Compliance: Key Trends and Potential Vulnerabilities

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Robert E. Mazer, Esquire
Baker Donelson
rmazer@bakerdonelson.com
(410) 862-1159

Kristin C. Carter, Esquire
Baker Donelson
kcarter@bakerdonelson.com
(410) 862-1109

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- Proficiency Testing Referrals
- False Claims Applicable to Labs
  - The Match Game
  - *Medical Necessity and Related Documentation Issues*

Content of Presentation

- Reporting & Returning Overpayments
- Federal Anti-Kickback Statute
- Commercial Payor Issues
- Stark Self-Referral Prohibition
- Miscellaneous Issues

Compliance Principles

Beware of Newtonian Principles

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- Inertia
- Every Action Results in Equal and Opposite Reaction

Compliance Formula

Intent

+ Knowledge of Rules

+ Process

Compliance

Compliance Formula

Rules - Compliance is a many-headed beast

- Federal and state laws and regulations
  - Licensure, certification and enrollment requirements
  - Claims for payment
  - Relationships with referral sources
  - Miscellaneous
- Private payer requirements

Compliance Formula

Process

- Ongoing Process
- Coordination of Activities – Need to know
- Forms, Forms, Everywhere Forms

Proficiency Testing Referrals

Regulatory Principles

- Lab prohibited from intentionally referring PT samples to another lab for analysis. CMS: Referral is "intentional" if lab employee requests another lab to test PT sample
- CMS cannot revoke CLIA certificate of lab that provided PT samples to another lab, when it did not direct that lab to test PT samples or seek its test results. *J.B. and Greeta B. Arthur Comp. Cancer Ctr. Lab.*, Dept. Appeals Board, CR 2436 (Sept. 21, 2011)

Proficiency Testing Referrals

CMS Application of PT Referral Prohibition

- Reflex, distributive or confirmatory testing may not be "intentional" referral. 42 C.F.R. § 493.801(b)(4)
- Prohibition applied broadly, to cover virtually any handling of PT samples or test results by another lab
- Includes lab in same hospital building with separate CLIA certificate
- Applies to waived tests, at least those performed by labs with waiver certificates

False Claims Applicable to Laboratories

- Billing for tests not ordered or performed
- Miscoding of CPT codes
- Misrepresentation of diagnosis codes
- Lack of medical necessity
- Overpayments
- Stark/Kickback violations
- Regulatory violations

False Claims Applicable to Laboratories

- Intent under FCA
  - "Intent to defraud" not required
  - "Reckless disregard" of claim's truth or falsity sufficient
- Other Federal and State statutes may prohibit similar conduct related to governmental and *non-governmenta*l payment claims

The Match Game

- First Generation
  - Test ordered
  - Test performed
  - Test billed (CPT or HCPCS code)

The Match Game

Test Orders

- CMS does not require physician's signature on laboratory requisition, but signature should prove that test was ordered
- In absence of signed requisition, labs may be dependent on physician’s medical record to prove test was ordered

The Match Game

- Second Generation Additions
  - Test *knowingly* ordered
  - Lab did not contribute to unnecessary tests

The Match Game

Medical Necessity – OIG Advice

Lab's responsibility (per OIG compliance guidance)

- Not contribute to unnecessary testing
- Educate physicians and other reasonable steps to avoid claims for unnecessary services

The Match Game

Medical Necessity – Custom Profiles

U.S. pled FCA action against medical group and related physicians based on:

- Use of custom panels that included unnecessary tests
- Use of "lab standing orders" ("house orders") not ordered by treating physician

U.S. v. Family Med. Ctrs., 2016 WL 6601017 (D. S.C. Nov. 8, 2016)

Family Medicine Centers (Update)

Settlement - $2 million (Sept. 2017)

- Family Medicine Centers - $1.56 million
- Principal owner, CEO and lab director - $443,000
- Corporate Integrity Agreement

The Match Game

- Third Generation Additions
  - Lab's responsibility to demonstrate that tests were *actually* medically necessary
    - Compliance issue
    - Financial issue

See Mazer, Robert E., Medicare Medical Necessity Requirements Continue to Vex Clinical Laboratories, G2 Compliance Advisor (Sept. 2014) http://www.g2intelligence.com/wp-content/newsletters/gca/2014-09-GCA.pdf

Medical Necessity

"[N]o payment may be made . . . for items or services . . . [that] are not reasonable and necessary for the diagnosis and treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A).

"No payment shall be made . . . unless there has been furnished such information as may be necessary in order to determine the amounts due such provider . . .." 42 U.S.C. § 1395l(e).

Medical Necessity Documentation

CMS Regulations

- "All . . . diagnostic laboratory tests . . . must be ordered by the physician who is treating the beneficiary, that is, the physician . . . who uses the results . . .. Tests not ordered by [such] physician . . . are not reasonable and necessary . . .." 42 C.F.R. § 410.32(a)
- Lack of documentation related to *physician's use* of lab *results* can result in determination that tests were not medically necessary

Medical Necessity Documentation

CMS Regulations

- Lab must maintain documentation (1) received from ordering physician and (2) that its payment claim accurately reflects such information. 42 C.F.R. § 410.32(d)(2).
- Information may be inadequate to demonstrate medical necessity.
- Lab may request additional information from ordering physician. 42 C.F.R. § 410.32(d)(3).
- *Regulations do not require physician's cooperation!*

Medical Necessity

Limitation of Liability

Where payment may not be made based on lack of medical necessity and the patient and provider "did not know, and could not reasonable have been expected to know, that payment would not be made . . . then . . . payment shall . . . be made for such items or services . . .." 42 U.S.C. § 1395pp(a)(2).

Medical Necessity

Without Fault

- There shall be no recovery where incorrect payment made to individual who is “without fault” or if such recovery would defeat the purposes of Medicare or be against equity and good conscience. 42 U.S.C. § 1395gg(c)
- “Without fault” requires laboratory to have exercised reasonable care in billing for and accepting payment for test

Medical Necessity Documentation

Proactive Steps

- Educate physicians related to medical necessity criteria, supporting documentation and ABNs
- Securing physician's cooperation, particularly agreement to provide documentation *(which may or may not be helpful)*

Medical Necessity – Special Stains

Pathologists may order medically necessary special stains, but related payment claims have been subject to increasing scrutiny.

- Pathology group required to pay $600,000 for billing allegedly unnecessary special stains. DOJ: "The government considers use of special stains before the analysis of the routine H & E stained specimen to be medically unnecessary."
- Organization required to pay $900,000 based on allegedly improper promotion of stain as able to definitively diagnose particular condition.

https://www.justice.gov/usao-wdnc/pr/hickory-pathology-lab-agrees-pay-united-states-601000-settle-false-claims-act

https://www.justice.gov/asao-ri/pr/poplar-healthcare-pay-nearly-900000-resolve-false-claims-act-allegations

Medical Necessity

- Claims for lab tests with specific diagnoses were "legally false" based on lab's CMS-1500 certification that tests were medically necessary
- Lab has "independent obligation" to certify tests are medically necessary
- USA ex rel. Groat v. Boston Heart Diagnostics Corp., 2017 WL 2533341 (D. D.C. 2017)

Return of Overpayments

Medicare Program; Reporting and Returning Overpayments; Final Rule 81 Fed. Reg. 7654 (Feb. 12, 2016); 42 C.F.R. § 401.305

Overpayment recipient must "report and return" overpayment within 60 days of date on which overpayment is "identified."

Overpayment "identified" when person:

1. *Has* determined that it has received an overpayment and quantified overpayment; or
2. *Should have* determined that it has received an overpayment and quantified overpayment through reasonable diligence.

Return of Overpayments

General Principles

- Regulation applies to any overpayment identified within 6 years of its receipt.
- Obligation to report and return applies irrespective of reason for overpayment.
- Payment properly received will not become overpayment based on change in law or regulation (beware of “clarifications”).

Return of Overpayments

- "Reasonable diligence" includes:
  1. "Proactive compliance activities" conducted in good faith to monitor claims for overpayments, and
  2. "Reactive investigative activities" conducted in good faith in timely manner in response to "credible information" about potential overpayment.
- "Credible information includes information that supports a reasonable belief that an overpayment may have been received."

Return of Overpayments

Return of Overpayments (to whom)

- To OIG – “potential fraud against the Federal health care programs”
- To CMS – Stark only violation
- To Contractor – “merely an overpayment”
- To U.S. Attorney’s Office – (does not satisfy 60-day rule)
- To State

Return of Overpayments

- *United States ex rel. Malie v. First Coast Cardiovascular Inst.,* M.D. Fla., No. 3:16-cv-01054, settlement 10/13/17
  - Cardiovascular Group will pay $448,882 to settle alleged FCA violations that it retained overpayments
  - Learned about overpayments no later than June 2016; Former executive director filed whistleblower complaint in August 2016
  - Alleged Group delayed repayment of $175,000, despite repeated warnings, until it was notified gov't opened investigation

Federal Anti-Kickback Statute ("FAS")

- Prohibited Conduct
  - Knowing & willful
    - Solicitation or receipt or
    - Offer or payment of
  - Remuneration
    - In return for referring a Program patient, or
    - To induce the purchasing, leasing , or arranging for or recommending, purchasing or leasing items or services paid by Program

Federal Anti-Kickback Statute

Special Fraud Alert: Laboratory Payments to Referring Physicians (2014)

- *Previously* emphasized that providing free or below-market goods to physician referral source, or paying more than FMV for services, could constitute illegal remuneration
- Payments intended to induce or reward referrals are unlawful, even if payments are FMV for services; payments exceeding FMV increase probability of unlawful payment

Federal Anti-Kickback Statute

Biodiagnostic Laboratory Services (NJ)

- Lab admitted to paying millions of dollars in bribes to physicians and other health care providers
  - Resulted in more than $100 million in payments to Lab from Medicare and private insurers
- Utilized sham lease agreements, sham service agreements, and sham consulting agreements to induce physicians to refer patient blood samples and induce them to order unnecessary tests
- Investigation has resulted in 50 convictions – 36 of them physicians

Federal Anti-Kickback Statute

In-Office Phlebotomists (IOPs)

- Labs may provide IOPs at no cost, provided
  - IOPs provide only specimen collection and processing services for the lab
  - No services for physician's practice or in-office lab
- May labs pay rent to physician practices for space used by the IOP?
- State law issues

Federal Anti-Kickback Statute

Marketing Arrangements

- Statutory and regulatory exception for payments related to *bona fide* employment relationship
- Independent contractor arrangements may violate the FAS and may be legally unenforceable. *Joint Technology, Inc. v. Weaver*, Case No. CIV-11-846-M (CCH) ¶ 304,295 (W.D. Okla. Jan. 23, 2013)
- *Management* arrangements that include marketing services may raise issues under FAS (and/or state laws)
- Laboratory marketing company potentially liable under FCA and other statutes for participation in arrangement that violates FAS. *Berkley Heart Lab*

Federal Anti-Kickback Statute

Contract arrangements that purport to be limited to private pay business may raise issues under FAS (and related state laws)

Waiver of copayments and deductibles related to private insurance policies can violate FAS and FCA. *USA ex rel Lutz v. Berkley Heart Lab., Inc.*, 225 F. Supp.3d 487 (D. S.C. 2017)

Federal Anti-Kickback Statute

Advisory Opinion 15-4

- Provide clinical lab testing without charge for patients in commercial plans in which the lab was out of network
- Referring physicians not at financial risk for the lab services
- OIG determined "remuneration" to the physician
  - Physician's convenience in working with a single lab
  - "relieve physician practices of the expense for any interface that the physician practice no longer would maintain."

Commercial Payer Issues

- Contract terms
- Payment rules incorporated in contract (if any) frequently unclear
- State law issues
  - contract interpretation
  - limits on recoupment period

Commercial Payor Issues

- Waiver of Copayments/Deductibles
  - Routine waivers prohibited for government payers
  - Hardship waivers permitted
  - Prohibited in certain states
    - FL, CO
- Commercial Payers' Lawsuits against Providers
  - "No legal obligation to pay clause" can be used against full waivers
  - Private insurance fraud claims

Commercial Payor Issues

- Hospital/Independent Laboratory Arrangements
  - Partnership between hospital and lab or management company to expand use of hospital in-network status or obtain hospital's favorable rates applicable to commercial insurance
  - Independent laboratory performs testing services and client-bills services to hospital
- Issues
  - Payment claims accurate and compliant with applicable billing rules, particularly hospital claims for tests performed by "partner."
  - Related marketing arrangements compliant with FAS (if applicable) and state law?
  - General restrictions on hospital based on its organizational status (N-F-P, governmental), CLIA, etc.

Commercial Payor Issues

- *Blue Cross & Blue Shield of Miss. v. Sharkey-Issaquena Community Hospital et al.,* 3:17-cv-00338-DPJ-FKB (S.D. Miss., Filed May 4, 2017)
  - BCBS claims community-based hospital entered into contract with non-network laboratories to allow laboratories to submit claims using hospital's name and billing information
    - Hospital also leased the laboratories its personnel and space at one or more locations
  - *Allegations:* breach of contract against the hospital, as well as fraud, civil conspiracy, negligent misrepresentation and unjust enrichment against the laboratories and their affiliates.
  - Hospital's payor contract includes favorable percentage of charge reimbursement
    - BCBS states it contracted at this rate with the hospital as a hospital, and not as a laboratory for non-hospital patients, and certainly not to allow third parties to take advantage of the percentage of charge rate.

Stark Self-Referral Prohibition

- Physician may not refer:
  - Medicare or Medicaid patients
  - for “designated health services”
  - to an entity with which the physician or an immediate family member has
  - a “financial relationship”
- Subject to exceptions in statute and regulations

Stark Self-Referral Prohibition

- Stark remuneration excludes
  - Forgiveness of amounts owed for inaccurate or mistaken tests or billing errors
  - Items, devices or supplies used solely to
    - Collect, transport, process, or store specimens
    - Order testing or communicate test results

Stark: CMS Advisory Opinion 2017-01

- Laboratory Alert Functionality (Pop-Up Notifications) in Web-Based Ordering/Results Portal – not “remuneration” under Stark
- Keys to analysis:
  - Alerts only provided when results are communicated through portal; limited to issues related to specific results
  - Recommendations are based on peer-reviewed guidelines available for without charge through internet
  - Alerts can be turned off and time limited (14 days or less)
  - No “select all” button available for follow-up tests

Direct to Consumer Testing

- Increasing focus on personalized medicine and empowerment of patients to take more active role in managing healthcare
- CMS Rule (2014) – Amended CLIA and HIPAA to provide patients with right of access to test *results*
- Who is authorized to *order* testing remains state law issue
  - CLIA regulations "authorized person" defined under state law (42 C.F.R. 493.1241)
  - Some states expressly allow, other allow limited DTC testing, others require order by physician or other authorized health care professional

Direct to Consumer Testing

- Other considerations
  - State restrictions on advertising (e.g., Maryland)
  - Laboratory tests v. FDA-approved over-the-counter diagnostic tests (“OTC”)

Toxicology Testing

- Medical Necessity
- Billing Issues

Payment for Hospital Outpatient Tests

Submission of Claims – Outpatients vs. Non-Patient Tests

- Provision of services in hospital-based clinic may cause individual to be outpatient
- Can such an outpatient become a non-patient by obtaining lab tests from unrelated entity?

Payment for Hospital Outpatient Tests

- Packaged into Hospital Outpatient Prospective System unless:
  - "Non-patient" test
  - No other hospital outpatient services from same "encounter"
- Applies to tests performed by hospital directly or "under arrangements"
- CMS assigned codes designate packaging status of particular lab test

OIG Work Plan – FY 2017

New Web-Based Work Plan Effective June 2017 – Monthly Updates

Initiatives in 2017 Work Plan:

- Analyze top 25 laboratory tests in 2016 to monitor PAMA implementation
- Review payments to independent clinical laboratories to identify those that submit improper claims, and recommend related recovery actions
- Review payments to histocompatibility labs determined on reasonable cost basis
- Review payments for outpatient services (including lab) provided within 3 days prior to, or during inpatient stays

QUESTIONS?