Maintaining Laboratory Compliance in an Ever 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 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: CRF Reporting System
Appendix J: Clinical Laboratory Orders/Ordering Procedure

Appendix K: Clinical Laboratory Medical Necessity Procedure
Appendix L: Clinical Laboratory Billing Procedure
Appendix M: Clinical Laboratory Billing Procedure
Appendix N: Marketing, Sales and Business Development of Laboratory
Appendix O: Service Procedure, Improper Inducements, Kickback and Self-Referrals
Appendix P: Clinical Laboratory Research Procedure
Appendix Q: Application for Laboratory License (CLIA) License
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

Annual Tasks

• 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
Evidence of Compliance

<table>
<thead>
<tr>
<th>Question Number</th>
<th>Compliance Plan</th>
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<tbody>
<tr>
<td>2. Ask interviewee to show you the current package insert and demonstrate how he/she knows that is most current.</td>
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<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>
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<tr>
<td>Look at Test Kit and individual components and check to see that all are within expiration date</td>
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<tr>
<td>Look at control results and confirm that they are within the manufacturer’s expectations</td>
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<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>
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<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>
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<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>
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<td>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?</td>
<td></td>
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<tr>
<td>6b,c,d. Ask interviewee to demonstrate how results are entered/documented in patient chart, How they would troubleshoot bad controls or instrument readings?</td>
<td></td>
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<tr>
<td>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. (Best practice documents that fact)</td>
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<tr>
<td>9b. Ask staff to show you in the manufacturer’s insert where the manufacturer describes the correct specimen to collect for analysis.</td>
<td></td>
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<tr>
<td>9c. Ask testing staff to show you evidence of a typical test order.</td>
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<tr>
<td>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)</td>
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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 of the three months. Fifty (50) accounts will be 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 CIO 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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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

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
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

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: SAC: 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) MS or BS 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
Thank You ....