DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR BENEFICIARY CHOICES

To: Part D Plan Sponsors

From: Anthony Culotta
Director, Medicare Enrollment & Appeals Group

Date: February 27, 2007

Subject: Revisions to Chapter 18 of the Prescription Drug Benefit Manual

The attached document provides a summary of changes made to Chapter 18 of the Prescription Drug Benefit Manual. Chapter 18 provides guidance to Part D plan sponsors regarding Part D grievances, coverage determinations, and appeals. The revised version of Chapter 18 supersedes the previous version dated June 22, 2006, and is posted on CMS' Medicare Prescription Drug Appeals & Grievances webpage:
http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/11_Guidance.asp

We ask plan sponsors to carefully review the attached summary of changes and the revised version of Chapter 18. Thank you for your continuing cooperation.

Summary of Significant Changes to Chapter 18 of the Prescription Drug Benefit Manual
Part D Grievances, Coverage Determinations, and Appeals

(Rev. 3, 2/1/07)

The following changes have been made to Chapter 18 of the Prescription Drug Benefit Manual:

A. We added page numbers.

B. In §10.4.1 (Appointed Representative Filing on Behalf of the Enrollee), we clarify that a plan sponsor must send written notice of a dismissal to an enrollee and a person who asserts representative status when:

- The person who asserts representative status files a request on behalf of an enrollee,
- The person does not provide the appropriate documentation indicating his or her representative status,
- The plan sponsor makes and documents its reasonable efforts to secure the necessary appointment forms, and
- The Part D plan sponsor does not receive the form or statement within a reasonable time.

C. In § 20.2.2 (Co-Payment Complaints), we clarify that an enrollee's dispute about the amount he or she is asked to pay for a drug must be processed as a coverage determination, even when the basis for the dispute is the plan sponsor's TrOOP calculation. This policy is not new since any dispute about a plan sponsor's decision on the amount of cost-sharing for a drug is considered a coverage determination and is subject to appeal. In such circumstances, the enrollee must:

- Allege that a plan sponsor made an error in calculating his or her TrOOP costs, and the error caused the plan sponsor to charge him or her full-price for a drug because the enrollee was placed between the initial coverage limit and annual out-of-pocket threshold as a result of the calculation, and
- Produce some evidence (e.g., receipts, records, an Explanation of Benefits) in support of the allegation.

D. In § 20.2.4, we revised the language regarding how plan sponsors should treat complaints involving drugs that are not covered Part D drugs (as defined in section 1860D-2(e)(1) of the Act). We clarify that complaints involving drugs that are not covered Part D drugs under section 1860D-2(e)(1) of the Act may be processed in the same manner as complaints involving drugs excluded from coverage under section 1860D-2(e)(2) of the Act (the complaints may be treated as inquiries, grievances, or coverage determinations depending on the circumstances). Appendix 12 was revised accordingly.

E. In §§ 40.4 and 50.6, 70.7.1, 70.8.2, 70.10, and 70.20, we explain CMS' expectation that, when an enrollee who is in the transition period files an exception request and the plan does not make its decision timely and/or fails to forward a request/case file to the IRE as required, the plan sponsor should provide the enrollee with a temporary supply of the requested prescription drug (when not medically contraindicated) until the case is resolved by the plan sponsor or the IRE issues a reconsideration decision.

F. In § 70.9.1 (Adverse Standard Redeterminations), we clarify that written notice of a plan sponsor's adverse standard redetermination must be sent to the enrollee.

G. In § 70.9.2 (Adverse Expedited Redeterminations), we clarify that notice of a plan sponsor's adverse expedited redetermination must be sent to the enrollee.

H. In §90.2 (Determination of Amount in Controversy), we clarify that the 2007 AIC threshold for requesting an ALJ hearing is $110.

I. In §90.2 (Judicial Review), we clarify that the 2007 AIC threshold for requesting judicial review is $1,130.

J. We deleted §§ 140.1, 140.2, and 140.3 and inserted a link to CMS' Plan Reporting and Oversight webpage (where the actual reporting requirements are located): http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp