Optum Rx®

Knowledge Chronicles: Government Programs Edition

CMS Program Audit Perspectives

Team Introductions

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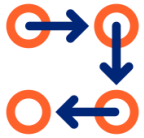
CMS Program Audit: Highlights & Key Themes

2023 Highlights

Formulary Administration (FA)

- Part B versus Part D benefit coordination
- Authorization management and impact of rogue or errant authorizations to claim adjudication
- Medically Accepted Indication Drugs

Coverage Determination and Exceptions (CDE)



- Application of authorizations across different dosage formulations of the same drug
- Comprehensiveness of denial language and associated clarity
- Notification Timeliness

2024 Watch List

- Coverage determination timeliness and processing accuracy
- Transitional benefits and claims rejecting or paying appropriately during this window
- IRA claim rejections
- Authorization management
- Part B versus Part D care coordination

Any common themes identified will be communicated to the correct audience.

Expert CMS audit support

Dedicated CMS Audit Team

Centralized Audit Management

16 Successful CMS Program Audits in 5 Years

No ICARs on ORx Delegated Services

Incorporated New 2022 Protocols

Audit Preparation

Audit notification

Client onboarding

SME engagement

Mock audit and universe walk throughs

Audit prep sessions to review CMS process

Universe Extraction & QA

Manage audit universe activity

Deliver CMS required data elements

Oversee QA by functional SMEs

Identify outliers for analysis

Live Audit Support

Audit oversight and real-time guidance

Coordination of CMS requests, deliverables

Daily updates to stakeholders

Conducts debriefs

Capture audit intelligence

Supported large regional Medicare plan in 2022 CMS program audit with favorable outcomes

I want to thank you and your team for an exceptional job! (We) reported yesterday the PBM did a stellar job, and I couldn't agree more!

…. All the hard work of practice sessions and touch point meetings led to very successful presentations to CMS. The Optum team was very well prepared! What a great job by all resulting in great audit results!

Please thank all the drivers/presenters, support teams in the rooms, as well as everyone who supported behind the scenes. Awesome work by everyone! THANK YOU ALL !

–Director, Process Governance Regional Health Plan

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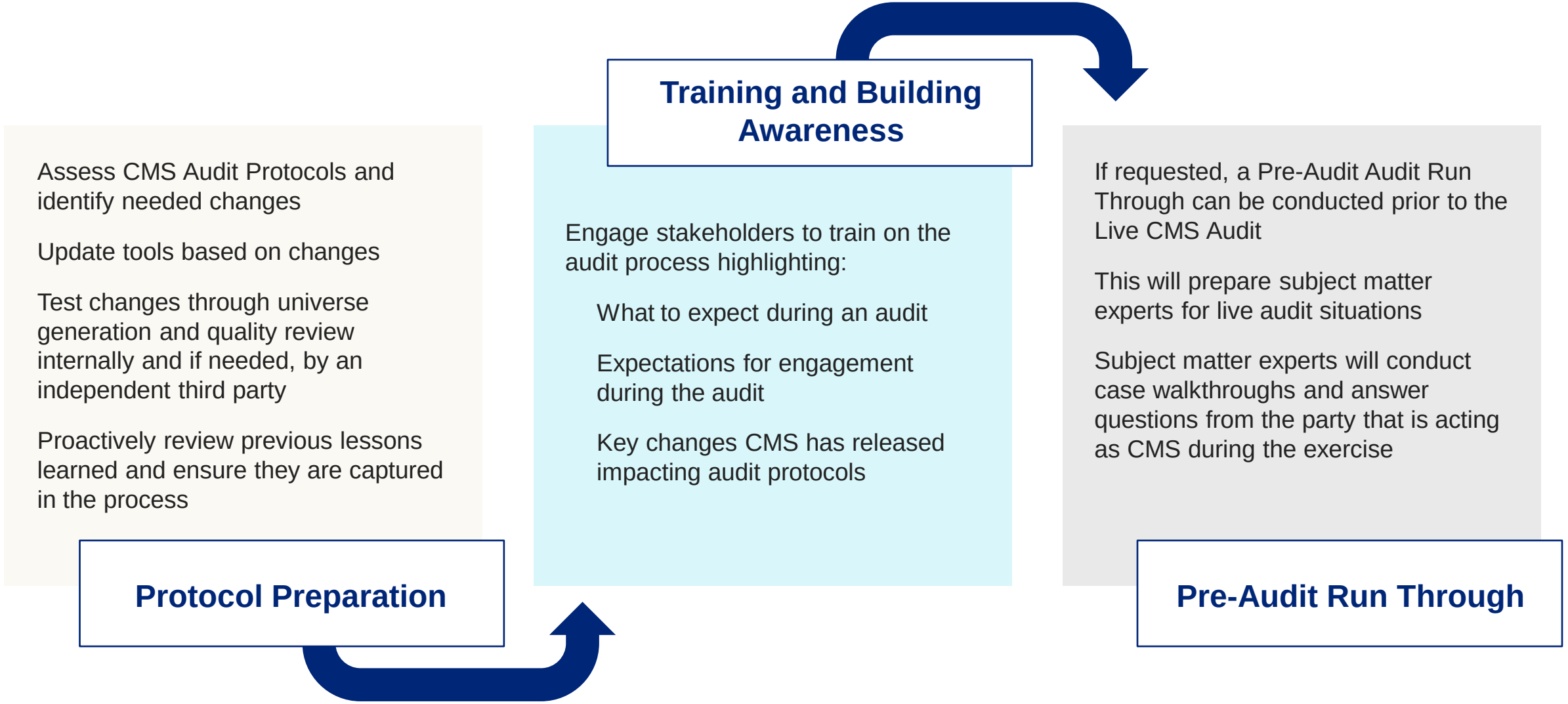
Pre-Audit Engagement



Best Practices

Case Presentation – Common Issues

Speakers

Suggesting screens to CMS

Trying to research an issue while speaking

Responding on behalf of other departments

Allowing CMS to expedite review cadence

Drivers

Inconsistency in the methods used to display content

Driving “ahead” of CMS

Incorrect screens displayed

Unfamiliarity with systems

Researchers

Not escalating issues

Missing data discrepancies between system and universe sample

Case Presentation – Best Practices

Speakers

Wait for CMS

Have other teams research and take notes

Use MUTE button

Drivers

Have laptop ready with all necessary hardware (power cord, mouse, etc.)

“Hands off” when not navigating screens

Validate that all passwords work prior to audit sessions

Turn off email and instant messaging

Researchers

Have reference material readily available

Keep room leadership in the loop

Escalate, and know who to escalate to

CMS Responses: Don’ts

Audit Speaking Don’ts:

Mumbling

Use of jargon

Filler words (Um, Oh, Sure, Uh)

Answering what you do not know (I do not know, I do not recall)

More than one person speaking

Speaking without introduction

Guessing when responding to a question

Speaking quietly or unconfidently (It looks like, I think so)

Answering questions not asked

General Audit Response Don’ts:

Awkward silences

Providing information that is not requested

Over-complicated explanations

Assignment of culpability

Uneven or uncoordinated messaging

Over-communication

Concealing or giving misinformation

Chewing gum or candy while speaking

CMS Responses: Best Practices

Audit Speaking Do's:

Ask for clarification if a question is unclear

Take time in answering questions

Answer questions factually and to the point

If appropriate, let CMS know that you will help find the answer

Use MUTE: CMS can hear everything

Help keep the interview conversational-stay calm and respectful

Use simple, jargon-free language

Offer to respond in writing if a verbal explanation would be too complicated

General Audit Response Do's:

Give CMS your undivided attention

Ensure all PHI is appropriately handled

Work with researchers and other leadership to craft responses

Use MUTE while researching

Answer only the question that was asked

Become comfortable with CMS' pauses and silences

Know what chapter out of the Manuals your work refers to

2022 Part C And Part D Program Audit Insights

Compliance Program Effectiveness (CPE)

Compliance issues were not quickly addressed and corrected.

- Optum Rx Compliance maintains a Compliance Intake Site where Account Management and Business Operations can report potential issues of non-compliance.
- Every issue is thoroughly reviewed to identify root cause, impact and remediation activity.
- Corrective Action Plans and Business Improvement Plans are issued as appropriate.
- All issues are acknowledged, responded to and validated prior to closing.
- Processes are documented via procedure documents and flow charts.
- Weekly issue reporting is completed to maintain oversight of all issues, review aging items and trend data.
- Training on the Compliance Intake Site is provided to applicable Optum Rx employees to ensure visibility and answer questions.
- Corrective Action Plan (CAP) training is conducted with Account Management and internal teams.

Systems for monitoring, auditing, and identifying compliance risks weren't comprehensive or current.

- The Optum Rx Compliance Program is committed to implementing comprehensive monitoring and auditing activities related to its operational activities.
- Audit activities are focused on business processes that could result in erroneous, wasteful, abusive, or non-compliant claims or decisions.
- OptumRx implements an annual risk assessment process that examines potential compliance risks and addresses them via the execution of compliance work plans as well as an Anti-Fraud program.
- Various monitoring reports are reviewed on a regular basis and there is continuous monitoring of business activities and delegated functions.
- Compliance audits, assessments, and investigations are initiated throughout the year in response to identified non-compliance and may result in corrective action plans.
- The effectiveness of the Compliance Program is reviewed on at least an annual basis.

Formulary Administration (FA)

Sponsors applied utilization management (UM) edits that were not part of their CMS approved formulary.

Sponsors forgot to review prior authorization approval edits for existing enrollees in their adjudication system when they were setting up their new formulary for the upcoming plan year. When these edits were carried over into the new plan year, the edits were more restrictive than the updated formulary.

Mitigations

RxClaim PA functionality compares quantity limit values from the authorization and the formulary to prevent claims from rejecting for quantity limits that are more restrictive than the filed formulary.

Risks

N/A for Optum clients

Coding edits in a sponsor's adjudication system did not allow for an extended day supply up to the Food and Drug Administration (FDA) approved duration for certain drugs.

Mitigations

RxClaim unbreakable functionality allows for extended day supply for all medications based on various factors such as route of administration and package sizes.

Risks

N/A for Optum clients

Approved prior authorization requests were inappropriately effectuated in Sponsors' systems.

Authorizations were not configured to effectuate at the same Generic Product Identifier (GPI) level for drugs where the clinical criteria are the same across dosage forms.

Mitigations

Optum Rx standard will be to effectuate coverage determinations for PA and ST at a GPI 10 level to include all dosage forms. QL coverage determinations will remain at a GPI 14 level. This will alleviate any concerns from a new formulation release or GPI reclassification.

Risks

Will be addressed with action defined above.

Overrides of opioid naïve edits were not applied to all opioids on the formulary

Mitigations

All authorizations to override opioid naïve are completed via a list which contains all opioids. This list is regularly updated when new opioids come to market.

Risks

N/A for Optum clients

Enrollees were denied their full transition benefit under Medicare Part D.

Incorrect transition timeframes that were coded into systems shortened the transition period for continuing enrollees to receive medications that were removed from the formulary.

Mitigations

Transition is applicable at the plan level for changes across contract year as defined by the client, but it applied to all members in the plan.

Risks

N/A for Optum clients

Data entry errors caused systems to apply incorrect transition of care start dates.

Mitigations

RxClaim does not use a transition start date. Instead, transition is automated based on the client provided daily eligibility file. The member's CMS Contract ID and PBP data drives transition. RxClaim identifies if the member is a new start, has a break in coverage, or a change in Contract/PBP or is a current enrollee who qualifies for a negative formulary change across contract year transition fill.

Risks

N/A for Optum clients

Medically-Accepted Indication (MAI) edits were inappropriately applied to transition eligible medications for continuing enrollees when MAI information was provided with related coverage determination requests.

Mitigations

Optum Rx has created MAI transition benefit functionality, where a MAI product override record can be loaded onto the member to trigger a transition fill. For 2024, Optum Rx has identified all products with a negative formulary change across contract years. Next, we will identify all members who have a Part D authorization on file that is effective in 2024. Member MAI Product Overrides will then be loaded so that continuing enrollees will receive a transition fill as applicable. Additional process details will be shared in a separate communication.

Risks

Will be addressed with action defined above.

Hard-coding transition effective dates prevented sponsors from updating enrollee transition effective dates when necessary.

Mitigations

Optum Rx does not hard code members dates of eligibility. Dates are taken directly from member eligibility files loaded daily into the adjudication system. For transition, the member's Contract and PBP dates are evaluated to ensure a delineation between a new and continuing member.

Risks

N/A for Optum clients

Coverage Determinations, Appeals, and Grievances (CDAG)

Sponsors did not meet the timeframes for making redetermination decisions

Staff were not properly trained on the process for taking extensions or the appropriate method and/or timeframe for communicating decisions when an extension was taken.

Mitigations

Optum Rx has procedures in place that outline the process for extending a redetermination request. If a request for redetermination is made outside of 60 calendar days of the notice of initial coverage determination, the requestor must submit documentation to support a good cause extension. There are several scenarios where a good cause extension may be approved. If a benefit redetermination request is received after 60 calendar days and good cause supporting documentation is not received the case will be dismissed and all parties involved will received a dismissal notification informing them the request is out of the 60 calendar day time limit and the good cause for late filing was not provided.

Risks

N/A for Optum clients

Staff did not follow established procedures for providing notification once a decision was made.

Mitigations

Optum Rx has procedures in place that outline the notification process for both approvals and denials of initial determinations and redeterminations. These notifications are both written and oral and are made within CMS mandated timelines.

Risks

N/A for Optum clients

Approved exception requests were not effectuated through the end of the plan year

Quality control processes did not sufficiently identify and resolve manual errors.

Mitigations

Optum Rx approves exception requests through the end of the plan year. Optum Rx also has significant adherence and monitoring in place to ensure quality control. Optum Rx conducts both retrospective and live monitoring of initial coverage determination and redeterminations to validate numerous aspects of case quality.

Risks

N/A for Optum clients