CATHOLIC HEALTH INITIATIVES

Lessons Learned Implementing a Laboratory Compliance Program in a National Healthcare System

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Catholic Health Initiatives

Catholic Health Initiatives (CHI) Denver based national health care system with 87 Hospitals and growing,16 LTCs, over 500 (CLIA) Clinical Laboratories most of which are Waived testing laboratories.

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How did I get here?

- Worked as a PA Department of Health examiner, performed state and Medicare surveys within Pennsylvania
- Worked in both university and primary care hospital setting in laboratory leadership positions
  - Most recently at a CHI hospital St. Joseph Medical Center Reading PA as the Director of Laboratories

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How did I get here?

- CLMA Clinical Laboratory Management Association
  - Government Relations Committee
  - Health Care Policy Committee
  - Medicare Billing Issues Committee
  - Legislative Compliance and Reimbursement Committee
  - The Joint Commission Laboratory Advisory Committee
  - Governmental
    - o Pennsylvania Laboratory Advisory Committee
    - o CMS Negotiated Rule Making
      - ❖Developed first 23 National Coverage Decisions

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Lab Advocate Recommendation!

- **Get to know your lab leadership**
  - The lab is not just the black box in the basement that runs itself!
  - Put a laboratory representative on your Hospital Compliance Committee

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The Laboratory is Loaded with Compliance Landmines

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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The Laboratory is Loaded with Compliance Landmines

Why did the OIG develop this guidance for the lab industry?

" As with previously-issued compliance program guidances, we believe that the development of this guidance for clinical laboratories will continue as a positive step towards promoting a higher level of ethical and lawful conduct throughout the entire health care community."

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The Laboratory is Loaded with Compliance Landmines

WHAT ARE LABS WORRIED ABOUT?

- Technical Licensure
  - CMS/State
    - » CLIA Complexity- Waive, Moderate, High
  - Accreditations
    - » The Joint Commission
    - » The College of American Pathologists
    - » COLA
- Billing/Coding
- Provider Interface
  - Supplies
  - Holiday Gifts "Stark"

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The Laboratory is Loaded with Compliance Landmines

WHAT ARE LABS WORRIED ABOUT?

- Fee Schedules- Medicare's Stand
  - Clients
  - Providers
  - Nursing Home
  - Outpatient/Non Patient
- Point of Care Testing usually (moderate and waived testing)
- Staffing Issues

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Why CHI Determined They Needed a Director of Laboratory Compliance

CMS (CLIA) Clinical Laboratory Improvement Amendments as in other healthcare regulations can be UNCLEAR

- **CHI Incident**
  - What happened?
    - CHI owned hospital purchased a local provider's practice which included a moderately complex CLIA licensed laboratory
    - The laboratory received a Proficiency Testing (PT) sample and the Doctor's Office lab staff ordered the tests required … BUT…….

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PART 493—LABORATORY REQUIREMENTS
Subpart H—Participation in Proficiency
Testing for Laboratories Performing Nonwaived Testing

(b) *Standard; Testing of proficiency testing samples.* The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens.

(1) The samples must be examined or tested **with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory,** using the laboratory's routine methods. The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

(2) The laboratory must test samples the same number of times that it **routinely tests patient samples.**

(3) Laboratories that perform tests on proficiency testing samples must **not engage in any inter-laboratory communications** pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

(4) The laboratory **must not send PT samples or portions of samples to another laboratory for any analysis** which it is certified to perform in its own laboratory.

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Some Background Data

As of June 2013, there were 239,922 CLIA certified laboratories. Of these laboratories, 35,035 are required to enroll in an HHS-approved PT program and are subject to all PT regulations.

From 2007 through 2011, there were 41 cases of cited, intentional PT referral. (averaging 8 per year).

How CMS Responded to the CHI Incident

After many appeals and hundreds of thousands of dollars later a settlement was reached. (3/8/12)

- Required CHI to train all lab testing staff (25,0000) according to the CMS published requirements
  - » Pathologists
  - » Contractors
  - » Testing personnel… Nurses, RTs, Lab Techs
  - » Required to Document by CLIA number all laboratories within CHI
- All Medical Directors had to attest to having compliant PT policies (Documentation submitted)

How CMS Responded to the CHI Incident

- Could not have any additional occurrences within twelve months of the settlement corporate wide
  - » If another incident occurred, settlement would be null and void.
- Close referring laboratory
- Prohibited Medical Director of record from acting as laboratory director for 2 years
- The laboratory itself would be closed for a period of two years

Very real potential to have all CLIA licenses revoked

- Regional OIG discussed this possibility

How CHI Responded (Short Term)

Short term

- Engaged legal council
- Investigated incident
- Conducted educational webinars for all CHI entity and laboratory leadership
- Created an electronic educational module to educate laboratory staff on the proficiency testing requirements

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Proficiency Testing Training

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Laboratory Proficiency Testing

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Proficiency Testing

What is proficiency testing?

Proficiency testing or PT is the testing of unknown specimens sent to the laboratory by a CMS approved PT program. Most sets of PT specimens are sent to participating laboratories three times per year. After testing the PT specimens in the same manner as its patient specimens, the laboratory reports its specimen results back to their PT program. The program grades the results using the CLIA grading criteria and sends the laboratory scores reflecting how accurately it performed the testing. CMS and accrediting organizations routinely monitor their laboratories' performance.

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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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How CHI Responded (Short Term)

- Required each laboratory CLIA Medical Director to review and submit their actual proficiency policy
- Required each Medical Director to submit an attestation through corporate office to CMS stating their staff understood the laboratory PT policy

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How CHI Responded (Short Term)

- Each Medical Director was to sign and submit an attestation through corporate office to CMS stating that their laboratory was in compliance with all of the settlement terms
- Hired me 
- http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html #8

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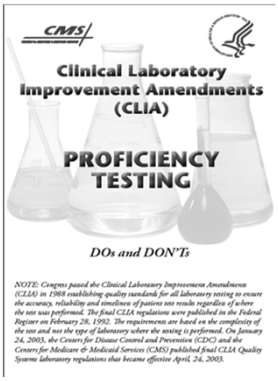
How CHI Responded (Short Term)



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How CHI Responded (Short Term)

- Submitted proof of education of all laboratory staff in the proper handling of proficiency testing
  - Required documentation of competency for all testing personnel (25,000)
  - Waived -- Nurses performing waived POC finger glucoses
  - CHI contested stating not required by regulation to no avail
    - Moderate
    - High Complexity
- Completed 8/1/12 with final submission to CMS
- Follow-up

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How CHI Responded (Long-Term)

- Centralized all compliance functions/staffing using a national model.
- Determined that CHI was responsible for over 500 laboratories most of which were waived.
- Developed an expanded (Online risk assessment) to assess and monitor level of laboratory compliance throughout all CHI Moderate and above licensed CLIA laboratories.

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Annual Risk Assessment

CHI 2013 Laboratory

1. Is a compliance representative responsible for independently investigating and acting on matters related to compliance, including the flexibility to design and coordinate internal investigations and any resulting corrective action? *Citation# 20425*
2. Is the compliance committee responsible for developing a system to solicit, evaluate, and respond to complaints and problems? *Citation# 20616*
3. Is there an open line of communication between the compliance representative and clinical laboratory employees? *Citation# 20611*
4. Has the compliance committee developed several independent reporting paths for an employee to report fraud, waste or abuse so that such reports cannot be diverted by supervisors or other personnel? *Citation# 19735*
5. Is targeted training provided to laboratory leadership, managers and other employees whose actions affect the accuracy of the claims submitted to the Government and private payors, such as employees involved in the coding, billing, and marketing processes? *Citation# 20609*
6. Does the clinical laboratory retain adequate records of its training of employees, including attendance logs and material distributed at training sessions? *Citation# 19828*
7. Does the clinical laboratory perform regular compliance audits by internal or external auditors who have expertise in Federal and state health care statutes,

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Annual Risk Assessment

16. Are physicians or other authorized individuals required to insert diagnosis information for each test ordered on the lab requisition? (2009 NonCAH B.12.h / CAH B.3.f) *Reference# 1340*
17. Does the requisition form require physicians to clearly identify the condition under which a reflex test is ordered? *Citation# 3537*
18. If physicians or clients are allowed to customize profiles, is there a lab policy and procedure addressing appropriate billing of customized profiles? *Citation# 1383*
19. Does the lab require that quality performance be reported to lab management and medical leadership on a regular basis, and is this reporting a key element of laboratory management oversight? *Citation# 2518*
20. Does the lab have a policy and procedures prohibiting the charging of ordered tests that were not performed or not completed? (2009 NonCAH B.12.b / CAH B.3.b) *Reference# 2532*
21. Does the compliance program communicate to physicians that claims submitted for services will only be paid if the service is covered, reasonable, and necessary for the beneficiary? *Citation# 19753*
22. Has the laboratory constructed its requisition form to ensure that the physician or other authorized individual has made an independent medical necessity decision with regard to each test the laboratory will bill? *Citation# 19757*

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Findings of Risk Assessment

- Most CHI laboratories had some form of a compliance plan in place; however, existing plans were varied. Needed to be standardized
- Some did not have a laboratory compliance committee in place
- The majority of laboratory leadership was not involved with or had input into the institutional compliance committee
- Personnel constraints were a major concern for laboratories
- Many were trying to just keep up with new developments in regulation and perform patient testing

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How CHI Responded (Long-Term)

Assembled a CHI Laboratory National Compliance Committee

- **Accomplishments**
  - Developed a national laboratory addendum complimentary to the national CRP plan

CHI Laboratory Compliance Addendum

Corporate Responsibility Program
Clinical Laboratory Addendum

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CHI Laboratory Compliance Addendum

Appendix F
Designation of a Clinical Laboratory Compliance Officer and Clinical Laboratory Compliance Committee

Each CHI entity clinical laboratory(ies) will appoint a Clinical Laboratory Compliance Officer[2] and a Clinical Laboratory Compliance Committee[3] comprised of staff from its operations who will adopt national compliance policies into its local operations. Their responsibilities will include monitoring compliance activities to achieve and maintain a culture of compliance within the operations of the clinical laboratory.

The name of the Clinical Laboratory Compliance Officer is listed in Appendix G. The Clinical Laboratory Compliance Officer, in concert with the Clinical Laboratory Compliance Committee, is the focal point for all clinical laboratory compliance activities and for any questions concerning clinical laboratory compliance policies, procedures and practices.

The clinical laboratory compliance officer's primary responsibilities include[4]:

- Overseeing and monitoring the implementation of the Clinical Laboratory Addendum
- Reporting on a regular basis, at a minimum of annually, to the entity's clinical laboratory leadership, entity CRO, entity Compliance Committee and the CHI Director of Laboratory Compliance on the progress of implementation and utilization of this Addendum in establishing methods to improve the clinical laboratory's efficiency, quality of services, and to reduce the clinical laboratory's vulnerability to fraud, waste and abuse
- Developing and distributing to all affected employees the written clinical laboratory compliance procedures contained in this Addendum and any other entity level compliance polices/procedures
- Coordinating and participating in a multifaceted education and training program that focuses on the elements of this Addendum, and seeks to ensure that all appropriate clinical laboratory staff and management are knowledgeable of, and comply with, pertinent federal, state and private payer standards
- Implementing revisions to the Addendum as directed by CHI's CRP Oversight Committee, the National Laboratory Compliance Committee and/or the Director of Laboratory Compliance to address changes in organizational needs and in the law, policies and procedures of government and private payer health plans

[2] 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).
[3] 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

CHI Laboratory Compliance Addendum

Appendix J
Clinical Laboratory Orders/Ordering Procedure

Orders for clinical laboratory tests and services must be documented and include the elements defined in this procedure.

Only tests that are medically necessary, for the diagnosis or treatment of the patient, may be ordered. Medicare does not generally pay for tests for screening except in limited cases allowed by law, and may not pay for non-FDA approved tests or those tests considered experimental. Orders for clinical laboratory tests will not be changed unless the ordering physician/practitioner has been contacted. Current CLIA requirements state that an ordering physician's/practitioner's signature[8] is not required on a laboratory requisition/request for outpatient/nonpatient clinical laboratory testing unless required by state or local regulation.

1. Standing Orders:
   a. The clinical laboratory bills for properly ordered and documented standing orders and maintains appropriate documentation.
   b. Standing orders are renewed at least annually.
   c. Standing orders must contain a frequency, beginning and end date (i.e., once a week from MM/DD/YYYY to MM/DD/YYYY).
   d. Tests with frequency limitations (i.e., lipid panels) should be reviewed for appropriateness before initiating any standing orders.
   e. If the frequency and/or the test(s) ordered should change during the course of the standing order, a new order must be written.
   f. According to need (PRN) or orders with an annual frequency is not considered a standing order.

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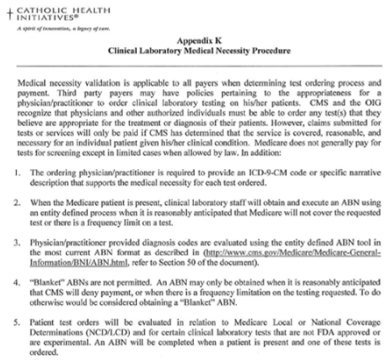
CHI Laboratory Compliance Addendum



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Appendix K
Clinical Laboratory Medical Necessity Procedure

Medical necessity validation is applicable to all payers when determining test ordering process and payment. Third party payers may have policies pertaining to the appropriateness for a physician/practitioner to order clinical laboratory testing on his/her patients. CMS and the OIG recognize that physicians and other authorized individuals must be able to order any test(s) that they believe are appropriate for the treatment or diagnosis of their patients. However, claims submitted for tests or services will only be paid if CMS has determined that the service is covered, reasonable, and necessary for an individual patient given his/her clinical condition. Medicare does not generally pay for tests for screening except in limited cases when allowed by law. In addition:

1. The ordering physician/practitioner is required to provide an ICD-9-CM code or specific narrative description that supports the medical necessity for each test ordered.
2. When the Medicare patient is present, clinical laboratory staff will obtain and execute an ABN using an entity defined process when it is reasonably anticipated that Medicare will not cover the requested test or there is a frequency limit on a test.
3. Physician/practitioner provided diagnosis codes are evaluated using the entity defined ABN tool in the most current ABN format as described in (http://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html, refer to Section 50 of the document).
4. "Blanket" ABNs are not permitted. An ABN may only be obtained when it is reasonably anticipated that CMS will deny payment, or when there is a frequency limitation on the testing requested. To do otherwise would be considered obtaining a "Blanket" ABN.
5. Patient test orders will be evaluated in relation to Medicare Local or National Coverage Determinations (NCD/LCD) and for certain clinical laboratory tests that are not FDA approved or are experimental. An ABN will be completed when a patient is present and one of these tests is ordered.

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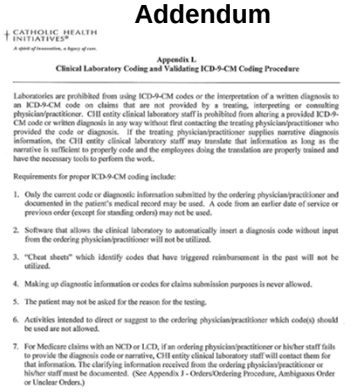
CHI Laboratory Compliance Addendum



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Appendix L
Clinical Laboratory Coding and Validating ICD-9-CM Coding Procedure

Laboratories are prohibited from using ICD-9-CM codes or the interpretation of a written diagnosis to an ICD-9-CM code on claims that are not provided by a treating, interpreting or consulting physician/practitioner. CHI entity clinical laboratory staff is prohibited from altering a provided ICD-9-CM code or written diagnosis in any way without first contacting the treating physician/practitioner who provided the code or diagnosis. If the treating physician/practitioner supplies narrative diagnosis information, the CHI entity clinical laboratory staff may translate that information as long as the narrative is sufficient to properly code and the employees doing the translation are properly trained and have the necessary tools to perform the work.

Requirements for proper ICD-9-CM coding include:

1. Only the current code or diagnostic information submitted by the ordering physician/practitioner and documented in the patient's medical record may be used. A code from an earlier date of service or previous order (except for standing orders) may not be used.
2. Software that allows the clinical laboratory to automatically insert a diagnosis code without input from the ordering physician/practitioner will not be utilized.
3. "Cheat sheets" which identify codes that have triggered reimbursement in the past will not be utilized.
4. Making up diagnostic information or codes for claims submission purposes is never allowed.
5. The patient may not be asked for the reason for the testing.
6. Activities intended to direct or suggest to the ordering physician/practitioner which code(s) should be used are not allowed.
7. For Medicare claims with an NCD or LCD, if an ordering physician/practitioner or his/her staff fails to provide the diagnosis code or narrative, CHI entity clinical laboratory staff will contact them for that information. The clarifying information received from the ordering physician/practitioner or his/her staff must be documented. (See Appendix J - Orders/Ordering Procedure, Ambiguous Order or Unclear Orders.)

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How CHI Responded (Long-Term)

What else did we do?

- Provided Webinars for moderate and above complexity laboratories and invited all laboratorians to attend (Leadership and Bench techs)
- Required each entity to appoint a laboratory compliance officer and committee

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How CHI Responded (Long-Term)

- Required each laboratory to conduct an annual compliance assessment in a multitude of ways
  - External compliance review
  - Internal compliance review
  - Conduct specific education with staff (monthly meetings)
- Required each laboratory to monitor OIG guidance's issued separately or through annual work plan

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How CHI Responded (Long-Term)

- Instructed Laboratory leadership and Staff via Webinars and Addendum Electronic learning as to procedures for proper:
  - Ordering protocols
  - Billing protocols
  - Coding protocols
  - ABN protocols
  - Marketing, sales and contract protocols

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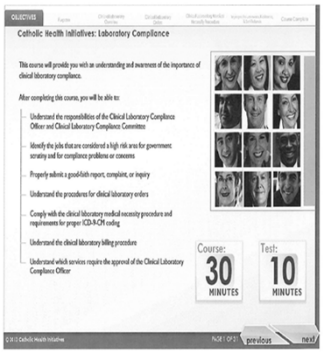
Staff Education and Competency



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Staff Education and Competency

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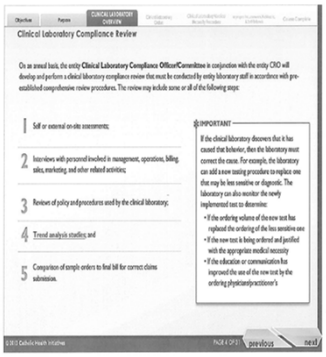
Staff Education and Competency



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How CHI Responded (Long-Term)

- Director of Laboratory Compliance (DoLC)
  - 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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Example Waived Testing Document

← ENTER CLIA # On LINE 1				Any Questions/Clarifications Please Contact: Tim Murray
Name of Lab:	Highlight in Yellow Testing Done At This Lab			Tim Murray
Address:	Cholesterol	Prothrombin Time		Director, Laboratory Compliance
	Fecal Occult Blood	Rapid Strep		Catholic Health Initiatives
Medical Director/Confirm on CLIA License	Glucose	Sedimentation Rate		Ph 610-594-5102
Consultant:	Hemoglobin	Urinalysis Dipstick		timothymurray@catholichealth.net
	Hemoglobin AC1	Urine Pregnancy		
Testing personnel Interviewed:	Hematocrit	Other List to Right		
	Influenza			
	Lyme Disease			Rev 4-13
Date Assessment Completed:	Ovulation			
	Place "X "in Box for Answer			
FY 2013 - Waived Testing Assessment # 1	YES	NO	N/A	Please write answers to the NON Yes/No questions here:
1.Are all tests performed classified as waived? §§493.15(c), and 493.1775(b)(3)See 15 for abbreviated list of waived tests				
2. Does the laboratory have the current manufacturer's instructions for all tests performed?				
3. Does the laboratory follow the current manufacturer's instructions for all tests performed by: §493.15(e)(1)				

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Example Waived Testing Document

a) Using the appropriate specimen?				
b) Adding the required reagents in the prescribed order?				
c) Adhering to the manufacturer's storage and handling instructions?				
d) Using the proper expiration date for the storage method?				
e) Performing the quality control as required by manufacturer?				
f) Performing function checks or calibration?				
g) Performing confirmatory tests as required?				
h)Temp Checks and documents results each day of supply/reagent storage?				
h1)Are there hi/ low acceptable temperature ranges established and documented for each device monitored? Including Room temp if storage requires it?				
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?				
5. Does the testing personnel:				
a) Document the name of the test, reagent/control lot number, and expiration date for all tests performed?				
b) Are laboratory personnel given training when they are newly hired?				
cIF answered YES to 5 b, how is the training documented?				
6. Are testing staff:				

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How CHI Responded (Long-Term)

- DoLC developed a standardized tool to be used to evaluate Moderate and High Complexity laboratories.
  - Included in-house auditing network to assist in onsite reviews
    - » DoLC reviewed sampled pre-audit data and post audit data and added recommendations where appropriate

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Standardized Review Document

Laboratory Compliance Checklist
FY 2014

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

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. (Select 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	

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Standardized Review Document

PART 2 – CERTIFICATION/ ACCREDITATION/ SELF-INSPECTION SURVEYS
Action Item prior to onsite review: Obtain a copy of the deficiency letter and the Laboratory's responses to the deficiencies, and submit them to the Director of Laboratory Compliance (DOLC) before the onsite visit. Additional focus areas or prioritization may be determined after the DOLC's review.

QUESTION	DESCRIPTION	ADDITIONAL INSTRUCTIONS AND ENFORCEMENT RATIONALE	RESULTS
2-1.Has laboratory received a final letter of Certification/Accreditation? If not are responses or action plans in response to accrediting or other governmental agency deficiency letter complete?	Review most current (Full) Licensing/ Accreditation Surveys. Obtain a copy of the deficiency letter and compare for completeness to response or action plan. No review needed if lab already received final letter of accreditation. List name of inspecting agency and date(s) of Survey(s). Review and attach deficiency letter.	Full inspections are normally every other year with a self-inspection on the alternate year.	
2-2. If compliance issues were noted, was the following performed: a. Were noncompliance issues identified? b. Were corrective actions made or plans put into place for any deficiency regardless of severity? c. Was follow-up implemented and documented including new policies or process changes where appropriate? d. Were all corrective action plans and process changes reviewed and signed off by Medical Director and staff? e. If policies were updated or developed, is there documentation that staff was educated on these policies?	For each of the deficiencies selected by the DOLC, obtain survey reports and related documentation to identify if corrective actions were made and put into place, follow-up was implemented and documented, corrective actions and process changes were signed off by Medical Director and staff, and staff was educated on new and revised policies.	Corrective actions must be developed for each deficiency regardless of severity. Follow-up is typically verified by first reviewing the cited deficiency and asking the laboratory's director to show examples of compliance in the months following the date of correction stated in the entities response to inspecting agencies findings. Look for ongoing follow-up.	

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How CHI Responded (Long-Term)

- Gained access to accrediting bodies summation material CAP,TJC and COLA, looked at inspections, PT results.
  - Helped determine the next year's (onsite reviews)
- Worked with Divisional and local CROs to determine onsite work schedule development Emergent or routine

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How CHI Responded (Long-Term)

- Established a mechanism for facilities to notify DoLC of new CLIA applications (moderate and above)
  - Reviewed for accuracy
  - Reviewed PT policies and education when appropriate (reviewed common compliance concerns) Temperatures, competencies, validations, SOPMs
- Established a mechanism for laboratories to notify DoLC of any regulatory adverse actions/ notifications
  - Would be actively involved with council with any response

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How CHI Responded (Long-Term)

- Issued guidance
  - CBC
  - Urinalysis
  - IHC staining changes 88342 and 88343 and G0461 and G0462
- Maintain a Q+A library on CHI intranet site

CATHOLIC HEALTH INITIATIVES

Guidance Issued

CBC, Urinalysis Ordering and Billing Advisory

The CBC (Complete Blood Count) is one of the most widely ordered laboratory tests. The most frequently reported CBC codes are:

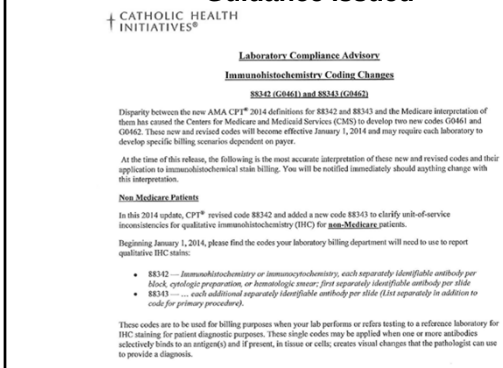
- CPT® 85025 *Blood count; complete (CBC), (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count*
- CPT® 85027 *Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count)*

The descriptions of these two codes are very clear. In the event the physician or practitioner orders just a CBC with no documented mention of automated differential, the laboratory may only perform and bill CPT® 85027; Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count). If the physician or practitioner specifically orders a CBC with differential the laboratory may perform and bill CPT® 85025; Blood count; complete (CBC), (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count.

The performance and billing of any other level of testing must be specifically ordered and the medical necessity documented by the physician or practitioner in the patient's medical record and on the laboratory requisition. Manual differentials may only be performed and billed if the ordering physician or practitioner specifically orders a CBC, (CPT® 85027), with manual differential.

CATHOLIC HEALTH INITIATIVES

Guidance Issued



CATHOLIC HEALTH INITIATIVES®

Laboratory Compliance Advisory

Immunohistochemistry Coding Changes

88342 (G0461) and 88343 (G0462)

Disparity between the new AMA CPT® 2014 definitions for 88342 and 88343 and the Medicare interpretation of them has caused the Centers for Medicare and Medicaid Services (CMS) to develop two new codes G0461 and G0462. These new and revised codes will become effective January 1, 2014 and may require each laboratory to develop specific billing scenarios dependent on payer.

At the time of this release, the following is the most accurate interpretation of these new and revised codes and their application to immunohistochemical stain billing. You will be notified immediately should anything change with this interpretation.

Non Medicare Patients

In this 2014 update, CPT® revised code 88342 and added a new code 88343 to clarify unit-of-service inconsistencies for qualitative immunohistochemistry (IHC) for **non-Medicare** patients.

Beginning January 1, 2014, please find the codes your laboratory billing department will need to use to report qualitative IHC stains:

- 88342 — *Immunohistochemistry or immunocytochemistry, each separately identifiable antibody per block, cytologic preparation, or hematologic smear; first separately identifiable antibody per slide*
- 88343 — *…, each additional separately identifiable antibody per slide (List separately in addition to code for primary procedure).*

These codes are to be used for billing purposes when your lab performs or refers testing to a reference laboratory for IHC staining for patient diagnostic purposes. These single codes may be applied when one or more antibodies selectively binds to an antigen(s) and if present, in tissue or cells; creates visual changes that the pathologist can use to provide a diagnosis.

CATHOLIC HEALTH INITIATIVES

Related Synergies and Activities

- Worked closely with:
  - **L**egal - Interpretation and guidance
  - **A**dvocacy - Emerging regulatory issues
  - **B**usiness operations throughout the enterprise on various issues involving lab and other related regulations.
- Thank You