



# What You Need to Know About CMS Enforcement Actions



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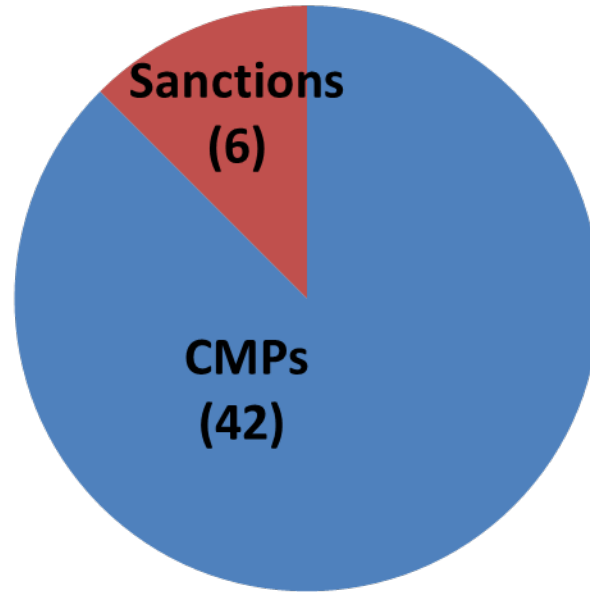
# Topics That Will Be Covered

- Enforcement Action Data 2014 – Present
- Civil Money Penalty Calculation
- Intermediate Sanctions
  - Granting a Limited Marketing and Enrollment Period
  - Validation audits conducted by independent auditors
  - What to expect while under sanctions – a first-hand account from Todd Shamash, Capital BlueCross

# Enforcement Actions 101

- Includes Civil Money Penalties (CMPs), Intermediate Sanctions (suspension of enrollment, marketing, payment), and CMS for-cause terminations
- Imposed at the contract level on Medicare Advantage, Prescription Drug, PACE, or Cost Plan contracts
- All actions come with appeal rights

# Enforcement Action Data from 2014 to Present



**Total of 48 Enforcement Actions**

# CMP Data

- Levied \$8,806,000 in CMPs for:
  - Violations found during program audits/validation audits (38)
  - Issuance of Late Annual Notice of Change/Evidence of Coverage documents (2)
  - Inaccurate Network Pharmacy Directories (1)
  - Enrollment processing (1)
- Average CMP amount - \$209,667
  - Highest: \$1,000,000
  - Lowest: \$20,700

# Intermediate Sanction Data

- Imposed intermediate sanctions for:
  - Violations found during program audits (4)
  - Violating enrollment requirements due to State-imposed suspensions of enrollment (2)
- Average duration of intermediate sanctions related to program audits since 2014 – 292 days

# CMPs and Sanctions Effects On Organizations

- Potential to reduce Star Rating (CMPs), Reduces Star Rating to 2.5 Stars (sanctions)
- Increased Past Performance Points (both actions)
- Tarnished reputation/branding impact (both actions)
- Loss in profits (both actions)
- Decreased enrollment (sanctions)
- Employee turnover (sanctions)
- Demand on time of senior leadership (sanctions)

# CMP Calculation Methodology

- Why have a methodology?
  - Provides consistent and fair treatment across all sponsors
  - Lets the nature and scope of the violation(s) dictate the penalty



# CMP Calculation

- Establishes standard penalty amounts for per enrollee and per determination penalties
- There are different standard penalties for 3 types of beneficiary harm:
  - Inappropriate delay or denial of access to health services or prescription drugs
  - Incorrect premiums charged or unnecessary costs incurred
  - Inaccurate or untimely information provided during the annual election period

# CMP Calculation – Aggravating Factors

- Involved the delay/denial of high priority drugs beyond 24 hours
- History of prior offenses within the past 2 years
- Expedited coverage requests exceeding CMS required timeframes
- Audit condition listed as a top 5 occurring condition in prior HPMS Common Conditions, Improvement Strategies, and Best Practices memos

# CMP Calculation – Mitigating Factors

- Inappropriate rejection of a drug at the point of sale, but the beneficiary received the drug on the same day
- Per violation penalty cap - banded by enrollment of the organization
  - Applies to both per determination and per enrollee penalties

# CMP Amount

- A penalty is calculated for each violation listed in the CMP notice.
- The total CMP amount in the notice is the sum of all the violations rolled up into one amount.

# What is a Limited Marketing and Enrollment Period?

- In instances where intermediate sanctions have been imposed, CMS **may require** an MA/PDP organization to market or to accept enrollments
- Allows CMS the opportunity to observe a sponsor's performance while under normal operating conditions during a period where the sponsor's deficiencies are believed to have been corrected
- Sanctions remain in place until CMS can validate (by CMS audit or independent audit) that the deficiencies have indeed been corrected

# When will CMS grant this limited period?

When the following criteria have been met:

1. Sponsor's Corrective Action Plan (CAP) is fully implemented
2. Self-monitoring results are reporting favorable outcomes in the once deficient operational areas
3. Sponsor has submitted an attestation to CMS that the deficiencies that were the basis for the sanctions have been corrected and are not likely to recur
4. The validation audit plan and schedule have been reviewed and approved by CMS

# When does the limited period end?

- The limited marketing and enrollment period will end when the validation audit has concluded and CMS has determined whether the sponsor has corrected the deficiencies that were the basis of the intermediate sanctions.
- If CMS determines that the deficiencies have been sufficiently corrected, the limited marketing and enrollment period will end, and the sanctions will be lifted.
- If CMS determines that the deficiencies have not been sufficiently corrected, CMS will end the limited period and reinstate the marketing and enrollment suspensions.

# CMS has required you to hire an independent auditor – now what?

- The Sponsor is responsible for choosing/hiring the audit firm that will conduct the validation audit
- The audit firm must be independent and there must be no conflicts of interests
  - e.g., the firm hired to develop and implement your CAP cannot also conduct the validation audit



# Roles and Responsibilities When Using an Independent Auditor

## Independent Auditor

- Provide Sponsor with an audit work plan and schedule acceptable to Sponsor and CMS
- Evaluate the performance of the Sponsor
- Provide a written audit report outlining the findings from the audit to the Sponsor

\*The auditors do not make any determinations about whether sanctions should be released

# Roles and Responsibilities When Using an Independent Auditor (cont.)

## Sponsor

- Submit the audit work plan and schedule to CMS
- Allow CMS access to the audit firm to discuss audit protocols, evaluation, expectations, and the final audit report (Sponsor may participate on these calls)
- Provide unfettered access of information to the independent auditors on matters related to the audit
- Submit the original audit report to CMS along with any comments or rebuttals prepared by the Sponsor
- Be responsive to additional requests for information by CMS

# Roles and Responsibilities When Using an Independent Auditor (cont.)

## CMS

- Review and approve audit work plan and schedule prior to the audit
- Review the final audit report and any additional information submitted by the Sponsor
- Request additional calls with the Sponsor and audit firm as needed to answer questions related to the audit results
- Make a determination about whether non-compliant cases found during the audit indicate “new” or “recurring” conditions that are systemic in nature
- Make a final determination about whether to release the sanctions

# Intermediate Sanctions: Lessons Learned and Takeaways



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# Agenda

- Overview
- Sanctions
- Protocol and Working with CMS
- Process – CAPs and Remediation
- Third Party Audit Process
- Lessons Learned

# Overview

- Capital BlueCross – Operates primarily in Central Pennsylvania and the Lehigh Valley in Eastern Pennsylvania
- Products include Medicare Advantage Prescription Drug (PPO and HMO) and PDP Plans
- Strong history in the local market for over 75 years and strong Star Ratings

# Sanctions Overview

- 2014 Audit Protocols
- Program Audit of Capital in April of 2014
- Issue Areas:
  - Organization/Coverage Determinations, Appeals and Grievances
  - Oversight of FDR and Formulary Administration

# Protocol and Process

- Company-Wide Priority and Resources
- Tone and Transparency
- CAPs and Remediation – Move Efficiently but Think Long Term
- Beneficiary Access and Focus
- Mock Audits and Attestation
- Third Party/Independent Validation Audit and Process



# Global Timeline

- Intermediate Sanctions imposed on May 28, 2014
- Intermediate Sanctions released on February 25, 2015

# Lessons Learned

- CMS Partnership
- Top to Bottom Involvement and Buy-In
- Internal and External Resource Management
- Long-Term Solutions (Process, People, Policies and Training)
- Test and Validate
- Not sure.... Ask
- Goal – Get it Right and React Efficiently When Issues Arise

# Enforcement Website

Please see the Part C and Part D Compliance and Audits webpage where all of the enforcement actions are posted:

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

# QUESTIONS

