Strategic Considerations in Resolving Voluntary Government Disclosures

Health Care Compliance Association
Annual Compliance Institute

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Agenda

• Review relevant legal authorities
• Discuss CMS Final Overpayment Rule and obligations
• Review CMS and OIG self-disclosure protocols
• Discuss practical strategies and key considerations for disclosures
Determine Potential Liability

Relevant legal authorities:

- False Claims Act
- CMS 60-day Overpayment Final Rule
- Civil Monetary Penalties Law (CMP)
- Anti-Kickback Statute (AKS)
- Physician Self-Referral (Stark) Law
- OIG Exclusion

False Claims Act

The False Claims Act imposes liability on one who:

- Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.
- Knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim.
- Knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the U.S.
FCA

• Knowingly:
  – has actual knowledge of the information, OR
  – acts in deliberate ignorance of the truth or falsity, OR
  – acts in reckless disregard of the truth or falsity.
  – no specific proof of intent to defraud is required.

Overpayment Statutory Requirements

• In general – If a person has received an overpayment, the person shall –
  – report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
  – notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.
    • ACA, Section 6402(a); SSA Section 1128J(d); 42 U.S.C. § 1320a-7k(d)
• An overpayment must be reported and returned by the later of:
  – 60 days after the overpayment is identified, or
  – the date any corresponding cost report is due, if applicable.
• Retained overpayments beyond deadline trigger FCA liability.
CMS 60-Day Overpayment Rule

• Final 60-Day Rule published in 2016
  • see 42 C.F.R. § 401.303 et seq
  – Applies to Medicare Parts A & B
  – Established 6-year lookback period
  – Defined when an overpayment is “identified”
  – Clarified standard of investigation required
    ▪ Reasonable diligence

CMS 60-Day Overpayment Rule

• A person has “identified” an overpayment when the person has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment.

• Reasonable diligence
  – Timely, good faith investigation of credible information
  – Completed within 6 months
    • Except in extraordinary circumstances (i.e. Stark investigations, natural disasters, or states of emergency)
  – Proactive & Reactive
60-Day Clock

- 6 months to conduct reasonable diligence after receiving credible information of a potential overpayment.
- The 60-day clock begins to run:
  - after reasonable diligence identifies an overpayment, OR
  - when credible information was received
    - (if the provider failed to conduct reasonable diligence and in fact received an overpayment)

Options for Disclosure

- Refund to Medicare Contractor
- CMS SRDP
- OIG SDP
- State Medicaid Agency
- DOJ
Refund to CMS Contractor

- Identified overpayments
- Satisfies report and return obligation
- Simple Process
  - Claims adjustment
  - Credit balance
  - Contractor refund process
- No release

CMS Self-Referral Disclosure Protocol (SRDP)

- Actual or potential Stark violations only
- Separate from Advisory Opinion process
- Release of Stark overpayment liability only
- No FCA, CMP, or AKS release
- Stop 60-day clock
- Potential AKS & FCA referral to OIG or DOJ
SRDP Recent Developments

- Lookback period changing from 4 to 6 years
  - Revising information collection authority under Paperwork Reduction Act
  - Currently reporting years 5 and 6 is optional
  - Based on date overpayment is identified
- Pervasiveness of noncompliance
  - Quantitative
  - Not certifying other arrangements were compliant

SRDP Form

- Optional until approved by OMB
- Required information:
  - disclosing DHS entity
  - referring physicians
  - financial analysis quantifying overpayment
  - certification (hard copy and electronic)
- Cover letter with additional information optional
Stark Updates

- Clarification of writing requirement
  - Collection of contemporaneous documents
  - allow reasonable person to verify compliance w/ applicable exception
- Missing signatures (90 days)
- Indefinite holdovers

OIG Provider Self-Disclosure Protocol (SDP)

[Image of OIG Provider Self-Disclosure Protocol]

UPDATED

OIG's Provider Self-Disclosure Protocol

[Logo of U.S. Department of Health and Human Services Office of Inspector General]
OIG/SDP: OIG Administrative Sanctions

- OIG Exclusion Authority
  - § 1128 of the Social Security Act (42 U.S.C. § 1320a-7)

- Civil Monetary Penalties Law (CMP)
  - § 1128A of the Social Security Act (42 U.S.C. § 1320a-7a)

OIG/SDP: CMP Case Types

- Billing while excluded
- Kickbacks and Physician self-referral (“Stark”) violations
- False or Fraudulent Claims
- Reporting and Returning of overpayments
- About 40 other OIG CMPs
  - 42 C.F.R. § 1003.102 catalogues available CMPs
  - 42 C.F.R. § 1003.103 catalogues the amount of penalty and assessment available for each CMP
OIG/SDP: Background

- Created 1998, Updated 2013
- Receive about 100 submissions a year
- What for? Potential violations of federal criminal, civil, or administrative law for which CMPs are authorized
- Not admitting liability

OIG/SDP: Ineligible Submissions

- What is not eligible for OIG’s SDP?
  - Errors or overpayments with no potential violation of CMPL
  - Requests for opinion on whether there is a potential violation
  - Stark-only conduct
  - Settlement less than $10,000 ($50,000 for AKS)
OIG/SDP: Percentage of CMP Monetary Recoveries by Allegation

2016
2015
2014
2013
2012
2011

0.00% 10.00% 20.00% 30.00% 40.00% 50.00% 60.00% 70.00% 80.00% 90.00% 100.00%

- Employment of Excluded Individual
- False Claims
- EMTALA
- Stark/Kickback

OIG/SDP: Resolutions

- Benchmark 1.5 multiplier
  - Claims Calculation
    - All claims or statistical sample of 100 claims minimum
    - Use point estimate (not lower bound)
  - Excluded persons – salary and benefits-based
  - AKS – remuneration-based
- Presumption of no CIA
- Six-year statute of limitations
- Tolling of the 60-day period after submission
- No FCA release, but can help limit exposure, including 60-day issues
- More predictable process, but DOJ may become involved
OIG/SDP: Common Mistakes Providers Make

- States in the initial disclosure or at settlement that there is no fraud liability
- Does not identify potential laws violated
- Discloses the conduct too early
- No plan to quantify damages
- Conduct only violates the Stark law
- Refuses to pay a multiplier
- Lack of cooperation
- Argues damages should be calculated in a manner contrary to the revised SDP

Key Considerations

- Legal exposure
  - Potential overpayment vs. fraud liability
  - Whistleblower concerns
- Releases
- Amount of repayment
- Timing of resolution
- Finality of resolution
- Optics of conduct and resolution
CMS Refund

- Overpayment
- Simple and Fast
- No release
- 6 year lookback period

CMS SRDP

- Historically reasonable settlement amounts
- Stark only release (No AKS, CMP, FCA)
- Delayed resolution
OIG SDP

- 1.5x multiplier
- CMP and exclusion release (No FCA)
- AKS and Stark (w/ colorable AKS conduct)
  - Remuneration based damages
- 6 year SOL
- Tolls 60-day overpayment clock

State Medicaid Agency

- Release of State authorities only
- Uncertain penalty
- Disclosure protocols and procedures vary
DOJ

- Broadest release
- No official disclosure protocol
- Uncertain damages calculation and penalty
- Experience may vary widely

Summary

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<th>Refund</th>
<th>SRDP</th>
<th>SDP</th>
<th>State Agency</th>
<th>U.S. Attorney</th>
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<tr>
<td>• Simple process/</td>
<td>• Track record</td>
<td>• Benchmark 1.5</td>
<td>• Release of State</td>
<td>• Broadest release</td>
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<td>suggests likelihood of</td>
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<td>• No reduction in</td>
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<td>• Release of COMPL and</td>
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<td>Stark only</td>
<td>exclusion</td>
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<td>amount</td>
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<td>• No release of any kind</td>
<td>• 1877(g)(1) release</td>
<td>• Potentially reduce FCA</td>
<td>• Experience may vary</td>
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<td>• Six-year lookback period</td>
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Practical Takeaways

• Conduct timely investigation
• Determine scope of investigation
• Evaluate potential exposure
• Assess disclosure options
  – Weigh benefits and risks

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