
HOLLAND & HART LLP



**All You Should Know About Medicaid And Medicare Fraud
Montana Bar Association
Health Care Law Section CLE**

By William W. Mercer

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I. Introduction

II. Orientation to the civil and criminal enforcement of payments made pursuant to the federal health care benefit programs

- an overview of the criminal statutes applicable to health care fraud and overpayment cases pursued by the government;
- an overview of the law regarding civil penalties, including the False Claims Act (FCA) provisions central to citizens authority to pursue cases as relators in qui tam lawsuits brought pursuant to the FCA;
- a focus on legal duties with respect to repayments of overpayments made by a federal health care benefit program;
- an overview of the statutes creating criminal liability for obstructing investigations and destroying evidence;
- law on debarment and program exclusion as a collateral consequences of wrongdoing; and
- a discussion of significant cases.



III. The anatomy of an investigation

- What generates an investigation? Who investigates?: a profile of complainants, the relevant Offices of Inspectors General, the Medicaid Fraud Control Units, federal and state law enforcement agencies, and the alphabet soup of entities involved in data mining and claims evaluation (analysis and assessments conducted by third-parties (RACs, UPICs, ZPICs, MICs, and PSCs);
- HHS-OIG work plan priorities and trends observed from recent enforcement activities;
- Response to an investigation or proactive steps to take if an investigation seems probable, including an awareness of triggers and trip wires, which signal when providers should consider an internal investigation;



IV. Best practices to avoid civil and criminal investigations and present a persuasive case for leniency if investigated

- Importance of a robust compliance plan with appropriate implementation and evaluation;
- Internal review of data for trends and outliers, including program denials by code;
- Monitoring and oversight of obvious red flags: practices outside the scope of licensure and credentialing, providers excluded from program participation based upon past problems; and
- Review of HHS OIG' s Self-Disclosure Protocol.

Preliminaries



- This program provides an overview of the relevant statutes and regulations. The application depends upon the circumstances of each case.
- Regulations and statutes are sometimes highly technical with exceptions and nuances.
- Read regulations and confer with qualified expert when applying the law to facts.
- Consider other applicable laws, not a focus of today's presentation.
 - Anti-Kickback Statutes
 - State laws
- This program does not establish an attorney-client relationship.
- This program does not constitute the giving of legal advice.

Failure to comply with conditions for payment



- Examples of billing practices that may result in overpayment:
 - Services not medically necessary
 - Services not covered by federal program
 - Services not provided as claimed/not rendered as billed
 - Services not provided by licensed provider
 - Services not properly supervised
 - Substandard care
 - Double billing or duplicate payments
 - Unbundling
 - Upcoding
 - Etc., etc., etc.

18 U.S.C. § 1347 Health Care Fraud



- (a) Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice—
- (1) to defraud any health care benefit program; or
 - (2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, in connection with the delivery of or payment for health care benefits, items, or services

Criminal False Claims Act and Statements



- 18 U.S.C. § 287 Criminal False Claims

It is a crime to make any claim "upon or against the United States. . . knowing such claim to be false, fictitious or fraudulent ..."

- 18 U.S.C. § 1001 Criminal False Statements to the Government; see *also*, health care specific false statement statutes (18 U.S.C. § 1035; 42 U.S.C. § 1320a-7b(a); 42 U.S.C. § 1320a-7b(c))

- Makes it a crime in any matter within the jurisdiction of the executive branch of the Government of the United States and/or in connection with the delivery or payment of health care benefits or services, to knowingly and willfully —

- (1) falsify, conceal, or cover up by any trick, scheme, or device a material fact;
- (2) make any materially false, fictitious, or fraudulent statement or representation (oral or written); or
- (3) make or use any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry;

18 U.S.C. § 1341 Mail Fraud



Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises, for the purpose of executing such scheme or artifice or attempting so to do, places in any post office or authorized depository for mail matter, any matter or thing whatever to be sent or delivered by the Postal Service, or deposits or causes to be deposited any matter or thing whatever to be sent or delivered by any private or commercial interstate carrier, or takes or receives therefrom, any such matter or thing, or knowingly causes to be delivered by mail or such carrier according to the direction thereon, or at the place at which it is directed to be delivered by the person to whom it is addressed, any such matter or thing

18 U.S.C. § 1343 Wire Fraud



Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises, transmits or causes to be transmitted by means of wire, radio, or television communication in interstate or foreign commerce, any writings, signs, signals, pictures, or sounds for the purpose of executing such scheme or artifice

CONSPIRACY



A criminal conspiracy is an agreement among two or more persons to accomplish an unlawful purpose. If one or more co-conspirators committed an overt act to execute the agreement, the government may seek to charge the conspirators under 18 U.S.C. § 371 or 18 U.S.C. § 1349.

18 U.S.C. § 669 - Theft or embezzlement in connection with health care



A person is guilty of this crime if she knowingly and willfully embezzles, steals, or otherwise without authority converts to the use of any person other than the rightful owner, or intentionally misapplies any of the moneys, funds, securities, premiums, credits, property, or other assets of a health care benefit program.

Anti-Kickback provision



- 42 U.S.C. § 1320a–7b(b)

Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

- (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
- (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

Safeharbor provision



Paragraphs (1) and (2) shall not apply to—

(A) a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program;

(B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services;

(C) any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program if—

(i) the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract, and

(ii) in the case of an entity that is a provider of services (as defined in section 1395x(u) of this title), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity;

Safeharbor provision (con't)



(D) a waiver of any coinsurance under part B of subchapter XVIII of this chapter by a Federally qualified health care center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act [42 U.S.C. § 201 *et seq.*];

(E) any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 or in regulations under section 1395w-104 (e)(6) [1] of this title;

(F) any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1395mm of this title or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide;

Safeharbor provision (con't)



(G) the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under part D of subchapter XVIII of this chapter, if the conditions described in clauses (i) through (iii) of section 1320a-7a (i)(6)(A) of this title are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1395w-114 (a)(3) of this title), section 1320a-7a (i)(6)(A) of this title shall be applied without regard to clauses (ii) and (iii) of that section);

(H) any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1395w-23 (a)(4) of this title;

Safeharbor provision (con't)



(I) any remuneration between a health center entity described under clause (i) or (ii) of section 1396d (l)(2)(B) of this title and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity; and

(J) a discount in the price of an applicable drug (as defined in paragraph (2) of section 1395w-114a (g) of this title) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1395w-114a of this title.

Illegal Admitting and Retention of Patients



- 42 U.S. Code § 1320a–7b(d)
- Whoever knowingly and willfully—
 - (1) charges, for any service provided to a patient under a State plan approved under subchapter XIX of this chapter, money or other consideration at a rate in excess of the rates established by the State (or, in the case of services provided to an individual enrolled with a Medicaid managed care organization under subchapter XIX of this chapter under a contract under section 1396b (m) of this title or under a contractual, referral, or other arrangement under such contract, at a rate in excess of the rate permitted under such contract), or
 - (2) charges, solicits, accepts, or receives, in addition to any amount otherwise required to be paid under a State plan approved under subchapter XIX of this chapter, any gift, money, donation, or other consideration (other than a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to the patient)—
 - (A) as a precondition of admitting a patient to a hospital, nursing facility, or intermediate care facility for the mentally retarded, or
 - (B) as a requirement for the patient's continued stay in such a facility,
 - when the cost of the services provided therein to the patient is paid for (in whole or in part) under the State plan, shall be guilty of a felony and upon conviction thereof shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

False Statement



- 42 U.S. Code § 1320a–7b(c) False statements or representations with respect to condition or operation of institutions

Whoever knowingly and willfully makes or causes to be made, or induces or seeks to induce the making of, any false statement or representation of a material fact with respect to the conditions or operation of any institution, facility, or entity in order that such institution, facility, or entity may qualify (either upon initial certification or upon recertification) as a hospital, critical access hospital, skilled nursing facility, nursing facility, intermediate care facility for the mentally retarded, home health agency, or other entity (including an eligible organization under section 1395mm (b) of this title) for which certification is required under subchapter XVIII of this chapter or a State health care program (as defined in section 1320a–7 (h) of this title), or with respect to information required to be provided under section 1320a–3a of this title, shall be guilty of a felony and upon conviction thereof shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

False Claims Act



- Cannot knowingly submit a false claim for payment to the federal government.
- Must report and repay a false claim within 60 days.
- Penalties
 - Repayment plus interest
 - Civil monetary penalties of \$5,500 to \$11,000 per claim
 - 3x damages
 - Exclusion from Medicare/Medicaid

False Claims Act: Private Actions



- *Qui Tam* Suits: private entities (e.g., employees, patients, providers, competitors, *etc.*) may sue the hospital under False Claims Act on behalf of the government.
 - Government may or may not intervene.
 - *Qui tam* relator.
 - Receives a percentage of any recovery.
 - Recovers their costs and attorneys fees.

False Claims Act: Examples



- Claims for services that were not provided or were different than claimed.
- Failure to comply with conditions of payment.
 - Express or implied certification of compliance when submit claims (*e.g.*, cost reports or claim forms).
- Failure to comply with quality of care.
 - Express or implied certification of quality.
 - Provision of “worthless” care.

False or Fraudulent Claims



- Cannot knowingly present or cause to be presented to federal or state program a claim that is:
 - For an item or service that the person knows was not provided as claimed (e.g., upcoding).
 - False or fraudulent.
 - Presented as physician service or physician extender service but the person who presented the claim knew that:
 - Physician was not licensed,
 - Physician's license was improperly obtained, or
 - Physician misrepresented that he/she was board certified.
 - For a pattern of items or services that a person knows or should know are not medically necessary.

(42 U.S.C. § 1320a-7a(a)(1); 42 C.F.R. § 1003.102)

False or Fraudulent Claim



- Penalties:
 - Denial of payment.
 - \$10,000 for each item or service claimed.
 - 3x amount claimed for item or service.
 - Exclusion from Medicare and Medicaid.
- (42 U.S.C. § 1320a-7a(a))
- May also trigger False Claims Act
 - \$5,500 to \$11,000 per false claim.
 - 3x the amount claimed.
 - Qui tam lawsuit.
 - Repayment of amounts improperly paid.

False Record or Statement



- Cannot knowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program.
 - Penalty
 - \$50,000 per each false statement or misrepresentation.
 - 3x amount claimed.
 - Denial of payment.
 - Repayment of amounts improperly paid.
 - Exclusion from Medicare and Medicaid.
- (42 U.S.C. § 1320a-7a(a)(8); 42 C.F.R. § 1003.102)

False Certification for Home Health Services



- Physician cannot execute a document representing that patient meets requirements for home health services if the physician knows that all of the requirements are not met.
- Penalty
 - \$5,000
 - 3x amount of payments for home health services made per such certification.

(42 U.S.C. § 1320a-7a(b)(3); 42 C.F.R. § 1003.102)

Violation of Provider Agreement



- Cannot knowingly present or cause to be presented to any person a request for payment that violates:
 - Assignment limitations.
 - Arrangement with a state agency not to charge a person for an item or service over allowed charge.
 - Agreement to be a participating provider.
- Penalty
 - \$10,000 per item or service
 - 3x amount claimed.
 - Repayment of amounts paid.
 - Exclusion from Medicare and Medicaid.

(42 U.S.C. § 1320a-7a(a)(2); 42 C.F.R. § 1003.102)

False Information re Discharge



- Cannot knowingly give or cause to be given to any person, with respect to Medicare inpatient coverage, information that he knows or should know is false or misleading, and that could reasonably be expected to influence the decision when to discharge such person or another individual from the hospital.
 - Penalty
 - \$15,000 for each individual for which false information given.
 - 3x amount claimed.
 - Repayment of amounts paid.
 - Exclusion from Medicare and Medicaid.
- (42 U.S.C. § 1320a-7a(a)(3); 42 C.F.R. § 1003.102)

Repayment Law



- If provider has received an “overpayment”, provider must:
 - Return the overpayment to federal agency, state, intermediary, or carrier, and
 - Notify the entity of the reason for the overpayment.
- Must report and repay within the later of:
 - 60 days after overpayment is identified, or
 - date corresponding cost report is due.
- If have notice of potential overpayment, must make “reasonable inquiry” with “all deliberate speed” to determine whether overpayment exists.
- *No “finders keepers”*

Repayment Law



- “Overpayment” = funds a person receives or retains to which the person, after applicable reconciliation, is not entitled, *e.g.*,
 - Payments for non-covered services
 - Payments in excess of the allowable amount
 - Errors and non-reimbursable expenses in cost reports
 - Duplicate payments
 - Receipt of Medicare payment when another payor is primary
 - Payments received in violation of:
 - Stark
 - Anti-Kickback Statute
 - Exclusion Statute

Repayment Law



- “Knowing” failure to report and repay by deadline =
 - False Claims Act violation
 - \$5,500 to \$11,000 per violation
 - 3x damages
 - *Qui tam* lawsuit
(31 U.S.C. § 3729)
 - Civil Monetary Penalties Law violation
 - \$10,000 penalty
 - 3x damages
 - Exclusion from Medicare or Medicaid
(42 U.S.C. § 1320a-7a(a)(10))

Repayment Law



- “Knowing” =
 - Has actual knowledge of overpayment
 - Acts in deliberate ignorance of overpayment
 - Acts with reckless disregard of overpayment
 - Does not require specific intent to defraud
(31 U.S.C. § 3729(b)(1))
- Original conduct giving rise to overpayment may not violate FCA or Civil Monetary Penalties Law.
- Failing to timely repay overpayment may violate FCA or Civil Monetary Penalties Law.

Repayment Rule



- To report and repay overpayments, use existing voluntary refund process (“self-reported overpayment refund process”)
 - Use form that contractors maintain on their website.
 - Among other things, must disclose:
 - how error was discovered
 - corrective action plan to avoid repeat
 - reason for refund
 - total amount of refund
 - if statistical sample used, method for calculation.
 - Include refund.

Repayment Rule



- Examples of “identified” overpayment
 - Upon reviewing records, discover erroneous codes used.
 - Discover services were rendered by unlicensed or excluded provider.
 - Internal audit reveals overpayment.
 - Compliance hotline tip notifies provider of possible overpayment but provider fails to make reasonable inquiry.
- Overpayment is “identified” when:
 - Existence of an overpayment is confirmed, or
 - Put on notice and failed to make reasonable inquiry.

Repayment Rule



- Not perfectly clear how far back provider must look when evaluating repayment.
 - CMS may reopen claims:
 - Within 1 year for any reason.
 - Within 4 years for good cause.
 - Anytime due to fraud or fault.

(See 42 C.F.R. § 405.980)
 - Be mindful of the False Claims Act statute of limitations

Repayment Rule



- Repayment per Repayment Law does not resolve violations or penalties under other laws, *e.g.*,
 - Anti-Kickback Statute, Civil Monetary Penalties Law, False Claims Act, or other criminal provisions, which are resolved by OIG or DOJ.
- If Medicare contractor believes repayment involves violation of federal law, contractor may report repayment to the OIG, CMS, or other federal agency.
 - Be careful how and what you disclose.

Obstruction of Justice



- 18 U.S.C. § § 1503, 1505, 1510, 1511, 1512, 1513, 1519
- 18 U.S.C. § 1505 Obstruction of proceedings before departments, agencies, and committees

Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States, or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress.

- 18 U.S.C. § 1516 Obstruction of A Federal Audit

Whoever, with intent to deceive or defraud the United States, endeavors to influence, obstruct, or impede a Federal auditor in the performance of official duties relating to a person, entity, or program receiving in excess of \$100,000, directly or indirectly, from the United States in any one year period under a contract or subcontract, grant, or cooperative agreement.

18 U.S.C. § 1518 Obstruction of Criminal Investigations of Health Care Offenses



- (a)** Whoever willfully prevents, obstructs, misleads, delays or attempts to prevent, obstruct, mislead, or delay the communication of information or records relating to a violation of a Federal health care offense to a criminal investigator shall be fined under this title or imprisoned not more than 5 years, or both.
- (b)** As used in this section the term “criminal investigator” means any individual duly authorized by a department, agency, or armed force of the United States to conduct or engage in investigations for prosecutions for violations of health care offenses.

18 U.S.C. § 1519 Destruction, alteration, or falsification of records in Federal investigations



Whoever knowingly alters, destroys, mutilates, conceals, covers up, falsifies, or makes a false entry in any record, document, or tangible object with the intent to impede, obstruct, or influence the investigation or proper administration of any matter within the jurisdiction of any department or agency of the United States or any case filed under title 11, or in relation to or contemplation of any such matter or case, shall be fined under this title, imprisoned not more than 20 years, or both.

Document Retention



- **“Whoever alters, destroys ... any record, document, ... with the intent to impede, obstruct, or influence the investigation [of] ... any Federal agency ... shall be ... imprisoned not more than 20 years”**
 - 18 U.S.C. § 1519

Document Retention



- **“Whoever corruptly alters, destroys, ... or conceals a record ... with the intent to impair the object’s integrity ... in an official proceeding, or otherwise obstructs or impedes any official proceeding, shall be imprisoned not more than 20 years”**
–18 U.S.C. § 1512(c)

Document Retention



■ “[O]bligation to preserve documents ... rests squarely on the shoulders of senior corporate officers.”

– *In re Prudential Ins.*, 169 F.R.D. 598 (D.N.J. 1997)

Exclusion/Debarment



- Certain offenses trigger mandatory exclusion from participation in Medicare and Medicaid, including
 - A felony conviction for fraud, theft, or embezzlement involving a health care program;
 - A conviction for abuse and neglect of patients; and
 - A conviction for failure to deliver services authorized by the Medicare and/or Medicaid programs.
- HHS-OIG may also debar parties from participation in Medicaid and Medicare even where it is not mandatory. Permissive exclusion can occur as the result of a number of infractions (e.g., obstructing a healthcare overpayment investigation).

Excluded Entities



- HHS may exclude individuals and entities from participating in federal health care programs if they have been convicted of fraud, abuse, or many other offenses.
 - Mandatory exclusions: 42 C.F.R. § 1001.101
 - Permissive exclusions: 42 C.F.R. § 1001.201
 - States are required to exclude from Medicaid any person who has been excluded from federal programs.
 - Exclusion continues until OIG reinstates the entity or withdraws exclusion.
 - Must apply for reinstatement.
- (42 U.S.C. § § 1320a-7 and 1320c-5; 42 C.F.R. § 1001 parts B and C)

Excluded Entities



- Excluded person cannot order or prescribe item or service if the person knows or should know that a claim for such item or service will be made under a federal health care program.
 - Penalty
 - \$10,000 per item or service.
 - 3x amount claimed.
 - Repayment of amounts paid.
- (42 U.S.C. § 1320a-7a(a)(8); 42 C.F.R. § 1003.102)

Excluded Entities



- Cannot knowingly present or cause to be presented a claim to a federal or state program that is for an item or service furnished by an excluded person.
- Penalty:
 - \$10,000 per item or service.
 - 3x amount claimed.
 - Repayment of amounts paid.
 - Exclusion from Medicare and Medicaid.
 - Criminal sanctions

(42 U.S.C. § 1320a-7a(a)(1)(D); 42 C.F.R. § § 1001.1901 and 1003.102).

Excluded Entities



- Cannot hire or contract with an excluded entity or arrange for an excluded entity to provide items services payable by federal program if knew or should know if the exclusion.
- Penalties
 - \$10,000 per claim submitted.
 - 3x amount of claims.
 - Repayment of amounts paid.
 - Exclusion from Medicare and Medicaid.

(42 U.S.C. § 1320a-7a(a)(6); 42 C.F.R. § 1003.102).

Excluded Entities



- Medicare, Medicaid, or other federal program will not pay claim if person “knew or should have known” of exclusion.
 - Exception for certain emergency services.

(42 C.F.R. § § 1001.1901(b) and 1003.102(a))
- Knowledge =
 - Have actual knowledge of exclusion or sufficient facts that you should have known of exclusion.
 - Notified by HHS of exclusion, *e.g.*, in response to claim.
 - Prohibition takes effect certain number of days after notice mailed.
 - Listed on the List of Excluded Individuals or Entities (“LEIE”).

List of Excluded Individuals and Entities (“LEIE”)



- “Providers and contracting entities have an affirmative duty to check the program exclusion status of individuals and entities prior to entering into employment or contractual relationships, or run the risk of CMP liability if they fail to do so.”
- Check LEIE before hiring or contracting with entities.
 - Employees, contractors, vendors, medical staff, etc.
- Check LEIE periodically to determine status.
 - Employees, providers, vendors, medical staff members, ordering providers, others?
 - Excluded provider list updated monthly.
 - CMS Medicare: check LEIE “periodically” or “routinely”, e.g., at least annually
(OIG *Supplemental Compliance Guidance*, 70 FR 4876)
 - CMS Medicaid: check LEIE monthly
(Letter from H. Kuhn, CMS Medicaid, 1/16/09)

Increased Enforcement



■ Players In Enforcement

- U.S. Attorney's Office
 - Health Care Fraud Coordinator and Other Assistant U.S. Attorneys
 - Health Care Fraud Investigator

■ U.S. Department of Health & Human Services Office of Inspector General (HHS-OIG)

- Special Agents who investigate allegations of fraud and abuse and refer matters to USAOs for prosecution
- Issue annual work plan identifying cases of particular concern and other guidance
- Debarment authority allows it to exclude providers from participating in the federal health care benefit programs as the result of fraud and abuse

■ Federal Bureau of Investigation

- Special Agents

Increased Enforcement (con't)



- Medicaid Fraud Control Units (MFCU), Department of Criminal Investigation
 - If State Medicaid Program administrators detect fraudulent activities in audits, the matters must be referred to the MFCU (42 C.F.R. § 455.21)
 - Attorney
 - Special Agents & Auditors

- State Auditor's Office / Insurance Commissioner
 - Attorney
 - Investigators

- Centers for Medicare and Medicaid Services
- Determine overpayment appeals when providers challenge payment denials and overpayment demands.
- Provides Guidance to the Contractors Administering the Program

Non-Law Enforcement Players



- **Medicare Administrative Contractors (MACs)** - - as the entities responsible for administering the claims processing and payment functions for Medicare on a regional basis, these private companies have program integrity units, which have access to substantial claims and payment information to determine patterns and errors;
- **Recovery Audit Contractors (RACs)** - - by focusing on errors, RACs recoup overpayments through data mining; they have authority to review Parts A – D of Medicare and Medicaid payments made to providers, paid based upon a percentage (9 to 12% in Fiscal Year 2012) of improper payments recovered;
- **Zone Program Integrity Contractors (ZPICs)** - - four private firms assigned to regions; data mining and analytics by regional contractors to detect waste, fraud, and abuse in Medicare (Parts A & B); investigation of matters; referrals to OIG and other law enforcement and MACs;
- **Fraud Prevention Partnership** - - HHS/DOJ initiative with private insurers; more data mining and analytics.

The United States Senate Committee on Finance

For Immediate Release

June 25, 2013

Contact:

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Baucus Statement on Saving Medicare Dollars, Preserving High-Quality Care

Benjamin Franklin once said, “Waste neither time nor money, but make the best use of both.”

This Committee has oversight of Medicare. Forty-nine million seniors and disabled Americans depend on this program. Making sure the government spends Medicare dollars wisely is one of our chief responsibilities – one I take seriously.

In 2011, \$29 billion of Medicare payments were considered improper. Our goal should be to lower this amount to zero. Regular audits save Medicare money by recouping these errant payments. Since 2010, audits have identified \$4.8 billion of incorrect Medicare payments, but they also can impose burdens on providers.

Today we will examine the audits performed by private contractors called Recovery Audit Contractors. Their mission is to uncover and collect inappropriate payments made to medical providers – both under- and overpayments.

The 2003 Medicare prescription drug law created the Recovery Audit Contractor program as a six-state demonstration. Over the three-year test period, the program returned \$900 million to Medicare. It was so successful that Congress expanded it nationwide. The Affordable Care Act further expanded the program to cover Medicare managed care and Medicaid.

As the “Baby Boom” generation ages, Medicare must remain financially strong. The Medicare Trustees determined last month that the Medicare Trust Fund will last two years longer than previously estimated, until 2026. Per-beneficiary spending is at a historical low. We have made real progress ensuring Medicare will be strong for future generations.

Private audits play a key role in strengthening Medicare’s finances. In 2011, these audits returned nearly half a billion dollars to the Medicare Trust Fund. We need to build on this success, but we can’t overburden legitimate providers who play by the rules. We need balance.

Providers should focus on patient care, not senseless red tape. Recovery Audit Contractors frustrate many Montana providers.

One is Kalispell Regional Medical Center. In the last year, the hospital has had to spend nearly one million dollars and hire three new full-time staff just to deal with the audits. In total, eight of their employees respond to audits. For a small hospital in Montana, that's a serious investment.

Charles Pearce serves as the hospital's Chief Financial and Information Officer. What is it that frustrates Mr. Pearce the most? The randomness of the audit process.

He believes the auditors are over-zealous and incur no penalties or consequences when an audit is overturned on appeal. Mr. Pearce provides example after example of audits that were eventually overturned on appeal.

One case involved a sixty-five year old man who had leg surgery and was fitted with a cast. Several weeks later he came to the emergency room with severe chest pain. A CT scan showed he had a blood clot in his lung. The doctor on duty admitted the man and prescribed medication.

Almost three years later, a private contractor's audit said this admission was unnecessary. The audit claimed the patient's medical history did not support the admission. As a result, Kalispell Regional was forced to pay back Medicare.

The hospital appealed the decision, arguing that the admission was necessary because the original surgery and cast increased the risk for a lethal blood clot. Kalispell Regional won its appeal. Kalispell Regional has won appeals in 90 similar cases. All told, Kalispell Regional was successful in 53 percent of its appeals.

There must be better ways to spend the government's and hospitals' time and money. Here are three steps Medicare should take.

One, incentivize private contractors to focus on the most at-risk services and providers. This way, providers with a long track record of following the rules are rewarded.

Two, bolster provider education by Medicare and its contractors. Providers can't follow the rules if they don't know the rules. Medicare regulations can often be confusing and require more time than providers have.

Three, make the appeals process more efficient. One of my top rules to live by is, "do it right the first time."

As Kalispell Regional's experience shows, appealed cases often face a long and expensive road for both the provider and the government.

The Inspector General for the Department of Health and Human Services found rulings in the final stage of the appeals process – a hearing in front of a judge – are highly inconsistent. The IG report found the same facts and circumstances often lead to two opposite decisions.

Recovery audit contractors are only one piece of a larger concern with the growing use of contractors. Ensuring Medicare pays accurately is difficult and complex. Over the years, different contractors, all with their own acronyms, have been layered over one another.

While some overlap may be necessary, Congress should work to simplify the way the contractors interact with providers. This should increase efficiency and may also reduce some unnecessary burden on doctors and hospitals.

As we work to strengthen our federal health care system, we must keep Benjamin Franklin's words in mind. We must waste neither time nor money, but make the best use of both. And we must do so to improve patient care.

###

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08/22/2012

Obama Administration Announces Fraud Prevention Partnership

By Bill Mercer

Last month, Secretary Sebelius and Attorney General Holder announced a new collaboration with health insurance companies to provide both government and private payer claims data to a third-party to detect overpayments and fraud.

<http://www.hhs.gov/news/press/2012pres/07/20120726a.html>

<http://www.justice.gov/opa/pr/2012/July/12-ag-926.html>

By pooling claims data and having the third-party analyst look for suspicious billing patterns, the federal government and participating insurers believe outliers would be readily identifiable. Claims data which appear to suggest the existence of fraud or overpayments would be referred to federal law enforcement for further investigation.

By commingling claims information from private insurers, Medicaid, and Medicare, the Administration believes it could detect, for example, a provider who bills all payers for more than 24 hours in a day or bills the same claims to multiple insurers. Attorney General Holder's statement

[<http://www.justice.gov/iso/opa/ag/speeches/2012/ag-speech-120726.html>] refers to the prospect of detecting claims made to multiple public and/or private insurance plans for the same patient on the same day in more than one city.

A number of private sector participants have volunteered to participate in the partnership, including:

- America's Health Insurance Plans
- Amerigroup Corp.
- Blue Cross and Blue Shield Association
- Blue Cross and Blue Shield of Louisiana
- Humana Inc.
- Independence Blue Cross
- Travelers
- Tufts Health Plan
- UnitedHealth Group
- WellPoint Inc.

Significant details necessary to the creation of a functional partnership have yet to be resolved. According to the HHS press release, the Executive Board and two committees will meet for the first time next month. The initial work plan is also a work-in-progress.

The partnership received support from Senator Coburn and Senator Hatch, who wrote to the Acting Administrator of CMS that "this is an effort which is long overdue."

[http://www.coburn.senate.gov/public/index.cfm?a=Files.Serve&File_id=b3d5048d-a395-49af-b4ac-2c2b65b9a4a0] The lack of detail in the Administration's rollout of the initiative generated a series of follow-up





12/12/13

Obama Administration Announces Fraud Prevention Partnership - Holland & Hart Health Law Blog

questions from Senators Coburn and Hatch. They have asked for responses on the following issues by the end of August:

"Specifics regarding exactly how this collaboration will work including what entities will be involved, whether HHS/CMS or another entity will be overseeing the effort and a timeline for expected key milestones of the effort.

A step-by-step explanation of how the information will be shared (e.g., what systems will be used to transmit the data), what authorities allow the exchange of information, what impediments exist to sharing information (e.g., statutory language) and where the information will be stored/analyzed.

A description of the third party who will be analyzing the data, as well as an explanation of how that entity will be selected and what their capabilities are to integrate and analyze such a large amount of information.

Specifics regarding what will happen when leads are identified, how that information will be disseminated, and what the process will be for following up on those leads."

Posted at 01:17 PM in [Fraud and Abuse](#) | [Permalink](#)
[|Reblog \(0\)](#)



AUG 27 2012

Administrator
Washington, DC 20201

The Honorable Orrin G. Hatch
United States Senate
Washington, DC 20510-6250

Dear Senator Hatch:

Thank you for your letter regarding the Centers for Medicare & Medicaid Services's (CMS) implementation of the Fraud Prevention System and the Fraud Prevention Partnership. CMS is strongly committed to aggressively combating fraud, waste, and abuse in its programs. I appreciate this opportunity to elaborate on CMS's advanced technological initiatives and look forward to working with you as we continue to make improvements toward protecting the integrity of federal health care programs and safeguarding taxpayer resources.

Fraud Prevention System and Data Analytics

As you know, following the passage of the Small Business Jobs Act of 2010 (Pub. Law 111-240), CMS deployed predictive analytics technology to review all Medicare fee-for-service claims. The Fraud Prevention System (FPS), a part of CMS's National Fraud Prevention Program (NFPP), was launched prior to the statutorily mandated implementation date of July 1, 2011. Section 4241(e) of the law also required CMS to report, no later than 3 months after the completion of the first implementation year, on the use of predictive analytics in the first year, and to obtain certification from the Department of Health and Human Services's (HHS) Office of Inspector General (OIG) on the actual and projected savings to the Medicare fee-for-service program from use of this technology.

As you point out in your letter, performance metrics are critical to ensure the success of our new predictive analytics technology and we share your interest in tracking our operations in this regard. We anticipate issuing the report to both Congress and the public by the end of September. This report will include the results of the FPS in the first year, including a detailed breakout of any dollar amounts that have been saved as a direct result of the FPS. As required by law, the savings and the methodology for calculating those savings will be certified by the OIG.

In response to your question, the Integrated Data Repository (IDR) and One PI are key components of our comprehensive, advanced data analytics. The IDR is a data warehouse that will integrate Medicare and Medicaid claims data into a single source for users across the agency. One PI is a web-based, single point of access to the analytic tools that are used to conduct data analysis on the IDR. CMS uses the historical Medicare data from the IDR to develop and refine predictive analytic models prior to integration into the Fraud Prevention System. Analysts and investigators also rely on the data in the IDR to develop leads identified by the Fraud Prevention System. The Health Care Fraud and Abuse Control Program wholly funds One PI and is one of several funding sources for the IDR.



To develop and test more comprehensive models more quickly, analysts use historical claims from the IDR to analyze patterns and develop models for the FPS. In turn, the FPS uses aggregate historical information about billing behavior in the models and applies this information to all claims nationwide, creating more effective analytics. CMS develops FPS models during collaborative working sessions, but the adoption of models into the FPS are controlled through the FPS governance board. Our first report to Congress will provide additional detail on the model development process.

Command Center

As health care fraud schemes become more sophisticated, we need the right tools and people to stay a step ahead. In contrast to how claims were analyzed and investigated in the past, the center provides a collaborative workspace for CMS staff, contractors and law enforcement partners to better collaborate and leverage several fraud detection and prevention tools, including the FPS and our Automated Provider Screening (APS) system. We recognize that technology alone cannot solve all problems, and the Command Center approach, bringing together individuals with diverse skills and expertise in such areas as behavioral economics, law enforcement, and payment policy, enables CMS to incorporate a multi-disciplinary approach to combat fraud.

The Command Center uses a team of experts and decision makers to more efficiently coordinate policies and case actions, reduce duplication of efforts, streamline fraud investigations for more immediate administrative action, and continuously refine the analytics. Its cost of \$3.6 million included expenditures related to development and design, construction, furniture, information technology equipment support, and security. There are five staff currently dedicated to the Command Center full time, and they are teamed with experts to develop predictive models, expedite investigations and impose administrative actions. The Command Center will be used by experts from CMS, its contractors, our law enforcement partners, and other expert personnel on a rotational basis. The Zone Program Integrity Contractors (ZPICs) and Program Safeguard Contractors (PSCs) are one of the primary users of the FPS, using it to conduct investigations, perform data analysis, and recommend a range of possible administrative actions such as pre-payment review, payment suspensions and/or revocation of billing privileges. ZPICs also use FPS to refer cases to law enforcement for consideration and initiation of civil or criminal prosecution.

Traditional Fraud Detection Tools

We continue to use our traditional methods such as beneficiary complaint investigations to make referrals to law enforcement. Alert and vigilant beneficiaries, family members, and caregivers are some of our most valuable partners in stopping fraudulent activity. CMS screens every complaint received at its national 1-800-MEDICARE Contact Centers for information indicating suspicious behavior or potential fraud. In 2011 alone, nearly 50,000 complaints of potential fraud reported by beneficiaries and others to 1-800-MEDICARE passed initial screening and were evaluated further. These complaints are subsequently being incorporated into FPS by becoming part of a provider's risk score used to generate leads for investigation.



If law enforcement declines a referral, CMS continues to evaluate the matter for the potential imposition of administrative actions to recoup overpayments, suspend payments or revoke billing privileges.

We are also using technologies such as Google Earth to determine a provider or supplier's physical practice location. While Google Earth or other geospatial analysis may indicate that a provider's or supplier's location appears to be a false store front, CMS must undertake additional validation of such information. For these types of leads, validation involves a site visit to the location to verify if the provider or supplier is operational. CMS has implemented a national site visit contractor that will facilitate efficiency and increase capacity for additional announced and unannounced site visits when required or needed.

The CMS also continues to use revocation of provider billing privileges as a critical tool in fraud prevention. OIG uses its broader exclusion authority to remove many bad actors from all federal health care programs. Both CMS revocations and OIG exclusions bar the provider or supplier from participating in the program.

In response to the list of physicians and non-physicians that you previously provided, CMS reported that as of November 9, 2011, of the 27 physicians and non-physician practitioners still enrolled, CMS was pursuing revocations against 22. At this time, all 22 have been revoked from the Medicare program, with the revocation becoming effective on the date of the felony conviction. After review, CMS is not pursuing revocation for the remaining five because facts and circumstances in their particular cases do not support a revocation.

Public Private Partnership

The HHS and Department of Justice recently announced the formation of the new public-private partnership, the Fraud Prevention Partnership. While potential goals have been identified, the operational structure of the partnership and the initial work plan are still under development, as well as the use and identity of a third party and any specifics on data sharing. The first Executive Board meeting of the partnership will be in September, and it is anticipated that this information will be the topic of the meeting.

We are continually evaluating how our fraud prevention efforts affect providers and beneficiaries. I am committed to reducing the impact of auditing on providers and we are reviewing this issue across the agency to determine what changes will improve the process. Specifically we are working to ensure all letters issued by any Medicare review contractor are in the same format with a detailed review rationale, provider due dates and deadlines are consistent, and audits are effective and efficient. I am always open to hearing any new ideas or recommendations you may have to help alleviate audit burden.





Page 4 – The Honorable Orrin G. Hatch

Thank you for your interest in this issue. I will also provide a copy of this response to the co-signer of your letter.

Sincerely,

Marilyn Tavener
Acting Administrator



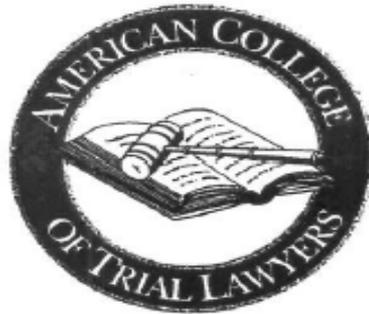
- The Means of an Investigation
- HIPAA Administrative Subpoenas
- OIG Requests for Information or Assistance
- OIG Administrative Subpoenas
- Demands For Immediate Access by OIGs and MFCU
- DOJ Civil Investigative Demands, including Interrogatories and Deposition Notices
- Grand Jury Subpoenas

Tripwires



- What Factors Counsel In Favor Of An Internal Investigation?

The American College of Trial Lawyers has identified events that should serve as triggers.



RECOMMENDED PRACTICES FOR
COMPANIES AND THEIR COUNSEL IN
CONDUCTING INTERNAL INVESTIGATIONS

Approved by the Board of Regents
February 2008





II. Initial Organizational Issues

A. Factors to Consider When Evaluating Whether to Commence an Internal Investigation When Allegations Have Been Lodged of Significant Corporate Malfeasance Or Where an Outside Auditor Suspects Illegality

Internal investigations typically result from discovery -- by the Company, the media, an external auditor, or a whistleblower -- of circumstances that raise a serious concern of potential liability or financial misconduct. The investigations are thus meant to determine the validity and seriousness of the circumstances alleged or disclosed and what action, if any, the Company should take consistent with the best interests of the shareholders. Among the possible responsive actions are remediation, market disclosure, and preparation for, and defense of, potential prosecutorial and regulatory actions or civil lawsuits. Depending on whose conduct is the focus of the investigation, senior management, the Board of Directors, an audit committee or a special committee of disinterested directors may decide to commence an investigation. There are some respected corporate lawyers who counsel that Boards should resist the trend of having audit committees or special committees of independent directors routinely investigating whistleblower complaints and the like.²

Whether to commence an internal investigation may be a discretionary decision, *supra*, or in limited circumstances may be prescribed by statute. In the latter case, Section 10A of the Exchange Act requires external auditors, who detect or otherwise become aware that an illegal act has or may have occurred, to determine whether it is likely such an illegal act has occurred and the effect of any illegal act on the Company's financial statements. Auditors look to the Company to investigate and evaluate such possible illegalities and then assess whether the Company and the Board of Directors have taken "timely and appropriate remedial actions" regarding such possible illegalities. In this regard, the methodology used in "10A investigations" is not materially different from an internal investigation commenced on the company's own initiative, and therefore, for the purposes of this paper they will be treated collectively.

Outside of the 10A context, there are several circumstance that have traditionally triggered the initiation of internal investigations by senior management, a Board, audit committee or special committee:

- a. Receipt of a whistleblower letter or communication that raises allegations of misconduct by senior or significant members of management;
- b. Shareholder demand in the nature of an actual or threatened derivative action against directors and officers, possibly leading to formation of a Special Litigation Committee;
- c. Allegations of misconduct raised by external auditor, internal auditor, or compliance;
- d. Board member suspicion of misconduct by officers or employees;
- e. Receipt of subpoena or informal request for information by a government or self-regulatory organization (SRO), or an announcement by a government agency or SRO of suspicions of misconduct by the Company or industry; or
- f. Allegations of misconduct by the media, watchdog groups, or academics.

² Andrew Ross Sorkin, *Questioning an Adviser's Advice*, N.Y. TIMES, Jan. 8, 2008 (interview of Martin Lipton).

In addition, although there have been no reported enforcement actions under the section yet, the "reporting up" provisions of the Sarbanes-Oxley Act of 2002 require in-house counsel to ensure that the corporation takes appropriate steps in response to allegations of wrongdoing.

B. External Factors, Such as The Existence or Anticipated Existence of a Parallel Government Investigation or Shareholder Lawsuit, Should Be Considered When Making Decisions About How To Conduct and Document An Internal Investigation

There is a reasonable likelihood that any major internal investigation will be followed by, or conducted parallel to, an actual (or anticipated) external investigation by (one or more of): the Department of Justice, Securities and Exchange Commission, NYSE (or other self regulatory organization ("SRO")), a state attorney general or local district attorney, or other enforcement or regulatory authority. The Company and the Board may also be facing civil lawsuits, including shareholder class actions and derivative suits, pertaining to the alleged misconduct; and in certain instances, may be dealing with criminal investigations initiated by federal and, more recently, state prosecutors.³

The existence or threatened existence of any of these external events necessarily affects how the Company, Board, audit or independent committee, and outside counsel conduct and document an internal investigation. As discussed more fully below, counsel and the Company should anticipate that all documents created, facts uncovered, and witness statements made to them, may be disclosed to the government or regulator, and also may be discoverable by a private plaintiff. This assumption should be a factor in all major decisions about the procedure and protocol for any major internal investigation. In particular, the company, the Board or its independent committees, and counsel may want, or may be forced, to make an early determination about whether and how they will "cooperate" with government or regulatory investigations.

During approximately the last decade, driven by regulatory policies promulgated by the Department of Justice,⁴ the Securities and Exchange Commission and other regulators,⁵ and

3 See, e.g., Mark Gimoin, *Elliot Spitzer: The Enforcer*, Fortune, Sept. 16, 2002, at 77; Charles Gasparino & Paul Beckett, *Quick Fix May Elude Citigroup and Weill*, Wall St. J., Sept. 10, 2002, at C1; Gregory Zuckerman & Mitchell Pacelle, *Now, Telecom Deals Face Scrutiny*, Wall St. J., June 28, 2002, at C1.

4 See text, *infra* at n. 7-10, 13-14.

5 See "Report of Investigation Pursuant to Section 21(a) of the Securities Exchange Act of 1934 and Commission Statement on the Relationship of Cooperation to Agency Enforcement Decisions," issued on October 23, 2001 as Releases 44969 and 1470, available at <http://www.sec.gov/litigation/investreport/34-44969.htm>, and referred to as the "Seaboard Report." The Seaboard Report is the SEC's current policy regarding waiver of privilege and work product, and sets forth the criteria that it will consider in determining the extent to which organizations will be granted credit for cooperating with the agency's staff by discovering, self-reporting, and remedying illegal conduct, which cooperation, or lack thereof, in the eyes of the staff will be taken into consideration when the SEC decides what, if any, enforcement action to take. The Seaboard Report has been read by practitioners as encouraging companies not to assert, or to waive, their attorney-client privilege, work product, and other legal protections as a sign of full cooperation. See Seaboard Report at paragraph 8, criteria no. 11, and footnote 3.

Another example of a regulatory agency promulgating similar policies is the Commodity Futures Trading Commission ("CFTC"), the Enforcement Division of which issued an Enforcement Advisory on August 11, 2004, entitled "Cooperation Factors in Enforcement Division Sanction Recommendations," promoting the waiver of appropriate privileges. The CFTC issued a revised Enforcement Advisory eliminating the waiver language on March 1, 2007. See <http://www.abanet.org/poladv/priorities/privilege waiver/ncprivilege.html>.





1. "Do I Have To?"



2010-01-12 10:00 AM

UNITED STATES DISTRICT COURT

for the
Northern District of Oklahoma

In the Matter of the Search of
[redacted] at [redacted]
or [redacted] the person or persons and address:

Building A
123 Main Street

SEARCH AND SEIZURE WARRANT

To: Any authorized law enforcement officer

An application by a [redacted] law enforcement officer or an attorney for the government requests the search of the following person or property located in the [redacted] District of [redacted]:
[redacted] the person or describe the property to be searched and give the location.

The person or property to be searched, described above, is believed to contain [redacted] the person or describe the property to be searched.

I find that the affidavit(s), or any reported testimony, establish probable cause to search and seize [redacted] the property.

YOU ARE COMMANDED to execute this warrant on or before **December 31, 2011**

in the daytime, 6:00 a.m. to 10 p.m. at any time in the day or night as I find reasonable cause has been established.

Unless delayed notice is authorized below, you must serve a copy of the warrant and a receipt for the property taken to the person from whom, or from whose premises, the property is to be taken, and leave the copy and receipt at the place where the property was taken.

The officer executing this warrant, or an officer present during the execution of the warrant, shall file a return in accordance with the law and promptly return this warrant and inventory to United States Magistrate [redacted].

I find that immediate notification may have an adverse result listed in 18 U.S.C. § 2703 (except for delay of trial), and authorize the officer executing this warrant to delay notice to the person who, or whose property, will be searched or seized unless the magistrate has [redacted] for [redacted] days (unless waived by [redacted]) until the facts justify the later specific date of [redacted].

Date and time issued: 12/29/2011 10:00 am

City and state:

U.S. Magistrate Judge
[redacted]

**Building A
123 Main Street
Tulsa, OK**

**YOU ARE COMMANDED
to execute this
warrant on or before
December 31, 2011**

**in the daytime
6:00 a.m. to 10 p.m.**

HOLLAND & HART



1. "Do I Have To?"



00107 (06/11) CIVIL Return and Seizure Warrant (Page 2)

Return		
Case No.	Date and time warrant executed	Copy of warrant and inventory left with:
Inventory made in the presence of:		
Inventory of the property taken and name of any person(s) seized:		
Certification		
<i>I declare under penalty of perjury that the inventory is correct and was returned along with the original warrant to the designated judge.</i>		
Date:	Executing officer's signature:	
	Printed name and title:	

Return

Inventory made in the presence of:

Inventory of the property taken and name of any person(s) seized:

HOLLAND & HART 

Counsel – A.S.A.P.

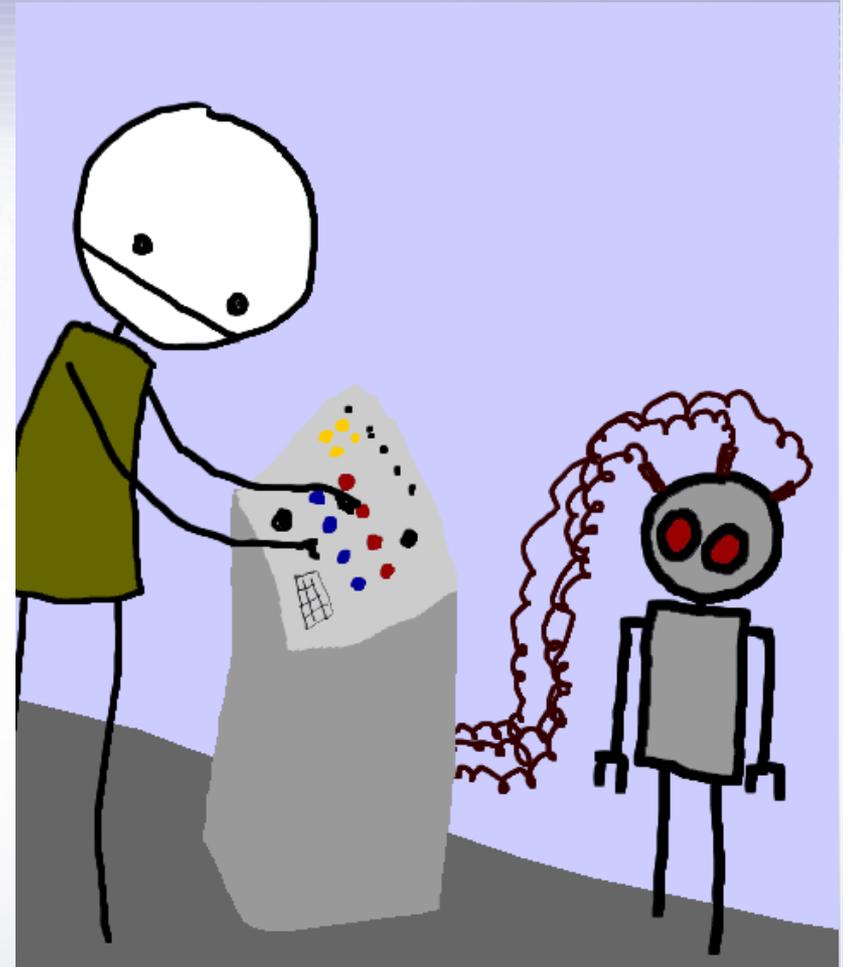


- **Call counsel ASAP**
 - in-house or outside counsel
- **BOTH:**
 - search warrant (subpoena)
 - “knock & talk”
- **Do not worry about the optics**

Counsel – A.S.A.P.



- No “interview” without counsel
- Don’t take on the company’s burden
- Don’t hide misstep



Responding to Non-Compliance



- Suspend relevant claims until situation resolved.
 - Submitting claim with knowledge of problem could violate False Claims Act or health care fraud statutes.
- Assess scope of problem.
 - Isolated event or extensive problem?
 - “Knowing” misconduct or innocent error?
 - Amount and type of payments involved?
- Consider involving knowledgeable healthcare attorney.
 - Expertise in evaluating relevant laws and regulations.
 - May provide some protection if act on advice of counsel.
 - May maximize attorney-client privilege.

Responding to Non-Compliance



- Immediately investigate.
 - Remember 60-day deadline; must act with “all deliberate speed”.
 - Immediately take steps to preserve relevant documents, including electronic files.
 - Gather and review relevant documents.
 - Interview relevant persons.
 - Document investigation.
 - Assume whatever you document will be discoverable.
- Never destroy relevant documents or falsify information.
 - Federal crime to destroy documents that are subject of existing or pending investigation. (18 U.S.C. § 1519)
- Never retaliate against whistleblowers.

Responding to Non-Compliance



- Determine whether a violation actually occurred.
 - Consider all relevant regulations and exceptions.
 - Did transaction involve federal program payments?

Responding to Non-Compliance



- Apply regulations that were relevant at the time.
 - Regulations have been amended at times.
 - Apply exception as it existed during relevant time period.
- Consider official commentary and decisions relevant to the compliance issue.
 - Advisory Opinions
 - Preamble to regs published in Federal Register (“FR”)
 - Advisory Bulletins and Fraud Alerts
 - CMS Frequently Asked Questions
 - Local guidance

Responding to Non-Compliance



Exception for providers “without fault”?

- “A provider is liable for overpayments it received *unless* it is found to be without fault.... The FI or carrier considers a provider without fault, if it exercised reasonable care in billing for, and accepting, the payment; i.e.,
 - It made full disclosure of all material facts; and
 - On the basis of the information available to it, including, but not limited to, the Medicare instructions and regulations, it had a reasonable basis for assuming that the payment was correct, or, if it had reason to question the payment; it promptly brought the question to the FI or carrier’s attention.”
(Medicare Fin. Mgmt Man. Ch. 3 § 90)
- A provider is presumed to be without fault after 3 years. (See 42 C.F.R. § 1395gg(b)-(c)).

Responding to Non-Compliance



- If a problem exists, fix it.
 - Modify processes.
 - Discipline employees.
 - Document remedial efforts.

Responding to Non-Compliance



- Implement and document voluntary corrective action plan to avoid similar problems in the future.
 - Update policies or processes.
 - Obtain additional guidance.
 - Conduct appropriate training.
 - Document remedial actions.
 - Include remedial efforts in any disclosure.

Compliance Programs: 7 Elements



- Standards and Procedures
- Education and Training
- Oversight
- Monitoring and Auditing
- Reporting
- Enforcement and Discipline
- Response and Prevention
- PLUS: risk assessment to modify over time
 - U.S. Sentencing Guidelines, Section 8B2.1
 - See Attachment A - - HHS OIG's Compliance Program Guidance for Hospitals

Compliance Programs: Prevention



- Standards and procedures
 - Commitment to compliance
 - How to do it right
 - Anti-retaliation protection
- Education and training
 - At hire and then at least annually
 - Review P&Ps, disciplinary guidelines
 - Test and document results
- Oversight
 - Deterrent value
 - Early detection

Compliance Programs: Detection



- **Monitoring and Auditing**
 - Identify high risk areas
 - OIG Work Plan
 - RAC audit areas
 - Claims monitoring
- **Reporting**
 - Hotline
 - Track complaints, investigations, results
 - Communication
 - Report to leadership
 - Exit interviews

Compliance Programs: Resolution



- Enforcement and Discipline
- Response and Prevention
- Modify all of above to prevent recurrence

Compliance Programs: Resolution



- When issue surfaces:
 - Determine scope of allegations
 - Preserve documents
 - Investigate thoroughly
 - Determine course of action
 - Remediate
 - Refund overpayments
 - Train
 - Disclose?
 - Audit and document success of remediation

Better to Comply



– Resource materials

- **OIG Compliance Education Materials available at <https://oig.hhs.gov/compliance/101/index.asp>.**
- **OIG Compliance Program Guidance at <https://oig.hhs.gov/compliance/compliance-guidance/index.asp>.**

Better to Comply



- Implement an effective compliance program
 - See OIG Compliance Program Guidance, available at <https://oig.hhs.gov/compliance/compliance-guidance/index.asp>.
 - Compliance officer / Compliance committee
 - Compliance policies and procedures
 - Open lines of communication
 - Training and education
 - Auditing and monitoring
 - Responding to non-compliance
 - Discipline for non-compliance
 - May help ensure compliance.
 - May mitigate exposure if there is a compliance failure.

Advisory Opinions



- OIG may issue advisory opinions.
 - Listed on OIG fraud and abuse website, www.oig.hhs.gov/fraud.
- Not binding on anyone other than participants to the opinion.
- But you are probably fairly safe if act consistently with favorable advisory opinion.

Fraud Alerts, Bulletins, etc.



- OIG periodically publishes other:
 - Special Fraud Alerts
 - Bulletins
 - Open Letters
 - Listed on OIG fraud and abuse website, www.oig.hhs.gov/fraud.
- Provide guidance concerning OIG's enforcement position.

Action Items



- Ensure your compliance policies address fraud and abuse laws. (See, e.g., OIG Supplemental Hospital Compliance Program Guidance, 70 FR 4858 (2005)).
- Train key personnel regarding compliance.
 - Administration.
 - Compliance officers and committees.
 - Human resources.
 - Physician relations and medical staff officers.
 - Marketing / public relations.
 - Governing board members.
 - Purchasing.
 - Accounts payable.
- Document training.

Fraud and Abuse: Minimizing Risk



- Make compliance a priority.
- Have effective compliance plan.
 - Written standards of conduct, policies, and procedures
 - Competent compliance officer/committee
 - Effective ongoing education and training
 - Process for reporting suspected compliance issues
 - Prompt response to compliance concerns.
 - Auditing and monitoring
 - See OIG Compliance Program Guidance for Physicians
 - See OIG Supplemental Compliance Program Guidance for Hospitals
- Available at <http://oig.hhs.gov/fraud/complianceguidance.asp>.
- Compliance plan will become mandatory soon.

Fraud and Abuse: Minimizing Risk



- Pay attention to risk areas
 - Submission of accurate claims and information, *e.g.*,
 - Billing for services not rendered
 - Medically unnecessary services
 - Upcoding, unbundling, DRG creep, etc.
 - Duplicate billing
 - Documentary support
 - Referral and kick-back statutes (Stark and Anti-Kickback)
 - Payments to reduce or limit services (*e.g.*, gainsharing)
 - Substandard care
 - Inducements to Medicare/Medicaid beneficiaries

See Compliance Program Guidance, fraud alerts, special advisory bulletins, etc. at

Repayment Rule



- Participation in OIG Self-Disclosure Protocol (“SDP”)
 - Suspends time for refund under Repayment Law.
 - Timely disclosure to OIG per SDP constitutes report for purposes of repayment rule.

OIG Self-Disclosure Protocol



- Voluntary program
- Benefits
 - OIG may reduce penalties if fully disclose and cooperate.
 - Probably no corporate integrity agreement.
 - May preclude *qui tam* lawsuits.
 - Suspends repayment under Proposed Repayment Rule.

OIG Self-Disclosure Protocol



■ Risks

- No guarantee that OIG will reduce penalties.
- Penalties may bankrupt provider.
- OIG may broaden investigation.
- New matters discovered by OIG are outside protocol.
- Failure to fully disclose or cooperate may result in additional penalties.
- OIG may report to other government agencies.
- Participation is burdensome.
- Likely will waive of privilege.
- Information may become public.

OIG Self-Disclosure Protocol



- SDP should only be used to resolve matters that “potentially violat[e] Federal, criminal or civil or administrative laws. Matters exclusively involving overpayments or errors that do not suggest that violations of law have occurred should be brought directly to the attention of the [contractor].” (63 FR 58400)
 - Generally, SDP applies to violations that involve:
 - Actual knowledge
 - Reckless disregard
 - Deliberate ignorance
 - Not honest mistakes or errors.

OIG Self-Disclosure Protocol



SDP Process

- If you discover historical or ongoing fraud, conduct initial investigation to determine facts and confirm SDP applies.
- If decision is made to make self-disclosure, submit initial written disclosure to OIG, including:
 - Information about provider.
 - Complete description of conduct disclosed.
 - Description of internal investigation or estimate for completion.
 - Estimate of damages to federal programs, method for calculation or estimate for completion.
 - Laws potentially violated.
- Complete investigation within 3 months.
(See OIG SDP and Open Letter dated 4/15/08).

OIG Self-Disclosure Protocol



SDP Process

- Internal investigation
 - Nature and extent of improper practice.
 - Discovery and response to matter.
 - Self-assessment of impact on federal programs.
 - Certification.
- OIG verifies information in report
 - Access to all audit and other papers without regard to privilege.
 - Respond timely to OIG requests for additional information.

OIG Self-Disclosure Protocol



- “The disclosing entity’s diligent and good faith cooperation throughout the entire process is essential.... [T]he OIG expects to receive documents and information from the entity that relate to the disclosed matter without the need to resort to compulsory methods. If a provider fails to work in good faith with the OIG to resolve the disclosed matter, that lack of cooperation will be considered an aggravating factor when the OIG assesses the appropriate resolution.... Similarly, the intentional submission of false or otherwise untruthful information, as well as the intentional omission of relevant information, will be referred to the DOJ or other Federal agencies and could, in itself, result in criminal and/or civil sanctions....” (63 FR 58403)

OIG Self-Disclosure Protocol



- Do not assume that you will avoid all penalties by self-disclosing.
- OIG seems to have established formulas or protocols for handling certain types of claims, e.g., excluded providers.
- Under FCA, disclosure within 30 days reduces penalties to 2x damages.

OIG Self-Disclosure Protocol



- Select SDP settlements since 2010 per OCR website

Conduct	Settlement
Provider employed excluded individual	\$56,663
Billed Medicare for PT services without adequate documentation	\$403,935
Billed Medicare for services under wrong physician's name	\$64,494

Responding to Non-Compliance



- Once you take the step to self-report, there is no turning back

Responding to Non-Compliance



- When reporting to government:
 - Fully cooperate with investigation.
 - Do not misrepresent information.
 - Do not omit material information.
 - Do not provide more than is reasonably relevant.
 - Make your best case.
 - Discuss adverse financial impact on provider.
 - Assume that the government will check your facts and analysis.
 - Assume that the government investigation may go beyond your initial disclosure to consider other issues.

Responding to Non-Compliance



- When calculating exposure, verify actual payments received from federal programs during relevant period.
 - Were payments received for DHS?
 - Were there cost report adjustments or write offs?
- Limit analysis to relevant lookback or other period.

Responding to Non-Compliance



- When calculating repayment, use credible methodology.
 - No established or required methodology.
 - Must be reasonable under the circumstances.
 - Ensure personnel preparing the analysis are looking at the right issues.
 - See OIG SDP suggestions for methodology.
 - Government will evaluate appropriateness of methodology.

Responding to Non-Compliance



- Not obligated to accept government's proposed settlement.
 - May withdraw.
 - Lose benefits of self-disclosure.
 - May reopen claims process.
 - Document settlement in an agreement.
 - Beware: settlement agreement with one agency does not bind other agencies who are not parties to agreement.
 - Unless released, may still be liable for additional suit or penalties, including:
 - Criminal penalties
 - Civil penalties
 - Administrative penalties
- But these may be harder for government to prove; less incentive to pursue additional claims.

OIG Self-Disclosure Protocol



Benefits

- OIG may reduce penalties if fully disclose and cooperate.
- Probably no corporate integrity agreement.
- May preclude *qui tam* lawsuits.
- Suspends repayment under Proposed Repayment Rule.

Risks

- **Minimum \$50,000 settlement for AKS violations.**
- OIG may broaden investigation.
- New matters discovered by OIG are outside protocol.
- Failure to fully disclose or cooperate may result in additional penalties.
- OIG may report to other government agencies.
- Participation is burdensome.
- Likely will waive of privilege.

Failure to Grant Access



- Cannot fail to grant timely access, upon reasonable request, to the OIG for purposes of audits, investigations, evaluations or other statutory functions of the OIG.
- Penalties
 - \$15,000 for each day that fail to grant access.
 - Exclusion from Medicare and Medicaid.

(42 U.S.C. § 1320a-7a(a)(9); 42 C.F.R. § § 1001.1301 and 1003.102)

Repayment Obligation



- False Claims Act:
 - Must report and repay “overpayment” within 60 days.
 - Overpayment = payment to which you are not entitled, including payment in violation of Anti-Kickback Statute.
- Knowing failure to repay =
 - Violation of False Claims Act
 - \$5,500 to \$11,000 per claim
 - 3x damages
 - Violation of Civil Monetary Penalties Law
 - \$10,000 per claim
- See CMS’s Proposed Repayment Rule, 77 FR 9179 (2/16/12)

Self-Disclosure



Disclosure Decision Factors

- Need: violation?
- Risks?
 - Cost/disruption/penalties
 - No leniency guarantee
 - Trigger investigations, civil lawsuits, market repercussions
 - Potential waiver of confidentiality
- Timing?
- Which entity/agency?
 - OIG/HHS, DOJ/US Attorney Office
 - Medicaid Fraud Control Unit
 - CMS Contractors (FI, MEDICs, etc.)



Possible outcomes may include:

- CMP settlement at lower end of range
- Settlement of federal FCA at double damages rather than triple
- Refund
- No recovery/settlement
- State FCA penalty and damages
- Ongoing compliance obligations? CIA/CCA?

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Questions?



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