Criminal and Civil Heath Care Fraud

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Overview

- Emerging Trend? Government increasingly using fraud statutes to challenge medical necessity decisions.
- Corporate Liability? Institutional providers can face fraud liability for the medical decisions of their employees and agents.
  - Civil Liability: False Claims Act, including Obligations to Report & Refund Overpayments to CMS
  - Criminal Liability: *Filip* Factors and *Yates* Memo

Historical Perspective

- Traditional HCF Cases
  - Kickbacks
  - Services Not Rendered
  - Double Billing
  - Upcoding
  - Billing for non-covered services
  - Services by unlicensed or unsupervised personnel
  - Worthless Services

Historical Perspective

Historical Concerns with Using Fraud Statutes to Address Medical Necessity Cases

- Latitude of medical judgment
- Physicians often have different opinions
- Diagnostics imagery can be subjective
- Physicians can rely on contemporaneous observations from exam room
- Medical malpractice v. fraud

False Claims Act Basics: Medical Necessity Liability

Liability under the Federal False Claims Act ("FCA"), 31 U.S.C. § 3729

(a)(1)(A) – knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(a)(1)(B) – knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(a)(1)(C) – conspires to commit a violation of subparagraph (A), (B) …

Form CMS-1500

"In submitting this claim for payment from federal funds, I certify that: … 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service …"

False Claims Act Basics: Medical Necessity Liability

- 42 U.S.C. § 1395y(a)(1)(A): "no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services which … are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."
- Medicare statutes do not contain a list of specific items or services eligible for Medicare coverage.

  Health and Human Services Secretary has authority to make initial determinations about which specific items or services will be covered under Medicare. 42 U.S.C. § 1395ff(a). These are known as **National Coverage Determinations.**

  Local Medicare contractors have authority to determine whether or not a particular item or service is covered within that contractor's locality. 42 U.S.C. § 1395ff(f)(2)(B). These are known as **Local Coverage Determinations.**

False Claims Act and Medical Necessity Liability

Bottom Line--there are more medical necessity cases

- More *qui tam* cases filed
- More referrals
- More data analysis for outliers
- More investigations—civil and criminal
- More resources allocated

False Claims Act and Medical Necessity Liability

- Key to these cases is “reasonable and necessary”
- Patterns and trends; not single instances
- Patient harm
- Cases begin and end with the medicine
- Experts
- Review of charts
- Potentially statistical sampling
- Defenses

False Claims Act: Medical Necessity Liability

Recent Examples:

Cardiac Defibrillator Investigation

U.S. ex rel. Ford et al. v. Abbott Northwestern et al. No. 08-cv-20071 (S.D. Fla.)

- *Qui tam* action naming more than 1300 hospitals nationwide
- Involved a Medicare National Coverage Determination, which is the Secretary's determination of what is "reasonable and necessary"
- Reviewed thousands of medical records
- Hundreds of hospitals settled for more than $280M

False Claims Act: Medical Necessity Liability

Recent Examples:

Skilled Nursing Facilities

U.S. ex rel. Halpin & Fahey v. Kindred Healthcare, Inc., et al., No. 1:11-cv-12139-RGS (D. Mass.)

Government alleged that skilled nursing facility submitted false claims to Medicare for rehabilitation therapy services that were not reasonable, necessary, or never occurred by, *inter alia*:

- Presumptively placing patients in the highest therapy reimbursement level
- Not basing treatment on the needs of the individual patients
- Inflating reporting time on initial evaluations
- Not reporting actual minutes of therapy time with patients

Kindred Healthcare/RehabCare settled for $125 million on January 12, 2016

False Claims Act: Medical Necessity Liability

Recent Examples:

- *U.S. v. Bajoghli*, No. 1:14-cr-00278 (E.D. Va.)
  - Government alleged that dermatologist, *inter alia*, fraudulently diagnosed patients' benign lesions as cancerous, subjecting them to medically unnecessary Mohs surgery
  - Acquitted on November 30, 2015

False Claims Act: Medical Necessity Liability

Recent Examples:

- *U.S. ex rel. Scott, et al. v. Durrani, et al.*, No. 1:13-cv-194 (S.D. Ohio) (West Chester Medical Center & University of Cincinnati Health)
  - Government alleged that Hospital submitted claims for reimbursement related to medically unnecessary spine surgeries through the off label use of the drug called Infuse/BMP-2, experimental surgeries, and false diagnoses.
  - West Chester Hospital and UC Health settled for $4.1 Million on October 9, 2015.

False Claims Act: Medical Necessity Liability

Recent Examples:

- *U.S. v. Novak, et al.,* (N.D. Ill.) (Sacred Heart Hospital and West Side Community Hospital, Inc.)
  - Government alleged that hospital sought reimbursement for emergency care evaluation, testing and observation services that were not medically necessary.
  - Government alleged that hospital sought reimbursement for sedation, intubation, and tracheotomy procedures that were not medically necessary because patients did not suffer any condition justifying a tracheotomy.
  - Jury criminally convicted the hospital executives in March 2015.

False Claims Act: Medical Necessity Liability

Recent Examples:

- *U.S. ex rel. Wells v. Baptist Health System Inc., et al.,* No. 3:12-cv-47-J-34JBT (M.D. Fla.)
  - Government alleged that two neurologists in the Baptist Health network in Jacksonville, Florida, misdiagnosed patients with neurological disorders, such as multiple sclerosis and Parkinson's disease, causing Baptist Health to bill for medically unnecessary services, such as unnecessary CT scans and EEGs.
  - Baptist Health settled for $2.5 million on May 6, 2014.

False Claims Act: Medical Necessity Liability

Recent Examples:

U.S. ex rel. Stone v. Hospice of the Comforter Inc., No. 6:11-cv-1498-ORL-22-DAB (M.D. Fla.)

Government alleges that hospice billed for patients who were not terminally ill, falsified medical records, employed nurses without hospice training, established procedures to limit physicians' roles in assessing patients' terminal status, and delayed discharging benefits.

Hospice settled for $3 million on November 5, 2013

False Claims Act: Medical Necessity Liability

- These examples demonstrate the Government's continued pursuit of medical necessity cases.
- The Government is intervening in and litigating more medical necessary cases with physicians, hospitals, skilled nursing facilities, home health, hospice, and other providers dealing with a wide range of services.

Corporate Duty to Report Medically Necessity Issues?

Affordable Care Act: 42 U.S.C. 1320a-7k(d):

(1) IN GENERAL.—If a person has received an overpayment, the person shall—

(A) **report and return the overpayment** to the Secretary . . . .; and

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

(2) DEADLINE FOR REPORTING AND RETURNING OVERPAYMENTS.—An overpayment must be reported and returned under paragraph (1) by the later of—

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

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

(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 [the False Claims Act].

(4) DEFINITIONS.—In this subsection:

(B) OVERPAYMENT.—The term "overpayment" means any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.

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Uncovering Medically Unnecessary Services

HHS Promulgates Rules Regarding Reporting and Returning of Overpayments on February 12, 2016:

- From the commentary: HHS notes "that section 1128J(d) of the Act does not require the Secretary to issue regulations for the statute to be effective, and the statute's requirements are in effect in the absence of regulation."
- "We remind all stakeholders that even without a final regulation they are subject to the statutory requirements found in section 1128J(d) of the Act and could face potential FCA liability, CMPL liability, and exclusion from federal health care programs for failure to report and return an overpayment."

Uncovering Medically Unnecessary Services

HHS Promulgates Rules Regarding Reporting and Returning of Overpayments on February 12, 2016:

- From the commentary: "An overpayment must be reported and returned regardless of the reason it happened – be it a human or system error, fraudulent behavior, or otherwise."
- From the commentary: "Sufficient documentation and medical necessity are longstanding and fundamental prerequisites to Medicare coverage and payment."
- Following examples of "overpayment" in commentary:
  - Medicare payments for noncovered services
  - Medicare payments in excess of the allowable amount for an identified covered service
  - Errors and nonreimbursable expenditures in cost reports
  - Duplicate payments
  - Receipt of Medicare payment when another payor had the primary responsibility for payment

Uncovering Medically Unnecessary Services

HHS Promulgates Rules Regarding Reporting and Returning of Overpayments on February 12, 2016:

"A person who has received an overpayment must report and return the overpayment by the later of either of the following: (i) The date which is 60 days after the date on which the overpayment was identified. (ii) The date any corresponding cost report is due, if applicable." 42 C.F.R. § 401.305(b)(1).

"A person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment." 42 C.F.R. § 401.305(a)(2).

Uncovering Medically Unnecessary Services

HHS Promulgates Rules Regarding Reporting and Returning of Overpayments on February 12, 2016:

- Commentary elucidates "identified" as used at 42 C.F.R. § 401.305(a)(2):
  - Apply definitions "knowing" and "knowingly" from FCA to "identified"
  - "[D]efining 'identification' in this way gives providers and suppliers an incentive to exercise reasonable diligence to determine whether an overpayment exists. Without such a definition, some providers and suppliers might avoid performing activities to determine whether an overpayment exists, such as self-audits, compliance checks, and other research."

Uncovering Medically Unnecessary Services

HHS Promulgates Rules Regarding Reporting and Returning of Overpayments on February 12, 2016:

- Commentary provides examples of "identified":
  - A provider of services or supplier reviews billing or payment records and learns that it incorrectly coded certain services, resulting in increased reimbursement
  - A provider of services or supplier learns that a patient death occurred prior to the service date on a claim that has been submitted for payment
  - A provider of services or supplier learns that services were provided by an unlicensed or excluded individual on its behalf
  - A provider of services or supplier performs an internal audit and discovers that overpayments exist
  - A provider of services or supplier is informed by a government agency of an audit that discovered a potential overpayment, and the provider or supplier fails to make a reasonable inquiry
  - A provider of services or supplier experiences a significant increase in Medicare revenue and there is no apparent reason – such as a new partner added to a group practice or a new focus on a particular area of medicine – for the increase

Uncovering Medically Unnecessary Services

HHS Promulgates Rules Regarding Reporting and Returning of Overpayments on February 12, 2016:

- Commentary elucidates "reasonable diligence" as used at 42 C.F.R. § 401.305(a)(2)
  - 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 by qualified individuals in response to obtaining credible information of a potential overpayment
  - "We believe that undertaking no or minimal compliance activities to monitor the accuracy and appropriateness of a provider or supplier's Medicare claims would expose a provider or supplier to liability under the identified standard articulated in this rule based on the failure to exercise reasonable diligence if the provider or supplier received an overpayment."
  - Part of conducting reasonable diligence is conducting an appropriate audit to determine if an overpayment exists and to quantify it. Providers and suppliers are obligated to conduct audits that accurately quantify the overpayment

Uncovering Medically Unnecessary Services

HHS Promulgates Rules Regarding Reporting and Returning of Overpayments on February 12, 2016:

- Commentary elucidates "quantified" as used at 42 C.F.R. § 401.305(a)(2)
  - Difference between the amount that Medicare paid and the amount that should have been paid
  - Statistical sampling
  - Extrapolation

Uncovering Medically Unnecessary Services

HHS Promulgates Rules Regarding Reporting and Returning of Overpayments on February 12, 2016:

- Deadline to Report and Return Overpayments
  - 60 days after the date on which the overpayment was identified. 42 C.F.R. § 401.305(b)(1)(i)
  - From commentary: deadline is 8 months after receipt of credible information, absent extraordinary circumstances (6 months for investigation + 2 months for reporting)
    - "Credible information" includes information that supports a reasonable belief of an overpayment
    - Results from internal statistical analyses
    - Results from contractor or government audit
    - Hotline complaints
  - For cost reporting providers, deadline triggered after receiving credible information of improper cost report payment after reconciliation process

Uncovering Medically Unnecessary Services

HHS Promulgates Rules Regarding Reporting and Returning of Overpayments on February 12, 2016:

- 2 Methods of Reporting and Returning Overpayments:
  - "A person must use an applicable claims adjustment, credit balance, self-reported refund, or other reporting process set forth by the applicable Medicare contractor to report an overpayment, except as provided in paragraph (d)(2) of this section. If the person calculates the overpayment amount using a statistical sampling methodology, the person must describe the statistically valid sampling and extrapolation methodology in the report." 42 C.F.R. § 401.305(d)(1)
  - "A person satisfies the reporting obligations of this section by making a disclosure under the OIG's Self-Disclosure Protocol or the CMS Voluntary Self-Referral Disclosure Protocol resulting in a settlement agreement using the process described in the respective protocol." 42 C.F.R. § 401.305(d)(2)

Corporate Criminal Liability for Medical Necessity Issues ?

***Filip* Factors / Corporate Prosecution Principles**

1. The nature and seriousness of the offense, including the risk of harm to the public . . .
2. The pervasiveness of wrongdoing within the corporation, including the complicity in, or the condoning of, the wrongdoing by corporate management
3. The corporation's history of similar misconduct . . . . .
4. The corporation's willingness to cooperate in the investigation of its agents
5. The existence and effectiveness of the corporation's pre-existing compliance program
6. The corporation's timely and voluntary disclosure of wrongdoing
7. The corporation's remedial actions, including any efforts to implement an effective corporate compliance program or to improve an existing one, to replace responsible management, to discipline or terminate wrongdoers, to pay restitution, and to cooperate . . .
8. Collateral consequences, including whether there is disproportionate harm to shareholders, pension holders, employees, and others . . . .
9. The adequacy of remedies such as civil or regulatory enforcement actions
10. The adequacy of the prosecution of individuals responsible for the corporation's malfeasance

DOJ Focusing On Corporate Prosecutions

Yates Memo (Sept. 9, 2015)

One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing

6 key steps to strengthen DOJ pursuit of corporate wrongdoing:

1) In order to qualify for any cooperation credit, corporations must provide to DOJ all relevant facts relating to the individuals responsible for the misconduct
2) Criminal and civil corporate investigations should focus on individuals from the inception of the investigation
3) Criminal and civil attorneys handling corporate investigations should be in routine communication with one another
4) Absent extraordinary circumstances or approved departmental policy, DOJ will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation
5) 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
6) 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

DOJ Focusing On Corporate Prosecutions

Revisions to *Filip* Factors to US Attorneys' Manual

New 9-28.210: Prosecution of a corporation is not a substitute for the prosecution of criminally culpable individuals within or without the corporation. Because a corporation can act only through individuals, imposition of individual criminal liability may provide the strongest deterrent against future corporate wrongdoing. Provable individual culpability should be pursued, particularly if it relates to high-level corporate officers, even in the face of an offer of a corporate guilty plea or some other disposition of the charges against the corporation, including a deferred prosecution or non-prosecution agreement, or a civil resolution. . .

DOJ Focusing On Corporate Prosecutions

Revisions to Filip Factors to US Attorneys' Manual

New 9-28.700: In order for a company to receive any consideration for cooperation under this section, the company must identify all individuals involved in or responsible for the misconduct at issue, regardless of their position, status or seniority, and provide to the Department all facts relating to that misconduct. . .

DOJ Focusing On Corporate Prosecutions

- Revisions to Parallel Criminal, Civil, Regulatory, and Administrative Proceedings
  - Intake: From the moment of case intake, attorneys should consider and communicate regarding potential civil, administrative, regulatory, and criminal remedies, and explore those remedies with the investigative agents and other government personnel;
  - Investigation: During the investigation, attorneys should consider investigative strategies that maximize the government's ability to share information among criminal, civil, and agency administrative teams to the fullest extent appropriate to the case and permissible by law, including the use of investigative means other than grand jury subpoenas for documents or witness testimony; and
  - Resolution: At every point between case intake and final resolution (e.g., declination, indictment, settlement, plea, and sentencing), attorneys should assess the potential impact of such actions on criminal, civil, regulatory, and administrative proceedings to the extent appropriate.