2013 Audit Process and Protocols
Frequently Asked Questions (FAQs)
Last Updated 5/15/2013

The following frequently asked questions (FAQs) were received from various sponsors since the release of the HPMS memo dated January 25, 2013, titled, "2013 Program Audit Process and Protocols". CMS has provided answers to these questions below.

Questions marked with an asterisk (*) denote new questions as of May 15, 2013.

General Audit Questions

1. **Q: Since the 2013 process and protocols are different from the 2012 process and protocols that were released in May, 2012, does 2013 supersede 2012? Or is 2012 for 2012 membership/dates of service and 2013 for 2013 member/dates of service? Or are we to merge the 2 processes/protocols together going forward?**

   A: Protocols released in 2012 were to be used for the 2012 calendar year. Protocols released on January 25, 2013 are to be used for the 2013 calendar year. We recommend using the most recent protocols released via HPMS when conducting internal auditing/monitoring of your operations. However, this is not the only tool that you should use to monitor/audit your operations as sponsors are required to be in compliance with all Part C and D regulations. This is just one tool to help sponsors with internal auditing/monitoring.

2. **Q: In previous CMS audits, CMS held plans to a 95% compliance standard with case files reviewed. The newly released audit protocols reference a pass/fail score for each case reviewed. There is no reference to what percentage of cases must pass in order for the plan to receive a passing score with no corrective action required. Is a 95% compliance rate still the measurement used to determine if corrective action (non-ICAR) is needed? Is there a different percentage or is corrective action required for any failed case?**

   A: There is no threshold to receive a corrective action required. Conditions identified during the audit that appear to be systemic (based on the cause of failure) will require corrective action regardless of the number of cases failed.

   In an effort to improve our audit process for 2013, we are moving from a pass/fail threshold utilized in 2012 to counting "common conditions" for 2013. Instead of focusing on whether or not an audit area passes or fails, we will concentrate on the number of common conditions and the remediation required (observation, corrective action required, or immediate corrective action required).

   Please reference the March 13, 2013 HPMS Memo titled, 'Draft Program Audit Scoring Methodology for Public Comment' that describes the new audit approach and audit scoring methodology.

3. **Q: Are new 2013 plans subject to 2013 audit?**

   A: Yes. If the plan is demonstrating significant non-compliance it may be subject to audit.

Part C Organization Determinations, Appeals, and Grievances (ODAG)

4. ***Q: Is the ODAG review period timeframe based on the organization determination decision date?**

   A: The ODAG review period timeframe is a three (3) month period preceding the date of the audit engagement letter. For example, if the audit engagement letter is for 4/1/13, the review period would be 1/1/13 to 4/1/13; therefore any organization determinations in this date range should be included in the ODAG universe.

5. ***Q: Please confirm that when plans submit the whole universe on the ET – Pre-service tab, the universe report should include data within columns 1 through 19.**

   A: Please complete columns 1 through 19 only. The remaining columns are what the auditors use to determine a sponsor's compliance. This information was provided in the universe template to assist sponsors with understanding how each sample case will be reviewed during the actual audit.

6. **Q: I have a question with regard to the audit protocols that were just released in the CMS memo dated 1/25/13. My question is specific to the note in section I. Effectuation Timeliness – Organization Determinations and Appeals (ODA). The note indicates that the dates of the *unfavorable determinations* and the IRE, ALJ and MAC reversals (overturns), should fall within the review period specified. Should that note say "favorable determinations" since this universe is strictly looking at favorable plan determinations as well as favorable IRE, ALJ, and MAC determinations?**

   A: This is correct. The note found in section I. Effectuation Timeliness – Organization Determinations and Appeals (ODA) should read, Note: The dates of the favorable determinations and the IRE, ALJ and MAC reversals (overturns) should fall within the review period specified above. CMS will update its ODAG protocol to correct this error.

7. **Q: Under the audit protocols, is CMS only looking for the reconsiderations submitted by the member and the effectuation date/time of that member reconsideration? If this is the case, then the ET Pre-Service tab's columns for date effectuated in plan's system and time effectuated in plan's system on the audit protocol template: Attachment VII-A - Part C ODAG Universe Template 2012 will be blank.**

A: No, the reconsideration sample includes samples from members and providers. Indicating "N/A" in the above referenced columns is acceptable, when applicable.

8. **Q: In the protocols listed for CDM-Payment it states "A claim consists of one or more service line item(s), if any item is denied the entire claim is considered adverse. This universe should only include one record for the entire claim." Should this also apply to the universes in Attachment VII-A Effectuation Timeliness- Payment?**

   A: Yes, the language was added to the 2013 ODAG protocol recently released through HPMS.

9. **Q: For the ET-Payment universe, in the instance of a hospital claim where services are bundled under IPPS and/or OPPS, would approved status be based on the whole claim, or individual lines and each show up in their respective "approved" list or "denied" list?**

   A: The entire claim must be paid.

10. **Q: Is the column on the ET Pre-Service tab for Date and Time effectuated in plan's system intended to be filled in if a case appeared on the ET-Reconsideration tab (kindly note that there data and time columns appear on the ET- Reconsideration tab as well).**

    A: No, this is not CMS' intention. Enter the date and time effectuated for all reconsiderations when applicable.

Part C and D Agent/Broker Oversight

11. **Q: I noticed a discrepancy in Attachment X of the new OEV audit protocol and the current marketing guidelines. The current marketing guidelines state the plan sponsor must make a minimum of three documented attempts to contact the applicant by telephone within 15 calendar days <u>of receipt of the application</u>; the first two attempts must be made within the first 10 days. The new OEV protocols state the first two attempts must be made within 10 days <u>of the effective enrollment date.</u> Can you please clarify?**

    A: Correct, the protocol should reference "receipt of application", not "enrollment effective date". The protocol has now been revised to be consistent with the Marketing Guidelines (Ch. 3 Section 70.8).

Part C and D Compliance Program Effectiveness

12. ***Q: From the call on March 21, the guidance, and it is clear in the transcript, is that the CDAG and ODAG universe period is no longer determined by enrollment size but rather it is a 3-month fixed period determined by CMS and posted in the engagement letter. Will the universe requests for the Compliance program data be a fixed 3-month period, same as ODAG and CDAG, or will it be a 1-year look-back universe request?**

    A: The universe request for the compliance effectiveness program area request is the 12 months preceding the notice of the CMS program audit.

13. ***Q: Is it okay for a Sponsor to submit an SAQ in Word format with a "typed" signature, rather than a physical signature?**

    A: It is acceptable for the signature to be handwritten, typewritten, engraved or stamped. Whoever signs it will be held accountable during audit interviews, etc.

14. **Q: I have a general question about the Compliance Program Data and Document Request (Attachment III). It indicates that plans should submit the information in excel for data requests. It does not indicate if we should use separate excel files for each of the numbered requests or if all information can be provided in one file with separate worksheets.**

    A: Plan Sponsors can submit the data requests via multiple spreadsheets/tabs in one Excel workbook or separate Excel spreadsheets for each of the requests.

15. **Q: In reviewing the 2013 protocols, Attachment IV, Organizational Structure and Governance power point template, the amount of information requested, if using power point slides, will create an extremely large presentation. For instance slide 8 requests org charts for every operational area and flow charts of operations. In my organization, just the org chart alone will be approximately 40 slides. I would imagine upon completion, we could have close to 150-200 slides. Can you confirm that this is your expectation?**

    A: The Sponsor can either place the flow and organizational charts into the slides or submit the documents as supporting documentation to Attachment IV - Organizational Structure and Governance PPT. If the Sponsor chooses the option of submitting flow charts and organizational charts as an appendix, we kindly ask that you include the documents into one zip file and refer corresponding documents to the appropriate slide number in the PPT template.

16. **Q: On page 2 of Attachment III, 5(d), it indicates that we need to supply a copy of the Compliance Committee charter and it also requests a copy of the Charter of the Board of Directors committee in 5 (e)(3). As our organization has 2 committees, one at the organizational level and one at the Board level, is having a charter at the organizational level required if we have a Charter at the Board level?**

    A: Please provide the charter for either the board-level or the organizational compliance committee, whichever is available. CMS would like to review the charter for specifics pertaining to the mission, purpose, accountability, and operations of the committee tasked with overseeing and resolving Medicare C and/or D compliance issues.

17. **Q: Attachment V, Questions 31 and 32 of the questionnaire refer to incidents and FWA not identified in question 14; however, question 14 refers to HPMS memos. Please clarify the reference should be to question 15 instead.**

    A: Yes, questions 31 and 32 should refer to question 15.

Part D Coverage Determinations, Appeals, and Grievances (CDAG)

18. **Q: Our Organization has been conducting an in-depth review of the 2013 Audit Protocols and Universe Templates that were released on January 25, 2013. As a result, we are seeking clarification on Column L in the CDAG universe template as we do not see a correlating compliance standard for this item: Y/N to indicate if the prescriber is in-network (Y) or out-of-network (N). If possible, we are requesting further details on how this data correlates to the audit expectations for Effectuation Timeliness and Appropriateness of Clinical Decision-Making.**

    A: CMS is requesting whether a provider is in or out of network for the Clinical Decision-making portion of the CDAG audit to assist us with determining if provider outreach was reasonable. An in-network provider has a contract with the sponsor and should be held accountable for providing information to the sponsor upon request.

19. **Q: Regarding coverage determinations and redeterminations; for approved cases in which oral notification was attempted but failed, what is the timeline the member written notification must be postmarked in reference to the case due date?**

    A: The member notification must be postmarked within 3 calendar days of the oral notification (Ch. 18, 40.3.2).

20. **Q: Regarding coverage determinations and redeterminations; for denied cases in which oral notification was attempted but failed, what is the timeline the member written notification must be postmarked in reference to the case due date?**

A: Written notice of the decision must be immediately sent to the enrollee (Ch. 18, 40.3.3).

21. **Q: Regarding coverage determinations and redeterminations; for denied cases in which oral notification was attempted and successful, what is the timeline the member written notification must be postmarked in reference to the case due date?**

    A: The member notification must be postmarked within 3 calendar days of the oral notification (Ch. 18, 40.3.2).

22. **Q: In Attachment II-A (CDAG Universe) that accompanied the CMS memo of 1/25/2013 describing the 2013 Program Audit Process and Protocols, there is a data element pertaining to in/out of network status for the "prescriber". Please advise as to if "prescriber" refers to the medical provider or to the network pharmacy.**

    A: "Prescriber" refers to the medical provider.

Part D Formulary and Benefit Administration

23. ***Q: Is it acceptable for the Plan Sponsor to submit a universe in a data file (.csv format) that includes all of the PDE data elements [mirrors the PDE file layout]?**

    A: Submission of PDE in a .csv file format with the inclusion of all reportable fields is acceptable.

24. ***Q: How will the audit of formulary be handled? You said you would be checking the approved formulary with what is on the sponsor's website. Will this review/audit be done as part of the webinar or will this be done at CMS and not actively with the sponsor?**

    A: The formulary administration website review for 2013 audits occurs after the engagement letter is sent to sponsor and prior to the start of the webinar audit. CMS will conduct this review independently.

25. **Q: I am working on a best practices document for a Part D plan with respect to rejected claims review. I was wondering if in addition to the January, 2012 memo if CMS had shared any best practices with regard to the review, i.e. protect class review, etc.**

    A: You may also refer to the September 10, 2012 HPMS memo titled, 'Best Practices and Common Findings from 2012 Program Audits'. CMS anticipates releasing another best practice memo and common findings memo shortly.

26. Q: Attachment I, Formulary and Benefit Administration Audit Process and Universe Request, 2) Transition, iii) New Member Universe requests that the sponsor supply a universe of all new members. How is a new member defined?

A: CMS does not make this determination. It is up the Part D sponsor to notify CMS how they identify new members for the purposes of Part D transition. For example, are new members newly enrolled in a plan? Or are they new to the sponsor?

Special Needs Plan – Model of Care (SNP MOC)

27. *Q: In the Attachment IX protocol, section Part II Appropriateness of HRA, ICT and ICP, Use of Evidence-Based Clinical Guidelines, #1, 3rd bullet (p. 3 of the protocol) requests "Prescription Drug Events." Please confirm whether CMS wants to see the actual PDE record, or the Part D claim as it appears in the PBM's claims system. Also, how does CMS want to see the "Encounters" information?

A: We will look in the sponsor's system for PDEs or the PBM's system for pharmacy claims. Also, the sponsor's claims system would have encounter data shown as claims without payment.

28. *Q: What is the naming convention for the data and documents that are received?

A: Please use the names as indicated in the universe request (i.e. Health Risk Assessment Tool, etc.)

29. *Q: I have a clarifying question regarding the recently released audit protocol. The memo states the following "CMS will work with sponsors who have a SNP contract and who were audited prior to the release of the SNP-MOC protocol to schedule the audit of their applicable SNP contracts." Is this inclusion apply to plan sponsors recently selected for 2013 program audits, or all plan sponsors previously selected including 2012 program audits?

A: We plan to utilize the SNP-MOC protocols for those sponsors selected for audit in 2013.