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Trends in CMS Audits and Enforcement Actions Against Medicare Advantage and Part D Plans

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Health Care Compliance Association
Managed Care Compliance Conference
February 2, 2016

Agenda

- 2015 CMS Program Audit Tracer Sample Methodology
  - Implications for Plans and First Tier, Downstream and Related Entities (FDRs)
- Effective Self-Disclosure
  - Self-Disclosure in Audit Process
- Analysis of Recent Enforcement Actions

2015-2016 CMS CPE Program Audit Process

- Sponsor Disclosed and Self-Identified Issues of Non-compliance
  - Include only those relevant to areas being audited,
  - For 2016: from the starting date of each universe period, through the date of the audit start notice
- Data Universes
  - First-Tier Entity Auditing and Monitoring (FTEAM)
  - Employee and Compliance Team (ECT)
  - Internal Auditing (IA)
  - Internal Monitoring (IM)
  - Fraud, Waste and Abuse Monitoring (FWAM)
- Tracer Samples

CMS Tracer Sample Methodology

- CMS will select 6 tracer samples (compliance and/or FWA activities or events)
- All 6 tracer samples will be pulled from Plan's universe submissions
- CMS reserves the right to substitute or select additional tracers from internal or external resources.
- Each tracer sample case is used to evaluate all applicable compliance program requirements.

Tracer Audit Elements

I. Written Policies, Procedures & Standards of Conduct

II. Compliance Officer, Compliance Committee, Governing Body

III. Effective Training and Education

Tracer Audit Elements

- IV. Effective Lines of Communication
- V. Effective Systems for Routine Auditing & Monitoring
- VI. Procedures & Systems for Promptly Responding to Compliance Issues
- VII. Accountability for and Oversight of FDRs

CMS Audit Findings & Mitigation Strategies

I. Written Policies, Procedures & Standards of Conduct

- Sponsor did not distribute its standards of conduct (SOC) and policies & procedures (P&Ps) to employees and volunteers who support the Medicare business, within 90 days of hire, when there were updates to the P&Ps and annually thereafter

Mitigation Strategies

- Collaborate with business units and HR to identify employees & volunteers who support the Medicare plan
- Develop reporting structure to track distribution of these documents, particularly when compliance P & Ps are revised

CMS Audit Findings & Mitigation Strategies

II. Compliance Officer, Compliance Committee & Governing Body

- Sponsor's compliance officer or his/her designee did not provide updates on results of monitoring, auditing and compliance failures (i.e. Notices of Noncompliance to formal enforcement actions) to the compliance committee, senior executive/CEO, senior leadership, and governing body
- Unable to demonstrate governing body had knowledge about operations of Medicare Compliance program & exercised reasonable oversight with respect to implementation and effectiveness of Medicare Compliance Program, especially regarding CMS notices of non-compliance and results of internal and external audits

Mitigation Strategies

- Develop and utilize MCO report template, which includes 7 elements
- Ensure meeting minutes contain sufficient detail to reflect feedback, guidance, or direction provided to MCO

CMS Audit Findings & Mitigation Strategies

III. Training and Education

- Unable to demonstrate distribution of Code of Conduct, Compliance and FWA training to its volunteers who supported Medicare line of business.

Mitigation Strategies

- Presence of adequate processes and systems, which ensure that its employees, volunteers, and/or governing body members received required compliance and FWA training
- Maintain supporting documentation of training efforts

CMS Audit Findings & Mitigation Strategies

IV. Effective Lines of Communication

- Waited until annual ethics training to update employees about changes to compliance P&Ps
- Did not maintain documentation that showed dissemination of HPMS memos in timely manner to all applicable parties

Mitigation Strategies

- Develop and implement training policy & procedure to support timely notification to employees regarding changes to compliance P&Ps
- Develop and implement tracking mechanism for HPMS memos

CMS Audit Findings & Mitigation Strategies

V. Effective Systems for Routine Auditing and Monitoring

- Did not verify OIG & GSA exclusion list for parent organization employees on a monthly basis & its FDRs prior to hiring or contracting & monthly thereafter
- Did not establish and implement a formal risk assessment and an effective system for routine monitoring and auditing of identified compliance risks
- Did not monitor and audit to test compliance with Medicare regulations
- Staff dedicated to audit function did not have adequate knowledge of Medicare requirements

Mitigation Strategies

- Implement reporting and tracking process for OIG & GSA
- Develop and implement formal risk assessment process
- Develop regulatory notification process that captures information from business owners

CMS Audit Findings & Mitigation Strategies

VI. Procedures & Systems for Promptly Responding to Compliance Issues

- Lacked root cause analysis to determine why issue occurred
- Did not conclude investigation within reasonable time after issued discovered
- Corrective actions were not designed to prevent future non-compliance
- Did not maintain thorough documentation of all deficiencies identified and corrective actions taken resulting from an external review of its compliance program effectiveness

Mitigation Strategies

- Include root cause analysis and beneficiary impact for all issues
- Develop a robust standard template for development and tracking of corrective action plans that includes time lines and post-implementation testing
- Develop, document, and retain P&Ps

CMS Audit Findings & Mitigation Strategies

VII. Accountability for and Oversight of FDRs

- Did not provide evidence that general compliance information was communicated to its first tier, downstream related entities (FDRs).
- Did not monitor & audit to test compliance with Medicare regulations
- Inconsistent monitoring FDRs as didn't address all Medicare requirements
- Did not provide adequate oversight over its PBM to ensure coverage determinations, appeals, and grievances were processed in accordance with CMS requirements
- Could not demonstrate that entities downstream from First Tier Entities also performed required training.

Mitigation Strategies

- Utilize tracking mechanism that captures distribution of changes in Plan's compliance P&Ps and Medicare regulations or requirements
- Include FDRs in annual risk assessment
- Receive, evaluate, and react to FDR operational compliance metrics
- Include FDR issues and activities in MCO reports
- Ensure regulatory oversight process requires a response from the FDRs regarding their evaluation of the HPMS notice and include a description as to how current operations support the guidance or actions that need to be taken in order to achieve compliance

FDR Oversight Best Practice, Tips & Tools

1. Share audit tools with Delegates so that they clearly understand the elements they are responsible for performing and how they will be measured
2. Frequent communication with Delegates to confirm understanding of CMS regulatory and sub-regulatory requirements; this can be a monthly or quarterly Joint Operating Meeting which includes updates on the delegation relationship with current performance standards and current compliance status, including CAP updates as needed
3. Assign a specific auditor to a group of delegates. Helps to create understanding of specific delegate issues and needs. All have different systems, forms, etc.

FDR Oversight Best Practice, Tips & Tools

4. Conduct periodic reviews and assessments of written arrangements/contracts
5. Tie delegate results to auditor performance, supported by QA review
6. Consistent monitoring and follow-up by the Plan to ensure corrective actions are implemented by Delegates
7. Establish an active Delegation Oversight Committee that reports to the Quality or Compliance Committee

Effective Self-Disclosure
Self-Reporting as a Mechanism for Managing Risk

- Self-reporting outside of a CMS Audit
  - When self-reporting is mandatory
  - Factors to consider in self-reporting

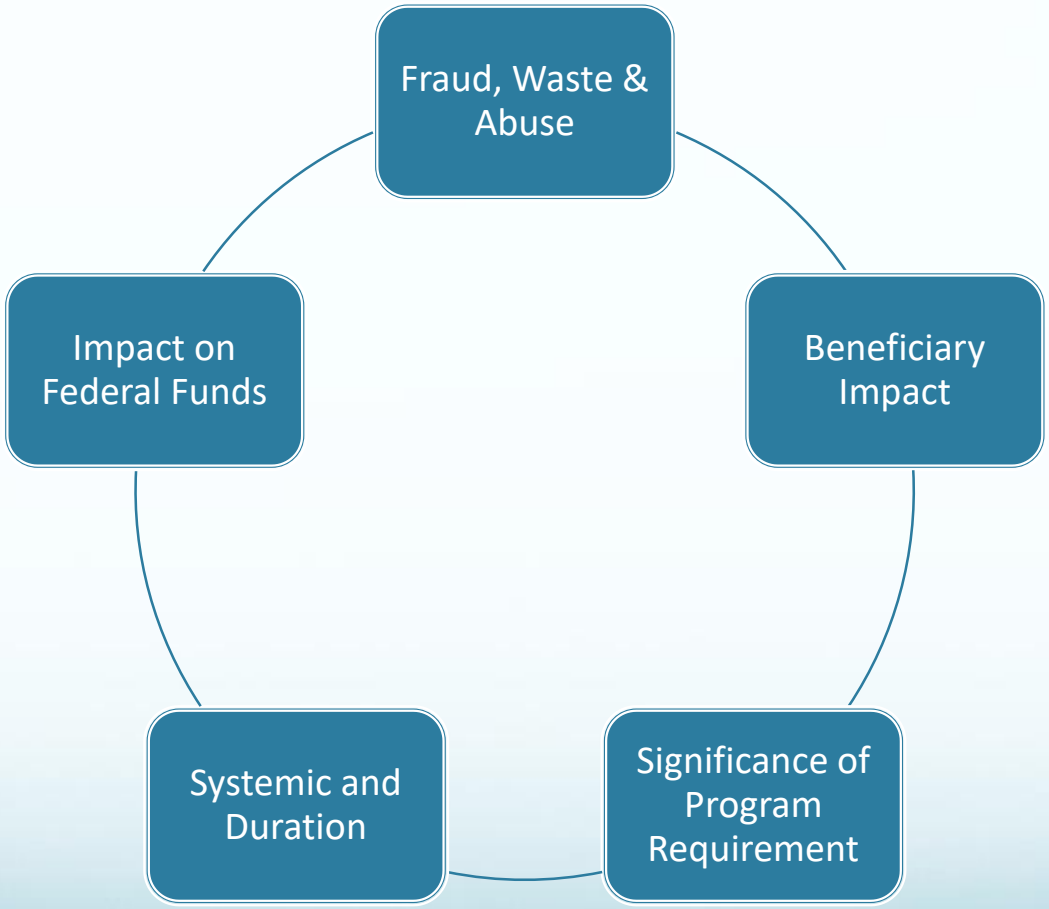
- Self-disclosure and the CMS audit process

Voluntary Self-Reporting

- Self-reporting is *not* required by the Social Security Act
- "Self-reporting of FWA and Medicare program compliance is voluntary."
- Past efforts to make self-reporting mandatory by regulation have not been finalized.
  - Ex. Federal Register, Vol. 72, No. 233 (Dec. 5, 2007) at 68700

Medicare Managed Care Manual, Chapter 21 and Prescription Drug Benefit Manual, Chapter 9, Compliance Program Guidelines (CPGs), § 50.7.3

Factors to Consider in Self-Reporting



When You Must Self-Disclose: Overpayment

- Report and return within 60 days of identification
- Look-back period of six most recently completed payment years
- Enforced through False Claims Act
  - Amounts retained past deadline become reverse false claims under 31 USC 3729(b)

42 CFR §§ 422.326, 423.360; Cheri Rice, Director, Medicare Plan Payment Group, "Guidance for Reporting and Returning Medicare Advantage Organization and/or Sponsor Identified Overpayments to the Centers for Medicare and Medicaid Services," HPMS Memo, February 18, 2015 p. 5

Overpayment Categories

CMS Consideration of Self-Disclosure in the Audit Process

- Pre-Audit Issue Summary
- Sponsors must provide CMS with a list of all previously disclosed and self-identified issues of non-compliance that may be found in data universes.
  - Submitted with 5 days of issuance of the audit start notice.
  - Must include each issue's remediation status.
  - From the starting date of universe period through date of the audit start notice (2016).

Gerald Mulcahy, Director, Medicare Parts C and D Oversight and Enforcement Group, "2015/2016 Program Audit Protocols and Process Updates," October 20, 2015; CY 2016 Addendum to Audit Protocols.

Disclosed or Self-Identified?

Disclosed

Reported to CMS prior to the date of the audit start notice

Self-Identified

Notification made after the audit start notice or discovered by CMS

Real Question: Was the Issue Fixed?

- Correction determined based on status prior to the receipt of the audit start notice.
- "Corrected" if evidence of appropriate and adequate remediation before the receipt of the audit start notice.
- Issues that are reported as corrected prior to the audit universe period will be assumed to be corrected (2015).

Gerald Mulcahy, Director, Medicare Parts C and D Oversight and Enforcement Group, "2015/2016 Program Audit Protocols and Process Updates," October 20, 2015

Importance of Timely Correction

- If reported as corrected during the audit universe review period, the correction will be validated.
  - If correction is validated, will be noted as an observation.
  - If cannot be validated, will be cited as a condition.
- If reported as corrected after the date of the audit start notice, treated as uncorrected.
- If reported as uncorrected, automatically cited as a condition.

Gerald Mulcahy, Director, Medicare Parts C and D Oversight and Enforcement Group, "2015/2016 Program Audit Protocols and Process Updates," October 20, 2015

If you didn't know about it ….

- You couldn't have fixed it.
- If the issue is identified during the course of the audit, CMS will cite the applicable conditions in the audit report.
- Pre-Audit Issues Summary is not easy and cannot be left to the last minute.
  - Ongoing compilation and evaluation of the same factors that are self-reporting considerations.
  - Requires an effective compliance program.

Gerald Mulcahy, Director, Medicare Parts C and D Oversight and Enforcement Group, "2015/2016 Program Audit Protocols and Process Updates," October 20, 2015

Validation of Correction of Deficiencies

- Plan sponsors can be required to hire independent auditors to validate the correction of deficiencies found in program and CMS provided a copy of the audit findings.
  - Audit remains open during the validation process.
  - Must validate correction of all sanction-related and non sanction-related conditions.
  - "Clean" period for validation is the same length as audit universe period.
- CMS estimates cost of 2M per year:
  - 75% of 30 organizations audited per year
  - $1,202 per hour for each audit team
  - 80 hours per validation
  - $96,160 per sponsor

80 Fed. Reg. at 7956, 7960, 7964 (42 CFR §§ 422.503(d)(2), 423.504(d)(2)); Gerald Mulcahy, Director, Medicare Parts C & D Oversight and Enforcement Group, "Independent Auditor (IA) Validation Process for Medicare Advantage and Prescription Drug Plan Program Audits," November 12, 2015, HPMS Memo.

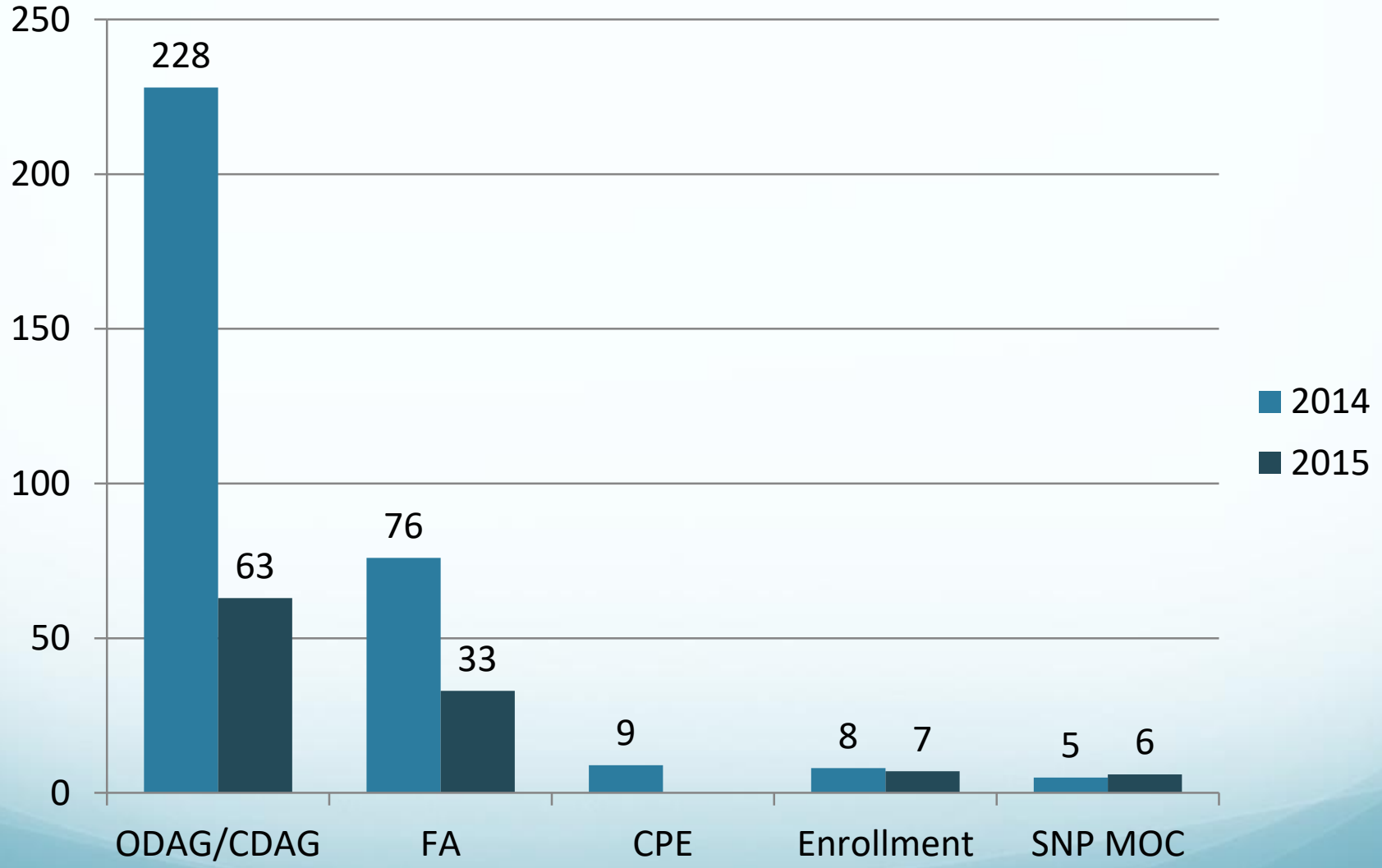
In-Depth Analysis of 2014 and 2015 Enforcement Letters

- Distinct from CMS Common Audit Findings memos, which include data from all audits conducted in a year, including those of high-performing plans that receive no penalties
- We analyzed findings from plans with enforcement penalties
- Broke out every finding by operational area and subcategorized by type
- Functions performed by vendors and internal operations
- Number of enforcement letters:
  - 35 letters in 2014
  - 22 letters in 2015

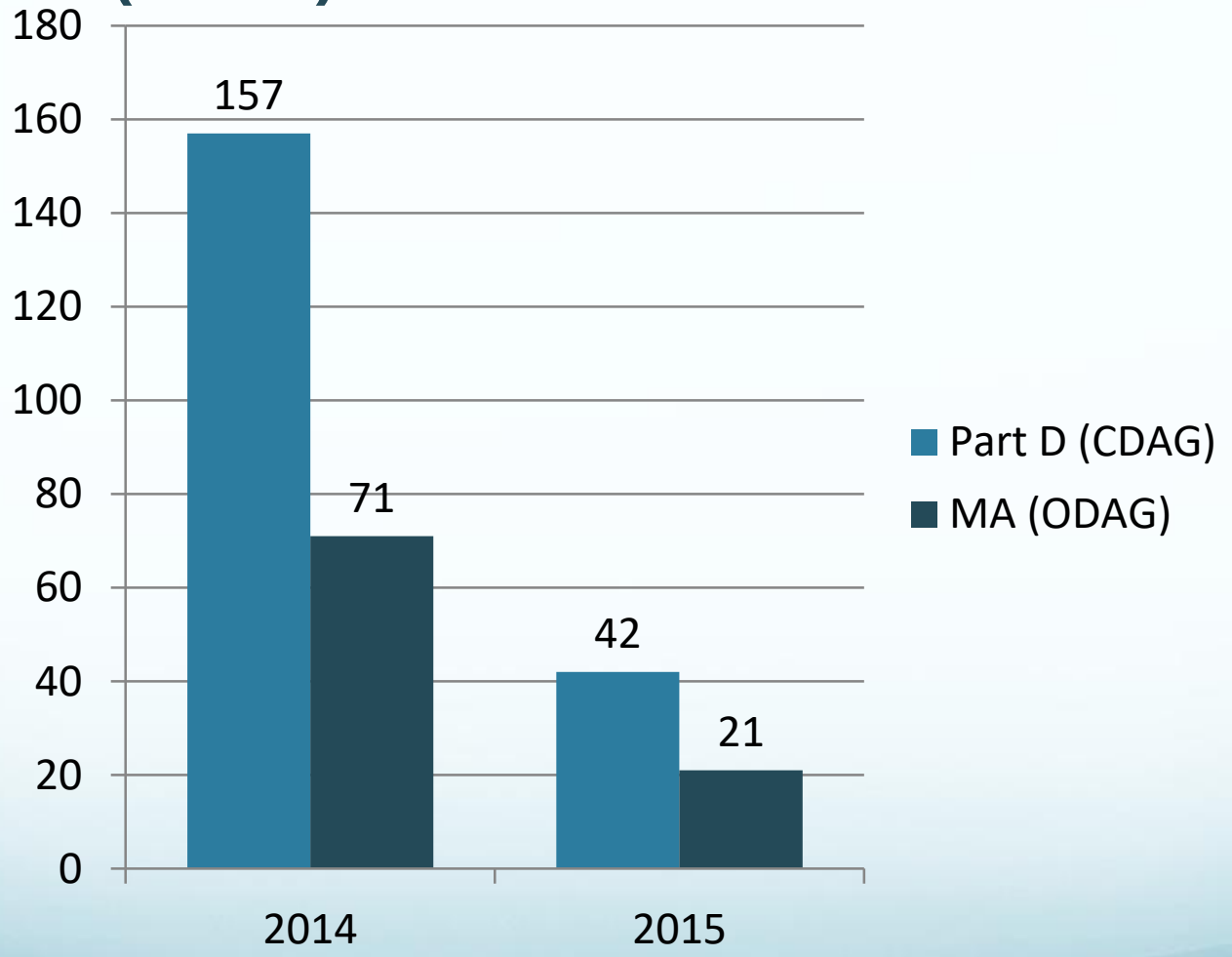
Goals

1. *Identify greatest legal risk*
2. *Clarify where to focus compliance and audit resources*

2014 and 2015 Enforcement Letters Findings by Functional Area



Organization Determinations, Appeals & Grievances (ODAG) v. Coverage Determinations, Appeals & Grievances (CDAG)



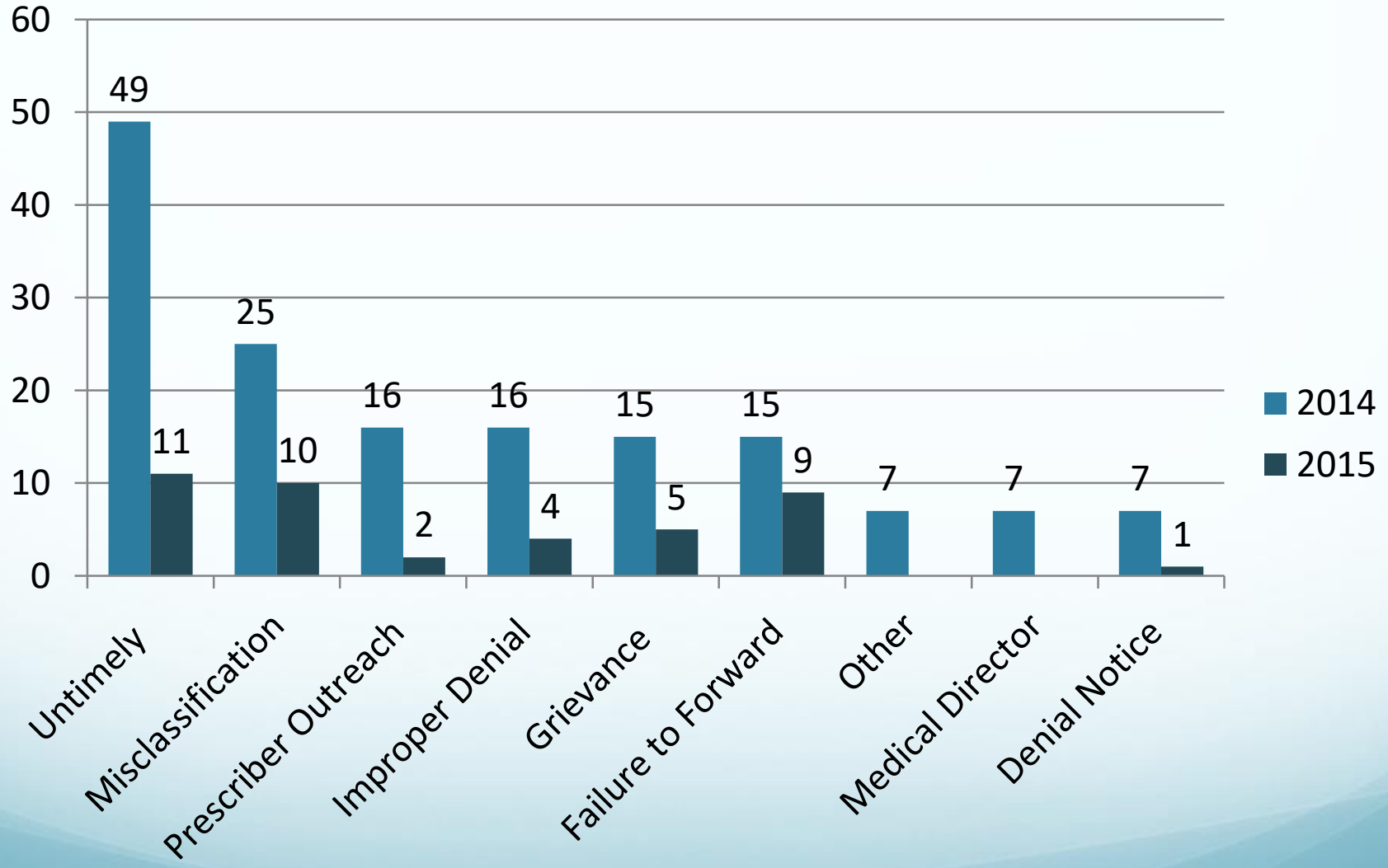
Thinking About MA vs. Part D Risk

- Part D (CDAG) = 68% of CDAG/ODAG Findings in 2014 and 2015 (199 of 291 Findings)
- Even 68% is an understatement of proportion of Part D risk
  - Part D – higher claims volume
  - Likely many more occurrences and affected beneficiaries associated with each finding
  - Relevant to penalty calculation and sanction severity assessment

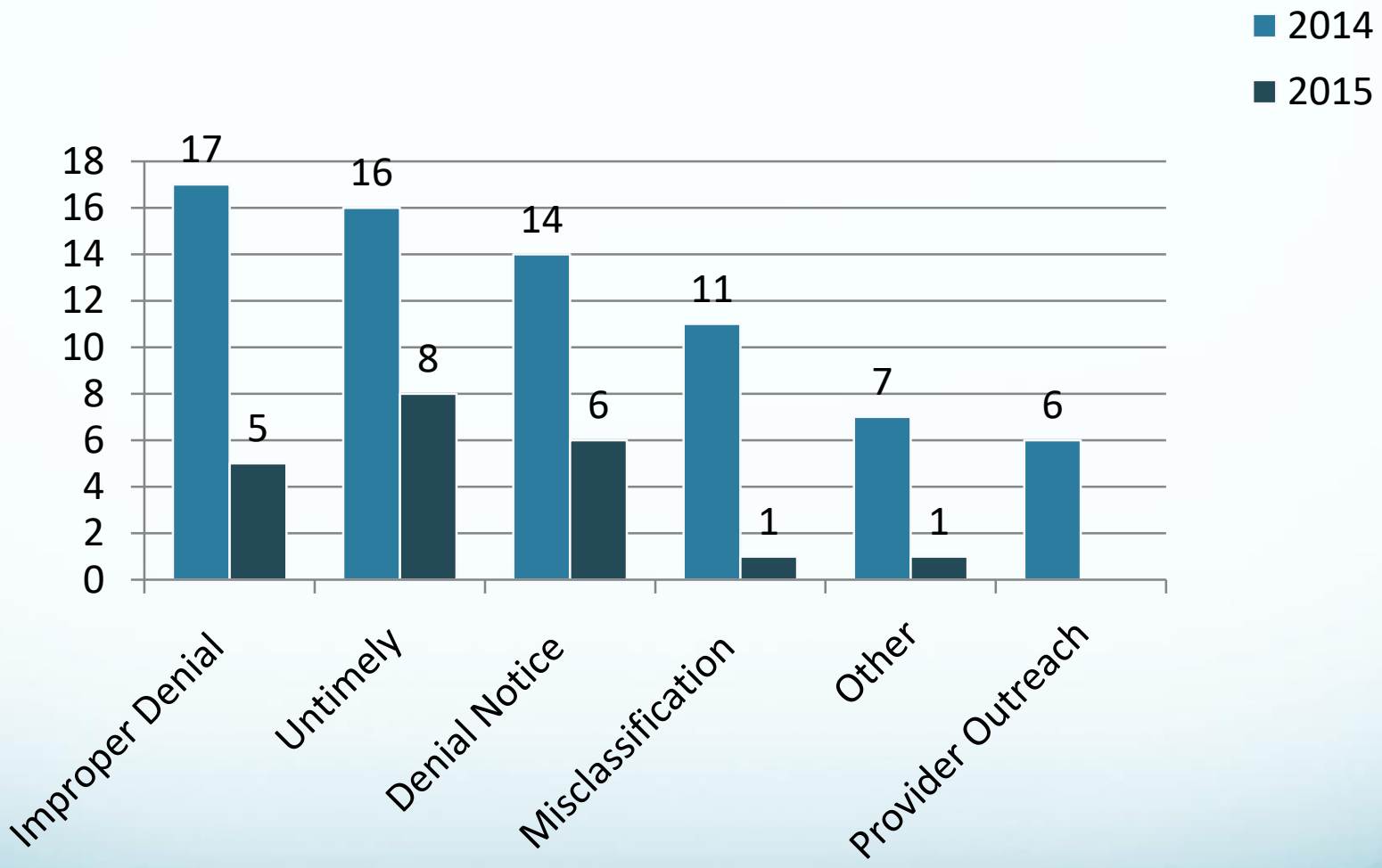
Key to Abbreviations on Slides 32-34

- CPE - Compliance Program Effectiveness
- Denial Notice – Inadequate Denial Notice
- FA - Formulary Administration
- Failure to Forward - Failure to Forward to IRE
- Grievance - Grievance Process
- Medical Director – Insufficient Medical Director Involvement
- Prescriber Outreach – Inadequate Prescriber Outreach
- SNP MOC – Special Needs Plan Model of Care
- Untimely – Untimely Notice and/or Effectuation

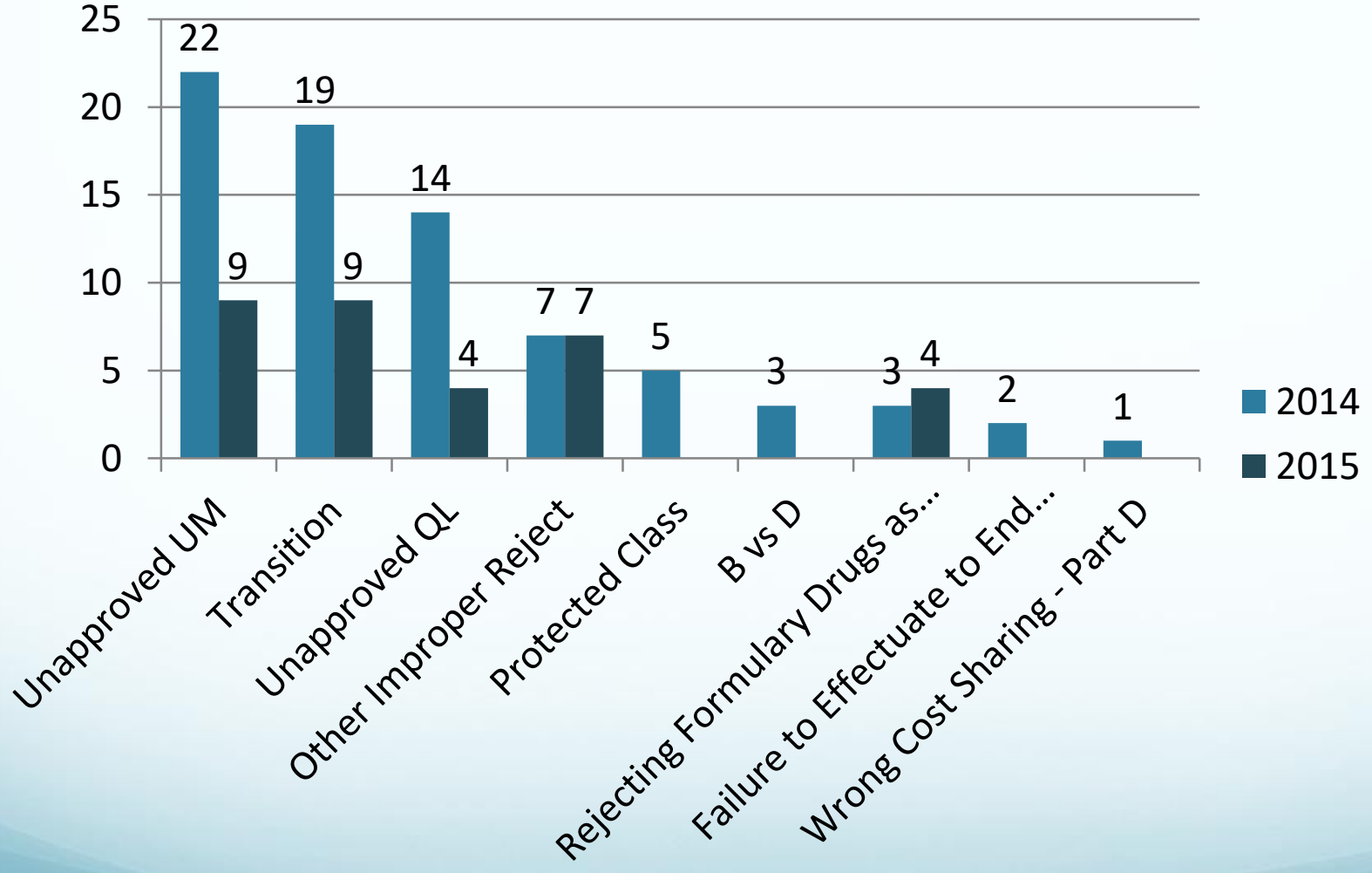
2014 and 2015 Part D CDAG Findings



2014 and 2015 MA ODAG Findings



2014 and 2015 Formulary Administration Findings



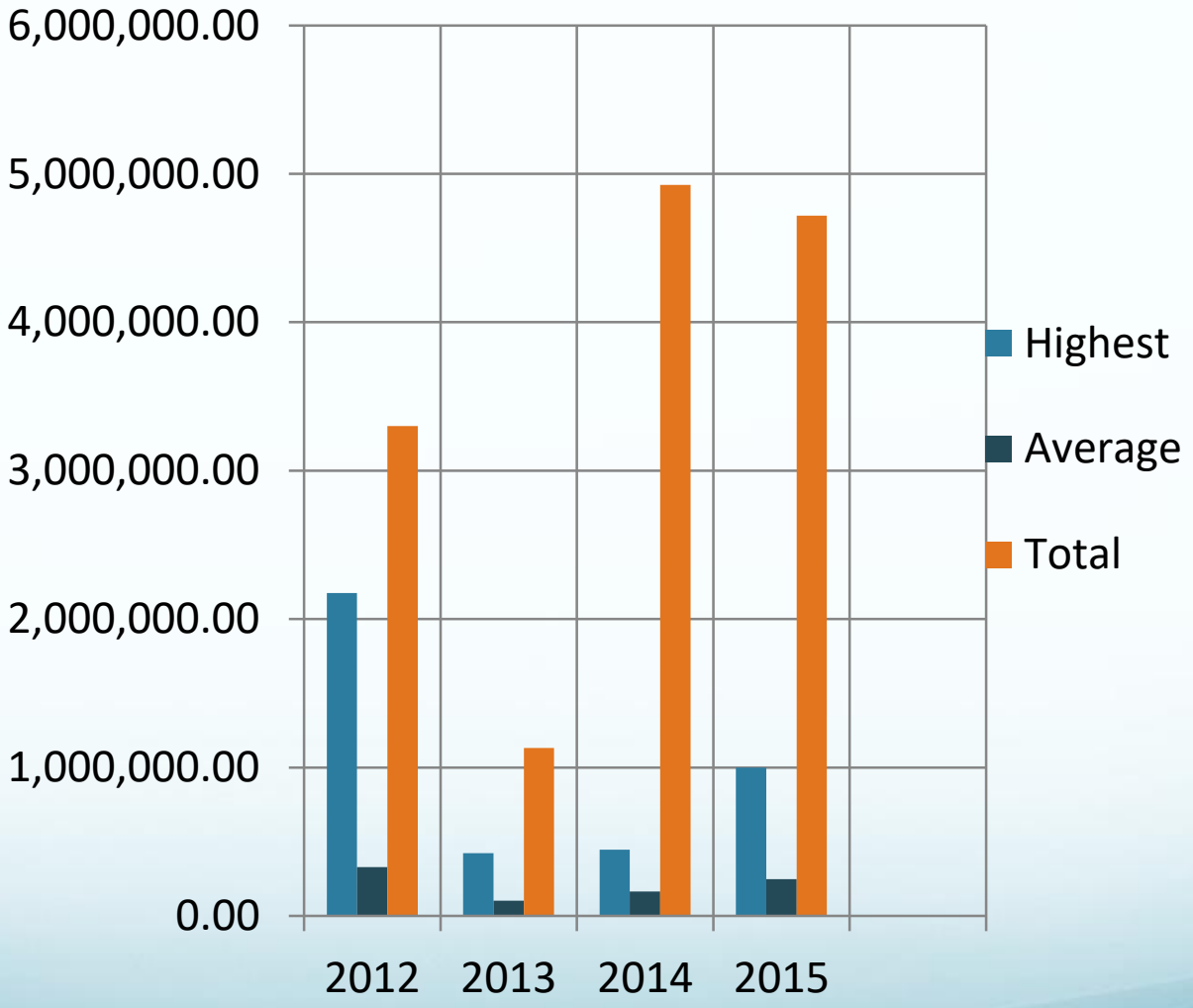
CMS Civil Monetary Penalties

- **Penalty amounts**
  - Up to $25,000 per finding that has adversely affected an enrollee (or substantial likelihood of adverse effect)
  - Up to $25,000 per enrollee adversely affected (or substantial likelihood of adverse effect)
  - Up to $10,000 for each week that deficiency remains uncorrected after notice of CMS determination

  Authority to Impose CMPs: 42 CFR §§ 422.760, 423.760; OIG Authority: 42 CFR §§ 422.752(c)(2), 423.752(c)(2)

- **Observations**
  - 2012 - 2014 CMPs seem restrained compared with maximum regulatory authority
  - Part D is high risk area
    - Membership
    - Claims volume
- **OIG CMP Authority**
  - In **addition to** or in place of CMS sanctions
  - For same violations as CMS or false, fraudulent, or abusive activities, including submission of false or fraudulent data

MA and Part D Civil Monetary Penalties 2012 - 2015



Factors to Consider in Setting CMP Amount

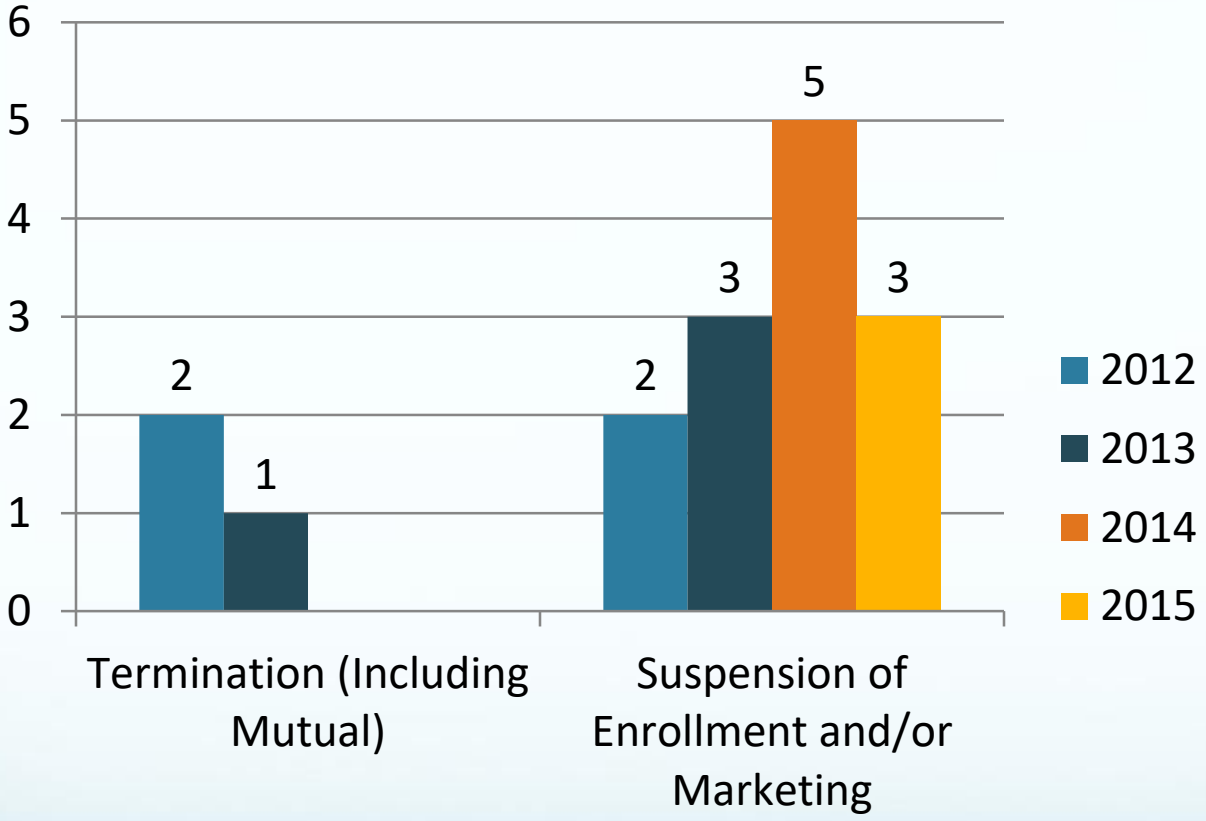
- Factors from Regulation:
  - Nature of the conduct
  - Degree of culpability of plan sponsor
  - Adverse effect on enrollees that resulted or could have resulted
  - Financial condition of plan sponsor
  - History of prior offenses of plan sponsor or principals
  - Other matters as justice may require

42 CFR §§ 422.760(a), 423.760(a)

- Examples of aggravating or mitigating factors:
  - Type of medication of service affected
  - How long beneficiary went without
  - Whether request standard or expedited
  - Whether sponsor previously cited for same failure
  - Number of enrollees adversely impacted (or substantial likelihood of adverse impact)

Ann Levinstim, Division of Compliance Enforcement, "Medicare Part C and Part D Enforcement Actions Update," September 11, 2014

2012 to 2015 MA and Part D Sanctions



Bases for Enforcement Actions – Sanctions and CMPs

- Healthcare related
  - Delay or denial of access to healthcare or medication
- Additional grounds
  - Imposing excess premiums
  - Improper disenrollment or refusal to re-enroll
  - Any practice reasonably expected to deny or discourage enrollment for health reasons
  - Misrepresentations to government or individuals or entities
  - Employing or contracting with excluded individual or entity (including downstream)
  - Enrolling individual without consent
  - Failure to comply with marketing regulations or guidance
  - ***Employing or contracting with anyone who commits one of the above violations***

42 CFR §§ 422.752, 423.752

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