DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C1-22-06
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

Date: February 13, 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 Program Audit Protocols and Process Updates

BACKGROUND

The Medicare Parts C and D Oversight and Enforcement Group (MOEG), is one of the groups within the Center for Medicare (CM) that conducts a variety of oversight activities, primarily via Part C and Part D program audits. These program audits are one way that CMS is reasonably assured that sponsors deliver benefits in accordance with the terms of their contract and plan benefit package. Program audits evaluate sponsors' compliance with a number of core program requirements, especially those that safeguard beneficiaries' access to medically necessary services and prescription drugs. This comprehensive approach to auditing, including validating correction of deficiencies and referring sponsors with egregious findings for possible enforcement action ensures the integrity of the Part C and Part D programs and protects the health and safety of Medicare beneficiaries.

The purpose of this memorandum is to provide updates related to the 2015 Program Audit Cycle. We will discuss the start of a new audit cycle, changes to the scope of audits, new audit program areas, 2015 protocols, and modifications to the 2015 audit process.

START OF A NEW AUDIT CYCLE

In 2015, we will begin a new audit cycle. This means that all sponsors, even those audited in the previous cycle (2010-2014), will be considered for audit selection. With the completion of the 2014 audits, CMS has audited parent organizations that provide services to 96% of Medicare Advantage and Prescription Drug enrollees since it redesigned the audit process in 2010 and began auditing with outcome-based audit protocols. While a number of smaller sponsors were not audited in this first cycle, the publishing of a wealth of audit related performance data and information on our external website[1] (e.g., best practices and common findings memos, audit protocols, audit scores, etc.) should have improved the level of compliance of all sponsors throughout the industry. We have confidence that the majority of our enrollees are in plans that are far more likely to be in compliance with our requirements.

For the second cycle, we will continue to utilize a risk-based approach to selecting sponsors for audit (both high and low risk), while also taking into account other key factors like: the sponsor has never previously been audited; the sponsor is new to the program (i.e., is in their first 2 years of operation and has no previous affiliation with the Medicare program); or the sponsor represents a large percentage of MA or Part D enrollment.

[1] http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html

Organizations are audited at the parent organization level. If an MA or Part D sponsor also operates a Medicare-Medicaid Plan (MMP), we will audit the MMP contract as part of the larger parent organization audit. Since most MMPs have agreed to follow Medicare rules in the administration of their Medicare formulary and benefits, we are able to utilize our existing protocols to audit MMP compliance and operations.

The audit strategy, including our list of sponsors to be audited, is shared with the Medicare-Medicaid Coordination Office (MMCO) annually, and they will notify the applicable State, when an audit is scheduled for a sponsor who has an MMP contract. The State may choose to observe our audit or perform an independent assessment in coordination with our audit.

MODIFICATIONS TO PROGRAM AUDIT SCOPE

I. Program Areas/Elements Discontinued for 2015

1. Formulary & Benefit Administration: The review of the P&T Committee was removed. We will continue to find ways to evaluate the use of the P&T Committee and the implementation of the committee's recommendations.

II. Program Areas/Elements Modified for 2015

1. The following changes apply to universe timeliness tests and submission of universes for:
   a. Organization Determinations, Appeals and Grievances (ODAG)/ Universe Timeliness Tests and Submission of Universes
   b. Coverage Determinations, Appeals and Grievances (CDAG)/ Universe Timeliness Tests and Submission of Universes

   Timeliness will again be measured at the universe level for standard and expedited organization determinations (ODs), appeals and grievances and for standard and expedited coverage determinations (CDs), appeals and grievances. Previous universe request templates consolidated various types of requests into one spreadsheet, but it was difficult to conduct a timeliness test this way, as the various types of requests in one spreadsheet had different processing timeframes associated with them. In 2015, the same data are being requested as in past years, but now each separate request will have its own universe template (e.g., a record layout for standard, pre-service ODs, a separate layout for expedited, pre-service ODs, a separate record layout for standard, pre-service CDs, and a separate record layout for expedited, pre-service CDs).

2. Compliance Program Effectiveness - The Compliance Protocol has been redesigned to be more outcomes focused and less burdensome. For example, the content review, which required the sponsor to submit a large number of documents (32 pre-audit), has been eliminated. Instead, the seven elements will be tested by conducting 5 "tracer" samples, which means that an issue will be selected and the team will "trace" the issue as it moves through the organization's compliance program. CMS will continue to conduct interviews, but the interview guides have been streamlined.

III. New Program Areas/Elements Added for 2015

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 mid-2015. As with other piloted protocols, sponsors who receive an MTM or Network Adequacy audit in 2015 will not have the score count against their total program audit score. A score will not be provided in the final audit report, nor will the pilot area scores be posted to CMS' website. We encourage sponsors subject to these pilot audits to provide as much feedback as possible about the new protocols. These new protocols will then be incorporated into the 2016 audit scope and these scores will count in the total audit score.

RELEASE OF 2015 AUDIT PROTOCOLS

As in previous years, we are releasing the 2015 audit process documents and protocols that will be utilized to measure outcomes in the following areas:

- Part D Formulary and Benefit Administration
- Part D Coverage Determinations, Appeals, and Grievances
- Part C Organization Determinations, Appeals, and Grievances
- Special Need Plans– Model of Care (SNP-MOC)
- Part C and Part D Compliance Program Effectiveness

The audit process documents and associated audit documents define the audit purpose, universe and sample selection processes, the evidence required for review and submission, and the compliance standards tested. These are not the Methods of Evaluation (MOEs) that describe step by step how to conduct the audit. However, CMS has included additional examples of the types of compliance standards that are being applied throughout these documents. The standards listed in these documents are examples and not intended to be all inclusive. MOEs are internal to CMS and will not be released. However, they are not necessary to effectively monitor, audit, and oversee your organization's operations.

We remain committed to continuous improvement in the development of our audit processes and protocols, and value the input and feedback of all sponsors and stakeholders, especially those who have demonstrated exceptional performance. The 2015 audit protocols are updated based on comments received from the sponsors and the industry. We will also continue to send a post audit questionnaire to obtain feedback on the audit process and encourage sponsors to utilize this mechanism to provide valuable input.

Audits will continue to be conducted over a two week period. Specifically, the first week of an audit will start with an entrance conference and the audit of all applicable operational areas (Part D Formulary Administration; Part D Coverage Determinations, Appeals, and Grievances; Part C Organization Determinations, Appeals, and Grievances; and SNP-MOC) virtually via webinar. The Compliance Program Effectiveness portion of the audit will occur during the second week and will be on-site. This will allow the sponsor's compliance officer to be actively engaged during the audit of all operational areas in the first week and fully engage in the compliance program audit the second week.

The protocols and other associated audit documents can be found in the *Downloads* section of the CMS Program Audit website, located at: http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-

Part-D-Compliance-and-Audits/ProgramAudits.html

The two pilot protocols for Network Adequacy and Medication Therapy Management will not be posted until mid-2015. We will inform sponsors of the release of these two pilot protocols via a separate HPMS email.

MODIFICATIONS TO THE PROGRAM AUDIT PROCESS

I. Timing for receipt of audit start notice and universe submission (Beginning in 2015)

If a sponsor has been selected for an audit, an engagement letter will be sent 6 weeks prior to the audit start date, notifying them of the date the audit will begin, the scope of the audit, the contact information for the MOEG Auditor-In-Charge, and information being requested from the sponsor (e.g., universes). Sponsors will be expected to submit universes 3 weeks prior to the start date of the audit. To ensure we receive accurate universes, we are giving two additional weeks of notice before the audit start date including one additional week to submit universes. This will allow more time for sponsors to pull and quality check their universes and will give us additional time to validate the accuracy of the universes prior to selecting samples and beginning the audit.

II. Universe Submission Accuracy

Sponsors are expected to provide accurate and timely universe submissions. In 2015, sponsors will have a maximum of 3 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 plan's program audit report. After the third failed attempt the sponsor will be cited Immediate Corrective Action Required (ICARs) for every condition that cannot be tested due to the inaccurate universe (i.e., if there are 11 audit conditions that could have been tested in a given universe, we will automatically cite 11 ICARs, one for each possible condition that could have been tested). Although these will be referred to as ICARs in 2015, they will not require proof of correction within 72 hours, as typical ICARs currently require. However, CMS will include these areas in their validation exercises and sponsors will be expected to be able to produce a universe for that effort.

Sponsors are expected to abide by the universe submission deadlines and sponsors who fail to produce accurate universes or documentation required by audit could face possible enforcement action.

In 2016, the audit scoring methodology will be updated to reflect that inaccurate data submissions (IDS) will be counted similar to ICARS (2 x number of conditions), but will differ in that they will not require validation in 72 hours, as typical ICARS require. In addition, an IDS condition will be created that sponsors will be cited for based on the inaccurate data provided.

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

III. Previously Disclosed versus Self-Identified Issues

We also want to clarify the difference between disclosed and self-identified issues. A disclosed issue is one that has been 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 but notification was not made to CMS until after the date of the audit start notice. Sponsors will be asked to provide a list of all previously disclosed and self-identified issues of non-compliance, from January 1, 2015 through the date of the audit start notice, which we may

find in your data universes.

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 will review the summary for accuracy and completeness. In addition, for each disclosed and self-identified issue the sponsor will be required to complete a Beneficiary Impact Analysis (BIA). The BIA should include every impacted beneficiary across all of the sponsor's contracts for the time period January 1, 2015 through the date of the audit start notice. Both the issue summary and the associated BIA(s) are due within 5 business days after receipt of the engagement letter. These documents will be reviewed by the sponsor's Account Manager. Account Managers (AMs) will review the pre-audit issue summary submitted to validate that issues identified as "disclosed" were known to CMS prior to the date of the audit start notice and determine if any issues listed as "self-identified" should instead be classified as "disclosed". The AMs will validate the "disclosed" issue status of "corrected" and may also be asked to validate that issues have not been omitted from the "disclosed" summary.

Sponsors will have a maximum of 3 attempts to provide the Pre-Audit Issue Summary and the associated BIAs. If multiple attempts are made, we will only use the last Pre-Audit Issue Summary and BIAs submitted. Because these data impact sample selection and the timeliness tests conducted for CDAG and ODAG, complete and accurate documents must be received no later than the universe submission(s) due date. If the sponsor fails to provide accurate and timely data twice, we will document this as an observation in the program audit report. If a sponsor fails to provide accurate data for the Pre-Audit Issue Summary and every associated BIA by the universe submission deadline (regardless of the number of attempts), the sponsor will not receive credit for any disclosed or self-identified issue during the course of the audit.

Disclosed and self-identified issues will be considered 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, both in the sponsor's systems and for the sponsor's enrollees. The correction can occur prior to or during the "audit review period", but must occur before receipt of the audit start notice. The "audit review period" refers to the period covered by the related universe request. No distinction will be made between disclosed and self-identified issues with respect to sample selection and timeliness tests for corrected issues.

CMS will select samples to validate all disclosed and self-identified issues reported as having been corrected. Any "corrected" issue that still exists after the date the correction was reported by the sponsor, will be cited for the applicable condition(s) of non-compliance (Observation, CAR or ICAR depending on the severity of the issue). If CMS determines that the issue is corrected as reported by the sponsor, the issue will be included in the audit report as an observation noting correction. The issue may not negatively impact the audit score; however, CMS reserves the right to issue a compliance action for these issues.

CMS will make allowances for corrected issues when performing timeliness tests provided that after the reported correction date, at least 6 weeks of data remain in the audit review period. If at least 6 weeks in the audit review period are available the usual timeliness test will be performed on the post-correction portion of the universe. Conditions will be cited based on the results of the timeliness test. In addition, an observation will be included in the audit report to document the reported correction and its impact on the timeliness universe. If at least 6 weeks in the audit review period are not available, the usual timeliness test will be conducted on the entire universe. Conditions will be cited based on the results of the timeliness test.

Uncorrected issue: CMS will consider an issue uncorrected when appropriate and adequate remediation

to the sponsor's systems and its beneficiaries has not been completed prior to receipt of the engagement letter. Therefore, any issue included in the Pre-Audit Issue Summary that is detected and/or corrected after the date of the audit start notice will be treated as uncorrected.

For all uncorrected self-identified issues, CMS will cite the applicable condition(s) of non-compliance (Observation, CAR or ICAR depending on the severity of the issue) and include the findings in the audit report. CMS will not include these cases as audit samples to corroborate that there is an issue.

For uncorrected disclosed issues CMS will not include these cases as samples. The issue will be included in the audit report as an observation provided no other related case is identified during the audit. If a case is found during the audit that relates to the uncorrected disclosed issue, CMS will cite the applicable condition(s) of non-compliance (Observation, CAR or ICAR depending on the severity of the issue) and include the findings in the audit report.

Beneficiary Impact Analysis (BIA) Templates
BIA templates are provided to sponsors when noncompliant conditions are found, CMS expects the sponsor to identify how many beneficiaries were adversely impacted by the noncompliance. CMS expects sponsors to populate these templates using the instructions provided. CMS has added a column to the BIA template titled *"Methodology - Describe the process that was undertaken to determine the # of members impacted"*. Here the sponsors must describe the methodology used to identify all of the beneficiaries impacted by the noncompliance. The instructions have also been updated to require sponsors to identify all beneficiaries impacted dating back to the start of the plan year (January 1). CMS may conduct data integrity checks on selected BIA submissions to ensure accuracy and inclusion of all effected beneficiaries.

For more information with respect to the submission of disclosed/self-identified issue summaries and BIAs, please refer to the Sponsor Disclosed and Self-Identified Issues section of any of the 2015 audit protocols.

Thank you for your continued dedication to serving our beneficiaries. 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.