Compliance Issues Affecting Laboratories

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Clinical Laboratory Services

- Fungible
- High Volume
- Reliance on Referring Physicians

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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

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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

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OIG.HHS.GOV

APRIL 2016

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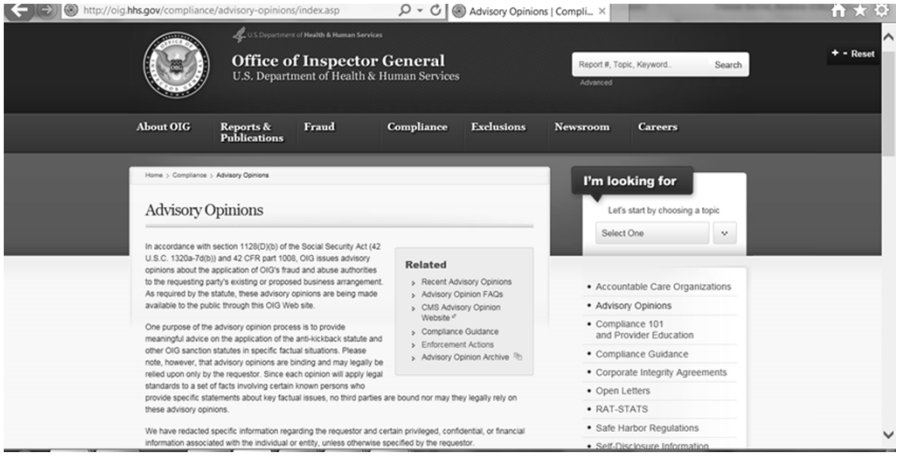
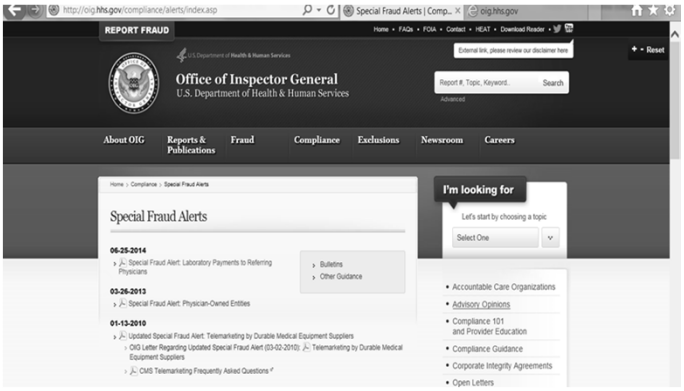
Advisory Opinions



Special Fraud Alerts

June 25, 2014

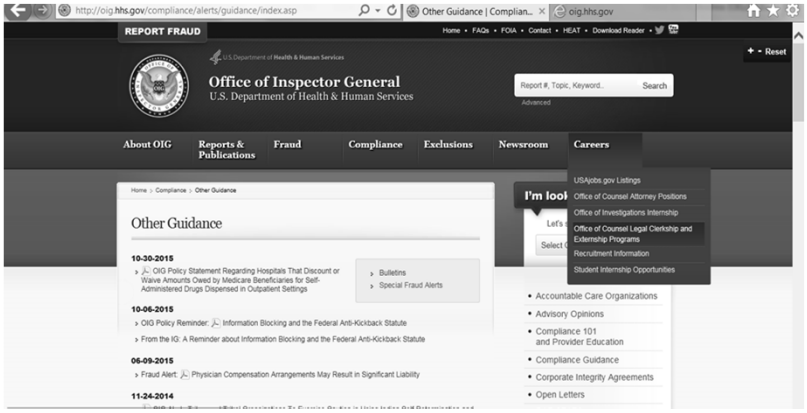
Laboratory Payments to Referring Physicians



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

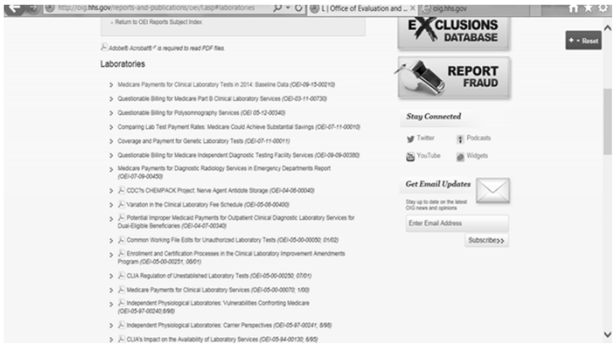
Questionable Billing for Medicare Part B Clinical Laboratory Services

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

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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

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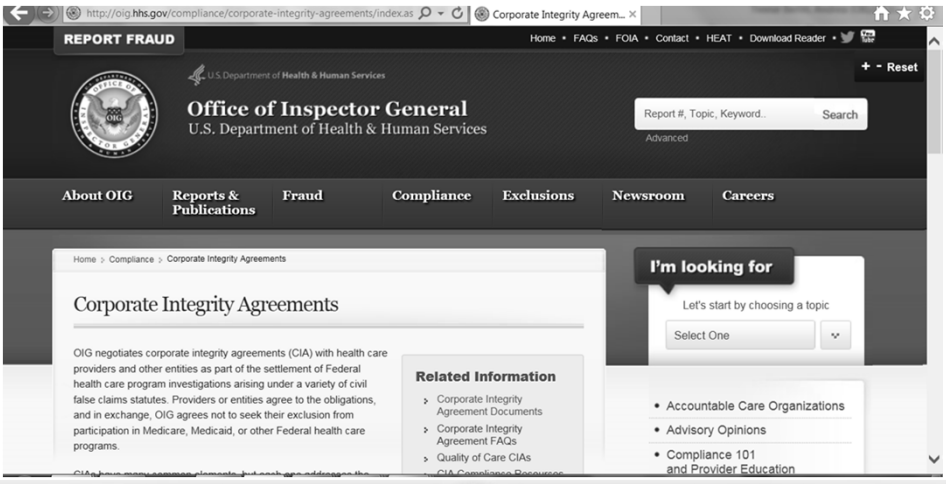
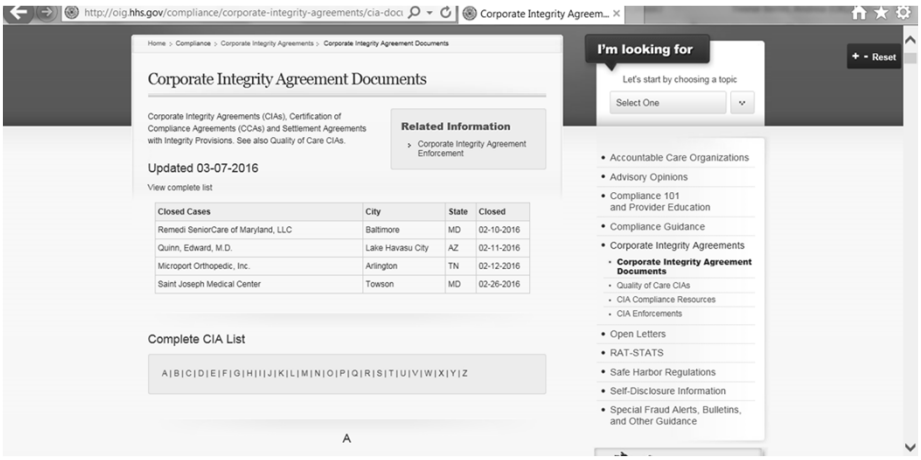
Issues

- Claims
- Arrangements
- Marketing

Corporate Integrity Agreements



Search for Same-Industry CIAs



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 B.	Final Compliance Program Guidance for Clinical Laboratories - 08/1998
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 020116 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

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Compliance Plans- Operationalization
Compliance Officer and Compliance Committee

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

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Compliance Plans- Operationalization
Annual Tasks

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Laboratory Name:	Laboratory Address:	Completed By:

CHI Clinical Laboratory Addendum Annual Responsibilities Checklist FY 2016

As an aid to assist laboratory leadership in completing laboratory addendum review and monitoring expectations, the list below has been compiled to provide general guidance on tasks listed in the addendum which must be completed annually to assure a functioning laboratory compliance program. The results of these reviews and monitor tasks should be documented	Date of Completion	Comments
1. Review any Laboratory Addendum updates after 02/01/YY with laboratory compliance committee and laboratory staff.		
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.		
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.		
4. Review the Office of the Inspector General (OIG) annual work plan at: http://oig.hhs.gov/reports-and-publications/workplan/index.asp You can sign up for automatic notification of the yearly publication at: OIG Work Plan notification		

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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.** a. This report should also include the status of accomplishing the responsibilities listed in the addendum for the Laboratory Compliance Officer and the Laboratory Compliance Committee as listed in **Appendix F**.		
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 computers 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 1-1e, 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.catholichealth.net/gm/document-1.9.3069501/CHI_Laboratory_Compliance_Addendum_FINAL_02.01.16.pdf

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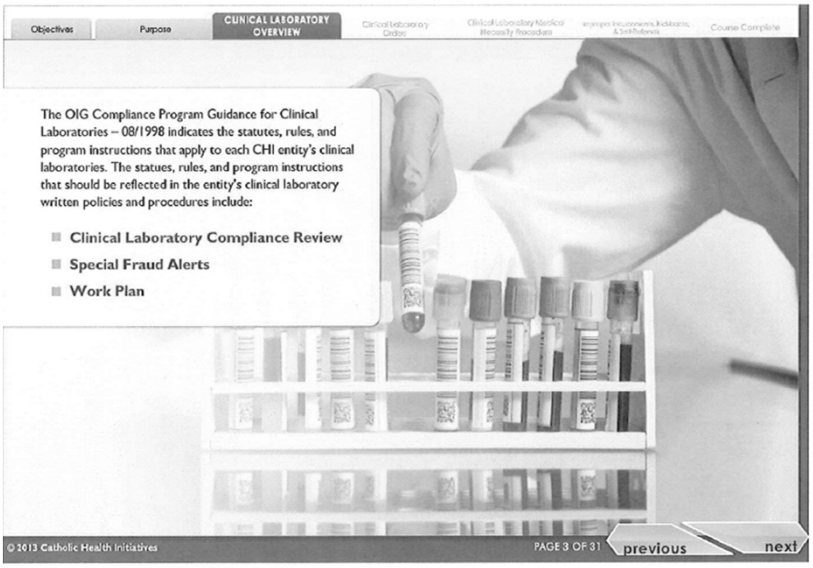
Compliance Plans- Operationalization
Staff Education and Competency



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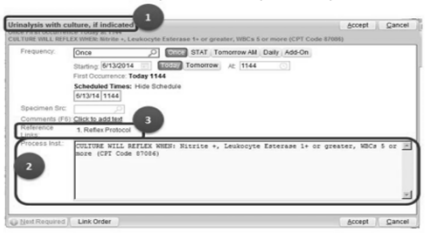
Compliance Plans- Operationalization
Reflex Testing

Decision Document:

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

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



1	**Option 1: Build the reflex tests into the name of the orderable procedures** Example: Urinalysis with culture, if indicated Urinalysis with culture, if indicated Once First occurrence Today at 1144 **Consideration:** 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, longer reflex protocols would clutter up the name field and might inadvertently degrade the validity of search results for providers making it more difficult to find the test they want to order.
2	**Option 2:** Build the reflex protocols into the process instructions of the orderable procedures. Example: CULTURE WILL REFLEX WHEN: Nitrate +, etc...

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Compliance Plans- Operationalization
Reflex Testing

	Process Inst: CULTURE WILL REFLEX WHEN: Nitrite +, Leukocyte Esterase 1+ or greater, WBCs 5 or more (CPT Code 87086) **Considerations:** This has the added benefit of displaying additional information around the specific parameters of when the additional test will be reflexed. This does not require a converged policy on reflex tests because we can display different process instructions in each region. This does require significantly more maintenance as any changes to policy would need to be built in each individual procedure per region.
3	**Option 3: Link out the reflex protocol in the orderable procedure.** Example: Link to Reflex Protocol Reference Links: 1. Reflex Protocol **Considerations:** This option would be easiest to implement from a maintenance perspective. You would build the links to the appropriate protocols in the EAP one time. Any updates to those protocols would be updated in the linked information. This would ensure that there would be no mismatches in what is built in Epic and what the protocols are because we are linking directly to the protocols. However, the parameters around when a test would be reflexed are not displayed directly to the ordering user.

Recommendation: Option 2
Option 2 provides maximum specificity and maximum flexibility across the regional deployments. We can display different SmartTexts 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.

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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

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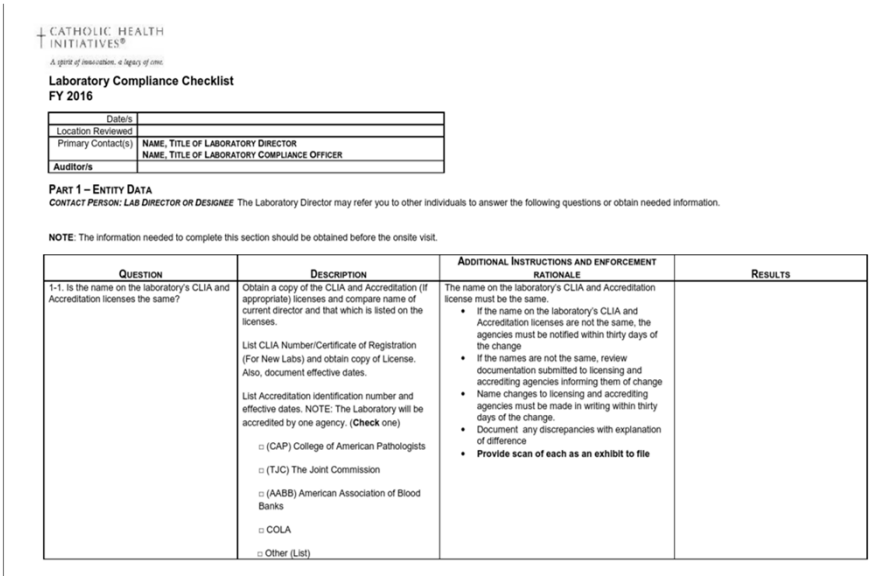
Compliance Plans- Operationalization
Monitoring



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Laboratory Compliance Checklist
FY 2016

Date/s	
Location Reviewed	
Primary Contact(s)	NAME, TITLE OF LABORATORY DIRECTOR NAME, TITLE OF LABORATORY COMPLIANCE OFFICER
Auditor/s	

PART 1 – ENTITY DATA

CONTACT PERSON: LAB DIRECTOR OR DESIGNEE The Laboratory Director may refer you to other individuals to answer the following questions or obtain needed information.

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

QUESTION	DESCRIPTION	ADDITIONAL INSTRUCTIONS AND ENFORCEMENT RATIONALE	RESULTS
1-1. Is the name on the laboratory's CLIA and Accreditation licenses the same?	Obtain a copy of the CLIA and Accreditation (if appropriate) licenses and compare name of current director and that which is listed on the licenses. List CLIA Number/Certificate of Registration (For New Labs) and obtain copy of License. Also, document effective dates. List Accreditation identification number and effective dates. NOTE: The Laboratory will be accredited by one agency. (**Check** one) □ (CAP) College of American Pathologists □ (TJC) The Joint Commission □ (AABB) American Association of Blood Banks □ COLA □ Other (List)	The name on the laboratory's CLIA and Accreditation license must be the same. • If the name on the laboratory's CLIA and Accreditation licenses are not the same, the agencies must be notified within thirty days of the change • If the names are not the same, review documentation submitted to licensing and accrediting agencies informing them of change • Name changes to licensing and accrediting agencies must be made in writing within thirty days of the change. • Document any discrepancies with explanation of difference • **Provide scan of each as an exhibit to file**	

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Compliance Plans- Operationalization
Monitoring

Question	Description	Additional Instructions and Enforcement Rationale	Results
Is the person(s) signing off on the testing personnel's competency qualified per CLIA requirements (see Linked CLIA Regulations)?	Review the qualification of the person/s signing off on testing personnel's competency to confirm that he/she qualifies as described in the links to the right.	6. Ensure that the six competency criteria listed in the PDF to right are included in the competency evaluations. Reviewer qualifies as General Supervisor? High Complex Laboratories CLIA REGULATIONS Subpart M 493.1461 (At least an associates with 2yr of lab experience) Review Qualifications for Technical Consultant Moderate complexity Laboratories CLIA REGULATIONS Subpart M 493.1411 (At least BS and two years lab experience) NOTE: Waived laboratories have no personnel requirements.	
3-6. 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)	Document that each of the personnel files reviewed in 3-5 (Testing personnel only) contains transcripts or Diploma verifying highest educational level.	Testing personnel are anyone who actually performs laboratory tests. Note: Phlebotomists (Persons who obtain blood samples from patients) are generally not included unless they perform some basic testing such as point of care (finger stick glucoses, bleeding times) by the patient's side. Ask director of their laboratory's use of phlebotomists and or use of nursing staff on patient care units for moderate and above testing.	SC10_07.CLIAPersonnel_Consolidated.pc Staff_Record_Review.xlsx ***Record*** **review should be documented either on the attached form or an equivalent**

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Compliance Plans- Operationalization
Monitoring

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

If the information on the license is not accurate, confirm and document (use box to the right) that appropriate agencies have been notified of change. i.e. new director, moved (Document Correct Information) Note: Licenses are generally not updated immediately, normally updates are made on a two year payment renewal cycle.	Name of Agency notified and date of the notification. List any other comments if necessary:			
CLIA/state license # as it appears on license :				**Questions/Clarifications/Follow-up as needed, please contact:**
Name of lab as it appears on the CLIA/state license and any correction:	**Yellow Highlight EachTest Done At This Lab**			**Tim Murray**
Lab Address as it appeared on the license and any correction:	Cholesterol	Prothrombin Time		**Director, Laboratory Compliance**
	Fecal Occult Blood	Rapid Strep		**Catholic Health Initiatives**
	Glucose	Sedimentation Rate		**Ph 610-594-5102**
	Hemoglobin	Urinalysis Dipstick		timothymurray@catholichealth.net
Consultant Name (If Any) :	Hemoglobin AC1	Urine Pregnancy		
Testing personnel Interviewed:	Hematocrit	**OthersList to Right**		
Name of Laboratory Contact:	Influenza			
Laboratory Contact Number:	Lyme Disease			Rev 9-15
Date Assessment Completed:	Ovulation			
	Place "X "in Box for Answer			
FY 2016 - Waived Testing Assessment	**YES**	**NO**	**N/A**	**Additional guidance and answers to the NON Yes/No questions:**
1.Are all tests performed classified as waived? §§493.15(c), and 493.1775(b)(3)**See below for abbreviated list of waived tests**				
Cholesterol, Fecal Occult Blood, Glucose , Hemoglobin, Hemoglobin A1C, Hematocrit, Influenza, Lyme Disease, Ovulation, Prothrombin Time, Rapid Strep, Sedimentation Rate, Urinalysis Dipstick, Urine Pregnancy				
2. Does the laboratory have the current manufacturer's instructions for all tests performed?				Evidence of Compliance (Click on tab for interpretation.)
3. Does the laboratory follow the current manufacturer's instructions for all tests performed by:				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?				

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Compliance Plans- Operationalization
Monitoring

Waived Testing Assessment

h2)Corrective action if out of range?				
i) Reporting the patients' test results with the terminology or in the units described in the package insert?				
j) Performing and documenting instrument maintenance as described by the manufacturer?				
4. Does the testing personnel understand the manufacturer's instructions for all tests performed?				Use information from 3 above for subjective assessment
5. Does the testing personnel:				
a) Document the name of the test, reagent/control lot number, and expiration date for all tests performed?				Recommended (Evidence of Compliance)
b) Are laboratory personnel given training when they are newly hired?				Please describe i.e. OJT/vendor training
b1)If answered YES to 5 b, how is the training documented?				
6. Are testing staff:				
a) Observed or evaluated to assure they can provide accurate and reliable testing?				
a1)If answered YES to 6 a, how is the observation/evaluation documented?				
b)Shown how to document the patient's test results?				Evidence of Compliance (Click on tab for interpretation.)
c) Shown how to identify inaccurate results and/or test system or device problems?				
d) Shown how to handle inaccurate results or device problems?				Staff should verbalize that patient results would not be reported until all quality checks are within manufacturers specifications.
7. Are the testing personnel informed when there's a change in the test procedure or if there's a new test kit?				Evidence of Compliance (Click on tab for interpretation.)
a)If answered YES to 7, how is that process documented?				
b) Does the laboratory routinely check incoming package inserts to ensure there have been no changes in the product or procedure?				
c) Are all the products clearly labeled to advise of a revision?				Evidence of Compliance (Click on tab for interpretation.)
8.Have the testing personnel ever been asked to repeat a waived test?				
a)If yes, was the second result different than the original result?				
b)If the second result was different from the first result, what result did the physician use?				
9. Does the laboratory phlebotomy/testing staff:				
a) Check patient identification?				Conversation confirms that two patient identifiers must be used
a1)Is there a written procedure?				Best practice
b) Collect the proper specimen for the test requested?				Evidence of Compliance (Click on tab for interpretation.)
b1)Is there a written procedure?				Best practice not required
c) Require a Lab order (On patient's chart or hard copy) before performing a test?				Evidence of Compliance (Click on tab for interpretation.)

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Compliance Plans- Operationalization
Monitoring

Evidence of Compliance Red= extra emphasis and review

Question Number

2. Ask interviewee to show you the current package insert and demonstrate how he/she knows that is most current.

3. Choose a representative test ask the interviewee to walk through the procedure with you and point out the items listed in lines 3a-j

Look at Test Kit and individual components and check to see that all are within expiration date

Look at control results and confirm that they are within the manufacturer's expectations

Look at temperature records and compare to manufacturer's storage requirements (room temp, refrigerated and frozen where appropriate) Recommend that acceptable temp ranges be included on documentation chart

If any of the above are not within expected parameters investigate what the corrective action was and review with interviewee the "follow-up actions. (See below)

i.e. Patients not reported, called manufacturer to troubleshoot, told supervisor/lab director, if temperatures were off, moved specimens/reagents to an acceptable temperature controlled area

5a. Seperate documentation of this information is not required but ask how the lab would handle identifying patients tested using a recalled defective test kit?

6b,c,d. Ask interviewee to demonstrate how results are entered/documented in patient chart, How they would troubleshoot bad controls or instrument readings?

7. Testing staff should verbalize that they review each new kit instructions for changes or that their supervisor informs and educates them of new changes. Someone MUST review each new insert for changes. (Best practice documents that fact)

9b. Ask staff to show you in the manufacturer's insert where the manufacturer describes the correct specimen to collect for analysis.

9c. Ask testing staff to show you evidence of a typical test order.

9e.Log is not required (Best Practice) but interviewee needs to be able to verbalize how to confirm to an inspector or the laboratory medical director that controls were acceptable after the fact (days, weeks later)

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

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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.

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

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 PPS 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

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

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

Entity Location Details	
Initiation date	Click here to enter a date.
Entity Name	Enter MBO Name
Hospital/Location(s) and City, State	Enter Hospital Name and Locations (as applicable) and City, State
Entity Project Owner	Enter Name here
Entity Laboratory Director Name	Enter Name here
Entity Laboratory Department Administrative Executive (VP)	Enter Name here
Entity CRO Name	Enter Name here

Project Details	
What billing discrepancy was identified at the entity? Include details test name, billing identification number, HCPCS code.	
Describe the issue that was identified here.	
How was the Issue Identified?	
Explain how the issue was identified here	
What caused the Issue?	
Explain what caused the billing discrepancy here	
Was the Issue corrected?	Choose an item.
If Yes, When was the Issue corrected?	Click here to enter a date.
If known, when did the issue start?	Explain the length of time

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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? Normaly 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 payer/s. 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 .	

Version: 06.15.15
Location: M:\Laboratory\Lab_Repayment_Data_Form

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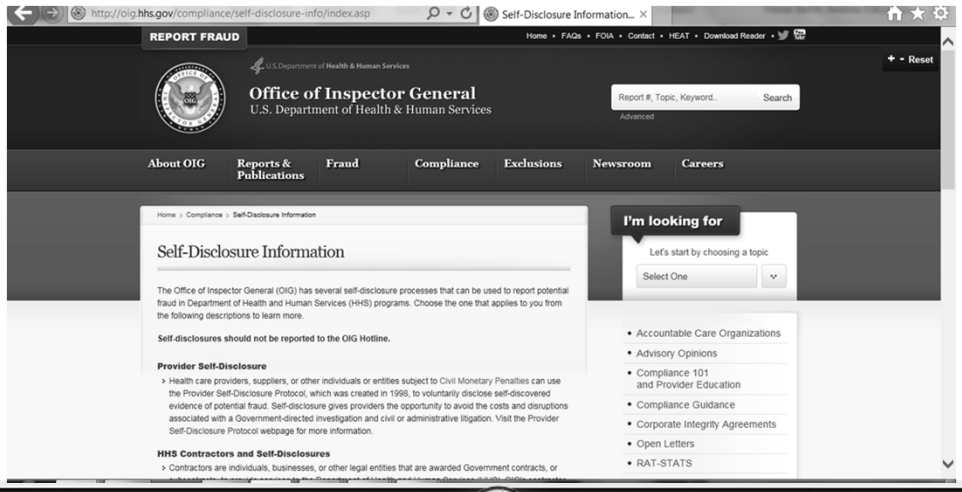
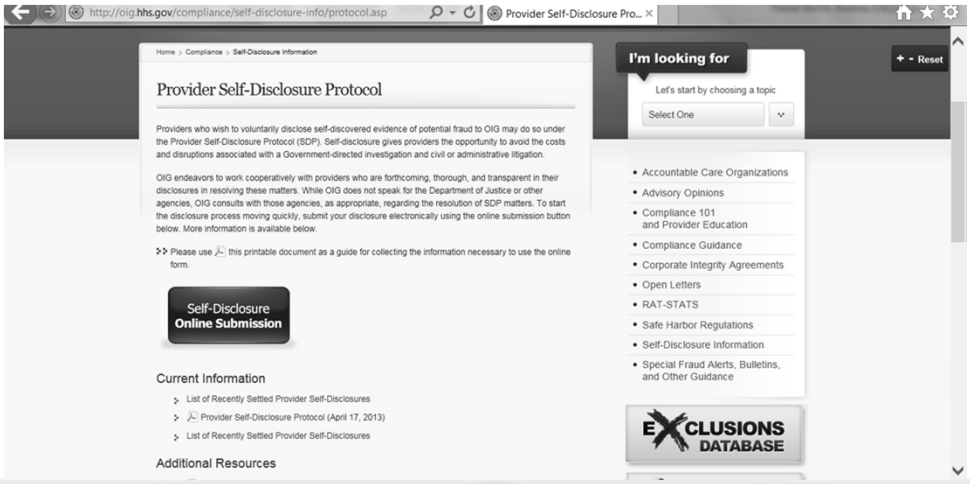
Self-Disclosure

- Should I disclose?
- Where should I disclose?
  - Contractor
  - OIG
  - DOJ
  - CMS
- Get some advice

Self-Disclosure



On-Line Submissions



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

39

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

40

Selected Licensure/Certification Enrollment Issues

41

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

42

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)

43

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

44

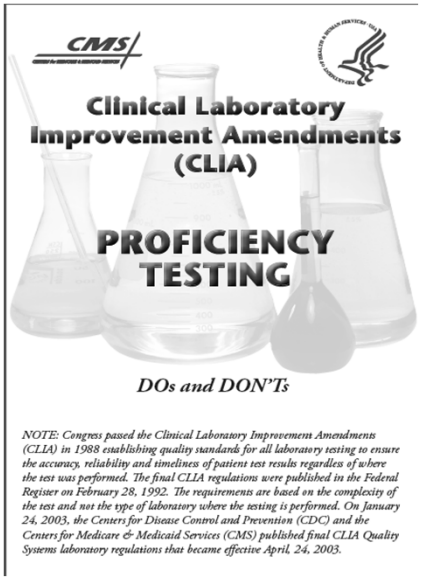
TEST Act Implementation

- 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)

45

Proficiency Testing Referrals



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Proficiency Testing – Electronic Training

CATHOLIC HEALTH INITIATIVES®

A spirit of innovation, a legacy of care.

Laboratory Proficiency Testing

47

Proficiency Testing – Electronic Training

CATHOLIC HEALTH INITIATIVES®

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.**

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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)

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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.

50

Claims for Payment

51

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

52

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

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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

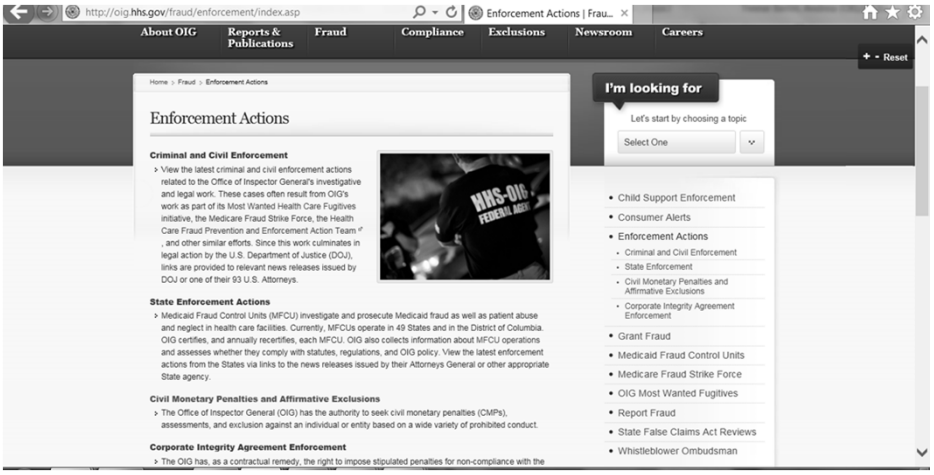
Recent Laboratory CMPs

- 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

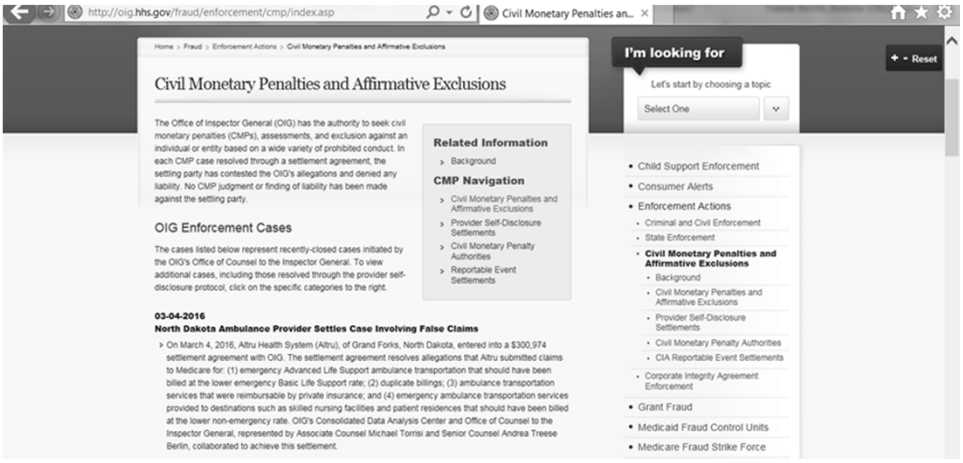
Settlement Details

Provider	Date of Settlement	Settlement Amount
C.F. Health Management, Inc., d/b/a Gainesville Pain Management	5/17/2013	$1,577,597.00
Medicus Laboratories, LLC	2/14/2014	$5,000,000.00
Nabil Attalla Barsoum, M.D.	7/25/2014	$334,528.90
Florida Family Laboratory, Inc	8/5/2014	$197,400.09
Pain Specialists of Greater Chicago	9/10/2014	$590,763.45
Clinical Laboratory Partners	9/29/2014	$145,789.34
Dennis Conrad Harper, M.D.	1/20/2015	$305,168.54
Alan J. Wayne, M.D. and Stevenson Medical Center, Inc.	2/24/2015	$225,000.00
American Institute of Toxicology	7/20/2015	$229,924.74
David Irving Stein, M.D. and Milwaukee Pain Treatment Services	8/14/2015	$374,864.78

Enforcement Actions



CMP Summaries



Exclusions

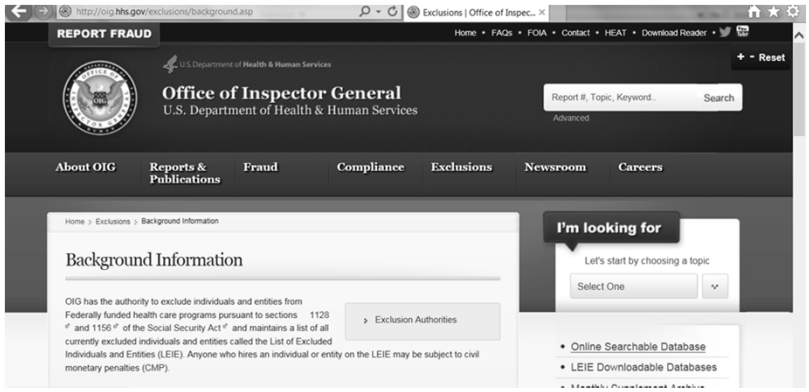
- **Mandatory** (5 year minimum) – Section 1128(a)
  - conviction of "program related" crime
  - conviction of patient abuse & neglect
  - felony conviction of health care fraud
  - felony conviction relating to controlled substances

- **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

63

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.

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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”).

65

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.

66

"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."

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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.

68

U.S. ex rel Kane v. Continuum Health Partners, 2015 W.L. 461 9686 (S.D. N.Y. Aug 3, 2015)

FACTS

Realtor, 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.

69

U.S. ex rel Kane v. Continuum Health Partners, 2015 W.L. 461 9686 (S.D. N.Y. Aug 3, 2015)

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 . . . ."

70

U.S. ex rel Kane v. Continuum Health Partners, 2015 W.L. 461 9686 (S.D. N.Y. Aug 3, 2015)

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.

71

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)

72

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

73

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

74

The Match Game – Billing Issues

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

75

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)

76

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*, No. 1:08-CV-00354 (S.D. Ohio Dec. 18, 2012)

77

Billing Issues

- *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

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The Match Game – Billing Issues

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

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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)

80

Medical Necessity

Corporate Integrity Agreement Between OIG and Millennium Health, LLC

81

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

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. Sebelius,* 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)

83

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)

•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)

84

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.
  - *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

85

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)

86

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

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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

89

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

90

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."

91

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

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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

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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

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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

95

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."

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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.*

98

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)

99

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

100

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)

101

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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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

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

105

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

106

Other Issues

- Stark <u>statutory</u> 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 <u>regulatory</u> 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

108

Pricing Issues for Laboratories

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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

110

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

111

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

112

Recent Enforcement Activity

- *U.S. and California ex rel. Pasqua v. Kan-Di-Ki, LLP et al, dba Diagnostic Laboratories and Radiology*.
  - 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

113

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

114

"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

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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)

116

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

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QUESTIONS?

118