Compliance Issues Affecting Laboratories

Robert E. Mazer, Esquire
Ober|Kaler, A Professional Corporation
100 Light Street
Baltimore, Maryland 21202
(410) 347-7359
remazer@ober.com

Tim Murray, MS, MT (ASCP), CHC
Director of Laboratory Compliance
Corporate Responsibility
Catholic Health Initiatives
Denver, Colorado
timothymurray@catholichealth.net

Laboratory Compliance

Andrea L. Treese Berlin, Senior Counsel, ACRB
330 Independence Ave., SW
Cohen Building, Rm. 5527
Washington, DC 20201
(202) 205-9501
andrea.treeseberlin@oig.hhs.gov
Clinical Laboratory Services

- Fungible
- High Volume
- Reliance on Referring Physicians

Compliance Plan Benefits

- “It’s not who I am underneath, but what I do that defines me.”
- From the inside – prevents, detects, and resolves unlawful conduct
- From the outside – potential reduction of penalties for violations
- Ongoing Process
- Coordination of Activities
Compliance Plan Benefits

They need your help!

Laboratories have their own guidance from the Office of the Inspector General for developing a compliance plan published in the FR 8/24/1998. Described seven fundamental elements that were to be contained in each plan. This was to replace the previously issued plan published March 3, 1997 and was more consistent with the compliance program guidance issued with respect to the hospital and homecare industries.
Advisory Opinions

Special Fraud Alerts

June 25, 2014

Laboratory Payments to Referring Physicians
Other Guidance

June 9, 2015

Physician Compensation Arrangements May Result in Significant Liability

Office of Evaluations and Inspections (OEI) Reports

Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data

Questionable Billing for Medicare Part B Clinical Laboratory Services

Questionable Billing for Polysomnography Services

Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings

Coverage and Payment for Genetic Laboratory Tests

Questionable Billing for Medicare Independent Diagnostic Testing Facility Services
Compliance – Overall Purpose of Compliance Programs

• Effective internal controls that promote adherence to legal requirements
• Culture that promotes prevention, detection, and resolution of unlawful conduct
• Demonstrate commitment to compliance process

Compliance – Overall Purpose of Compliance Programs

• Written policies, procedures and standards of conduct
• Compliance officer and compliance committee
• Effective training and education
• Effective lines of communication
• Enforcement of standards through well-publicized disciplinary guidelines
• Internal monitoring and auditing
• Responding promptly to detected offenses and developing corrective action
Issues

- Claims
- Arrangements
- Marketing

Corporate Integrity Agreements

Office of Inspector General
U.S. Department of Health & Human Services

Corporation Integrity Agreements

OIG mediates Corporate Integrity Agreements (CIA) with health care providers and other entities as part of the settlement of Federal health care program investigations arising under a variety of civil false claims statutes. Providers or entities agree to the obligations and in exchange, OIG agrees not to seek their exclusion from participation in Medicare, Medicaid, or other Federal health care programs.
Millennium Health, LLC Claims

- No “Custom Profiles”
  Orders must be patient-specific
- Thoughtful approach to reflexive testing
- Submission of diagnostic information for tests ordered
- Audit of referral patterns to address potential issues with referral sources

Chief Clinical Officer

Oversight over clinical content in marketing materials, messaging to referral sources, etc.
Millennium Health, LLC
Arrangements and Marketing

- Arrangements
  - Review and training
  - Tracking anything of value provided to an actual or potential referral source

- Monitoring of marketing
  - Field force monitoring
  - Compliance observations

Compliance Plans- Operationalization
Written policies, procedures and standards of conduct

- Appendix A. Clinical Laboratory Overview
- Appendix C. Areas of Concern Identified by the OIG
- Appendix D. Sample Monitoring Tool
- Appendix E. Special Fraud Alerts, Advisory Bulletins and other Communications by the OIG
- Appendix F. Designation of a Clinical Laboratory Compliance Officer and Clinical Laboratory Compliance Committee
- Appendix G. Names of a Clinical Laboratory Compliance Officer and Clinical Laboratory Compliance Committee Members
- Appendix H. Education and Training
- Appendix I. CRP Reporting System
- Appendix J. Clinical Laboratory Orders/Ordering Procedure
- Appendix K. Clinical Laboratory Medical Necessity Procedure
- Appendix L. Clinical Laboratory Coding and Validating ICD Coding Procedure
- Appendix M. Clinical Laboratory Billing Procedure
- Appendix N. Marketing, Sales and Business Development of Laboratory Services Procedure, Improper Inducements, Kickback and Self-Referrals
- Appendix O. Clinical Laboratory Research Procedure
- Appendix P. Application for Laboratory Licensure (CLIA) License
- Appendix Q. Non Routine Information Requests or Communications from Governmental or Regulatory Agencies
- Appendix R. Clinical Laboratory Specific Procedures

Printed documents are for reference only. Refer to Lab Addendum FINAL 02/01/16 for the most current version.

1. Laboratory Compliance CRP Plan Addendum Effective Date: 02/01/14 Addendum Revised 02/01/16 Annual Review 02/01/16
The Laboratory Compliance Officer is an individual who is assigned the responsibilities listed within this addendum and may perform them in addition to any existing job duties. Depending on the laboratory size and complexity, this individual could be responsible for a single or multiple laboratory(ies).

The Laboratory Compliance Committee may be a standalone laboratory committee or its duties assigned to another entity/divisional committee whose members understand the importance and confidentiality of the laboratory compliance materials developed and reviewed.

4 Adapted from the OIG Final Compliance Program Guidance for Clinical Laboratories -08/1998
http://oig.hhs.gov/authorities/docs/cpglab.pdf

### Compliance Plans- Operationalization

**Compliance Officer and Compliance Committee**

**Annual Tasks**

<table>
<thead>
<tr>
<th>CHI Clinical Laboratory Addendum Annual Responsibilities Checklist FY 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Laboratory Name:</strong></td>
</tr>
<tr>
<td>1. Review any Laboratory Addendum updates after 02/01/YY with laboratory compliance committee and laboratory staff.</td>
</tr>
<tr>
<td>2. If required by entity policy or your specific accrediting agency, have appropriate laboratory personnel sign off on the annual reviewed/updated document. Laboratory Administrative Director, Laboratory Medical Director, Etc.</td>
</tr>
<tr>
<td>3. Perform an annual laboratory compliance review activity as described in The Clinical Laboratory Addendum, Appendix A, paragraph three. This requirement may be superseded by a National Compliance Committee assigned yearly monitor. Released in December each year.</td>
</tr>
</tbody>
</table>

You can sign up for automatic notification of the yearly publication at: OIG Work Plan notification
Compliance Plans- Operationalization
Annual Tasks

5. The Clinical Laboratory Compliance Officer or designee reports to the entity Corporate Responsibility Officer (CRO) on a regular basis or at a minimum annually the compliance activities of the laboratory as directed in the Clinical Laboratory Addendum. This task can be accomplished in the form of compliance meeting minutes or as a separate report to the entity compliance committee or CRO. Appendix F, dot point two.

6. Review and update as needed the names of the Clinical Laboratory Compliance Officer and the members of the Laboratory Compliance Committee. Appendix G

7. Ensure all required compliance education requirements are met. Appendix H

8. If laboratory tests are billed any other way than upon test completion, i.e., on receipt or order, the results of the developed monitoring program to ensure no incomplete or test not performed is billed in error are reported annually to the local CRO. Appendix M

9. Laboratory supplies furnished to referral sources are tracked to ensure that said supplies are provided in quantities that are appropriate. Appendix N

10. If appropriate, the results of the periodic monitoring of computer and interface contracts as required by the entity policy. Appendix N

11. Review any local CRO approved referral source gifts as they apply to CHI CRP Policy.

View items 1-3a, 2 in the CHI CRP Policy. The results of this monitor will be reported to the entity CRO. Appendix N

Click the link below to view the current CHI Clinical Laboratory Compliance Addendum:

http://collab.cantrellhealth.net/not/document-1.3.6.6.9501/Clinical_Laboratory_Compliance_Addendum_FI

Compliance Plans- Operationalization
Staff Education and Competency
Compliance Plans - Operationalization
Reflex Testing

Decision Document:
Options for alerting Providers at the time of ordering of a potential reflex test

Background:
The National CCHC Compliance office determined that the ordering provider needs to know what tests could be refused for any given lab order. Below are several examples of how we could implement this in Epic.

Option 1: Build the reflex test into the name of the orderable procedures.
Example: "urine dipstick" will return if indicated.

Considerations:
This would require a combined, national, reflex protocol. We would not be able to change the names of the procedures in the different regions. Additionally, reflex protocols would clutter up the name field and might inadvertently degrade the quality of search results for providers making it more difficult to find the test they want to order.

Option 2: Build the reflex protocols into the process instructions of the orderable procedures.
Example: "Culture will reflex when bacterial + x...."

Recommendation: Option 2
Option 2 provides maximum specificity and maximum flexibility across the regional deployments. We can display different SmartTests in the process instructions per regions or even per hospital. However, divergence on reflex protocols increase the time and cost of maintaining the process instruction option.
Compliance Plans - Operationalization

Monitoring

- Director of Laboratory Compliance Performed onsite compliance reviews
  - Invite entity and divisional compliance officers to accompany onsite reviews.

- Developed checklist for waived laboratories
  - Local CROs or Physician Enterprise Specialists used this tool to review 25% of the POLs annually
    - Purpose was to make typically non-professional laboratorians aware that there were testing requirements

Compliance Plans - Operationalization

Monitoring

Laboratory Compliance Checklist
FY 2010

Part 1 - Site Visit

NOTE: The information needed to complete this section should be obtained before the onsite visit.

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>DESCRIPTION</th>
<th>ADDITIONAL INSTRUCTIONS AND ENFORCEMENT</th>
<th>RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the name on the laboratory's CLIA and Accreditation license the same?</td>
<td>Obtain a copy of the CLIA and Accreditation licenses and compare name of 25% of POLs annually.</td>
<td>Purpose was to make typically non-professional laboratorians aware that there were testing requirements</td>
<td>This is the laboratory's CLIA and Accreditation license must be the same.</td>
</tr>
</tbody>
</table>

- The laboratory's CLIA and Accreditation licenses must be the same.
- If the name on the laboratory's CLIA and Accreditation licenses are not the same, the names must be notified within forty-five days of the change.
- If the names are not the same, review documentation submitted lending and receiving agencies indicating their identity change.
- Name changes to licensing and accrediting agencies must be made in writing within thirty days of the purchase.
- Document any discrepancies with explanation of difference.
- Provide each on an exhibit to file.
Compliance Plans - Operationalization

Monitoring

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>DESCRIPTION</th>
<th>ADDITIONAL INSTRUCTIONS AND ENFORCEMENT MATERIALS</th>
<th>RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.2. Do HR records contain transcripts or a Diploma for Lab staff verifying highest educational level attained for testing personnel? (See attached PDF which explains/validates the need for this documentation)</td>
<td>Document that each of the personnel files reviewed in 3.2 (Testing personnel only) contains transcripts or Diploma verifying highest educational level.</td>
<td>Ensure that the following criteria is met in the PDF to right ascended in the competency evaluations.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reviewer qualifies as General Supervisor, High Complex Laboratories</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CLIA REGULATIONS: (Subpart M, Sections (A) and (N) at least an associates with an additional year of experience)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Review Qualifications for Technical Consultant Moderate complexity Laboratories</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CLIA REGULATIONS: (Subpart M, Sections (A) and (N) at least BS and two years lab experience)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>NOTE: Waived laboratories have no personnel requirements.</td>
<td></td>
</tr>
</tbody>
</table>

Compliance Plans - Operationalization

Monitoring

Please complete all demographic info and answer questions 1 - 14a.

If the information on this license is not accurate, confirm and document (see box to the right) that appropriate agency has been notified. (See enclosed document for details.) Note: Licenses are generally not updated immediately, normally updated on a two year renewal renewal cycle.

CLIA/state license # as it appears on license:

Name of lab as it appears on the CLIA/state license and any corrections:

Lab Address as it appears on the CLIA/license and any corrections:

Consultant Name (if any):

Testing personnel interviewed:

Name of Laboratory Contact:

State Assessment Completed:

FY 2016 - Waived Testing Assessment

<table>
<thead>
<tr>
<th>Question/Clarifications/Follow up as needed, please contact:</th>
<th>Name of Agency notified and date of the notification. List any other comments if necessary:</th>
</tr>
</thead>
</table>

YES | NO | N/A | Additional guidance and answers to the NON Yes/No questions: | Place "X" in box for answer |

FY 2016 - Waived Testing Assessment

2. Are all tests performed classified as waived? 24419.15(c) and 403.1779(c)(3)(i) see below for abbreviated list of waived tests:

Cholesterol, Fecal Occult Blood, Glucose, Hemoglobin, Hemoglobin A1C, Hematocrit, Influenza, Lyme Disease, Ovulation, Prothrombin Time, Rapid Group, Sedimentation Rate, Urinalysis, Pap smear, Urine Pregnancy

2. Does the laboratory have the current manufacturer's instructions for all tests performed? Evidence of Compliance (Click on tab for interpretation)

a) Using the appropriate specimen?

b) Adding the required reagents in the prescribed order?

c) Adhering to the manufacturer's storage and handling instructions?
Compliance Plans - Operationalization

Monitoring

Evidence of Compliance

Red marks emphasize review

Q1. Did the patient receive the appropriate test kit and does he/she know how to perform the test?

Q2. Was the patient informed about the importance of the test and the potential implications if the test results are positive?

Q3. Did the patient sign the consent form before the test was performed?

Q4. Was the test protocol followed rigorously, including the correct handling and transport of the specimen?

Q5. Was the test performed by a qualified and trained individual?

Q6. Was the test result interpreted correctly by the laboratory or healthcare professional?

Q7. Was the result communicated to the patient and the appropriate healthcare provider in a timely manner?

Q8. Was the patient provided with appropriate follow-up instructions and referrals if necessary?

Q9. Was the patient’s privacy protected during the test and result communication process?

Q10. Was the test retested if required by the protocol or if the result was inconclusive?

Q11. Was the test kit properly disposed of after use, to prevent contamination or risk of exposure?

Q12. Was the test performed in a sterile environment to ensure accuracy and reliability of the result?

Q13. Was the test performed within the specified time frame, if applicable?

Q14. Was the test result documented accurately in the patient’s medical record?

Q15. Was the test result confirmed by another laboratory, if required by the protocol or guidelines?

Q16. Was the test result reviewed by a qualified healthcare provider before being acted upon?

Q17. Was the test result communicated to the patient or their authorized representative in a clear and understandable manner?

Q18. Was the test result used to inform necessary interventions or adjustments in the patient’s care plan?

Q19. Was the test result evaluated for potential complications or side effects?

Q20. Was the test result used to inform the patient or their authorized representative about the risks and benefits of the test?

Q21. Was the test result shared with the appropriate healthcare professionals as per the established communication protocol?

Q22. Was the test result reviewed and documented in the patient’s medical record for future reference and compliance monitoring?

Q23. Was the test result used to inform the patient’s primary care provider or specialist as required by the test protocol?

Q24. Was the test result communicated to other healthcare facilities or providers involved in the patient’s care?

Q25. Was the test result used to inform the patient or their authorized representative about the need for follow-up testing or additional investigations?

Q26. Was the test result used to inform the patient or their authorized representative about the need for lifestyle changes or additional interventions?

Q27. Was the test result used to inform the patient or their authorized representative about the need for referral to a specialist or additional healthcare services?

Q28. Was the test result used to inform the patient or their authorized representative about the need for additional testing or follow-up appointments?

Q29. Was the test result used to inform the patient or their authorized representative about the need for further education or information about the test?

Q30. Was the test result used to inform the patient or their authorized representative about the need for additional resources or support services?

Q31. Was the test result used to inform the patient or their authorized representative about the need for legal or ethical considerations?

Q32. Was the test result used to inform the patient or their authorized representative about the need for additional counseling or psychological support?

Q33. Was the test result used to inform the patient or their authorized representative about the need for additional financial assistance or resources?

Q34. Was the test result used to inform the patient or their authorized representative about the need for additional insurance or coverage?

Q35. Was the test result used to inform the patient or their authorized representative about the need for additional research or clinical trials participation?
Compliance Plans - Operationalization
When Errors are Discovered – What to do?

SAMPLE

Dear Laboratory Administrative Director:

A potential laboratory miscoding error has been identified in your laboratory charge description master (CDM) that may potentially end in governmental plan repayment. In order to be able to assure that a thorough analysis is performed, there are recommended steps to be followed to ensure good communication, data analysis accuracy/integrity and timely reporting. Please make certain that your entity Corporate Responsibility Officer (CRO) is aware of the situation. I also advise letting your entity VP and other senior leaders as required know of the situation and keep them updated as we progress. Please see attached typical data request for repayment analysis when appropriate.

The normal chain of events that occurs when a billing/coding error is discovered:
1. Notify Vice President or senior executive responsible for the laboratory department
2. Notify entity (CRO)
3. Notify national laboratory compliance director
4. Complete Laboratory Repayment Information Form (included)
5. A meeting with CHI legal you and the Director of Laboratory Compliance will be set up by the Entity CRO after items 1 and 2 below are accomplished. The purpose of this meeting will be direct analysis, develop an action plan and assign responsibilities on a go forward basis.

Simultaneously you should:
1. Identify the date that the correction of the error was completed, implemented and confirmed.
2. Determine when the error first occurred if possible for example there was a software change, new test initiated and assigned an incorrect code or old code discovered to be incorrect.
3. Legal will hear the presented information and determine a repayment corrective action if necessary.
4. If repayment is determined, legal will direct that the identification of all non-bundled (Post 1/2014) and all (Pre 1/2014) out and non-patients from FPS or sole community hospitals having the following federal payer types Medicare, Medicaid, their managed care plans and Tricare are to be identified and repayment amounts will be determined. Providing the data in the format as required by the legal department’s Repayment spreadsheet template (Attached). This can be accomplished at the entity level or assigned by the entity to the Catholic Health Auditing Network (CHAN) to complete.[Recommended]
5. Once legal accepts the repayment data, repayment will be made by the entity as directed by the assigned attorney within 60- days of their acceptance date.
6. At the entity level, the repayment process will be directed and completed by the local (CRO).

Please contact me if you or your leadership have any questions.

Tim Murray, MS, MT (ASCP), CHC
Director Laboratory Compliance
Corporate Responsibility
367 Eagleview Boulevard, Exton, PA 19341
P 610-594-5102 | F 610-363-1790
timothymurray@catholichealth.net
Compliance Plans - Operationalization
When Errors are Discovered – What to do?

Laboratory Repayment Project Information Form
All information is to be completed by Project Owner

<table>
<thead>
<tr>
<th>Entity Location Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entity Name</td>
</tr>
<tr>
<td>Hospital/Location(s) and City, State</td>
</tr>
<tr>
<td>Entity Project Owner</td>
</tr>
<tr>
<td>Entity Laboratory Director Name</td>
</tr>
<tr>
<td>Entity Laboratory Department Administrative Executive (VP)</td>
</tr>
<tr>
<td>Entity CRO Name</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Project Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>What billing discrepancy was identified at the entity? Include details test name, billing identification number, HCPCS code.</td>
</tr>
<tr>
<td>Describe the issue that was identified here.</td>
</tr>
<tr>
<td>How was the issue identified?</td>
</tr>
<tr>
<td>Explain how the issue was identified here</td>
</tr>
<tr>
<td>What caused the issue?</td>
</tr>
<tr>
<td>Explain what caused the billing discrepancy here</td>
</tr>
<tr>
<td>Was the issue corrected?</td>
</tr>
<tr>
<td>If Yes, When was the issue corrected?</td>
</tr>
<tr>
<td>If known, when did the issue start?</td>
</tr>
</tbody>
</table>

Compliance Plans - Operationalization
When Errors are Discovered – What to do?

Project Logistics Determined During Legal Consult
What is the lookback period (i.e., Time Period) for the repayment analyses?
Provide the lookback start and end dates
What payers will be included in repayment analyses? Normally Medicare, Medicaid and their managed care plans.
Provide the payers to be included in the analyses
Name of attorney directing repayment | Enter Name here |
Will the project be performed under the Attorney Client Privilege (ACP)? | Choose an item. |
Will CHAN be requested to perform the project | Choose an item. |

Laboratory Repayment Project Finalization Information
Date data analysis accepted by directing attorney | Click here to enter a date. |
Date directing attorney provided templates and direction for entity repayment | Click here to enter a date. |
Date reimbursement was made to payers. Must be less than 60 days from attorney acceptance date | Click here to enter a date. |
Date CRO entered incident into EthicsPoint | Click here to enter a date. |
Return copy of this completed form to attorney director, entity CRO and Director of Laboratory Compliance.
Self-Disclosure

• Should I disclose?

• Where should I disclose?
  - Contractor
  - OIG
  - DOJ
  - CMS

• Get some advice
**Self-Disclosure Possible Resolutions**

- **OIG = Civil Monetary Penalties law settlement**
  - Outlined in April 17, 2013, Updated Provider Self-Disclosure Protocol
    - Cooperation is key
    - OIG’s general practice is to require a minimum multiplier of 1.5 times the single damages, although in each case, we determine whether a higher multiplier is appropriate.
    - Presumption against requiring integrity agreement obligations in exchange for a release of OIG’s permissive exclusion authorities in resolving an SDP matter.

- **DOJ = False Claims Act settlement**
Compliance Is A Many-Headed Beast

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

Danger Signals

- Substantial Government Expenditures re: Fraud and Abuse/Coordinated Efforts
- Qui Tam Actions
  - Aggressive Application of Laws
  - Review as Criminal Actions
- Personal Liability Claims
- Blurring Between Mistakes/Overpayments v. False Claims
- Reduction in Third-Party Payments – Search for Offsetting Revenues
Selected Licensure/Certification
Enrollment Issues

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
Proficiency Testing Referrals

- **Intentional” Referral – Traditional Test**
  - 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)

- **Recent Development**
  - PT sample referred for reflex, distributive or confirmatory testing under valid procedures for patient specimens considered improper, but not intentional referral, so long as not “repeat” PT referral. 42 C.F.R. §493.801(b)(4)

---

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
TEST Act Implementation

- Sanctions for intentional referrals of PT samples.
  - Lab may, rather than must, have CLIA certificate revoked for intentional referral 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 (penalties depend on whether other lab’s results received before challenge cutoff date).

42 C.F.R. § 493.1840(b)

Proficiency Testing Referrals

DOs and DONTs

**Clinical Laboratory Improvement Amendments (CLIA)**

**PROFICIENCY TESTING**

*NOTE: Congress passed the Clinical Laboratory Improvement Amendments of 1988 mandating quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April 24, 2003.*
Proficiency Testing – Electronic Training

Laboratory Proficiency Testing

Proficiency Testing – Electronic Training

Remember:

PT specimens may **NEVER**, under any circumstances, be sent out of your laboratory.

- **NEVER** enter into discussion with another laboratory about PT results before the due date set by the testing agency for reporting results.
- **NEVER** analyze a PT specimen sent to you from another laboratory - even if the laboratory is located in or owned by your hospital or CHI.
Medicare Enrollment

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

Medicare Enrollment

• Effective February 3, 2015, a provider or supplier’s Medicare billing privileges may be revoked if CMS determines that it “has a pattern or practice of submitting claims that fail to meet Medicare requirements.” 42 C.F.R. §424.535(a)(8)(ii)

• CMS indicates that such claims include those for services that are not reasonable and necessary.

• CMS declined to impose intent standard.
Claims for Payment

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
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

- State FCAs

Recent Laboratory FCA Settlements

- Calloway Laboratories, Inc.
- Strata Pathology Laboratory, Inc. (StrataDX)
- Millennium Health, LLC
- Singulex, Inc.
- Health Diagnostic Laboratory, Inc.
- Bostwick Laboratories, Inc.
Civil Monetary Penalties

– Kickbacks
– Physician self-referral ("Stark") violations
– False or fraudulent claims
– Billing while excluded
– Select agents
– Patient dumping (EMTALA)
– About 40 other OIG CMPs

FCA vs. CMP

**FCA**
- Civil Penalty of no less than $5,000 and not more than $11,000
- 3 times damages sustained by the U.S.

**CMP**
- Monetary Penalty up to $10,000 for each item or service improperly claimed
- 3 times the amount improperly claimed
Recent Laboratory CMPs

• Data-Mining:
  • Billing multiple claims for urine drug screening when only a single unit may be billed per patient encounter
  • Up-coding low to moderate complexity drug screening tests to high complexity

• Results:
  • Ten settlements totaling more than $8.9 million
    • Gainesville Pain Management & Dr. Britton - $1.58 million settlement and five year CIA
      • Exclusion for default
    • Medicus - $5 million settlement and five year CIA

Settlement Details

<table>
<thead>
<tr>
<th>Provider</th>
<th>Date of Settlement</th>
<th>Settlement Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicus Laboratories, LLC</td>
<td>2/14/2014</td>
<td>$5,000,000.00</td>
</tr>
<tr>
<td>Nabil Attalla Barsoun, M.D.</td>
<td>7/25/2014</td>
<td>$334,528.90</td>
</tr>
<tr>
<td>Florida Family Laboratory, Inc</td>
<td>8/5/2014</td>
<td>$977,400.00</td>
</tr>
<tr>
<td>Pain Specialists of Greater Chicago</td>
<td>9/10/2014</td>
<td>$590,763.45</td>
</tr>
<tr>
<td>Clinical Laboratory Partners</td>
<td>9/29/2014</td>
<td>$435,789.34</td>
</tr>
<tr>
<td>Dennis Conrad Harper, M.D.</td>
<td>1/20/2015</td>
<td>$305,168.54</td>
</tr>
<tr>
<td>Alan J. Wayne, M.D. and Stevenson Medical Center, Inc.</td>
<td>2/24/2015</td>
<td>$225,000.00</td>
</tr>
<tr>
<td>American Institute of Toxicology</td>
<td>7/20/2015</td>
<td>$220,924.74</td>
</tr>
<tr>
<td>David Irving Stein, M.D. and Milwaukee Pain Treatment Services</td>
<td>8/14/2015</td>
<td>$374,864.78</td>
</tr>
</tbody>
</table>
Enforcement Actions

Criminal and Civil Enforcement
- Here is the latest criminal and civil enforcement actions taken by the Office of Inspector General (OIG) throughout the Department of Health and Human Services (HHS). These cases often result from HHS work as part of its efforts to guard against fraud and waste. The OIG investigates allegations of fraud, waste, and abuse, and it takes action to prevent and reduce fraud, waste, and abuse. The OIG’s work is focused on protecting the public interest, and it is committed to ensuring that the health care system is safe, secure, and accessible.

State Enforcement Actions
- Medicaid Fraud Control Units (MFCUs) invest in Medicaid fraud and waste. The Outlooks page lists each MFCU’s caseload, the number of cases they are currently handling, and the status of each case. This information is updated weekly and is available to anyone who visits the MFCU’s website. The MFCU’s website also includes a searchable database of all cases handled by their agency.

Civil Monetary Penalties and Affirmative Exclusions
- The OIG’s Office of Civil Rights (OCR) enforces civil rights laws that protect the rights of individuals with disabilities. OCR investigates complaints of discrimination and takes appropriate action to prevent discrimination.

Corporate Integrity Agreement Enforcement
- The OIG has the authority to enter into Corporate Integrity Agreements (CIA) with entities to enforce and/or prevent enforcement actions. CIA agreements are entered into between the entity and the OIG to prevent future violations of the laws enforced by the OIG.

CMP Summaries

Civil Monetary Penalties and Affirmative Exclusions
- The Office of Inspector General (OIG) has the authority to impose civil monetary penalties (CMPs), assessments, and exclusion orders against any person or entity found to have engaged in prohibited conduct. CMPs are a monetary penalty for non-compliance with the law, and exclusion orders are a bar to participation in the Medicare and Medicaid programs.

North Dakota Ambulance Provider Billed Patients Case Involving False Claims
- On March 7, 2016, the North Dakota Department of Health (ND DOH) announced the settlement of a civil case involving false claims.

Related Information
- CMP Navigation
- Civil Monetary Penalties and Affirmative Exclusions
- Provider Self-Disclosure Settlements
- Civil Monetary Penalty Authorities
- Responsible Event Settlements

I’m looking for
- Let’s start by choosing a topic
- Related Information
- CMP Navigation
- Civil Monetary Penalties and Affirmative Exclusions
- Provider Self-Disclosure Settlements
- Civil Monetary Penalty Authorities
- Responsible Event Settlements
- Corporate Integrity Agreement Enforcement
- Grant Fraud
- Medicare Fraud Control Units
- Medicare Fraud Strike Force
Exclusions

- **Mandatory** (5 year minimum) – Section 1128(a)
  - conviction of “program related” crime
  - conviction of patient abuse & neglect
  - felony conviction of health care fraud
  - felony conviction relating to controlled substances

- **Permissive** – Section 1128(b)
  - 16 authorities, including:
    - certain misdemeanor convictions
    - loss of state license to practice
    - failure to repay health education loans
    - failure to provide quality care

---

Exclusion Information

May 8, 2013

Updated Special Advisory Bulletin on the
Effect of Exclusion from Participation in Federal Health Care Programs
Accountable Care Act

• Section 6402
  – Requires reporting and repayment of overpayments within 60 day of **identification** (or due date of next cost report, if applicable)
  – Violations actionable under the FCA

---

Medicare Program; Reporting and Returning Overpayments; Final Rule 81 Fed. Reg. 7654 (Feb. 12, 2016)

Overpayment recipient must “report and return” overpayment within 60 days of date on which overpayment is “identified.”

Overpayment is considered “identified” when person:

1. Has determined that it has received an overpayment and quantified overpayment; or
2. Should have determined that it has received an overpayment and quantified overpayment through use of reasonable diligence.
General Principles

- Obligation to report and return applies irrespective of reason for overpayment.

- Overpayment generally consists of difference between amount received and amount that should have received.

- Payment properly received will not become an overpayment as a result of a subsequent change in law or regulation (but watch out for “clarifications”).

Lookback Period

- Regulation applies to any overpayment identified within 6 years of its receipt.

- Providers and suppliers reporting Stark Law violations are required to report and return overpayments back 4 years only.
“Reasonable Diligence” to Determine and Quantify Overpayment

- “Reasonable diligence” includes:
  1. “Proactive compliance activities” conducted in good faith by qualified individuals to monitor claims for receipt of overpayments, and
  2. “Reactive investigative activities” conducted in good faith in timely manner by qualified individuals in response to “credible information” about potential overpayment.

- “[C]redible information’ includes information that supports a reasonable belief that an overpayment may have been received.”

Medical Necessity

- Principles in final rule apply to “medical necessity” determinations.

- CMS: “There may be situations where a significant increase in Medicare revenue should lead a laboratory to conduct reasonable diligence.”

- Limitation of liability does not impact obligation to report and return overpayment.
**Facts**

Realto, an employee of Continuum, prepared a spreadsheet of over 900 potentially improper Medicaid claims in 2010.

Continuum did not repay bulk of claims until June 2012 after receipt of Civil Investigation Demand, and did not complete repayment until March 2013.

**Court:** Continuum’s awareness that overpayments likely existed triggered 60-day clock.

“
To allow defendants to evade liability because . . . email did not conclusively establish each erroneous claim and did not provide the specific amount owed to the Government would contradict Congress’s intention . . . .”

Court: Ruling should not be read to create FCA liability for provider who diligently worked to investigate potential overpayment, but had not returned overpayment within 60 days, so long as provider could establish that it did not intend to withhold repayment once repayment amount established.

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)

OIG Work Plan for 2016

- OIG will use results to identify routine submission of improper claims and recommend overpayment recoveries

- OIG will review payments to independent labs to determine compliance with selected billing requirements

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
- Others
The Match Game – Billing Issues

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

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)
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)


Billing Issues

  - 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
The Match Game – Billing Issues

• Second Generation Additions
  – Test knowingly ordered
  – Test medically necessary

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)
Medical Necessity

Corporate Integrity Agreement Between OIG and Millennium Health, LLC

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
Risks from Unnecessary Tests

Financial Loss


• 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)

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)

• They may not apply, however, depending on circumstances. According to the OIG, 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)
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.

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)
Advanced Beneficiary Notices

Generally, the “routine” use of ABNs is not "effective".

Exceptions:

• NCD prohibits any coverage

• Experimental items and services (RUO and IUO lab tests)

• Items or services subject to frequency limits

MCPM, Ch. 30, §40.3.6

Payment for Hospital Outpatient Tests

Packaged into Hospital Outpatient Prospective System unless:

– “Non-patient” test

– No other hospital outpatient services from same “encounter” or

– Tests “clinically unrelated” from other hospital services from same “encounter” and ordered by different physician

Applies to tests performed by hospital directly or “under arrangements”

CMS has assigned codes to be used by hospitals to designate the packaging status of a particular lab test.
OIG Data Brief
Medicare Payment for Clinical Laboratory Tests in 2014; Baseline Data

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
Intent: ACA

• Section 6402 (f) (2)
  
  “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.”

Federal Anti-Kickback Statute

• Statutory Exceptions
  
  – Discounts
  – Bona fide employment relationships
  – GPO fees
  – Certain co-payment waivers
  – Certain managed care arrangements

• Regulatory Safe Harbors

• Advisory Opinions
  
  – Posted on OIG Website
    • www.hhs.gov/oig
Federal Anti-Kickback Statute

• Penalties
  – Criminal fines & imprisonment
  – Civil money penalty of $50,000 plus 3X the amount of the remuneration
  – Exclusion
  – False Claims Act liability – Affordable Care Act, §6402(f)(1)
  – Private Cause of Action

Anti-Kickback Statute Developments

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

General Principles:
  – Previously emphasized that providing free or below-market goods to physician referral source, or paying more than FMV for services, could constitute illegal remuneration
  – Payments intended to induce or reward referrals are unlawful, even if payments are FMV for services; payments exceeding FMV increase probability of unlawful payment
  – Payments for services paid for by others, such as Medicare, provides evidence of unlawful intent
Anti-Kickback Statute Developments

Specific Principles:

– Physicians and labs which participate in Special Processing Arrangements may be at risk under AKS

– Physicians and labs which participate in Registry Arrangements in which payments are related to test referrals, and do not reflect physician’s efforts, may be at risk under AKS

Anti-Kickback Statute Developments

Advisory Opinion 15-4

• Provide clinical lab testing without charge for patients in commercial plans in which the lab was out of network

• Referring physicians not at financial risk for the lab services

• OIG determined “remuneration” to the physician
  – Physician’s convenience in working with a single lab
  – “relieve physician practices of the expense for any interface that the physician practice no longer would maintain.”
Common Problem Arrangements

- Supplies
  - Point of care test cups
- Specimen collectors
  - Activities
  - Space
- Processing/Packaging
- Registries
- Payments exceeding services provided
- Payments based on volume or value of referrals
- Ownership

OIG Position Statements

Provision of free POCT Cups To Physicians under Stark Law and Antikickback Statute, *Brief of U.S.A. as Amicus Curiae, Ameritox, Ltd. v. Millennium Laboratories, Inc.*
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* (M.D. Fla., Aug 16, 2013).

Whether or not FAS and the Stark Law are relevant to state unfair competition law is a novel and complex issue of state law.  *Ameritox, Ltd. V. Millennium Labs*, 803 F.3d 518 (11th Cir. 2015)

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

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
Stark Self-Referral Prohibition

- Denial/Refund of Payments
- Civil money penalty of $15,000 for submission of claim for services person knows or should know violated statutes or for failing to make required refund, plus 2x reimbursement claimed
- Exclusion
- Additional Penalties for Circumvention Schemes

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 or FAS violation to violate FCA. *Daugherty v. Bostwick Labs*, No. 1:08-CV-00354, 2012 WL 6593804 (S.D. Ohio Dec. 18, 2012)
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

Client Entertainment

- Stark non-monetary compensation exception
  - Items or Services
  - Annual aggregate limit ($392 for CY 2016)
  - Not take into account volume or value of referrals or other business generated
  - Not solicited by physician
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

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
Pricing Issues for Laboratories

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
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

Discounts

• Compliance Guidance for Clinical Laboratories
  – 63 Federal Register 45,076 (August 24, 1998)
    • Uses “fair market value” concept
  – Advisory Opinion 11-11 reiterates “below cost” theory of “swapping”

• Stark Exception for payments by physicians
  – Fair market value not required for clinical laboratory services
  – Fair market value required for all other services
Recent Enforcement Activity

  - Government alleged that clinical lab/mobile x-ray company gave kickbacks in the form of below-cost discounted pricing to nursing homes on client-billed work to induce Medicare Part B referrals
  - False Claims Act allegations settled for $17.5 million in September, 2013

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
“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) http://oig.hhs.gov/fraud/docs/safeharborregulations/lab.htm

“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)
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.

QUESTIONS?