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Medicare and Medicaid Repayments and Disclosures

Meeting Refund and Reporting Obligations to Comply With Regulatory Requirements

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TOPICS COVERED

- The 60-Day mandatory refund statute and its implications under the False Claims Act
- The final rule implementing the 60-Day refund statute for purposes of Medicare Parts A and B
- The effect of the 60-Day refund requirement on provider operations and compliance programs
- Practical considerations when investigating and auditing potential overpayments
- Options for reporting and repaying identified overpayments
- Effect of the 60-Day refund statute on overpayments involving Medicaid, Medicare Advantage, and Medicaid Managed Care Organizations (MCOs), including the recent decision in *UnitedHealthCare Co. v. Azar*, No. 16-157 (RMC) (D.D.C.) (September 7, 2018)

HYPOTHETICAL

- Hospital Compliance Officer hears from physician practice manager that some of the clinics may not be meeting Medicare “incident to” rules and gives a few specific examples
- No formal audit work yet started
- Physician practices are relatively new business line for hospital

INTRODUCTION

Three Sources of Liability for Failure to Report/Repay Medicare and Medicaid Overpayments

- Overpayment liability under 42 U.S.C. §1320a-7k(d)) –Added by the Patient Protection and Affordable Care Act ("ACA")
- Federal False Claims Act (“FCA”) liability under 31 U.S.C. §3729(a)(1)(G) – Added by Fraud Enforcement and Recovery Act of 2009 ("FERA")
- Civil Monetary Penalty and Exclusion liability under 42 U.S.C. §1320a-7a(a)(10) – Added by the ACA

ACA 60-DAY RULE PROVISIONS

- ACA Section 6402(a) (42 U.S.C. § 1320a-7k(d))

(d) Reporting and returning of overpayments

(1) In general. If a person has received an **overpayment**, the person shall—

(A) **report and return** the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and

(B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.

(2) Deadline for reporting and returning overpayments. An overpayment must be reported and returned under paragraph (1) by the later of–

(A) the date which is 60 days after the date on which the overpayment was **identified**; or

(B) the date any **corresponding cost report** is due, if applicable.

ACA 60-DAY RULE PROVISIONS

(3) Enforcement. Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an **obligation** (as defined in section 3729(b)(3) [the FCA)] for purposes of section 3729.

(4) Definitions.

(A) Knowing and knowingly. The terms "knowing" and "knowingly" [have the FCA meanings].

(B) Overpayment. The term "overpayment" means any funds that a person receives or retains under subchapter XVIII or XIX of this chapter to which the person, after **applicable reconciliation**, is not entitled under such subchapter.

(C) Person

(i) In general. The term "person" means a provider of services, supplier, Medicaid managed care organization (as defined in section 1396b(m)(1)(A) of this title), Medicare Advantage organization (as defined in section 1395w-28(a)(1) of this title), or PDP sponsor (as defined in section 1395w-151(a)(13) of this title).

(ii) Exclusion. Such term does not include a beneficiary.

ACA CMP PROVISIONS

- ACA Section 6402(d) amends the Federal CMP statute
- New 42 U.S.C. § 1320a-7a(a)(10) exposes CMP liability to any person "that **knows** of an **overpayment** (as defined in paragraph (4) of [42 U.S.C. § 1320a-7k(d)]) and does not report and return the overpayment in accordance with such section."
- Penalties: up to $10,000 for each item or service, plus an assessment of up to three times the amount claimed for each such item or service
- Also potential exclusion from participation in federal health care programs, including Medicare and Medicaid

FINAL RULE FOR MEDICARE PART A/B OVERPAYMENTS

- Provides guidance to mitigate risk but perpetuates uncertainty by relying on several vague terms.
- The Overpayment Refund Buck Stops With Providers – even if they did not cause the overpayment.
- Need to Operationalize the Overpayment Investigation and Refund Process
- "Throwaway" sentences in Preamble important
- Actually, the entire Preamble is important

FINAL RULE FOR MEDICARE PART A/B OVERPAYMENTS

- Published in Federal Register on February 12, 2016 (81 Fed. Reg. 3564)
- Effective March 14, 2016
  - Statutory obligations effective March 23, 2010
  - Reports and returns made before March 14, 2016 require "good faith" compliance with statute
- Applies only to Medicare Parts A and B, Final Rule on Parts C and D published May 23, 2014, no rulemaking yet on Medicaid
- Less than one page of new regulations
- 29 pages of explanations (important to read!)

OVERPAYMENT

- "Any funds a person has received or retained under title XVIII of the Act to which the person, after applicable reconciliation, is not entitled under such title."
- Includes overpayments not caused by provider, such as a MAC edit problem paying for non-covered services
- In general, no offset for underpayments, but check MAC websites on use statistical sampling

EXAMPLES

- Medicare payments for non-covered services
- Medicare payments in excess of the allowable amount for an identified covered service
- Errors and non-reimbursable expenditures in cost reports
- Duplicate payments
- Receipt of Medicare primary payment when another payer had the primary responsibility for payment

EXAMPLES

- Lack of medical necessity
  - Is it a “one-off” situation?
  - Is it part of a pattern?
- Insufficient documentation or other technical shortcoming – consider rationality of the statute in light of economic harm analysis
  - Is documentation a “condition of payment”?
  - Materiality?

DEADLINE FOR REPORTING AND RETURNING

Later of:

- 60 days after the date on which the overpayment was "identified"
- Date "any corresponding cost report is due"
- Deadline may be suspended in some cases
  - OIG or CMS Self-Disclosures (DOJ Disclosure does not suspend)
  - Person requests a payment plan, but only until the request is rejected or failure to comply with the plan

IDENTIFIED AN OVERPAYMENT

- "A 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."
- Overpayment is identified "if the person fails to exercise reasonable diligence and the person in fact received an overpayment."
- Note overpayment in Final Rule not identified until quantified or should have been quantified with reasonable diligence.

IDENTIFIED AN OVERPAYMENT

In the 60-Day Report and Return Proposed Rule, 42 C.F.R. §401.305(a)(2) read:

A person has identified an overpayment if the person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment. 77 Fed. Reg. 9179, 9187 (Feb. 16, 2012)

In the 60-Day Report and Return Final Rule, 42 C.F.R. §401.305(a)(2) read:

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. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment. 81 Fed. Reg. at 7683

IDENTIFIED AN OVERPAYMENT

- The Medicare Act specifies that where the final rule "is not a logical outgrowth of a previously published notice of proposed rulemaking . . ., such provision shall be treated as a proposed regulation and shall not take effect." 42 U.S.C. §1395hh(a)(4).
- CMS used a similar approach in the regulation implementing the 60-day report and return statute for purposes of Medicare Advantage plans.

IDENTIFIED AN OVERPAYMENT

- In *UnitedHealthCare Co. v. Azar*, No. 16-157 (RMC) (D.D.C.) (decision issued September 7, 2018), the Court vacated that regulation, stating (at 29):
- *Agencies may not "pull a surprise switcheroo on regulated entities" by adopting an interpretation that significantly departs from the one proposed. Envtl. Integrity Project v. EPA, 425 F.3d 992, 996 (D.C. Cir. 2005). The Court agrees that CMS did so here, and that 2014 Overpayment Rule imposed a distinctly different and more burdensome definition of "identified" without adequate notice*.
- The Court also vacated that regulation finding that it imposed "FCA consequences" based on a "negligence standard," instead of the "knowing" standard under the FCA. Slip Op. at 26-28.
- Appeal filed but held in abeyance No. 18-5326.

REASONABLE DILIGENCE

- " 'Reasonable diligence' includes both proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayment and investigation conducted in good faith in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment."
- "We believe that compliance with the statutory obligation to report and return received overpayments requires both proactive and reactive compliance."

PROACTIVE COMPLIANCE – WHAT IS IT?

A physician group does not operate what many would consider a formal compliance program, but it monitors whether its claims are getting paid. The group believes that it does a pretty good job billing because most of its claims get paid and seldom are claims denied. Consequently, the group sees no reason to do much more.

PROACTIVE COMPLIANCE

- "We advise those providers and suppliers [that do not have active compliance programs] to undertake such efforts to ensure they fulfill their obligations under section 1128J(d) of the Act."
- "We believe that undertaking no or minimal compliance activities to monitor the accuracy and appropriateness of a provider or supplier's Medicare claims would expose a provider or suppler to liability under the identified standard articulated in this rule. . ."

PROACTIVE COMPLIANCE

Raises Troubling Questions:

- Standard is unreasonably vague in light of risk of possible CMPs, program exclusion, and FCA liability
- Unclear what a provider must do to comply
- If a provider does not but arguably could have discovered an overpayment by being "proactive" has the provider identified the overpayment?
- If so, when does the 60-day deadline commence?
- Will this lead to challenges to the adequacy of providers' compliance efforts?

CREDIBLE INFORMATION

- "Information that supports a reasonable belief that an overpayment may have been received."
- Appears to endorse examples from proposed rule
  - Hotline complaint that qualifies as credible information (i.e., not all hotline complaints)
  - Provider reviews records and learns it incorrectly coded services resulting in increased reimbursement
- Can arise from a single claim
- Pepper Reports, OIG Work Plan, new policies, overpayments involving others in the system

CREDIBLE INFORMATION – WHAT IS IT?

- A provider contracts with a vendor organization to do its cardiac coding and billing. The vendor issues the provider a report on a quarterly basis and the most recent report shows an increase in the provider's Medicare cardiac payments by 25% over the last quarter.
  - Is this Credible Information of a potential overpayment?
  - If so, when was it received?

CREDIBLE INFORMATION

- Provider learns patient death occurred prior to the service date on a claim submitted for payment
- Internal audit reveals overpayments
- Informed by a government agency of an audit that discovered a potential overpayment
- Provider experiences significant increase in Medicare revenue for no apparent reason
- Learning that profits from a practice were unusually high in relation to hours worked or RVUs

CREDIBLE INFORMATION

- Increase in Medicare revenue could be credible information of overpayment
- Rejects comment that a lab or other provider that does not order tests or services must investigate when Medicare volume goes up
- What does the lab investigate under these circumstances?

Office of Inspector General

U.S. Department of Health & Human Services

Reports

_____Hospital Reported Overstated Wage Data Resulting in Medicare Overpayments

Hospital (the Hospital), located in Anywhere, USA, did not always comply with Medicare requirements for reporting wage data in its fiscal year (FY) 2011 Medicare cost report. Specifically, the Hospital reported overstated wage data totaling $4.9 million and 10,000 hours, which affected the numerator and denominator of its wage rate calculation. These errors occurred because the Hospital did not sufficiently review and reconcile the data to ensure that it was accurate, supportable, and in compliance with Medicare regulations. Because of the errors, we estimated that in FY 2014 Medicare overpaid the Hospital approximately $249,000 and overpaid five other hospitals in the same core-based statistical area a total of approximately $741,000.

Integrity ★ Credibility ★ Impact

CREDIBLE INFORMATION

- The assistant to the compliance officer receives a call on Friday afternoon reporting that the provider is billing certain services incorrectly. The compliance officer is on an extended vacation and the assistant makes note to speak with the compliance officer after return.
- The compliance officer returns 3 weeks later, but the assistant forgets to speak about the call.
- The compliance officer receives a call 2 months later raising the same billing concern as was raised in the first call.

WHO MUST RECEIVE CREDIBLE INFORMATION

- CMS rejects comment that a senior official in the organization must receive the credible information to give rise to reasonable diligence obligation
- "Organizations are responsible for the activities of their employees agents at all levels."
- So, when does 6 months begin?
- Perhaps emphasize to employees importance of promptly reporting potential overpayments internally

OVERPAYMENT LIABILITY

- Liability arises only if there is actually an overpayment
- Failure to exercise reasonable diligence does not create liability unless there is an overpayment
- Risky to rely on non-existence of overpayment and ignore credible information of potential overpayment
- Materiality and effect of DOJ's Brand Memorandum

SIX MONTH GUIDELINE

- Reasonable diligence demonstrated “through the timely, good faith investigation of credible information”
- At most 6 months from receipt of the credible information “except in extraordinary circumstances”
- Total of 8 months, 6 months to investigate, 60 days to report and return, but must act with reasonable speed

QUANTIFICATION

- Identification includes quantifying the amount of the overpayment
- 60 days does not begin until overpayment is quantified or should have been quantified upon exercise of reasonable diligence
- CMS declined to adopt a minimum materiality threshold
- Limited references to beneficiaries

PROBE SAMPLE

- If identify a single overpaid claim, appropriate to inquire further to determine where there are more overpayments on the same issue before reporting and returning
- If use a probe sample, not appropriate only to return overpayments identified in probe and fail to extrapolate
- “In most cases this can be done in a timely manner consistent with the identification requirements of this rule”
- Do not report and return specific claims from probe until full overpayment is identified

AUDIT ISSUES – SAMPLING ISSUES

- Hospital department does E&M review of claims 1-1-14 – 2-20-14 affiliated physician practice
- 100 claims reviewed – claims pulled subjectively by staff
- 50 contain errors
- 50 claims refunded
- Any duty to do further auditing?
- Change facts – the 50 claim statistically valid probe audit – Any duty to do further auditing?

EXTRAORDINARY CIRCUMSTANCES

- Fact specific, appears narrow
- Unusually complex investigations that provider reasonably anticipates will require more than 6 months to investigate
- Example is Stark violation reported under the SRDP
- Other examples include natural disasters or state of emergency
- Perhaps investigation requiring review of numerous medical records?
- Document basis for extraordinary circumstances

60-DAY PERIOD

60-Day Period Begins:

- If provider receives credible information that an overpayment may exist, and exercises reasonable diligence to determine if there is an overpayment, 60 day period begins when reasonable diligence completed, BUT
- If provider receives credible information that an overpayment may exist, and fails to exercise reasonable diligence to determine if there is an overpayment, the 60 day period begins when provider received the credible information.

COST REPORT ISSUES - WHAT TO DO WITH THE NPR?

- A hospital receives an NPR for its 2012 cost reporting year and the Medicare Administrative Contractor makes an adjustment that reduces the hospitals Medicare reimbursement by $1,000,000.
- The Hospital's reimbursement manager disagrees with the adjustment and laments that the hospital has been doing things the same way for years and the MAC has never adjusted the particular item at issue.
- The reimbursement manager calls outside counsel, who agrees that the adjustment is incorrect and recommends that the hospital appeal the adjustment to the PRRB.

COST REPORT OVERPAYMENTS

- Due later of 60 days after identification or date cost report is due (5 months after end of cost reporting period)
- Overpayment arises if provider has received or retained funds to which it is not entitled after "applicable reconciliation"
- CMS rejects view that cost report overpayments need not be reported and returned until the cost report is settled despite reconciliation language

COST REPORT OVERPAYMENTS

- Provider that self-identifies a cost report overpayment after filing must report and return with 60 days of identification
- Submit an amended cost report with return with sufficient documentation to allow MAC to adjust the cost report
- If overpayment identified by MAC during the audit, MAC determines and demands repayment at final settlement. Provider is responsible for addressing other years.

LOOKBACK PERIOD

- Proposed Rule—10 year lookback period
- Final Rule—6 year lookback period
- All identified overpayments made within the 6 year period

REPORT AND RETURN (but to whom?)

- The Medicare contractor
  - Part A/B MAC
  - DME MAC
- The OIG under the SDP
- CMS under the SRDP
- Disclosures to DOJ or MFCU do not suspend the deadline

REPORT AND RETURN – HOW?

- When making a report/return to a MAC, be sure to check the MAC's website for instructions, which generally require:
  - Provider identifying information
  - Description of how the error was discovered
  - Circumstances that led to repayment
  - Applicable timeframe
  - Whether a statistical sampling was used to quantify the overpayment and, if so, an explanation
  - The corrective action plan to prevent the error from recurring
  - List of claims to which the overpayment applies unless sampling used

OPERATIONAL POINTERS

- Engage in proactive auditing and monitoring
- Train staff to identify and report overpayments
- Promptly investigate every report of a potential overpayment to determine if it is credible
- If the information is credible, promptly begin an inquiry and take steps to determine whether an overpayment exists and accurately and efficiently quantify it

OPERATIONAL POINTERS

- Ensure prompt repayment of the overpayment – don't wait 8 months if you can do it faster
- Does FCA liability automatically apply after 8 months?
- If it is taking longer than the 8 months to refund the overpayment, consider keeping the government or contractor informed of the progress and why it is taking longer
- Document steps done to investigate and quantify the overpayment in a manner you can use it to convince the government to decline intervention and any relator not to proceed with an FCA case

OPERATIONAL POINTERS

- Consider adopting an overpayment policy, that addresses auditing, coordination between units, internal reporting, acceptable error rates, lookback period, and overpayment retort and return process
- If a policy is adopted, make sure it is disseminated and followed
- Don’t forget coordination with counsel’s office about use of legal privileges
- When auditing, consider carefully the structure and scope so that it appropriately ties to the credible evidence found
- Probe audit vs. statistical sampling

AND DON'T FORGET YOUR DEFENSES

- Wavier of Liability
  - Liability for return of overpayments for medical necessity and custodial care is waived under the Medicare Act if provider did not know or could not reasonably have known of the overpayment
- Appeals - If report and return of a claim gives rise to a revised payment determination, can file appeal
- Statute of Limitations
- Administrative Finality

MEDICAID OVERPAYMENTS

- Subject to 60-Day Report and Return Statute
- CMS has not promulgated a 60-day regulation specifically applicable to Medicaid
- Open question whether the Medicare Part A/B Rule will be persuasive authority with respect to Medicaid overpayments? And, if so, on what issues?
- *U.S. ex rel. Kane v. Healthfirst, Inc.*, No. 11-2325 (S.D.N.Y.) – Federal Government and State of NY intervene; decision issued Aug. 3, 2015.

MEDICARE/MEDICAID MCOs

- Are overpayments to "downstream" providers in Medicare Advantage and Medicaid Managed Care Plans subject to the 60 day rule statute?
  - Definition of "person" in the 60 day rule statute
  - Definition of "claim" in FCA added by FERA
- The focus of the final rule for MAO and PDP sponsor overpayments is on MAO and PDP sponsor obligations and silent with regard to provider and supplier obligations arising from plan payments.

MEDICARE/MEDICAID MCOs

- Different approach under Medicaid
- Under 42 C.F.R. § 438.2 (emphasis added): "Overpayment means any payment made to a network provider by a MCO, PIHP, or PAHP to which the network provider is not entitled to under Title XIX of the Act or any payment to a MCO, PIHP, or PAHP by a State to which the MCO, PIHP, or PAHP is not en titled to under Title XIX of the Act." See also Preamble of Medicaid MCO Final Rule, 81 Fed. Reg. 27498 (May 6, 2016).

MEDICARE/MEDICAID MCOs

- Do contractual provisions always control?
  - Applicability of "applicable reconciliation"
  - Effect of Federal and State coverage and payment provisions
  - To whom are overpayment refunds made?
  - Contractor performance

Self-Disclosure Process

- Investigation
  - Privilege or not?
  - Retain consultants under privilege?
  - Extent of document review? Review electronic records?
  - Quantify with internal or external resources?
  - Netting, sampling, and offsetting
- Corrective Action

Disclosure Options

- Disclose and refund to Medicare Administrative Contractor, Medicaid Agency
- Disclose Stark Law only matters to CMS under Self-Referral Disclosure Protocol ("SRDP")
- Disclose to OIG under OIG Self-Disclosure Protocol ("SDP")
- U.S. Attorney's Office
- New York Medicaid Inspector General

Stark Law Disclosure Protocol (SRDP)

- Issued September 2010 under PPACA.
- For "potential" or actual Stark Law violations.
- Matters that "may also raise liability risks" under Anti-Kickback Statute should be disclosed under OIG's SDP, and parties should not disclose same conduct to both CMS and OIG.

Stark Law Disclosure Protocol

- Required Elements of a Disclosure
  - Facts surrounding potential/actual violation
  - Legal analysis
  - Remedial action description
  - Why potential/actual violation occurred
  - When discovered
  - What was done to investigate
  - Pervasiveness
  - Description of Compliance Program

Stark Law Self-Disclosure Protocol

- Elements of a Disclosure (cont'd)
  - Medicare payments under six-year lookback.
    - Factual disclosure not limited to six years, just financial analysis is.
    - Boxes 76 and 77 from UB-04.
    - Describe assumptions in making the financial analysis.
  - Payments to/from physician during six-year lookback.
  - Certification
  - Can package many violations in a single disclosure

Stark Law Disclosure Protocol - Process

- Submit electronically and include relevant documents
- Immediate electronic confirmation, including confirmation that 60-day rule is suspended.
- Eventually, CMS will ask for more documents or other questions
- Multiple CMS components review (Office of Technical Payment Policy, Office of General Counsel, Financial Management)
- Then, one day, CMS will call and tell you of its compromise. CMS intends for no negotiations, but at that point will be willing to hear about ability-to-pay issues.
- BUT, CMS will refer matters to OIG and DOJ when it feels law enforcement may be appropriate.

Stark Law Disclosure Protocol

- Include discussion of exculpatory factors
  - Evidence of non-willful conduct
  - Involvement of counsel in preparing documents
  - Lack of impact to patients or Medicare
  - Sole community provider
  - Ability to pay
  - Effective response to identified issues
- Mention any other relevant facts
  - E.g., business need to expedite settlement

Stark Law Self-Disclosure Protocol

- Settlements
  - No release of civil penalties or any other laws. Release strictly covers overpayment liability.
  - Handful of referrals to OIG or DOJ
  - Settlement agreements are subject to FOIA. Are the disclosures themselves?

OIG Self-Disclosure Protocol

- Premise: To self-disclose and settle matters that could involve liability under the Civil Money Penalties Law or serve as basis for exclusion
- 85 SDP settlements announced in first eleven months of 2018, including:
  - $12.37 million, Northwell Health (NY), for billing vertobroplasty procedures that were not covered by an LCD (failure to demonstrate non-surgical efforts failed and that vertebral fracture had a non-traumatic cause)
  - $4.47 million, Shands Jacksonville Medical Center, for billing for ophthalmology surgical services, where medical records did not support medical necessity.
  - $3.91 million, Nazareth Living Centers (TX), for failing to follow requirements for "change of therapy" forms for rehabilitative therapy.
  - $3.67 million, Visionworks, for alleged non-FMV leases with ophthalmologists and failure to collect lease payments.
  - $3.27 million, St. Francis Hospital (GA),for: (i) remuneration to a management company in the form of incentive payments for performance metrics that were not met and were not materially updated to incentivize performance; (ii) remuneration to a cardiology practice in the form of a forgiven or uncollected debt owed as a result of the practice exceeding the tenant improvement allowances of their lease agreement.
- No Stark-Law-only disclosures

OIG Self-Disclosure Protocol

- Benefits
  - Release of CMP and exclusion
  - Typically, no Corporate Integrity Agreement.
  - Lower damages. As low as 1.5 times the overpayment.
  - Suspends 60-day rule

OIG Self-Disclosure Protocol

- Required elements
  - Factual summary (including names of individuals responsible), statement of laws potentially violated, corrective action
  - Certification
- Other features
  - Must admit that there was a “potential” violation
  - Federal health care program financial impact must be computed and provided within 90 days of initial disclosure
  - OIG commits to resolve within 12 months
  - Six-year lookback

OIG Self-Disclosure Protocol

- April 2013 Guidance on computing damages
  - May audit all claims or a sample of at least 100 claims (which may include the probe sample)
  - No minimum precision required, just at least 100 claims
  - No “netting” of underpayments
  - Use mean point estimate to determine damages.
  - Full report required on damages calculations

OIG Self-Disclosure Protocol

- Disclosure of employment of, contracting with, excluded persons
  - Disclose reimbursement amount of separately billed services of that person (e.g., pharmacist)
  - Settlement likely based on employment cost adjusted by payor mix for federal programs.
  - Must explain how excluded status was missed and corrective action.
  - Must screen all current employees and contractors against LEIE before making disclosure.

OIG Self-Disclosure Protocol

- Anti-Kickback Statute disclosures
  - April 2013 Guidance lays out pointed questions to answer
  - Settlements will often be at a multiple of the potential unlawful remuneration
  - Minimum settlements of $50,000

OIG Self-Disclosure Protocol

- What is released?
  - CMP Law, exclusion
  - OIG confers with DOJ on settlements.
  - False Claims Act is not released, unless disclosing party requests DOJ participation or DOJ chooses to participate.
  - How about 31 U.S.C. 3730(e)(3)?
- Criminal matters may be disclosed under protocol
- Don't disclose a matter to both OIG and CMS. But, as part of a broader review of physician financial relationships, some may be suitable for the OIG SDP and others for only the Stark Law SRDP.

QUESTIONS