


CENTERS FOR MEDICARE & MEDICAID SERVICES

Title



GENERAL SESSION: CMS Update
Vikki Ahern, Director
Medicare Parts C and D Oversight and Enforcement Group (MOEG)
Center for Medicare (CM)
February 13, 2018

Objectives

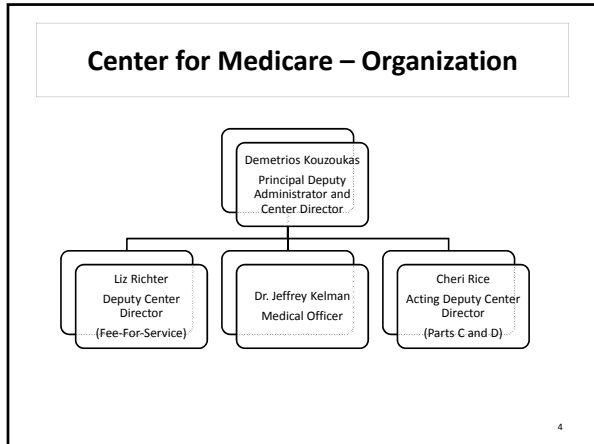
1. Understand the organizational structure and function of the Part C and Part D side of the Center for Medicare
2. Increase knowledge of CMS' Parts C and D program audit cycle, process, protocols, reports, and best practices.
3. Increase knowledge of enforcement actions.
4. Learn about other activities within the Medicare Parts C and D Oversight and Enforcement Group.
5. Learn about key aspects of the CMS proposed rule 4182-P and the 2019 Call Letter.

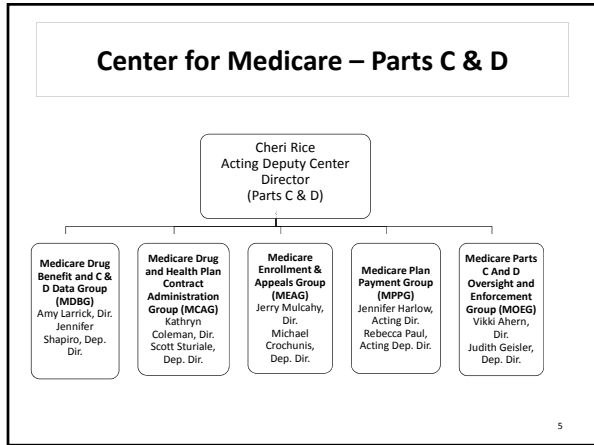
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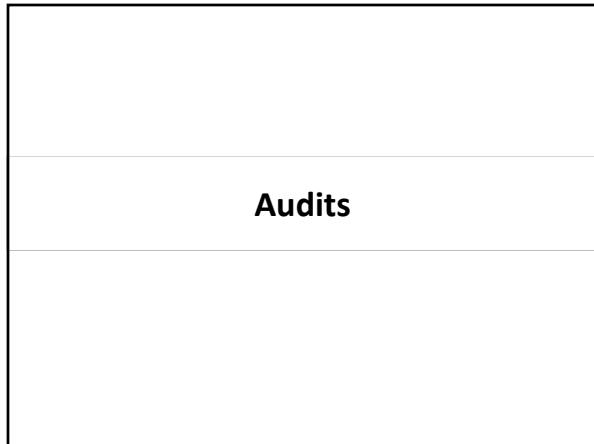
Agenda

- Center for Medicare organizational structure
- Audits
- Audit Data
- Enforcement Actions
- Other Activities

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Audit Cycles

- Audit approach redesign - 2010
- First cycle: 2010 – 2014
 - Audited 49% of sponsors/parent organizations
 - Covering 96% of all Parts C and D enrolled beneficiaries
- Second cycle: 2015 - 2018
 - From 2015 – 2017, audited 95 sponsors
 - At the end of 2017, covering 95.3% of all Parts C and D enrolled beneficiaries
 - For 2018 audits, engagement letters will be sent beginning March 2018
- Third cycle to begin in 2019

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2018 Program Audits

- Pilot Protocol Updates
 - The two Medicare-Medicaid Plan focused audit protocols will be fully operational program areas in 2018
 - The Medication Therapy Management (MTM) pilot protocol is suspended
- Availability of the Audit Submission Checklist on the program audit website

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Audit Process

Four Phases to an Audit:

- Audit Engagement and Universe Submission (weeks 1 – 6)
- Audit Fieldwork (weeks 7-9)
- Audit Reporting (weeks 10-21)
- Audit Validation and Close Out (weeks 22 – 48)

2018 Program Audit Process Overview is posted to our webpage

<https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html>

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Audit Process Timeline

**Audit
Engagement
and Universe
Submission**

Weeks 1-6

- Engagement Letter
- Universe Submission
- Universe Validation

Enhancements/Changes

- Reduced review period of Part C and Part D Call Logs
- Acceptance of either the MBI or HICN in Part D Formulary and Benefit Administration universes

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Audit Process Timeline

**Audit
Fieldwork**

Weeks 7-9

- Entrance Conference
- Webinar Audit
- Onsite Review of Compliance Program (as applicable) Issuance of Preliminary Draft Audit Report
- Exit Conference

Enhancements/Changes

- Fieldwork extended from 2 weeks to 3 weeks for all Sponsors

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Audit Process Timeline

**Audit
Reporting**

Weeks 10-21

- Notification of Immediate Corrective Action Required (ICAR)
- Draft Report Issuance
- Sponsor Response to Draft Report
- Final Report Issuance

Enhancements

- ICAR Notification Letters sent via HPMS
- Comments to Draft Audit Reports within HPMS

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Audit Process Timeline

**Audit
Validation and
Close Out**

Weeks 22-48

- Sponsor CAP Submission
- CMS Review and Acceptance of CAP Sponsor Validation Audit
- Audit Close Out

Enhancements

- Proposed improvements to the independent audit validation process in response to industry listening session

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Independent Validation Audit

- Conducted an industry wide listening session mid-2017.
- Identified opportunities for clarification and changes.
- Creating more standardization for ease of implementation.

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Protocol Redesign

- CMS is currently redesigning program audit protocols
 - Simplify data collection tools (i.e. record layouts, impact analysis templates, etc.)
 - Program area protocols posted to our webpage
- Redesigned collection tools will be submitted to OMB for PRA approval in the second quarter of 2018

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Audit Data

Annual Report

- The 2016 Annual Report was released May 9, 2017 and covers a variety of audit-related information:
 - The most common conditions seen during 2016 audits
 - Audit scores by various organizational characteristics, including: Enrollment size, Program experience, and Tax status
- The 2017 Annual Report is expected to be released in May 2018

https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2016_Program_Audit_Enforcement_Report.pdf

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Frequently Cited Common Conditions

Compliance Program Effectiveness

- Sponsor did not review Office of Inspector General (OIG) and General Services Administration (GSA) exclusion lists for any new employee, temporary employee, volunteer, consultant, or governing body member prior to hiring or contracting and monthly thereafter.
- Sponsor did not provide evidence that it audits the effectiveness of the compliance program at least annually and that the results are shared with the governing body.

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Frequently Cited Common Conditions
(continued)

Formulary Administration

- Sponsor failed to properly administer the CMS transition policy.
- Sponsor improperly effectuated prior authorizations or exception requests.
- Sponsor failed to properly administer its CMS-approved formulary by applying unapproved quantity limits.

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Frequently Cited Common Conditions
(continued)

Part D Coverage Determinations, Appeals and Grievances (CDAG) and Part C Organization Determinations, Appeals, and Grievances (ODAG)

- Denial letters did not include adequate rationales, contained incorrect/incomplete information specific to denials, or were written in a manner not easily understandable to enrollees.
- Sponsor did not demonstrate sufficient outreach to prescribers/providers or beneficiaries to obtain additional information necessary to make appropriate clinical decisions.
- Sponsor misclassified coverage determination or redetermination requests as grievances and/or customer service inquiries.

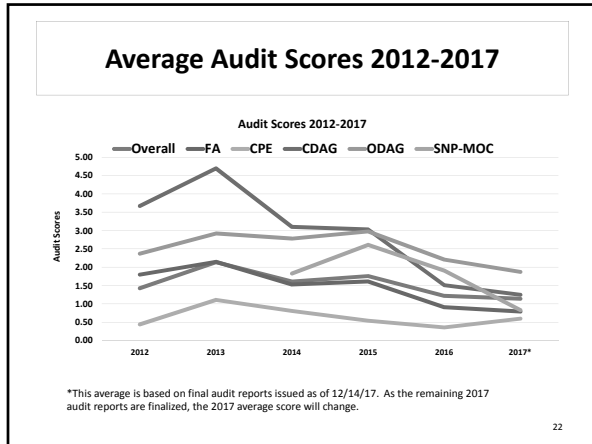
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Frequently Cited Common Conditions
(continued)

Special Needs – Model of Care (SNP-MOC)

- Sponsor did not show documentation of interdisciplinary care team (ICT) coordination of member care.
- Sponsor did not administer comprehensive annual reassessments within 12 months of the last annual health risk assessments (HRAs).
- Sponsor did not review/revise individualized care plans (ICPs) consistent with its model of care (MOC) or as warranted by changes in the health care status or care transitions of beneficiaries.

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- ### Best Practices
- Suggestions for improved performance
- Assess
 - Evaluate
 - Correct
 - Communicate
 - Practice/ Conduct Mock Audits
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Enforcement Actions

Enforcement Actions

- CMS detects sponsor non-compliance through monitoring and auditing. Serious or sustained non-compliance can result in an enforcement action.
- Enforcement actions include:
 - Civil money penalties (CMPs)
 - Intermediate Sanctions (suspension of enrollment, marketing, or payment)
 - CMS for-cause terminations

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Civil Money Penalties

- CMPs are the most common enforcement action
 - Majority of CMPs issued are based on referrals from program audits
 - Some CMPs are issued for errors related to plan benefit information in 2017 ANOC/EOC documents
 - In 2017, two CMPs were issued for high rates of auto-forwarding cases to the Independent Review Entity (IRE)
 - Other CMPs are issued based on referrals of non-compliance

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One-third Financial Audits

- Began evaluating findings for enforcement actions from One-third Financial Audits
- Issues evaluated and considered include:
 - Charging incorrect Part C and D cost sharing in excess of approved amounts
 - Failing to correctly calculate enrollee True Out-of-Pocket (TrOOP) costs
 - Incorrectly calculating and overbilling Part D Late Enrollment Penalties (LEP)
 - Incorrect applying enrollee Part D Low-Income Cost-Sharing Subsidy payments (LICS)

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2017 Enforcement Process Enhancements

- Increased due diligence prior to CMP issuance
 - Sponsors are reminded to scrutinize submitted impact analyses during audit
 - Final impact numbers are confirmed with sponsors before enforcement evaluation begins
- Increased transparency in enforcement evaluation and CMP calculation
 - Release of CMP Calculation Methodology
 - Referrals and referral closures are communicated to sponsors
 - Calculation tables are provided to plan sponsors for CMPs imposed

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Enforcement Action Updates

- CMPs for 2017 program audits are scheduled to be released at the end of February, 2018.
- All enforcement notices and the final CMP methodology are posted at:
<https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDEnforcementActions-.html>

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Other Activities

Timeliness Monitoring Project

- Initiated in 2017 to assess the completeness of the data at the Independent Review Entity (IRE) across all contracts.
- Evaluation of data completed and individual findings were sent to sponsors on December 12, 2017.

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Timeliness Monitoring Project

- Summary of percent of missing Part C IRE data

No. of Contracts	Mean	Median	Minimum	Maximum
327	24.41	4.76	0.00	100.00

 - There were 66 contracts that had no cases that should have been forwarded to the IRE in the TMP time period and were excluded from the analysis above.
- Summary of percent of missing Part D IRE data.

Contract Type	No. of Contracts	Mean	Median	Minimum	Maximum
MA-PD	277	41.86	45.00	0.00	100.00
PDP	54	35.15	31.92	0.00	100.00

 - There were 166 contracts that had no untimely cases (152 MA plans and 14 PDPs) and were excluded from the analysis above.

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Timeliness Monitoring Project

- On January 8, 2018, CMS began issuing requests for sponsors' 2017 timeliness data
 - Select ODAG and CDAG Universes
 - Time periods of data collected: March, April, and May 2017
- Use of these data in scaled reductions for the appeals Star Ratings measures is outlined in the proposed regulation CMS 4182-P

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Programs of All-Inclusive Care for the Elderly (PACE)

- In 2017, CMS implemented revised audit protocols for the Programs of All-Inclusive Care for the Elderly (PACE).
- The audit protocols went through the PRA process and are posted publicly on our website.
- Reduction in the amount of data/information collected.
- New protocols focus on clinical care and participant experience.
- Modeling execution of PACE audits similar to Part C and Part D program audits.

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2019 Call Letter

- 2019 Draft Call Letter released on February 1, 2018, comments due March 5, 2018.
- Part C and Part D key topics:
 - Improving Drug Utilization Review Controls in Medicare Part D
 - Expanding Health Related Supplemental Benefits
 - Medicare Advantage Uniformity Flexibility
 - Improving Beneficiary Communications and Reducing Burden

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**2019 Call Letter
MOEG Topics**

- Validation Audits
 - Threshold to require an Independent Auditor
 - Conflict of Interest
 - Validation work plan template
 - Timeframe to complete validation audits
 - Independent Validation Audit report submission

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2019 Call Letter
MOEG Topics (continued)

- Plan Finder Civil Money Penalty (CMP) Icon or other type of Notice
- Compliance Program Effectiveness
 - Seeking comment on proposal to allow program audits to meet the annual compliance program audit requirement.

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Part C and D Regulation

- Proposed regulation CMS-4182-P issued by CMS on November 16, 2017 and published in the Federal Register on November 28, 2017.
- Comment period closed January 16, 2018.
- Promotes innovation and empowers MA and Part D sponsors with new tools to improve quality of care and provide more plan choices for MA and Part D enrollees.

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Part C and D Regulation
(continued)

Patients over Paperwork Initiative

- CMS recently launched the Patients Over Paperwork Initiative, a cross-cutting, collaborative process that evaluates and streamlines regulations with the goal of reducing unnecessary burden, increasing efficiencies, and improving the beneficiary experience.
- The proposed rule furthers this initiative and would empower patients and doctors in making decisions about patient healthcare.

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Key Provisions Proposed in 4182-P

- Additional Transparency for Star Ratings
- Artificial Limits on Medicare Advantage Plan Variety
- Artificial Limits on Part D Enhanced Alternative Plans
- Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA)
- Maximum Out-of-Pocket and Cost Sharing Limits
- Part D Tiering Exceptions
- Limitation to the Part D Special Enrollment Period for Dual and Other LIS-Eligible Beneficiaries

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Key Provisions Proposed in 4182-P
(continued)

- Changes to the Days' Supply Required by the Part D Transition Process
- Lengthening Adjudication Timeframes for Part D Payment Redeterminations and Independent Review Entity Reconsiderations
- Eliminating MA Plan Notice of Forwarded Appeals
- Preclusion List Requirements for Prescribers in Part D and Providers and Suppliers in Medicare Advantage, Cost Plans and PACE
- Reducing Unnecessary Paperwork Burden: Medical Loss Ratio

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Key Compliance Provision Proposed in 4182-P

- Propose to reduce Compliance Program training requirements by removing:
 - the requirement to use CMS-developed training
 - first tier, downstream and related entities compliance training requirements

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Contact Us

- **Audit mailbox:**
part_c_part_d_audit@cms.hhs.gov
- **Compliance mailbox:**
Parts_C_and_D_CP_Guidelines@cms.hhs.gov
- **Part C and Part D Compliance and Audits website:**
<https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/index.html>

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Thank you!

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