); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.2.2.1, 30.2.2 and 30.2.
- Failure to properly administer its CMS approved formulary by applying unapproved utilization management practices. This is in violation of 42 C.F.R. § 423.104(a) and § 423.120(b)(2); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2 and Chapter 7, Section 20.4.
- Failure to properly administer its CMS approved formulary by rejecting formulary medications as non-formulary. This is in violation of 42 C.F.R. § 423.120(b)(2); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.2 and 30.3.3.1.
- Failure to provide new and continuing enrollees with a transition supply of medication when there was a CMS approved prior authorization requirement or when the medication was a non-formulary medication. This is 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, 30.4.5 and 30.4.8.
- Failure to properly administer its CMS approved formulary by applying unapproved quantity limits. This is in violation of 42 C.F.R. § 423.120(b)(2); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.2, 30.2.2.1 and Chapter 7, Section 60.6.

**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 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 serious violations of Part D coverage determination, appeal, and grievance requirements that resulted in Express Scripts' enrollees being inappropriately delayed or denied or facing the substantial likelihood of being delayed or denied access to their medications. Express Scripts' violations include:

- Failure to ensure that expedited and standard coverage determination and redetermination requests were effectuated and enrollees (or their prescribers, as appropriate) were notified within the required timeframes. This is in violation of 42 C.F.R. § 423.568(b); § 423.572(a); § 423.590(a, b, d); and § 423.636(a); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 40.2, 40.3.3, 40.3.4, 40.3.5, 50.4, 70.7, 70.9, 130.1, 130.2.1 and 130.2.2.

- Failure to forward untimely coverage determinations and redeterminations to the Independent Review Entity (IRE) within the required timeframes. This is in violation of 42 C.F.R. § 423.568(h); § 423.572(d); and § 423.590(c); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 40.4, 50.6, 70.7.1 and 70.10.
- Failure to properly effectuate prior authorizations or exception requests. This is in violation of 42 C.F.R. § 423.120(b)(2); and IOM Pub. 100-18 Medicare Prescription Drug Manual, Chapter 6, Section 30.2.2 and Chapter 18, Section 130.
- Failure to make appropriate clinical decisions when processing a coverage determination. This is in violation of 42 C.F.R. § 423.566(a-b); and IOM Pub. 100-18 Medicare Prescription Drug Manual, Chapter 18, Section 30.

### **Basis for Civil Money Penalty**

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

- To carry out the terms of its contract with CMS (42 C.F.R. § 423.509(a)(1));
- To comply with the Part D service access requirements in 42 C.F.R. § 423.120 (§ 423.509(a)(7)); and
- To comply with the requirements in Subpart M relating to grievances and appeals (42 C.F.R. § 423.509(a)(5)).

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

Express Scripts may request a hearing to appeal CMS's determination in accordance with the procedures outlined in 42 C.F.R. Part 423, Subpart T. Express Scripts 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 12, 2014. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which Express Scripts disagrees. Express Scripts 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 Express Scripts 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 13, 2014. Express Scripts may choose to have the penalty deducted from its monthly payment, transfer the funds electronically, or mail a check to CMS.

Please note that further failures by Express Scripts 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. Part 423, Subparts K and O.

If Express Scripts 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: Reginald Slaten, CMS/ CMHPO/Region II  
Mitchell Croll, CMS/ CMHPO/Region II  
Michael Regusters, CMS/ CMHPO/Region II