

COLA'S

inSights

INTO *Recovery Audits*

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**NEW
THIS ISSUE**



FROM THE CHAIR

The deadline to file taxes always comes to mind in April. So, our thoughts for the March/April issue of Insights focused on deadlines and income.

The article entitled “*Physician Office Laboratory Financial Considerations*” should get you thinking about ways to **increase** your income. It may be more profitable to perform laboratory testing in-house compared to sending testing to outside labs. Several of the sessions at the next Symposium for Clinical Laboratories (April 27 – 30, 2011 in Atlanta) will help you refine this line of thought for your particular circumstances.

Confirming that you meet the deadlines for the “*ICD-10 Upgrade*” will help ensure that you don’t experience a **decrease** in income due to reimbursement delays.

Finally, our cover article, “*Recovery Audit Contractors (RAC) Expansion*” explains one way to **maintain** your income. The article provides a brief history of RAC and why it is important to physicians, medical laboratories and other health care providers. Implement the pointers and avoid the pitfalls mentioned in the article and your lab may be able to prevent “improper payments” subject to Medicare recovery.

At COLA, our focus is not limited to money and time frames. We also strive to **increase** your awareness of regulatory and other issues through educational updates; to **decrease** your deficiencies and citations through our consultative efforts; and to help you **maintain** quality patient care through our accreditation services.

Verlin K. Janzen, MD, FAAFP
Chair, COLA Board of Directors



COLA INSIGHTS

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Recovery Audit Contractors (RAC) Expansion

WHAT ARE RAC AUDITORS AND WHY DO THEY HAVE QUESTIONS ABOUT THE LAB? FOR THAT MATTER, WHAT IS RAC?

“The Medicare Fee-for-Service (FFS) program consists of a number of payment systems, with a network of contractors that process over 1.2 billion claims each year. ... These contractors ... process claims, make payments to health care providers in accordance with Medicare regulations, and are responsible for educating providers about how to submit accurately coded claims that meet Medicare’s medical necessity guidelines.”¹

Due to the tremendous number of claims, the contractors pay most claims without scrutinizing medical records associated with the billed services. This results in a large number of improper payments.

Improper payments can be in the form of overpayments or underpayments. In addition to other reasons, “overpayments can occur when health care providers submit claims that do not meet Medicare’s coding or medical necessity policies. Underpayments can occur when health care providers submit claims for a simple procedure but the medical record reveals that a more complicated procedure was actually performed.”²

Due to the anticipated dollar amounts involved, Congress enacted legislation³ to protect the Medicare Trust Funds. The Medicare Recovery Audit Contractor (RAC) program was initiated in 2005, in a limited number of states, as a three year demonstration project. Its primary goal was to determine if recovery auditing could be effectively used in Medicare. Effective utilization was clearly shown, since the demonstration resulted in the return of over \$900 million in overpayments to the Medicare Trust Funds and nearly \$38 million in underpayments to health care providers, from 2005 to 2008.⁴

Following this successful three year demonstration project, Congress passed additional legislation⁵ that required the Centers for Medicare and Medicaid Services (CMS) to establish the RAC program nationwide by January 1, 2010. The national program was phased-in during 2009, but many hospitals felt its effects throughout 2010. As the RAC program continues to expand, physician offices and medical laboratories may experience similar growing pains during 2011 and beyond.

The expansion means that physicians, medical laboratories, pharmacies, and other providers or suppliers that bill Medicare Parts A and B will also be included in RAC audits. In other words, if you submit fee-for-service claims to Medicare, your claims will be subject to review by RAC auditors.

RAC expansion continued under legislation⁶ passed in March 2010, which requires claims submitted under the Medicare Advantage Plans and Prescription Drug Coverage (Medicare Parts C & D) to be reviewed by RAC auditors. Additionally, this legislation requires all states to establish individual Medicaid RAC Programs.⁷



1.2 billion claims per year equates to
4.5 million claims per work day,
574,000 claims per hour, **9,579** claims per minute

>> CONTINUED ON PAGE 6

ICD-10 Upgrade

IMPROVING THE NUMBER OF INCORRECTLY CODED CLAIMS

The cover article in this issue of *Insights* states that the majority of Medicare improper payments are due to providers billing for services that are incorrectly coded. The upgrade to ICD-10 should improve many areas, including the number of incorrectly coded claims.



[Click here for the Latest News from CMS.](#)

“The Internal Classification of Diseases (ICD) is the global standard to report and categorize diseases, health-related conditions and external causes of disease and injury in order to compile useful health information related to deaths, illness and injury (mortality and morbidity).”¹ ICD-9 is the current version in use in the United States, but not for long. All entities covered by the Health Insurance Portability and Accountability Act (HIPAA) must enact the upgrade to ICD-10 on October 1, 2013.²

There are several reasons for the upgrade to ICD-10.

- ICD-9 is several years outdated, with only a limited ability to accommodate new procedures and diagnoses.
- ICD-9 uses terminology inconsistently and lacks codes for preventive services.
- ICD-10 is expected to accurately define services and provide specific diagnosis and treatment information.
- ICD-10 should ensure more accurate payments for new procedures with fewer rejected claims.

Additionally, ICD-10 should allow the US to more easily compare its data with international data to track the incidence and spread of

disease and treatment outcomes. Currently, this cannot be done since the US is one of the few developed countries not using ICD-10.

There is an additional step, which involves electronic health care transaction standards, that has to be taken prior to the ICD-10 implementation. HIPAA requires the adoption of standards that covered entities must use when electronically conducting certain transactions (such as claims, remittance, eligibility, claims status requests and responses, and others). The current version of these standards, Version 4010/4010A1, is widely recognized as being outdated and lacking certain functionality needed by the health care industry. The new version, 5010, institutes many improvements, including the ability to accommodate the greatly expanded ICD-10 code sets, which the current Version 4010/4010A1 cannot support.

The following information is taken directly from the Centers for Medicare & Medicaid Services (CMS) website:³

“On **October 1, 2013**, medical coding in U.S. health care settings will change from ICD-9 to ICD-10. The transition will require business and systems changes throughout the health care industry. Everyone who is covered by the Health Insurance Portability and Accountability Act (HIPAA) must make the transition, not just those who submit Medicare or Medicaid claims.

The compliance dates are firm and not subject to change.
If you are not ready, your claims will not be paid.
Preparing now can help you avoid potential reimbursement issues.

The first ICD-10-related compliance date is less than [a] year away. On January 1, 2012, standards for electronic health transactions change from Version 4010/4010A1 to Version 5010. Unlike Version 4010, Version 5010 accommodates the ICD-10 code structure. This change occurs before the ICD-10 implementation date to allow adequate testing and implementation time.

The compliance dates are firm and not subject to change. If you are not ready, your claims will not be paid. Preparing now can help you avoid potential reimbursement issues.

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Physician Office Laboratory Financial Considerations

JOIN US AT THE SYMPOSIUM FOR CLINICAL LABORATORIES TO LEARN MORE!

Have you thought about opening and/or expanding your own Physician Office Laboratory (POL), but thought that it would prove to be impractical or unprofitable? According to Tim Dumas, laboratory consultant and president of Tim, “The Lab Guy,” Inc., this couldn’t be farther from the truth.

“With today’s technology and advancements in waived testing, it is more practical and profitable than it has ever been to perform lab tests in house. Laboratory analyzers of today run leaner and more economical than ever before, lab computers have made the processing of test specimens more efficient and less prone to human error, and the EMR practice systems have streamlined the billing process to capture more of the revenue.

“Having a POL can prove rewarding and profitable, if you take time to plan. There are three basic steps for determining what is right for your practice and reaping the many benefits of a POL:

- Decide which tests are medically right for your patients and your practice;
- Calculate the financial impact and Return On Investment (ROI); and
- Choose the procedures and vendors.”¹

Dumas will discuss these basic steps at the next *Symposium for Clinical Laboratories*, to be held April 27-30, 2011 at the Hyatt Regency in Atlanta, GA. The presentation will provide relevant formulas and insightful examples to help you determine if bringing a test in-house is right for your practice.

The discussion pertains to non-waived testing as well as waived testing. Dumas shows that by providing non-waived testing in-house, it is possible to create revenues of thousands of dollars per year, when compared to referring testing to an outside laboratory. He will walk you through the various items to consider when determining what will work for you:

- Waived vs. non-waived methods
- Staffing issues
- Test volume
- Cost per test
- Reimbursement
- Gross/net revenue



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- Implement skills focused on complying with the CLIA regulations and improved laboratory practices
- Develop internal processes addressing quality assessment and quality management systems practices

For more information and to register please visit www.COLA.org.

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RECOVERY AUDIT CONTRACTORS (RAC) EXPANSION

RECOVERY AUDIT CONTRACTORS

To help the RAC program operate efficiently, CMS has authorized different RAC contractors and subcontractors to review claims in different parts of the country. The nation is divided into four regions so that each region includes approximately one quarter of the total claims submitted. The following map shows which states are included in each region and Table 1 lists featured information for each RAC.

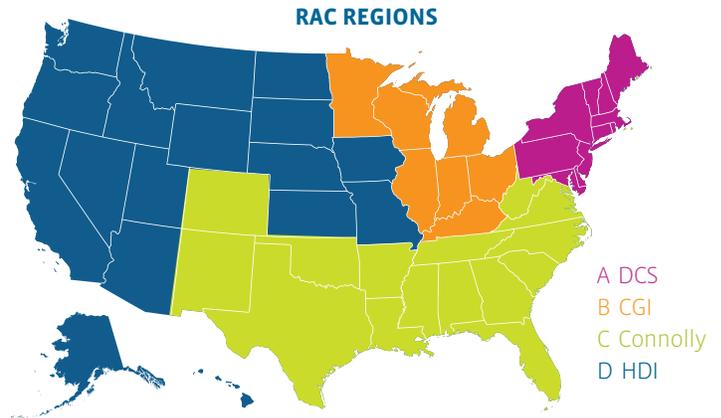


Table 1

CMS RAC information Website: http://www.cms.gov/RAC Email: RAC@cms.hhs.gov		
Region	Contractor	Website / Email
A	Diversified Collection Services, Inc. (DCS)	http://www.dcsrac.com/providerportal.aspx info@dcsrac.com
B	CGI Technologies and Solutions, Inc. (CGI)	http://racb.cgi.com racb@cgi.com
C	Connolly, Inc.	http://www.connolly.com/healthcare/Pages/CMSRACProgram.aspx racinfo@connollyhealthcare.com
D	HealthDataInsights, Inc. (HDI)	https://racinfo.healthdatainsights.com/home.aspx racinfo@emailhdi.com
Region	Subcontractor	Website
A	ihealth Technologies	http://www.ihealthtechnologies.com/index.html
A, B, D	PRGX	http://www.prgx.com
C	Viant	http://www.viant.com

REVIEW PROCESS

The RAC program is the latest of several programs designed to detect and limit fraud and abuse of the Medicare system.⁸ Typically, when conducting claims reviews, RAC auditors will follow the Medicare policies that are currently in use; only slight modifications, based on the RAC demonstration findings, have been instituted.

RAC auditors perform two types of post-payment reviews. Automated reviews address “black & white” issues and require no additional documentation. Complex reviews focus on more complicated issues which require providers to submit additional records to the RACs. To ensure that they are properly performing the claims reviews, RACs are required to employ physicians as full-time medical directors and staff consisting of nurses, therapists, and certified coders.⁹

The number of medical records that RACs can request is subject to limitations based on the number of Medicare claims submitted by the provider. Time limitations also exist. Requested records must be dated during the three year period prior to the date the claim was paid. An additional limitation states that they cannot request medical records dated prior to October 1, 2007.

If an overpayment is discovered, the collection process is also similar to current procedures, except for two differences. Demand letters will be issued by the RAC, and there will be opportunities for providers to discuss overpayments with the RAC after the demand letters are sent. These discussion periods are in addition to the appeals process.¹⁰ If providers choose not to appeal the overpayment, they have several re-payment options, including paying by check, applying for an extended payment plan, or allowing recoupment from future Medicare claims payments.

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RECOVERY AUDIT CONTRACTORS (RAC) EXPANSION

RAC PROGRAM IMPROVEMENTS

Several observations were noted during the RAC demonstration, which led to several improvements being made to the permanent RAC program. Table 2 lists some of these improvements.

Table 2

Improvements Made to the RAC Permanent Program ¹¹		
Issue	Demonstration RACs	Permanent RACs
RAC Medical Director	Not required	Mandatory
Coding Experts	Optional	Mandatory
Credentials of reviewers provided, upon provider request	Not required	Mandatory
Discussion with Contractor Medical Director (CMD) regarding claim denials, if requested by provider	Not required	Mandatory
Standardized base notification of overpayment letters to providers	Not required	Mandatory
Look back period (from claim payment date to date of medical record request)	Four (4) years	Three (3) years
Maximum look back date	None	01 Oct 2007
Allowed to review claims in current fiscal year (FY)	No	Yes
Limits on number of records requested	Optional, each RAC set their own limits	Mandatory, CMS has established uniform limits (including capped limit)
Time frame for paying hospital medical record photocopying vouchers	None	Within 45 days of receipt of medical record
Medicare Secondary Payor (MSP) included	Yes	No
Quality assurance / Internal control audit	No	Mandatory
Remote call monitoring	Yes	Yes
Reason for review listed on Request for <i>Records</i> letters & <i>Overpayment</i> letters	Not required	Mandatory
RAC claim status web page	Not required	See individual RAC websites

PREPARATION AND COMPLIANCE

The demonstration project showed three main reasons why improper payments occurred. The majority were due to providers billing for services that were incorrectly coded or did not meet Medicare's medical necessity policies. The third reason was that the procedures were performed in a medically unnecessary setting, which usually means that the procedure should have been performed in an outpatient setting but were billed as being performed during an inpatient stay.

CMS offers several suggestions to help providers overcome improper

billing practices and comply with RAC requirements:¹²

- Learn about previous improper payments – these have been found in OIG (Office of the Inspector General) and CERT (Comprehensive Error Rate Testing) reports as well as in the RAC (Recovery Audit Contractor) demonstration.¹³ To increase transparency, the RACs are required to make future findings available electronically. They have developed secure links on their websites to allow providers access to claims' status and still maintain patient privacy.

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RECOVERY AUDIT CONTRACTORS (RAC) EXPANSION

- Conduct a self-assessment – providers should conduct internal audits to ensure they are in compliance with Medicare billing rules, and institute corrective actions if they are not.
- Prepare to respond to RAC medical record requests – identify a contact person, and inform the appropriate RACs of this person’s contact information.
- Appeal when necessary – note that there is a discussion period that is separate from the appeals process. Appeals are processed according to strict timelines.

- Learn from past experiences – document and monitor denied claims. Examine them for patterns and institute appropriate corrective actions.

Although improper payments cannot be completely eliminated, by working together and utilizing lessons learned, CMS and providers can use the RAC program to drastically decrease the number of future improper payments. CMS can analyze the RAC data to implement corrective actions. Providers can utilize the RAC findings to ensure that they are submitting correctly coded claims for services that meet Medicare’s medical necessity criteria. ■

Table 3

For more detailed information about:	See:
Claims Review Programs	Medicare Claim Review Programs: MR, NCCI Edits, MUEs, CERT & RAC http://www.cms.gov/MLNProducts/downloads/MCRP_Booklet.pdf
Affordable Care Act	Department of Labor, Employee Benefits Security Administration http://www.dol.gov/ebsa/healthreform
CMS Provisions in the Affordable Care Act	The Patient Protection and Affordable Care Act All CMS Provisions – As of December 10, 2010 http://www.cms.gov/LegislativeUpdate/downloads/PPACA.pdf
Tax Relief & Health Care Act	Library of Congress http://www.thomas.gov/cgi-bin/query/z?c109:H.R.6111.ENR :
CMS Provisions in the Tax Relief & Health Care Act	Tax Relief and Health Care Act of 2006 All CMS Provisions As of March 2, 2007 http://www.cms.gov/LegislativeUpdate/downloads/TRHCA0307.pdf
Medicare Modernization Act	Interactive hyperlinked index http://www.cms.gov/LegislativeUpdate/downloads/MMAProvisions.pdf

RESOURCES:

- Centers for Medicare and Medicaid Services (CMS), *The Medicare Recovery Audit Contractor (RAC) Program: An Evaluation of the 3-Year Demonstration*; http://www.cms.gov/RAC/Downloads/RAC_Demonstration_Evaluation_Report.pdf
- CMS, Fact Sheet: *CMS Announces New Recovery Audit Contractors to Help Identify Improper Medicare Payments*; <http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3292&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cbOrder=date>
- Medicare Prescription Drug Improvement and Modernization Act of 2003, Section 306; See Appendix A of *The Medicare Recovery Audit Contractor (RAC) Program: An Evaluation of the 3-Year Demonstration*; http://www.cms.gov/RAC/Downloads/RAC_Demonstration_Evaluation_Report.pdf
- CMS, Fact Sheet: *CMS Announces New Recovery Audit Contractors to Help Identify Improper Medicare Payments*; <http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3292&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cbOrder=date>
- Tax Relief and Healthcare Act of 2006, Section 302; See Appendix B of *The Medicare Recovery Audit Contractor (RAC) Program: An Evaluation of the 3-Year Demonstration*; http://www.cms.gov/RAC/Downloads/RAC_Demonstration_Evaluation_Report.pdf
- Patient Protection and Affordable Care Act of 2010, Section 6411; http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ148.pdf
- CMS, Medical Learning Network (MLN) booklet, *Medicare Claim Review Programs: MR, NCCI Edits, MUEs, CERT & RAC*; http://www.cms.gov/MLNProducts/downloads/MCRP_Booklet.pdf
- For more detailed information on existing Medicare claims review programs, see the CMS MLN booklet: *Medicare Claim Review Programs: MR, NCCI Edits, MUEs, CERT & RAC*; http://www.cms.gov/MLNProducts/downloads/MCRP_Booklet.pdf
- CMS, Slide Presentation for RAC 101 Calls: *Recovery Audit Contractors (RACs) and Medicare*; <http://www.cms.gov/RAC/Downloads/RACODFslides.pdf>

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- 10 For more detailed information on the appeals process, see the MLN Matters article: *Limitation on Recoupment (935) for Provider, Physicians and Suppliers Overpayments*; <http://www.cms.gov/MLNMattersArticles/downloads/MM6183.pdf>. Appeal timeframes can be found here: <http://www.cms.gov/OrgMedFFSAppeals/Downloads/AppealsprocessflowchartAB.pdf>
- 11 Table 2 adapted from: CMS, Table 10, page 25, *The Medicare Recovery Audit Contractor (RAC) Program: An Evaluation of the 3-Year Demonstration*; http://www.cms.gov/RAC/Downloads/RAC_Demonstration_Evaluation_Report.pdf
- 12 CMS, RAC Slide Presentation: *Recovery Audit Contractors (RACs) and Medicare, The Who, What, When, Where, How and Why?*; <http://www.cms.gov/RAC/Downloads/RACSlides.pdf>
- 13 OIG reports: www.oig.hhs.gov/reports.asp, CERT reports: www.cms.gov/cert, RAC demonstration findings: www.cms.gov/rac;
- See Table 1 for website information for each of the RAC contractors.

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ICD-10 UPGRADE

BASIC STEPS TO PREPARE FOR VERSION 5010/ICD-10

Begin preparing now for the ICD-10 transition to make sure you are ready by the **October 13, 2013**, compliance deadline. The following quick checklist will assist you with preliminary planning steps.

- *Identify your current systems and work processes that use ICD-9 codes.* This could include clinical documentation, encounter forms / superbills, practice management system, electronic health record system, contracts, and public health and quality reporting protocols. It is likely that wherever ICD-9 codes now appear, ICD-10 codes will take their place.
- *Talk with your practice management system vendor about accommodations for both Version 5010 and ICD-10 codes.*
 - Contact your vendor and ask what updates they are planning to your practice management system for both Version 5010 and ICD-10, and when they expect to have it ready to install.
 - Check your contract to see if upgrades are included as part of your agreement.
 - If you are in the process of making a practice management or related system purchase, ask if it is Version 5010 and ICD-10 ready.
- *Discuss implementation plans with all your clearinghouses, billing services, and payers to ensure a smooth transition.* Be proactive, don't wait. Contact your payers, clearinghouse, billing service with whom you conduct business, ask about their plans for the Version 5010 and ICD-10 compliance, and when they will be ready to test their systems for both transitions.
- *Talk with your payers about how ICD-10 implementation might affect your contracts.* Because ICD-10 codes are much more specific than ICD-9 codes, payers may modify terms of contracts, payment schedules, or reimbursement.
- *Identify potential changes to work flow and business processes.* Consider changes to existing processes including clinical documentation, encounter forms, and quality and public health reporting.

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ICD-10 UPGRADE

- *Assess staff training needs.* Identify the staff in your office who code, or have a need to know the new codes.
 - There are a wide variety of training opportunities and materials available through professional associations, online courses, webinars, and onsite training.
 - If you have a small practice, think about teaming up with other local providers. You might be able, for example, to provide training for a staff person from one practice, who can in turn train staff members in other practices.
 - Coding professionals recommend that training take place approximately 6 months prior to the October 1, 2013 compliance date.
- *Budget for time and costs related to ICD-10 implementation, including expenses for system changes, resource materials, and training.* Assess the costs of any necessary software updates, reprinting of superbills, training and related expenses.
- *Conduct test transactions using Version 5010/ICD-10 codes with your payers and clearinghouses. Testing is critical.* Allow yourself enough time to first test that your Version 5010 transactions, and subsequently, claims containing ICD-10 codes are being successfully transmitted and received by your payers, clearinghouses, etc. Check to see when they will begin testing, and the test days they have scheduled.”

As you can see, there are a multitude of items to consider prior to implementing the required upgrades. Since all of these steps take time and the upgrade deadline dates are not going to change, do not delay your implementation strategy. ■

RESOURCES:

- 1 *World Health Organization; Revision of the International Classification of Diseases (ICD);* <http://www.who.int/classifications/icd/ICDRevision/en/>
- 2 “The ICD-10 final rule concurrently adopts the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) for diagnosis coding, and the International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) for inpatient hospital procedure coding. The ICD-10-CM code set is maintained by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC) for use in the United States. It is based on ICD-10, which was developed by the World Health Organization (WHO) and is used internationally. The ICD-10-PCS code set is maintained by CMS.”

Centers for Medicare & Medicaid Services; *HHS Modifies HIPAA Code Sets (ICD-10) and Electronic Transaction Standards;* <http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3407&intNumPerPage=10&checkDate=&checkKey=2&srchType=2&numDays=0&srchOpt=0&srchData=icd%2D10&keywordType=All&chkNewsType=6&intPage=&showAll=1&pYear=&year=0&desc=&cbOrder=date>

Please consult the respective websites if you need more detailed information. NCHS: <http://www.cdc.gov/nchs/>, CDC: <http://www.cdc.gov/>, WHO: <http://www.who.int/en/>, and CMS: <http://www.cms.gov>

- 3 Centers for Medicare & Medicaid Services; ICD-10, *Provider Resources;* http://www.cms.gov/ICD10/05a_ProviderResources.asp#TopOfPage



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PHYSICIAN OFFICE LABORATORY FINANCIAL CONSIDERATIONS

Other presentations will address additional financial considerations.

- Toni Clinton, Vice-President, Laboratory Operations of Sonic Healthcare, USA, will present *POCT: Issues and Answers*. This session will help you determine if Point-of-Care Testing makes sense for your practice.
- *Finding the Fix to Common Laboratory Coding Errors*, presented by Shannon DeConda, Partner and Director of Coding & Reimbursement Services for DoctorsManagement, will help you identify the proper codes and modifiers to use to enhance revenue generated by laboratory testing.
- Dumas will also speak on *Negotiating with Insurance Companies* in a way that both your practice and the insurance company will reap benefits.

Join us in Atlanta during National Medical Laboratory Professionals Week for these and many more educational sessions to improve the quality of the laboratory testing you provide! ■

RESOURCES:

- 1 Dumas, Tim; *Point of Care: Bringing Testing In-house*; P.O.L. Insight – A Continuing Education Publication for the Physician Office Laboratory, 2009-C, issue 56; <http://www.timdumas.com/timdumas/index.cfm>

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- Webinar CEExpress 6: Introduction to Quality Control

Coming Soon! Webinar CEExpress 7: Evaluate Quality Control & Take Corrective Action

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COLA Compliance Tip PER 3

Focus: COLA criterion PER 3

Does the personnel record contain documentation of the person's education and experience that qualifies them for the position they hold in the laboratory?

Not only do personnel have to be qualified to fill CLIA defined positions in the laboratory, there must be documented proof of their qualifications.

When defining required positions for laboratory personnel, CLIA distinguishes between labs that perform moderate complexity testing and high complexity testing.

For moderate complexity, the positions that must be filled are

Laboratory Director, Clinical Consultant, Technical Consultant and Testing Personnel.

For high complexity, the required positions are

Laboratory Director, Clinical Consultant, Technical Supervisor, General Supervisor and Testing Personnel.

There are several different eligibility pathways available for personnel to qualify for each position. Each pathway requires a combination of education, experience and training. To meet the PER 3 criterion, for each individual performing non-waived testing in your laboratory, you must provide COLA with proof of these qualifications. This includes legible copies of required diplomas and degrees.

COLA does not accept certifications (including CMA, MLT and MT) or licenses (including RN and RT) as the only documentation of qualification to perform moderate complexity testing. To verify that the individual is eligible to fill a CLIA defined position, COLA will need a copy of the high school diploma or higher degree.

An exception to this occurs when the state requires personnel licensure to perform laboratory testing. In these states, COLA will accept the state license as proof of qualification for laboratory testing.

If personnel have only foreign credentials, COLA requires that the credentials be evaluated by a reputable credentialing agency**. It is the responsibility of the individual, not COLA, to get this credential evaluation.

To help you manage your compliance documents, COLA offers the use of the Document Repository, which is available to all members on *COLACentral*. All of your documents can be stored in one central, easily accessible location.

** The International Education Research Foundation (www.ierf.org)

The National Association of Credential Evaluation Service (www.naces.org)

The Association of International Credential Evaluators (www.aice-eval.org)

COLA Compliance Tip *PER 4*

Focus: COLA criterion PER 4

Does each laboratory employee adequately fulfill the responsibilities of the position(s) they hold?

When PER 4 is cited during a survey, the citation will specify the applicable position.

PER 4A relates to Laboratory Director (LD) responsibilities and could be cited under many different circumstances, including:

- failure to ensure that personnel are qualified
- failure to address systemic issues, such as ineffective quality assurance (QA)
- failure to ensure that successful corrective actions are taken to resolve the systemic issues, quality control (QC) concerns, or proficiency testing (PT) problems
- non-compliances that could negatively affect patient safety.

PER 4B is frequently cited because laboratories fail to designate a Clinical Consultant, which is a required position for all labs performing non-waived testing. Many times, the LD fills this role. If this is true for your laboratory, be sure that your LD is aware of the added responsibilities of this position and that he/she adequately fulfills them.

PER 4C, which relates to Technical Supervisor/Technical Consultant (TS/TC) responsibilities, may be cited if the individual does not ensure that QC/PT/QA documentation is completed within a timely manner. This is because the TS/TC must determine acceptable QC ranges, evaluate PT results, and ensure that the QA plan effectively identifies areas for improvement. PER 4C is also cited when the TS/TC fails to ensure that laboratory staff are evaluated for competency at the required time intervals.

PER 4D pertains only to high complexity laboratories and is cited when the General Supervisor does not adequately fulfill his/her responsibilities.

PER 4E, relating to Testing Personnel (TP) responsibilities, may be cited if staff fail to perform QC, PT and/or patient testing according to the laboratory's procedure manual.

Multiple CLIA required positions and the corresponding responsibilities make PER 4 a very challenging criterion. You can help ensure compliance by taking the following actions:

- **Create job descriptions.** For all of your laboratory's required positions, ensure that a written job description exists and that each job description defines the position's specific tasks.
- **Train your staff.** Make sure all lab personnel have written procedures that tell them how to perform their duties.
- **Evaluate your staff.** Ensure that everyone correctly follows laboratory procedures and that their competency is assessed as required.
- **Meet frequently.** Timely communication is key to your laboratory's success! Use meetings to recognize what is done well and to identify areas that need improvement. Allow time for personnel to voice their concerns and suggestions. Documenting the meeting date, agenda, participants, and discussion helps you monitor your team's successes and failures.

Create job descriptions.

Train and evaluate your staff.

Meet Frequently.

COLAcentral can help keep everything organized!

COLA Compliance Tip PER 5

Focus: COLA criterion PER 5

Does your director or Technical Supervisor / Technical Consultant follow written policies and procedures to periodically evaluate personnel performance and competency of all staff involved in pre-analytic, analytic and post-analytic phases of testing, as well as those responsible for supervision and consultation?

This COLA criterion is based on the CLIA regulation addressed under Personnel Responsibilities that states that the Laboratory Director must

"Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytical, analytical, and post-analytical phases of testing to **assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently**, and whenever necessary, identify needs for remedial training or continuing education to improve skills."

While it is the Laboratory Director's responsibility to ensure that these policies are in place, it is the responsibility of the Technical Consultant/Technical Supervisor to actually perform the competency assessments. The assessment must be performed every six months during the first year of employment and annually thereafter, and when test methodology and/or instrumentation changes.

Personnel evaluation forms or statements from those performing the assessments detailing how and when the assessment was conducted can be used as documentation of the assessments. Your documentation should include the name(s) of the person(s) performing the assessment, the date of the evaluation, the tasks/areas that were evaluated and the outcome of the assessment.

The focus of the competency assessment is the individual's ability to perform tasks according to the laboratory's defined processes and procedures, in order to assure accurate and reliable test results. The evaluation must address the ability of each individual to fulfill the duties and responsibilities of their position and must include an assessment of their actual test performance and interpretation of results.

The assessment procedures must include, but are not limited to:

- direct observation of test performance, and instrument maintenance and function checks
- monitoring the recording and reporting of test results
- review of worksheets, quality control (QC) records, proficiency testing (PT) performance, and preventive maintenance records
- testing of previously analyzed specimens or blind samples (having values known only to the person conducting the evaluation)
- assessment of problem solving skills.

The COLA surveyor will look for evidence that these assessments are performed at the required time intervals for all laboratory staff, including all individuals involved in specimen collection and processing, laboratory testing, and/or supervision and compliance.

Go to www.COLACentral.com to see the numerous options for managing your personnel, tracking your compliance efforts, and monitoring your documents and records