

Medicare Prescription Drug Part D Compliance Conference



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Session 402 – CMS Audit Readiness

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Definitions

- Desk Audit
 - Systematic review of documentation, case samples (e.g., universe file), policies and procedures, interviews, etc.
- Site Visit
 - Desk audits conducted at the PDP or MA-PD location
- Corrective Action Plan
 - A process by which CMS communicates the requirements to bring a PDP or MA-PD into compliance with the regulations and the timeframe in which it needs to be completed. These will always be communicated in writing
- Audit Guide
 - This is the primary document that CMS will utilize for their audits
 - There is a PDP and MA-PD version
 - CMS will not provide audit worksheets or tools to the industry outside of the audit notification

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Definitions (cont.)

- Review Period
 - This is the audit coverage period and defines the period in which CMS will request a full universe file of data in order to determine their audit sample
 - The review period can be as short or long as CMS desires, however, based on experience, the average universe period is averaging six months
- Universe List
 - This is the total population of data from which CMS will select their audit sample
 - Once CMS has received the data and has reviewed the file, the sample selection will be sent to the PDP or MA-PD for response

Pre Audit Preparation

- Internal Audit Readiness Assessment
 - Review of internal policies/procedures
 - Ongoing communication with your PBM
 - Review of periodic reporting
 - Coordinate with your PBM to ensure that appropriate documentation is in place for activities and services delegated to the PBM
 - Development of template presentation on your operations and process including key contacts
 - Recognize that CMS can look at any documents needed to determine overall compliance with CMS regulations

Standard Audit Process

- Notification letter
- Pre-audit meeting to discuss scope
- Solicitation of case samples
- CMS review of case samples
- CMS review of other documentation requested (e.g., policies and procedures, flowcharts, training manuals, etc.)
- Personnel interviews

Standard Audit Process (cont.)

- Systems review (generally for onsite audits only)
- Summary of findings
- Communication of findings and exit meeting
- Corrective action development
- Corrective action monitoring and closure

CMS Presentation

- Recommend having a pre defined presentation that outlines the following:
 - History of the organization
 - Key contacts within the administration of the program
 - Key policies and procedures
 - Copy of your compliance plan including fraud, waste and abuse
 - Internal committees conducting oversight activities. (e.g., Compliance, Delegation Oversight/Accreditation, SIU, Audit)

CMS Presentation (cont.)

- Process improvements already identified and corrected
- Process improvements documented in corrective action plans
- Subcontractor oversight program for activities or services delegated to the PBM
- Subcontractor oversight program for activities or services delegated outside of the PBM

Delegated Entities

- Services are typically outlined in the PBM Agreement itself.
- PBM Clients will need to obtain the universe file from their PBM for those activities that have been delegated in order to respond to CMS for their audit
- Clients must combine their own internal data and that of their delegated entities prior to submitting the files to CMS for review and sample selection

Sample Selection Criteria

- CMS may utilize any of the following methods for their audit sample selection:
 - Data provided under the reporting requirements
 - CTM data
 - PDE Data
 - Prior non-compliance notifications
- It is important that all documentation be readily available to the auditors when requested and be organized consistent with CMS' direction to the plan sponsor

Performance Measures vs. Audit

- CMS utilizes new plan sponsor performance metrics that are available via medicare.gov to assist Medicare beneficiaries in evaluating the various Medicare Part D plans
- These performance measures are to ensure ongoing monitoring and enrollee protection and will be used for determining subsequent audits. These measures can be organized as follows:
 - Customer Service
 - Complaints
 - LIS Matching
 - Exceptions/Appeals
 - Data Systems
 - Pricing
 - Drugs

What Else Can You Do?

- Training
 - The key to a solid training program and audit readiness assessment is determining how well the plan sponsor personnel are trained in doing what they need to do from a program perspective
 - Ensuring that your subcontractors have adequate training in place
 - Compliance
 - Operational
 - Communication of Issues
 - Investigation
 - Ongoing review and updating as needed to conform with changes in business practice
 - Ongoing review and updating as needed to incorporate new CMS regulations and guidance

What Else Can You Do? (cont.)

- Policies and Procedures - **CRITICAL**
 - Determine what you have and don't have in place
 - Must be clear & specific and address how the policies and procedures are implemented
 - Determine how accessible the documents are in order to promptly respond to any request from CMS or their MEDIC
 - Understand your process for periodically reviewing and updating policies to ensure full compliance
 - Review the PDP and MA-PD audit guides to outline key focal points for audits
 - Develop formal process for developing, communicating and maintaining key policies and procedures

What Else Can You Do? (cont.)

- Sub Contractor Relationships
 - Develop proactive communications between key contacts including Account Management, Compliance, Special Investigations Units, and Clinical Program Staff
 - Review policies and procedures for services and activities delegated to a third party (e.g., PBM, pharmacy, medical review board, etc.)
 - Develop internal oversight program for sub contracted activities (e.g., desk or onsite)
 - Encourage periodic meetings and discussions with your PBM Compliance Officer

The Post Audit Process

- CMS will communicate any findings of non-compliance in writing via HPMS
- Plans will generally be notified within 45 days after the audit has concluded
- A target compliance rate of 95% is generally what CMS is looking for during an audit
- The audit may or may not result in a formal corrective action plan and/or penalty. The ability of a plan sponsor to demonstrate self identification of issues and internal oversight and monitoring will be essential to this phase of the audit

The Corrective Action Process

- A Corrective Action Plan (CAP) is the document CMS issues to a plan that outlines the following items:
 - Where the area of non-compliance occurred
 - Analysis for the finding
 - What CMS expects the plan to do in order to correct the underlying problem
 - When CMS expects the plan to be completed and implemented
- Please note that until CMS is satisfied that the corrective action plan is “effective,” the plan is not off the hook
- It is important to recognize that once CMS accepts the corrective action plan, it will be posted on their website

Compliance/Fraud Waste and Abuse Program Oversight

- CMS has begun auditing Part D plan sponsor compliance and fraud, waste and abuse programs
- These audits will be conducted by the MEDIC's
- Part D plan sponsors should review their programs in preparation for an audit and may want to obtain and read the following reports:
 - Medicare Drug Plan Sponsors Identification of Potential Fraud and Abuse (OEI-03-07-00380 dated October, 2008)
 - Oversight of Prescription Drug Plan Sponsors' Compliance Plans (OEI-03-08-00230 dated October, 2008)
 - Some Plan Sponsors Have Not Completely Implemented Fraud and Abuse Programs, and CMS Oversight Has Been Limited (GAO-08-760 dated July, 2008)
 - CMS' Implementation of Safeguards During Fiscal Year 2006 to Prevent and Detect Fraud and Abuse in Medicare Prescription Drug Plans (OEI-06-06-00280 dated October, 2007)

Summary

- There is no true right or wrong way to prepare for an audit
- As you receive your audit notices, please let your PBM or subcontractor know ASAP so they can help to the extent necessary
- CMS is not publishing their audit worksheets, but they could be made available during the audit request
- Don't wait until you get the audit notice to begin your preparation for an audit
- Based on what we know thus far from several clients who are in this phase, audit requests are extensive, do not always provide a lot of response time, and include documentation, samples, and evidence of policy implementation
- Have defined processes in place to quickly receive and coordinate the audit to ensure a collaborative effort