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Compliance Issues Affecting Laboratories

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Compliance – Overall Purpose of Compliance Programs

- Effective internal controls that promote adherence to legal requirements
- Culture that promotes prevention, detection, and resolution of unlawful conduct
- Demonstrate commitment to compliance process

Compliance Plan Components

- Written policies, procedures and standards of conduct
- Compliance officer and compliance committee
- Effective training and education
- Effective lines of communication
- Enforcement of standards through well-publicized disciplinary guidelines
- Internal monitoring and auditing
- Responding promptly to detected offenses and developing corrective action

Compliance Plan Benefits

- From the inside – prevents, detects, and resolves unlawful conduct
- From the outside – potential reduction of penalties for violations

Compliance Is A Many-Headed Beast

- Federal and state laws
- Licensure and certification requirements
- Claims for payment
- Relationships with referral sources
- Miscellaneous

*Indicates that additional information related to designated topic may be accessed at http://www.ober.com/attorneys/robert-mazer-recently-released

Selected Licensure/Certification Issues

Proficiency Testing Referrals

- Longstanding Principles
  - Lab prohibited from intentionally referring PT samples to another lab for analysis
    - 1 year revocation required
    - Lab's owner or operator cannot own or operate lab for 2 years
  - Prohibition may be construed broadly, to cover virtually any handling of PT samples or test results by another lab prior to PT testing close date

Proficiency Testing Referrals

- "Intentional" Referral
  - 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)
  - Proposed rule, 78 Fed. Reg. 9216 (Feb. 7, 2013). PT sample referred for reflex or confirmatory testing under procedures for patient specimens considered improper, but not intentional referral, so long as not "repeat" PT referral

Proficiency Testing Referrals

- Taking Essential Steps for Testing ("TEST") Act of 2012
  - Permits, but no longer requires, revocation of CLIA certificate for intentional referral of PT samples
  - Permits imposition of intermediate sanctions rather than 2 year prohibition on lab's owner or operator

Proposed TEST Act Implementation (78 Fed. Reg. 58386)

- Sanctions for intentional referrals of PT samples.
  - Lab may, rather than must, have CLIA certificate revoked for intentional referral of PT samples
  - Repeat PT referral, or reporting results of another lab – 1 year revocation, 1 year ban on owning/operating lab, civil money penalty (CMP)
  - Lesser penalties when lab obtains results from other lab testing its PT samples but reports own results (penalties depend on whether other lab's results received before close date)

Medicare Enrollment

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

Claims For Payment

Civil 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
- Intent
  - "Intent to defraud" not required
  - Filing claims with "reckless disregard" of claim's truth or falsity is sufficient

Civil False Claims Act

- Liability
  - 3X Damages
  - $5,500 to $11,000 *per claim*
- *Qui Tam* Provisions
  - "private attorney generals"
  - Can proceed even if Government declines
  - Can receive up to 30% of recovery
- State FCAs

FERA Amendments – "Reverse" False Claims

- False Claims Act – Changes to the FCA language made as part of Fraud Enforcement and Recovery Act of 2009 (FERA)
  - it is now illegal to "knowingly conceal…or knowingly and improperly avoid…or decrease…an obligation to pay or transmit money or property to the Government…"
    - 31 U.S.C. §3729(a)(1)(G)
- Eliminated the need for a "false statement or record" – mere knowledge is apparently enough

Accountable Care Act

- Section 6402
  - Requires reporting and repayment of overpayments within 60 day of ***identification*** (or due date of next cost report, if applicable)
  - Reports to be made to:
    - Secretary (OIG, CMS)
    - State, or
    - Carrier, intermediary or contractor
  - Violations actionable under the FCA

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
- Court recognized potential liability for refusal to investigate possibility of overpayments received during audit period and subsequent submission of claims (including under "reverse false claims" provisions added in 2009)

U.S. and Wisconsin, ex. rel. Keltner v. Lakeshore Med. Clinic, Ltd., 2013 WL 1307013 (E.D. Wisc. 2013)

FCA Theories Applicable to Laboratories

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

The Match Game – Billing Issues

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

Test Orders

Labs are vulnerable to claims that there was no physician order based on content of patient's medical record of which they have no knowledge*

Court upholds denial of reimbursement 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)

Test Orders

Laboratory could not be reimbursed for biopsies based on lack of 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 (S.D. Ohio Dec. 18, 2012)

Recent Developments

- *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, rather than one per-case report
  - Court dismissed holding that no rule clearly required such separate per-slide reports as a condition of payment

The Match Game – Billing Issues

- Second Generation Additions
  - Test knowingly ordered
  - Test medically necessary

The Devil's Triangle – Medical Necessity

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 Devil's Triangle – Medical Necessity

- Educate physicians and other reasonable steps to avoid claims for unnecessary services
  - Requisition – conscious ordering of each test by physicians
  - Notices
    - General
    - Custom profile
  - Educate re ABNs
  - Monitor to make sure not contributing to unnecessary tests

Risks from Unnecessary Tests

Risk of Sanctions

- Various statutes specifically prohibit or can be interpreted to provide for 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)
- They may not apply, however, depending on circumstances. According to the OIG, the regulatory exception to the prohibition against furnishing services substantially in excess of a patient's needs "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)

Risks from Unnecessary Tests

Financial Loss

- Provider of clinical laboratory services 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)
- Laboratory may not be liable under limitation of liability provisions if it did not know and had no reason to know that services were not medically necessary. 42 U.S.C. § 1395pp(g)(2); *see generally, Maximum Comfort, Inc. v. Secretary,* 512 F.3d 1081 (9th Cir. 2007). The same is true if lab was "without fault," i.e., exercised reasonable care in billing for and accepting payment. 42 U.S.C. 1395gg(c)

Recent Developments

- Conditions of payment vs. conditions of participation
  - Most courts have held that non-compliance with Medicare conditions of participation does not give rise to FCA liability. *See e.g., U.S. ex. rel Rostholder v. Omnicare, Inc.,* 2014 WL 661351 (4th Cir. Feb. 21, 2014) (no FCA claim for violation of FDA regulations related to good manufacturing practice)
  - *U.S. ex. rel. Hansen v. Deming Hosp. Corp.,* CV 11-0566, (D.N.M. Nov. 21, 2013) – No claim for liability under FCA for CLIA violations

Advanced Beneficiary Notices

ABN considered "last minute," "coercive" and "invalid" when provided to patient when he presented to lab for tests ordered by physician

Olympic Med. Ctr., ALJ Appeal No. 1-1097162747, DHHS, Office of Medicare Hearings & Appeals (Southern Region Dec. 9, 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"

Federal Anti-Kickback Statute

- 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

Intent:ACA

- Section 6402 (f) (2)
  - "With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section."

Federal Anti-Kickback Statute

- Statutory Exceptions
  - Discounts
  - Bona fide employment relationships
  - GPO fees
  - Certain co-payment waivers
  - Certain managed care arrangements
- Regulatory Safe Harbors
- Advisory Opinions
  - Posted on OIG Website
    - www.hhs.gov/oig

Federal Anti-Kickback Statute

- Penalties
  - Criminal fines & imprisonment
  - Civil money penalty of $50,000 *plus* 3X the amount of the remuneration
  - Exclusion
  - False Claims Act liability – Affordable Care Act, §6402(f)(1)
  - Private Cause of Action

Private Cause of Action*

"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).

In-Office Phlebotomists

- 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

Arrangements with Sales Representatives

- Statutory exception for payments related to *bona fide* employment relationship
- Related safe harbor adopts IRS definition of employee
- Independent contractor arrangements may violate the FAS and may be legally unenforceable. *Joint Technology, Inc. v. Weaver,* (CCH) ¶ 304,295 (W.D. Okla. Jan. 23, 2013)

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"
- Prohibition subject to exceptions provided for in statute and regulations

Stark Self-Referral Prohibition

- Denial/Refund of Payments
- Civil money penalty of $15,000 for submission of claim for services person knows or should know violated statutes or for failing to make required refund, plus 2x reimbursement claimed
- Exclusion
- Additional Penalties for Circumvention Schemes

Cause of Action Under FCA

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 (S.D. Ohio Dec. 18, 2012)

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

Client Entertainment

- Stark non-monetary compensation exception
  - Items or Services
  - Annual aggregate limit ($385 for CY 2014)
  - Not take into account volume or value of referrals or other business generated
  - Not solicited by physician

Other Issues

- Stark statutory definition of 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 regulatory definition states that exclusion does not apply to surgical items, devices or supplies

CMS Advisory Opinions 2013-01 & 02 (Oct. 13, 2013)

- Biopsy needles were surgical items, devices or supplies not subject to exclusion
- Pap smear collection kits were not surgical items, devices or supplies
- CMS analysis reflected review of materials related to each item, including CPT codes for related procedures performed by physicians

Pricing Issues for Laboratories

Discounts

- "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

Discounts

- 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

Discounts

- Compliance Guidance for Clinical Laboratories
  - 63 Federal Register 45,076 (August 24,1998)
    - Uses "fair market value" concept
  - Advisory Opinion 11-11 reiterates "below cost" theory of "swapping"
- Stark Exception for payments by physicians
  - Fair market value not required for clinical laboratory services
  - Fair market value required for all other services

Recent Enforcement Activity

- *U.S. and California ex rel. Pasqua v. Kan-Di-Ki, LLP et al, dba Diagnostic Laboratories and Radiology*.
  - Government alleged that clinical lab/mobile x-ray company gave kickbacks in the form of below-cost discounted pricing to nursing homes on client-billed work to induce Medicare Part B referrals
  - False Claims Act allegations settled for $17.5 million in September, 2013

Pricing Rules of Thumb

- Never tie client pricing to referrals of Medicare/Medicaid work
- Try to ensure that client bill pricing is profitable on a stand-alone basis
- Be cognizant of pricing patterns across clients

"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) http://oig.hhs.gov/fraud/docs/safeharborregulations/lab.htm

"Substantially in Excess"

- Proposed Rule (9/2003)
  - "Substantially in excess" defined as 120% of "usual charge"
    - Good cause exception
  - "Usual charge" defined as mean of all charges (median also being considered)
- Rule withdrawn (6/2007)

State Law Issues

- Medicaid pricing limitations-various state laws
  - Most states simply require providers to bill at "usual and customary" rates
  - Massachusetts
    - "Usual and customary" is defined as the lowest fee in effect at the time of service that is charged by the lab for any service.
      - Mass. Regs. Code tit. 130, § 401.402

QUESTIONS?