

Questions and Answers
Supplement to the Compliance Program Guidelines Focused Training
Element 6: Routine Monitoring, Auditing and Identification of Compliance Risks
March 27th and April 18th, 2013

Background

The following Questions and Answers (Qs&As) are a supplement to the Compliance Element VI Focused Trainings conducted by CMS via webinar on March 27th and April 18th, 2013. The training elaborated on Element VI of the Compliance Program Regulations and Guidelines: Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks. Participants submitted questions prior to, during and following the presentation. Following are questions related to Element VI, with answers from CMS. These answers are provided in the context of the Compliance Program Guidelines (Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual) only. Clarification provided may not reflect other CMS program area policies, which should be considered as well. Please note that some questions received pertain to other Compliance Program Elements, and will be addressed in more detail in future focused trainings.

Questions and Answers

- 1. Q: We treat monitoring reviews and audits as interrelated because they pertain to the same regulations and we use the same criteria to conduct both. Would it be acceptable during a CMS Compliance Program audit for us to demonstrate to CMS that we use monitoring reviews and audits interchangeably as evidence of an effective program, as long as both are comprehensive and routine?**

A: Some organizations use the terms “monitoring reviews” and “auditing” interchangeably. However, the two activities have different meanings and expectations.

CMS considers monitoring as an ongoing daily event which includes conducting analyses and tracking trends to correct issues” in real time” at the lowest level of detection. As is explained in Chapters 9 and 21, monitoring reviews occur regularly during normal operations. The staff in the department being monitored often performs the monitoring activities. Monitoring occurs on a regular basis, e.g. daily, weekly, monthly, semi-monthly, bi-monthly, etc. Monitoring is, for example, a check to see if procedures are working as intended. For example, staff might perform a check once a month or once every three months to make sure that the process for distribution of HPMS memos is being followed and is working such that all persons who should receive a particular HPMS memo is receiving it.

Auditing is a formal retrospective review with a methodical approach and sampling of cases. It is performed periodically, though less often than monitoring – e.g. every 6 months or annually. Those performing audits must be independent of, and not employed in the department being audited. An audit is a more comprehensive review than is monitoring. Auditors review compliance against a set of standards, such as compliance with statutes and regulations or compliance with the sponsor’s internal requirements, used as base measures. Thus, for example, the sponsor might audit its sales department to confirm compliance with all of CMS’ agent/broker requirements. Auditors would pull a number of sample cases and review them to determine if they meet CMS sales and marketing requirements.

Both monitoring and auditing activities should involve asking probing questions to the root cause of why issues are happening and further development to correct the issues at hand.

2. Q: We currently do not track who has read the SOC. Would it be appropriate if we took a sample of 30 employees and verify they have read and understood the SOC or must we receive confirmation from all employees?

A: CMS is looking for evidence of the distribution of the Standards of Conduct. Sponsors must be able to demonstrate to CMS that their Standards of Conduct and compliance policies and procedures were distributed to *all* of their employees within 90 days of hire, when there are updates and annually thereafter. CMS will audit this requirement by pulling a sample of employees. Since the sponsor will not know until the audit begins which employees are in the sample, it should have a reliable method of showing distribution to every employee.

3. Q: Using real-life examples, please clarify the distinction between ongoing monitoring and auditing of FDRs.

A: *Scenario:* Suppose RutRo required its first tier entities to submit an attestation by the 15th of each month, attesting that it had screened its employees against the OIG/GSA exclusion lists the previous month.

Example of monitoring FDRs: The monitoring of this requirement might be a spot check of varying first tier entities monthly to see if they had timely submitted the attestations. If the sponsor found from this monitoring that month after month a significant percentage of the number of entities checked were not submitting the attestation, then the sponsor has a good early indication that there is a compliance problem.

Example of auditing FDRs: The outcomes of RutRo’s ongoing monitoring trigger a formal audit of the non-compliant first tier entities. The Sponsor’s independent audit team uses its organization audit tools and CMS audit protocols to perform a detailed review of the entities’ policies and processes to identify the root cause of the noncompliance. Some questions that may be asked during the audit may include: Is there a problem with submitting the attestation?

Is it too burdensome to be realistically complied with? If so, what kind of confirmation of screening would be less burdensome but still provide some assurance that the first tier entity was screening employees against OIG/GSA exclusion lists monthly? Is this a result of lax enforcement by RutRo or poor communication, such that first tier entities are not aware of the requirement to submit attestations monthly? Conversely, are first tier entities not submitting the attestation because they are not doing the screening, which may raise a different set of questions?

4. Q: Please clarify when it is permissible for FDRs to perform their own audits.

A: FDRs may perform their own audits (using auditors independent of the department being audited) at their discretion. CMS encourages sponsors to obtain a copy of the audit reports generated from these audits. However, even if FDRs perform their own audits, this does not relieve sponsors of the obligation to have their own auditing and monitoring work plan and to monitor and audit their high risk operational and compliance risk areas. It is a best practice to investigate the deficiencies identified in the FDRs' audit reports and require appropriate and timely corrective action.

5. Q: Section 50.6.4 states that Sponsors may conduct a risk assessment for auditing FDRs. Does this statement apply only when the sponsor has a large number of first tier entities and only audits high-risk first tiers?

A: Due to limited resources, sponsors may not have the capacity to conduct a full audit each year of all of its first tier entities. These types of audits inform the sponsor as to where compliance problem areas lay for each first tier entity, enabling the sponsor to work with that first tier entity to correct the problem and eliminate or significantly reduce program noncompliance or fraud, waste and abuse. Some sponsors do not have a large number of first tier entities and may be able to audit every first tier entity every year. However, we have heard from numerous sponsors that they do not have the resources to conduct an audit every year of every first tier entity. It is in that circumstance that CMS requires that the sponsor conduct a risk assessment to identify its highest risk first tier entities and to devote its limited resources to the auditing of those high risk entities. The sponsor will want to also have a rotation so that every first tier entity is audited at some time.

6. Q: To the extent that Part D sponsors do not use either pharmacists or pharmacy technicians to conduct audits or monitoring activities involving Part D operations (i.e., formulary administration, coverage determinations, appeals, and grievances, etc.), would this be a potential finding in the compliance area?

A: CMS' requirement is that participants in the audit function be knowledgeable about CMS operational requirements for the areas under review. In areas highly technical and specialized such as formulary administration, coverage determinations and appeals and grievances, the

burden is on the sponsor to demonstrate what specialized knowledge the auditor has that qualifies him or her to conduct the audit of those areas. Many sponsors have found it extremely helpful to have Part D policy experts and medical professionals (e.g. pharmacists, pharmacy technicians, nurses, physicians) involved with auditing and monitoring activities and/or validating the results of those oversight activities.

7. Q: The list in Chapters 9 and 21 provide examples of reports that Sponsors should receive, and seem to be focused on identifying fraud, waste, and abuse. Should the Sponsor receive similar reports from its FDRs as it relates to ongoing compliance with Medicare C/D operational functions (i.e., enrollments, organization/coverage determinations, appeals, grievances, call center compliance, etc.) that have been delegated to a first-tier or downstream entity?

A: Yes. The list of reports in Chapters 9 and 21 are only examples of the many kinds of reports a sponsor may wish to obtain from its FDRs. The reports the sponsor obtains from the first tier entity depend upon the function being performed.

8. Q: What does the 10 year record retention include? As for the Compliance Program Guidelines, most of our FDRs believe this only pertains to FWA training. They are citing that for any audit conducted of them under 50.6.11, they would only have to retain FWA Training. Should they not be keeping general compliance training and disciplinary actions taken on non-compliance, as well as basically any documents pertaining to day-to-day operations of their organization?

A: The HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the end of the final contract period or completion of audit, whichever is later. The records include books, documents, records, and other evidence of accounting procedures and practices for the Medicare Advantage and Prescription Drug programs. As for the Compliance Program Guidelines, documentation should include disciplinary violations/actions, training records, audit reports, etc. See 42 CFR 422.503 and 42 CFR 423.505 for specific requirements under contract provisions.

9. Q: A Vision Vendor (first tier) for a Sponsor is required to conduct monthly OIG/GSA verifications on all their employees, temporary employees, volunteers, consultants, etc. However, are they required to carry the requirement forward to their contracted providers, i.e., XYZ's Optical's entire organization? Should the Vision Vendor conduct audits of their provider network to ensure the provider's entire staff is being verified through OIG/GSA on a monthly basis?

A: Yes, the first tier entity is required to carry out the monthly OIG/GSA exclusion verification requirement to its downstream entities. The sponsor and its FDRs must work together to develop an effective monitoring strategy to ensure all persons working on the Medicare program are verified through both listings and none of these persons or entities are

excluded or become excluded from participation in federal programs. Monthly screening is essential to prevent inappropriate payment to individuals, providers, pharmacies, and entities that have been added to exclusions lists since the last time the list was checked.