Lessons Learned from a CMS Part D and Part C Appeals & Grievances Audit

What to expect and how to prepare

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Agenda

Ready, set, GO: receiving the CMS audit letter and beyond... (suggested next steps)

Re-wind: what should you be doing now to prepare for that letter (detect and correct)

Back to the present: Lessons learned - preparing for and presenting sample case files to CMS

Always in the background: how can I demonstrate an effective Compliance Program to CMS (tools to use with CMS)
What happens first?

It begins with the Universe

- CMS sends the audit letter and asks for universes of your data
- The vast (or not so vast) universe will be filtered and sifted to get to your sample case files
  - Depending on your plan’s size, this could be lines and lines and lines of transactions and may need to come from multiple data sources
  - Do not forget delegated entities – have a good inventory of who does your relevant transactions
  - This data needs to be collected quickly... CMS gives plans 10 business days from receipt of the letter
What happens first?

A Few Logistics

- Compliance (including internal audit) quickly **looks over audit letter and gathers questions**
- **Cascade to the business** and gather their questions
- **Make an outreach to your CMS audit lead to ask questions** – CMS may be able to quickly clarify questions or explain applicable attachments

**But let’s rewind . . .**
**But let’s rewind . . .**

This is NOT the first time you want to prepare CMS universe files

- Begin to practice pulling CMS universe transaction data NOW
- Practice, practice, practice
- When you get the audit letter it should be “second nature” or close to it

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**Why invest the time?**

**Two reasons:**

- ✓ Work out the kinks (**PREPARE**)
- ✓ Look for areas to improve (**DETECT**)
First: PREPARE

You need to be able to quickly gather universe data and the only way to learn your challenges or questions is to actually “do it”

Remember to include your delegates in this practice; establish relationships and expectations ahead of time

Compliance and the business will learn things through this process — about:

- Your systems
- Data definition questions that need to be ironed out
- Who you need to go to for the actual data
- Whether you need to merge data, how long that takes, and how long it takes for a QA review

This applies to small plans and large plans. Your membership may dictate how often you want to do “sample” universes; larger plans may need to do it more often.

Next: DETECT

Why else do you want to do universes pulls BEFORE the letter arrives? Detect, Detect, Detect

You can and should use this data as CMS would to get in front of potential issues

- CMS takes the universe files and starts to “mine” the data
- CMS is very sophisticated with the data; you should be too
- CMS isolates cases that may be potential problems so you want to do the same before the actual review
What to look for

- Cases that appear late from the dates on the spreadsheet (late ODs, late appeals, etc.); case may not actually be late, but CMS will start there
- Timeliness is one of the easiest areas to target
- Part D: Cases that involve high member impact prescriptions – cancer, behavioral health, diabetic and cardiac, for example
- Part C: Cases that involve high member impact health conditions or other unique cases – cancer, transplant, behavioral health, MRIs, dental, wheelchairs, skilled nursing, home care, to name a few

Other detection tools – analyze the universe for...

- Repeat appeals
- CTMs
- Grievances
- Call center records
- Other data tools to stratify the higher risk cases
Then what?

DATA TRENDS

Look for overall data trends
- Are there cases where you can’t populate the universe spreadsheet (so need to use an N/A) – can this be fixed so you have more data to provide
- Analyze the universe to see how many cases overall are timely, how many involve which conditions (begin to engage requisite delegates)

MONITOR CASES

Start monitoring the cases
- Pick cases and go over them with the business, or have the business provide you with data about the cases
- Use a macro (analyze timeliness of whole universe, or other trends) and micro approach (pull and review cases with the business to detect trends)
- On micro approach, work end-to-end (review a case starting when it comes in the door and walk through it chronologically)
- Consider your results against the CMS guidance – what has most member impact – Immediate Corrective Action Request (ICAR) - versus cases that could be a Corrective Action Request (CAR)
- Work with business to determine root cause
- CORRECT, CORRECT, CORRECT

A few words about the latest CMS scoring methodology

✓ A lot of information out there in

Protocols and CMS Best Practices

Memos for you to incorporate into your monitoring and risk reviews
ICAR

Immediate Corrective Action Required (ICAR)

An ICAR is the result of non-compliance with specific requirements that has the potential to cause significant beneficiary harm in the areas of Part D formulary administration (Formulary); Part D coverage determinations, appeals, and grievances (CDAG); Part C organization determinations, appeals, grievances, and dismissals (ODAG).

Significant beneficiary harm exists if the non-compliance resulted in the plan’s failure to provide medical services or prescription drugs, causing financial distress, or posing a threat to beneficiary health and safety due to non-existent or inadequate policies and procedures, systems, internal controls, operations or staffing. Below are examples of conditions resulting in an ICAR:

<table>
<thead>
<tr>
<th>Part D Coverage Determinations (CD), Appeals &amp; Grievances</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Misclassifying CDs or appeals as grievances or failure to effectuate overturns or approvals</td>
</tr>
<tr>
<td>▪ Failure to provide appropriate appeal rights</td>
</tr>
<tr>
<td>▪ Failure to auto-forward cases to the Independent Review Entity (IRE) as required</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Part C Organization Determinations (OD), Appeals, and Grievances and Part C Access to Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Failure to follow National Coverage Determinations (NCDs) / Local Coverage Determinations (LCDs) or other CMS coverage policy when making coverage decisions on any medical or other health service that is covered by Medicare</td>
</tr>
<tr>
<td>▪ Misclassifying ODs or appeals as grievances or failure to effectuate overturns or approvals</td>
</tr>
<tr>
<td>▪ Failure to provide appropriate appeal rights</td>
</tr>
<tr>
<td>▪ Failure to auto-forward adverse reconsideration cases (including cases that are not adjudicated within the required timeframe) to the IRE as required</td>
</tr>
</tbody>
</table>

ICAR (continued)

Further clarification provided by CMS during 2013 Fall Conference

▪ Material significant non-compliance issues
▪ Cause beneficiary harm could be access or financial (systematic issues)
▪ Example: formulary errors, on HPMS formulary doesn’t require prior authorization and sponsor imposing prior authorization
▪ CMS will notify plans during an audit of any potential ICARS identified
▪ The plan will need to provide root cause analysis to CMS
  ▪ CMS will then review and make determination on whether an ICAR will be issued
▪ Once an ICAR is formally issued, the sponsor will have three business days to:
  ▪ Explain how the potential or real beneficiary harm has been stopped
  ▪ Explain how and why when the sponsor will implement a long term, sustainable fix; and
  ▪ Provide reasonable assurance that the problem will not recur
▪ Once a sponsor has submitted its ICAR Corrective Action Plan (CAP) to CMS, CMS will:
  ▪ Reject the CAP, giving the sponsor one business day to resubmit;
  ▪ Recommend revisions; or
  ▪ Accept the response and schedule a validation.
▪ Validation is scheduled based on the date the sponsor states the issue will be remediated in the CAP
▪ Validation universes will use the same template as the initial audit, and case selection will be focused based on the condition
▪ Issues identified during validation activities will be assessed to determine whether they are "one-off" and related to the same root cause of the initial condition for the purposes of validating whether the condition has been remediated.
▪ All corrective actions on conditions related to formulary administration will be on an accelerated timeline, even if the issue is not officially deemed to be an ICAR for scoring purposes. In other words, while the correction action may not be classified as "immediate" and may not be held to a three-day response like an ICAR, CMS will expect correction activities to be expedited.

Supplemented with CMS information presented at 2013 Fall Conference.
CAR

Corrective Action Required (CAR)

A CAR is the result of a material non-compliance with specific requirements that does not have the potential to cause significant beneficiary harm. A material non-compliance is usually due to non-existent or inadequate policies and procedures, systems, internal controls, operations or staffing. Below are examples of conditions resulting in a CAR:

- Sponsor inappropriately rejected claims for drugs that were required to be dispensed in certain package sizes based on the prescribed dose
- Failure to make a determination and notify the beneficiary within 72 hours after receiving an expedited organization determination request
- Failure to establish and implement an effective system for monitoring and auditing its FDRs’ compliance with CMS requirements
- Failure to produce evidence that at least three OEV calls were made and/or that a follow-up enrollment verification letter was sent to the beneficiary

Further clarification provided by CMS during 2013 Fall Conference

- Material non-compliance (systematic issue)
- Example: many notices sent to beneficiaries are late, team members perhaps not sure how to determine timelines or unsure of time frames

Observations

Observations are either immaterial events of non-compliance with specific requirements or other items that may be useful to management in preventing contract non-compliance in the future. Below are examples of items resulting in an observation:

- Failure to include correct criteria in a coverage determination denial letter due to an isolated human error
- Failure to effectuate a coverage determination in a timely manner as a result of a human error when entering the prescription drug into the system
- Failure to appropriately determine coverage under Part B vs. Part D. The error appeared to be an isolated oversight not indicative of a lack of understanding of CMS requirements or a lack of internal controls
- Failure to conduct an Outbound Enrollment Verification call or send an enrollment verification letter as a result of a non-systemic human error miscoding a new beneficiary enrollment as a like plan to plan change

Further clarification provided by CMS during 2013 Fall Conference

- Immaterial non-compliance issue
- Example: one-off issue such as expedited request from beneficiary or provider received via fax, team member responsible had to leave early and timeliness missed (didn’t pull fax)
Methodology

The following items are considered when scoring an audit:

- Number of conditions identified
- Remediation required for each condition
- Number of audit elements tested

The audit score is calculated by assigning:

- 0 points for each Observation,
- 1 point for each Corrective Action Required (CAR),
- 2 points for each Immediate Corrective Action Required (ICAR), and
- dividing the sum of these points by the number of audit elements tested

A lower score is better than a higher score. The following is the formula for calculating the audit score:

\[
\frac{\# \text{ CARs} + (\# \text{ ICARs} \times 2)}{\# \text{ of audited elements tested}}
\]


LESSON

The universe templates are a useful tool – start using them now

- No matter your size, you will improve your readiness and get ahead of issues
- Demonstrates an effective compliance program – can incorporate issues into your risk assessments, potential disclosures, correction issue log, and more
Fast forward . . . back to present

Your plan has (easily) submitted the universe:  

- Data mine, as you have hopefully been doing!
- Start to work with the business
- Depending on your size, you may be able to research and summarize all your cases (find the important documents, assemble summaries)
- Various business sections or teams (clinical versus appeals) may be able to research all their cases: do as much as you can
Preparation?

After you have filtered, select some cases and conduct “walk throughs”. Time consuming? So why do it given CMS will likely look at other cases?

**WHY**

- Helps identify key participants (those that will have most knowledge and can answer CMS questions efficiently)
- Use a WebEx system to practice “hand-offs” between business owners
- Practice working with the delegates or your account managers (determine who is on point for questions on these cases)
- Go end to end... Start with the “transaction coming in the door” and go all the way to the end – that’s what the auditors will do
- Have supporting teams available (call center; claims); they can add context and may be able to answer CMS questions

Now, it’s show time . . .
Sample List

Now you have the sample list – CMS has not indicated when this will be provided so plan for fact you could get the day of the review

- Have staff assigned to help research
- Is the provided order the most efficient in terms of your logistics?
- CMS has been flexible on re-ordering the cases so that common teams or groups can present together
- Clinical versus appeals, certain delegates, etc.
- This minimizes disruption and allows for more quick presentation of cases versus lots of hand-offs
- Start discussing this with CMS early

During Your CMS Conference Call

Depending on your size, consider having teams in same physical location

- Minimizes disruption and handoffs (even though CMS likely not on site) — less downtime on the conference call

Who from your plan should be there or at least readily available...

- Call Center (even for appeals and ODs) — CMS may ask if there were calls and the call center may have call notes that can help give a complete picture
- Claims (CMS frequently asks questions on what happened with a claim)
- All teams involved with a transactions, the whole picture, the OD, the appeal, etc.
  - CMS may pull a case as an “appeal” but they very well may ask about the OD and what happened at the IRE
  - CMS may pull a case as an OD, but then ask if it was appealed, and what happened, etc.
  - Particularly on the initial audit, CMS looks up and downstream to get a sense of the case and the more you can answer during the review the better for both sides
Post Audit Session

*CMS will want screen shots of everything you have reviewed with a case*

- Have someone specifically assigned to take notes on this and be capturing what is shown to CMS so this can be easily uploaded
- If additional information is discovered, ask to re-review a file and provide it
- If there are regulatory questions during a review – suggest taking it offline to save time and submitting your position to CMS in writing

Prepare for the next stage (CMS feedback)

*It’s obvious, but . . .*

- Compliance and audit should take detailed notes during the case file reviews and analyze the cases themselves
- This will be useful when you have verbal or written feedback from CMS; you can turn to these summaries and not need to re-learn everything from the review
- Don’t assume someone is doing this – be deliberate on who is doing it and then review summaries together after the review to stay aligned (this saves time for later)
Considerations for Validations

Scope, Scope, Scope

Different auditors may handle a validation than the original audit

- Stay very focused on scope of a validation – CMS may ask a number of questions to understand a transaction, but be prepared to discuss scope and keep validation tied to specific findings

Always in the background . . .
Why Prep?

**Beneficial lens** into your own organization
**Connect** with organizational peers you may not have otherwise met
Helps your business partners see you as their **advocate/trusted ally**
Strengthen relationships by **partnering** in intense project work
Jump start on **developing future audit plans** (maybe out-of-scope vulnerabilities found while pouring over universe)

**Credibility** built with CMS contact
Aids in future audit/validation activities—won’t wander down roads that will not provide value
**Guidance with scope:** you have history that can save legwork
Build **personal trust/empathy** for the future
*Don’t forget to find ways to have fun!*

Always in the background

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**How do you demonstrate an effective compliance program to CMS and stay audit ready?**

Audits come as part of a CMS Compliance Program Effectiveness Review

> How can you build in the preparation above and beyond detection tools to your program to demonstrate effectiveness
Evaluating Your Program

Measurement Framework:
Structure x Process x Outcome = Effectiveness

- **Structure** measures refer to the *capacity* of a health care organization to ensure compliance
- **Process** measures refer to the *manner* in which an organization actually provides compliance coverage
- **Outcome** measures refer to *observable, measurable* compliance outcomes

Compliance Scorecard

- 15 individual measures across the categories of structure, process, and outcome with a total available point value of 100
- All compliance program areas implement and manage a scorecard
- The same 15 measures are applied to each program while allowing some flexibility in how the program responds to or meets the common measure objectives
- Measures and objectives are defined within a companion document titled the 'Explanation of Terms'
- Progress and results are assessed and reported on a quarterly basis
Oversight Structure

- Program Oversight
  - Accountability & Oversight
  - Engaged & Effective Governance
- Standards, Policies & Procedures
  - Focusing on compliance 'best practice' reviews
- Reporting Mechanisms
  - Investigations, Compliance Issue Tracking, & Compliance Exit Interviews
- Education & Training
  - Includes both organization mandated courses and program specific training activity
- Communication and Awareness Strategy
  - Program specific communication plan
Explanation of Terms

S1 – Program Oversight: (5 points)

- A core element of an effective compliance program is to demonstrate support and engagement of business leadership and the governing body (i.e. Sr. Management, Board of Directors, Oversight Committees*, etc). Effective program oversight may be accomplished through the identification of a compliance officer and creation of a structure or committee to oversee the effective administration of the compliance program within the business unit. Points will be assessed as follows:
  - 2 points = Accountability and Oversight:
    - Identification of compliance officer within program area who is accountable to senior management and the identification of accountable business leader(s) who collaborates with and supports the compliance officer in management of the compliance program.
    - As applicable, identification of compliance officers will be at an individual business unit level, which may include individual plan, program or delegated entity relationship.
    - Establishment of an oversight committee with membership comprised of key management staff with relevant functional responsibilities within the program area or plan. The compliance officer, accountable business leader(s), and oversight committee members will utilize common tools to align program efforts with the expectations of key regulators.

3 points = Engaged and Effective Governance: Program area activities that demonstrate an engaged and effective oversight structure include but are not limited to:

- Demonstrate (through charter /agenda /minutes) that the oversight structure is in place.
- Demonstrate periodic education of oversight committee membership on compliance program, member’s roles/responsibilities within the oversight structure, and emerging risk areas.
- Demonstrate committee membership participation and engagement through regular attendance at oversight committee meetings.
- Demonstrate quarterly compliance activity reporting to senior management including but not limited to self-disclosures made to regulators/government agencies, annual audit plan, scorecard progress, compliance issues of concern, and any disciplinary actions taken as a result of compliance violations.
- Demonstrate oversight of delegated relationships within committee structure including but not limited to documented periodic review of compliance performance, identified issues and response to applicable identified issues.
- Demonstrate oversight and periodic review of program anti-fraud, waste, and abuse activities and efforts relating to providers, members, and employees.
Measurement Framework

Process

- Assessment, Identification, and Prioritization of Compliance Risks
  - Ongoing process to assess identified risks
- Key Compliance Indicators (KCIs) – Prevention, Detection, & Monitoring
  - Processes to demonstrate ongoing monitoring and assessment of identified KCIs
- KCIs – Response & Correction
  - Processes to demonstrate review and response to monitoring results.
- External Regulatory Requirement & Internal Policy Implementation
  - Processes to review and implement as applicable
- Corrective Action Plans, Enforcement & Disciplinary Guidelines
  - Effective CAP management processes and engagement of program in supporting consistent enforcement / disciplinary guidelines
  - Program specific communication plan

Evaluating Your Program

OUTCOMES

- Compliance Audit Results
  - All external and internal audit results are assessed
- Regulatory Compliance Results (notices, fines, etc.)
  - Includes notices received from CMS and state regulators
- Privacy & Security Disclosures
  - Assessed by quantity and severity
- Delegated Entity Compliance
  - Appropriate oversight structure, vendor performance, and identified compliance concerns
- Vital Signs Survey – Ethical Compliance Dimension
  - Activities to impact organizational culture and annual survey results
### Always in the background . . .

**How do you demonstrate an effective compliance program to CMS and stay audit ready?**

<table>
<thead>
<tr>
<th>Reporting the Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Executive Team</td>
</tr>
<tr>
<td>- Board of Directors</td>
</tr>
<tr>
<td>- Regulators</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Board Accountability</th>
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<tbody>
<tr>
<td>Ensure that the organization’s governing authority is knowledgeable about the content and operation of the program</td>
</tr>
<tr>
<td>AND</td>
</tr>
<tr>
<td>Exercises reasonable oversight with respect to the program’s effectiveness</td>
</tr>
</tbody>
</table>
Always in the background . . .

- Beneficiaries, Beneficiaries, Beneficiaries!
- These audits are intended to safeguard the interests of beneficiaries
- Preserve the value of taxpayer expenditures

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What to Expect and how to Prepare

Questions?

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THANK YOU!

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