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CENTER FOR MEDICARE

Date: November 30, 2015

To: All Medicare Advantage Organizations and Prescription Drug Plans

From: Gerard Mulcahy, Director
Medicare Parts C and D Oversight and Enforcement Group

Subject: Classification of Audit Conditions: ICARs, CARs and Observations

In May of 2013, CMS issued an HPMS memo detailing our final audit scoring methodology for CMS program audits. In that memo, we explained that an audit condition is classified in one of three ways:

- Immediate Corrective Action Required (ICAR)
- Corrective Action Required (CAR); or
- Observation

We also provided descriptions of what would constitute an ICAR, CAR and Observation. In the two years since that memo was released, we have received feedback from audited sponsors that they do not feel the process for determining what is an ICAR, CAR or Observations is transparent and have indicated they often cannot predict how audit conditions will ultimately be classified.

In order to address this feedback, CMS is further clarifying our definition of an ICAR, CAR and Observation and the process for determining how a condition is classified. In addition, we have added a new condition category - Invalid Data Submission (IDS) as explained below. CMS will incorporate these clarifications into our annual training to ensure consistent application across all audits. These updated definitions also appear in *Attachment X—The Audit Process Document*. Attachment X, the protocols and other associated audit documents are located in the *Downloads* section of the CMS Program Audit website, found here: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html

- **Immediate Corrective Action Required (ICAR) -** If CMS identifies systemic deficiencies during an audit that are so severe that they require immediate correction, the sponsor will be cited an ICAR. These types of issues would be limited to situations where the identified deficiency resulted in a lack of access to medications and/or services or posed an immediate threat to enrollee health and safety. The sponsor has 3 business days from formal email notification to provide their plan to address or remediate the deficiency. For example, if CMS identified that a sponsor's formulary was programmed incorrectly resulting in inappropriate denials of needed medications, while the sponsor may not be able to re-program their formulary in 3 business days, the sponsor would have to demonstrate to CMS the work around they implemented to immediately ensure that enrollees were receiving needed medications. The ICAR counts as two points in the audit scoring methodology.

- **Corrective Action Required** – If CMS identifies systemic deficiencies during an audit that must be corrected, but the correction can wait until the audit report is issued, the sponsor will be cited a CAR. These issues may affect beneficiaries, but are not of a nature that immediately affects their health and safety. Generally, they involve deficiencies with respect to non-existent or inadequate policies and procedures, systems, internal controls, training, operations or staffing. The sponsor will be afforded a total of seven (7) calendar days from the issuance of the final audit report to submit a corrective action plan for all conditions with a "corrective action required (CAR)" in appendix A. The sponsor should include a brief summary describing the process and give a timeframe for correction. Once submitted, CMS will review the corrective action plans. Once accepted by CMS, the sponsor will have 150 calendar days from the date of acceptance of the corrective action plan to undergo a validation (unless extension is requested and granted). The CAR counts as one point in the audit scoring methodology.

- **Observations**—If CMS identifies conditions of non-compliance that are not systemic, or represent a "one-off issue" the sponsor will be cited an observation. A "one-off issue" may be an issue dealing with one employee or a singular case that was lost or misidentified. Observations do not count in the audit scoring methodology.

- **Invalid Data Submission (IDS)** – An IDS condition is cited when a sponsor fails to produce an accurate universe within 3 attempts. IDS conditions are new for 2016 and are cited for each element that cannot be tested, grouped by type of case (e.g., *CMS was unable to evaluate timeliness for your coverage determinations (standard or expedited, pre-service or payment), due to invalid data submission(s)*). When the sponsor goes through their audit validation, they must produce the universes that auditors were unable to test during the original audit, to demonstrate their compliance with CMS requirements. The IDS condition will count as one point in the audit scoring methodology.

If you have questions about any of the information provided in this memo, please send an email to part_c_part_d_audit@cms.hhs.gov.