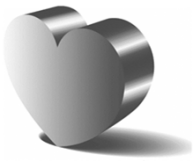


Preparing for, and Surviving

a CMS Program Audit

Presented by:
Deborah L. Marine, JD, CHC, Compliance & Privacy Officer, Health Alliance Plan
Kathleen Harkness, RN, MHSA, CPHQ, Sr. Director of Corporate Quality, Midwest Health Plan

Date: February 26, 2013

Topics

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

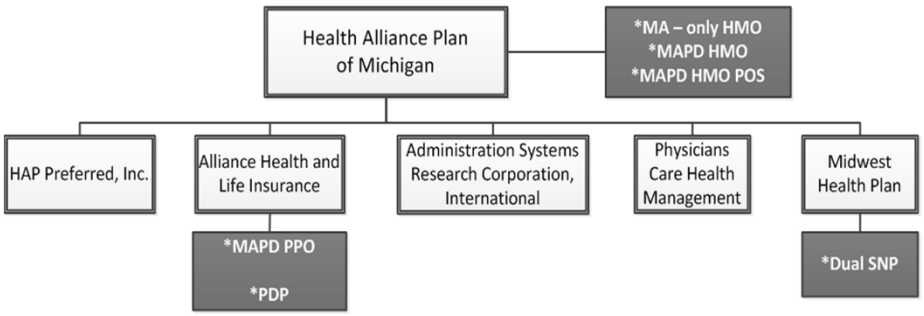
Who We Are: Health Alliance Plan (HAP)

- 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

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**

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

Audit Area	Webinars	Staff Involved
Part D Formulary Webinar	Monday 11 – 5 Tuesday/Wed/Thursday 9 – 5 Friday 9 – 1	Formulary administration staff; coverage determination staff
Part D CDAG Webinar	Monday 12 – 4 Tuesday/Wed 2 – 5 Thursday 12 – 3	Coverage determination staff; Benefits staff; PBM representatives; Grievance & Appeals staff
ODAG Part C Access Webinar	Monday 11 – 12 Tuesday/Wed 10:30 – 1:30 Thursday/Friday 10:30 – 4:30	Utilization management staff, delegate (vendor) representative; Medical director(s); Claims staff; Grievance & Appeals staff
Enrollment/Disenrollment/LEP	Monday 11 – 1 Wednesday 10 – 4 Thursday 10 - 1	Enrollment and Billing Staff
Agent Broker Oversight	Monday 11 – 2 Tuesday 4:30 – 6 Wednesday 9 – 4 Thursday 4:30 – 6	Medicare Sales staff

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.

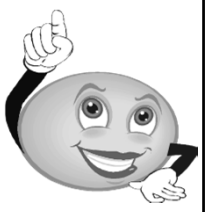
Compliance Program: Midwest

- **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.**

Compliance Matters At Midwest

Volume 3, Issue 3

May 2012

Special points of interest:

- Compliance Week is first week in May 2012
- Sheldon Mandelbaum is Medicaid Compliance Officer
- Kathy Harkness is Medicare and County Programs Compliance Officer
- Policy and Procedures on shared drive
- Department Helpers

Inside this issue:

Compliance Week 1
Compliance Detector Helper 1
Disciplinary Procedures 2
Reporting 2
Code of Conduct 3
Compliance Contest 4

Happy Compliance Week

To celebrate Compliance Week in May, this newsletter is being published to give you updated news, reminders about the Compliance Program at Midwest and the chance to win a $10 gift card! Please read this newsletter and answer the questions at the end of the newsletter. Return the last page to Kathy. If you answered the questions correctly, your name will go into the gift card drawing.

Become a Compliance Detector Helper

How about being your department's compliance detector helper? This job means you will occasional walk through your department during and after work hours to ensure no member's PHI (Personal Health Information) is viewable-easy to see when walking by the cubes, look for potential was to help detect and prevent fraud, waste or abuse and generally be the eyes and ears to help ensure your department complies with our compliance program. If you volunteer, your name will go into the $10 gift cared drawing. Kathy will meet with you to give you examples of what to look for and what to do.

Be on the look out for Fraud and Abuse at work

Compliance Officers

Sheldon Mandelbaum, JD, MBA, is now the Compliance Officer for our Medicaid health plan (Midwest Health Plan). Kathy will continue to assist him in responding to allegations of fraud and abuse, reporting and in the annual training. This change was due to the request from the Michigan Department of Community Health to have a full time Compliance Officer.

Kathy Harkness, RN, MS, CPHQ continues to be the Compliance Officer for our Medicare Product (Midwest Advantage) and the County Programs (MedBasic, Macomb Health Plan, Macomb Care Connect and Basic Care) and Health Choice.

Preparing for, and Surviving, a CMS Program Audit

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?

Midwest Health Plan	Health Alliance Plan
Kathy Harkness, RN, MSHSA, CPHQ	Deborah Marine, JD, CHC
Telephone: (313) 586-6063	Telephone: (313) 664-8711
kharkness@midwesthealthplan.com	dmarine@hap.org