# Tools to be a Successful Laboratory Compliance Officer

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## Agenda

I. Lab Scam Overview
- Tale as Old as Time
- Consequences and Resources

II. Just what the doctor ordered…or is it?
- EMR challenges
- In Office Phlebotomists/Processor challenges

III. Risk at Each Step of the Lab Process
- Risk Based Audit Protocols

IV. Toxicology Risks
- Authorized Provider
- Testing Method
- Medical Necessity

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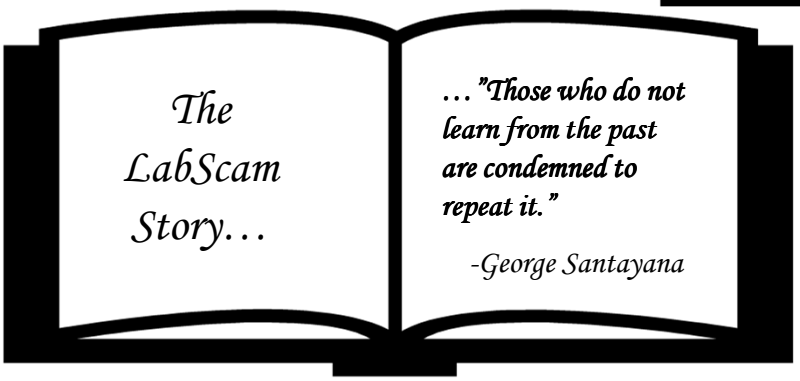
# Tale as Old As Time…




**…The first systematic nation-wide law enforcement project in the medical field. -**Grob, George (2,000, Jan). Medicare Payments for Clinical Laboratory Services, Vulnerabilities and Controls. www.oig.hhs.gov

## The Labscam Story

National Health Laboratories (NHL)-the government alleged the laboratory had induced physicians into ordering tests that were not medically necessary.

- Alleged that NHL added HDL and serum ferritin to its standard chemistry profile. These tests were then billed separately to the Medicare Program in addition to the charge for the standard chemistry.
- The government alleged that it was significant that the price charged to physicians for their non-Medicare patients only increased nominally. (Client Billing)
- NHL paid $111 million, and pled guilty to criminal violations.

The government then sued other clinical laboratories alleging violations of the Federal False Claims Act and collected over $800million dollars.

# Labscam-Two Alleged Themes

**Requisition**

- The "Tool of the crime". Panels were offered that didn't disclose the individual components, though billed individually, or give the option to order individual tests.
- Unbundling-running specimens through a single piece of automated multi-channel equipment, then billing separately for each component.
- Incomplete or missing orders from providers.

**Free Services**

- Or discounted to be less than fair market value (FMV)
- Professional courtesy testing
- Client Pricing like value meals for profiles
- Free equipment, supplies, services
- Gifts





# "Labscam" Changed the Landscape

- The government brought suit against hospitals that provided clinical laboratory testing: Operation Bad Bundle
  - alleged hospitals were overpaid because they had billed separately for certain tests that were ordered as "panels".
  - DRG Window-Tests for beneficiary within 3 days of admission are considered "in patient" covered by the hospital's DRG payment, not the clinical lab fee schedule (Medicare Part B)

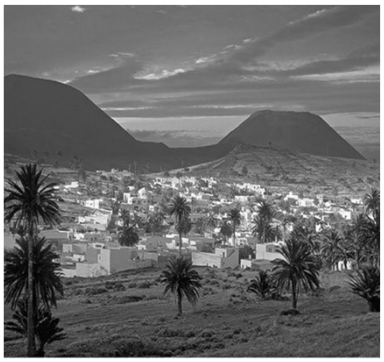
## "Labscam" Changed the Landscape

**1st Model Compliance Plan by the OIG**

August 1998, 63 *Fed. Reg*. 45079

Includes guidance on variety of topics:

- Medical Necessity
- Billing
- Use of Standing Orders
- Custom Profiles
- Disclosure
- Pricing to Physicians
- Billing & ABN's
- An Annual Notice to Providers





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## Just What the Doctor Ordered…

- Medicare requires that the test be ordered by the physician or other authorized person who is involved in treating the patient. 42 C.F.R. § 410.32. CMS
- Non-physician practitioners (such as clinical nurse specialists, clinical psychologist, clinical social workers, nurse midwives, nurse practitioners, and physician assistants) who provide services that would be covered as physician services, if furnished by a physician, may be considered physicians under the treating physician rule. They must be acting within their authority under state law and within the scope of their Medicare statutory benefit. 42 C.F.R. § 410.32(c).



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## Just What the Doctor Ordered…

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) *Ordering diagnostic tests.* All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or 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 the physician who is treating the beneficiary are not reasonable and necessary (see § 411.15(k)(1)

Section 2. (ii) Submitting the claim- The entity submitting the claim must maintain the following documentation:

- A. The documentation that it receives from the ordering physician or nonphysician practitioner.
- B. The documentation that the information that it submitted with the claim accurately reflects the information it received from the ordering physician or non-physician practitioner.



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## Just What the Doctor Ordered?

Scenario:

Susie is a lab Phlebotomist at Dr. Pepper's office. She received a script written order for "testosterone". Your lab offers five different tests that contain the word "testosterone".

- Testosterone, Free Bioavailable, LC/MS/MS ($54.15)
- Testosterone, Total Immunoassay ($35.17)
- Testosterone, Free (Dialysis) and Total LC/MS/MS ($69.86)
- Testosterone, Total and Free and Sex Hormone Binding Globulin ($99.47)
- Testosterone, Free, LC/MS/MS ($34.69)




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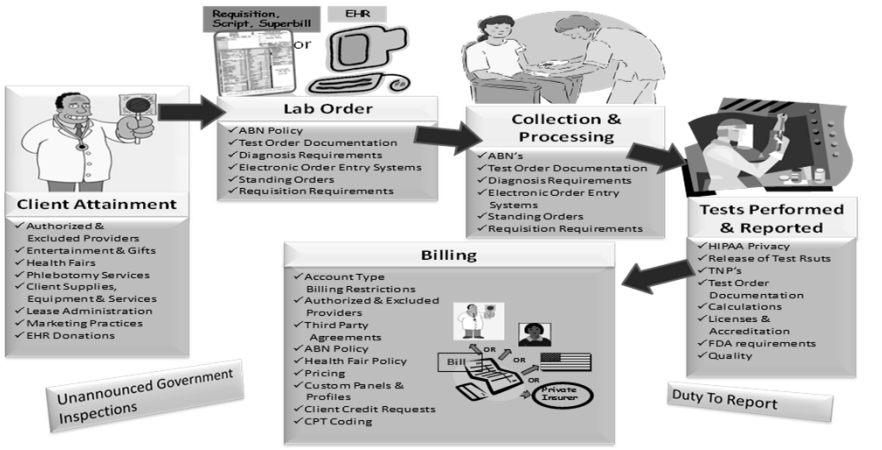
# Risk areas in each step-Audit Protocols



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# Client Attainment


| Risk | Reference | Mitigation |
|---|---|---|
| Marketing Practices | Millennium CIA, OIG Guidance for Clinical Labs | Ensure marketing materials & messaging are aligned with company clinical guidance. Document approval process, audit. Ensure clinical leaders are making clinical decisions. Compliance & CMO partnership. |
| Authorized & Excluded Providers | Medicare allows states to determine authorized providers. 42 C.F.R. § 410.32. CMS | Ensure a process to review non-MD provider types prior to set-up and verify OIG Exclusion Lists. Example: Optometrist, Psychologist, Nurse Practitioner, Mid-wife, etc. Audit |
| Entertainment & Gifts | Stark Law, Special Advisory Bulletin Aug. 2002 | Prohibit non-reimbursed expenditures, Stark Tracking, an Exception process, train on beneficiary hardship scenarios. |
| Focused Arrangements | Fraud Alert June 2015 | Ensure process for Focused Arrangements contracts, FMV calculation process/documentation, services provided, etc. |
| Client Supplies | Can create compensation arrangements: Laboratories should only provide supplies directly related to the collection and processing of lab specimens. | Review the items being supplied. Single use needles, vials, specimen cups are permitted. Reusable items such as biopsy needles, snares, injection needles are not. Dual-use supplies such as gloves and band aids are not permitted as they may be used by the physician's office. The rule states that labs or the physician should be able to demonstrate that the number of permitted items and supplies were appropriate for the level of referrals expected. |



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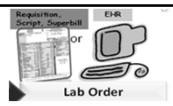


# Lab Test Order

| Risk | Rationale | Mitigation |
|---|---|---|
| Are all tests received or confirmed (within 30 days) in writing from an authorized provider? | Performing tests without a specific test order may violate CLIA and state law. Billing for tests that were not ordered may violate the False Claims Act. Failure to obtain or maintain documentation of test orders could violate CLIA and state law. | Train Phlebotomists & Lab<br>Audit, Audit, Audit |
| Do the same controls apply to your electronic ordering system? | Same as above. Refer to Labscam lawsuits "requisition was the tool of the crime" because of how tests were marketed. | Audit to ensure proper controls of profiles, proper disclosures, and translations. |
| Custom Profiles | | |

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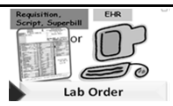


# Lab Test Order

| Risk | Rationale | Mitigation |
|---|---|---|
| Attaining original order if Lab Phlebotomist enters into electronic ordering system. | Only an authorized person may choose laboratory tests. | Determine if the client or Lab Phleb is entering orders, audit for original provider orders to ensure they match. |
| Requisition Design<br>-constructed for providers to make individual decision<br>-Review the test options to ensure proper menu that doesn't steer providers to higher reimbursable tests. | OIG Guidance for Clinical Labs | Review the requisition and marketing material. Collaborate with Coders and CMO. |
| Ambiguous Orders | *Labs should not bill for testing until the tests the provider intended are clarified Id*. At 45080-81 | Phlebotomist & Lab Training, Audit! |

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# Laboratory Audit Protocols

| Audit Protocol | Rationale | Elements Monitored |
|---|---|---|
| Accounts Payable Ledger | Ensure compliant relationships with current, potential referral sources, & that proper agreements are in place. | FMV for Medical Director (consultants), Charitable Contributions, Specimen Collection Services, Test Send Outs, Payments to any provider |
| Anatomic Pathology | | Direct Billing State Laws, CPT Coding, Technical & Professional Component Review |
| Facility Information | Ensure proper permits, licenses and accreditation. | Accurate performing site disclosure, CLIA #, Medicare/Medicaid Provider #, Medical Director (FMV if contracted. |



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| Audit Protocol | Rationale | Elements Monitored |
|---|---|---|
| Co-pays & Deductibles | Could implicate the Anti-Kickback statute Federal Register Dec. 19, 1994 | Review Sales and Billing process. Audit. Implement financial hardship exception. |




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# Toxicology





## Toxicology Laboratory Issues

- Testing Method
  - Presumptive vs. Definitive
  - Cutoffs
- Medical Necessity
  - Audits
    - Average Tests Per Requisition
    - Average # of times panels ordered on same patient in 12 months

## Presumptive vs. Definitive Methodology

Palmetto Local Coverage Determination (LCD) L35724, " Controlled Substance Monitoring and Drugs of Abuse Testing"

*Limitations of Presumptive UDT:*

*Primarily screens for drug classes rather than specific drugs, and therefore, the practitioner may not be able to determine if a different drug within the same class is causing the positive result; Presumptive IA is limited due to:*

- *Produces erroneous results due to cross-reactivity with other compounds or does not detect all drugs within a drug class.*
- *Given that not all prescription medications or synthetic/analog drugs are detectable and/or have assays available, it is unclear as to whether other drugs are present when some tests are reported as positive.*
- *While presumptive tests vary in their ability to detect illicit drugs such as tetrahydrocannabinol (THC), cocaine, 3,4 methylenodioxy—methylamphetamine (MDMA-ecstasy) and phenycyclidine (PCP), they may not be optimal tests for many prescription drugs, namely opiates, barbiturates, benzodiazepines and opioids.*





## Presumptive vs. Definitive methodology

Palmetto Local Coverage Determination (LCD) L35724, " Controlled Substance Monitoring and Drugs of Abuse Testing"

- *Definitive UDT is reasonable and necessary for the following circumstances: Identify a specific substance or metabolite that is inadequately detected by a presumptive UDT.*
- *Identify a specific substance or metabolite that is not detected by presumptive UDT such as fentanyl, meperidine, synthetic cannabinoids and other synthetic/analog drugs;*
- *Identify non-prescribed medication or illicit use for ongoing safe prescribing of controlled substances and*
- *Use in a differential assessment of medication efficacy, side effects, or drug-drug interactions.*

## Conflicting Policies

Anthem Clinical UM Guideline: Drug Testing or Screening in the Context of Substance Use Disorder and Chronic Pain.2/4/16

Definitive urine drug testing is considered medically necessary when all of the following criteria are met:

- The presumptive urine drug testing was done for a medically necessary reason; and
- The presumptive test was negative for prescribed medications, positive for a prescription drug with abuse potential which was not prescribed, or positive for an illegal drug and
- The specific definitive test(s)ordered are supported by documentation specifying the rationale for each quantitative test ordered and
- Clinical documentation reflects how the results of the test(s) will be used to guide clinical care.



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## Medical Necessity

- Medicare coverage is limited to items and services that are “reasonable and necessary for the diagnosis or treatment of illness or injury.” 42 USC 1395y(a)(1)(A)
- Medicare requires health care practitioners and providers to assure that health services ordered for government patients are “provided economically and only when, and to the extent, medically necessary.” 42 USC 1320c-5(a)(1)



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## Toxicology Risk Reduction

- ✓ Educate providers on the proper use of tests.
  - Medical Necessity, Frequency, Chart Documentation
- ✓ Partner with Chief Medical Officer to conduct audits.
  - Average tests per requisition
  - Specific patient groups vs. drug risks
  - Review profile utilization
- ✓ Annual Disclosure Letter
- ✓ Specimen Processor & Lab Test Order Audits



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The best prize that life offers is the chance to work hard at work worth doing.

-Theodore Roosevelt



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