



HCCA New York Regional Annual Conference HOT TOPICS

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Agenda

- The 60 day overpayment Final Rule
- Government enforcement actions
- The relationship between compliance and hospital readmissions/overall quality
- False Claims Act developments

60 Day Overpayment Final Rule

Overpayment Reporting

- Affordable Care Act Section 6402(a) (42 U.S.C. 1320a-7k) established a requirement that overpayments must be reported and returned by the later of:
 - **60 days** after the date on which the overpayment was **identified**; or
 - the date any corresponding cost report is due, if applicable.

Section 6402(a) Definitions

- Overpayment: Any Medicare and Medicaid funds that a **person** receives or retains to which the person, **after applicable reconciliation**, is **not entitled** under the Medicare or Medicaid laws.
- Person: a provider of services, supplier, Medicaid managed care organization, Medicare Advantage organization or Part D sponsor.
 - does not include a beneficiary.

Section 6402(a) Requirements

- Overpayments must be reported and returned to the appropriate party (i.e., DHHS, the State, an intermediary, a carrier, or a contractor), at the correct address, and
- Must include a written explanation of the reason for the overpayment.
- Any overpayment retained after the deadline for reporting/returning is an “obligation” for purposes of the Federal False Claims Act.



The Federal False Claims Act

- The Federal Government’s “Weapon of Choice.”
- Provisions prohibit any person from:
 - knowingly presenting or causing to be presented, a false **claim** for payment or approval;
 - knowingly making, using, or causing to be made or used, a false record or statement material to a false **claim**;
 - knowingly concealing or improperly avoiding or decreasing an **obligation** to pay or transmit money or property to the Government.



The Federal False Claims Act

- Obligation: includes an established duty arising from the retention of any overpayment.
- Claim: includes a request for payment presented to the U.S. government or to a contractor if the money or property is to be spent or used on the Government’s behalf, and if the Government provides any portion of the money requested; or will reimburse such contractor any portion of the money requested.

The Federal False Claims Act

- **Consequences:**
 - **Treble** damages;
 - Per claim penalty of **\$5,500** to **\$11,000**;
 - **Exclusion** from Federal and state health care programs (including Medicare and Medicaid).



Overpayment Final Rule

- On February 12, 2016, the Centers for Medicare and Medicaid Services (CMS) adopted a Final Rule regarding certain Medicare overpayments.
 - Clarified when an overpayment is “identified.”
 - Limited the “look back period” to six years.
 - *See 81 Federal Register 7654.*

Overpayment Final Rule

- CMS's Final Rule only applies to providers who submit claims to Medicare Part A and/or Part B.
 - CMS adopted other rules in 2014 that apply to overpayments received from Medicare Parts C and D.

Overpayment Final Rule

- Although the Final Rule does not apply to Medicaid overpayments, providers are nonetheless required to report and return Medicaid overpayments in compliance with Section 6402(a) of the ACA.
 - See NYS Office of Medicaid Inspector General (OMIG) Self-disclosure Program.
 - <https://www.omig.ny.gov/self-disclosure>

Overpayment Final Rule

- A person has “identified” an overpayment when “the person has or should have, through the exercise of reasonable diligence,” determined that an overpayment has been received and has “quantified the amount of the overpayment.”
 - Once a provider determines that an overpayment has been received and it has been quantified, the 60 day period to report and return the overpayment begins.

Overpayment Final Rule

- The 60 day period to report and return the overpayment can also begin on the day the person received credible information of a potential overpayment if:
 - the person fails to conduct reasonable diligence; and
 - in fact received an overpayment.
- There is no *de minimis* threshold.

Overpayment Final Rule

- “Reasonable diligence” includes both:
 - proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments; and
 - investigations conducted in good faith and in a timely manner (i.e., at most six (6) months from receipt of the credible information, except in extraordinary circumstances) by qualified individuals in response to obtaining credible information about a potential overpayment.

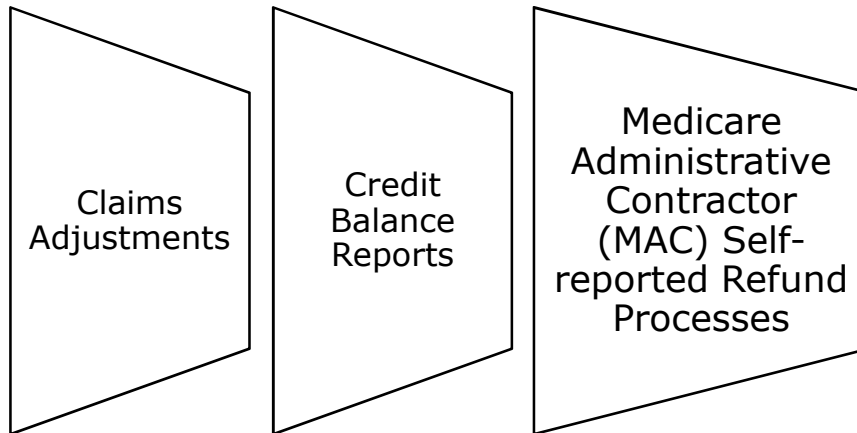
Overpayment Final Rule

- Once an overpayment has been identified, Medicare providers are obligated to look back six years from the date of identification to determine if they have received similar overpayments.



Overpayment Final Rule

- How to report and return: CMS will allow providers to utilize existing refund processes, e.g.,:



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Overpayment Final Rule

- The report and return obligation is tolled if the Medicare provider is participating in:
 - the CMS Self-Referral Disclosure Protocol (SRDP) (available for disclosing potential violations of the Stark Law), or
 - the Office of Inspector General's Self-Disclosure Protocol (available for disclosing evidence of potential fraud).
- Tolling provisions are not applicable to self-disclosures made to the Department of Justice or to a Medicaid Fraud Control Unit.

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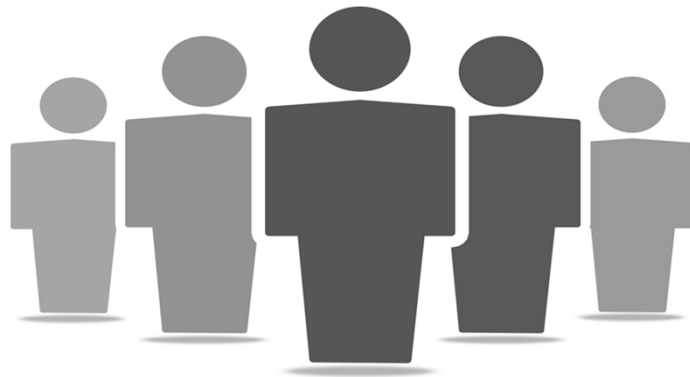
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Government Enforcement Actions



The Focus is on Individual Liability



The “Yates” Memo

- Issued September 2015
- Focus on individual wrongdoers
- Criminal and civil cases

6 key directives:

The “Yates” Memo

- In order to qualify for any cooperation credit, corporations must provide to the DOJ all relevant facts relating to the individuals responsible for the misconduct;
- criminal and civil corporate investigations should focus on individuals from the inception of the investigation;

The “Yates” Memo

- Criminal and civil attorneys handling corporate investigations should be in routine communication with one another;
- Absent extraordinary circumstances or approved departmental policy, the DOJ will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation;

The “Yates” Memo

- DOJ attorneys should not resolve matters with a corporation without a clear plan to resolve related individual cases, and should memorialize any declinations as to individuals in such cases; and
- Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual's ability to pay.

Yates - DOJ in Action

- October 2015: DOJ announces guilty plea to Health Care Fraud by pharmaceutical company.
 - Will pay \$125 million to resolve criminal and civil liability.
 - Allegations: Company paid kickbacks to physicians to prescribe the company's drugs.
- Simultaneous to announcement, president of company separately indicted for his involvement, as were 3 lower level managers.

Yates - DOJ in Action

- January 2016: CEO of laboratory agreed to settle False Claims Act case for up to \$3.725.
 - Allegations:
 - claims for unnecessary medical tests submitted to Federal health care programs.
 - Incentives paid to prescribers in exchange for referrals.
- The laboratory itself had previously settled for \$6.5 million.

Yates – DOJ in Action

- March 2016: Federal jury convicts director of nursing assistants of 3 counts of Health Care Fraud.
 - Evidence presented: \$300,000 in “bonus money” was accepted over 3 years in return for referring terminally ill patients to a higher than needed level of hospice care.
 - Previously convicted:
 - the Company itself, co-owner, former administrator, former director of clinical services, former compliance officer, former head of marketing.

The Yates Memo - Fallout

- How far does an entity have to go to conduct an internal investigation?
 - Who decides what encompasses “all relevant facts”?
- Will employees cooperate in internal investigations?
 - Does everyone need their own legal counsel?
- Are there limits to what needs to be disclosed to DOJ?
 - Will DOJ give any credit to partial disclosures?



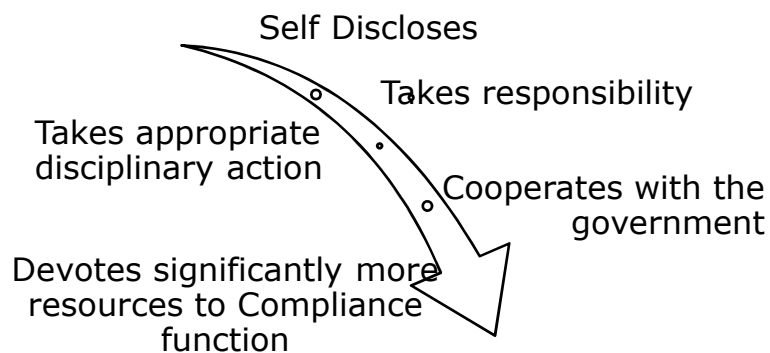
OIG Revised Exclusion Criteria

- OIG has authority to exclude individuals and entities from participating in Federal health care programs.
- April 2016: OIG released new guidance on how it will exercise its discretion.



OIG Revised Exclusion Criteria

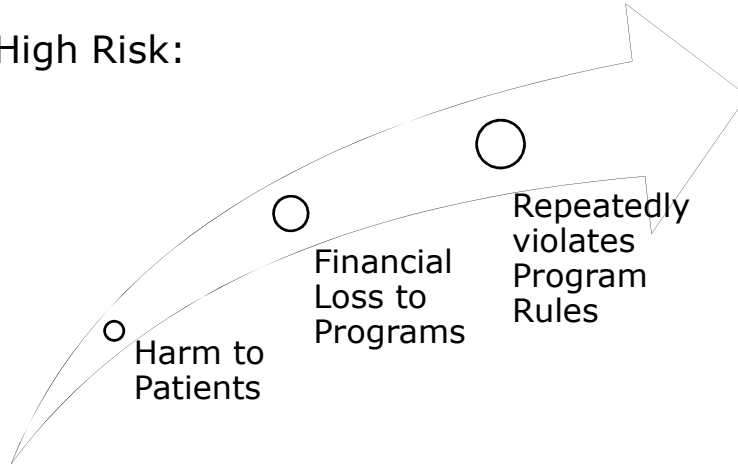
- Low Risk:





OIG Revised Exclusion Criteria

- High Risk:



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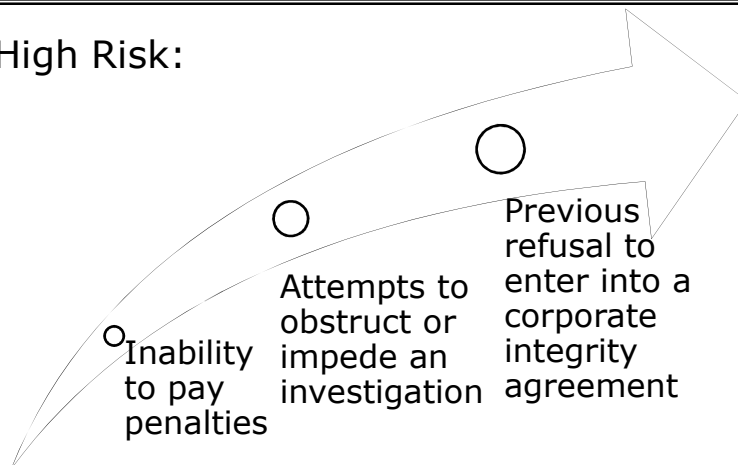
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OIG Revised Exclusion Criteria

- High Risk:



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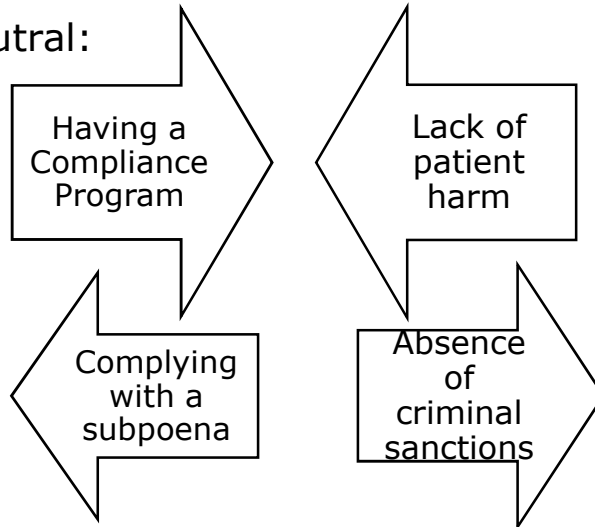
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OIG Revised Exclusion Criteria

- Neutral:



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The Relationship Between Compliance and Hospital Readmissions/Overall Quality

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Compliance and Quality

In New York, compliance programs must be applicable to:

Billings

**Medical
Necessity/Quality
of Care**

Governance

Mandatory reporting

Credentialing

18 NYCRR § 521.3



Pay for Performance

Value Based

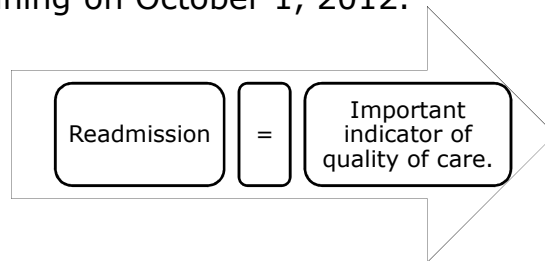
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Volume Based



Affordable Care Act Provisions

- Section 3025 of the ACA established the Hospital Readmissions Reduction Program.
 - Required CMS to reduce payments to inpatient prospective payment system hospitals with excess readmissions, effective for discharges beginning on October 1, 2012.



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Hospital Readmissions Reduction

- In FY 2015, the maximum reduction in payments under the Hospital Readmissions Reduction Program increased from 2 to 3 percent of base discharge amounts, as required by law.

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Affordable Care Act Provisions

- Section 3008 of the ACA established the Hospital-Acquired Condition (HAC) Reduction Program.
 - Effective with Federal Fiscal Year 2015 (i.e., beginning on October 1, 2014), DHHS required to adjust payments to hospitals that rank in the worst-performing 25 percent with respect to HAC quality measures.



Fiscal Year 2016

- HAC score is based on data for 4 quality measures grouped into two domains:
- Domain 1: Agency for Health Care Research & Quality (AHRQ) Patient Safety Indicator (PSI) measures (PSI 90 composite):
 - Pressure ulcers
 - Iatrogenic pneumothorax
 - Central venous catheter-related bloodstream infections

Fiscal Year 2016

- Postoperative hip fracture
- Perioperative pulmonary embolism or deep vein thrombosis
- Postoperative sepsis
- Postoperative wound dehiscence
- Accidental puncture or laceration



Fiscal Year 2016

- Domain 2: National Health Care Safety Network (NHSN) health care associated infection measures:
 - Central Line-Associated Bloodstream Infection
 - Catheter-Associated Urinary Tract Infection
 - Surgical Site Infection – colon and hysterectomy

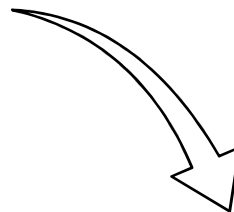
Payment Cuts

- December 2015: CMS identified 758 hospitals in the HAC bottom quartile nationally.
- Their payments were reduced by 1%.
 - applied to all Medicare discharges from October 1, 2015 – September 30, 2016.
- Total savings to Medicare = \$364 million.

Quality Improvement

- AHRQ estimates 1.3 million fewer patients were harmed in U.S. hospitals between 2010 and 2013.

17% Reduction



The Critics Say:

- These quality initiatives are not without criticism:
 - Hospitals with disproportionate amounts of poorer/sicker patients are being penalized.
 - Better recordkeeping or better quality?
 - Many problems are hard to measure.
 - Lack of well-defined studies.

OMIG Guidance for General Hospitals

- Compliance program may impact clinical services/overlap with a facility's quality management program, but . . .
 - the compliance program is not a substitute for an effective quality management program.



OMIG Guidance for General Hospitals

- Code of Conduct should include compliance expectations with regard to quality of care.
- Compliance Officer should regularly participate in senior management meetings/receives reports on compliance-related matters in areas that include quality and risk management.

OMIG Guidance for General Hospitals

- Compliance Officer should be provided information about patterns or significant concerns related to quality of care.



OIG Recommendations:

- Establish a board level quality committee.
- Make quality of care a standing board agenda item.



OIG Guidance for Health Care Boards of Directors

- Board quality committees should work with management on goal of identifying and responding to risks and improving quality of care.
- Boards should consider establishing a risk-based reporting system.
 - those responsible for the compliance function provide reports to the Board when certain risk-based criteria are met.

OIG Guidance for Health Care Boards of Directors

- Boards should be provided with regular internal reviews.
 - a snapshot of where the organization is, and where it may be going, in terms of compliance and quality improvement.
 - should produce better compliance results and higher quality services.



OIG Guidance for Health Care Boards of Directors

- The Board should consider conducting regular “executive sessions” (i.e., excluding senior management) with leadership from the compliance, legal, internal audit, and quality functions to encourage more open communication.
 - Boards may choose to compare accessible data against organizational peers and incorporate national benchmarks when assessing organizational risk and compliance.



OIG Guidance for Health Care Boards of Directors

- Compliance/Quality Metrics
 - Some companies have made participation in annual incentive programs contingent on satisfactorily meeting annual compliance goals.
 - Others have instituted employee and executive compensation claw-back/recoupment provisions if compliance metrics are not met.



OIG Guidance for Health Care Boards of Directors

- Resources:
 - <http://oig.hhs.gov/compliance/compliance-guidance/compliance-resource-material.asp>

False Claims Act Developments

Implied Certification

- Can a health care provider's failure to comply with a statute, regulation or contractual provision that does not state that it is a Medicare or Medicaid condition of payment . . .
 - Give rise to a false implied certification?
 - And form the basis for False Claims Act liability?

Implied Certification

- *Universal Health Services, Inc., v. U.S. and Massachusetts, ex rel. Escobar and Correa*
 - Whistleblowers alleged fraud involving a mental health clinic's failure to comply with state supervision requirements and linked that to claims for payment the clinic submitted to the Medicaid Program.
 - 1st Circuit Court of Appeals held that compliance with supervision requirements was implicitly contained in payment claims.

Implied Certification

- Circuit courts are split on the question of whether an implied certification can give rise to False Claims Act liability and on what type of regulations are conditions of payment (as opposed to conditions of participation).
 - U.S. Supreme Court heard oral argument on April 19.
 - 26 amici curiae briefs filed.



False Claims Act Damages

- *U.S. ex rel. Wall v Circle C Construction*
 - February 2016: Sixth Circuit Court of Appeals held that damages in false certification case should be based on the difference between the value of the items/services the government should have received and the value of the items/services it actually provided.

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False Claims Act Damages

- *U.S. ex rel. Wall v Circle C Construction*
 - Improper wages paid to workers by government contractor that built warehouses on army bases.
 - Government sought treble damages, as allowed by the False Claims Act, based on entire amount that it paid to contractor for the work.

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False Claims Act Damages

- *U.S. ex rel. Wall v Circle C Construction*
 - Court disagreed – “government turns the lights on every day.”
 - It reduced damages to treble the government’s *actual damages* – the difference between what was paid to the workers and what should have been paid.



False Claims Act Damages

- *U.S. ex rel. Wall v Circle C Construction*
 - Implications for health care providers?
 - Good argument against overreaching damage calculations.
 - Court: Actual damages by definition are damages grounded in reality. . . . *The damages the government seeks to recover here are fairyland rather than actual.*



THANK YOU

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