Quality of Care and Medical Necessity
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Kirk Ogrosky
Healthcare & White Collar Groups
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

Enforcing Quality of Care
Through the FalseClaims Act

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.”

Focus on Quality: Healthcare Reform Implements Payment 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."

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

Quality Care – Medicare, Medicaid, & Tricare

Medicare requires submission of claims that are "of a quality which meet professionally recognized standards of healthcare." In addition, each claim must be supported by evidence that it is medically necessary and of the appropriate quality. See 42 U.S.C. 1320c-5(a)(2).

Medicaid requires services that "are within accepted professional standards of practice." Practices vary by state. See, e.g., Georgia Medicaid Program Part I; section 106(k).

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).
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

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

- Quality of Care Theories: Express false certification, Implied false certification, Worthless services, Inadequate services
- Traditional Theories: Claims for services not rendered, Unbundling, Claims for services not covered (e.g., wound care kits, urinary incontinence devices), Duplicate payments
- Themes present in cases:
  - Special treatment to big admitters
  - Fraudulent documentation
  - Poorly structured, or failure to follow, internal process
  - Underlying regulatory violations
  - Kickbacks

Worthless Services Cases

Does FCA Liability Attach to All Services Deemed to be in the Bottom 50%: Does worth less mean worthless?
- Even assuming the FCA “worthless services” theory applied, the Seventh Circuit found that it would not apply to situations in which sub-par contract performance was alleged to have resulted in services that were simply worth less. *U.S. ex rel. Absher v. Momence Meadows Nursing Center, Inc.*, 764 F.3d 699 (7th Cir. 2014).
- The Complaint in *Absher* was filed by two former nurse employees alleging that the SNF submitted false claims because treatment was below the standard of care. DOJ declined to intervene, and relators proceeded to trial. The jury awarded a judgment of approximately $3 million, which the district court trebled.
- The Seventh Circuit held that “[i]t is not enough to offer evidence that the defendant provided services that are worth some amount less than the services paid for.” The Court then concluded that the evidence did not support the verdict because relators failed to prove that services were “truly or effectively ‘worthless.’”
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

- 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).

- First Circuit: “distinction between factually and legally false ... Derives from 2001 decision of the Second Circuit ... [t]hese categories may do more to obscure than clarify ....” *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377, 385-86 (1st Cir. 2011).
Implied False Certification Claims

- **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.

Can't Spell Quality without FCA

Quality reporting requirements - such as the Physician Quality Reporting System (PQRS) - result in both incentive payments and adjustments based on quality. These representations may result in liability under the False Claims Act.

EHR: Friend and Foe?
Electronic health records will offer an easy way for outcomes—and representations of outcomes—to be verified and analyzed.
Attention to Details -- 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't ignore or explain away complaints and expect government to accept excuses
- 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:
  - National Coverage Determination
  - Local Coverage Determination
  - Federal Register
  - 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

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.

Personalized Medicine and Practical Coverage Points
Public Policy and Coverage Fundamentals

- **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

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

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

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- 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?

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