

Laboratory Compliance: Maintaining Compliance in an Uncertain and Changing Environment

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Compliance

Compliance Formula

Intent

+ Knowledge of Rules

+ Process

Compliance

Compliance

Intent

“If you’re going to talk the talk, you’ve got to walk the walk.”

Compliance

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

Process

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

Compliance

Beware of Newtonian Principles

- Inertia
- Every Action Results in Equal and Opposite Reaction

Compliance

Lab Related Self-Disclosures 2016-2017

- Employment of excluded individual
- Receipt of payments for “process, handing and collection” and consulting fees
- Improper services by lab-employed phlebotomist
- Excess rental payments
- Lack of physician order (hospital outpatient facility)
- Profit splitting arrangement for non-governmental business that induced referrals of government business
- Claims lacking indicia of medical necessity

Compliance

Danger Signals

- Substantial Government Expenditures re: Fraud and Abuse/Coordinated Efforts
- Blurring Between Mistakes/Overpayments v. False Claims
- *Reduction in Third-Party Payments (by labs and physicians) – Search for Offsetting Revenues*
- Review as Criminal Actions
- Personal Liability Claims
- Legal Actions by Private Payers
- Increased Attention to Medical Necessity by Government and Private Payers
- Increasing use of accreditation organizations to report wrongdoings

Licensure/Certification/Enrollment

Enrollment Form

Civil monetary penalty of up to \$50,000 for any false statement, omission or representation on any enrollment application. 42 C.F.R. §§ 1003.200(b)(7), .210(a)(6)

Licensure/Certification/Enrollment

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

Medical group's Medicare billing privileges revoked based on conviction of physician listed as managing employee on group's enrollment record, and related failure to report. 42 C.F.R. § 424.535. Physician no longer worked 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)

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, CCH ¶ 122,766 (June 18, 2013)*
- Similar theory applied against lab closed at time of inspection. *Cmty. Med. Lab., LLC v. CMS, Dept. Appeals Board, CR 2635, CCH ¶ 122,650 (Oct. 2, 2012)*

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

Licensure/Certification/Enrollment

Proficiency Testing (“PT”) Referrals

- Lab prohibited from intentionally referring PT samples to another lab for analysis. CMS: Referral is “intentional” if request another lab to test PT sample
- Prohibition applied broadly, to cover virtually any handling of PT samples or test results by another lab
- Includes lab in same hospital with separate CLIA certificate
- Applies to waived tests, at least those performed by waived labs

Licensure/Certification/Enrollment

PT Referrals

- CMS cannot revoke CLIA certificate of lab that provided PT samples to another lab, when it did not direct 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

Practices To Avoid PT Referrals

- Detailed Policies
- Employee Education
- Internal Audits
- Use of Different PT Organizations for Related Labs
- No shared computer access between labs with separate CLIA certificates

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 "passive behavior," including lack of cooperation and failure to attend scheduled visit, results in *immediate* suspension

Malaria & Rheumatic Disease Research Inst., Inc. v. CMS, Dep't. App. Bd., Civ. Rem. Div., Dec. No. CR4918 (Aug. 14, 2017). <https://www.hhs.gov/sites/default/files/alj-cr4918.pdf>

Licensure/Certification/Enrollment

Use of CLIA to sanction labs for billing violations, kickbacks, etc.

False or Improper Claims

- False Claims Act (FCA) prohibits
 - Filing, or causing to be filed, “false or fraudulent” claim, including claim resulting from kickback violation
 - Using false statement to “conceal, avoid or decrease” a government obligation
 - Failure to return overpayment

False or Improper Claims

DOJ Memo, Limiting Use of Agency Guidance Documents (Jan. 25, 2018)

- Guidance documents (such as CMS manuals) cannot create requirements that are not in statute or regulation
- DOJ may not use noncompliance with guidance document as basis for FCA claim
- Exceptions
 - Guidance documents that explain or paraphrase statute or regulation
 - Evidence that party read guidance document may help prove party’s knowledge of law

False or Improper Claims

- Other Federal and State statutes may prohibit false governmental and *non-governmental* payment claims
- Improper claims that are *not* unlawful may *not* be *paid*

False or Improper Claims

- First Generation – The Match Game
- Second Generation – Clean Hands Requirement
- Third Generation – Strict Liability

The Test Is Cumulative!

False or Improper Claims

First Generation – The Match Game

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

False or Improper Claims

Test Orders

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

False or Improper Claims

Test Orders

Laboratory not *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*, 2012 WL 6593804 (S.D. Ohio Dec. 18, 2012)

False or Improper Claims

Second Generation - Clean Hands Requirement (per OIG compliance guidance)

- Test *knowingly* ordered
- Individual who knowingly causes submission of false claim may be subject to sanctions

False or Improper Claims

Clean Hands Requirement

Lab's responsibility

- 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)

False or Improper Claims

Clean Hands Requirement

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

False or Improper Claims

Clean Hands Requirement - Custom Profiles - OIG

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

Annual notices do not guarantee payment of claim(s) by Medicare or commercial insurers

False or Improper Claims

Clean Hands Requirement – 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

USA ex rel. Groat v. Boston Heart Diagnostics Corp., 2017 WL 6327540 (D. D.C. 2017)

False or Improper Claims

Clean Hands Requirement – Custom Profiles - Courts

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

- Custom panels that included unnecessary tests
- “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)

Case later settled: \$2 million + Corporate Integrity Agreement

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False or Improper Claims

Clean Hands Requirement - Courts

Lab owner and spouse *criminally* liable for submitting medically unnecessary tests when they, not referring physicians, selected tests to be performed based on patient’s insurance status.

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

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False or Improper Claims

Third Generation – Strict Liability

Lab may rely on ordering physician's determination that tests are medically necessary for purposes of False Claims Act (*only*)

USA ex rel. Groat v. Boston Heart Diagnostics Corp., 2017 WL 6327540 (D. D.C. 2017)

False or Improper Claims

Third Generation – Strict Liability

Lab's responsibility to demonstrate tests were *actually* medically necessary for *payment purposes*

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

Statutory Requirement

“[N]o payment . . . 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 . . . 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

Administrative Case Law

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

Medical Necessity Documentation

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)(3).
- *Regulations do not require physician's cooperation!*

Medical Necessity Documentation

CMS Regulations

- “All . . . 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 - Intent

“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

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 reasonably 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 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 and accepting payment for test

Medical Necessity Documentation

Administrative Case Law

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

Proactive Steps

- Educate physicians regarding medical necessity criteria, supporting documentation and ABNs
- Securing physician's cooperation – physician's agreement to provide documentation
 - Existing contract, such as for client-billing
 - Acknowledgement of annual notices
 - Laboratory requisition

Medical Necessity

Special Stains

Pathologists may order medically necessary special stains, but 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>

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 FCA liability for CLIA violations (pre-*Escobar*) (result may be different for lack of CLIA certificate)
- *U.S. v. Palin*, 874 F. 3d 418 (4th Cir. 2017). Lack of medical necessity considered material
- Stark/FAS Violations

Return of Overpayments

General Principles

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

42 C.F.R. § 401.305

Return of Overpayments

Based on Medical Necessity

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

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

Self-Audits Can Result in FCA Liability

- FCA potentially violated when medical group failed to follow up on self-audit identifying incorrect payment claims
- Potential liability for refusal to investigate possibility of overpayments received during audit period *and* for subsequent claims

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

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 pays \$448,882 to settle allegations
 - Learned about overpayments no later than June 2016; former executive director filed whistleblower complaint in August 2016
 - Alleged that Group delayed repayment of \$175,000, despite repeated warnings, until notified of government investigation

Return of Overpayments

Enforcement

- Government may recover mistaken payments from person who participated and benefited from arrangement in addition to payment recipient
- Lab's owner-president personally liable for overpayment based on signature on payment claims and control of lab payments

U.S. ex rel. Drummond v. BestCare Lab. Servs., 2017 U.S. Dist. LEXIS 212729 (S.D. Tex. Dec. 28, 2017). https://www.gpo.gov/fdsys/pkg/USCOURTS-txsd-4_08-cv-02441/pdf/USCOURTS-txsd-4_08-cv-02441-3.pdf

Commercial Payer Issues

- Contract terms
- Payment rules incorporated in contract (if any) frequently unclear
- State law issues, including limits on recoupment period
- Arrangements for commercial business can violate FAS

Commercial Payor Issues

Waiver of Copayments/Deductibles

- Specifically prohibited in certain states
- “No legal obligation to pay clause” can be used against full waivers
- Fraud claims
- Possible violation of FAS. *USA ex rel. Lutz v. Berkley Heart Lab., Inc.*, 225 F. Supp.3d 487 (D. S.C. 2017)

Commercial Payor Issues

- Hospital/Independent Laboratory 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 billing rules?
 - Marketing arrangements compliant with FAS and state law?
 - Restrictions based on hospital’s organization (N-F-P, governmental), CLIA, etc.

Commercial Payor Issues

Court Action

- 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 637594 (S.D. Miss., Dec. 13, 2017)

Commercial Payor Issues

Pre-Authorization Requirement

- Commercial insurers requiring for expensive lab tests
- 2012 HHS Office of Inspector General ("OIG") advisory opinion regarding radiology services
 - OIG distinguishes between *physicians* with express financial obligation to seek approval vs. no such express requirement
 - OIG would not impose sanctions under FAS

OIG Advisory Opinion No. 12-10 (Aug. 23, 2012),
<https://oig.hhs.gov/fraud/docs/advisoryopinions/2012/AdvOpn12-10.pdf>

Commercial Payor Issues

Pre-Authorization Requirement

- Available to all referring physicians/patients without regard to volume/value of referrals from physician
- Radiologists unlikely to know physician’s responsibility for pre-authorization
- Arrangement operates transparently
- Radiologists had little opportunity to influence referrals
- Radiologists had “legitimate business interest in offering uniform pre-authorization services”
- No guarantee that insurer will accept lab’s pre-authorization requests
- Stark compliance uncertain

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)

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

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

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 lab
 - No services for physician's practice or in-office lab
- May labs pay rent to physician practices for space used by IOP?
- State law issues

Federal Anti-Kickback Statute

Marketing Arrangements

- Statutory exception for payments related to *bona fide* employment relationship. See *U.S. ex rel. Carrel v. AIDS Healthcare Found.*, 262 F. Supp. 3d 1353 (S.D. Fla. 2017) (appeal pending)
- Independent contractor arrangements may violate FAS. *Joint Tech., Inc. v. Weaver* (CCH) ¶ 304,295 (W.D. Okla. Jan. 23, 2013)

Federal Anti-Kickback Statute

Marketing Arrangements

- Laboratory marketing company potentially liable for participation in arrangement that violates FAS. *USA ex rel. Lutz v. Berkley Heart Lab., Inc.*, 225 F. Supp.3d 487 (D. S.C. 2017)
- *Management* arrangements may include unlawful marketing services

Federal Anti-Kickback Statute

Marketing Arrangements-Recent Settlement

- Allegations:
 - Primex, clinical lab; DNA Stat, laboratory management company that “employed sales representatives” (per DOJ press release)
 - Provision of in-office medical techs related to lab – sponsored study
 - Lab’s agreement with Management Co. and Management Co.’s agreements with sales reps took into account volume/value of referrals
 - Lab submitted claims for medically unnecessary tests
- Settlement: Lab pays \$3.5 million, Management Co. owner pays \$270,000

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

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

Remuneration Exclusion

- Items, devices or supplies used solely to
 - Collect, transport, process, or store specimens
 - Order testing or communicate test results

Stark Self-Referral Prohibition

Excluded Services - 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 provided only when results communicated through portal; limited to issues related to specific results
 - Recommendations based on peer-reviewed guidelines available 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

Stark Self-Referral Prohibition

Client Entertainment

- Non-monetary compensation exception
 - Items or Services
 - Annual aggregate limit (\$407 for CY 2018)
 - Not take into account volume or value of referrals or other business generated
 - Not solicited by physician

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 “Clarification”
 - Discounts below fully loaded costs not automatically unlawful
 - Must be “linkage” between 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
 - Many states require providers to bill at “usual and customary” rates
 - “Usual and customary” may be defined as lab’s lowest charge

Pricing Issues for Laboratories

Recommended Policies

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

QUESTIONS?

