Laboratory Compliance: Maintaining Compliance in an Uncertain and Changing Environment

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Maintaining Laboratory Compliance in an Uncertain and Changing Healthcare Regulatory Environment

OR
Labland, it is **NEVER** a dull moment!

Do you ever feel like this as a compliance professional?
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.

Compliance – Overall Purpose of Compliance Programs

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

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

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 Report System
Appendix J  Clinical Laboratory Orders/Ordering Procedure
## Compliance Plans - Operationalization

**Written Policies, Procedures and Standards of Conduct**

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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: 02/01/18-Annual Review: 02/01/18

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## Compliance Plans - Operationalization

**Staff Education and Competency**

The OKI Compliance Program Guidance for Clinical Laboratories - 081998 indicates the standards, rules, and program instructions that apply to each CHI entity’s clinical laboratories. The enact, rules, and program instructions that should be reflected in the entity’s clinical laboratory website policies and procedures include:

- Clinical Laboratory Compliance Review
- Special Fraud Alerts
- Work Plan
### Compliance Plans – Operationalization

#### Annual Tasks

<table>
<thead>
<tr>
<th>Laboratory Name</th>
<th>Laboratory Address</th>
<th>Completed By</th>
</tr>
</thead>
</table>

**CHI Clinical Laboratory Addendum Annual Responsibilities Checklist CY 2018**

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 in the entity

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:
   

   You can sign up for automatic notification of the yearly publication at:

   OIG Work Plan notification

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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. Any laboratory results “Internal or outside” transcribed manually into the health record must be validated and comply with **Appendix K.**

9. 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 N**
Compliance Plans – Operationalization

Annual Tasks

<table>
<thead>
<tr>
<th>Laboratory Name:</th>
<th>Laboratory Address:</th>
<th>Completed By:</th>
</tr>
</thead>
</table>

10. Laboratory supplies furnished to referral sources are tracked to ensure that said supplies are provided in quantities that are appropriate. [Appendix O]

11. If appropriate, the results of the periodic monitoring of computers and interface contracts as required by the entity policy. [Appendix O]

12. Review any local CRO approved referral source gifts as they apply to CHI CRP Policy. View Items 1-2e in the CHI CRP Policy. The results of this monitor will be reported to the entity CRO. [Appendix O]

13. Report any non-routine information requests from governmental or accrediting agencies to Corporate responsibility. [Appendix R]

14. Review the Proficiency Testing Procedure Requirement and ensure that current policy meets the expectations within that Appendix.

[HIPAA Privacy Self-Assessment Checklist]

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

Laboratory Compliance Addendum

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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 10% of the POLs annually
  - Purpose was to make typically non-professional laboratorians aware that there were testing requirements
## Compliance Plans - Operationalization Monitoring

### Laboratory Compliance Checklist
**FY 2018**

### 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.

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Additional Instructions and Enforcement NB Required</th>
<th>Results</th>
</tr>
</thead>
</table>
| 1.1. Is the name on the laboratory’s CLIA and accreditation licenses the same? | Obtain a copy of the CLIA and Accreditation of applicable licenses and compare name of current director and that which is listed on the licenses. | List CLIA Number/Certificate of Registration (if new lab) 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): | The name on the laboratory’s CLIA and Accreditation licenses must be the same:  
- If the name on the laboratory’s CLIA and Accreditation licenses are not the same, the agencies must be notified within thirty days of the change.  
- If names are not the same, review documentation submitted to licensing and accrediting agencies containing both names. Name changes to licensing and accrediting agencies must be made in writing within thirty days of the change.  
- Document any discrepancies with explanation and resolution. | Provide scan of each as an exhibit to file. |

### Compliance Plans - Operationalization Monitoring

Is the person(s) signing off on the testing personnel’s competency qualified per CLIA requirements? (see 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.

Reviser qualifies as General Supervisor? High Complex Laboratories

CLIA REGULATIONS Subpart M 493.1411 (At least BS and two years 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 a Diploma or primary source verification (PSV) 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 3.6 (Testing personnel only) contains transcripts, Diploma or PSV 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 glucometers, 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.

Record of review should be documented either on the attached form or an equivalent.
### FY 2018 - Waived Testing Assessment

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Additional guidance and answers to the NON Yes/No questions:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Use information from 8 above for subjective assessments.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Evidence of Compliance (Click on tab for interpretation.)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Evidence of Compliance (Click on tab for interpretation.)</td>
</tr>
</tbody>
</table>

#### Compliance Plans - Operationalization

**Monitoring**

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

**Name of Agency notified and date of notification:**

- **Lab Address as it appears on the license and any correction:**
- **Name of Laboratory Contact:**
- **Consultant Name (If Any):**
- **Lab Address as it appeared on the license and any correction:**
- **Laboratory Contact Number:**
- **Date Assessment Completed:**

**1. Are all tests performed classified as waived? §§493.15(c), and 493.1775(b)(3)**

- **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:**

<table>
<thead>
<tr>
<th>a) Using the appropriate specimen?</th>
<th>Evidence of Compliance (Click on tab for interpretation.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>b) Adding the required reagents in the prescribed order?</td>
<td>Evidence of Compliance (Click on tab for interpretation.)</td>
</tr>
<tr>
<td>c) Adhering to the manufacturer's storage and handling instructions?</td>
<td>Evidence of Compliance (Click on tab for interpretation.)</td>
</tr>
</tbody>
</table>

**4. Are testing staff:**

| DO activity in 3. above result in accurate and reliable testing? | evidence of Compliance (Click on tab for interpretation.) |
| All staff activities that generate results would not be reported unless quality control checks are within manufacturer specifications. |
| All staff activities that generate results would not be reported unless quality control checks are within manufacturer specifications. |

**5. Are the test results:**

| Consistent with the test results? | Evidence of Compliance (Click on tab for interpretation.) |
| Are the test results consistent with the physician's order? | Evidence of Compliance (Click on tab for interpretation.) |
| Are the test results consistent with the patient's condition? | Evidence of Compliance (Click on tab for interpretation.) |

**6. Does the laboratory ensure that patients' test results are communicated to the requesting physician?**

| Evidence of Compliance (Click on tab for interpretation.) |
| Evidence of Compliance (Click on tab for interpretation.) |

**7. Does the laboratory include all test results in the patient's health record?**

| Evidence of Compliance (Click on tab for interpretation.) |
| Evidence of Compliance (Click on tab for interpretation.) |

**8. Are all test results within the normal range?**

| Evidence of Compliance (Click on tab for interpretation.) |

**9. Does the laboratory take steps to ensure that patient identifiable information is protected?**

| Evidence of Compliance (Click on tab for interpretation.) |

**10. Does the laboratory take steps to ensure that test results are protected?**

| Evidence of Compliance (Click on tab for interpretation.) |

**11. Does the laboratory take steps to ensure that test results are protected?**

| Evidence of Compliance (Click on tab for interpretation.) |

**12. Does the laboratory take steps to ensure that test results are protected?**

| Evidence of Compliance (Click on tab for interpretation.) |

**13. Does the laboratory take steps to ensure that test results are protected?**

| Evidence of Compliance (Click on tab for interpretation.) |

**14. Does the laboratory take steps to ensure that test results are protected?**

| Evidence of Compliance (Click on tab for interpretation.) |
### Compliance Plans - Operationalization Monitoring

<table>
<thead>
<tr>
<th>Evidence of Compliance</th>
<th>Red - extra emphasis and review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question Number</td>
<td></td>
</tr>
<tr>
<td>2. Ask interviewee to show you the current package insert and demonstrate how he/she knows that is most current.</td>
<td></td>
</tr>
<tr>
<td>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</td>
<td></td>
</tr>
<tr>
<td>Look at Test Kit and individual components and check to see that all are within expiration date</td>
<td></td>
</tr>
<tr>
<td>Look at control results and confirm that they are within the manufacturer's expectations</td>
<td></td>
</tr>
<tr>
<td>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</td>
<td></td>
</tr>
<tr>
<td>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)</td>
<td></td>
</tr>
<tr>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>

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) | |

8b. Ask staff to show you in the manufacturer's insert where the manufacturer describes the correct specimen to collect for analysis. | |

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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### OIG Work Plan for 2018

**How do we develop our monitoring plan?**

- As of June 15, 2017 the OIG will update its work plan website monthly rather than twice per year.
- Focus Areas - Corporate Integrity Agreements - Whistle Blower Activities
  - Billing and coding of lab services.
    - Ensuring Program Integrity - Reducing Improper payments
    - Review fraud alerts
  - Ordering and Medical Necessity
    - Ensuring Program Integrity - Reducing Improper payments
    - Review fraud alerts
Internal Monitoring and Auditing

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

- This year the National Laboratory Compliance Committee has reconfigured the process and with the auditing assistance of CHAN Healthcare (CHAN), have chosen to focus on three high risk/high volume laboratory tests. The selected tests for review are Complete Blood Count (CBC) with or without automated differential, Urinalysis (UA) with or without microscopic for the time period 10/1/2015 to 9/30/2017 and Urine Drug Screen coding during the time period of 1/1/2011 and 12/31/2015 confirming the correct assignment of the following codes:
  - G0431 Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay)
  - G0434 Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter

- Utilizing available laboratory volume data contained in the CHI billing repository for these three tests, CHI Laboratory Compliance will select a sample group of laboratories for which a CHAN representative will inquire further requesting more in depth information and documentation and review process and practice with laboratory leadership.

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

SAMPLE

Dear Laboratory Administrative Director:

A potential laboratory miscoding error has been identified in your laboratory charge description master (CDM) that may potentially end in governmental plan repayment. In order to be 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 and the Director of Laboratory Compliance will be set up by the Entity CRO after Items 1 and 2 below are accomplished. The purpose of this meeting will be direct analysis, develop an action plan and assign responsibilities on a go forward basis.
Simultaneously you should:

1. Identify the date that the correction of the error was completed, implemented and confirmed.
2. Determine when the error first occurred if possible for example there was a software change, new test initiated and assigned an incorrect code or old code discovered to be incorrect.
3. Legal will hear the presented information and determine a repayment corrective action if necessary.
4. If repayment is determined, legal will direct that the identification of all non-bundled (Post 1/2014) and all (Pre 1/2014) out and non-patients from 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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Compliance Plans - Operationalization
When Errors are Discovered – What to do?

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.”

Proficiency Testing – Electronic Training

Laboratory Proficiency Testing
Proficiency Testing – Electronic Training

Remember:

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

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

Proficiency Testing (PT) Referrals

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NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results, regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the proficiency of the test and are the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) published final CLIA Quality System Laboratory regulations that become effective April 24, 2005.
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:
Options for alerting Providers at the time of ordering of a potential reflex test.

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

1. Option 1: Build the reflex text into the name of the orderable procedures. Example: SMA10 with culture, if indicated.

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

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

Example: CULTURE WILL REFLEX WHEN BLOOD + HEG...
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? CMS going to Correct?

• 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

One-two punch!

All laboratory testing is Packaged into Hospital Outpatient Prospective System on the same 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.

• Unless:
  - “Non-patient” test
  - No other hospital outpatient services from same “encounter” or

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

These exceptions will be paid according to the CLFS

Medicare Reimbursement APC/OPPS Bundled Payments

- Effective January 1, 2018

  • From the 14 day rule in 2017 for molecular and ADLTs to the CY 2018 OPPS/ASC Final Rule: This new exception to the laboratory DOS policy permits independent laboratories to bill Medicare directly for molecular pathology tests and Advanced Diagnostic Laboratory Tests (ADLTs), which are excluded from the OPPS packaging policy, if the specimen was collected from a hospital outpatient during a hospital outpatient encounter and the test was performed following the patient’s discharge from the hospital outpatient department.
Protecting Access to Medicare Act 2014 (PAMA)

Second Punch!

- PAMA reimbursement went into effect 1/1/18

- 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.

Thank You .....