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CENTER FOR BENEFICIARY CHOICES

Date: July 5, 2006

To: Part D Plan Sponsors

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

The attached document provides a summary of significant 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 majority of revisions to Chapter 18 reflect policies previously released through HPMS.[1] The revised version of Chapter 18 supersedes the previous version dated November 30, 2005, and is posted on CMS's Part D Enrollment and Appeals Guidance webpage:
http://www.cms.hhs.gov/PrescriptionDrugCovContra/06_RxContracting_EnrollmentAppeals.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.

[1] FAQs on Exceptions and Appeals (May 31, 2006), and Next Steps on Formulary Transition Policies, Attachment II (March 17, 2006).

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

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

A. Reorganized §20.2 (Distinguishing Between Grievances and Coverage Determinations) into 5 subsections:
   - 20.2.1 - Quality of Care Complaints
   - 20.2.2 - Co-Payment Complaints
   - 20.2.3 - Benefit Design Complaints
   - 20.2.4 - Excluded Drug Complaints (the only new section added)
   - 20.2.5 - Enrollment or Disenrollment Complaints

- The excluded drug complaint section (§20.2.4) is new. It clarifies our policy that transactions involving excluded drugs may fall into three categories: inquiries, grievances, and coverage determinations. In general, most should be treated as inquiries.

  Example
  - An enrollee calls his or her plan sponsor to determine if Valium is covered for him or her (it doesn't matter if the enrollee has a prescription for the drug or not).
  - The plan sponsor tells the enrollee that certain drugs are excluded from coverage under Part D, and Valium is one of those drugs.
  - The enrollee does not complain about the policy to exclude the requested drug from coverage, or argue that the drug should be covered on the basis that it is not excluded, is not excluded for the purpose for which it was prescribed, or is covered by the plan as a supplemental benefit.
  - The transaction should be treated as an **inquiry**.
  - We developed a model notice to be used when a plan responds to an enrollee's inquiry in writing (a plan may respond to an inquiry orally or in writing). The model notice is Appendix 12.

- If an enrollee is not disputing that a drug is an excluded drug, but he/she is complaining about the policy that excludes the drug, the complaint should be processed as a **grievance**.

- If an enrollee or physician argues that a drug should be covered on the basis that it is not an excluded drug (i.e., the enrollee or physician believes the plan sponsor incorrectly classified/identified a Part D drug as excluded from coverage, a drug is not excluded for the purpose for which it was prescribed, or a drug is covered by the plan as a supplemental benefit), the plan sponsor must process the complaint as a **coverage determination**, which is subject to appeal.

B. Added new §30.1 (Prior Authorization or Other Utilization Management Requirements)

- Clarify that, when a plan sponsor processes a prior authorization (PA) or other utilization management (UM) requirement request, the plan sponsor's determination on whether to grant approval of a drug for an individual enrollee constitutes a coverage determination and is subject to appeal. Thus, the timeframe, notice, and other requirements applicable to coverage determinations also apply to requests that involve a PA or other UM requirement.

- Explain that plan sponsors must carefully determine how to categorize requests involving a PA or other UM requirement because some are subject to the exceptions process. A request that involves a PA or other UM requirement must be treated as an exception if the enrollee/physician argues that the PA or other UM requirement should not apply for reasons of medical necessity.

C. Moved the section on exceptions (previously §30.1) to new §30.2 and added the following clarifications:

- If a plan sponsor decides not to continue coverage granted under the exceptions process into the subsequent plan year for a renewing enrollee, the plan must send a written notice to that enrollee prior to the end of the plan year, unless the plan sponsor clearly identified the date that coverage will end in its favorable decision letter (i.e., the plan sponsor's favorable coverage determination or redetermination decision). The notice must explain that the exception will not be extended, and provide the date that the exception will end (e.g., December 31, 2006);

- Under the exceptions process, we clarify that the adjudication time frame begins when a physician provides a written or oral statement indicating one of the factors listed in 42 CFR 423.578(a)(4) or (b)(5), and the time frame is not tolled if the plan sponsor believes it needs additional information to support one of those factors. Also, if a physician provides an oral statement and the plan sponsor requires a written follow-up statement from the physician, the time frame begins when the physician provides a written statement indicating one of the factors listed in 42 CFR 423.578(a)(4) or (b)(5), and the time frame is not tolled if the plan sponsor believes it needs additional information to support one of those factors;

- We clarify that a physician may use the model Medicare Part D Coverage Determination Request Form for physicians (a/k/a model Part D Exception & Prior Authorization Request Form) to request an exception and/or submit a supporting statement;

- We explain that plan sponsors are required to accept any supporting statement that is made in writing, and are prohibited from requiring a physician to submit a supporting statement on a specific form.

D. In regard to standard or expedited written requests for coverage determinations, we clarify the following:

- A written request for a coverage determination/exception may be made on CMS's Model Coverage Determination Request Form, the model Medicare Part D Coverage Determination Request Form for physicians (a/k/a model Part D Exception & Prior Authorization Request Form), a request form developed by a plan sponsor or any other entity, or any other written document; and

- Plan sponsors are required to accept any request that is made in writing (when made by an enrollee, an enrollee's prescribing physician, or an enrollee's appointed representative) and are prohibited from requiring an enrollee or physician to make a written request on a specific form.

E. Explain that requests for coverage determinations, requests for redeterminations, and supporting statements provided by prescribing physicians are deemed "received" by a plan sponsor on:

- The date and time the plan sponsor initially stamps a document sent by regular mail (e.g., via US Postal Service);

- The date and time a delivery service that has the ability to track when a shipment is delivered (e.g., US Postal Service, UPS, Federal Express, or DHL) delivers the document;

- The date and time a faxed document is successfully transmitted to the plan sponsor, as indicated on the fax confirmation sheet;

- The date and time an oral request is made by telephone with a customer service representative; or

- The date and time a message is left on the plan sponsor's voicemail system if the plan sponsor utilizes a voicemail system to accept requests or supporting statements after normal business hours.

F. In §70.9 (Notification of the Result of an Adverse Redetermination), we clarify that plan sponsors must complete the applicable sections of the Model Request for Reconsideration form (new Appendix 13) and send it to enrollees with each adverse redetermination notice.

G. In §90.2 (Determination of Amount in Controversy), we revised the formula for computing the amount remaining in controversy requirement for Administrative Law Judge hearings.

H. Added new §130.1 (Effectuating Coverage Determinations) and clarified the following:

- If plan sponsor approves a standard request for benefits, it must authorize or provide benefits within 72 hours after receipt of request or supporting statement.

- If plan sponsor approves a standard request for payment, it must authorize payment within 72 hours after receipt of request or supporting statement, and make (mail) payment within 30 calendar days after receipt of request or supporting statement.

- If plan sponsor approves an expedited request for benefits, it must authorize or provide benefits within 24 hours after receipt of request or supporting statement.

I. Made a number of revisions to Appendix 4 - Model Notice of Redetermination.

J. Added Appendix 12 (Notice of Notice of Inquiry Regarding an Excluded Drug) and Appendix 13 (Request for Reconsideration).

- Appendix 12- Plan sponsors must send this notice to notify enrollees or physicians whenever an inquiry for an excluded drug is received.

- Appendix 13- Plan sponsors must complete this form (where applicable) and send it with adverse redetermination decisions.