Recent and Emerging Issues Related to Clinical Laboratory Testing and How to Avoid Them

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Compliance

Compliance Formula

Intent

+ Knowledge of Rules

+ Process

Compliance

Compliance

Knowledge of Rules

- Lab required to comply with CMS' informal pronouncements such as Medicare Learning Network (MLN) Matters articles and Medicare Administrative Contractor publications. *Maghareh v. Inspector General,* Dept. Appeals Board, No. CR 5166 (H.H.S. Aug. 17, 2018)
- Compliance with Self-Imposed Rules

Compliance

Process

- Need to Know (facts and regulations)
- Coordination of Lab Activities

Licensure/Certification/Enrollment

Enrollment Form

- Signature of authorized official on enrollment application made lab responsible for false or misleading information, even if lab did not *intend* to provide false information. *Premier Integrity Sols., Inc. v. CMS*, Dept. Appeals Board, CR 5018 (Feb. 1, 2018)
- All forms should be accurate and current

Licensure/Certification/Enrollment

Medicare Billing Privileges

Medical group's Medicare billing privileges revoked based on conviction of physician listed as managing employee and related failure to report, even though physician did not work for medical group at time of guilty plea, of which medical group was unaware.

Meadowmere Emergency Physicians, PLLC v. CMS, Dept. Appeals Board, CR 4971 (Nov. 20, 2017); 42 C.F.R. § 424.535

Licensure/Certification/Enrollment

Medicare Billing Privileges

Medicare payments may be suspended based on reliable information that overpayment exists (or when payments to be made may not be correct, or credible allegation of fraud). 42 C.F.R. § 405.371

False or Improper Claims

Medicare Billing Privileges

- 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)
- Includes claims for services that are not reasonable and necessary
- CMS declined to impose intent standard

Licensure/Certification/Enrollment

Medicare Billing Privileges

- Lab's Medicare enrollment and billing privileges revoked when on-site review indicated not yet "operational." *TC Foundation, Inc. v. CMS, Dept. Appeals Board*, CR 2834 (June 18, 2013)
- Similar theory applied against lab closed at time of inspection. *Cmty. Med. Lab., LLC v. CMS, Dept. Appeals Board*, CR 2635 (Oct. 2, 2012)
- *CMS may revoke CLIA certificate under similar circumstances*

Licensure/Certification/Enrollment

Protecting Access to Medicare Act of 2014 (PAMA)

Civil monetary penalties up to $10,017/day for each

- failure to report
- misrepresentation
- omission

CMPs based on facts and circumstances, not for minor errors

42 C.F.R. 414.504(b)

Licensure/Certification/Enrollment

CLIA Access Requirements

- Regulations permit *immediate* revocation or suspension of CLIA certificate for refusing reasonable request to inspect facility.
- Lab director's general failure to cooperate sufficient to suspend CLIA certificate.
- *The Malaria & Rheumatic Disease Research Inst., Inc. v. CMS,* Dept. Appeals Board, No. 2872 (May 28, 2018).

False or Improper Claims

- Test ordered
- Test performed
- Test billed (CPT or HCPCS code)
- Medical Necessity

False or Improper Claims

Lab Test Orders

CMS:

- Physician order does *not* require physician's signature
- Documentation reflecting physician's intent that test be performed *is* required
- Documentation of intent requires *signed* order, *signed* requisition, or authenticated (*signed*) medical record

Medicare Program Integrity Manual ("MPIM"), Ch. 6, § 6.9.1 (effective Dec. 17, 2018)

False or Improper Claims

Lab Test Orders

CMS:

- *Signed* documentation must specify tests to be performed
- Unsigned order or requisition listing specific tests plus *authenticated* medical record supporting intent to order lab tests sufficient

Id.

Payment Issue – Medical Necessity

Toxicology

CMS:

- Amounts improperly paid for drug screenings based on insufficient documentation of physician's intent to order test, unsigned medical records, and unnecessary tests
- Unnecessary tests include tests performed too frequently, based on standing orders unrelated to patient's needs, and unnecessary or excessive quantitative testing

Medicare Learning Network, Urine Drug Screening (September 2016)

False or Improper Claims

Test Billed

- CPT/HCPCS Code and Modifiers
- Improper use of modifiers can result in False Claims Act ("FCA") liability. *USA v. Wagoner,* 2018 WL 4539819 (N.D. Ind. 2018) (modifier 91)

False or Improper Claims

Tests Not Billed by Appropriate Entity

- Lab that performed test
- Referring lab for tests performed by reference lab
  - Part of rural hospital
  - Compliance with 70/30 rule
  - Common ownership

  Referring lab – Lab receives specimen and refers specimen to other lab for testing
- Arrangement made by hospital, CAH or SNF

Medicare Claims Processing Manual ("MCPM"), Ch. 16, §§ 10, 40.1

Medically Unnecessary Tests

Laboratory Liability

- Denial of Payment
- Administrative Liability
- False Claims Act ("FCA")
- Criminal Penalties

Payment Issue – Medical Necessity

Statutory Requirement

"[N]o payment . . . for . . . 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 . . . unless . . . furnished such information . . . necessary . . . to determine . . . amounts due . . . provider . . .." 42 U.S.C. § 1395l(e).

Payment Issue – Medical Necessity

CMS Regulations

- "All . . . laboratory tests . . . must be ordered by the physician . . . 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

Payment Issue – Medical Necessity

CMS Regulations

- Lab must maintain documentation (1) received from ordering physician and (2) that its payment claim accurately reflected such information. 42 C.F.R. § 410.32(d)(2).
- Information may not demonstrate medical necessity.
- Lab may *request* additional information from ordering physician. 42 C.F.R. § 410.32(d)(2)(iii).

Payment Issue – Medical Necessity Documentation

CMS Regulations

- If lab's documentation does not demonstrate medical necessity, Medicare contractor requests medical records from physician. 42 C.F.R. § 410.32(d)(3)(ii)
- Physicians who do not respond risk loss of Medicare billing privileges. 42 C.F.R §424.516(f); *see Dominquez v. CMS*, Dept. Appeals Board, CR 5035 (March 12, 2018)

Payment Issue – Medical Necessity Documentation

- Medicare contractor must verify that *authenticated* medical record supports medical necessity. MPIM, Ch. 6, § 6.9.1
- Clinical lab has burden of producing documentation of medical necessity to obtain payment. *See Meridan Lab. Corp. v. Advance Med. Corp.*, Dept. Appeals Board, Decision of Medicare Appeals Council, No. M-11-568 (June 24, 2011)

Payment Issue – Medical Necessity

- Limitation of liability – Medicare makes payment when provider "did not know, and could not reasonably have been expected to know" that test not medically necessary. 42 U.S.C. § 1395pp(a)(2)
- Without fault – Incorrect payment not recovered from individual who was "without fault", i.e., exercised reasonable care in billing and accepting payment. 42 U.S.C. § 1395gg(c)

Medical Necessity Documentation

Administrative Case Law

Documentation requirement generally trumps limitation of liability and without fault principles (currently). *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*

False or Improper Claims

Medical Necessity - Clean Hands Requirement

Lab's responsibility

- Not contribute to unnecessary testing
- Insure test "knowingly ordered"
- Educate physicians and other reasonable steps to avoid claims for unnecessary services

Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45076 (Aug. 24, 1998)

False or Improper Claims

Medical Necessity

Lab may rely on ordering physician's determination that tests are medically necessary for purposes of FCA *(only). USA ex rel. Groat v. Boston Heart Diagnostics Corp.*, 296 F. Supp.3d 155 (D. D.C. 2017)

But not if lab "had a specific basis to second-guess" physician or notice of substantial risk that certification was false. *U.S. ex rel. Allen v. Alere Home Monitoring, Inc.,* 334 F. Supp.3d 349 (D. Mass. 2018)

False or Improper Claims

Medical Necessity – Custom Profiles – Courts

Encouraging physicians to order medically unnecessary tests through false marketing and test panels on pre-printed requisitions could violate *lab's duty* to ensure it was not submitting false or incorrect claims

Groat v. Boston Heart Diagnostics, 296 F. Supp.3d 155 (D. D.C. 2017)

False or Improper Claims

Medical Necessity Issues – *Special Stains*

- DOJ: "[G]overnment considers use of special stains before the analysis of the routine H & E stained specimen to be medically unnecessary."
- Pathology group required to pay $600,000 for billing allegedly unnecessary special stains.

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

False or Improper Claims

Medical Necessity

Lab owner and spouse *criminally* liable for submitting medically unnecessary tests when they selected tests based on patient's insurance status.

U.S. v. Palin, 874 F.3d 418 (4th Cir. 2017)

False or Improper Claims

Medical Necessity

Toxicology lab owners *convicted* for filing claims for testing frozen urine samples 7-10 months after receipt

- Had reason to know that tests were no longer medically necessary
- Claims omitted date on which tests were ordered and samples collected
- Could no longer rely on physician's certification of medical necessity

U.S. v. Bertram, 900 F.3d 743 (6th Cir. 2018)

Federal Anti-Kickback Statute (AKS)

- Prohibited Conduct
  - Knowing & willful
    - Solicitation or receipt or
    - Offer or payment of
  - Remuneration
    - In return for referring a federal health care program ("FHCP") patient, or
    - To induce the purchasing, leasing, or arranging for or recommending, purchasing or leasing items or services paid by an FHCP

Federal Anti-Kickback Statute

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

- Payments intended to induce or reward referrals are unlawful, even if payments are FMV for services; payments exceeding FMV increase probability of unlawful payment
- Submission of claims resulting from AKS violation may violate FCA

79 Fed. Reg. 40115 (July 11, 2014)

Federal Anti-Kickback Statute

Enforcement – Labs *and Physicians*

Biodiagnostic Laboratory Services (NJ)

- Lab paid bribes to physicians and other providers
- Sham lease agreements, service agreements, and consulting agreements to induce physicians to refer tests and to order unnecessary tests
- More than 50 convictions – most of them physicians

Acceptance of free urine cups by physicians have been pursued by OIG

Federal Anti-Kickback Statute

Marketing Arrangements

- Marketing company potentially liable for participation in arrangement that violates AKS. *USA ex rel. Lutz v. Berkley Heart Lab., Inc.,* 225 F. Supp.3d 487 (D. S.C. 2016); *Berkley Heart Lab.*, 2017 WL 4803911 (D. S.C. Oct. 23, 2017)
- Provision of false information (Medicare testing recommendations) to induce unnecessary referrals can result in FCA liability. *U.S. v. Alere Home Monitoring*, 334 F. Supp.3d 349 (D. Mass. 2018)

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"
- Exceptions and exclusions

Stark Self-Referral Prohibition

Client Gifts & Entertainment

- Non-monetary compensation exception
  - Items or Services (not cash or cash equivalent)
  - Annual aggregate limit ($416 for CY 2019)
  - Not take into account volume or value of referrals or other business generated
  - Not solicited by physician
- Excess compensation not exceeding 50% of limit may be returned earlier of 180 days after payment received or end of CY

Commercial Payor Issues

- Tests Ordered, Reported & Billed
- Medical Necessity
- Waiver of Copayments/ Deductibles

Commercial Payor Issues

- Insurers suing labs to recover payments, alleging tests resulted from kickbacks or were not ordered, performed, or medically necessary
- Labs suing insurers for denial of claims
- Unknown number of arbitrations

Commercial Payor Principles

- Contract terms
- Payment rules incorporated into contract
- State law issues, including limits on recoupment period and general contract law principles

Pass-Through Arrangements

- Arrangements
  - Expand use of hospital's in-network status/favorable payment rates
  - Independent lab performs tests for which hospital submits claims
- Issues
  - Payment claims accurate and compliant with applicable contract terms and billing rules?
  - Marketing arrangements compliant with federal and state law?
  - Restrictions based on hospital's organization (N-F-P, governmental), CLIA, etc.

Pass-Through Arrangements

- Community hospital contracts with non-network labs to allow labs to submit claims using hospital's name and favorable rates
- *Allegations:* breach of contract vs. hospital; fraud, civil conspiracy, negligent misrepresentation, unjust enrichment vs. labs and affiliates

Court denies motions for summary judgment permitting case to proceed. *Blue Cross & Blue Shield of Miss. v. Sharkey-Issaquena Cmty. Hosp.,* 2017 WL 6375954 (S.D. Miss., Dec. 13, 2017)

The Eliminating Kickbacks in Recovery Act of 2018 (EKRA) (to be codified at 18 U.S.C. § 220)

- Part of Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act
- Expansion of Kickback Prohibition to Private Pay Business
- Effective October 24, 2018

EKRA Prohibition

- Solicits or receives remuneration or patronage for referring a patient to a recovery home, clinical treatment facility, or laboratory ("EKRA Provider")
- Pays or offers remuneration to induce a referral or in exchange for individual using services of EKRA Provider

EKRA Prohibition

- Prohibited remuneration includes “any kickback, bribe or rebate”
- Prohibited remuneration paid “directly or indirectly, overtly or covertly, in cash or in kind”
- Intent – knowing and willful conduct

EKRA Payers

Prohibitions apply to services covered by a “health care benefit program,” which is:

- “[A]ny *public* or *private plan* or contract . . . under which any medical benefit, item, or service is provided . . ..”
- “[I]ncludes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.”

EKRA Sanctions

Penalties – fine up to $200,000 and/ or imprisonment of up to 10 years, per occurrence

EKRA Relationship to AKS

- EKRA does not apply to conduct prohibited under AKS, which remains unlawful under AKS
- Conduct that is not prohibited under AKS may violate EKRA

EKRA Exceptions

Payments to Employees/Independent Contractors

Payment by employer to bona fide employee if payment not determined by or does not vary by –

- number of individuals referred to particular EKRA Provider;
- number of tests or procedures performed; or
- amount billed to or received from EKRA Payer from individuals referred to particular EKRA Provider.

Exception applies to independent contractors

EKRA Exceptions

Waiver or Discount of Coinsurance or Copayment

Waiver or discount (as defined in 42 C.F.R. 1001.952(h)(5)) of any coinsurance or copayment if –

- not routinely provided; and
- provided in good faith

Similar to exception from "remuneration" in patient inducement prohibition, 42 U.S.C. 1320a-7a(i)(6)(A)

EKRA Exceptions

Possible Future Exceptions

- Any other payment, remuneration, discount or reduction, determined by Attorney General, in consultation with Secretary, included in regulation
- Legislation creating new statutory exceptions or revising existing exceptions

QUESTIONS?