# Compliance Issues Affecting Clinical Laboratories

**Robert E. Mazer, Esquire**
**Baker, Donelson, Bearman, Caldwell & Berkowitz, P.C.**
**100 Light Street**
**Baltimore, MD 21202**
**rmazer@bakerdonelson.com**
**(410) 862-1159**



## Content of Presentation

Clinical Laboratory Services

Compliance Formula

Selected Licensure/Certification/Enrollment Issues

False Claims Applicable to Labs

- The Match Game
- *Medical Necessity and Related Documentation Issues*

## Content of Presentation

- Regulatory Violations
- Return of Overpayments
- Payment for Hospital Outpatient Tests

Federal Anti-Kickback Statute

Stark Self-Referral Prohibition

Pricing Issues for Laboratories



## Clinical Laboratory Services

- Fungible
- High Volume
- Reliance on Referring Physicians
- Lack of Medical Necessity Documentation
- Potential Revenue from Reference Tests

## Compliance Formula

Intent

+ Knowledge of Rules

+ Process

Compliance



## Compliance Formula

### Intent

"If you're going to talk the talk, you've got to walk the walk."

# Compliance Formula

## Rules - Compliance is a many-headed beast

- Federal and state laws and regulations and private payer requirements
  - Licensure, certification and enrollment requirements
  - Claims for payment including medical necessity issues
  - Relationships with referral sources
  - Miscellaneous



# Compliance Formula

## Process

- Ongoing Process
- Coordination of Activities
- Those who should know, do know

# Compliance Formula

- Continuous monitoring of referral patterns and related receipts
- "Small" or uncomplicated issues can result in big problems, e.g., failure to update enrollment application, failure to maintain and produce Medicare with requested records or information



# Licensure/Certification/Enrollment

**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)

# Licensure/Certification/Enrollment

## 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



# Licensure/Certification/Enrollment

## Best Practices To Avoid Prohibited PT Referrals May Include

- Detailed Policies
- Employee Education
- Internal Audits
- Use of Different PT Organizations for Related Labs

# Licensure/Certification/Enrollment

## Medicare Billing Privileges

- Lab's Medicare enrollment and billing privileges revoked when on-site review indicated that it was not yet "operational." *TC Foundation, Inc. v. CMS, Dept. Appeals Board*, CR 2834, CCH ¶ 122,766 (June 18, 2013)
- Similar theory applied against lab closed at time of inspection. *Community Medical Lab., LLC v. CMS, Dept. Appeals Board*, CR 2635, CCH ¶ 122,650 (Oct. 2, 2012)



# Licensure/Certification/Enrollment

## Medicare Billing Privileges

- Provider or supplier's Medicare billing privileges may be revoked based on "a pattern or practice of submitting claims that fail to meet Medicare requirements." 42 C.F.R. §424.535(a)(8)(ii)
- CMS indicates that such claims include those for services that are not reasonable and necessary
- CMS declined to impose intent standard

## Licensure/Certification/Enrollment

### Enrollment Form

- Effective January 6, 2017, civil monetary penalties of up to $50,000 for any false statement, omission or representation on any enrollment application. 81 Fed. Reg. 88334, 88341, 88358 (Dec. 7, 2016)



## 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
- Regulatory violations
- Stark/Kickback violations

## False Claims Applicable to Laboratories

- False Claims Act prohibits
  - filing, or causing to be filed "false or fraudulent" claims
  - Using false statement to "conceal, avoid or decrease" a government obligation
  - Failure to return overpayments



## 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 a physician's signature on a laboratory requisition, but such a signature may prove that a test was ordered.
- In the absence of a signed requisition, labs may be dependent on content of physician's medical record to prove test was ordered.

# The Match Game

## Test Orders

- Court upholds *denial* of claims for audiological testing when medical records did not reflect physician's intent or knowledge that tests were to be performed. *Doctors Testing Ctr. v. HHS*, 2014 WL 112119 (E.D. Ark., Jan. 10, 2014), *aff'd*, 588 Fed. Appx. 517 (8th Cir. 2015)



# The Match Game

## Test Orders

Laboratory could not be *paid* for biopsies because no documentation of physician order. *Nephropathology Assocs., PLC v. Sebelius*, 2013 WL 3285685 (E.D. Ark. 2013)

Relator stated claim *under FCA* in alleging that laboratory performed unordered FISH tests. *Daugherty v. Bostwick Labs*, No. 1:08-CV-00354, 2012 WL 6593804 (S.D. Ohio Dec. 18, 2012)

# The Match Game

## Tests Performed and Billed

- *U.S. ex rel. Ketroser et al v. Mayo Foundation*, 729 F.3d 825 (8th Cir. 2013)
  - Relator alleged that Mayo filed false claims because it did not prepare a per-slide separate written report for each special stain
  - Court dismissed because no rule clearly required such separate per-slide report as a condition of payment



# 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
- Honest, straightforward, fully informative and non-deceptive marketing (including tests offered, tests resulting from order, financial consequences to payers)
- Provide freedom of choice (e.g., reflex or not)



# The Match Game

## Medical Necessity – OIG Advice

- Educate physicians and other reasonable steps to avoid claims for unnecessary services
  - Requisition – conscious ordering of each test by physicians
  - Notices – General and Custom profiles
- Educate re ABNs
- Monitor tests utilization

# The Match Game

## Medical Necessity – OIG Advice – Custom Profiles

Annual Notices

- Medicare reimbursement for each component of profile
- Custom profiles may result in tests which are not covered, reasonable and necessary and will not be billed
- Individual who knowingly causes submission of false claim may be subject to sanctions

*Annual notices do not guarantee payment of particular claim(s)!*



# 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)

# 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



# The Match Game

## Sanctions vs. Lost Revenue

- Various statutes can result in imposition of penalties for submission of claims that the person knows or should know were not medically necessary. See, e.g., 42 U.S.C. § 1320a-7a(a) (civil monetary penalties)
- May not apply, however, if laboratory did not contribute to unnecessary testing. According to OIG, regulatory exception "would normally protect a laboratory from being subject to exclusion for providing unnecessary tests ordered by a physician…." 57 Fed. Reg. 3298, 3307 (Jan. 29, 1992)
- *Protections have little, if any, impact on loss of revenues from tests deemed unnecessary!*

# Medical Necessity

## General

"[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).



# Medical Necessity

## Burden of Proof

"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)

Payments to providers are precluded unless provider furnishes information to determine amounts due upon request. OIG Work Plan – FY 2017

# Medical Necessity Documentation

## CMS Regulations Related to Use of Diagnostic Tests

"All . . . diagnostic laboratory tests . . . must be ordered by the physician who is treating the beneficiary, that is, the physician who . . . treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by [suc]h physician . . . are not reasonable and necessary . . .." 42 C.F.R. § 410.32(a).

Lack of documentation related to *physician's use* of lab *results* has resulted in determination that tests were not medically necessary.



# Medical Necessity Documentation

## Intent - CMS Regulations Related to Use of Diagnostic Tests

"This policy is designed to assure that beneficiaries receive medically necessary services and to prevent patterns of abuse, such as the furnishing of diagnostic tests that are screening (non-covered) services . . . For example, we have heard of situations in which a physician is employed for the sole purpose of ordering diagnostic tests (in nursing homes or mobile centers).

* * *

"The intent of the policy is to assure that the physician who orders the test is responsible for the management of some aspect of the patient's care."

61 Fed. Reg. 59490, 59497 (Nov. 22, 1996).

# Medical Necessity Documentation

## CMS Regulations

Physician ordering diagnostic service required to maintain documentation of medical necessity in patient's medical records. 42 C.F.R. § 410.32(d)(2).

Lab submitting claim must maintain (1) documentation received from ordering physician and (2) documentation that its payment claim accurately reflects such information. *Id*.



# Medical Necessity Documentation

## CMS Regulations

CMS may find information required to be maintained by lab inadequate to demonstrate medical necessity, and may request medical records from physician. If information not provided, CMS may deny claim. 42 C.F.R. § 410.32(d)(2).

Lab may request additional information from ordering physician to document that services are reasonable and necessary. 42 C.F.R. § 410.32(d)(3).

*Regulations do not require physician's cooperation!*

# Medical Necessity Documentation

## Administrative Case Law

Clinical laboratory has burden of producing documentation of medical necessity. *See Meridan Laboratory Corp. v. Advance Med. Corp.*, Dept. Appeals Board, Decision of Medicare Appeals Council, Doc. No. M-11-568 (June 24, 2011), remanded, *Meridan Laboratory Corp. v. Sebelius*, 2012 WL 3112066 (W.D. N.C., July 31, 2012) (remanded for consideration of limitation of liability principles).



# Medical Necessity

## Limitation of Liability

Where a determination is made that 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



# Medical Necessity Documentation

## Proactive Steps

Educate physicians related to medical necessity criteria, supporting documentation and ABNs

Physician's agreement to hold lab harmless for tests denied based on lack of documentation of medical necessity (if possible)

# Medical Necessity Documentation

## Proactive Steps

Securing Physician's Cooperation – Physician's agreement to provide documentation *(which may or may not be helpful)*

- Existing contract, such as for client-billing
- Acknowledgement of annual notices
- Laboratory requisition

Physician – Lab Relations



## Regulatory Violations as Basis for FCA Claim

- *U.S., ex. rel. Escobar v. Universal Health Servs., Inc.,* 136 S. Ct. 1989 (2016). FCA not "vehicle for punishing garden variety . . . regulatory violations." False claim must be material to government's decision to pay claim.
- *U.S. ex. rel. Hansen v. Deming Hosp. Corp.,* 992 F. Supp.2d 1137 (D. N.M. 2013) – no claim for liability under FCA for CLIA violations (pre-*Escobar*)

## Regulatory Violations as Basis for FCA Claim

Execution of supplier agreement requiring claims to comply with laws, regulations, and program instructions could cause claims related to Stark or FAS violation to violate FCA. *Daugherty v. Bostwick Labs*, No. 1:08-CV-00354, 2012 WL 6593804 (S.D. Ohio Dec. 18, 2012)



# Return of Overpayments

**Medicare Program; Reporting and Returning Overpayments; Final Rule 81 Fed. Reg. 7654 (Feb. 12, 2016)**

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

Overpayment is considered "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 use of 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 an overpayment as a result of a subsequent change in law or regulation (but watch out for “clarifications”).



# Return of Overpayments

- “Reasonable diligence” includes:
  1. “Proactive compliance activities” conducted in good faith by qualified individuals to monitor claims for receipt of overpayments, and
  2. “Reactive investigative activities” conducted in good faith in timely manner by qualified individuals 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

## Overpayments Based on Medical Necessity

- Requirements apply to "medical necessity" determinations.
- CMS: "There may be situations where a significant increase in Medicare revenue should lead a laboratory to conduct reasonable diligence."
- Limitation of liability principles do not impact obligation to report and return overpayment.



# 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

## Enforcement

- Civil False Claims Act (on which regulations are based)
- Effective January 6, 2017, Civil Monetary Penalties of up to $10,000 for each item on service for which an overpayment was not timely returned. 81 Fed. Reg. 88334, 88341, 88358 (Dec. 7, 2016)



# Return of Overpayments

## Impact of Compliance

- Does not eliminate CMP liability (or other liability) if it exists. 81 Fed. Reg. 88339.
- Medicare regulations permit suspension of Medicare payments when there is reliable information that an overpayment exists or when payments to be made may not be correct (as well as when there is a credible allegation of fraud). 42 C.F.R. § 405.371

# Return of Overpayments

**Self-Audits Can Result in FCA Liability**

- FCA potentially violated when medical group failed to follow up on self-audit that reflected incorrect claims for payment
- Potential liability for both refusal to investigate possibility of overpayments received during audit period and for subsequent submission of claims
- *U.S. and Wisconsin, ex. rel. Keltner v. Lakeshore Med. Clinic, Ltd.*, 2013 WL 1307013 (E.D. Wisc. 2013)



# Payment for Hospital Outpatient Tests

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

# 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?



# 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

- Statutory Exceptions
- Regulatory Safe Harbors
- Advisory Opinions
- ACO waivers

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



# Federal Anti-Kickback Statute – ACO Waivers

Clinical laboratories may enter into arrangements with ACOs *participating in Medicare Shared Savings Program ("MSSP")* that would otherwise violate the FAS (and Stark Law) if the arrangements:

- Reasonably related to purposes of MSSP and properly documented, including governing board's meaningful determination of such
- Purposes of MSSP include:
  - Promoting accountability for the quality, cost, and overall care for Medicare patient population as described in the MSSP, managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO, or encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare beneficiaries.

# Federal Anti-Kickback Statute

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

General Principles:

- *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
- Payments for services paid for by others, such as Medicare, provides evidence of unlawful intent



# Federal Anti-Kickback Statute

Specific Principles:

- Physicians and labs which participate in Special Processing Arrangements may be at risk under FAS
- Physicians and labs which participate in Registry Arrangements in which payments are related to test referrals, and do not reflect physician's efforts, may be at risk under FAS

# Federal Anti-Kickback Statute

## Advisory Opinion 16-12

- Labeling test tubes and specimen collection containers for dialysis facilities, at no cost, by lab personnel in lab's facility
- Offered as necessary to obtain or retain dialysis center business
- OIG: Potentially violates FAS
  - Services would otherwise be performed by dialysis center's employees
  - Inference, supported by lab's representation, that free services intended to influence laboratory selection



# 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."

# 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)

# Federal Anti-Kickback Statute

## Competitor Lawsuits

"Conduct violating the [FAS] and the Stark Law may provide the basis for liability under recognized common law causes of action and other state statutory laws," such as prohibitions against unfair or deceptive conduct. *Millennium Labs, Inc. v. Universal Oral Fluid Labs, LLC* (M.D. Fla., Aug 16, 2013).

Whether or not FAS and the Stark Law are relevant to state unfair competition law is a novel and complex issue of state law. *Ameritox, Ltd. V. Millennium Labs*, 803 F.3d 518 (11th Cir. 2015).



# 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

**Compensation Arrangements Exceptions (generally)**

- In writing
- Not exceed what is reasonable and necessary
- Term at least one year
- Payments set in advance and unrelated to referrals or other business generated
- Commercially reasonable without regard to volume or value of referrals



# Stark Self-Referral Prohibition

## Discounts

- Exception for payments by physicians
  - Fair market value *not* required for clinical laboratory services
  - Fair market value required for other services

## Stark Self-Referral Prohibition

### Client Entertainment

- Stark non-monetary compensation exception
  - Items or Services
  - Annual aggregate limit ($398 for CY 2017)
  - Not take into account volume or value of referrals or other business generated
  - Not solicited by physician



## 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

## Pricing Issues for Laboratories

- "Swapping" - Advisory Opinion 99-13, discount arrangement between Pathology Group and Hospitals or Physicians
- OIG Indicia of "Suspect" Discounts
  - Discounted prices below fully loaded (not marginal) costs
  - Discounted prices below those given to buyers with comparable "account" volume, but without potential Program referrals



## Pricing Issues for Laboratories

- Subsequent Retreat
  - Discounts below fully loaded costs not per se unlawful
  - Must be a "linkage" between the discount and referrals of Program business

Letter of Kevin G. McAnaney, OIG Industry Guidance Branch (April 26, 2000) http://oig.hhs.gov/fraud/docs/safeharborregulations/lab.htm

# Pricing Issues for Laboratories

## Fair Market Value vs. Cost

- Compliance Guidance for Clinical Laboratories, 63 Fed. Reg. 45,076 (August 24,1998), uses "fair market value" benchmark

  Advisory Opinion 11-11 reiterates "below cost" theory of "swapping"



# Pricing Issues for Laboratories

## "Substantially in Excess"

- May not bill Medicare "substantially in excess" of "usual" charge
- No enforcement activity since law passed in 1972
- Overall volume of test charges made to payers other than Medicare or Medicaid that are below Medicare/Medicaid fee schedule should be substantially less than one-half of non-Medicare/non-Medicaid test volume. Letter of Kevin G. McAnaney, OIG Industry Guidance Branch (April 26,2000)

# Pricing Issues for Laboratories

## State Law Issues

- Medicaid pricing limitations-various state laws
  - Many states require providers to bill at "usual and customary" rates
  - "Usual and customary" may be defined as lowest fee charged by lab.



# Pricing Issues for Laboratories

## Recommended Policies

- Never tie client pricing to Medicare/Medicaid referrals
- Ensure that client bill pricing is profitable on a stand-alone basis
- Be cognizant of pricing patterns across clients
- Carefully review state law regarding Medicaid pricing

# QUESTIONS?