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

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TO: All Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and 1876 Cost Plans

FROM: Gerard J. Mulcahy, Director
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SUBJECT: Independent Auditor (IA) Validation Process for Medicare Advantage and Prescription Drug Plan Program Audits

On February 12, 2015, CMS issued CMS-4159-F2 (*See 80 FR 7912–7966*) which finalized changes to 42 CFR §§422.503(d) (2) and 423.504(d) (2). In that final rule, CMS has the authority to require a sponsoring organization (hereinafter referred to as the Sponsor) to hire an IA to validate if the deficiencies that were found during a CMS full or partial program audit have been corrected. Based on the 2015 program audit results and going forward, CMS will inform the Sponsor in the final audit report whether an IA is required. The purpose of this memorandum is to outline the steps of the IA validation process, should an IA be required, and to describe the roles and responsibilities of all parties involved.

Step 1: Hiring an IA

CMS will not provide recommendations on IA firms. However, the IA hired must meet the following requirements:

- The Sponsor must attest that the IA is independent and has no conflicts of interest. Independent means not employed, contracted, sub-contracted, represented or considered to be a first-tier, downstream or related entity by the sponsoring organization (the definitions of these terms are in the federal regulations at 42 CFR § 422.500 and § 423.501). A conflict of interest is any relationship between the Sponsor and the IA that would prevent, or give the appearance of preventing, the IA from providing an objective assessment of the Sponsor's performance, including current or prior consulting relationships. For examples of relationships that do not meet the standard for organizational independence, see https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/StandardsforSelectingaDVContractor_20101012.pdf.
- The auditor must have subject matter expertise in the areas of Medicare Part C & Part D that will be subject to review in the validation.

CMS recommends that you solicit proposals and select an IA early in the post-audit phase (i.e. once CMS issues the final audit report to the Sponsor) because this step must be completed before a Sponsor will be eligible to enter the validation phase of its program audit. If a sanction is imposed as a result of the initial audit, the Sponsor will need to hire an IA to validate correction of all sanction related conditions as well as non-sanction related conditions. The Sponsor may use the same IA to validate both sanctioned and non-sanctioned conditions and may conduct validation of sanctioned and non-sanctioned conditions together or separate.

Step 2: Developing a Validation Work Plan & Timeline

The Sponsor should meet with the IA to discuss the scope of the validation. The purpose of the validation review is for the Sponsor to demonstrate corrections of the conditions of non-compliance identified in the final CMS audit report and to serve as the basis for the CEO attestation that the conditions are corrected and are not likely to recur. Additionally, the Sponsor should provide the final CMS audit report and its Corrective Action Plans to assist the IA in understanding what needs to be evaluated during the validation. The IA will create a validation work plan that details how it will conduct the validation and a validation schedule that identifies key milestones in the validation process.

The validation work plan should test the compliance outcomes of sampled cases and/or an entire universe of data. It should not be a review that evaluates only policies and procedures, or processes. Rather, the validation work plan should test the effectiveness of the Corrective Action Plans and whether the Sponsor's transactions now comply with CMS requirements. The validation will test transactions dating back to the "clean" period. A "clean" period is the period of time where a Sponsor believes its operations are free from any audit-related deficiencies. The Sponsor will continue operations in this "clean" period until enough time has passed for a complete universe to be submitted for validation. CMS recommends that the "clean" period be at least as long as the universe period provided in the current CMS Program Audit Protocols for the given subject matter area. The "clean" period timeframe should generate enough transactions for the IA to sufficiently test whether Sponsor has corrected the deficiencies.

Once the Sponsor and IA have agreed on the validation work plan and schedule, the Sponsor will submit these documents to CMS and schedule a call with CMS and the IA. On the call, CMS expects the IA to walk through the validation work plan, including explaining the proposed duration of the validation process, and CMS will ask questions and/or request changes. After the call, the IA and Sponsor should update the final validation work plan and submit it to CMS for final approval.

Step 3: Conducting the Validation

IAs must conduct validations in accordance with the validation work plan approved by CMS.[1] During the validation process, the Sponsor must provide unfettered access to information related to the areas of validation and be responsive to the IA's requests for additional information. The IA works directly with the Sponsor to obtain universes and documentation in accordance with the CMS approved validation work plan. The IA must conduct data integrity tests of universe submissions to assure they

[1] Should the IA need to deviate from the approved validation work plan, the IA and Sponsor would need to contact CMS to seek approval for the change in work plan.

are complete and an accurate representation of the Sponsor's systems. This step should be done prior to sample selection and the review of any sample cases or analyses. If the IA is unable to ascertain complete and reliable data universes from the Sponsor, the IA should not proceed with the validation and should contact CMS for further guidance.

If the IA discovers sample case failures during its review, the IA should request that the Sponsor review the failed cases and determine if additional beneficiaries have been impacted. If the Sponsor discovers additional beneficiaries were impacted by the condition of non-compliance, it should provide a beneficiary impact analysis (BIA) to the IA for the IA to include in its validation report to the Sponsor.[2] The IA should validate whether the beneficiary impact analysis from the Sponsor is accurate.

The sponsor must respect the independence of the IA during the execution of the validation and not attempt to inappropriately influence how the validation is conducted or the findings derived from the review despite the sponsor's financial responsibility to the IA.

Step 4: Reporting the Results of the Validation Audit

The IA will draft a validation report that details the findings from the validation. The validation report should not make any recommendations to CMS about whether violations or audit conditions have been adequately corrected. It should report the outcomes of the sample cases and universes reviewed. CMS will make determinations about whether individual deficiencies have been corrected and whether CMS will close the audit process.

The IA will submit the validation report to the Sponsor. The Sponsor should thoroughly review the results of the validation and have discussions with the IA to address any disagreements or responses.

If Sponsor decides it has sufficiently corrected its audit-related deficiencies based on the IA's validation report, it must attest within HPMS that all the deficiencies have been corrected and are not likely to recur. Sponsor must include with its attestation the IA's report and any additional information Sponsor would like CMS to consider when reviewing the final validation report. If the Sponsor decides that it has not adequately corrected all of the audit-related deficiencies, it should contact its CMS Validation Lead to discuss issues that need further correction. The Sponsor will need to implement new CAPs and repeat the validation process until its CEO can attest within HPMS that all of the findings from the audit final report have been corrected.

Step 5: CMS Review of the Validation Report and Other Information

CMS will review the IA's validation report and additional information submitted by the Sponsor. CMS will likely request a follow-up call with the IA and the Sponsor to seek clarification and ask questions about the information provided. Once CMS has all the information needed, CMS will make a determination about whether to close the audit process. CMS will schedule a phone call with the Sponsor's CEO and Medicare Compliance Officer to inform them of CMS's determination and next steps, or issue an audit close-out notice.

[2] The criteria for any required BIAs requested (e.g. time span) should be addressed in the validation work plan developed in step 2.

For questions regarding the IA validation process, please email part_c_part_d_audit@cms.hhs.gov.