DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

TO: All Part D Sponsors

FROM: Michael Crochunis
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SUBJECT: Part D Compliance Issues – Grievances, Coverage Determinations, and Appeals

DATE: September 3, 2010

This memorandum is in response to recent compliance findings regarding Part D sponsors' administration of Part D grievance, coverage determination, and appeals processes pursuant to requirements set out in Subpart M of Part 423, Title 42 of the Code of Federal Regulations. The Centers for Medicare & Medicaid Services (CMS) has found several Part D plan sponsors non-compliant with these regulations. The identified areas of non-compliance raise significant concerns regarding prompt access to prescription drugs and potential risks to Part D enrollees.

The intent of this memorandum is to remind Part D plan sponsors of their obligation to process grievances, and requests for coverage determinations and appeals consistent with the Subpart M regulations and related manual requirements contained in Chapter 18 of the *Medicare Prescription Drug Benefit Manual*. In meeting this obligation, CMS expects Part D plan sponsors to carefully and routinely review their operations and processes in these areas to identify any potential deficiencies and make needed corrections. Below are the primary deficiencies that have been identified.

Lack of Adequate Tracking Systems Resulting in Missed Adjudication Timeframes

Several plans have been identified as lacking adequate systems and processes for tracking the receipt of coverage determinations and the deadline for notifying an enrollee of the plan's decision. Identified process deficiencies include a failure to date-stamp incoming requests and the lack of a triaging process to ensure that requests are sent to the correct department for processing. The inability to track requests and adjudication deadlines has resulted in plans failing to timely notify enrollees of decisions.

Improper tracking of incoming requests has also been identified in the area of coverage determinations that involve exceptions requests. When a coverage determination involves an exception request, the adjudication timeframe begins when the prescriber's supporting statement is received. Plans should have workflow processes to: (1) identify a coverage determination request as an exception request (request for an off-formulary drug, request for an exception to a utilization management tool, request for tiering exception); (2) promptly request necessary clinical information from the prescriber (supporting statement); (3) ensure that the exceptions

request case is only held in a "pending" status for a reasonable period of time while awaiting the prescriber's supporting statement; (4) determine decision notice deadlines based on the receipt of the supporting statement; and (5) ensure timely notice to the enrollee (and prescriber, as appropriate).

The inability to track decision notice deadlines has also resulted in plans failing to promptly auto-forward cases to the Part D Qualified Independent Contractor (QIC) when adjudication deadlines are missed. If a plan fails to notify an enrollee of its decision within the required time frame, the failure constitutes an adverse decision and the plan must forward the enrollee's request to the Part D QIC within 24 hours of the expiration of the adjudication time frame. Guidance on when a Part D sponsor must auto-forward a coverage determination can be found in Sections 40.4 and 50.6 of Chapter 18 of the *Medicare Prescription Drug Benefit Manual*.

Failure to properly track requests and decision notification deadlines, and the associated deficiencies noted above, was also identified at the redetermination level. Guidance related to redeterminations can be found in Section 70 of the *Medicare Prescription Drug Benefit Manual*.

Failure to Expedite Coverage Determination Requests

Another area of deficiency relates to insufficient processes for identifying and processing requests where the enrollee's life or health may be seriously jeopardized unless an expedited decision is rendered. Plans must have a process in place for receiving and responding to expedited requests after-hours and must ensure that their staffs are properly trained to recognize when an expedited decision is warranted (triggers such as "urgent", "life threatening", "immediate need").

Failure to Properly Classify and Process Grievances

The preponderance of Part D sponsors that have been reviewed have been identified as having deficient processes for distinguishing coverage determination and appeal requests from grievances. This deficiency has resulted in enrollees failing to receive necessary prescription drugs in a prompt manner due to incorrect classification and misrouting of requests. Even in cases where plans correctly processed a request as a grievance, Part D sponsors frequently provide a resolution that is not sufficiently tailored to address the nature of the complaint. In other instances, the plan is providing an untimely resolution. Part D sponsors must ensure that their customer service representatives are properly trained and able to distinguish between a grievance and a coverage determination request, and can correctly and promptly triaging these requests to the appropriate department(s) for processing.

Guidance related to distinguishing between grievances and coverage determinations can be found in Section 20 of Chapter 18 in the *Medicare Prescription Drug Benefit Manual*.

Failure to Promptly Effectuate Favorable Decisions

A number of deficiencies have been identified in the area of prompt effectuation of favorable decisions. For example, Part D sponsors are failing to enter necessary authorizations into their claims systems in conjunction with notifying an enrollee of a favorable decision, resulting in unnecessary delays in providing prescription drugs for which coverage has been approved. Part D sponsors should review their processes for ensuring timely effectuation of all favorable decisions, including those made by the Part D QIC and higher adjudicating entities.

Sanctions for Failure to Comply

Deficiencies in the area of grievances, coverage determinations, and appeals may constitute a significant risk to Part D enrollees to the extent such deficiencies result in denying prompt access to medically necessary covered prescription drugs. Part D sponsors that are determined to have material deficiencies will be subject to a compliance action, including the possibility of suspension of enrollment and marketing activities, inability to accept assignment of low income subsidy (LIS) enrollees, civil money penalties, and contract termination.

Further questions regarding our policy should be directed to PartD_Appeals@cms.hhs.gov.