DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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TO: All Part D Plan Sponsors

FROM: Amy K. Larrick, Acting Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Compliance Outreach to Select Sponsors Based on Medicare Part D Overutilization Monitoring System Information

DATE: April 24, 2015

The Centers for Medicare & Medicaid Services (CMS) continues to evaluate if sponsors' drug utilization management (DUM) programs are reasonable, appropriate and consistent with CMS policy to prevent overutilization of prescribed medications, including opioids and acetaminophen (APAP). CMS developed the Overutilization Monitoring System (OMS) to assist with this evaluation. Through the OMS, CMS provides quarterly reports to sponsors on beneficiaries with potential opioid or APAP overutilization identified through analyses of Prescription Drug Event (PDE) data. Sponsors are required to respond to CMS on the status of the review for each beneficiary case.

CMS will perform additional outreach to select Part D sponsors who are identified to be outliers based on their responses to the OMS to assess their compliance with CMS guidance. The Part D sponsors will be asked to provide additional information about their DUM processes, the rationale and criteria for their responses submitted to the OMS, and their interventions to prevent overutilization of medications. Sponsors will also submit additional information for specific OMS tickets previously processed through the OMS.

The following is an outline of the process:

- In May 2015, CMS will contact the Medicare Compliance Officer(s) and Part D Opioid Overutilization Contact(s) of the selected sponsors via secure email from the PartD_OM@cms.hhs.gov mailbox. The subject line of the email will be: Response Required: Compliance with CMS Drug Utilization Management Requirements.
- CMS will request that each sponsor provide its opioid and APAP overutilization criteria and applicable case management protocols for background information.
- Sponsors will be asked to respond to both general and specific questions for their tickets via a Response Template. The first set of questions requests general information on the criteria, policies and procedures related to each issue while the second set of questions is specific to the ticket and prior response codes submitted to the OMS (BSC, BOR, INC, and DMN; repetitive use of INC and BOR; and point-of-sale (POS) edit codes). Sponsors may also be asked to explain why a POS edit was not implemented for certain

cases, including comparison of similar tickets for which a POS edit was implemented for one but not the other ticket.

- Each sponsor will receive between 15 and 50 tickets for review and response.
- Specific instructions and Response Templates with contract-beneficiary OMS tickets for both opioid and APAP cases will be included in the secure email.
- Sponsors are expected to submit their written responses and completed Response Templates to CMS within 60 days of the initial communication from CMS.
- After CMS reviews the sponsor's written explanations and documentation, a follow-up conference call may be scheduled for further discussion of relevant issues.

Sponsors that fail to respond in a timely manner or that CMS determines have established inappropriate drug utilization review controls may be subject to a compliance action.

Questions should be directed to PartD_OM@cms.hhs.gov. Additional information about CMS guidance to prevent overutilization of prescribed medications is available on the CMS webpage, Improving Drug Utilization Controls in Part D (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html).