



HCCA New York Regional Annual Conference HOT TOPICS

May 13, 2016

Lourdes Martinez, Esq.
lmartinez@garfunkelwild.com
111 Great Neck Road
Great Neck, NY 11021
(516) 393-2200

www.garfunkelwild.com



Agenda

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

3802196

2

©2016 Garfunkel Wild, P.C.



60 Day Overpayment Final Rule

3802196

3

©2016 Garfunkel Wild, P.C.



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.

3802196

4

©2016 Gartunek Wild, P.C.



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.

3802196

5

©2016 Gartunek Wild, P.C.



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.

3802196

6

©2016 Gartunek Wild, P.C.



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.

3802196

7

©2016 Garfunkel Wilk, P.C.



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.

3802196

8

©2016 Garfunkel Wilk, P.C.



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).



3802196

9

©2016 Garfunkel Wilk, P.C.



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.*

3802196

10

©2016 Gartfunkel Wikt. P.C.



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.

3802196

11

©2016 Gartfunkel Wikt. P.C.



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>

3802196

12

©2016 Gartfunkel Wikt. P.C.



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.

3802196

13

©2016 Garfunkel Wild, P.C.



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.

3802196

14

©2016 Garfunkel Wild, P.C.



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.

3802196

15

©2016 Garfunkel Wild, P.C.

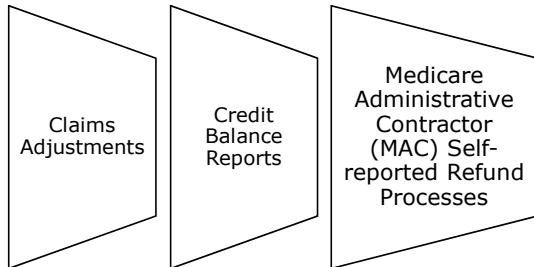
Overpayment Final Rule

- 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.,:



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.



Government Enforcement Actions

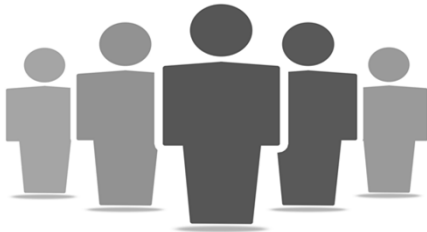
3802196

19

©2016 Garfunkel Wild, P.C.



The Focus is on Individual Liability



3802196

20

©2016 Garfunkel Wild, P.C.



The “Yates” Memo

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

6 key directives:

3802196

21

©2016 Garfunkel Wild, P.C.



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;

3802196

22

©2016 Garfunkel Wild, P.C.



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;

3802196

23

©2016 Garfunkel Wild, P.C.



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.

3802196

24

©2016 Garfunkel Wild, P.C.



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.

3802196

25

©2016 Garfunkel Wild, P.C.



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.

3802196

26

©2016 Garfunkel Wild, P.C.



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.

3802196

27

©2016 Garfunkel Wild, P.C.



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?

3802196

28

©2016 Garfunkel Wild, P.C.



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.

3802196

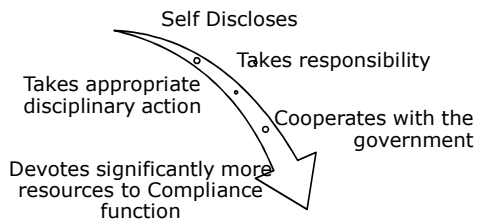
29

©2016 Garfunkel Wild, P.C.



OIG Revised Exclusion Criteria

- Low Risk:



3802196

30

©2016 Garfunkel Wild, P.C.

GW **OIG Revised Exclusion Criteria**

■ High Risk:

Harm to Patients

Financial Loss to Programs

Repeatedly violates Program Rules

3802196 31 ©2016 Garfinkel Wild, P.C.

GW **OIG Revised Exclusion Criteria**

■ High Risk:

Inability to pay penalties

Attempts to obstruct or impede an investigation

Previous refusal to enter into a corporate integrity agreement

3802196 32 ©2016 Garfinkel Wild, P.C.

GW **OIG Revised Exclusion Criteria**

■ Neutral:

Having a Compliance Program

Complying with a subpoena

Lack of patient harm

Absence of criminal sanctions

3802196 33 ©2016 Garfinkel Wild, P.C.



The Relationship Between Compliance and Hospital Readmissions/Overall Quality

3802196

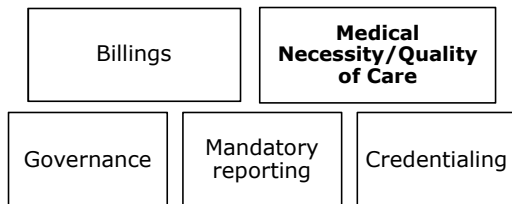
34

©2016 Garfunkel Wild, P.C.



Compliance and Quality

In New York, compliance programs must be applicable to:



3802196

35

18 NYCRR § 521.3

©2016 Garfunkel Wild, P.C.



Pay for Performance

Value Based

• vs. •

Volume Based

3802196

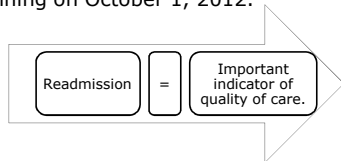
36

©2016 Garfunkel Wild, P.C.



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.



3802196

37

©2016 Garfunkel Wild, P.C.



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.

3802196

38

©2016 Garfunkel Wild, P.C.



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.

3802196

39

©2016 Garfunkel Wild, P.C.



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

3802196

40

©2016 Garfunkel Wild, P.C.



Fiscal Year 2016

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



3802196

41

©2016 Garfunkel Wild, P.C.



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

3802196

42

©2016 Garfunkel Wild, P.C.



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.

3802196

43

©2016 Garfunkel Wild, P.C.



Quality Improvement

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

17% Reduction



3802196

44

©2016 Garfunkel Wild, P.C.



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.

3802196

45

©2016 Garfunkel Wild, P.C.



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.



3802196

46

©2016 Garfunkel Wild, P.C.



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.

3802196

47

©2016 Garfunkel Wild, P.C.



OMIG Guidance for General Hospitals

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



3802196

48

©2016 Garfunkel Wild, P.C.



OIG Recommendations:

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



3802196

49

©2016 Garfunkel Wild, P.C.



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.

3802196

50

©2016 Garfunkel Wild, P.C.



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.



3802196

51

©2016 Garfunkel Wild, P.C.



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.

3802196

52

©2016 Garfunkel Wild, P.C.



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.

3802196

53

©2016 Garfunkel Wild, P.C.



OIG Guidance for Health Care Boards of Directors

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

3802196

54

©2016 Garfunkel Wild, P.C.



False Claims Act Developments

3802196

55

©2016 Garfunkel Wild, P.C.



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?

3802196

56

©2016 Garfunkel Wild, P.C.



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.

3802196

57

©2016 Garfunkel Wild, P.C.



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.

3802196

58

©2016 Garfunkel Wild, P.C.



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.

3802196

59

©2016 Garfunkel Wild, P.C.



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.

3802196

60

©2016 Garfunkel Wild, P.C.



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.



3802196

61

©2016 Garfunkel Wild, P.C.



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.*

3802196

62

©2016 Garfunkel Wild, P.C.



THANK YOU

Lourdes Martinez, Esq.
 Partner/Director
 Garfunkel Wild, P.C.
 111 Great Neck Road
 6th Floor
 Great Neck, NY 11021
 (516) 393-2200
 lmartinez@garfunkelwild.com

3802196

63

©2016 Garfunkel Wild, P.C.
