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Compliance Issues Affecting Laboratories

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Compliance Is A Many-Headed Beast

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

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Selected Licensure/Certification Issues

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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

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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)
- Final rule, 79 Fed. Reg. 27106 (May 12, 2014). PT sample referred for reflex, distributive or confirmatory testing under procedures for patient specimens considered improper, but not intentional referral, so long as not "repeat" PT referral. 42 C.F.R. § 493.801.

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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

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TEST Act Implementation (79 Fed. Reg. 25436)

- Sanctions for intentional referrals 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 (suspension or limitation depends on whether other lab's results received before PT close date)

42 C.F.R. § 493.1840.

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Medicare Enrollment

- Lab's Medicare enrollment and billing privileges revoked when on-site review indicated 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 closed at time of inspection. *Community Medical Lab., LLC v. CMS*, Dept. Appeals Board, CR 2635 (Oct. 2, 2012)

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Medicare Enrollment

Nexus Lab, Inc. v. CMS, DAB, CR 3382 (Sept. 23, 2014).

- Laboratory required to comply with regulatory requirements applicable to clinical labs. 42 C.F.R. § 424.516(a)(2) (compliance with federal and state licensure, certification and regulatory requirements).
- Medicare enrollment and billing privileges revoked when lab's billing agency submitted claims without NPI of ordering physician.

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Medicare Enrollment

Enrollment and billing privileges may be revoked based on "pattern or practice of submitting claims that fail to meet Medicare requirements." 79 Fed. Reg. 72500 (Dec. 5, 2014); 42 C.F.R. § 424.535 (effective Feb. 3, 2015).

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Seven horizontal lines for notes.

Claims For Payment

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Seven horizontal lines for notes.

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

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Seven horizontal lines for notes.

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
 - All *Qui Tam* complaints reviewed by DOJ for possible criminal investigation
- State FCAs

13
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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.*, 745 F.3d 694 (4th Cir. 2014) (no FCA claim for violation of FDA regulations related to good manufacturing practice)
 - *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

14
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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
- Overpayments
- Others

15
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The Match Game – Billing Issues

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

16
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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)

17
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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*, 2012 WL 6593804 (S.D. Ohio, 2012)

18
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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

19
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The Match Game – Billing Issues

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

20
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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)

21
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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

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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)
- 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)

23
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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. Sebellius*, 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)

24
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Risks from Unnecessary Tests

- Overpayment can result in suspension of Medicare payments (42 C.F.R. § 405.371)
- Medicare enrollment application may be denied if (1) current owner of applying provider or supplier; or (2) applying physician or non-physician practitioner, has existing overpayment of \$1500 (42 C.F.R. § 424.530(a)(6), MPIM, Ch. 15, § 15.13)
- Enrollment and billing privileges may be revoked based on "pattern or practice of submitting claims that fail to meet Medicare requirements."

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Accountable Care Act – Return of Overpayments

- 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

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Accountable Care Act – Proposed Regulations – 77 Fed. Reg. 9179 (Feb. 16, 2012)

- Person who identifies receipt of overpayment must report and return overpayment.
- Person has identified overpayment if has actual knowledge of overpayment or acts in reckless disregard or deliberate ignorance of its existence.
- Person must report and return identified overpayment by later of (1) 60 days after overpayment identified or (2) due day of related cost report.
- Overpayment must be reported and returned if identified within 10 years of receipt.

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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)

28
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Retaining Overpayments: Litigation

- *United States ex rel. Kane v. Continuum Health Partners, Inc., et al.*, Civ. Action No. 11-2325 (S.D.N.Y. 2014)
- DOJ intervened in False Claims Act case against Healthfirst MCO, its affiliate entities, and large number of NY & NJ Hospitals.
- Allegations that providers failed to report and return Medicaid overpayments related to secondary payor issues within 60 days
- Defendant repaid overpayments, but only after several years delay and receipt of Civil Investigative Demand.

29
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What Gets Disclosed Where?

- To OIG – only "potential fraud against the Federal health care programs, rather than merely an overpayment."
- "Potential fraud" does not include Stark only violations – must be at least a "colorable" AKS violation
- To CMS – Stark only violation
- To Contractor – "merely an overpayment"
- To U.S. Attorney's Office – depends
- To State – depends

30
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Claims for Payment for Hospital Tests

Civil monetary penalties may be assessed for knowingly and willingly presenting or causing to be presented claim that violates hospital "bundling" rule applicable to inpatients or outpatients. 42 C.F.R. § 1003.102 (b)(15).

31
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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)

32
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Advanced Beneficiary Notices

- ABN stating that "Medicare has not established coverage criteria . . . or does not cover this item" legally inadequate.
- CMS requires ABN to specify "a genuine reason that denial by Medicare is expected." MCPM, Ch. 30 § 40.3.6-6.1.

Int'l Rehab. Sci. v. Burwell, No. 08-cv-05442 (W.D. Wash. Feb. 13, 2015).

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Relationships With Referral Sources

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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

35
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ACA - Section 6402 (f) (2)

- Intent: "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."
- Violations of Federal Anti-Kickback Statute: "Claim that includes items or services resulting from a violation" of the FAS "constitutes a false or fraudulent claim for purposes of FCA."

36
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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*, Case No. 8:11-cv-1757-T35-TBM (M.D. Fla., Aug 16, 2013).

37
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Ameritox v. Millennium Labs, Inc.

- Court: Millennium’s provision of free point of care testing (POCT) cups constitutes remuneration under FAS and Stark Law when doctors could not bill for related testing for reasons other than agreement with Millennium. 20 F.3d 1348 (M.D. Fla. 2014).
- Jury: Millennium’s provision of POCT cups violated Stark Law and FAS – resulting in unfair competition and tortious interference – notwithstanding agreement not to bill for related testing.

38
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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

39
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Payments for Specimen Collection

- Investigation of Health Diagnostics Laboratory (“HDL”) related to practice of paying physicians to process blood specimens collected in their office; P + H - \$17, \$3 venipuncture, which according to HDL, reflected FMV.

WSJ – Sept. 8, 2014

40
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Special Fraud Alert: Laboratory Payments to Referring Physicians (June 25, 2014)

General Statements:

- Lawfulness of arrangement depends on parties’ intent, evidenced by arrangement’s legal structure, operational safeguards, actual conduct, etc.
- FAS implicated when laboratory pays physician for services; FMV payment may be unlawful
- Probability that payment is for illegitimate purpose increased when payment exceeds FMV
- Questionable arrangements that “carve out” federal health care program business may violate FAS

41
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Special Fraud Alert: Laboratory Payments to Referring Physicians (June 25, 2014) – Payment for Collecting, Processing and Packaging Specimens

Characteristics that may evidence unlawful purpose:

- Payment exceeds FMV of services rendered
- Payment is for services for which payment also made by third-party, such as Medicare
- Payment made to ordering physician rather than group practice
- Payment basis takes into account volume/value of referrals
- Payment offered on condition that physician order specified volume or type of tests
- Payment for services provided by employee of lab or third-party

42
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Payments for Specimen Collection

- HDL reported to have reached tentative settlement with DOJ involving payment of \$47 million.

WSJ – March 23, 2015

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Electronic Data Transmission Fees (OIG Advisory Opinion No. 14-03)

- EHR software provider charges physician transmission fee of up to \$1 per order when lab selected was not "in-network;" transmission fee paid by in-network lab for each order received
- OIG: Arrangement implicates FAS because physicians are relieved of financial obligation when they refer to in-network lab
- OIG: Arrangement poses more than minimal risk, so OIG could potentially impose sanctions

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Provisions of Free Testing (OIG Advisory Opinion No. 15-04)

- Arrangement: Lab performs tests for physicians' patients covered under a plan that required all tests to be referred to designated lab without charge.
- OIG declined to issue favorable opinion because of facts that "in combination, would amount to remuneration" to physicians practice:
 1. Free testing would permit physicians to work with single laboratory using single lab interface, resulting in increased "convenience" and "efficiency."
 2. Physicians may be relieved of monthly maintenance fees for interfaces to other laboratories that could be eliminated.

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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 FAS and may be legally unenforceable. *Joint Technology, Inc. v. Weaver*, (CCH) ¶ 304,295 (W.D. Okla. Jan. 23, 2013)

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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

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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 violation to violate FCA. *Daugherty v. Bostwick Labs*, No. 1:08-CV-00354 (S.D. Ohio Dec. 18, 2012)

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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

49
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Client Entertainment

- Stark non-monetary compensation exception
 - Items or Services
 - Annual aggregate limit (\$392 for CY 2015)
 - Not take into account volume or value of referrals or other business generated
 - Not solicited by physician

50
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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

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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

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Pricing Issues for Laboratories

53
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Discounts – Stark Law

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

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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

55
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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>

56
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Discounts

- Compliance Guidance for Clinical Laboratories uses "fair market value" concept. 63 Fed. Reg. 45,076 (Aug.24,1998)
- Advisory Opinion 11-11 reiterates "below cost" theory of "swapping"

57
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Discounts – Recent Decision

Discounted charges below “fully loaded cost” may not violate FAS.

- Court rejects Relator’s reliance on OIG advisory opinion.
- OIG opinions not binding or entitled to deference.
- OIG found charges below “fully loaded cost” only “suspect”

U.S. ex. rel. McDonough v. Symphony Diagnostic Servs., Inc., 36 F. Supp.3d 773 (S.D. Ohio 2014).

58
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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

59
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“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. See Letter of Kevin G. McAnaney, OIG Industry Guidance Branch (April 26,2000) <http://oig.hhs.gov/fraud/docs/safeharborregulations/lab.htm>

60
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“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)

61
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“Substantially in Excess” – OIG Advisory Opinion No. 15-04 (March 25, 2015)

“Plausible” that provision of free laboratory tests to individuals for whom laboratory could not receive payment could result in violation based on representation that 10% - 40% of patients might receive free testing.

62
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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

63
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QUESTIONS?



64
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