

Health Reform's Impact on Fraud & Abuse Enforcement: Eight Months in and Storm Clouds on the Horizon

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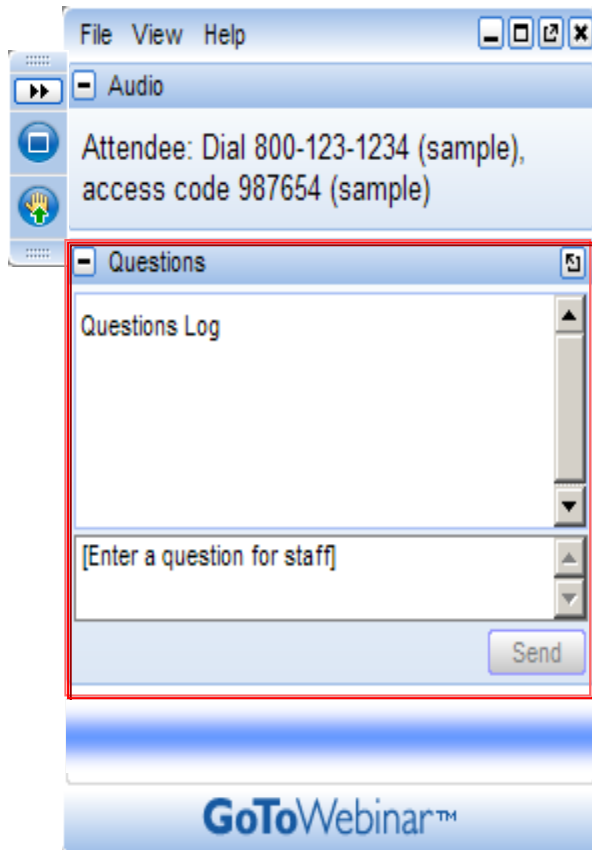


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Housekeeping



How to Participate

- Dial the conference number located in your Audio Pane.
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Overview of Presentation

When is an overpayment an independent basis for liability?

Sixty-Day Report and Return Obligation

Do overpayments ever die?

Retention under the False Claims Act (FCA) and the Civil Money Penalty statute (CMP)

Is there ever a time to say “*mea culpa*”?

CMS’s Stark Self-Disclosure Protocol

Guilty by association.

Program Exclusion Authority

Moving the goalposts.

Enforcement Standards

60-Day Report and Return Obligation

Old Law

Whoever . . . having knowledge of the occurrence of any event affecting

(A) his initial or continued right to any such benefit or payment, or

(B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment,

conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized . . . shall . . . be guilty of a felony

42 U.S.C. § 1320a-7b(a)(3).

60-Day Report and Return Obligation

More Old Law

Provider Agreement:

- “[T]he provider of services . . . agrees to conform to the provisions of section 1866 of the Social Security Act and applicable provisions in 42 CFR.”

Enrollment Requirements:

- “Any provider of services . . . shall be qualified to participate . . . if it files with the Secretary an agreement . . . to make adequate provision for return . . . of any moneys incorrectly collected from [an] individual or other person.” 42 U.S.C. § 1395cc(a)(1)(C) (SSA § 1866(a)(1)(C)).

60-Day Report and Return Obligation

New Law

Definition of Overpayment:

“[F]unds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.”

Report and Return Obligation:

- (1) In General—If a person has received an overpayment, the person shall—
 - (A) report and return the overpayment to the Secretary, the State . . . or a contractor . . . and
 - (B) notify the Secretary, State . . . or contractor . . . 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.
- (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) of title 31, United States Code) for purposes of section 3729 of such title. S.S.A. § 1128J(d) (2010).

60-Day Report and Return Obligation

Fact Patterns

1. A has fired billing clerks because of their sloppy work. Has it identified overpayments?
2. B learns that an employee “sometimes” furnished DME that was not medically necessary. Has it identified overpayments?
3. C realizes that its lease with a physician practice expired nine months ago. Has it identified overpayments?

Retention of Overpayments

Retention under the FCA

- “Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” 31 U.S.C. § 3729(a)(1)(G) (2009).
- “[T]he term ‘obligation’ means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.” 31 U.S.C. § 3729(b)(3) (2009).
- “Any overpayment retained by a person after the deadline for reporting and returning the overpayment...is an obligation...” S.S.A. § 1128J(d) (2010).

Retention of Overpayments

Retention under the CMP Statute

- “Improperly filed claims. Any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5)) that...knows of an overpayment (as defined in paragraph (4) of section 1128J(d) [42 USCS § 1320a-7k(d)]) and does not report and return the overpayment in accordance with such section...shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than \$10,000 for each item or service...” 42 U.S.C. 1320a-7a(a) (2010).
- The CMP statute incorporates the “knowing” standard of the FCA and the definition of “overpayments” set forth in the ACA.

Retention of Overpayments

Fact Patterns

1. A performs an audit and determines that claims submitted in 2007 were for services that were not medically necessary.
2. B performs an audit and determines that claims submitted in 1990 were for services that were not medically necessary.
3. C performs an audit and determines that claims submitted in 2007 were for services that were not medically necessary. Those involved have been in the same position for 15 years and “always did it that way.”

CMS Stark Self-Disclosure Protocol

- Required by the ACA
- Protocol repeats ACA factors in determining an entity's repayment amount:
 - Nature and extent of violation
 - Timeliness of self-disclosure
 - Disclosing party's cooperation
 - Litigation risk
 - Disclosing party's financial condition
- Substantial concerns:
 - No certainty
 - Disclosure of full period "during which the disclosing party may not have been in compliance with the physician self-referral law"
 - Potential waiver of privilege
 - Expectation of escrow
 - Increased scrutiny of disclosing party's compliance program

CMS Stark Self-Disclosure Protocol

Fact Patterns

1. A has paid a medical director for services never rendered. A's administration has been concerned for several years that the medical director's case volume has been low. Those concerns are likely to be reflected in "inartful" internal email.
2. B has paid modest call stipends to most members of the medical staff, without written agreements. The practice has been in place for 15 years.
3. C has expired leases with most tenants of an MOB. C's finances are shaky, and C plans to put itself to market.
4. D is under investigation. Its internal investigation has uncovered "borderline" arrangements.

Program Exclusion Authority

Mandatory Medicaid Exclusion of Affiliates

“[A] State [Medicaid] agency must exclude, with respect to a period, any individual or entity...if such individual or entity owns, controls, or manages an entity that (or if such entity is owned, controlled, or managed by an individual or entity that)...is affiliated with an individual or entity that has been suspended or excluded from participation under this title or whose participation is terminated under this title during such period...” 42 U.S.C. 1396a(a)(78) (to take effect January 1, 2011).

CMS’s proposed rules implement neighboring ACA provisions requiring Medicaid exclusion of those who themselves are excluded from Medicare or Medicaid, but do not address the affiliate exclusion provision. 75 Fed. Reg. 58204, 58228-29 (Sept. 23, 2010).

Program Exclusion Authority

Fact Pattern

- August 2010. Company A owns 50 hospitals, each in a separately incorporated subsidiary.
- September 2010. Company B owns 10 hospitals and one DME supplier, each in a separately incorporated subsidiary.
- October 2010. Company A creates a merger sub, which acquires all shares of Company B, leaving Company B and all of its subsidiaries intact, with Company A as the ultimate owner.
- November 2010. The DME supplier is excluded from participation in the Medicare and Medicaid programs.

Program Exclusion Authority

Permissive Exclusion of Individuals

- Individuals with an ownership or a control interest in a sanctioned entity may be excluded if they knew or should have known of the conduct.
- Officers and managing employees may be excluded based solely on their position.

Program Exclusion Authority

Permissive Exclusion of Individuals

- **OIG October 2010 Guidance:**
 - “OIG will operate with a presumption in favor of exclusion”
 - Consideration of four factors may preclude exclusion: (i) circumstances of misconduct; (ii) individual’s position; (iii) individual’s response to misconduct; (iv) entity’s enforcement history, corporate structure, etc.
 - Note: Only factor (iii) is within an individual’s control

Enforcement Standards

- Government's relation back to relators' FCA limitations period
- Public disclosure bar and original source rule
- Materiality standard under FCA (“Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim)
- Scienter in retention, without regard to scienter in submitting initial claim
- General intent under the AKS
- Suspension of Medicare and Medicaid payments if (i) “reliable information that an overpayment exists” or (ii) “a credible allegation of fraud”

Thank you



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