Preparing for, and Surviving

a CMS Program Audit

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Date: February 26, 2013

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
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-Publicized Disciplinary Standards
  - Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks
  - Procedures and Systems for Promptly Responding to Compliance Issues
  - Effectiveness Measure
  - First Tier, Downstream and Related Entities (FDR) – Compliance Program
The Audit Protocols: Scope

- Agent/Broker Oversight:
  - Licensure
  - Appointment
  - 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.

Exception:
Immediate Corrective Actions

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 (2 issues)
    - ODAG (3 issues)
  - Response due in 72 hours
- **August 3: Submitted initial CAPs**
  - Significant debate involving one issue not resolved until September 10
- **September 14: Notified that CAPs were accepted**
- **November 1: Notified of data validation audit for ODAG issues**
  - Provided ODAG 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**

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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.
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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>
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<tbody>
<tr>
<td>Part D Formulary Webinar</td>
<td>Monday 11 – 5</td>
<td>Formulary administration staff; coverage determination staff</td>
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<tr>
<td></td>
<td>Tuesday/Wed/Thursday 9 – 5</td>
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<td></td>
<td>Friday 9 – 1</td>
<td></td>
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<tr>
<td>Part D CDAG Webinar</td>
<td>Monday 12 – 4</td>
<td>Coverage determination staff; Benefits staff; PBM representatives; Grievance &amp; Appeals staff</td>
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<tr>
<td></td>
<td>Tuesday/Wed 2 – 5</td>
<td></td>
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<td></td>
<td>Thursday 12 – 3</td>
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<tr>
<td>CDAG Part C Access Webinar</td>
<td>Monday 11 – 12</td>
<td>Utilization management staff, delegate (vendor) representative, Medical director(s), Claims staff,</td>
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<tr>
<td></td>
<td>Tuesday/Wed 10:30 – 1:30</td>
<td>Grievance &amp; Appeals staff</td>
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<td></td>
<td>Thursday/Friday 10:30 – 4:30</td>
<td></td>
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<tr>
<td>Enrollment/Disenrollment/LEP</td>
<td>Monday 11 – 1</td>
<td>Enrollment and Billing Staff</td>
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<td></td>
<td>Wednesday 10 – 4</td>
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<td></td>
<td>Thursday 10 - 1</td>
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<tr>
<td>Agent Broker Oversight</td>
<td>Monday 11 – 2</td>
<td>Medicare Sales staff</td>
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<td>Tuesday 4:30 – 6</td>
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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?)
  – Return receipt mail (expensive)

• 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 the 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:
    - Focus instead on trends.
  - Lessons:
    - Difference in judgment between CO and CMS can lead to compliance deficiency.
    - CEO/Board may have to get further down in the weeds than 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/ no notes.
  - Lessons:
    - Document, document, document;
    - 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
  - Objective, 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 action
      - This is where you’ll find the due date for CAP
      - Includes information on what CMS will request during validation
    - CEO Attestation
    - Criteria details

Questions?

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