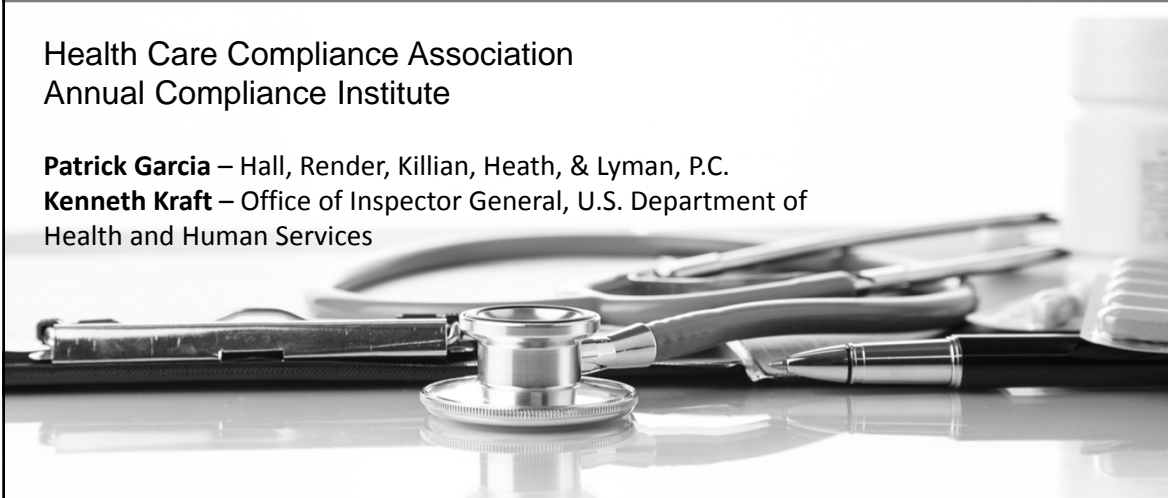


## Strategic Considerations in Resolving Voluntary Government Disclosures

Health Care Compliance Association  
Annual Compliance Institute

**Patrick Garcia** – Hall, Render, Killian, Heath, & Lyman, P.C.

**Kenneth Kraft** – Office of Inspector General, U.S. Department of  
Health and Human Services



## 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



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## 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.

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# 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.



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## 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.

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## 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



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## 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

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## 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)*



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## Options for Disclosure

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



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## Refund to CMS Contractor

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



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## 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



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## 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

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## 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



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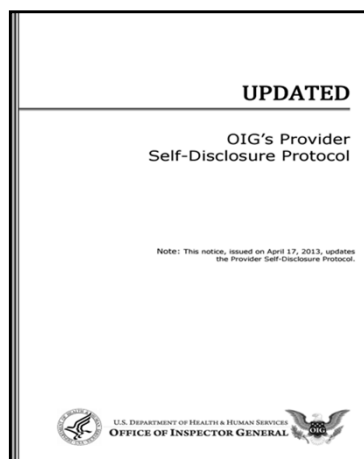
## Stark Updates

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



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## OIG Provider Self-Disclosure Protocol (SDP)



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## 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)



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## 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

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## 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



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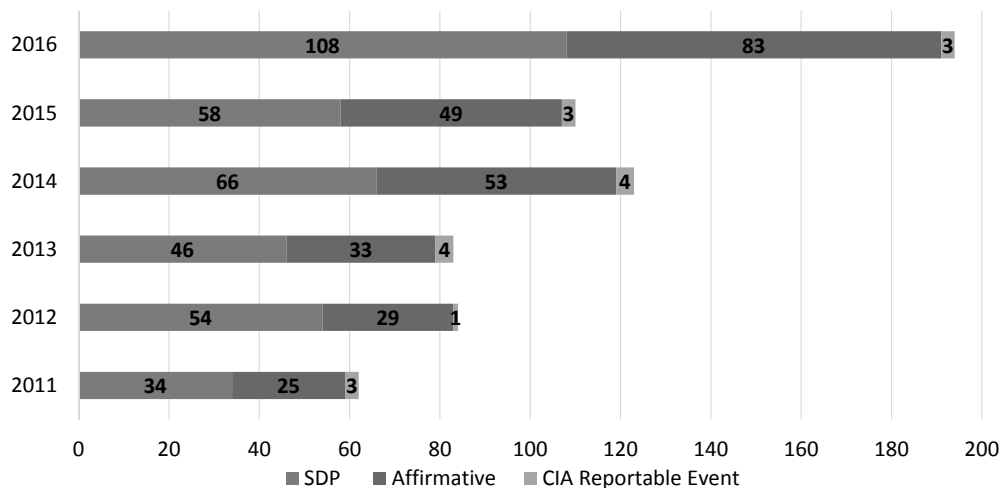
## OIG/SDP: Ineligible Submissions

- 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)



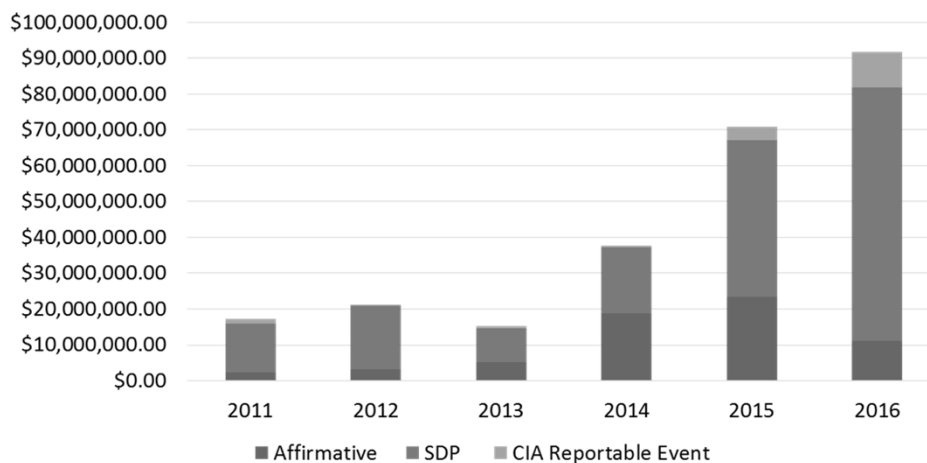
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## OIG/SDP: CMP Settlement Count by Case Type



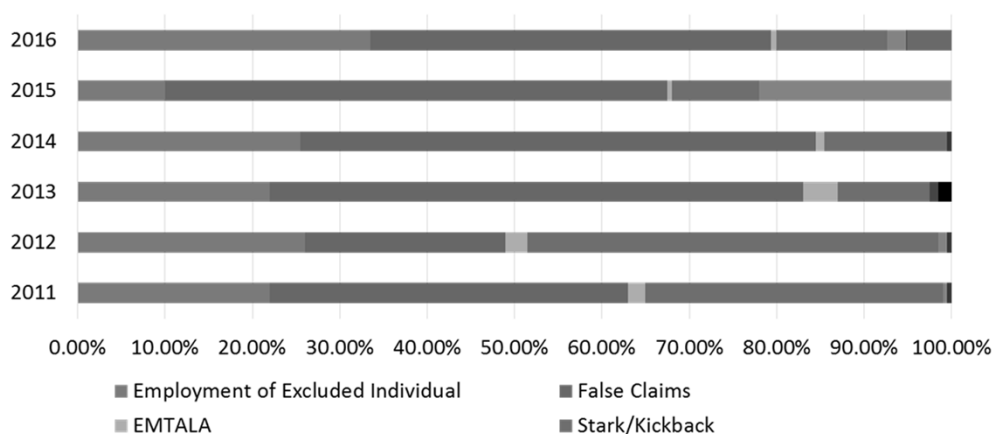
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## OIG/SDP: CMP Monetary Recoveries by Case Type



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## OIG/SDP: Percentage of CMP Monetary Recoveries by Allegation



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## 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



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## 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



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## 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



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## CMS Refund

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



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## CMS SRDP

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

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## 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

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## State Medicaid Agency

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

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## DOJ

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



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## Summary

Refund	SRDP	SDP	State Agency	U.S. Attorney
<ul style="list-style-type: none"> <li>• Simple process/ minimizes legal fees</li> <li>• No reduction in amount</li> <li>• No release of any kind</li> <li>• Six-year lookback period</li> </ul>	<ul style="list-style-type: none"> <li>• Track record suggests likelihood of reasonable settlement</li> <li>• Stark only</li> <li>• 1877(g)(1) release</li> <li>• <i>De facto</i> six-year lookback period</li> </ul>	<ul style="list-style-type: none"> <li>• Benchmark 1.5 multiplier</li> <li>• Release of CMPL and exclusion</li> <li>• Potentially reduce FCA exposure</li> <li>• Updated guidelines</li> <li>• Six-year SOL</li> </ul>	<ul style="list-style-type: none"> <li>• Release of State authorities only</li> <li>• Uncertainty on posture and penalty amount</li> <li>• Experience may vary widely</li> <li>• SOL varies</li> </ul>	<ul style="list-style-type: none"> <li>• Broadest release</li> <li>• Uncertainty on posture and penalty amount</li> <li>• Experience may vary widely</li> <li>• Six-year SOL</li> </ul>

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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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