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21st Annual Compliance Institute
March 26-29, 2017

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Maintaining Laboratory Compliance in an Ever Changing Healthcare Regulatory Environment

OR

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Labland, it is NEVER a dull moment!

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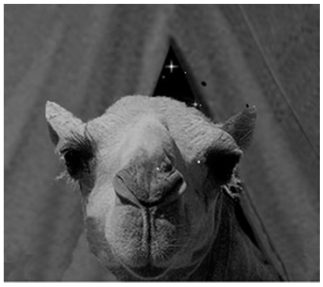
Do you ever feel like this as a compliance professional?



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Compliance Plan Benefits

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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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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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

Compliance Plans - Operationalization Written Policies, Procedures and Standards of Conduct

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
Appendix S Proficiency Testing (PT) Policy Requirements

Printed documents are for reference only. For the most current version refer to Inside CHI, Corporate Responsibility Community, Public Folders, Laboratory, Addendum
Laboratory Compliance CRP Plan Addendum Effective Date: 02/01/14 Addendum Revised 02/01/17 Annual Review 02/01/17

Compliance Plans- Operationalization
Staff Education and Competency

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Compliance Plans – Operationalization
Annual Tasks

Laboratory Name:	Laboratory Address:	Completed By:	
CHI Clinical Laboratory Addendum Annual Responsibilities Checklist FY 2017			
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			

Compliance Plans – Operationalization
Annual Tasks

Laboratory Name:	Laboratory Address:	Completed By:	
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**			

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Compliance Plans – Operationalization Annual Tasks

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Laboratory Name:	Laboratory Address:	Completed By:

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 in the CHI CRP Policy. The results of this monitor will be reported to the entity CRO. **Appendix N**	
12. Review **Appendix S** Proficiency Testing Procedure Requirement and ensure that current policy meets the expectations within that Appendix	

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 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

Laboratory Compliance Checklist
FY 2017

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 Identified 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 A1C	Urine Pregnancy		
Testing personnel interviewed:	Hemoccult	[illegible]		
Name of Laboratory Contact:	Influenza			
Laboratory Contact Number:	Lyme Disease			Rev 9-16
Date Assessment Completed:	Ovulation			
	Place "X" in Box for Answer			
FY 2017 - 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, Hemoccult, 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

h) 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 # 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.)

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. Separate 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)								

OIG Work Plan for 2017

- OIG will review payments to independent labs to determine compliance with selected billing requirements
- Billing of Lab Services in 2016
- Histocompatibility Lab Billing
- Protecting Access to Medicare Act (PAMA) & Medicare Access and CHIP Reauthorization Act (MACRA) Implementation

Internal Monitoring and Auditing

Annually the National Laboratory Compliance Committee reviews the OIG Work Plan and develops system wide monitoring for each moderate and above CLIA Laboratory.

- Each laboratory leader will be asked to review three months (July 1, 2016 - September 30, 2016) outpatient lab account data as the initial data set. Ten (10) accounts will be randomly selected from each month (total of 30 accounts). Each laboratory leader will be asked to review each of the thirty (30) randomly chosen laboratory accounts looking at the actual provider order versus the result report versus the bill versus coding for accuracy. If any systematic errors are discovered, a corrective action statement/plan will need to be submitted to the local CRO and the CHI National Laboratory Compliance Committee. This activity will meet the needs of self-monitoring requirement as described in the Laboratory Compliance Addendum.

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.

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

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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.

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

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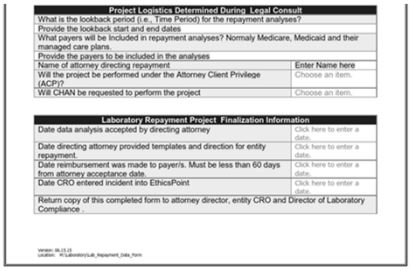
Laboratory Repayment Project Information Form
All information is to be Completed by Project Owner

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

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: W:\Laboratory\Lab_Repayment_Data_Form

Look Back Period

- Regulation applies to any overpayment identified within 6 years of its receipt. For Medicare! 4 years Medicaid, Managed Care Plans, Tricare etc.
- 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.**
- "Credible information' includes information that supports a reasonable belief that an overpayment may have been received."

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Proficiency Testing – Electronic Training

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Laboratory Proficiency Testing

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Proficiency Testing – Electronic Training

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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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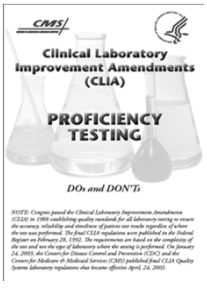
Proficiency Testing (PT) Referrals



Appendix S
Proficiency Testing (PT) Policy Requirements

Besides describing the actual process for handling the PT specimens and how the specimens are to be rotated to different representative testing personnel during all shifts on which those tests are being performed, the PT policy/plan must also include, at a minimum, the following statements:

- The laboratory must not send proficiency testing samples or portions of such samples to another laboratory for analysis.
- The laboratory staff must handle all PT specimens in the same manner as a patient sample.
- There may be no inter laboratory communication concerning a PT challenge until after the challenge cutoff date.

Appendix S (Continued)
Proficiency Testing (PT) Policy Requirements

- PT samples may only be analyzed on primary equipment and may not be analyzed on secondary equipment until after the challenge cutoff date.
- Any laboratory that receives proficiency testing samples from another laboratory for testing must notify Laboratory leadership who will notify CMS of the receipt of those samples.

The plan must also explicitly emphasize that PT challenges are only to be analyzed and reported on behalf of the CLIA licensed laboratory for which they were obtained. Laboratories may not share PT specimens with other licensed CLIA laboratories. Purchased PT samples are tied directly to the CLIA number of the purchasing laboratory and to share that specimen with another laboratory and to report the result of the second laboratory will be interpreted as specimen referral which carries steep penalties.

Proficiency Testing Pitfalls!

- PT Sharing
  - Proficiency testing is assigned by CLIA number and may only be ordered for and reported by that specific number.
    - Owned physician practice laboratories in same or contiguous building
      - Under main laboratory CLIA number
        - » Primary instrument- different PT vendor?
      - Separate CLIA number
    - Owned physician practice laboratories off campus
      - Separate CLIA number
    - Central Monitoring of Owned Physician Practice Laboratories by Hospital Laboratory Staff.
      - Different PT vendors!
      - "Never the twain shall meet"
      - Be leery of networks with multiple laboratory access

Reflex Testing - Common Errors

- 2010 Noridian Administrative Services- Error Rate Testing (CERT) analysis indicates providers are performing additional laboratory services based on a standard written or implied protocol, rather than a patient-specific physician order.
- Complete Blood Count (CBC), CBC with automated Differential, CBC with Automated Differential Reflex

  -Which one?

  Complete Blood Count, automated- 85027

  Complete Blood Count, with differential WBC, automated -85025
- Urinalysis (UA), UA Dipstick, UA with microscopic, UA with Microscopic Reflex, UA with Microscopic Reflex with Culture Reflex - Which one?

Common Errors- Reflex Testing


Decision Document:

Background:

Option 1: Build the reflex tests into the name of the orderable procedures
Example: Urinalysis with culture, if indicated

Considerations:

Option 2: Build the reflex protocols into the process instructions of the orderable procedures.

Common Errors- Incomplete Panels

- Incomplete Panels- Due to lipemia, hemolysis
  - **If all components of an approved panel cannot be performed for whatever reason i.e. due to the condition of the specimen, the full panel may not be billed. Only those components actually analyzed and reported may be billed.**

Common Errors- Environmental Monitoring

- Environmental conditions of storage and testing areas for supplies and equipment must be monitored to ensure that manufacturer required storage conditions are met.
  - Environmental conditions be monitored each day and results documented. Corrective action must be documented if results are not within acceptable limits. This includes weekends and holidays.
    - Humidity
    - Temperature
      - Room
      - Refrigerator
      - Freezer

Common Errors- Personnel Records

- Personnel Policies for Individuals Directing or Performing Non-waived Tests
  - **Educational Credentials 42 CFR, Part 493, Subpart M for**
    - What is required?
      - Transcripts
      - Diplomas
      - PSV primary source verification
        - » Ref: S&C: 16-18- CLIA, April 1, 2016
          - » Bachelor's and Associate's degrees in nursing meet the requirement for earning a degree in a biological science for, respectively, high complexity testing personnel and moderate complexity testing personnel.
          - » Professional certification, such as medical technology certification or nursing licenses IS NOT considered sufficient evidence of meeting the personnel qualifications.

Common Errors- Competency Assessment Who Can Perform?

- Competency documentation of testing personnel
  - Moderate Complex Laboratories
    - Technical Consultant (TC) BS in a chemical, physical or biological science or medical technology -2 years of laboratory training or experience, or both
    - Assignment of responsibilities by Laboratory Medical Director
    - Annual assessment by director
  - High Complex Laboratories
    - Technical Supervisor (TS) Micro, Chem ,bachelor's degree in a chemical, physical or biological science or medical technology- 4 years of laboratory training or experience, or both, in high complexity testing
    - General Supervisor (GS) Associate degree in a laboratory science, or medical laboratory technology-2 years of laboratory training or experience, or both, in high complexity testing
    - Assignment of responsibilities by Laboratory Medical Director
    - Annual assessment by director

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**

Payment for Hospital Outpatient Tests

Packaged into Hospital Outpatient Prospective System unless:

- "Non-patient" test
- No other hospital outpatient services from same "encounter" or
- Removed 1/1/17 :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"

Medicare Reimbursement APC/OPPS Bundled Payments

- **One-two punch!**
  - **Effective January 1, 2017**
    - Expansion of Molecular Pathology Laboratory Test Exception to Include Certain Advanced Diagnostic Laboratory Tests (ADLTs): In CY 2014, we adopted a policy to exclude molecular pathology tests from our laboratory packaging policy.
    - Discontinuation of the 'L1' Modifier: In CY 2014, we created modifier L1 to allow for separate payment of laboratory tests for use when (1) laboratory tests were the only services on the claim, or (2) when the laboratory test or tests were "unrelated" to the other services on the claim, meaning that the laboratory test was ordered by a different physician for a different diagnosis than the other services on the claim.
    - Packaging Based on Claim instead of Based on Date of Service: A hospital stay that may span more than one day are packaged according to OPPS packaging policies.

Protecting Access to Medicare Act 2014 (PAMA)

Second Punch!

Goal of PAMA is to overhaul the Clinical Laboratory Fee Schedule (CLFS). To set new reimbursement rates to match the weighted median of the reported commercial rates paid to large commercial laboratories. CMS estimates that laboratory Medicare revenues will decrease 5.2 Billion over the next 10 years.

After a year delay, CMS published the final rule for implementation of PAMA in the June 23, 2016 Federal Register. The final rule clarifies and changes several key requirements that were in the proposed rule that was released for public comment last fall. There still are a few unanswered questions, but in this briefing, I will give answers according to the information that CMS has released in the final rule and two MLN Matters articles.

It is applicable WHAT?

Applicable Laboratories

- Have a CLIA Certification
- Bill under their own NPI
- Have a majority of their Medicare revenue come from the CLFS or the PFS.
- Has received over $12,500 in Medicare reimbursement during the 6-month data collection period.

Applicable Data

- The specific HCPCS code associated with the test
- The private payer rate for each test for which final payment has been made during the data collection period.
- The associated volume for each test at each payment rate

PAMA Critical Dates For Applicable Laboratories

Data collection period
- **Jan. 1 through June 30, 2016**

Reporting period
- **Jan. 1 through March 31, 2017**

CMS will publish preliminary CLFS for public comment
- **Early September 2017**

Final CLFS rates published in November 2017
- **Effective Jan. 1, 2018**

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Thank You …..