

# ***Enforcement Analysis Process***

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# Introduction



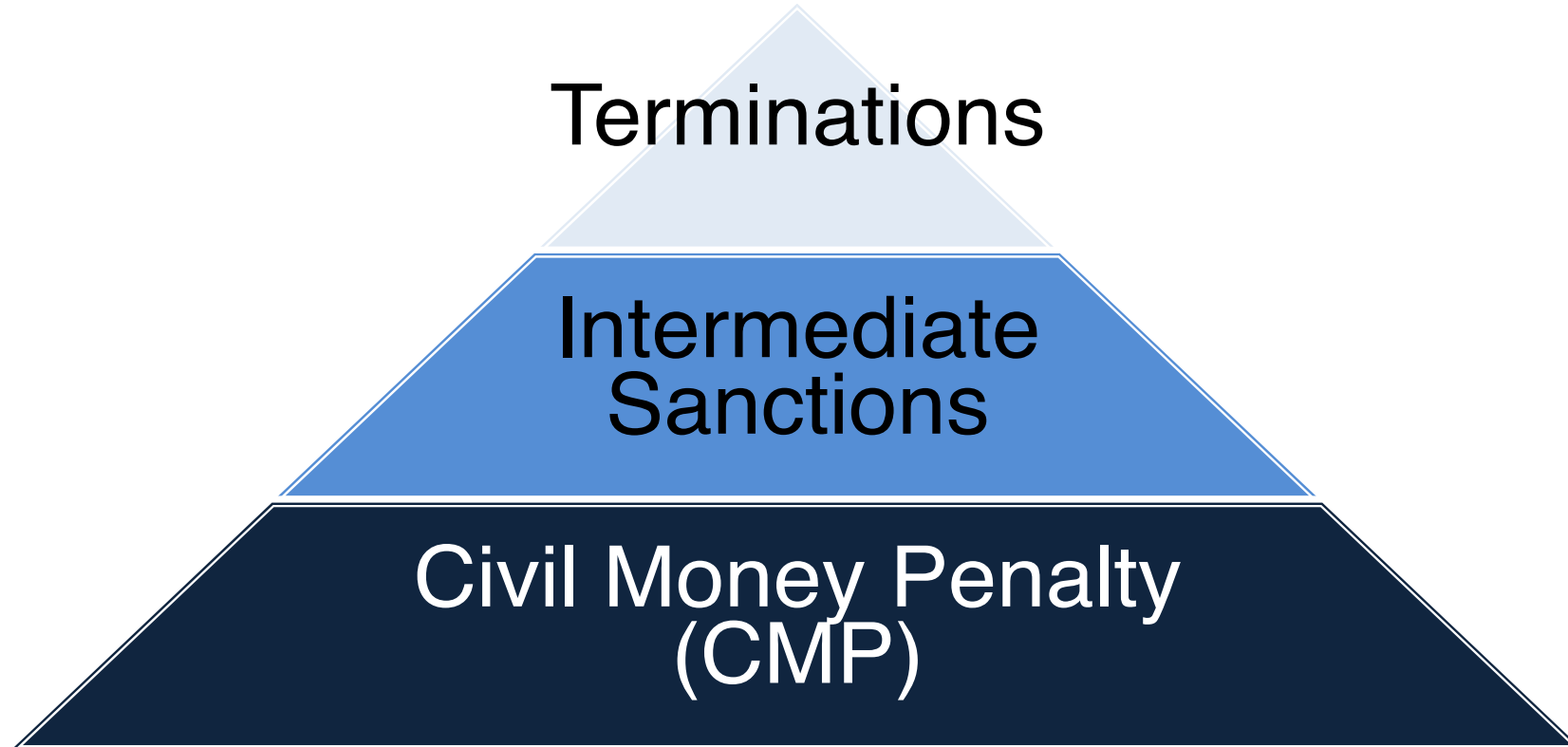


# Overview



- Enforcement Actions Overview
- Program Audit CMP Analysis Process
- CMP Calculation
- Sanction Analysis Process
- Analysis Process for Other Referrals
- Polling Questions
- Q & A

# *Enforcement Actions Overview*



# *Enforcement Actions Overview (continued)*

## Purpose of Enforcement Actions

Protect Medicare  
Beneficiaries

Compliance with  
Regulations

# *Program Audit CMPs*

Step 1	Receive referral
Step 2	Research the issue and gather data and documentation
Step 3	Analysis
Step 4	Final determination
Step 5	Use CMP methodology to calculate CMP
Step 6	Notification of CMP

## Basis for referral

- Audit score
- ICARs
- Impact to beneficiaries

## Email notification of referral

- Approximately when draft audit report is received



# *Research Issue/Gather Data and Documentation*



- Review audit documentation
- Outreach to audit team
- Outreach to sponsor
- Detailed review of impact analysis (IAs)
- IA validation
- Responses to the draft audit report



# *Analysis*

1) Violation of a clear requirement

2) Violation was substantial

- Number or % of enrollees impacted
- Number of cases that failed
- Root cause

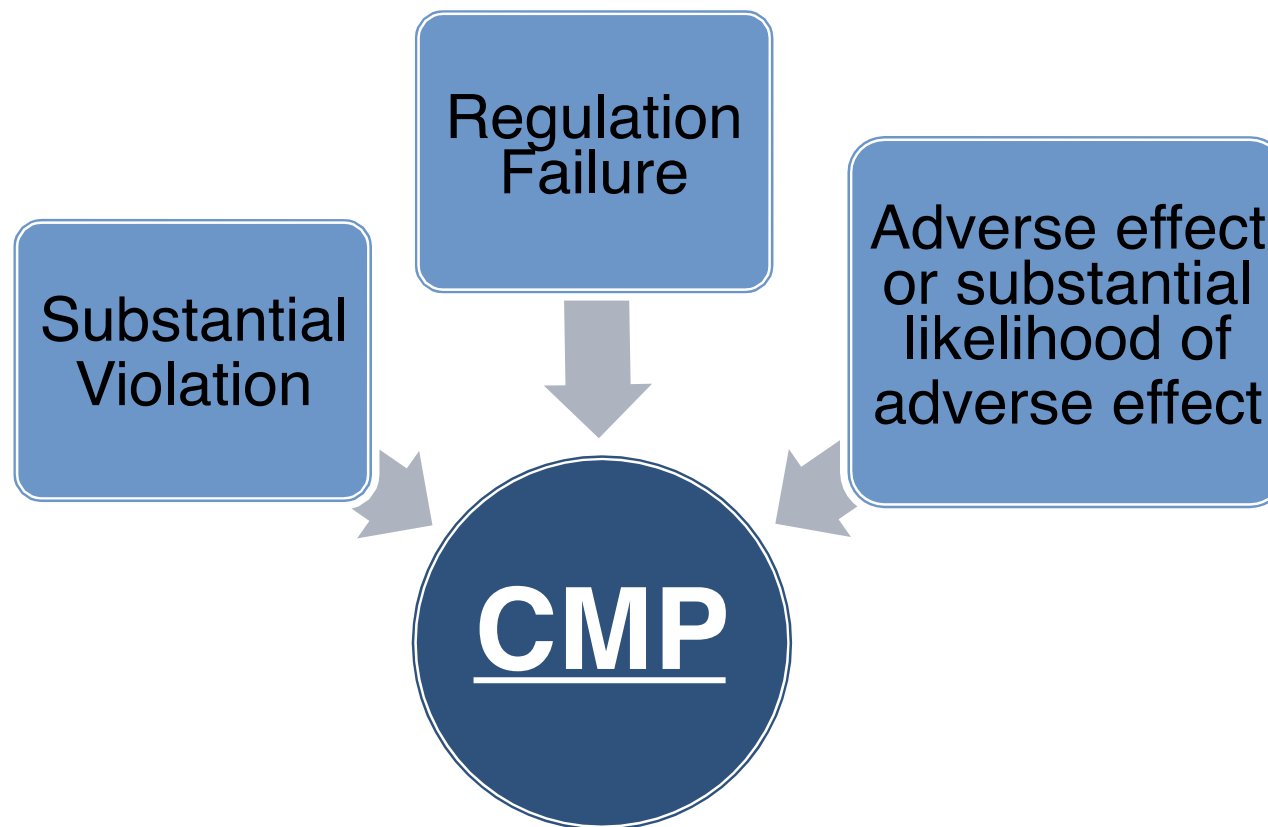
# *Analysis (continued)*

## 3) Adverse effect or substantial likelihood of adverse effect to enrollees

- Delay or denial of access to drugs or services
- Access to appeal process was impeded
- Financial impact

## 4) Other Considerations

# *Final Determination*



# *Calculation of CMP*

- IA (if available) is used to calculate the total CMP amount
- Each beneficiary is counted once for a violation
- A standard penalty amount is tied to each beneficiary
- Aggravating factor amounts may be added to the standard penalty amount

# Example of Calculation

<b>VIOLATION # 1 CMP CALCULATION PER ENROLLEE</b>		
<b><i>Standard Penalty</i></b>		
Inappropriate delay/denial of Part D drugs	\$200	
Number of Enrollees Adversely Effected (or Substantial Likelihood)	533	
Standard Penalty Subtotal		\$106,600
<b><i>Aggravating Factor #1</i></b>		
Delay/denial of drugs that generally require access to prescription drugs within 24 hours in order to treat acute conditions or maintain the therapeutic treatment of non-acute conditions	\$100	
Number of Enrollees	46	
Penalty Adjustment		\$4,600
<b><i>Total CMP Amount</i></b>		<b>\$111,200</b>



# *Calculation Updates*



- CMP Methodology published last year
- More enrollment bands for capping CMP amounts
- Removal of enrollees whose adverse impact was substantially mitigated

# *CMP Notification*

- DCE calls the sponsor prior to issuing a CMP
- CMP notice emailed to the CEO or highest level of senior executive for the sponsor
- Calculation template shared
- Conduct follow-up calls if there are any questions
- Appeal process included in the CMP notice



# *Sanctions – Data from Audit*



- Number of conditions
- Major breakdowns in certain program areas
- Compliance program failures
- Organizational culture
- Number of beneficiaries impacted
- IDS conditions
- Concerns about lack of program knowledge





# *Sanctions – Additional Research*



- Speak with Account Managers
- Review complaints
- Review compliance notices
- Discuss concerns with other CMS components



# *Other Referrals*



- ANOC/EOC Referrals
- IRE Auto-Referrals
- 1/3 Financial Audits
- PACE Audits

# *Polling Question #1*

DCE receives a referral where the sponsor has misclassified coverage determinations as grievances. There are 3 cases that failed on audit and the sponsor submits an IA showing that a number of enrollees either never had a coverage determination started or they never received their requested medication. Sponsor's root cause is that they do not accept oral coverage determinations from enrollees. Does DCE:

- A. Consider this for a CMP
- B. Consider this for a sanction
- C. Decide not to pursue any enforcement action

# *Polling Question #2*

DCE receives a referral where the plan has denied claims from non-contracted providers when the beneficiary was referred by the contract provider. Sponsor submits an IA showing that a number of enrollees were billed by the non-contracted provider or cannot confirm whether the enrollees received bills from the non-contract providers. Does DCE:

- A. Consider this for a CMP
- B. Consider this for a sanction
- C. Decide not to pursue any enforcement action

# *Polling Question #3*

DCE receives a referral where the plan had a high number of conditions in the area of CDAG, including IDS conditions where the plan couldn't produce universes for the audit team. There were also several concerning conditions in the Compliance Program portion of the audit. Does DCE:

- A. Consider this for a CMP
- B. Consider this for a sanction
- C. Decide not to pursue any enforcement action

# *Polling Question #4*

DCE receives a referral where the sponsor had failed to cover medications because they were imposing quantity limits that were more restrictive than what was approved on its formulary. Most of enrollees in the impact analysis received their medication within the same day. In addition, this issue had been identified by the sponsor quickly and they had worked to fix the issue as soon as it was discovered. Also, beneficiaries who did not receive their medications were remediated quickly. Does DCE:

- A. Consider this for a CMP
- B. Consider this for a sanction
- C. Decide not to pursue any enforcement action



# Questions?



- Contact the Audit and Enforcement Mailbox at:  
[part\\_c\\_part\\_d\\_audit@cms.hhs.gov](mailto:part_c_part_d_audit@cms.hhs.gov)