Overview

- Legal Theories
  - Factually vs. Legally False Claims
  - Worthless Services
  - Express False Certification
  - Implied False Certification
  - Condition of Payment
  - Condition of Participation (Materiality)
- Recent Case Examples
- Personalized Medicine and Practical Coverage Points
- Dealing with Allegations prior to FCA
- Chief of Staff and Medical Executive Committees
- Peer Review Process
- Compliance and Legal Counsel
- Internal Investigations
- Alienating Practitioners

Introduction

- This session will cover issues related to the practice of medicine, differences of opinion on medical treatment options, standard of care and related legal enforcement theories.
- Key takeaway: Address concerns early. Do not compromise quality of care when considering differences in professional judgment or employment issues.
- Understand applicable laws and appreciate False Claims Act (FCA) exposure.
- 2013-14 Focus on:
  - Acute-care Hospitals
  - Home Health Agencies (HHA)
  - Skilled Nursing Facilities (SNF)
- Factors that tend to be investigated:
  - Allegations of patient harm, abuse or neglect
  - Reports of low staffing levels
Focus on Value: Health Care Reform Implements Payment Reform

"Reform is not just about insurance. 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

Payments Tied to Value:
- Quality Reporting Programs for Hospitals, ASCs, SNFs, LTACHs, IRFs, etc.
- Hospital Value Based Purchasing
- Readmissions Reduction Program
- Hospital Acquired Conditions Penalties

Enforcement of Quality of 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 . . . cases 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
Enforcement of Quality of Care

- The government uses a variety of legal theories under the FCA to attack quality failures, but all follow the same principle: the government will not pay for medically unnecessary or substandard care.
- 2009 created HEAT (Health Care Fraud Prevention and Enforcement Action Team).
- FY 2013 - Department of Justice HCFAC Report:
  - Recovery of $2.6 billion for health care cases, and
  - Recovery of $4.3 billion total.

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

- The criterion of ‘medical necessity’ is a fundamental element for both the provision and payment of health care in our country.
- 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

- The Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) included in the OIG Compliance Program for Individual and Small Group Physician Practices a list of four important “risk factors.”
- The risk factor states “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 are admonished to “only bill those services that meet the Medicare standard of being reasonable and necessary for the diagnosis and treatment of a patient.” Id.

False Claims Act Legislation

- FERA and ACA enacted important changes to the FCA
- Changes lowered the bar for prosecutors and *qui tam* whistleblowers in FCA cases
  – Lowered public disclosure standard
- 2013-14 focus on:
  – Amended the “original source” provisions
  – Expanded conspiracy liability
- Expanded the scope of “reverse false claims”
  – Affects retention of Medicare & Medicaid overpayments
  – Overpayments must be reported and returned to the government within 60 days of the overpayment or becomes actionable under the FCA. CMS has yet to issue a final rule on reportable overpayments, but the statute is self-executing.

Enforcing Quality of Care Through the False Claims Act

- Basic Elements of a False Claim:
  – Submit or cause to be submitted, a claim for payment;
  – Claim is false or fraudulent (false statement); and
  – Scienter: “knew or should have known” or “reckless disregard” for the truth or falsity of the claim.
- No specific intent needed
Enforcing Quality of Care Through the False Claims Act

- Traditional Theories
  - Claims for services not rendered
  - Unbundling
  - Claims for services not covered (e.g., wound care kits, urinary incontinence devices)
  - Duplicate payments

- Quality of Care Theories
  - Express false certification
  - Implied false certification
  - Worthless services
  - Inadequate services
  - Criminal statutes

Themes present in cases:
- Unnecessary treatment/procedures
- Kickbacks
- Big admitters receiving special treatment
- Fraudulent documentation
- Poorly structured, or failure to follow, internal process
- Underlying regulatory violations

Worthless Services Cases
  - Allegations that defendant laboratory falsified medical test results and billed Medicare for worthless tests. Id. at 1050-51.
  - Relator tried to couch FCA action as one for express false certification of compliance with federal testing regulations. Id. at 1052-53.
  - In Ninth Circuit, filing claims for worthless services tantamount to submitting facially fraudulent claim:
    - "[K]nowingly billing for worthless services . . . may be actionable. . . Neither false certification nor a showing of government reliance on false certification for payment need be proven if the fraud claim asserts fraud in the provision of goods and services."
Express False Certification Claim

- An express false certification claim is a false representation of compliance with a federal statute, rule or regulation.
- Second Circuit: Claim is only legally false when the party certifies compliance with a law that is a precondition of payment. Claims that are based on certifications that involve conditions of participation are not viable because they are not material to government’s decision to pay. Mikes v. Straus, 274 F.3d 687, 699 (2d Cir. 2001).

Express False Certification Claim

United States ex rel. Riley v. St. Luke's Episcopal Hospital, 335 F.3d 370 (5th Cir. 2004).

- Hospital submitted Medicare claim forms stating: "[t]he services shown on this form were medically indicated and necessary for the health of the patient." Id. at 376 n.6.
- Nurse brought qui tam action, alleging hospital filed claims falsely certifying that patient hospitalizations were medically necessary.
- Fifth Circuit held that the relator stated FCA claim by alleging that hospital executed claim forms knowing that certifications were false and not merely scientifically debatable or erroneous. Id.

Implied False Certification Claim

- Implied false certification claim grounded in the notion that act of submitting claim for reimbursement implies compliance with governing laws that are a precondition to payment. In other words, underlying statute or regulation must be a condition of payment, as opposed to simply a condition of participation.
  - Support for this doctrine can be found in Congress’s stated purpose that the FCA encompass at least some kinds of legally false claims AND is intended to reach all types of fraud that might cause financial loss to government. See Mikes, 274 at 699.
- Second Circuit: “[i]mplied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid.” Id. at 700.
- First Circuit: Precondition of payment need not be found in a statute or regulation.
Implied False Certification Claim

*United States ex rel. Hutcheson v. Blackstone Medical, Inc., 647 F.3d 377 (1st Cir. 2011).*

- Relator alleged that Defendant engaged in a nationwide kickback scheme to induce physicians to use its medical devices. *Id.* at 380-81.
- District court dismissed relator’s claims, finding that relevant statutes and regulations did not expressly condition payment on compliance with anti-kickback statute. *Id.* at 383.
- First Circuit reversed, rejecting the arguments that “implied conditions of payment can only be found in statutes and regulations, and that these sources must expressly state the obligation.” *Id.* at 386.
- By rejecting *Mikes* and abandoning categorical approach (e.g., factual v. legal falsity; express v. implied certification), opinion holds potential for dramatic expansion of FCA liability.

Implied False Certification Claim

*United States ex rel. Blundell v. Dialysis Clinic, Inc., 5:09-CV-710 (N.D.N.Y. 2011).*

- Relator alleged that dialysis clinic’s failure to meet provisions in 42 C.F.R. § 494 et seq. resulted in compromised patient care. *Id.* at *2-*3.
- Defendant argued that regulation provides conditions for coverage, not conditions for payment. *Id.* at * 17-18.
- Court held that alleged non-compliance with 42 C.F.R. § 494, a condition of participation, did not create liability under implied false certification theory and dismissed with prejudice. *Id.* at *19-21.

Conditions of Payment

Under majority view, person submitting claim for payment only certifies compliance with statutory and regulatory health care quality requirements that are *conditions of payment.*

- *Mikes*, 274 F.3d at 700
Conditions of Payment

- Under majority view, can only impute certification of compliance if health care quality provision upon which the relator relies expressly states that the person seeking payment must comply with the provision to obtain payment. See Conner, 459 F. Supp. 2d at 1086-87.
- Express-language rule limits the scope of a defendant's potential FCA liability for sub-standard health care because so few quality provisions contain express condition-of-payment language.

Conditions of Payment

Courts have narrowly construed condition of payment language in Medicare, Medicaid provisions.

- Relator in Mikes argued that physicians' claims for certain medical tests were false because physicians impliedly certified compliance with medical standards of care for testing. 274 F.3d at 701-702.
- Second Circuit held that requirement for services to be 'reasonable and necessary' pertained to the physicians' selection of tests, and not their clinical performance. Mikes, 274 F.3d at 701.
- Medical acceptance and effectiveness of tests impacted reasonableness and necessity of selecting tests, but compliance with qualitative standard of care in administering the tests did not. Id.
- Because statute in question only established qualitative standard of care and did not expressly condition payment on compliance with that standard, defendants' certifications were not false. Id at 701-702.

Conditions of Payment

- Second Circuit noted that unreasonable, unnecessary service will typically be one performed solely for profit, unproven, or experimental. Mikes, 274 F.3d at 698.
- Billing for effective and medically-accepted services is actionable if performed solely to increase economic benefit or provider knows that the patient does not need the service.
  — Court concluded that statutory requirement for Medicare-reimbursable services to be medically necessary AND "economical" created a condition of payment. Kneepkins, 115 F. Supp. 2d at 42-43.
  — Court denied defendant's motion to dismiss, reasoning that government sufficiently pled implied false certification claim by alleging that laboratory performed tests in an "intentionally wasteful manner." Id.
Conditions of Payment

• Question: Can a *condition-of-participation* action involving providers operating on a fee-for-service basis be brought?

• Courts in Oklahoma and Missouri have held that claims for payment impliedly certified compliance with all express preconditions for payment, plus all health care quality requirements.


• 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.*

*United States v. NHC Healthcare Corp.*

• 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).
Condition of Participation

  - Finding that “questionable holdings” of Aranda and NHC Healthcare have not been adopted by the Ninth Circuit or any other appellate court.
- Also, the court in United States ex rel. Woodruff v. Hawai‘i Pacific Health, 2007 WL 1500275 at *7 (2007) found no “case holding that violations of conditions of participation are sufficient to state a [false certification] claim.”
- Providers should anticipate that relators and the government will push FCA cases into substandard care allegations against (1) acute care hospitals, (2) outpatient specialty clinics, and (3) other providers that bill on an itemized, fee-for-service basis.
  - United States ex rel. Main v. Oakland City University, 426 F.3d 914 (7th Cir. 2005).

Blundell v. Dialysis Clinic, Inc.


- Nurse filed FCA case against her employer, alleging compromised patient care for Medicare, Medicaid and VA patients (e.g., inadequate staffing, unqualified personnel, techs inappropriately providing nursing services, and failure to train personnel to handle emergencies).

Blundell v. Dialysis Clinic, Inc.

- CMS Form 855A: “I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider … I understand that payment of a claim by Medicare is conditioned upon … complying with such laws, regulations, and program instructions …”
  - Relator argued that language made compliance a precondition of payment.
  - Relator alleged defendant submitted fraudulent claims for payment based on false certification of compliance with rules and regulations for quality of care.
  - Clinic argued that form is merely an agreement to comply in the future with all applicable laws and regulations.
- Complaint made FCA claims on worthless services and implied false certification theories of liability.
  - Court rejected clinic’s argument, but held that relator failed to allege that defendant made false certifications knowingly.
  - Court found that allegations of federal regulatory violations, standing alone, insufficient to establish FCA claim if relator cannot identify with particularity false claim submitted by defendant.
Blundell v. Dialysis Clinic, Inc.

- Court analyzed relator’s claims under several theories of liability: worthless services, implied and express false certifications.
  - Relator asserted that procedures provided had no medical value.
  - Court found that “[p]laintiff does not allege that defendant failed to provide any services to their patients.”
  - Plaintiff challenged the quality of care arguing that defendant’s services did not conform with the guidelines set forth in 42 C.F.R. § 494.
  - Court found that relator’s allegation is not the “equivalent of no performance at all.”

- Case dismissed with prejudice under FRCP 12(b)(6).
  - “Plaintiff’s complaint contains imprecise references to ‘routine and systematic’ violations of Medicare regulations and while he claims that defendant submitted thousands of claims for reimbursement of Medicare claims,” did not identify one specific false claim.

Personalized Medicine and Practical Coverage Points

- Consumers want access to clear coverage information supported by fair and transparent coverage policies
- Providers and payers need a viable framework to address high cost treatments, emerging technologies, and complementary/integrative medicine
- The framework must be flexible and accommodate personalized medicine within traditional notions of “medically necessary” or “reasonable and necessary” items and services (or, a new paradigm)
Overview of Personalized Medicine and Coverage Workflow

- Genomic Test is performed
- Genomic Test results confirm a genomic mutation that may benefit from a targeted therapy
- The actionable therapy includes the use of an FDA-approved but “off-label” drug
- Reimbursement?

Medical Necessity Policy and Personalized Medicine

- Advances in Genomic Medicine
  - This area of medical science promises significant advances in the diagnosis and treatment of disease, including chronic diseases.
- Providers, payers, pharmaceutical companies and diagnostic testing companies currently are engaged in discussions of:
  - Analytical validity;
  - Clinical validity; and
  - Clinical utility of genomic diagnostics and therapeutics

Personalized Medicine Coverage Highlights

A 2012 Journal of Personalized Medicine study of the policies of the largest U.S. insurers for genomic (disease-related) and pharmacogenetic (PGx) testing reported:

- Factors determining coverage include overall strength of evidence, availability of clinical guidelines, current use by physicians, patient interest and cost-effectiveness. Underlying each is clinical utility.
- 50% (or less) covered by insurers mainly due to lack of clinical utility.
- The majority of coverage policies for disease-related genomic and PGx tests were deemed investigational and not medically necessary.
- 12 of the 49 tests were covered by at least one company, with twice as many PGx tests than disease-related tests covered.
Personalized Medicine Coverage Highlights (cont.)

A 2013 *Personalized Medicine* study reported that sources of coverage decisions among health care payers include:

- Health technology assessments by public or private organizations that are expensive and available for a limited number of genetic tests
- Professional guidelines that weigh heavily but are also limited in number
- Coverage decisions made by other payers, particularly Medicare, although Medicare decisions may not translate well to genetic tests intended to be preventative and often are most beneficial for those under age 65

Coverage and Policy/Advocacy Points

- Patient Cohorts: How do payers look at the combination of hospital services and physicians treating a cohort of patients who are similar; but, may have significant differences in treatment patterns?
- In other words, how can our health care system figure out how to focus medical necessity around treatment variations in the population base?
- Many traditional coverage and payment methodologies rely on central tendencies of patient populations and disease

References

Preparing for Medical Necessity and Quality of Care Challenges

- Pay attention and practice informed careful listening
- Education requirements for the applicable services and careful accurate documentation
- Strong oversight through UR Committee, Chief of Staff and Medical Executive Committee and Peer Review
- Coordinate and help connect medical necessity and quality oversight functions of the provider with a bridge to compliance

Pay Attention: Listen Carefully

Institutions and organizations must have a way to deal meaningfully with complaints about medical necessity and quality of care:

- Intelligent listening is key; can no longer ignore or explain away complaints
- Find a way to evaluate complaints that is removed from medical decision-making and institutional financial pressures
- Strict compliance, not risk assessment compliance

Educate Proactively

- Must educate staff about standards of care that are applicable to their practice
- Must involve individual provider in quality by developing an agenda that speaks to their concerns
Sources For Educating on Medical Necessity

- National Coverage Determination
- Local Coverage Determination
- Federal Register
- Coding Clinic, etc.

Additional Sources to Consider When Developing Medical Necessity Policies

General acceptance by the medical community as supported by:

- Medical and scientific peer-reviewed journals
- Consensus of expert medical opinion
- Medical opinion derived from medical associations or other health care experts

Careful Accurate Documentation

- Quality medical documentation is a key factor in predicting the likelihood of the outcome of a case
- Educate on appropriate process for updates to the medical record and late entries
UR Plan and UR Committee

Build a strong UR plan and UR Committee
- UR Committee is mandatory and charged with the task of creating and evaluating the UR plan. The Medicare CoP states the hospital must have a UR plan in effect that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.
- Use up-to-date screening criteria – medical necessity rules and guidance are constantly evolving and screening criteria change along with standards of care.

Chief of Staff and Medical Executive Committee

- Hospital medical staff and MEC holds ultimate responsibility for the quality of medical care provided at the facility, but...
  - “Hospitals must monitor the quality of medical services provided at the hospital by appropriately overseeing the credentialing and peer review of their medical staffs.” OIG Supplemental Compliance Program Guidance for Hospitals.
- Hospital administration often dependent upon MEC to police quality of care issues among the medical staff, as medical necessity is a matter of independent professional judgment.
- MEC must take role in hospital management seriously and administrators should encourage participation within framework of medical staff bylaws.
- Active MEC with clear, independent lines of communication to hospital administration often presents first line of defense against potential FCA liability.

Peer Review Process

- Peer review process should be a cornerstone of medical staff governance and one of several tools used by MEC.
- Hospital administration should ensure that MEC has access to necessary resources, without inserting hospital's interests into process.
- Critically important to protect independence and impartiality in order to avoid appearance of favoritism or conflicts of interest.
- Administration should encourage medical staff members to bring concerns with other practitioners to MEC as outlined in bylaws.
- Disputes between physicians that involve differences of opinion on appropriate standards of care must be addressed immediately.
- Quality of care concerns documented during peer review process must be resolved as soon as possible.
Coordinate and Create a Bridge to Avoid Government Scrutiny

Review your process to determine how best to coordinate peer review and compliance:

- Consider appointing a liaison at the provider to coordinate efforts between Peer Review and Compliance in order to assist with early detection of clinical issues.
- Consider appointing a Physician Executive who is responsible for oversight of medical staff quality-of-care matters, including but not limited to performance improvements, quality assessments, patient safety, utilization review, and medical staff peer review.
- Utilize processes from your Compliance Program to educate Peer Review on best practices regarding sampling, chart review and consider an audit of the Peer Review process.

Compliance Officer

- Stick to the map - OIG Compliance Program Guidance:
  - “Hospitals that fail to train and educate their staff adequately risk liability for the violation of health care fraud and abuse laws.”
  - “Open communication is essential to maintaining an effective compliance program. The purpose of developing open communication is to increase the hospital’s ability to identify and respond to compliance problems.”
  - “Are all instances of potential fraud and abuse investigated?”
  - When to self-report “credible evidence of a violation?”
- PPACA directly impacts the work of health care compliance officers by linking the retention of overpayments to FCA liability.
  - When does the clock start to run?
  - Do you have to be certain that you have “identified” an overpayment? What if you are not sure?
  - What if you are not sure and disgruntled employees have access to all the information?

Compliance Officer

Regularly monitor enrollment status

- Ensure information is up-to-date (e.g., address changes, ownership and control disclosures, etc.)
- Establish process for new provider enrollment
Legal Counsel

- Maintain open-door policy and high visibility.
- Educate, educate, educate.
- Once "credible evidence" of potential regulatory violation has been identified, legal counsel should guide internal investigation and resolve issues based on an analysis of the facts.
  - In-house counsel?
  - Outside counsel?
- Counsel for the corporate provider should be aware of the ethical rules and make clear to individuals that they represent the company's interests.

Legal Counsel

- Government agents and investigators must be treated seriously and accorded respect. Suspected obstructive conduct not taken lightly.
- All government investigatory requests and/or subpoenas should be directed to counsel as soon as possible.
  - Retain all responsive documents.
  - Assess status of records and ability to comply with government request.
  - Contact government to discuss compliance with request for documents and potential to narrow scope.
  - Assess whether client is a target or subject of a criminal investigation.

Internal Investigations

- Critically important to understand the facts as expeditiously as possible. Also, must understand the government’s claims and the way that it views its case.
- When providers fully understand underlying facts, they can influence the way the government perceives the case by guiding investigators through documents and witnesses.
- Initial stages of a government fraud investigation present a unique opportunity to develop a relationship with the investigating agency.
- Few things are more important than a provider's credibility during a government investigation.
- In some circumstances, internal investigations may ultimately serve as an indication of corporate responsibility and good citizenship.
Alienating Practitioners

- Administration and medical staff both have important roles to play. Collaboration and cooperation will be key.
- Don’t wait until after you’ve received a subpoena to involve practitioners in compliance and education process.
  - Direct employment of physicians and acquisition of physician practices makes ongoing education even more important.
- Practitioners will likely respond negatively to internal investigative efforts and try to create separation from facility. Particularly disgruntled practitioners may be relators or cooperating witnesses.
- Again, no confusion over who is the client.

Questions?

Kirk Ogrosky
White Collar Defense Group
Arnold & Porter LLP
Washington, DC
(202) 942-5330
kirk.ogrosky@aporter.com

John E. Steiner, Jr.
Chief Compliance & Privacy Officer
Associate General Counsel
Cancer Treatment Centers of America
Schaumburg, Illinois
(847) 342-6603
John.Steiner@ctca-hope.com

Jeffrey Dickstein
Assistant U.S. Attorney
Southern District of Florida
Civil Division, ACE
Miami, Florida
(305) 961-9453
Jeffrey.Dickstein@usdoj.gov