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CENTER FOR MEDICARE

Date:	October 20, 2015
To:	All Medicare Advantage Organizations and Prescription Drug Plans
From:	Gerard Mulcahy, Director Medicare Parts C and D Oversight and Enforcement Group
Subject:	2015/2016 Program Audit Protocols and Process Updates

BACKGROUND

On February 12, 2015, CMS issued the 2015 Program Audit Protocols for the Medicare Advantage (MA) and Prescription Drug (Part D) programs and posted these protocols on our website. Throughout the audit year, we received feedback from MA organizations and Part D sponsors, requesting certain changes or requesting clarification to certain items in the protocols, largely in the various record layouts. Record layouts detail all of the data CMS requests in advance of a program audit, and it is from this data that we pull our samples to perform the audit.

Based on that feedback from the industry, as well as audit experience throughout 2015, CMS has updated and is republishing the 2015 protocols and will post the revised versions to our Program Audits website. CMS will be making no additional changes to the protocols for 2016. Consequently, the revised protocols will function as the 2015 and 2016 MA and Part D program audit protocols.

The changes in policy approach, expressed in this memo, did not disadvantage any sponsor audited in 2015. CMS has taken steps to ensure that the final policy reflected in this memo was the policy applied to all sponsors audited in 2015.

The following audit process documents and protocols are being re-posted:
- Part D Formulary and Benefit Administration
- Part D Coverage Determinations, Appeals, and Grievances
- Part C Organization Determinations, Appeals, and Grievances
- Special Needs Plans– Model of Care (SNP-MOC)
- Part C and Part D Compliance Program Effectiveness

The audit process documents define the audit purpose, universe and sample selection processes, the evidence required for review and submission, and the compliance standards tested during the audit.

The protocols and other associated audit documents are located in the *Downloads* section of the CMS Program Audit website, located at: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html

The two pilot protocols for Provider Network Adequacy (PNA) and Medication Therapy Management (MTM) will not be posted until late-2015. As a result, we will pilot these two new protocols in 2016. Pilot protocols do not count against a sponsor and do not factor into the audit score. We will inform sponsors of the release of these two pilot protocols via a separate HPMS email.

Below we have summarized, at a high level, the changes made to the re-posted protocols as well the changes to our audit policy approach.

MODIFICATIONS TO PROGRAM AUDIT SCOPE

I. **Program Areas/Elements Modified for 2015/2016**
1. **Compliance Program Effectiveness – (UPDATE)**
   Starting in 2016, the CPE universe request will include additional documentation that will provide CMS with a general overview of the sponsor's Medicare compliance program structure and operations. The compliance interviews have been modified to eliminate the employee interviews (with some limited exceptions) and adds one interview with the individual(s) involved with managing the sponsor's accountability for and oversight of its first-tier, downstream and related entities (FDRs). CMS will continue to use the tracer approach to evaluate whether the sponsor's compliance program, as a whole, functions in a way that is effective to address compliance and FWA issues. The number of tracer samples used to test the seven elements has increased from five to six. Sponsors are required to provide PowerPoint presentations that document the full story of compliance tracers. In an effort to promote transparency, the CMS CPE Tracer PPT template is included with the audit protocol. Finally, based on sponsor feedback, CMS will conduct all tracers in week two, to ensure that compliance personnel are able to attend as many webinars as possible in week one.

2. **Record Layouts (Appendix A) – (UPDATE)**
   CMS added instructions to clarify the types of cases that should be included and/or excluded for individual record layouts. The format of the record layouts remains the same except for the addition of a "Column ID" field. CMS added changes to streamline and clarify the content, including: rearranging variables, adding or renaming variables, removing superfluous fields and revising field descriptions to include more detail, examples of what was being requested and/or additional entry options (e.g., N/A). Sponsors can submit record layouts as text (.txt) or Excel (.xlsx) files.

II. **Program Areas/Elements Discontinued for 2016**
1. No program areas or elements were discontinued for 2016.

III. **New Program Areas/Elements Added for 2016**
1. **Medication Therapy Management – (PILOT)**
   All Medicare Part D sponsors are required to have an established Medication Therapy Management program in place to ensure optimum therapeutic outcomes for targeted beneficiaries through improved medication use. The objectives of this program audit area will be to:
   - Assess a Medicare Part D sponsor's performance with their CMS-approved MTM Program in accordance with 42 CFR § 423.153(d) and other related CMS guidance;
   - Educate sponsors and correct area(s) of deficiency; and,
   - Initiate enforcement actions and/or identify possible performance measures for sponsors to implement.

2. **Provider Network Adequacy – (PILOT)**
   Sponsors are required to maintain an adequate provider network and ensure access to specialty and sub-specialties providers. The objectives of this program audit area will be to:

- Examine the adequacy of a sponsor's provider network,
- Examine the standards for accessibility and ensure that the providers in networks are open to treat enrollees.

These pilot audits will not start until 2016. As with other piloted protocols, sponsors who receive an MTM or Provider Network Adequacy audit in 2016, will not have the score count against their total program audit score. The final audit report will not include a score for this area, nor will they appear on CMS' website. We encourage sponsors subject to these pilot audits to provide as much feedback as possible about the new protocols. Based on feedback from auditors and the industry, CMS will update these two protocols and incorporate them into the 2017 audit scope.

MODIFICATIONS TO THE PROGRAM AUDIT PROCESS

I. **Universe Submission Accuracy – (UPDATE)**

Sponsors must provide complete, accurate and timely universe submissions. Sponsors will have a maximum of three attempts to provide each universe requested, whether these attempts all occur prior to the entrance conference or both before and during the audit. If the sponsor fails to provide accurate and timely universe submissions twice, CMS will document this as an observation in the sponsor's program audit report. After the third failed attempt the sponsor will be cited an Invalid Data Submission (IDS) condition relative to each element that cannot be tested grouped by the type of case. If the sponsor is unable to produce an accurate universe due to missing or unavailable data in fewer than three attempts, CMS will cite the IDS conditions as noted above. In addition, if a universe is completely unusable for purposes of evaluating an element, the sponsor will be cited every applicable condition for the affected element that cannot be tested and the sponsor may be referred for possible enforcement action.

For more information, please refer to the Universe Preparation and Submission section of any of the 2015/2016 audit protocols.

II. **Previously Disclosed versus Self-Identified Issues – (UPDATE)**

Disclosed issues are those reported to CMS prior to the date of the audit start notice. A self-identified issue is one that has been discovered by the sponsor for which no prior notification has been provided to CMS. Issues discovered by CMS throughout the year during the course of routine monitoring and reported to the sponsor will be treated as self-identified. For 2016, sponsors will be asked to provide a list of all previously disclosed and self-identified issues of non-compliance, from January 1, 2016 through the date of the audit start notice. Within 5 business days after receipt of the audit start notice, sponsors must provide a description of each issue as well as the remediation status using the Pre-Audit Issue Summary template. The sponsor's Account Manager (AM) will review the summary for accuracy and completeness. The AM will validate the "disclosed" issue status of corrected and may be asked to validate that issues have not been omitted from the "disclosed" summary.

Disclosed and self-identified issues are either "corrected" or "uncorrected" based on the issue's status prior to the sponsor's receipt of the audit start notice.

Corrected Issue: CMS will consider an issue corrected if there is evidence of appropriate and adequate remediation in the sponsor's systems and for its beneficiaries either prior to or during the "audit review period", but before the receipt of the audit start notice. The "audit review period" refers to the period covered by the related universe request.

Issues that are reported as corrected prior to the audit universe period will be assumed to be corrected. However, if the issue is identified during the course of the audit, CMS will cite the applicable

conditions in the audit report. CMS will not otherwise validate correction of issues identified as corrected.

Issues that are reported as corrected <u>during</u> the audit universe review period will either be validated for correction during the audit or during the validation of correction of audit findings, based on the type of issues identified.

Auditors will validate correction if it can be accomplished simply (e.g. running a test claim through the sponsor's system to ensure edits were properly reprogrammed or confirming a change was made in the system to a letter template, ensuring required language was included, etc.). When correction is validated, the issue will be noted as an observation in the sponsor's audit report. If validation of correction is not feasible during the audit, the sponsor will be cited the applicable conditions related to the disclosed/self-identified issue in their audit report and correction will be validated during the audit validation process.

CMS will make allowances for corrected issues when performing timeliness tests provided that after the reported correction date, at least 6 consecutive weeks of data remain in the audit review period. If at least 6 weeks are not available, the usual timeliness tests will be conducted on the entire universe and conditions will be cited based on the results. CMS will ensure correction of those timeliness conditions during the audit validation process.

Uncorrected Issue: Issues that are reported as uncorrected will automatically be cited as conditions in the CMS audit report. Issues reported as corrected <u>after</u> the date of the audit start notice will be treated as uncorrected issues.

III. Impact Analysis (IA) Templates (UPDATE)
The name of the templates has been changed from "Beneficiary Impact Analysis" to "Impact Analysis". An impact analysis must be submitted as requested by CMS for every issue discovered during the audit that has potential beneficiary impact and may be cited as a condition of non-compliance. Starting in 2016, an IA will not be required for the disclosed and self-identified issues that are communicated in the Pre-Audit Summary template. CMS may validate the accuracy of the IA submission(s). The revised templates have been loaded to the website, along with the revised audit protocols.

IV. Calculation of Score (UPDATE)
Starting in 2016, CMS will cite a new type of condition, called Invalid Data Submission (IDS). IDS conditions will be cited when a sponsor is not able to produce an accurate universe within a maximum of 3 attempts. IDS conditions will be worth one (1) point.

For more information with respect to the submission of disclosed/self-identified issue summaries, IAs and audit score calculations, please refer to the Audit Purpose and General Guidelines section of any of the 2015/2016 audit protocols.

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.