It's Lonely Being Picked First: CMS Program Integrity Audit is not a CMS Program Audit

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Who are we?

Candice Weatherly, Compliance Officer, Elderplan

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- Combined 20+ years experience in Health Plan regulatory Compliance and CMS auditing
- Our Compliancee Program oversees:
  - Corporate Compliance & Ethics
  - Regulatory Compliance
  - Delegated Vendor Oversight
  - Special Investigations Unit
  - HIPAA Privacy

Who are we?

- Elderplan is a non-for-profit specializing in safety net plans.
- It was founded in 1985 as one of the four original Medicare Social HMOs.
- We are a smaller Plan serving the greater New York area. Plan offerings include a Medicaid Partial-Capitation Managed Long Term Care Plan, and seven Medicare Advantage-Prescription Drug PBPs, including five Special Needs Plans (SNPs).

Currently 1 of only 4 plans selected for the CMS Program Integrity Audits first announced in August 2022.

What is a CMS Program Integrity Audit?

- Concentrates on efforts undertaken by the organization to prevent, detect, and correct Part C and Part D fraud, waste and abuse (FWA).
  - Identification and prioritization of FWA risks
  - Effective compliance with CMS-issued statutory and regulatory requirements, guidance, and direction
  - FWA complaints, investigations, referrals,
  - Requests for information (RFIs) from MEDIC and regulators
  - Effective compliance with reporting requirements for the Health Plan Management System (HPMS) FWA Reporting module
  - Proactive FWA initiatives
- Conducted by the CMS Center for Program Integrity (CPI).
- Only 4 plans selected in September 2022

How is it different from a CMS Program Audit?

- Program Audits measure a Sponsoring organization's operations and compliance with the terms of its contract with CMS, in particular, the requirements associated with access to medical services, drugs, and other enrollee protections required by Medicare.

- The Medicare Parts C and D Oversight and Enforcement Group (MOEG) is the Group within CMS responsible for creating and administering the audit strategy to oversee the Part C and Part D programs, including Program Audit protocols.

- Program audits have established protocols for all audit areas including Compliance Program Effectiveness (CPE).

How are these audits different?

Program Integrity Audit

- Run by CMS CPI
- Audits FWA activity only
- No protocols

Program Audit

- Run by CMS MOEG
- Audits plan operations and compliance, which can include FWA activity
- Published protocols
- CPE Protocols
- Past year audit performance reports available
- Transparency

Timeline of PI Audit

- Audit Lifecycle:
  - Document and Universe Submission
  - Sampling
  - Field work week (sample case review and interviews)
  - DRL submissions over several months
  - Exit conference
  - Root case review
  - Audit report
  - CAP/RAP submission, approval, and 3-4 month implementation phase
  - Validation
- Plans are provided a limited timeline that covers the engagement letter through the exit conference
  - Timeline did not include audit reporting, CAP/RAP submission, CAP/RAP implementation, and validation phases.
- Audit will span approximately 18-20 months

Knowing your regulations and when to align and distinguish between Compliance requirements & separate FWA requirements

Current Resources for MAPD "Program Integrity"

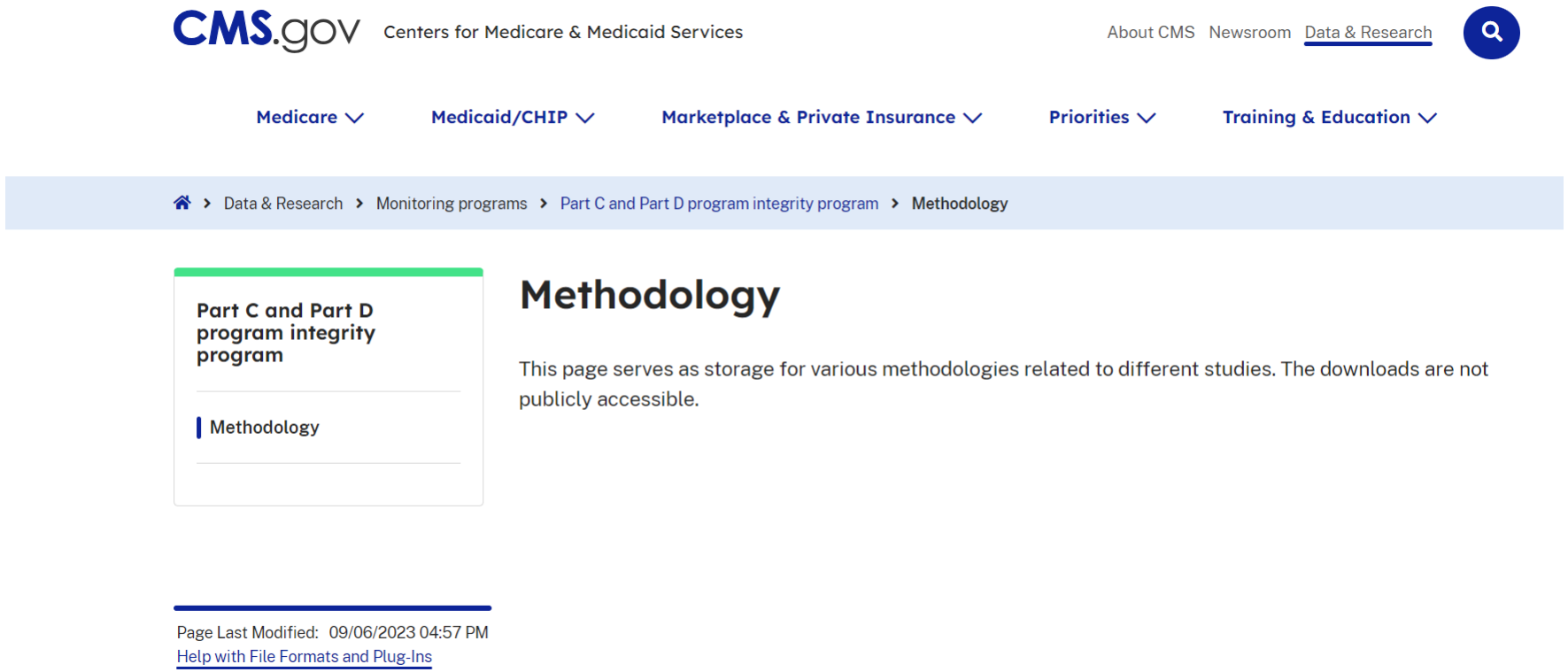
- CMS Compliance Program Guidelines (Chapter 21/ Chapter 9) focuses on compliance standards to prevent, detect and correct non-compliance, as well as FWA.
  - FWA is not a standalone topic in and of itself, with the except of having an SIU and reporting to I-MEDIC.
  - Guidelines have not been updated since 2013

- In the 2021 Report to Congress on Medicare and Medicaid Program Integrity, published May 2023, only three paragraphs were dedicated to Part C and Part D Program Integrity. They focused on increasing referrals to I-MEDIC, risk adjustment, accessing information through HPMS and enforcing standards of practice. But it falls short of providing detail or substance worth taking away.

Current Resources for MAPD “Program Integrity”

- CMS’ Program Integrity Website is sparce
- https://www.cms.gov/data-research/monitoring-programs/part-c-d-program-integrity

- Emphasis on sparce…



CMS PI Auditors are relying on guidance that was written for Compliance Programs but wants to apply it to FWA separately and wholly.

You must know when to align and distinguish between Compliance requirements & separate FWA requirements:

Compliance

- Effective compliance with CMS-issued statutory and regulatory requirements, guidance, and direction
- FWA complaints, investigations, referrals, and requests for information (RFIs)
- Effective compliance with reporting requirements for the Health Plan Management System (HPMS) FWA Portal

FWA

- Identification and prioritization of FWA risks
- FWA monitoring and auditing
- Proactive FWA initiatives
- SIU Activity
- Other FWA Investigations

Structure of your departments and team(s) matter, where is the overlap?

Start thinking about who in your organization would be involved in a PI Audit. Who has a hand in FWA activity?

- Compliance Department
- SIU
- Pharmacy Department
- PBP
- Delegated Vendor Oversight
- Delegated vendors/FTEs
- Others?

Audit Process: what's required, what to submit, what to push-back on

What do the auditors want to see? - Documentation

- Plan questionnaire
- Org structure
- Narrative overview of all FWA prevention, detection and correction activities throughout your organization
- All FWA policies and procedures
  - internal and FTE policies
- HPMS Memo management policies and process
- FWA Risk Assessment
- Policies on FWA referrals to MEDIC via HPMS FWA Reporting module

FWA Risk Assessment

- Auditors wanted to see a FWA dedicated Risk Assessment, separate from your Compliance Risk Assessment
  - Remember: regulations and compliance program guidelines require a Compliance Risk Assessment that considers compliance and FWA risks
  - There is no standalone FWA Risk Assessment requirement

- Even where FWA is include in the Compliance Risk Assessment, the auditors want to see specific discussion of Part C and especially Part D FWA issues
  - Down to evidence that individual FWA HPMS memos (i.e., opioid overpresribers, pharmacy outliers, etc.) were discussed and considered during the risk assessment process.

FWA Referrals to MEDIC via HPMS

- Auditors wanted to see detailed policies on how plan utilizes the FWA Reporting Module in HPMS and process for reporting FWA to the MEDIC
- Auditors were not pleased if there were no policies specific to the HPMS FWA Reporting Module and if there wasn't evidence of regular FWA referrals to HPMS
  - Remember: regulations and compliance program guidelines make FWA reporting voluntary, subject to judgement of the plan
  - Only pharmacy payment suspensions and opioid overprescribing are required to be reported

What do the auditors want to see? - Universes

- FWA Complaints Universe
- FWA Investigations & Referrals Universe
  - Separate universe per source (e.g., SIU, Pharmacy, Compliance, PBM, other FTEs)
  - Sampling was also split by source
- Requests for Information
  - From MEDIC and other regulators such as OIG, FBI, etc.

What do the auditors want to see? – Sample Documentation

- Detailed case files for each sampled case that include details and evidence for:
  - How the issue was identified
  - Process for investigation and timeline
  - Explanation for any deviation from your policies and timelines
  - Findings and resolution
  - Any corrective actions with specific dates and times actions were taken
  - Escalation to management, compliance committee, board of directors, when applicable
  - Reporting to CMS Account manager
  - Reporting to HPMS FWA Reporting module
- For RFI cases, show proof that documents were submitted timely, and if no the reason for the deviation

Demonstrating oversight of PBM and other First-Tier Entity FWA Activity to satisfy the auditor

- Do you delegate Part D FWA investigations to your PBM?
  - Who investigates pharmacy FWA on your behalf?
  - What about other vendors?
- What documentation do you receive from your PBM and other FTEs?
  - Does it contain all of the data elements the auditors want to see in the sample documentation?
  - If you want to see full investigation files will your PBM/FTE provide them?
- When in the investigation timeline does your PBM or FTE alert you to the investigations they performed on your behalf?
  - At onset? Once closed?
  - Are you given enough information to oversee that the investigations are performed timely?

Demonstrating oversight of PBM and other First-Tier Entity FWA Activity to satisfy the auditor

- Who handles any FWA reporting to HPMS for PBM or FTE investigation activity?
  - If the PBM or FTE is reporting on your behalf, do you know what they are reporting and when?
  - If you report their investigations, are you given enough information to submit a comprehensive report or payment suspension notice?
- What do your contracts say specific to FWA investigation activity and your access to any and all records?
- What is your delegated vendor oversight structure?
  - Does it vary by FTE?
  - Does it factor in oversight of FTE FWA activity?
  - Can you defend it against auditor scrutiny?

Field Work Week

Key Staff Interviews

- Compliance Officer
- SIU Director
- Risk Assessment Director, if applicable

Review of Sample Documentation

- Time to defend investigation processes
- Explain issues or gaps in sample documentation
- Defend reason for your internal policies and processes if not in alignment with what auditor believes they should be

Submission of Document Request List (DRL) Items throughout field work week and beyond

FINDINGS – CAP or RAP

- Root cause analysis – auditors provided a list of issues and potential “root causes” before the draft findings report.
  - This gave a preview to what auditors would be including in the audit report and allowed the plan to “concur” or “not concur” with issues and root causes.
- Draft Audit Report
- Final Audit Report will call for a CAP or RAP
  - Remedy Action Plans “RAPs” are new.
  - Less severe than a Corrective Action Plan.
- RAP or CAP submission and approval
- RAP/CAP implementation – we are here
- RAP CAP Validation – this will begin this week

Key Take-aways

- Know where all FWA activities are happening within your organization
  - Get credit for as much as you can
- Be in tune with your PBM
  - Get as much access to details of FWA activity from your PBM, or any other delegated vendor
- Do not be afraid to give rebuttals verbally and in writing multiple times. Fight for what you believe is best practices for conducting business at your plan.
  - Especially where there is grey area in the guidelines
- Be ready to fully explain and defend your Delegated Vendor Oversight Program and Structure.

Any questions, feel free to Contact Us:

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Thank you