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SCALPEL TO GAVEL: EXPLORING THE MODERN STATE OF HEALTH LAW

October 10, 2014

University of Toledo College of Law

CAUGHT IN THE CROSS-FIRE: THE INTERSECTION OF QUALITY OF CARE WITH THE FALSE CLAIMS ACT

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Focus On Quality: Health Care Reform

"The law is also a serious platform for improving the quality of healthcare and changing the delivery system so we stop doing things that don't work for patients and start doing things that will work. It's about better care: care that is safe, timely effective, efficient, equitable and patient centered."

Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
IHI Annual Meeting
December 7, 2010

Focus On Quality: Health Care Reform

Payments Tied to Quality:

- Quality Reporting Programs
- Hospital Value Based Purchasing
- Readmissions Reduction Program
- Hospital Acquired Conditions Penalties

The False Claims Act

- The False Claims Act, 31 U.S.C. § 3729 *et seq.*, authorizes the United States, or "relators" acting on behalf of the United States to recover monetary damages from parties who submit, or cause others to submit, fraudulent claims for payment by the federal government

The False Claims Act

- Basic Elements of the False Claims Act:
  - Submitting or cause to be submitted a claim for payment, or making a false record or statement in order to secure payment of a claim;
  - Claim is false or fraudulent; and
  - Scienter: "knew or should have known" or "deliberate ignorance" of truth or falsity or "reckless disregard" of the truth or falsity.
  - Liability for both those who submit claims, as well as those who cause claims to be submitted.
- No specific intent needed.

The FCA Prohibits a Range of Activities

- Knowing presentation or causing to be presented a false or fraudulent claim to the federal government (31 U.S.C. § 3729(a)(1))
- Knowing use or creation or causing the use or creation of a false record or statement to get such a claim paid by the government ((a)(2))
- Conspiring to defraud the federal government to get a false or fraudulent claim paid ((a)(3))
- Intentional failure to return all federal government money or property ((a)(4)
- Intentional making and issuance of a receipt for more than what the federal government actually received ((a)(5));
- Knowing purchase or receipt of property from an unauthorized federal official ((a)(6)
- Knowing creation or use of a false record or statement to decrease a monetary obligation to the government ((a)(7)).

The Consequences of Losing an FCA Case Are Great

- Treble damages assessed on a per claim basis
- Civil penalties of up to $11,000 per claim.
- Program suspension, debarment and exclusion for entities, officers, directors, employees and related parties.

The False Claims Act By the Numbers

FY 2013

- $3.8 billion in settlements and judgments
- $2.6 billion from healthcare fraud recoveries
- $2.9 billion from cases brought by relators under the FCA's qui tam provisions
- $345 million to relators

$17 billion in settlements and judgments since January 2009

- $12.1 billion from healthcare fraud recoveries
- $13.4 billion from cases brought by relators under the FCA's qui tam provisions
- $1.98 billion to relators

Enforcing Quality Care Through The False Claims Act

- "Fighting health care fraud has been a top priority for the President, the Attorney General and for me here in the Division."
- For the … numbers we are announcing today, you'll see a variety of cases … (c)ases that go to the heart of providing quality care to our most vulnerable citizens…."

Tony West
Assistant Attorney General for the Civil Division
Pen and Pad Briefing on Civil Fraud Recoveries
November 22, 2010

Enforcing Quality Care Through The False Claims Act

Some Say The False Claims Act Was Inspired By Poor Quality:

"For sugar, it often got sand; for coffee, rye; for leather, something no better than brown paper; for sound horses and mules, spavined beasts and dying donkeys; and for serviceable muskets and pistols, the experimental failures of sanguine inventors or the ruse of shops and foreign armories."

United States ex rel. Newsham v. Lockheed Missiles and Space Co., Inc., 722 F. Supp. 607, 609 (N.D. Cal. 1989) (quoting 1 F. Shannon, *The Organization and Administration of the Union Army*, 1861-1865, at 5456 (1965) (quoting Tomes, Fortunes of War, 29 Harpers Monthly Mag. 228 (1864))).

Medically Necessary Care

In 1998, the *American Medical Association* published this patient-and-physician oriented definition of "medical necessity":

> Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily … for the convenience of the patient, treating physician, or other health care provider.

AMA Policy, H-320.953: Definitions of "Medical Necessity."

Medically Necessary Care And Coverage

- Within Medicare there are coverage categories.
  - Medicare coverage is limited to items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 USC 1395y(a)(1)(A)
  - Medicare requires health care practitioners and providers to assure that health services ordered for government patients are "provided economically and only when, and to the extent, medically necessary." 42 USC 1320c-5(a)(1)

Medically Necessary Care And Coverage

- Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) Compliance Program for Individual and Small Group Physician Practices. *OIG Compliance Program for Individual and Small Group Physician Practices*, 65 Fed. Reg. 59,434,59,438-39 (Oct. 5, 2000):
  - "A physician practice should be aware that Medicare will only pay for services that meet the Medicare definition of reasonable and necessary." *Id.* at 59,439.
  - Physicians may "only bill those services that meet the Medicare standard of being reasonable and necessary for the diagnosis and treatment of a patient." *Id*.

Quality Care And Coverage

- Medicare requires submission of claims that are "of a quality which meet professionally recognized standards of health care." In addition each claim must be supported by evidence that it is medically necessary and of the appropriate quality. 42 U.S.C. 1320c-5(a)(2)
- Medicaid requires services that "are within accepted professional standards of practice."*
- TRICARE regulations require that "professional services be provided in accordance with good medical practice and established standards of quality." 32 C.F.R. § § 199.4(c)(1)

* Georgia Medicaid Program Part I; section 106(k) (Varies by State).

Enforcing Quality Of Care Through The False Claims Act

Theories:

- False Certification – Express and Implied
- Worthless Services
- Inadequate Services

False Certification

- Express False Certification
  - Allegation that party falsely certified compliance with a statute, rule or regulation in connection with a submission for payment.
- Implied False Certification
  - In submitting a claim, a party is impliedly certifying compliance with statutes/rules/regulations that are a precondition to payment.

False Certification

Is it a:

Condition of Participation

or

Condition of Payment

- Condition of Payment:
  - Submitting claim only certifies compliance with quality requirements that are a condition of payment.
  - Rule/Regulation must expressly state that compliance therewith is a condition of payment.

False Certification Cases – Express False Certification

US ex. rel Riley v. St. Luke's Episcopal Hospital, 355 F.3d 370 (5th Cir. 2004)

- Hospital submitted Medicare claim forms stating that the "services on this form were medically necessary for the health of the partners."
- Relator alleged the claim that these certifications were false – services were not medically necessary.
- Fifth Circuit – hospital executed claim forms that were knowingly false.

False Certification Cases – Implied False Certification

US ex. rel. Mikes v. Straus, 274 F.3d 687 (2nd Cir. 2001)

False Certification Theory

- 42 USC § 1320c-5(a)
  - Relator alleged that services were not "of a quality which meets professionally recognized standards of care".
  - Alleged that compliance with this obligation was a prerequisite for reimbursement under Medicare.
    - Court rejected Relator's theory.
    - Found it would improperly broaden the reach of the False Claims Act
      - "[I]mplied false certification is appropriately applied only when the underlying statute or regulation expressly states that the provider must comply in order to be paid.
      - 42 § 1320c-5(a) establishes conditions of participation, not prerequisites to payment.

False Certification Cases – Key Defense Arguments

- Submitting claims for payment only certifies compliance with requirements that are a condition of payment.
- Can only imply certification if the quality provision relied upon expressly states that compliance therewith is a condition precedent to payment.

Worthless Services

- Knowing submission of a claim for reimbursement for a procedure with no medical value violates the FCA , regardless of any certification.
- “Worthless Services” are services so deficient in quality as to constitute no service at all.

Worthless Services Cases

US ex. rel. Mikes v. Straus, 274 F.3d 687 (2nd Cir. 2001)

- Second Circuit found that worthless services is a distinct claim under the FCA.
- It is effectively derivative of an allegation that a claim is factually false because it seeks reimbursement for a service not provided.
  - The services are "so deficient that for all practical purposes it is the equivalent of no performance at all".
- Defendants submitted Medicare claims for spirometry; Relator alleged that the services were substandard because the spirometer was not properly calibrated.
- Defendants submitted evidence that they relied upon the spirometer instruction manual which provided that it was properly calibrated at the time of shipment and a product information book indicating that it was calibrated according to Federal regulations. Additionally, the spirometer was sent out once for recalibration and no issues found.
- Court found ample evidence that there was medical value to the tests.

Worthless Services Cases

U.S. v. Villaspring Health Care Ctr., Inc., 2011 WL 6337455 (E.D. Ky. Dec. 19, 2011)

- Allegations of fraud by nursing home in connection with billing for services that were non-existent or worthless.
- Pursued implied certification theory.
- Defendant asserted that a worthless services case could not be pursued because, regardless of services questioned, it did provide room and board and was paid on a per diem basis.
- Motion to Dismiss denied
  - Worthless services claim was fact intensive.
  - Asserting compliance "with such laws, regulations and program instructions… and on a provider/supplier being in compliance with any applicable conditions of participation in any federal healthcare program," sufficient to allow implied certification theory to proceed.

False Certification And Worthless Services Cases

U.S. ex rel. Spay v. CVS-Caremark Corp. (E.D. Pa. Dec. 20, 2012)

- Alleged submission of false claims to the government under Medicare Part D.
- Plaintiff allegations included: payment of claims that lacked proper prescribing physician identifiers; drugs exceeding approved limits; payment for drugs without authorization; and billing for expired drugs.
- Court determined plaintiff pled sufficient facts to survive dismissal both on "false certification" and "worthless services" (alleged failure to perform drug utilization review services) theories.
- Rejected argument that certification of the accuracy of claim information by the PBM would not be a "condition of payment."

Inadequate Services

United States ex rel. Aranda v. Cmty. Psychiatric Ctrs. Of Okla., 945 F. Supp 1485 (W.D. Okla, 1996)

- Government alleged that inpatient psychiatric hospitals impliedly certified compliance with provisions requiring that Medicaid beneficiaries receive "appropriate quality of care and a safe and secure environment." *United States ex rel. Aranda v. Cmty. Psychiatric Ctrs. Of Okla., Inc.,* 945 F. Supp. 1485, 1487 (W.D. Okla. 1996).
- Hospital argued that regulations did not impose "an objective standard of safety or quality of care as a billing requirement." *Id*. at 1488.
- District court rejected these arguments, reasoning that "a problem of measurement should not pose a bar to pursuing an FCA claim against a provider of substandard health care services under appropriate circumstances." *Id*.

Inadequate Services

United States v. NHC Healthcare Corp., 115 F. Supp.2d 1152 (W.D. Mo. 2000)

- Government alleged that nursing home failed to provide two residents with quality of care required by Medicare, Medicaid regulations. *United States v. NHC Healthcare Corp.,* 115 F. Supp.2d 1149 (W.D. Mo. 2000).
- Government claimed that nursing home billed Medicare and Medicaid despite knowing that it did not meet required quality of care. *Id.*
- Court characterized substandard care as failure to provide some of the items from menu of services for which nursing home billed on a capitated, per diem basis. *Id.* at 1155.
- Court explained that "the [nursing home] failed to adhere to the relevant standard of care and, therefore, billed the United States for care it did not actually perform." *Id.* at 1156 (emphasis added).

Enforcement Trends Reflect A Focus On Quality And Medical Necessity

- More Cases Filed
- More Inquiries
- More Investigations
  - Use of multi-agency data to identify outliers
- More Prosecutors and Agents
- Bigger Budgets
- More Cases Pursued By Whistleblowers

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