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Surviving a CMS-Mandated Independent Validation Audit (IVA): 150 Days and Counting

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Agenda

- Key Considerations When Determining "Clean Period" and Managing 150 Calendar Deadline to Start IVA
- Managing First Tier Entities and Downstream Entities
- How To Incorporate Lessons Learned From Plans Who Have Been Through IVAs
- After the Audit – Civil Monetary Penalty Calculations
- Contracts with First Tier Entities and use of legal counsel in Program Audits and IVAs

150 Days and Counting

- Submit Corrective Action Plans (CAPs) via HPMS for any conditions noted-
  - ❖ Within 3 business days of formal notification for ICARs
  - ❖ Within 30 business days from issuance of final audit report for CARs
- CMS accepts CAPS
- 150 days to undergo independent validation

Key Consideration When Determining "Clean Period"

- Estimate projected CAP completion dates for planning purposes and estimation of when clean operating period would begin for various operating areas
- Plan must operate in its clean period--
  - For Part C domains at least 60 days to allow for full cases (start/end) to complete
  - For Part D domains at least 30 days to allow for full cases (start/end) to complete
- Validation audits may be staggered in time across domains, they do not have to all occur at the same time

Independent Validation Audits and FDR Oversight Risk

- CMS Doesn't Differentiate Between a Plan and its FDRs

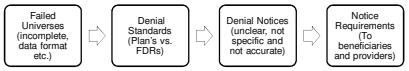
- Issues With FDR Compliance Have Had Significant Impact On Sponsors
  - Bad Audit Universe Data (Data Capture)
  - Undetected Non-Compliance – Invalid Data Submission (IDS)

FDR Oversight Through Universe Review

- Annual reviews of FDR have proven very ineffective – you simply can't see what's happening on a routine basis
  - Best Practice: Routine case reviews pulled from universes
- Universe Data from delegates should be tested, i.e. is the data in the universe what's supposed to be there

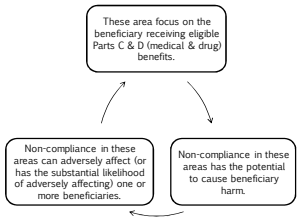
Program Audits and FDR Oversight
Lack of FDR Knowledge Training

- Plans have assumed that FDRs "know" how to implement things and have read the manuals and have Medicare experts.
- Plans *may* audit / test outcomes but don't test the pre-cursors.
  - Data Capture in Systems (e.g. data definition & actual mail date capture)
  - Internal FDR metrics and monitoring for key performance issues
- Key Issues:



Organization/Coverage Determinations, Appeals and Grievances

Why are ODAG and CDAG so important?



How To Incorporate Lessons Learned From Plans Who Have Been Through IVAs

Biggest Challenges in Managing an IVA

- Moving universes to a data analytic team for managing several hundred delegated universes & formats, which must be consolidated into one
- Our PBM
- Managing internal work teams with competing priorities

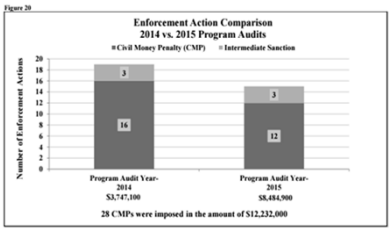
Lessons Learned---Process Improvements

- Need an automated process on Plan's end to validate universes
- Have the "A" team presenting to the IVA auditors
- Keep IVA focused on CMS findings being validated
- Transparency is important
- CMS does not expect perfection
- If it isn't documented; it wasn't done
- Helps to have POC identified on each end
- Need to account for time zone differences

Advice for Plans Audited in 2016 Who Will Go Through IVA

- Start the plan for the IVA the day of your CMS audit exit
- Look for experienced auditors who mirror CMS
- Work with the IVA auditor on the planning of the audit
- Make sure you have extensive documentation

Enforcement Actions: 2015 CMPs and Intermediate Sanctions



2015 Part C and Part D Program Audit and Enforcement Report, September 6, 2016

Civil Monetary Penalties (CMPs) – Maximums

- **Penalties imposed have been relatively restrained compared with CMS' maximum authority.**
- **Penalty amounts**
  - Up to **$25,000 ($36,794 adjusted for inflation) per finding** that has adversely affected an enrollee (or substantial likelihood of adverse effect)
  - Up to **$25,000 ($36,794 adjusted for inflation) per enrollee** adversely affected (or substantial likelihood of adverse effect)
  - Up to $**10,000 ($14,718 adjusted for inflation) for each week** that deficiency remains uncorrected after notice of CMS determination
  - Authority to Impose CMPs: 42 CFR §§ 422.760, 423.760; 42 CFR 102.3 (inflation adjustments)

CMS' 2017 CMP Methodology

- Key language: "The methodology described in this document does not limit CMS' authority to impose any penalty that is permissible under the law."
  - Used primarily to calculate deficiencies detected during routine Program Audits
  - Implicit assumption of good faith mistakes
  - Avoid prospective cost-benefit risk calculations using CMP Methodology amounts
- Standard formula
  - Per enrollee (CMP amount X # of affected enrollees) or
  - Per determination basis (CMP amount X # of affected contracts)

Beneficiary Impact

- Submit mitigating evidence in response to Draft Audit Report
- Beneficiary impact
  - At least one beneficiary was directly adversely affected
  - Substantial likelihood of adversely affecting enrollee(s)
- CMS takes the position that it has authority to determine that deficiency had the potential to adversely affect an enrollee even if sponsor can show evidence that it did not (e.g. paid claim) (see p. 4 of 12/15/16 CMP Methodology)

Standard Penalties

$200 per enrollee	• Inappropriate delay/denial of medical services or drugs • Incorrect premium charged or unnecessary costs incurred
$25 per enrollee	• Inaccurate or untimely plan benefit information • e.g. ANOC and/or EOC
$20,000 per violation/per contract	• Invalid data submission (failure to provide valid enrollee universes) • For other per contract violations, CMS uses maximum amount permitted by regulation

Aggravating and Mitigating Factors

- Program Audit CMPs Most sponsors received CMPs for non-compliance in the program areas of FA, CDAG, and ODAG because their actions adversely affected (or had the substantial likelihood of adversely affecting) one or more enrollees.
- CMS may either increase or decrease a sponsor's CMP by applying aggravating or mitigating factors to certain deficiencies

Aggravating Factors	Mitigating Factors
e.g., involved drugs where treatment should not be delayed, expedited cases, a prevalence of failed audit samples, the existence of a top-5 common findings condition, and/or a history of prior offense.	e.g., beneficiary received the drug on the same day or the enrollment based penalty cap per condition of non-compliance were reached.

Per Enrollee Aggravating Penalty Amounts

- Inappropriate delay/denial of medical services or drugs
  - Expedited decisions - $100
  - Prior offense ($100 for first; $1,000 for two or more)
  - Violation among top conditions in Annual Audit Report - $100
- Incorrect premiums or cost sharing
  - Inappropriate out-of-pocket cost exceeding $100 - $100
  - Prior offense - $100 for first; $1,000 for two or more
  - Violation among top conditions in Annual Audit Report - $100
- Untimely or inaccurate plan benefit information
  - Prior offense - $15
  - ANOC/EOC/errata after Dec. 31 - $15

Caps on Penalties Based on Total Enrollment

Enrollment of Parent Organization	CMP Violation Limit (Per Violation)
Below 1,000	$50,000
1,000 – 4,999	$100,000
5,000 – 19,999	$200,000
20,000 – 49,999	$300,000
50,000 – 99,999	$400,000
100,000 – 249,000	$500,000
250,000 – 499,999	$1,000,000
500,000 – 2,999,999	$1,500,000
3,000,000 or more	$2,000,000

First Tier Entity Contracts

- Familiarity with current CMS Audit Protocols
- Ability to generate accurate and compliant universes timely
- Audit support personnel with appropriate expertise
- Indemnification for violations leading to CMPs

Using Counsel During Audit and Validation

- Behind the scenes
- Review CAPs and other written responses
- Consult on concerns and development of narrative
- Trial runs of tracers

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