

Healthcare fraud enforcement in federal programs

an interview with
Amy Berne





I believe you will continue to see nursing home cases and kickback cases a priority, but the Office is also focusing on providers who prescribe and pharmacies that distribute opioids...



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VOLUME 20, ISSUE 6

by Tonya Teschendorf

Improving outcomes of Compliance Program Effectiveness audits

- » The Compliance Program Effectiveness (CPE) audit is considered to be the most rigorous and demanding audit conducted by CMS.
- » Past findings of CPE audit outcomes are a good indication of the deficiencies that CMS will be looking for in the future.
- » Plan sponsors who have not been audited in the last three to five years tend to struggle more with CPE audits.
- » Plans can improve the outcomes of CPE audits by concentrating on the Top 5 issues consistently uncovered since 2011.
- » The importance of documentation and communication cannot be overemphasized.

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Each year, the Centers for Medicare & Medicaid Services (CMS) conducts its rigorous Medicare program audits by carefully selecting a percentage of Medicare Advantage (MA) and Prescription Drug Plan (Part D) organizations for review.

As Plan sponsors know, the Compliance Program Effectiveness (CPE) audit, as a component of the annual program audit, is

considered to be the most rigorous and demanding audit within the six individual program audits. Several factors contribute to this:

- ▶ The CPE audit requires significant resources from both operational and compliance areas to respond to the audit requirements.
- ▶ The CPE audit is the only individual program audit that is conducted on-site at the Plan sponsor's headquarters.
- ▶ Plan sponsors must provide live presentations to CMS auditors regarding

targeted operational issues that CMS discovers in the CPE universes and supporting documentation.

- ▶ The CPE audit is a formidable and challenging endeavor.

In our experience helping Plan sponsors prepare for CMS audits, we take a historical approach in counseling sponsors regarding past findings of CPE audits. Simply put, those who don't know history are bound to repeat it. The case for this is based on the fact that CMS publishes annual audit reports that detail widespread, repetitive issues across the Medicare Part C and Part D programs.

In our research into CMS audit archives, we have studied and compiled CPE audit performance and CMS common findings from 2013 through 2016. The results demonstrate that even though CMS provides formal guidance in Chapter 21, findings in yearly audit reports and supplemental guidance through Health Plan Management System (HPMS) memos, certain issues continue to recur.



Teschendorf

A look at recent CPE audit outcomes

In the last several years, overall program audit scores have shown improvements from an average high of 2.20 in 2013 to 1.22 in 2016. In tandem with this drop in overall scores (lower numbers indicate improvement), the average number of conditions has dropped from 38 in 2012 to under 18 in 2016. CMS findings suggest that newer sponsors (i.e., those that have offered Medicare contracts for five years or less) tend to score somewhat higher audit scores than more experienced sponsors. And, Plan sponsors who have not been audited in the last three to five years tend to struggle more with CPE audits.

CMS reasons that more experienced Plans have had the benefit of time on their side to familiarize themselves with operational and compliance program regulatory guidance and time to build operations around that guidance. Established Plans have also experienced at least one CMS audit and multiple mock audits, which allows an opportunity to remediate deficiencies that should not recur.

The implications of these findings suggest that Plans that have not been audited in the last three to five years and young Plans in the market are susceptible to audit deficiencies. And, while audit scores have improved, there are areas of repeated deficiencies.

Common areas of non-compliance

We examined CPE audit deficiencies (i.e., common conditions) from 2013 to 2016. These findings directly correlate to the CMS *Medicare Managed Care Manual*, Chapter 21, Compliance Program Guidelines, and the CMS *Prescription Drug Benefit Manual*, Chapter 9 of the same title (hereafter referenced as Chapter 21).

It is understandable that these deficiencies were considered common conditions in 2013, because CMS first published the Compliance Program Guidelines in 2013. The guidelines provide clarity to Plans on how to structure and operate a Medicare compliance program.

However, even with the guidelines in place, CMS found that several audit conditions have been considered a Top 5 condition since 2011, when the agency first began charting common conditions found in program audits. In the following, we have combined conditions that fit in similar categories for simplicity.^{1,2}

Communication with the governing board

CMS found failure to provide evidence that the Plan audits the effectiveness of the compliance program annually and failure to provide the audit results to the governing body as common conditions in 2013 and again in 2015 and 2016. In 2015, CMS noted the latter condition as not providing updates to the compliance committee, senior leadership, and the governing body. Throughout Chapter 21, CMS reinforces that the compliance officer must not only conduct monitoring and auditing, but must also communicate these activities to upper management and the governing body. It is not enough to act on one portion of this requirement and not act on the second. It is also not enough to say that these activities were communicated and not be able to provide documented proof of the communication.

Exclusion screenings

Plan sponsors did not conduct federal exclusion screenings and/or sponsors did not ensure that their first-tier, downstream, and related entities (FDRs) are not excluded from participation in federal health care programs. Sponsors must review the Office of the Inspector General (OIG) and General Services Administration (GSA) exclusion lists prior to the hiring or contracting of any new employee, temporary employee, volunteer, consultant, governing body member, or FDR. Further, sponsors must conduct and document these checks monthly thereafter. CMS found that sponsors did not have a process to conduct the checks, and did not document the checks.

Training employees and FDRs

Plan sponsors did not establish and provide general compliance, and fraud, waste and abuse (FWA) training. Chapter 21 requires that general compliance and FWA training must be an established training program, that the trainings are provided to a defined audience, are provided on an annual basis, and are part of orientation for new employees, among other requirements. Organizations must be able to prove that their FDRs provided equal training to their organizations. In audits, Plans have failed to provide documented proof of training for the sponsor organization and documented proof that FDRs provided equal training to their organizations.

Two-way communication

Plan sponsors did not establish and implement effective methods of compliance communications. Chapter 21 requires Plan sponsors to have multiple compliance communication channels. The compliance officer must communicate compliance matters outward to the organization, senior management, its FDRs, the governing body, the compliance committee, etc. The compliance program also must have communication channels coming into the program from members, employees, FDRs, etc. to report compliance issues and concerns. All communication must be documented. Audit findings show that sponsors did not have an effective system of communication and that communications were not documented.

Risk assessments and audits

Sponsors did not establish an effective system for implementing a formal risk assessment and a system for monitoring and auditing compliance risks, including in their first-tier entities. Chapter 21 requires that this system include internal monitoring and auditing, as well as external audits to assess regulatory compliance and the effectiveness of the compliance program for sponsors and their FDRs.

In audits, CMS did not find evidence that risk assessments and monitoring and auditing were performed by sponsors, nor were results shared with the governing body. Although sponsors may be executing some of these requirements, they often fail to accurately document risk findings and all monitoring and auditing activities to reflect the full scope of their oversight actions.

The findings

Two reciprocal threads run throughout these findings: documentation and communication. The importance that CMS places on documentation and communication cannot be overemphasized. For instance, we often find that Plans may have a channel of communication, but that channel has not been formally affected. This is especially true of young and smaller Plans where communication is often of a relaxed nature. Chapter 21 repeats the theme of formal compliance operations. This means that the compliance officer must implement formal communication channels; document those in the compliance plan, compliance policies, and code of conduct; and abide by them. When the compliance officer communicates out to the organization, senior leadership, the compliance committee, and FDRs, the officer must document that communication occurred to be able to prove that it happened.

Documenting compliance activities such as meetings, trainings, and operational monitoring must be stressed. Using training as an example, sponsors must prove through documentation that employees took training. Training can be documented in many ways, including employee attestations post training or by using sign-in sheets. The same is required of the sponsor's FDRs.

Effective practices and tools

The following are effective practices and tools that yield successful CPE audit outcomes.

Be proactive in implementing the compliance program guidelines

The compliance officer must take a proactive approach to implementing the requirements in Chapter 21. For example, it is the compliance officer's responsibility to ensure that the board of directors and senior management are trained on compliance program requirements and the consequences of non-compliance, which include sanctions and civil money penalties (CMPs).

Use outside auditors to conduct audits

It is not enough to conduct internal monitoring and auditing. Outside auditors have the advantage of working with many clients, so they see the bigger picture in the industry and can help the compliance officer identify operational and compliance issues that may not be properly identified, documented, and communicated. Plan sponsors should use auditors who not only have audit experience, but also have prior experience in working for health plan sponsors in compliance and operational areas.

Document all compliance and operational activities in policies and procedures

Sponsors must document compliance and operational activities in their policies and procedures, communicate those to the appropriate personnel, and document that communication. Documenting can be labor-intensive and time-consuming, especially if a manual system is used. Cloud-based software is the best option to streamline the creation and distribution of policies and other compliance documents (e.g., the compliance plan, risk assessments, and the code of conduct), and communicate them as required.

Document and automate the distribution of compliance communications

Compliance communications can include any incoming regulatory correspondence, such as CMS Health Plan Management System

(HPMS) memos and state regulatory directives.³ The compliance officer should not have to worry if all HPMS memos were communicated to appropriate departments and people, and if those memos were acted on if required. The compliance officer needs a tool that can prove compliance communications are documented and communicated appropriately.

Use software that intakes compliance communications, distributes, and requires and tracks responses and due dates. Automated workflows allow compliance personnel to manage all incoming and outgoing correspondence and track it across the organization. For example, compliance personnel can store CMS audit enforcement reports or internal audit reports, and send those out to key stakeholders including the governing body.

Documentation and communication controls

We have shown that documentation and communication are key to a successful compliance program and a successful CPE audit. Ensuring that compliance processes are effectuated means migrating from burdensome manual operations to sophisticated workflows.

During an audit, the proof of documentation and communication in an automated workflow can be presented quickly and smoothly. This makes for an efficient and uncomplicated presentation to CMS auditors, which in turn allows Plan sponsors to realize the compliance and monetary benefits of preventing audit deficiencies.

Effective communication and documentation tools are key to identifying compliance risks and preventing risks from occurring, and they are key in demonstrating corrective actions. Automated controls provide demonstration of an effective compliance program. ©

1. CMS.gov: *Medicare Managed Care Manual*, Chapter 21 - Compliance Program Guidelines and *Prescription Drug Benefit Manual*, Chapter 9 - Compliance Program Guidelines. Available at <https://go.cms.gov/2sf79Ub>
2. CMS.gov: Part C and Part D Program Audit Reports. Available at <https://go.cms.gov/2qVsi2d>
3. CMS.gov: Health Plan Management System (HPMS) Memos Archive - Annual. Available at <https://go.cms.gov/2HWEAPR>