CMS Audit Success:

Prescriber Oversight and Documentation Strategies

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Agenda

➤ Overview of CMS Audits and Prescriber impact

➤ 2020 CMS audit changes

➤ Recent changes in Medicare Guidance (Chapter 13/18): Prescriber impact for documentation and oversight

➤ Plans and Prescriber interactions for enhanced compliance

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Overview of CMS Audits

Program Audit Areas

MAPD (Medicare Advantage Prescription Drug Program)

> Formulary Administration (FA)

> Part D Coverage Determinations, Appeals and Grievances (CDAG)

> Part C Organization Determinations, Appeals and Grievances (ODAG)

> Special Needs Plan Model of Care (SNP-MOC)

> Compliance Program Effectiveness (CPE)

MMP (Medicare-Medicaid Plan) 2 specific areas reviewed separately- others included in the other program audit areas

> Service Authorization Requests, Appeals and Grievances (SARAG)

> Care Coordination and Quality Improvement Program Effectiveness (CCQIPE)

Source: 2018 CMS Audit Protocols released December 2017

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CMS Audit Selection Process

> Plans are chosen annually on a cycle

> Risk assessment by (MOEG) include:
> > Stars ratings data
> > Past performance data
> > Plan reported data
> > Operational changes
> > Other factors, such as referrals, size, never audited
> > Does not matter if you were audited last cycle!

> Audit referrals from Regional or Central Office

> Sponsors that had not been previously audited

> Audit team made up of CMS' subject matter experts or "SMEs" as well as CMS contractors

> 2019 CMS audited many of the large plans like they do the first year of a cycle

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What Happened in this Audit Cycle?

> 2018 was the fourth year of the current audit cycle

> CMS has audited 95% of all Medicare beneficiaries as part of this audit cycle.

> Number of audits going up (30 vs 39)

> CMS has made guidance and expectations clear based on CMS program audit findings

> PBMs are implementing systemic changes following any audit findings to prevent further exposure

> Sanctions given for PACE plans, financial issues and MLRs

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Audits in 2018

> Two percent of all Medicare beneficiaries were audited in 2018 and focused on smaller Plans

> Overall audit scores are going down
>> In 2018 decreased to 1.03 (down from 1.10 in 2017)
>> Audit scores in FA and ODAG went down in 2018
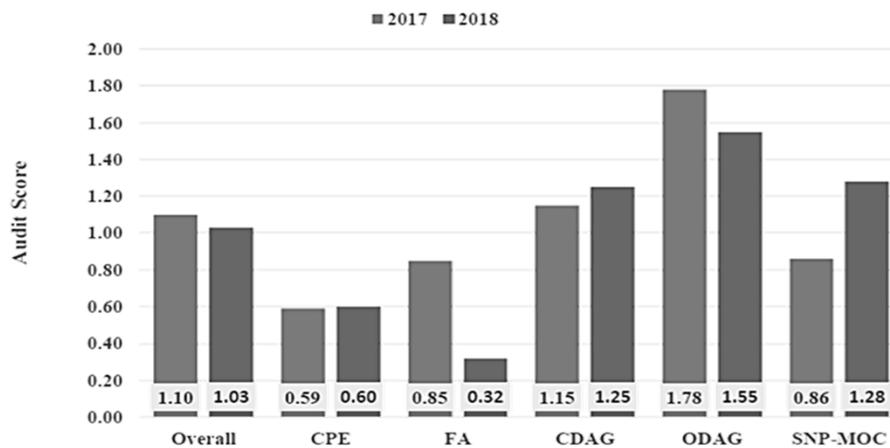>> The average FA score was down 62% in 2018
>> CDAG and SNP scores went up

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2017 vs. 2018 Average Audit Scores

* Audit scores are analyzed at the sponsor (parent organization) level. The average audit score is an unweighted score across all audited sponsors within each group. A lower audit score represents better audit performance. MMP audit results are excluded from this chart as the MMP audits were pilots in 2017 and no scores were included in final audit reports.
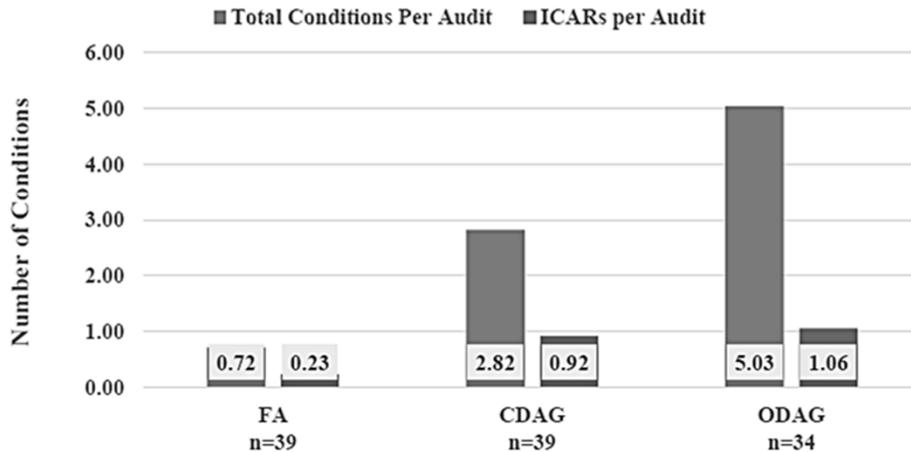
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Average Number of Conditions and ICARs per 2018 Audit

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2018 Enforcement Actions

➤ Enforcement actions decreasing
  - ➤ Of the 39 Sponsors audited in 2018, five (13%) received an enforcement action
  - ➤ Overall CMPs decreased significantly in 2018
    - ➤ CMS imposed 10 CMPs totaling $396,736
    - ➤ Eighteen CMPs were imposed in 2017 totaling $2,599,800

➤ One intermediate sanction was imposed due to non-compliance identified in 2018

➤ Other types of Enforcement Referrals
  - ➤ PACE non-compliance (21%)
  - ➤ Non-compliance with 1/3 Financial Audit (18%)
  - ➤ Validation Audits (7%)

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2018 Audit Lifecycle

> 2018 showed a decrease in time from 2016 in the overall Lifecyle of Program Audits
>> Average time from Exit Conference to ICAR email was 23 days (-4 days)
>> Average time from Exit Conference to Draft Audit Report was 58 days (-43 days)
>> Average time from Exit Conference to Final Audit Report was 80 days (-49 days)
>> Average time between Final Audit Report and Audit Closeout is still be calculated however this has decreased based on the following:
>>> Better internal documentation at CMS
>>> Specific and stronger training of auditors
>>> Greater transparency regarding audit protocols and guidance

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What does it all mean?

> More plans are getting audited year after year

> CMP frequency is on the rise, but the amounts have decreased

> The 'bar has been raised' and more plans have invested resources to mitigate audit risk (Mock Audits)

> CMS has made guidance and expectations clear based on CMS program audit findings

> Plan Benefit Managers (PBMs) are implementing systemic changes following any audit findings to prevent further exposure

> No significant changes to protocols for 2019 and 2020

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2020 Program Area Details and Changes

What is new in 2020?

What do the universes look like?

What are some of the common conditions?

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2020 Audit Protocols

> CMS released an HPMS memo on August 20, 2019 providing an overview of the upcoming changes to program audits through 2021.

> These changes are out for a 60-day comment period with comments being requested by October 15, 2019. These changes will supersede the proposed changes shared on April 2, 2018.

> CMS will continue to use the same audit protocols and record layouts for universes in 2020/2021 that were used in 2017,2018 and 2019.

> CMS is "reducing the volume" of information that must be submitted in audit year 2020/21.

> CPE-CMS clarified that if the audit review period crosses calendar years that requested documents (i.e. risk assessments) would need to be provided for both years within the audit period.

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2020 Audit Protocols

> **Formulary Administration (FA):**
> > Removed references to DMRs as they are not part of the FA process.
> > In the Transition section the number of samples has been increased from 15 to 30 samples.
> > The Website review has also been removed.

> **Coverage Determinations, Appeals and Grievances (CDAG):**
> > Removed references to Tables 9,10 and 16.
> > Updated Table 7 to clarify the compliance standard is no later than 14 days, instead of 7.
> > Timeliness samples reduced from 75 to 65 due to removal of Tables 9 and 10.
> > Samples for Grievances were increased from 10 to 20 due to the removal of Call Logs.
> > Exclusion Language was added to Tables 1-8, 14 and 15 to state "Exclude requests that require an AOR (or other conforming instrument) but the AOR has not been receive as of the date of the universe submission".

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2020 Audit Protocols

> **Organization Determinations, Appeals and Grievances (ODAG):**
> > Removed Table 14 Call Logs
> > Updated Table 3 to show the compliance standard as 95% in 30 days for clean claims and 60 days for unclean all other claims from non-contracted providers.
> > Timeliness section was updated to remove dismissals and changes samples from 65 to 60.
> > In Clinical Decision Making (CDM) the approved organization determination cases were removed updating the samples in this section from 40 to 35.
> > In the Grievance section samples were updated from 10 to 20 due to the removal of Call Logs.
> > For Tables 1,2,4,5,6 and 11, added the following exclusion language "Exclude requests that require an AOR (or other conforming instrument) but the AOR has not been received as of the date of the universe submission
> > For Tables 3,7,8,9 and 10, added the following exclusion language "Exclude requests for extensions of previously approved services, concurrent review for inpatient hospital and SNF services, post-service reviews, and notifications of admissions".
> > Table 12 added the following exclusion language "Exclude requests that require an AOR (or other conforming instrument) but the AOR has not been received as of the date of the universe submission"

> **Special Needs Plan Model of Care (SNP-MOC):**
> > Removed the audit element for enrollment verification
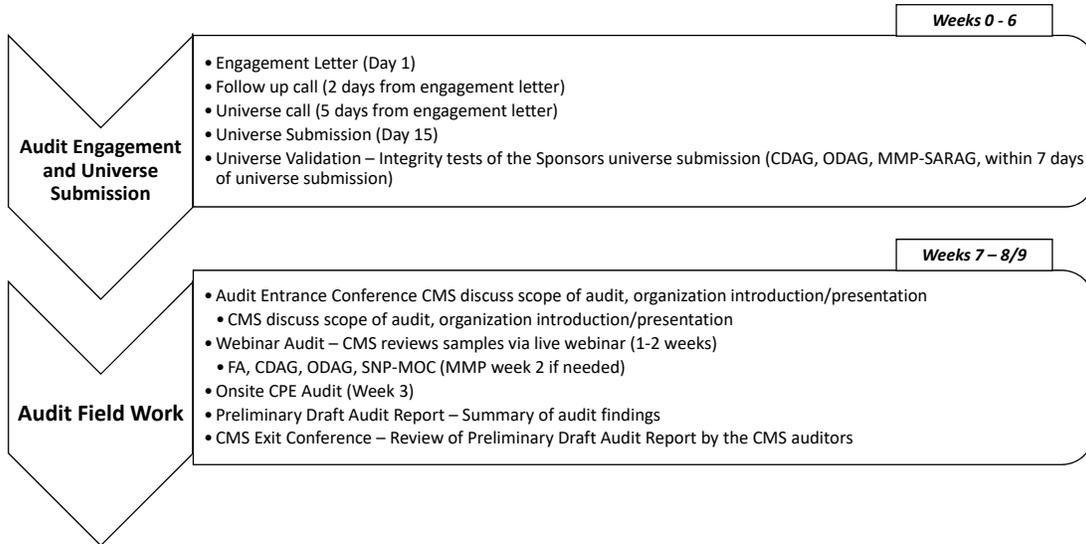> > In the Care Coordination section, the compliance standards have been simplified
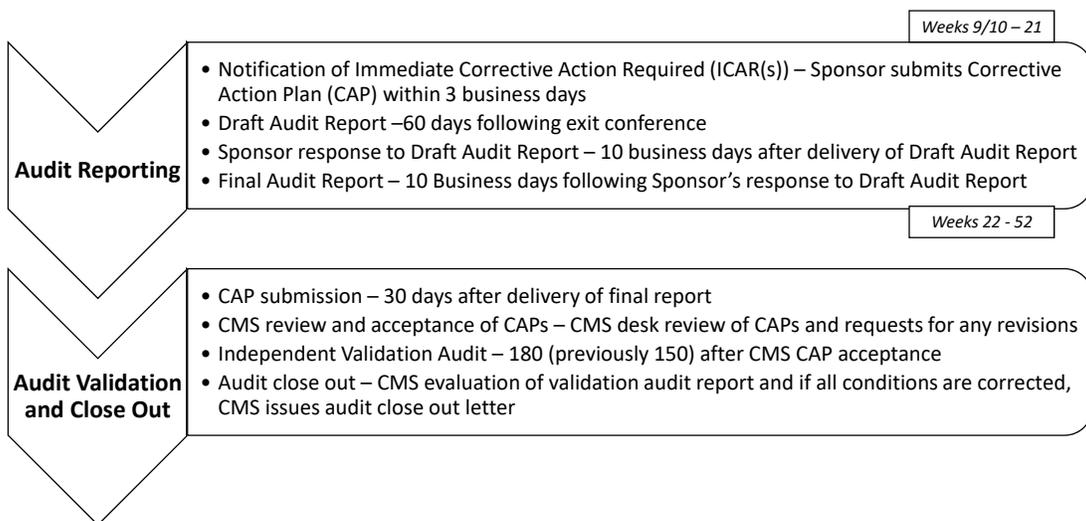
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Audit Timelines

Audit Engagement and Universe Submission

- Engagement Letter (Day 1)
- Follow up call (2 days from engagement letter)
- Universe call (5 days from engagement letter)
- Universe Submission (Day 15)
- Universe Validation – Integrity tests of the Sponsors universe submission (CDAG, ODAG, MMP-SARAG, within 7 days of universe submission)

Weeks 7 – 8/9

Audit Field Work

- Audit Entrance Conference CMS discuss scope of audit, organization introduction/presentation
  - CMS discuss scope of audit, organization introduction/presentation
- Webinar Audit – CMS reviews samples via live webinar (1-2 weeks)
  - FA, CDAG, ODAG, SNP-MOC (MMP week 2 if needed)
- Onsite CPE Audit (Week 3)
- Preliminary Draft Audit Report – Summary of audit findings
- CMS Exit Conference – Review of Preliminary Draft Audit Report by the CMS auditors

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Post-Audit Timelines

Weeks 9/10 – 21

Audit Reporting

- Notification of Immediate Corrective Action Required (ICAR(s)) – Sponsor submits Corrective Action Plan (CAP) within 3 business days
- Draft Audit Report –60 days following exit conference
- Sponsor response to Draft Audit Report – 10 business days after delivery of Draft Audit Report
- Final Audit Report – 10 Business days following Sponsor's response to Draft Audit Report

Weeks 22 - 52

Audit Validation and Close Out

- CAP submission – 30 days after delivery of final report
- CMS review and acceptance of CAPs – CMS desk review of CAPs and requests for any revisions
- Independent Validation Audit – 180 (previously 150) after CMS CAP acceptance
- Audit close out – CMS evaluation of validation audit report and if all conditions are corrected, CMS issues audit close out letter

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Universe Submission

> Data integrity is imperative
>> Dedicated QA team to review

> Cannot build this when they come….

> Build in internal review time if FDR is producing universe(s)

> Consequences for bad data

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Universe Data Integrity

> CDAG, ODAG, MMP-SARAG

> CMS conducts universe data integrity webinar prior to audit webinar or timeliness assessment of the universe

> Five samples from each universe are reviewed to confirm system and universe matches = Data Integrity

> If more than 1 sample out of the 5 reviewed has discrepancies = data integrity issue
>> Universe will need to be resubmitted before live audit
>> If universe is invalid after 3 attempts, Sponsor will receive an IDS condition

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Timeliness Tests

> CDAG, ODAG, MMP-SARAG

> After data integrity is confirmed, CMS determines overall timeliness tests for each universe and will share the results at the end of the webinar week
>> CMS reviews each universe and assesses timeliness of the universe
>> Identifies unique beneficiaries impacted by untimeliness

> No percentage given by CMS for number of untimely cases that would result in a condition
>> Depends on number untimely versus size of universe

> With the exception of the ODAG Table 3 (Claims), known requirement of 95%, assume all others to be 100%

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Webinar Week

> CMS selects samples from the submitted universes to test during audit fieldwork and informs the sponsor of the sample selection via HPMS upload

> Sponsor should have staff waiting and refreshing HPMS to pull down and distribute samples to all staff and delegates as soon as possible

1 hour	2 Business Days	2 Weeks prior to entrance conference*
FA	*SNP-MOC*	*CPE*
CDAG		
ODAG	*MMP-CCQIPE*	
MMP-SARAG		
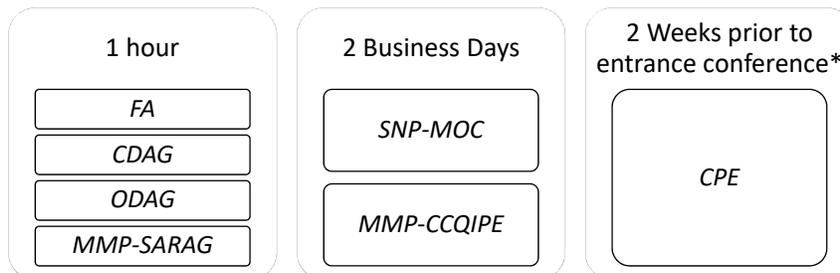
Tracer summaries due by entrance conference

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CDAG: Top Trends in 2019

Opioid Edits	CD/RD Denials	Exceptions	Member Letters	Grievances
• Review if member should be exempt from edit or is not naïve based on other information	• CMS focused on full clinical review of the case including outreach attempts (days of week/time of day), denial rationale (criteria/policy) and the letter. • RD denials, CMS confirmed if peer to peer outreach occurred. CMS confirmed that for a RD where the CD was denied for lack of medical necessity that a doctor reviewed not a pharmacist.	• CMS focused on handling or classification of step therapy cases, including a targeted review as part of the data integrity universe review.	• Was it member friendly and included specific denial reason? • When lack of information from the doctor is reason for the denial, CMS was looking for it to be specifically stated as the reason why the denial occurred in addition to clinical requirements. • CMS focused on the approval letter and the effectuation in the adjudication system (paid claim).	• Are same call resolutions classified as grievances? • Ensure all items within the grievances are addressed and resolved

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ODAG: Top Trends in 2019

Payment OD Processing	Pre-Service Denials	Member Letters
• CMS focused on the application of liability for denied claims on member EOBs and remittances, particularly for non-contracted provider. • CMS clarification that expects outreach on claims where the plan does not have enough information to make a decision.	• CMS focused on full clinical review of the case including outreach attempts (days of week/time of day), denial rationale (criteria/policy) and the letter. CMS focused on denied cases, and whether the plan ensured that the beneficiary received alternative services where needed. • CMS focused on denied cases, and whether the plan ensured that the beneficiary received alternative services where needed. • Application of appropriate clinical criteria	• CMS focused on whether the letter was member friendly and included specific denial reason. • When lack of information from doctor is reason for the denial, CMS was looking for this to be clearly stated as the reason for denial in addition to the clinical requirements.

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Tips for a Successful Audit

Have a Plan

- Leadership
  - One lead for each area
  - One lead for the overall audit
- Plan Ahead
  - Outline Dates
  - Define Roles
    - Before and during audit
  - Logistics/ Facilities
- Communicate the plan
  - CEO to all employees
  - Affected areas
  - FDRs

- Universes
  - Validate – layout/technical, as well as data
  - Ask questions
- Pull samples
  - Review samples with live team and offline
- Prepare Narratives
  - Specific to known issues and in general
  - Pull mock samples and put staff on spot with known issues

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Helpful Hints

- On-line systems will be needed for demonstration
  - Prepare well in advance of the audit
  - Test capabilities – make sure that all know what is being demonstrated and have a plan
    - Check for screen views – can all be seen?
    - Is WebEx (other systems) available for all involved?
  - Have IT available to ensure systems are working
- During Audit: DOCUMENT – Fill out worksheets, including completion of notes, criteria, cause and effect
- During Audit: Tune in to auditor desired response pattern quickly
- Confirm Daily Request Log: Repeat to auditor, sign-off on uploads
- Screenshots/capture (e.g. Snag-it, Snipping, Snip & Sketch) – Must be same screens as shown within the audit

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Key Players

- Primary Webinar Driver
- Primary Speaker (SME) – Should be different than the driver
- Medical Directors – Should be able to speak to case decision
- Scribe / Note Taker
  - Track each of the samples, along with final disposition
  - Track each action item, Root Cause Statements or Impact analyses requested
- Action Item Owner - Someone not attending the audit that can immediately begin to and follow up on any action items due at the end of the day/next day

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Presentation Hints

> Turn off all pop-ups, IM, emails, and anything else that will be a distraction (Including a busy desktop)

> Signed into all applicable systems that will be used

> Identify yourself when speaking and project clearly and confidently

> When accessing any system for the first time, provide the auditor with a brief description of the application

> Do not perform any research on the screen with the auditors- pause the screen

> Everyone speaking should be near the phone, and support should be in the back of the room

> Do not speak or whisper at all in the background and mute unless speaking

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General Reminders

> Be timely – be ready at least 15 minutes early

> Silence cell phones and laptops

> Limit introductions to assigned speakers, drivers, and key executives

> Limit traffic once the session begins

> When signing into the webinar use your full name followed by your organization first, then call in

> > Sally Jones – My Health Plan

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Chapter 13/18 Updates

Shared Updates

- Plan Responsibilities (Section 10.4)
  - Role of the Medical Director
  - Communication to an Enrollee
    - Alternate formats and languages
    - Notice by fax or e-mail if enrollee agrees
- Adjudication Requirements (Section 10.5)
  - 24/7/365 clarification
  - Calculation of Days for Assessing Plan Timeliness
    - "Day One" defined
  - When a Request is Considered Received by the Plan
    - Standard: any unit in Plan or delegated entity
    - Expedited: Appropriate department

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Shared Updates Continued

- Adjudication Requirements (Section 10.5) Continued
  - When Notification is Considered Delivered by the Plan
    - Written - date deposited in the courier drop box
    - EFT - date plan distributes funds for payment
  - Good Faith Effort to Provide Verbal Notification
    - Good Faith Effort versus Verbal Notice
- Outreach for Additional Information (Section 10.6)
  - Minimum of ONE attempt
  - None required if necessary information is provided

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Shared Updates Continued

- Representatives (Section 20)
  - Enrollees cannot verbally appoint a representative and must submit a valid representative form
  - If plans have a copy of an AOR on file, it may be used for any request from the representative for one year from the date it is signed
  - Obtaining an AOR form within a "reasonable timeframe" is clarified as the conclusion of the appropriate timeframe, plus extension
  - For representative request, plans may send notices or correspondence to the enrollee in addition to the representative

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Shared Updates Continued

- Grievances (Section 30)
  - Plans must inform enrollees if their issue is a grievance or an appeal
  - May be verbal and at the time of the call
  - When the enrollee is notified of the decision
    - Does not apply to requests for coverage
  - Withdrawals
    - Request may be verbal or written
    - Must be well documented in system
    - Should send written confirmation to enrollee within 3 calendar days of request to withdrawal
  - Quality of Care (QOC)
    - Additional definition
    - If withdrawn, the Plan is still required to investigate but not notify

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Shared Updates Continued

- Reopenings (Section 80)
  - Can be in writing or verbal
  - Reopening actions should be completed within 60 days from the receipt of reopening
  - Any determination or decision reopened and revised must deliver written notification to the parties to that determination or decision
  - A change in denial rationale constitutes a revised determination
  - Part D: clerical errors aren't required to be reopened

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Part C Updates / Clarifications

- Organization Determinations (Section 40)
  - Prior Authorization
  - Processing Timeframes
    - 95% of clean claims for non-contracted providers and enrollees must be paid within 30 calendar days of the request
  - Notification for Approvals
    - Expedited – initial verbal notice must be followed by written confirmation within 3 days of verbal notification
    - Pre-service:
      - May be verbal or in writing
      - Must include conditions of the approval
      - Best practice of written notice encouraged
    - Must notify enrollee and provider if request is made by provider on behalf of enrollee

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Part C Updates / Clarifications

- Organization Determinations (Section 40) Continued
  - Notification for Denials - Payment
    - May use EOB in lieu of IDN
    - EOB must contain OMB-approved language of the IDN verbatim, in its entirety
    - Must notify the enrollee via the EOB within required timeframe
    - An IDN is not required when there is no enrollee liability, an EOB would be issued showing any applicable cost sharing.
  - Withdrawal of Initial Determinations
    - Party who submits request may withdrawal request
    - Oral or in writing
    - Oral must be well documented, why is requestor not proceeding
    - Should send written confirmation within 3 calendar days of receipt of request to withdrawal

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Part C Updates / Clarifications

➢ Reconsiderations (Section 50)
  ➢ Notification Requirements
    ➢ Plans do not have to notify enrollees upon forwarding cases to the IRE
  ➢ Withdrawal
    ➢ Requestor may withdrawal orally or in writing prior to appeal decision being mailed
    ➢ Verbal request must receive written confirmation within 3 calendar days of the verbal request to withdrawal
  ➢ Untimely Cases
    ➢ Fully favorable determinations less than 24 hours after the end of the adjudication timeframe can be effectuated and enrollee notified of favorable determination in lieu of forwarding the appeal to the IRE
  ➢ Dismissals - do not have to be forwarded to the IRE
  ➢ Preparing the Case File – provides information regarding electronic submission via IRE web portal

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Part D Updates / Clarifications

➢ At Risk / CDs (Section 40)
  ➢ At Risk
    ➢ At-risk enrollee for prescription drug abuse
    ➢ Disagreement from Member – RD / Appeal
  ➢ Coverage Determination (Part D)
    ➢ Tier Exceptions
    ➢ Tolling – 14 days maximum
    ➢ PSS Indicating Factors for exception
    ➢ DMRs can be submitted by prescriber
    ➢ DMR checks can be mailed up to 30 days after receipt

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Plan Provider Interactions

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Plan and Prescriber Interactions

> Plans should utilize a multimodal approach for additional information
> > Phone
> > Fax
> > Electronic prior authorization

> Peer to Peer Outreach
> > Multiple attempts
> > Scheduled appointments

> Dedicated staff for authorization requests
> > Pharmacists or nurses
> > Timely response to requests for additional information
> > Review criteria to ensure necessary clinical is submitted
> > Ensure their contact information is on request

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Plan and Prescriber Interactions

- Real Time Benefit Tool
    - Final Rule (CMS-4180-F)
    - Part D plans must adopt one or more real time benefit tool
    - Integrated into electronic health record or electronic prescribing system
    - Real time information about patient's plan design and coverage
        - Formulary vs Non-Formulary
        - Utilization Management Costs
        - OOP costs
        - Therapeutic alternatives
    - Process electronic prior authorization from the electronic health record
    - Effective January 1, 2021

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Plan and Prescriber Interactions

- Use of electronic prescribing
    - Section 2003 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271) – Every Prescription Conveyed Securely
        - A prescription for a covered Part D drug under a prescription drug plan (or under an MA–PD plan) for a schedule II, III, IV, or V controlled substance shall be transmitted by a health care practitioner electronically
        - Drug prescribed on or after January 1, 2021

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Plan and Prescriber Interactions

- Use of electronic prior authorization
  - Section 6062 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271) – Electronic PA for Covered Part D Drugs
    - Amends Section 1860D–4(e)(2) of the Social Security Act (42 U.S.C. 1395w–104(e)(2))
    - No later than January 1, 2021
    - Secure electronic transmission of a PA request from prescribers and a response from the PDP or MA sponsor
    - Exclusions: fax, proprietary payer portal, or electronic form
    - Standards will be adopted by the Secretary, NCPDP, and other appropriate stakeholders
  - CMS 4189-P
  - Advantages
    - Timely response
    - Decreased paper…decreased costs

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Summary

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Summary

> CMS program audit success requires a collaborative relationship between prescribers and Plans.

> Plans should utilize a multi-modal approach to ensure effective outreach and all outreach attempts should be documented.

> Prescribers should have dedicated staff that are responsible for determination requests.

> Prescribers and Plans should be aware of changes in guidance and regulations to ensure compliance.

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Questions & Answers
Thank You!

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