Preparing for, and Surviving a CMS Program Audit

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Topics

• Who We Are
• Audit Protocols
  o Scope
  o Chronology
• Preparing for the Audit
• Lessons from the Audit
• Aftermath

Who We Are:
Health Alliance Plan (HAP)

• HAP and its subsidiary, Alliance Health and Life Insurance Co, offer MA-only, MAPD and PDP products under three contracts with CMS.

• 878 employees.

• 45,000+ Medicare Advantage/PDP members.
Who We Are:
Midwest Health Plan

- Acquired by HAP 11/1/11 (we thought it was a good thing!)
  - Wholly owned subsidiary
- 85 employees
- SNP (Dual Eligible) product with 650 beneficiaries
- No shared operations, systems, etc. with HAP
  - We even use a different PBM

Structure

Preparing for, and Surviving, a CMS Program Audit
THE AUDIT PROTOCOLS
**The Audit Protocols: Scope**

- **Part D Formulary and Benefit Administration:**
  - Formulary Administration
  - Transition
  - P&T Committee (conditional)

- **Part D Coverage Determinations and Appeals (“CDAG”):**
  - Effectuation Timeliness
  - Appropriateness of Clinical Decision Making and Compliance with Processing Requirements
  - Part D Grievances

- **Part C Organization Determinations and Appeals (“ODAG”):**
  - Effectuation Timeliness
  - Appropriateness of Clinical Decision Making and Compliance with Processing Requirements
  - Part C Grievances
  - Dismissals

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**The Audit Protocols: Scope**

- **Part C Access to Care:**
  - Misclassified grievances
  - Complaints (CTM)

- **Part C and Part D Compliance Program Effectiveness:**
  - Written Policies, Procedures and Standards of Conduct
  - Compliance officer, Compliance Committee and Governing Body
  - Effective Training and Education
  - Effective Lines of Communication
  - Enforcement of Well-Published Disciplinary Standards
  - Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks
  - Effectiveness Measure
  - First Tier, Downstream and Related Entities (FDR) – Compliance Program

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**The Audit Protocols: Scope**

- **Agent/Broker Oversight:**
  - Denials
  - Testing and Training
  - OEV Calls
  - Complaints

- **Enrollment/Disenrollment/LEP:**
  - Timely processing
  - Incomplete enrollment requests
  - Denials
  - Special Needs Plans
  - Non-Payment of Premium
  - Creditable Coverage Determinations
  - IRE Reconsideration Requests Timeliness
Audit Protocols

• 21 elements reviewed during webinars:
  – 24 universes, some with multiple parts
    • Date ranges of 1 to 3 months
    • 1 universe that CMS pulls from CTM
  • 9 Compliance Program elements:
    – Reviewed on-site
    – 13 Universes
      • 1 year look back period
      • Large amounts of additional documentation
      • Self-assessment questionnaire
      • Power point presentation
  • All documents uploaded through secure File Transfer Protocol (FTP)

Chronology, per Protocols

• Initial Notice and Data Request:
  – 4 weeks notice before audit begins;
  – 10 business days to submit universes and other documents.

• Audit lasts approximately 1 week

• Draft Audit Report to Sponsor 30 days after audit:
  – Sponsor has five business days to respond.

• Final Audit Report to Sponsor 10 days after receiving comments:
  – Sponsor has 90 days to correct deficiencies.

Our Experience: Chronology

• June 18: Initial notification and request for documents
  – June 19: Established internal audit team
  – June 20: Preliminary conference call with CMS
  – June 20 – 22: Internal meetings to review document requests

• June 29: Due dates for universes and other documentation
  – 50 documents requested, including universes for audit

• July 5 – 13: Preparation
  – Webinar testing
  – July 12: received first sample requests
  – July 13: samples and other documentation due

• July 16 - 20: Onsite audit and webinars
  – 136 additional document requests
  – Nightly debriefs with audit team

• July 24: Exit conference
Chronology, Post-Audit

- July 30: Received Immediate Corrective Action notice
  - 5 issues identified
    - Formulary Administration (3 issues)
    - MIS (2 issues)
  - Response due in 72 hours
- August 3: Submitted initial CAPs
  - Submitted initial CAPs
    - Significant debate involving one issue not resolved until September 10
- September 14: Notified that CAPs were accepted
  - Provided ODAI universes (claims, pre-service, grievances & appeals)
  - Due November 6
- November 15 – 16: Validation audit conducted via webinar
  - Reviewed everything, even if not subject to CAP (e.g., appeals and grievances)
  - Validation passed, but several unrelated issues found
  - ICA for remaining (2) issues not yet scheduled

Chronology, Post-Audit

- November 28: Received draft audit report
  - 5 business days to respond
    - Asked to address "misrepresentations, inaccuracies, or questions"
- December 5: Responded, made 14 comments on the report
- January 9, 2013: Received final audit report
  - CMS accepted many of our comments and revised the report accordingly.
  - Several findings were removed
- By April 9, 2013, HAP must provide documentation that the findings have been corrected and are not likely to recur. Response must include an attestation by CEO to this effect.
  - For findings requiring more than 90 calendar days to correct, must include a summary of the process and provide a timeframe.

Preparing for, and Surviving, a CMS Program Audit

PREPARATION
Preparing for the Audit

- Identify Challenges:
  - Multiple other priorities;
  - New PBM for HAP as of January 1, 2012;
  - HAP undergoing major organizational redesign;
    - Replacement of several core systems
  - Midwest already engaged in multiple other audits;
  - Use of multiple systems (internal and external) that would need to be accessed during webinars;
  - Involvement of delegated entities (e.g., PBM).

Preparing for the Audit

- Logistical Considerations
  - What systems will need to be accessed (where is your data stored)?
  - Do you have paper-based files?
    - CMS wants everything electronically
    - Lots of scanning
  - Where will webinars be conducted?
    - Set aside enough space for on-site auditors and multiple, concurrent webinars
    - Ensure rooms are equipped with appropriate equipment
- Staffing
  - Assign responsibilities;
  - Who will cover the work of those involved in the audit (business has to go on...);
  - Vacations (audit prep fell during week of July 4th).

Communicate!

- Initial communication to Senior Leadership
  - Outlined requirements, anticipated burdens on staff time, potential consequences of "failure"
  - Asked for them to support their staff in making the audit a priority
- Company-wide communication
  - Audit involved everyone, directly or indirectly
  - Co-workers had to cover for or otherwise support those involved in the audit
- Set expectations from the beginning
  - High stress, long hours
What Worked For Us

- Establish Core Audit Teams for each element
  - Make sure these are the same people who will be available during the week of the audit itself.
- Practice webinars
  - Review cases using WebEx and remote desktop from conference rooms
  - Include vendors
- Partner with IT
  - Have them on standby during the audit, for tech issues
- Esp. with small universes, get a head start on case reviews before sample selection

Prior to On-Site Visit

- Distributed fact sheet to all employees (Exhibit A):
  - Sent several reminders, to prepare staff for walk-arounds
- Ensured compliance program notices posted in common areas, clearly visible.
- Prepped interviewees with likely questions (Exhibit B):
  - Primary goal of interviews, per CMS, is to obtain assurance that Sponsor has implemented the seven elements of an effective compliance program
  - Assessment of “culture of compliance”
- Distributed copies of Compliance Officer Reports from the prior year to Board and members of Compliance Committee.

During the Audit Week

- Multiple, concurrent webinars:
  - Typically lasted most of the day
- 3 – 4 auditors onsite for compliance program review:
  - Interviews (Sample schedule, Exhibit C)
    - CEOs, Board members, Department leadership
  - Walk through departments
    - Asked questions of random staff
    - Document review
Sample Webinar Schedule

<table>
<thead>
<tr>
<th>Audit Area</th>
<th>Webinars</th>
<th>Staff Involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part D Formulary</td>
<td>Monday 11 – 5 Fri 9 – 5</td>
<td>Pharmacy administration staff, coverage determination staff</td>
</tr>
<tr>
<td>Part D CDAG</td>
<td>Monday 12 – 5 Fri 9 – 5</td>
<td>Pharmacy administration staff, CMS staff, PBM representative, Compliance staff</td>
</tr>
<tr>
<td>Part C Access</td>
<td>Monday 12 – 4 Wed 10:30 – 1:30</td>
<td>Utilization management staff, PBM representative, Medical director(s), Claims staff, Pharmacy &amp; Sales staff</td>
</tr>
<tr>
<td>Enrollment/Disenrollment</td>
<td>Monday 11 – 1 Thu 9 – 5</td>
<td>Enrollment and Billing staff</td>
</tr>
<tr>
<td>Agent Broker Oversight</td>
<td>Monday 11 – 2 Thu 10 – 4</td>
<td>Medicare Sales staff</td>
</tr>
</tbody>
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What We Did

- Daily (end-of-day) debriefs as a team:
  - Kept people focused
  - Allowed them to blow off steam
  - Kept compliance informed of issues

- Designated one person (with backup) to do all the uploading/downloading and keep an issues/requests log.

- Compliance Officer was principle liaison with CMS Auditors

- Communicated with Lead Auditor regularly as issues came up

Problems Encountered

- Webinars can be very frustrating:
  - Viewing large files;
  - Navigating multiple, complex systems in real time;
  - Documentation for a given case can be in multiple systems.

- Large number of additional data requests, impact analysis – short timeframes:
  - Screenshots and other documentation requested during webinar usually required by 1:00 the next day;
  - Impact analyses usually required involvement of the same people involved in the webinars.
Webinars: Lessons Learned

- Have a neutral/uninvolved party sit in on the webinars to take notes, keep track of all CMS requests:
  - We encountered a few misunderstandings because of our failure to do this.
- Have reference material available to staff during webinars.
- Easier to coordinate if everyone is in the same room.
- Ask for clarification if you don’t understand the question:
  - Don’t rush to answer anything if you’re not sure (no guessing!)
  - Don’t respond on behalf of other departments
  - Use MUTE button: CMS can’t see you, but they can hear everything!

Other Lessons Learned

- Debrief with Compliance and/or Legal before making any process or system changes based on CMS comments:
  - Each department/audit lead provided a write up of the issues they identified during the audit, including comments CMS made;
  - A comment by a CMS auditor is not the equivalent of a regulation!
- Don’t expect to know what all the findings will end up being:
  - Goal is for Plan to know pass/fail of each sample case during webinar;
  - This wasn’t our experience;
  - Pass/fail decision often depended on additional documentation provided after the webinar, not revisited with Plan;
  - Accordingly, some surprises in the audit report.
- Started corrective actions, where possible, prior to receipt of draft report:
  - Allowed us to keep focus on CMS compliance while we waited…and waited…

I Didn’t Know That!

- Are OEV scripts being followed?
  - Must record OEV calls
- Do members receive expedited determination notices within 72 hours?
  - Phone calls (but how do you prove?)
- Even if there is no explicit requirement to do “X”, you need to think about how you would prove something to CMS:
  - Burden of proof is on the Plan
Areas of Concern

- Use of Clinical Criteria more restrictive than Medicare:
  - How do you balance vague NCD/LCDs with need to make clinically appropriate coverage decisions based on medical necessity?

- Denials of claims from non-contracted providers when no authorization was obtained:
  - Has to be covered if plan provider directed the care;
  - How do you know this from the claim?

- Denial of coverage for Part D drug based on lack of clinical information is inappropriate:
  - But only have 24 – 72 hours, no option for extension;
  - Prescriber may not respond to requests for additional information.

HAP Compliance Program Review

- Extensive initial interview:
  - Clearly guided by a script
  - Mostly follow‐up on answers given in Self‐Assessment Questionnaire

- Daily meetings – additional questions, document requests, check‐in.

- Although we passed almost every element separately (except FDRs), failed compliance effectiveness test, based on two sample cases:
  - Tracer samples selected from Monitoring Activities universe and Compliance Reports universe
    - Not all monitoring activities are conducted or overseen by Compliance
  - CMS reviews samples to determine if they touched each of the 7 elements of an effective compliance program

Compliance Effective Test

- Sample case 1: Member being charged a copay as well as coinsurance:
  - Failed effectiveness test because the case was not reported to the CEO/Board;
  - At HAP, CO generally does not discuss individual cases with CEO or Board, unless it has a broad scope, risk of regulatory action or public relations aspect:
  - Lessons:
    - Difference in judgment between CO and CMS can lead to compliance deficiency.
    - CEO/Board may have to get further down in the weeds that they’re used to.

- Sample case 2: Client Services – Random quality audits:
  - Failed effectiveness test because there was no documentation of training/education provided to representative who failed quality audit:
  - This was done through a face-to-face, 1-1 meeting w/ or notes.
  - Lessons:
    - Compliance needs to be aware of department self‐monitoring activities.
Compliance Program: Midwest

- 3 persons interviewed me (no white light or torture instruments)
- Reviewed all elements of effective compliance program
- Had my hard copy of submitted information to prove met requirements as Reviewers not totally familiar with my submission
- Interviewed CEO and Compliance Manager, but no Board members:
  - Did not conduct a walk-around;
  - Everything took place at HAP offices.

Midwest: What They Didn’t Like

- Hotline rings to my phone:
  - Only me and IT phone person know it (and of course everyone who has these slides!)
- FDR oversight (or lack of):
  - Asked for best practices;
  - Auditors said everyone has problems with it.

Midwest: What They Liked

- Attend every board meeting and give a report.
- Able to show P/P flow from start up to board.
- Frequent communication with CEO (need to document it).
- Employee evaluations include:
  - Compliance with Code of Conduct;
  - Attend HIPAA and F/W/A training;
  - Reporting of F/W/A or compliance issues.
Compliance Matters at Midwest

- Newsletter twice a year;
  - Thought this was a best practice.
- Walk around and hand deliver.
- Contest in each newsletter.
- Disciplinary actions and code of conduct.

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AFTERMATH

Immediate Corrective Action

- Surprise!
  - No indication that this was coming.
- 72 hours to respond:
  - Initial expectation from CMS was that deficiencies would be corrected within those 72 hours;
  - Ultimately accepted plan with extended timeframe.
- Due to timing, no real opportunity to dispute findings:
  - Unlike opportunity to respond to draft audit report.
Validation Audit

• Conducted like initial audit:
  – Same or similar universes, just shorter review period;
  – Webinars (1.5 days).

• Thorough review of all samples:
  – Not just looking at Immediate Corrective Action issues;
  – Multiple impact analyses and other documentation requested, unrelated to ICA.

• Notified of having passed validation on December 6:
  – Issues outside ICA were noted, didn’t impact pass/fail;
  – Additional CAPs not requested for these issues:
    • All had been noted in the initial audit anyway.

Audit Report

• Draft report received 4 months later:
  – Contained findings we hadn’t expected, but some findings we did expect weren’t there.

• Review each finding ("condition") and associated sample cases, to make sure they match:
  – May not impact overall performance, but important for a clear record.

• For findings that we agreed with, revisited preliminary corrective actions to ensure they were still valid:
  – Began creating new CAPs for other findings.

Audit Report

• Multiple sections:
  – Background
  – Objectives, Scope and Methodology
  – Executive Summary of Findings
  – Findings
    • Condition
    • Criteria (fully described in appendix)
    • Cause
    • Effect
    • Corrective Action or Recommendation
  – Observations
  – Best Practices Summary
  – Appendices
    • Summary of corrective actions
      – This is where you’ll find the due date for CAP
    • CEO Attestation
    • Criteria details.
## Questions?

<table>
<thead>
<tr>
<th>Midwest Health Plan</th>
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<tbody>
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