Best Practices for Conducting Auditing and Monitoring

Pre and Post Audit Planning
Monitoring and Auditing

Purpose to prevent, detect, and correct non-compliance

• Monitoring: Regular reviews performed as part of normal operations to confirm ongoing compliance

• Auditing: Formal review of compliance
Importance of Monitoring and Auditing

• Required to have an effective compliance program
• Substantial compliance is not sufficient
• Knowing of the non-compliance is better than not knowing
• Even the well intentioned can get sanctioned
Auditing/Monitoring Expectations

- Part D plan sponsors are subject to and will routinely be audited by CMS, including for Compliance Program Effectiveness (CPE)
- Part D plan sponsors have an obligation to audit their FDRs
- Part D plan sponsors must undertake internal auditing to confirm compliance with Medicare regulations and sub-regulatory guidance, contractual arrangements, and applicable laws
- PBMs will:
  - Be asked to support Part D plan sponsors during CMS audits
  - Be the subject of the audit if the Part D plan sponsor is auditing the PBM as an FDR
  - Be asked to support Part D plan sponsor’s internal audit efforts related to PBM functions
Consequences of Non-Compliance

- CMS audit deficiencies
- Contractual issues
- STARs impact
- Damage to reputation
- Staff diversion from daily responsibilities
- Increased costs
  - CMPs*
    - 21 CMPs imposed in 2016
    - CMPs in 2016 totaled $7.5 million
    - Highest CMP almost $2.5 million
  - Enforcement actions / independent auditors
    - Responsible for cost of independent auditor

Common Obstacles to Monitoring and Auditing

• Failure to appropriately budget
• Insufficient staff resources
• Inadequate planning/preparation
• Lack of internal coordination/alignment
• Lack of clearly defined internal ownership
• Lack of coordination/communication between plan sponsors and PBMs
First Step to Monitoring/Auditing Work Plan

- Annual work plan
- Based on:
  - CMS requirements
  - Identified risk areas
  - Changes in regulatory environment
  - Organizational needs
  - CMS OIG Work Plan
  - CMS Readiness Checklist preparation
  - CMS Attestations
  - Prior remediation plans
  - Compliance Issue Notification(s)
  - Contractual commitments
Work Plan

• Compliance Officer responsibility
• Prioritize risk areas
• Define auditing vs monitoring activities
• Specify
  – Objective/scope
  – Frequency/timing
  – Responsible functional business area
  – Process for responding and follow ups
• Track / Report on Work Plan status
Work Plan
Challenges

• Prioritizing risk areas
• Staff resource limitations
• Coordination/assignment of ownership among cross-functional areas
• Integrating internal monitoring with day to day operations
• Avoiding day to day operation disruptions during audits
Monitoring and Auditing Best Practices

Planning

• Start early and update
• Identify cross-functional teams/owners
• Consider date/time period sensitivities of functional teams
• Assess common and significant prior internal and external audit findings
• Review recent trends and outliers
• Consider new CMS common findings/best practices
CMS Common Findings/Best Practices - 2016

- CMS 2016 Best Practices/Sponsor Tips*

“Please pay close attention to the common audit deficiencies listed by program area on the following pages. Understanding the failures of other organizations that operate in the Medicare Advantage and Prescription Drug programs can inform your internal auditing and monitoring efforts. Reviewing these common conditions can identify areas of potential weakness in your own operation. By evaluating your own organization’s compliance around these most common audit deficiencies, you may prevent them from being reflected in your audit report and negatively affecting your Star Ratings!”

CMS Common Findings/Best Practices - 2016

- CMS 2016 CPE Common Audit Deficiencies*

<table>
<thead>
<tr>
<th>CPE Common Audit Deficiency</th>
<th>% of Sponsors Affected in 2016</th>
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<tbody>
<tr>
<td>Failure to Review OIG/GSA Exclusion Lists upon hire and monthly thereafter</td>
<td>32%</td>
</tr>
<tr>
<td>Evidence of conducting audits of effectiveness of compliance program annually and that results are shared with governing body</td>
<td>26%</td>
</tr>
<tr>
<td>Failure to provide compliance and FWA training to employees, including senior administrators and managers and governing body members</td>
<td>26%</td>
</tr>
<tr>
<td>Failure to have effective lines of communication for confidential/anonymous report of potential compliance and FWA issues</td>
<td>16%</td>
</tr>
<tr>
<td>Failure to monitor/audit first tier entities</td>
<td>13%</td>
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CMS Common Findings/Best Practices - 2016

• More CMS 2016 Best Practices/Sponsor Tips*
  – “If you utilize delegated entities to perform any of the functions currently included in a program audit, ensure you are able to collect and consolidate the relevant universe data accurately. **When performing internal audits, sponsors should practice the submission of the universe data from delegated entities and ensure their accuracy to prepare for a future audit and to ensure compliance with CMS requirements.** If is important that both your organization and any delegated entities are prepared for all aspects of a CMS audit.”
  – “The audit protocols are valuable resources for audit preparation and detail the process for audits. **Sponsors are encouraged to perform practice audits, including practicing universe pulls.** Practice audits will not only help you prepare for an actual CMS audit, but may help you improve your operations by exposing areas that are problematic or otherwise non-compliant with CMS regulations. Because audit findings may impact Medicare Advantage and Part D Star Ratings, routine self-audits are encouraged to improve operations.”

Monitoring and Auditing Best Practices
Coordination/Communication between Plan Sponsor and PBM

CMS Best Practice: Develop effective working relationships and frequent communication between the compliance department and business functional areas

- Regularly inform Part D plan sponsors of training, monitoring, and auditing activities
- Promptly communicate compliance issues to Part D plan sponsors for reporting to CMS (self-reported issues taken into consideration by CMS so long as self reported prior to CMS audit)
- Maintain log of communications
Monitoring and Auditing Best Practices

Internal Coordination/Communication

CMS Best Practice: Develop effective working relationships and frequent communication between the compliance department and business functional areas

• Remove silos
• Assign ownership
• Establish communication plan
Monitoring and Auditing Best Practices

Internal Accountability

CMS Best Practice: Hold management and staff accountable for compliance results

• Performance evaluations
• Incentives
Monitoring and Auditing Best Practices

Senior Leadership Involvement

• Keep senior leaders apprised
  – Status and outcomes of work plan
  – Timely communication of non-compliance
  – Status of remediation plans
Monitoring and Auditing Best Practices
Leverage Internal Resources

• Leverage internal strategic partnerships
  – Example: Coordination with internal audit and/or quality assurance resources/initiatives
  – Expands scope/coverage of internal auditing and monitoring in order to accomplish more with limited resources
  – Less burden on business teams
Monitoring and Auditing Best Practices

Multiple Layers of Review

Ensure internal monitoring and auditing is multi-dimensional:

• Claims
• Systems
• Facilities
• Written policies and procedures
• Internal processes and procedures
Monitoring and Auditing Best Practices

Prompt Distribution/Tracking of New CMS Guidance

CMS Best Practice: Provide for appropriate internal distribution of HPMS memos within hours of release and external distribution to downstream entities within 24 hours

- Functional business team gap analysis
- Track to compliance effective date
- Test compliance prior to effective date
- Monitor/Audit post effective date
CMS Audit Best Practices

Establish and Use Trained Cross-Functional Audit Team

- Identify subject matter experts responsible for the various functional requirements who will be responsible for reviewing requests issued from CMS
- Train the audit team *in advance* to
  - Understand CMS deadlines and their significance
  - Know and be able to speak to CMS requirements with confidence
  - Understand and be prepared with respect to CMS key focus areas
  - Identify consistent system/reporting requirements as early as possible to support expedited turnaround times and complexity of system data pulls
  - Have a quality review process that has a standardized set of reporting and criteria definitions
  - Create a library containing information on historical impact analysis queries for given conditions
- Benefits
  - Provides more efficient and accurate responses
  - Limits strain on resources and relationships
  - Avoids distraction from day to day business operations
CMS Audit Best Practices

Plan Sponsor and PBM Collaborate Before, During, After CMS Audit

- PBM identify for sponsor the contact person for responding to CMS audit requests/inquiries
- Sponsors provide immediate notice to PBM of audit start
- Sponsors and PBM discuss universe requirements prior to call with or submission to CMS
- Both sponsor and PBM representatives participate in meetings/calls with CMS that involve PBM data
- Establish dedicated conference rooms to promote collaboration internally and externally as needed to fully understand the request and expectations from the sponsor and/or CMS throughout the CMS audit
- Daily meetings between sponsor and PBM to understand and assign document requests
- Daily meetings with cross-functional audit team to understand and assign document requests
- Plan sponsor provide draft audit report to PBM so PBM has opportunity to provide comments and assist with responses
Post Audit Best Practices
Continued Use of Cross-Functional Teams

- Compliance and cross-functional team work together to develop and implement corrective action plan
  - Root cause analysis
  - Member impact
  - Remediation plan with milestones
  - Feedback on “lessons learned” for future improvements
  - Training
  - Testing
  - Verify correction does not create other non-compliance issues
  - Monitoring
  - Reporting
Post Audit Best Practices
Tracer/Work Plan Follow Through

• Track compliance issues and improvement opportunities in central repository
  – Identify and categorize compliance issues
  – Track status of compliance issue through full remediation
  – Track process improvement opportunities
  – Identify inconsistencies in CMS audit positions

• Use tracking system to
  – Identify trends and/or inconsistencies
  – Identifying risk areas for annual work plan and improvement opportunities