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## Recent and Emerging Issues Related to Clinical Laboratory Testing and How to Prevent Them

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## Agenda

- Billing and certifications
- Risk Assessment Process
- Laboratory Risks
- Compliance Effectiveness

## Billing Medicare

### Medicare Enrollment Form 855b

“I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier’s compliance with all applicable conditions of participation in Medicare.”

## Billing Medicare

### Medicare Enrollment Form 855b:

“I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.”

## Billing Medicare

### CMS Form 1500

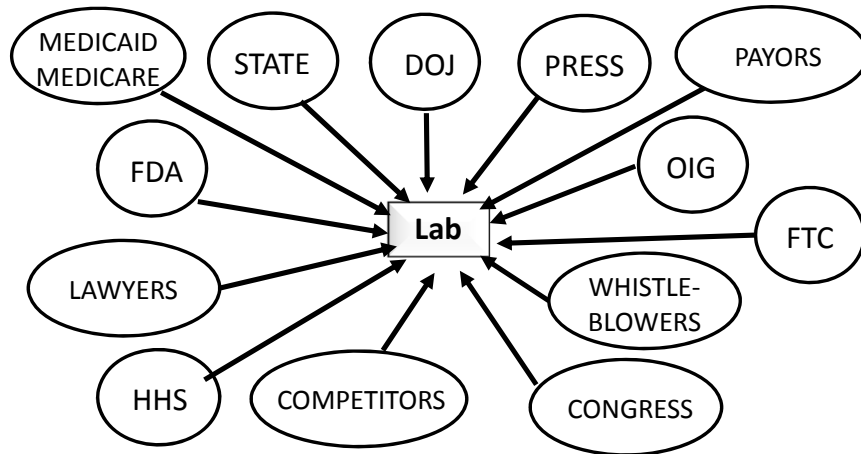
“In submitting this claim for payment from federal funds, I certify that :  
1)the information on this form is true, accurate and complete; 2)I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3)I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid services on this form where medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or Tricare;”

## Billing Medicare

### CMS Form 1500

“Notice: Any one who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.”

## Are you monitoring each?



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## Compliance Program Tools

### Lab Specific:

- ✓ OIG Model Compliance Plan for Clinical Labs
- ✓ Medicare Claims Processing Manual Chapter 16
- ✓ OIG Guidance Documents
- ✓ Local Coverage Determinations
- ✓ OIG Fraud Alerts
- ✓ Corporate Integrity Agreements

### General Compliance

- Corporate Governance Documents
- OIG Resource Guide
- U.S. Sentencing Guidelines Chapter 8



## Seven Elements of the OIG Model Compliance Program



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## Risk Assessment Expectations

### U.S. Federal Sentencing Guidelines

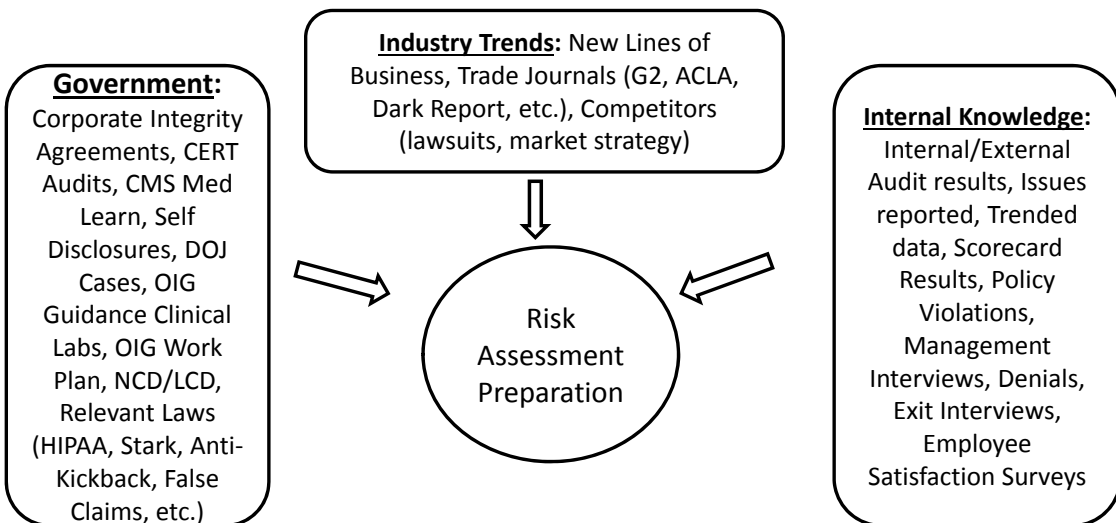
#### 8B2.1 Effective Compliance and Ethics Program

- a)...Such compliance and ethics program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct.
- (c)...the organization shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each requirement set forth in subsection (b) to reduce the risk of criminal conduct identified through this process.

## Two Types:

1. **Structural Risk Assessment-** Assess the effectiveness of the framework necessary to build and operate an effective compliance program including the OIG's Seven Elements of an Effective Compliance Program and U.S. Sentencing Guidelines.
2. **Substantive Risk Assessment-** relates to the specific body of substantive risks/laws and how they may be implicated. (Medicare, Medicaid, Anti-kickback, Stark, Privacy, etc.)

## Substantive Risk Assessment Preparation



## Potential State Expectations

- States may also have risk assessment requirements for providers.
- NY OMIG includes risk assessment activities in its Best Practices Compliance Program guidance
  - “Establish a list of the risk areas as part of the compliance program. This will focus efforts on the areas where weaknesses in the compliance program are most likely to exist and it will assist in the application of resources.”

[https://omig.ny.gov/images/stories/compliance/compliance\\_program\\_review\\_guidance.pdf](https://omig.ny.gov/images/stories/compliance/compliance_program_review_guidance.pdf)



## Risk Assessment Process Example

- I. Determine the Team
- II. Identify Potential Risks
- III. Assess and Prioritize Potential Risks
- IV. Manage and Monitor
  - I. Create Work Plan
  - II. Implement Policies
  - III. Proactively Train
  - IV. Audit
  - V. Trend
  - VI. Repeat



## 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 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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## Laboratory Risk Areas

Client Attainment	Lab Order	Collecting & Processing	Tests Performed & Reported	Billing
<ul style="list-style-type: none"> <li>• Authorized &amp; Excluded Providers</li> <li>• Entertainment &amp; Gifts</li> <li>• Health Fairs</li> <li>• Phlebotomy Services</li> <li>• Client Supplies, Equipment &amp; Services</li> <li>• Lease Administration</li> <li>• Marketing Practices</li> <li>• EHR Donations</li> </ul>	<ul style="list-style-type: none"> <li>• ABN Policy</li> <li>• Test Order Documentation</li> <li>• Diagnosis Requirements</li> <li>• Electronic Order Entry Systems</li> <li>• Standing Orders</li> <li>• Requisition Requirements</li> </ul>	<ul style="list-style-type: none"> <li>• ABN's</li> <li>• Test Order Documentation</li> <li>• Diagnosis Requirements</li> <li>• Electronic Order Entry Systems</li> <li>• Standing Orders</li> <li>• Requisition Requirements</li> </ul>	<ul style="list-style-type: none"> <li>• HIPAA Privacy</li> <li>• Release of Test Results</li> <li>• TNP's</li> <li>• Test Order Documentation</li> <li>• Calculations</li> <li>• Licenses &amp; Accreditation</li> <li>• FDA Requirements</li> <li>• Quality</li> </ul>	<ul style="list-style-type: none"> <li>• Account Type</li> <li>• Billing Restrictions</li> <li>• Authorized &amp; Excluded Providers</li> <li>• Third Party Agreements</li> <li>• ABN Policy</li> <li>• Health Fair Policy</li> <li>• Pricing</li> <li>• Custom Panels &amp; Profiles</li> <li>• Client Credit Requests</li> <li>• CPT Coding</li> </ul>

## Lab Compliance Risks

Risk	Mitigation
<p><b>Authorized Providers-</b> Billing for tests ordered by someone not authorized to order clinical lab tests could lead to false claims.</p> <ul style="list-style-type: none"> <li>• Not everyone with an NPI may order tests-(though Sales may try!)</li> <li>• Non-physician practitioners (such as mid-wives, Nurse Practitioners, Physician Assistants, Social Workers, etc.) must be acting within their authority under state law.</li> </ul>	<ul style="list-style-type: none"> <li>✓ Look up provider NPI upon client set-up</li> <li>✓ Audit NPI's out of LIS</li> <li>✓ Train Sales and support staff about those authorized in your states to order clinical lab testing</li> </ul>

## Lab Compliance Risks

Risk	Mitigation
<p><b>Performing and billing for tests <u>not ordered</u> could implicate the False Claims Act.</b></p> <ul style="list-style-type: none"> <li>• Ambiguous Orders</li> <li>• "Up-Testing"</li> <li>• Phlebotomy "Cheat Sheets"</li> </ul>	<ul style="list-style-type: none"> <li>✓ Audit the original provider's order versus what was performed and billed</li> <li>✓ Prohibit "Cheat Sheets" and audit IOP sites.</li> <li>✓ Evaluate the process for test mapping with EMR interfaces to ensure accuracy.</li> </ul>

## Lab Compliance Risks

Risk	Mitigation
<p><b>Hospital Billing</b></p> <ul style="list-style-type: none"> <li>• <b>Proper billing of laboratory testing depends on whether a patient is an inpatient, outpatient or non-hospital patient.</b></li> </ul>	<ul style="list-style-type: none"> <li>✓ Have controls in place to identify hospital clients.</li> <li>✓ Client bill to prevent lab billing Medicare Part B for in-patient and outpatient.</li> <li>✓ Review state laws for Medicaid billing.</li> <li>✓ If hospital is a lab draw site- have process to review collection log to ensure proper payment census.</li> </ul>

## Lab Compliance Risks

Risk	Mitigation
<p><b>Account types that should be client billed or receive special consideration.</b></p> <ul style="list-style-type: none"> <li>• Incarcerated Patients</li> <li>• ESRD Accounts</li> <li>• Health Fairs</li> <li>• Long Term Care</li> <li>• Transplant Accounts</li> </ul>	<ul style="list-style-type: none"> <li>✓ Ensure a method to determine accounts that need special consideration upon client set-up.</li> <li>✓ Client bill rates should be at Fair Market Value</li> <li>✓ Audit to ensure proper billing restrictions and account types are identified.</li> </ul>

## Lab Compliance Risks

### Risk

#### Professional Courtesy Testing to providers

Items and services of value given to referral sources and their immediate family could implicate fraud and abuse laws.

### Mitigation

- ✓ Ensure controls are in place that would not allow client (and their family members) testing charges to be waived.
- ✓ Train Sales and billing

## Lab Compliance Risks

### Risk

#### Waiving co-pays & Deductibles

- Payer contract violation
- May be viewed as an inducement
- Insurance fraud

### Mitigation

- ✓ Audit to ensure co-payments and deductibles are sought and are not routinely waived

## Lab Compliance Risks

Risk	Mitigation
<p><b>Client Billing-</b></p> <ul style="list-style-type: none"><li>• Cannot be used as an inducement for Medicare/Medicaid volume which the lab must bill directly.</li><li>• Waiving delinquent client bill accounts while continuing to bill Medicare/Medicaid.</li></ul>	<ul style="list-style-type: none"><li>✓ Ensure client pricing is not offered in order to get Medicare/Medicaid testing.</li><li>✓ Pricing should be at fair market value and include “more for more” pricing.</li><li>✓ Panel Pricing should be reviewed</li><li>✓ Ensure a process to address delinquent client bill accounts</li></ul>

## Lab Compliance Risks

Risk	Mitigation
<p><b>CPT Code Assignment</b></p> <p>Payment is derived by the CPT code assigned. An inappropriate CPT code assigned to a test could lead to a false claim.</p>	<ul style="list-style-type: none"><li>✓ Stay up-to-date on code changes.</li><li>✓ Implement process for new tests to ensure proper coding. Who is involved?</li><li>✓ Ensure a proper process for test method changes</li><li>✓ Ensure any changes are updated on requisitions and electronic systems.</li></ul>

## Lab Compliance Risks

Risk	Mitigation
<p><b>Diagnosis Codes</b> Diagnosis codes drive reimbursement.</p> <ul style="list-style-type: none"> <li>• Wrong narrative lab translation to ICD. 10</li> <li>• A dx from someone besides the treating physician or their staff</li> <li>• Lab steering client to “covered” codes”</li> </ul>	<ul style="list-style-type: none"> <li>• Have policies to ensure Dx are from the provider</li> <li>• Document verbal or written dx received and from whom, date</li> <li>• Audit</li> </ul>

## Lab Compliance Risks

Risk	Mitigation
<p><b>Requisition and Lab Ordering Systems</b></p> <ul style="list-style-type: none"> <li>• <b>During Lab scam the req was the “tool of the crime”.</b></li> <li>• <b>Panels and ability to order test components individually.</b> <ul style="list-style-type: none"> <li>• <b>Who is setting up panels/profiles</b></li> </ul> </li> <li>• <b>Reflex Tests</b></li> </ul>	<ul style="list-style-type: none"> <li>• Ensure provider documentation for custom panels/profiles (electronic and paper)</li> <li>• Disclose panel test components and offer them individually. Review client pricing.</li> <li>• Involve clinical leadership in approval of panels and reflexes</li> <li>• Send Annual Disclosure Letter</li> </ul>

## Lab Compliance Risks

Risk	Mitigation
<p><b>Standing Orders-Performing and billing for a test without a valid order may violate fraud and abuse laws.</b></p> <ul style="list-style-type: none"><li>• Length of standing order</li><li>• Test menu, medical necessity, frequency of testing</li><li>• Renewal</li></ul>	<ul style="list-style-type: none"><li>• Train on valid standing order requirements and audit.</li><li>• Determine state law for length of standing orders</li><li>• Assess medical necessity (especially for urine drug testing)</li></ul>

## Lab Compliance Risks

Risk	Mitigation
<p><b>Client Supplies- Giving an item or service for free or less than fair market value could impact the Anti-Kickback Statute.</b></p>	<ul style="list-style-type: none"><li>• Implement controls to ensure only supplies directly related to lab testing are provided.</li><li>• Track &amp; Audit Utilization</li><li>• 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.</li></ul>

## Lab Compliance Risks

Risk	Mitigation
<p><b>Provider Compensation Arrangements- meet Stark exceptions</b></p>	<ul style="list-style-type: none"><li>• Identify physician “vendors”</li><li>• Contract Database</li><li>• Fair Market Value Assessment</li></ul>

## Lab Compliance Risks

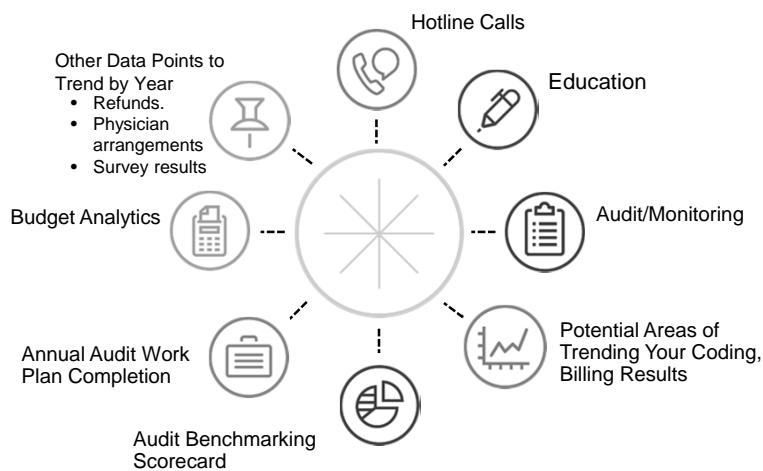
Risk	Mitigation
<p><b>Non Monetary Compensation to providers- The legal limit changes annually.</b></p> <p>Anti-Kickback Statute could also be implicated.</p> <ul style="list-style-type: none"><li>▪ Sales Reps related to physician clients</li></ul>	<ul style="list-style-type: none"><li>• Expense Report Tracking System</li><li>• Policy to address what can/cannot spend on referral sources</li><li>• Audit</li><li>• How to address an overage</li></ul>



# Lab Compliance Risks

Risk	Mitigation
<p><b>Phlebotomy Duties- Should only perform those tests directly related to your lab's testing.</b></p> <ul style="list-style-type: none"> <li>• Standing Orders</li> <li>• Ambiguous Orders</li> <li>• Prohibited Duties</li> <li>• Diagnosis Collection and Translation</li> <li>• Blanket Orders</li> <li>• Cheat Sheets</li> </ul>	<ul style="list-style-type: none"> <li>• Audit the original provider order versus what the Phleb input into ordering system.</li> <li>• Go onsite/unannounced</li> <li>• Draw Fees</li> </ul>

# Elements to Consider in Your Evaluation Efforts



## Compliance Effectiveness

***“Better compliance measurement leads to better compliance management”***

Measurement Tools:

- Risk Assessments
- Audits
- Surveys
- Denial Trending
- Reported Issues Trending
- Voluntary Refunds

Chen, Hui; Soltes, Eugene. “Why Compliance Programs Fail-and How to Fix Them.” *Harvard Business Review*, April 2018

## Compliance Program Effectiveness

If the DOJ were investigating your lab and asked how you know if your compliance program is effective, what would you say?

What information would you provide to demonstrate its' effectiveness?

(Oh...and the date range of their request will likely be 4+ years ago.)

## Compliance Effectiveness

- Mistaking legal accountability for compliance effectiveness
  - Is compliance a legal exercise or a behavioral science?
- Compliance Program Engineering
  - Risk Based
  - Effectiveness measurements
- Link Compliance Initiatives to Objectives