

NOVEMBER / DECEMBER '11

COLA'S

inSights

INTO 2011:

The Year in Review

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FROM THE CHAIR

As is the custom of many publications at the end of the year, this version of *Insights* was meant to be a “year in review” edition; however, it seems to have become more of an “alphabet soup” issue. This is true because so many of the pertinent topics in recent months have involved federal regulations.

The articles in this *Insights* provide background information and updates on **RACs** (Recovery Audit Contractors), **ACOs** (Accountable Care Organizations), **HIT** (Health Information Technology) and **EHR** (Electronic Health Record) Meaningful Use, and **ICD-10** implementation (International Classification of Diseases and Related Health Problems, 10th Revision). You’ll also learn about the latest news from **COLA** itself.

Another year-end tradition is for the publication to reference the holiday season. In sincerely keeping that tradition, it is the heartfelt wish of everyone at COLA that every one of you enjoys a happy and safe holiday season.

Regardless of the time of year, whether it is the hopeful start of a new year, the nostalgic end of the year, or anywhere in between, our goals here at *Insights* remain the same. We hope to provide information that proves to be relevant to your laboratory, and helps you practice excellent laboratory medicine resulting in high quality patient care.

W. James Stackhouse, MD, MACP
Chair, COLA Board of Directors



COLA INSIGHTS

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ICD-10 Update

VERSION 5010 STANDARDS DEADLINE: JANUARY 1, 2012

ICD-10 DEADLINE: OCTOBER 1, 2013

Version 5010 Grace Period

On November 17, 2011, the Centers for Medicare and Medicaid Services (CMS) announced that it will allow a 90-day grace period before enforcing compliance with the new HIPAA transaction (Version 5010) standards. The compliance date for converting to these new standards remains January 1, 2012, but enforcement will not occur until March 31, 2012. CMS encourages all covered entities to continue working to become compliant and determine their readiness to accept the new standards by the January 1 deadline.¹

Click [here](#) to view the complete CMS statement.

New ICD-10 Implementation Handbooks Now Available

“CMS has developed four Implementation Handbooks as additional resources to assist the health care industry with the transition from ICD-9 to ICD-10 codes. Each guide provides detailed information for planning and executing the ICD-10 transition process. Use the guides as a reference whether you’re in the midst of the transition or just beginning the process.”²

The appendix of each handbook references relevant templates, which have been created to be customizable to help entities clarify staff roles, set internal deadlines/responsibilities and assess vendor readiness.

The templates are available for download in both Excel and PDF formats from the [CMS website](#). Several additional resources are accessible from the same site.

American Medical Association Opposes ICD-10 Implementation

The American Medical Association (AMA), the nation’s largest physician organization, adopted several policies during the closing session of its semi-annual policy-making meeting on November 15, 2011. Among these was a policy stating strong opposition to the implementation of ICD-10.

“The AMA House of Delegates voted today to work vigorously to stop implementation of ICD-10 (The International Classification of Diseases and Related Health Problems, 10th Revision), a new code set for medical diagnoses. ICD-10 has about 69,000 codes and will replace the 14,000 ICD-9 diagnosis codes currently in use.

“The implementation of ICD-10 will create significant burdens on the practice of medicine with no direct benefit to individual patients’ care,” said Peter W. Carmel, M.D., AMA president. At a time when we are working to get the best value possible for our health care dollar, this massive and expensive undertaking will add administrative expense and create unnecessary workflow disruptions. The timing could not be worse as many physicians are working to implement electronic health records into their practices. We will continue working to help physicians keep their focus where it should be – on their patients.”³

Compliance Timeline Widget

In the past, CMS has stated that the already postponed deadline (for ICD-10 implementation) of October 1, 2013 is firm and will not be changed again. To help prepare for the changes, they are offering “compliance timeline widgets” which are “detailed timelines of activities that providers, payers, and vendors need to undertake to prepare for Version 5010 and ICD-10” conversion. Both downloadable and printer-friendly versions are available for large providers, small providers, payers, and vendors. Since the widgets and timelines are public domain, CMS encourages organizations to distribute them widely via posting to their websites as well as other channels.⁴

We will have to wait to see if CMS reverses its stance and delays implementation. In the meantime, you should take advantage of the available tools to prepare for the conversion according to the currently stated timelines. ■

Insights focused on the ICD-10 conversion in the March-April 2011 issue. Please refer to that issue for additional information.

RESOURCES:

¹Centers for Medicare and Medicaid Services, Statement Announcing the 90-Day Period of Enforcement Discretion for Compliance with New HIPAA Transaction Standards, *last accessed November 2011*; <http://www.cms.gov/ICD10/Downloads/CMSStatement5010EnforcementDiscretion111711.pdf>

²Centers for Medicare and Medicaid Services, ICD-10 Latest News, *last accessed November 2011*; http://www.cms.gov/ICD10/02b_Latest_News.asp#TopOfPage

³American Medical Association, News, AMA Adopts New Policies During Final Day of Semi-Annual Meeting, *last accessed November 2011*; <http://www.ama-assn.org/ama/pub/news/news/2011-11-15-ama-adopts-new-policies.page>

⁴Centers for Medicare and Medicaid Services, Implementation Widget and Timelines, *last accessed November 2011*;

ACO Update

AFFORDABLE CARE ACT, MEDICARE SHARED SAVINGS PROGRAM: ACCOUNTABLE CARE ORGANIZATION (ACO) PROGRAM

The Affordable Care Act¹ contains provisions for health care providers participating in Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program. (Refer to Table 1 for the definition of an ACO.) Under these provisions, providers can continue to receive traditional Medicare fee-for-service (FFS) payments under Medicare Parts A and B, and be eligible for additional payments if they meet specified quality and savings requirements.

Goals of the ACO Program include enhancing the patient experience by providing higher quality patient care resulting in better health for the general population, and using health care dollars more wisely (controlling costs). From the outset, most medical professionals have agreed that these goals should be pursued. There has, however, been great disagreement as to how to accomplish them. The Dark Daily reported that criticism of the proposed rules began shortly after they were published.³

Table 1:

42 CFR 425.20 Definitions ² :	
An ACO is a legal entity formed by one or more ACO professional(s).	
An ACO professional is an ACO provider / supplier who is either of the following:	
<p>A physician legally authorized to practice medicine and surgery by the State in which he performs such function or action.</p>	<p>A practitioner who is one of the following:</p> <ol style="list-style-type: none"> 1. A physician assistant 2. A nurse practitioner 3. A clinical nurse specialist
<p>ACO provider / supplier means an individual or entity that</p> <ol style="list-style-type: none"> 1. Is a provider or a supplier (as defined by 42 CFR 400.202); 2. Is enrolled in Medicare; 3. Bills for items and services it furnishes to Medicare fee-for-service (FFS) beneficiaries under a Medicare billing number in accordance with applicable Medicare regulations; AND 4. Is included on the list of ACO providers / suppliers that is required under §425.204(c)(5) 	

Comments on the Proposed Rules

Summarizing comments made by the American Society for Clinical Pathology (ASCP)⁴, they urged the Centers for Medicare and Medicaid Services (CMS) to ensure that

1. Pathologists and other clinical scientists are eligible to serve as ACO professionals;
2. Quality Measures are structured in such a way that they recognize the unique differences between different medical specialties, and that they don't adversely affect those specialties that cannot comply;
3. ACOs utilize a two-sided risk model; and
4. Waivers of federal laws (specifically anti-trust laws, self-referral regulations, and anti-kickback statutes) be limited to those reasonably necessary to enable ACOs to meet their mission and goals.

>> CONTINUED ON PAGE 5

The College of American Pathologists (CAP)⁵ also commented on the need to include pathologists as part of an Accountable Care Organization:

“While primary care is essential to ACO composition, a strong foundation of diagnostic capabilities is core to an ACO’s effectively assuming accountability for the full continuum of patient care. Of those diagnostic capabilities, anatomic pathology services and clinical laboratory testing are without question a major influence on health care decision making **driving an estimated seventy percent of clinical decision making and comprising a significant portion of the medical record.** Laboratory testing and the diagnostic skill of pathologists are therefore of even greater impact in models such as ACOs that seek to optimize coordination of care and population management.

“Other core diagnostic capabilities include pathologists’ ability to provide guidance and direction to practitioners to ensure that correct tests are being ordered for diagnosis, prognosis, and monitoring therapy serving to **reduce laboratory overutilization and avoid unnecessary courses of treatment that could adversely affect patient outcome and increase downstream costs.** Pathologists are also interpreters of increasingly sophisticated laboratory results for patients and guides in shared clinical decision making and can be key effectors in **ensuring quality, safety, value and lower costs throughout the health system.”**

The CAP letter continues with comments on specific Quality Measures and how they affect or how they can be affected by pathologists, laboratory professionals, and laboratory medicine.

ACO Final Rules

The final rules⁶, announced on October 20, 2011, go a long way in bringing all the players into agreement. They may not please all medical entities, but they add to the menu of options available to ACOs to provide better care for individual patients with the goal of better health for the general population, all while keeping costs low.

- There were originally 65 quality measures divided into five domains. The Final Rule pared these down to 33 measures in four domains: 1. Patient / Caregiver Experience, 2. Care Coordination / Patient Safety, 3. Preventive Health, and 4. At Risk Populations (including Diabetes, Hypertension, Ischemic Vascular Disease, Heart Failure, and Coronary Artery Disease). Each measure is associated with a weighted point value.

(Refer to Table 2 for a listing of the Quality Measures and to Table 3 for their associated point values.)

- Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) were specifically added to the list of groups eligible to participate in an ACO.



- Use of certified Electronic Health Record (EHR) technology was removed as a condition of participation, but remains as a Quality Measure.
- Modifications were made to the ACO governance and legal structure, payment measures, start dates, assignment processes, and reporting periods.

The Final Rule describes its intention and the modifications as follows:

“The intent of the Shared Savings Program is to promote accountability for a population of Medicare beneficiaries, improve the coordination of FFS [fee-for-service] items and services, encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery, and incent higher value care. As an incentive to ACOs that successfully meet quality and savings requirements, the Medicare Program can share a percentage of the achieved savings with the ACO. Under the Shared Savings Program, ACOs will only share in savings if they meet both the quality performance standards and generate shareable savings.

“In this final rule we have made significant modifications to reduce burden and cost for participating ACOs. These modifications include: (1) greater flexibility in eligibility to participate in the Shared Savings Program; (2) multiple start dates in 2012; (3) establishment of a longer agreement period for those starting in 2012; (4) greater flexibility in the governance and legal structure of an ACO; (5) simpler and more streamlined quality performance standards; (6) adjustments to the financial model to increase financial incentives to participate; (7) increased sharing caps; (8) no down-side risk and first-dollar sharing in Track 1; (9) removal of the 25 percent withhold of shared savings; (10) greater flexibility in timing for the evaluation of sharing savings (claims run-out reduced to 3 months); (11) greater flexibility in antitrust review, and (12) greater flexibility in timing for repayment of losses; and (13) additional options for participation of FQHCs [Federally Qualified Health Centers] and RHCs [Rural Health Clinics].

>> CONTINUED ON PAGE 6

Table 2:

Measures For Use In Establishing Quality Performance Standards⁹	
AIM: Better Care for Individuals	
1. Patient / Caregiver Experience	CAHPS (Consumer Assessment of Health Providers and Systems): Getting Timely Care, Appointments, and Information
2. Patient / Caregiver Experience	CAHPS: How Well Your Doctors Communicate
3. Patient / Caregiver Experience	CAHPS: Patients' Rating of Doctor
4. Patient / Caregiver Experience	CAHPS: Access to Specialists
5. Patient / Caregiver Experience	CAHPS: Health Promotion and Education
6. Patient / Caregiver Experience	CAHPS: Shared Decision Making
7. Patient / Caregiver Experience	CAHPS: Health Status / Functional Status
8. Care Coordination / Patient Safety	Risk-Standardized, All Condition Readmission*
9. Care Coordination / Patient Safety	Ambulatory Sensitive Conditions Admissions: Chronic Obstructive Pulmonary Disease (AHRQ Prevention Quality Indicator (PQI) #5)
10. Care Coordination / Patient Safety	Ambulatory Sensitive Conditions Admissions: Congestive Heart Failure (AHRQ Prevention Quality Indicator (PQI) #8)
11. Care Coordination / Patient Safety	Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment
12. Care Coordination / Patient Safety	Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility
13. Care Coordination / Patient Safety	Falls: Screening for Fall Risk
*Note: this measure has been under development and its finalization is contingent upon the availability of measures specifications before the establishment of the Shared Savings Program on January 1, 2012.	
AIM: Better Health for Populations	
14. Preventive Health	Influenza Immunization
15. Preventive Health	Pneumococcal Vaccination
16. Preventive Health	Adult Weight Screening and Follow-up
17. Preventive Health	Tobacco Use Assessment and Tobacco Cessation Intervention
18. Preventive Health	Depression Screening
19. Preventive Health	Colorectal Cancer Screening
20. Preventive Health	Mammography Screening
21. Preventive Health	Proportion of Adults 18+ who had their Blood Pressure measured within the preceding 2 years
22. At Risk Population – Diabetes	Diabetes Composite (All or Nothing Scoring): Hemoglobin A1c Control (< 8 percent)
23. At Risk Population – Diabetes	Diabetes Composite (All or Nothing Scoring): Low Density Lipoprotein (< 100)
24. At Risk Population – Diabetes	Diabetes Composite (All or Nothing Scoring): Blood Pressure < 140/90.
25. At Risk Population – Diabetes	Diabetes Composite (All or Nothing Scoring): Tobacco Non Use
26. At Risk Population – Diabetes	Diabetes Composite (All or Nothing Scoring): Aspirin Use
27. At Risk Population – Diabetes	Diabetes Mellitus: Hemoglobin A1c Poor Control (> 9 percent).
28. At Risk Population – Hypertension (HTN)	HTN: Blood Pressure Control
29. At Risk Population – Ischemic Vascular Disease (IVD)	IVD: Complete Lipid Profile and LDL Control < 100 mg/dl.
30. At Risk Population – Ischemic Vascular Disease	IVD: Use of Aspirin or Another Antithrombotic
31. At Risk Population – Heart Failure	Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)
32. At Risk Population – Coronary Artery Disease (CAD)	CAD Composite (All or Nothing Scoring): Drug Therapy for Lowering LDL-Cholesterol
33. At Risk Population – Coronary Artery Disease (CAD)	CAD Composite (All or Nothing Scoring): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD)

>> CONTINUED ON PAGE 7

“In developing the Shared Savings Program, and in response to stakeholder suggestions, [CMS] worked very closely with agencies across the Federal government, to develop policies to encourage participation and ensure a coordinated and aligned inter- and intra-agency program implementation. The result of this effort is the release of several documents that potential participants are strongly encouraged to review. These documents are described in more detail in Section II.C.5. of this final rule⁷, and include: (1) A joint CMS and DHHS OIG [Department of Health and Human Services, Office of the Inspector General] interim final rule with comment period published elsewhere in this issue of the Federal Register entitled Medicare Program; Final Waivers in Connection With the Shared Savings Program; (2) IRS Notice 2011-20 and other applicable IRS guidance viewable on [www.irs.gov](#); and

(3) a Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Shared Savings Program issued by the FTC [Federal Trade Commission] and DOJ [Department of Justice] (collectively, the Antitrust Agencies).”⁸

CMS realizes that the process will have to be modified in the future as the program continues. This is especially true of the Quality Measures. New measures will be added and older ones retired as appropriate through the rulemaking process. The current specifications are the most up-to-date for the 2012 Shared Savings Program performance period. In the future, the release of new measures will be balanced with the effort to keep them as up-to-date as possible while giving ACOs sufficient time to review them. ■

Table 3:

>> RESOURCES ON PAGE 17

Total Points for Each Domain Within the Quality Performance Standard				
Domain	Number of Individual Measures	Total Measures for Scoring Purposes	Total Potential Points per Domain	Domain Weight (Percent)
Patient / Caregiver Experience	7	1 measure with 6 survey module measures combined, plus 1 individual measure	4	25
Care Coordination / Patient Safety	6	6 measures, plus the EHR measure double-weighted (4 points)	14	25
Preventive Health	8	8 measures	16	25
At Risk Population	12	7 measures, including 5 component diabetes composite measures and 2 component CAD composite measures	14	25
Totals	33	23	48	100

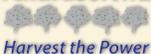


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RAC Update

RECOVERY AUDIT CONTRACTOR (RAC) PROGRAM WAS EXPANDED TO ALL 50 STATES IN 2010

The U.S. Congress established the Recovery Audit Contractor (RAC) program to detect improper Medicare payments made in the past and prevent improper payments from being made in the future. The nationwide expansion of the program was authorized through the Tax Relief and Health Care Act of 2006, which mandated that the expansion occur no later than 2010. Recovery Auditors contract with the Centers for Medicare and Medicaid Services (CMS) and are tasked with detecting and correcting improper payments. Demand letters are sent to health care providers when improper payments are identified.

In September, 2011, CMS provided notice that beginning in January 2012, the responsibility for sending these demand letters has been shifted from the Recovery Auditors to the Medicare Administrative Contractors (MACs). To prepare for this nationwide change, Region C will begin a pilot program in November 2011 to educate the providers and suppliers in that region about this change. Refer to MLN Matters #MM7436 on page 12 for additional information on this subject.

Recent RAC Activity

Updated information about the RAC program's efforts (payment corrections and top issues discovered) is presented in chart form below and includes:

- Corrections for FY 2010 and FY 2011 to date (Table 1);
- FY 2011, 3rd quarter activity, according to region (Table 2); and
- Top issue seen in each region (Table 3).

The last two resources are reprinted from the March-April, 2011 issue of Insights. Table 4 provides hyperlinks to access additional information about Federal regulations that affect Medicare, and Figure 1 is a map of the United States showing the RAC regions. Even though there are differing numbers of states in each region, each region is essentially equal in the number of Medicare claims processed.

COLA will continue to provide periodic updates as needed.

Table 1:

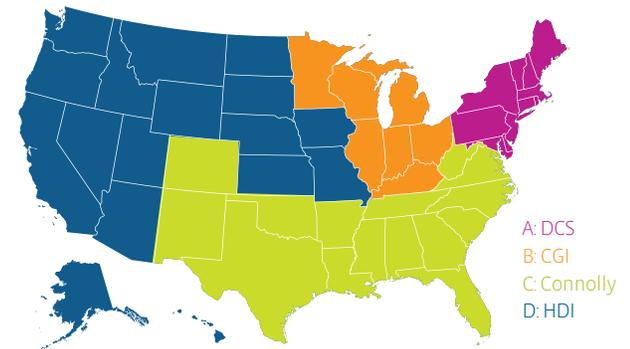
CMS Medicare Fee for Service National Recovery Audit Program Third Quarter, Fiscal Year 2011				
	Overpayments Collected	Underpayments Returned	Total Third Quarter Corrections	FY-to-Date Corrections
Region A: DCS <i>(Diversified Collection Services)</i>	\$40.4 M	\$5.0 M	\$45.4 M	\$98.2 M
Region B: CGI <i>(CGI Federal)</i>	\$33.9 M	\$9.8 M	\$43.7 M	\$118.5 M
Region C: Connolly, Inc.	\$46.9 M	\$7.4 M	\$54.3 M	\$133.3 M
Region D: HDI <i>(HealthData Insights)</i>	\$112.2 M	\$33.7 M	\$145.9 M	\$242.5 M
Nationwide Totals	\$233.4 M	\$55.9 M	\$289.3 M	\$592.5 M

Figures rounded to nearest tenth.

Nationwide figures rounded based on actual collections.

All correction data current through June 30, 2011 (retrieved July 02, 2011).

Figure 1:



Insights focused on the RAC program in the March-April 2011 issue. Please refer to that issue for additional information.

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Table 2:

CMS Medicare Recovery Audit Program as of June 2011					
	FY 2011 <i>(Oct 2009 – Sep 2010)</i>	Q1, FY 2011 <i>(Oct – Dec 2010)</i>	Q2, FY 2011 <i>(Jan – Mar 2011)</i>	Q3, FY 2011 <i>(Apr – Jun 2011)</i>	Total National Program
Overpayments Collected	\$74.4 M	\$81.2 M	\$185.2 M	\$233.4 M	\$575.2 M
Underpayments Returned	\$16.9 M	\$13.1 M	\$23.7 M	\$55.9 M	\$109.6 M
Total Corrections	\$92.3 M	\$94.3 M	\$208.9 M	\$289.3 M	\$684.8 M

Table 3:

Top Issue per Region Based on collected amounts through June 17, 2011	
Region A	Renal and Urinary Tract Disorders: (Medical Necessity) Medicare pays for inpatient hospital services that are medically necessary for the setting billed. Medical documentation for patients with renal and urinary tract disorders needs to be complete and support all services provided.
Region B	Extensive operating room procedure unrelated to principal diagnosis: (DRG validation) Principal diagnosis & principal procedure codes for an inpatient claim should be related. Errors occur when providers bill an incorrect principal and/or secondary diagnosis that results in an incorrect Medicare Severity Diagnosis- Related Group (MS-DRG) assignment
Region C	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) provided during an Inpatient stay: (DMEPOS Automated Review) Medicare does not make separate payment for DMEPOS when a beneficiary is in a covered inpatient stay.
Region D	Minor Surgery and other treatment billed as Inpatient: (Medical Necessity) When beneficiaries with known diagnoses enter a hospital for a specific minor surgical procedure or other treatment that is expected to keep them in the hospital for less than 24 hours, they are considered outpatient for coverage purposes regardless of <ul style="list-style-type: none"> • the hour they presented to the hospital, • whether a bed was used, and • whether they remained in the hospital after midnight.

Table 4:

For more detailed information about:	See:
Claims Review Programs	<i>Medicare Claim Review Programs: MR, NCCI Edits, MUEs, CERT & RAC</i> 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	<i>The Patient Protection and Affordable Care Act</i> <i>All CMS Provisions – As of December 10, 2010</i> http://www.cms.gov/LegislativeUpdate/downloads/PPACA.pdf
Tax Relief & Health Care Act	Library of Congress http://thomas.loc.gov/cgi-bin/bdquery/z?d109:h.r.06111:/
CMS Provisions in the Tax Relief & Health Care Act	<i>Tax Relief and Health Care Act of 2006</i> <i>All CMS Provisions – As of March 2, 2007</i> http://www.cms.gov/LegislativeUpdate/downloads/TRHCA0307.pdf
Medicare Modernization Act	Interactive hyperlinked index

EHR Update

FINAL RULE PUBLISHED IN JULY 2010; MEANINGFUL USE PROGRAM BEGAN IN EARLY 2011.

Electronic Health Records (EHR) claimed national attention with the passage of the HITECH Act (Health Information Technology for Economic and Clinical Health Act) in 2009. Since then, the term “meaningful use” has become a significant part of the medical vocabulary, mainly due to the implementation of the Medicare EHR Incentive Program.

This program will provide incentive payments to participants that demonstrate meaningful use of *certified* EHR technology. Incentive payments will be implemented in three stages over a five year period. To receive the maximum incentive payments, participation must begin no later than 2012. The penalty phase begins in 2015; medical entities that do not demonstrate meaningful use by then will see payment adjustments in their Medicare reimbursements.



Certified Electronic Health Records Technology

An important aspect of the program is the use of **certified** EHR technology. According to the Office of the National Coordinator for Health Information Technology (ONC), “Certification of Health Information Technology will provide assurance to purchasers and other users that an EHR system, or other relevant technology, offers the necessary technological capability, functionality, and security to help them meet the meaningful use criteria established for a given phase. Providers and patients must also be confident that the electronic health IT products and systems they use are secure, can maintain data confidentially, and can work with other systems to share information. Confidence in health IT systems is an important part of advancing health IT system adoption and allowing for the realization of the benefits of improved patient care.”¹

A Temporary Certification Program has been established expressly for the purposes of testing and certifying Health Information Technology (HIT) to assure the availability of certified EHR Technology prior to the reporting dates of the EHR Incentive Program.

In January 2011, ONC issued the final rule to establish the Permanent Certification Program for Health Information Technology. Eventually, the Permanent Certification Program will replace the Temporary Certification Program, which remains in effect until it sunsets on December 31, 2011, or at a later date when the processes necessary for the permanent certification program to operate are completed.²

IMPORTANT DATES FOR EHR INCENTIVE PROGRAM

01/03/2011	Registration for the EHR Incentive Program begins
04/18/2011	Attestation for the EHR Incentive Program begins
05/2011	EHR Incentive Program payments begin
09/30/2011	Last day of federal fiscal year; end of reporting year for eligible hospitals and CAHs*
11/30/2011	Last day for eligible hospitals and CAHs* to register and attest to receive incentive payments for federal fiscal year (FY2011)
12/31/2011	Last day of calendar year; end of reporting year for eligible professionals
02/29/2012	Last day for eligible professionals to register and attest to receive incentive payments for calendar year (CY2011)
	*CAH = Critical Access Hospital

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Privacy and Security Issues

Other major issues currently being addressed are patient privacy and HIT security. With the increased use of HIT comes the increased risk that patient privacy may be compromised. HIPAA (Health Insurance Portability and Accountability Act) regulations have been strengthened in an attempt to prevent security and privacy problems.

“The new regulations will improve patient privacy and security protections by extending the Office for Civil Rights’ enforcement [of HIPAA] to business associates and covered entities, strengthening individuals’ rights to request and receive their medical information in electronic form, and setting new limits on the use and sale of individuals’ information. (The Office for Civil Rights enforces the HIPAA Privacy and Security Rules and regulates any modifications to these rules.)

“Electronic health information exchange promises an array of potential benefits for individuals and the U.S. Health Care System through improved clinical care and reduced cost. At the same time, this environment also poses new challenges and opportunities for protecting individually identifiable health information. In health care, accurate and complete information about individuals is critical to providing high quality, coordinated care. If individuals and other participants in a network lack trust in electronic exchange of information due to perceived or actual risks to individually identifiable health information or the accuracy and completeness of such information, it may affect their willingness to disclose necessary health information and could have life-threatening consequences. Coordinated attention at the Federal and State levels is needed both to develop and implement appropriate privacy and security policies. Only by engaging all stakeholders, particularly consumers, can health information be protected and electronically exchanged in a manner that respects variations in individuals’ views on privacy and access.”³

A recent report (released November 8, 2011) by the Institute of Medicine (IOM) evaluated HIT safety concerns. The IOM realizes that HIT vendors and users as well as the government and private sectors all have roles to play in making HIT safe. Their recommendations include improving transparency in the reporting of HIT safety incidents and enhancing monitoring of HIT products.⁴

On a related note, the Office for Civil Rights announced recently that it will begin a pilot program to perform up to 150 audits of HIPAA covered entities to assess their privacy and security compliance. The pilot program will begin in November 2011 and conclude by December 2012. The program will assess all HIPAA compliance efforts, not just information stored and transmitted via HIT. The audits present a new opportunity to examine mechanisms for compliance, identify best practices, and discover risks and vulnerabilities that may not have come to light through the ongoing complaint investigations and compliance reviews.

As HIT continues to develop and improve, security and privacy protections will have to be continually evaluated. The ONC website offers several references and resources that address these important topics and is periodically updated to assure that the most reliable and pertinent information is available. To review this information, refer to http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__privacy_and_security/1147. ■

Insights focused on the HITECH Act and the EHR Incentive Program in the Sep-Oct 2010 issue. Please refer to that issue for additional information.

¹Office of the National Coordinator for Health Information Technology (ONC); Regulations & Guidance: Certification Programs http://healthit.hhs.gov/portal/server.pt?open=512&objID=2884&parentname=CommunityPage&parentid=357&mode=2&in_hi_userid=12059&cached=true last accessed November 2011

²ONC; Regulations & Guidance: Privacy and Security http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__privacy_and_security/1147
More information about the Permanent Certification Program can be found in the final rule entitled “Establishment of the Permanent Certification Program for Health Information Technology” (76 FR 1262, Jan. 7, 2011). <http://origin.www.gpo.gov/fdsys/pkg/FR-2011-01-07/pdf/2010-33174.pdf> last accessed November 2011

³Ibid.

⁴Institute of Medicine Report, Health IT and Patient Safety: Building Safer Systems for Better Care, released Nov. 8, 2011 <http://iom.edu/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx> View the report: <http://iom.edu/-/media/Files/Report%20Files/2011/Health-IT/healthITbrief.pdf>

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



News Flash – Under the Affordable Care Act, Medicare beneficiaries may now receive coverage for an Annual Wellness Visit (AWV), which is a yearly office visit that focuses on preventive health. In addition, Medicare also provides coverage for the Initial Preventive Physical Examination (IPPE), commonly known as the "Welcome to Medicare" visit. To learn more about the AWV and the IPPE, please refer to the CMS Medicare Learning Network® publication at http://www.cms.gov/MLNProducts/downloads/mps_guide_web-061305.pdf on the Centers for Medicare & Medicaid Services (CMS) website.

MLN Matters® Number: MM7436

Related Change Request (CR) #: 7436

Related CR Release Date: July 29, 2011

Effective Date: January 1, 2012

Related CR Transmittal #: R192FM

Implementation Date: January 3, 2012

Recovery Audit Program: Medicare Administrative Contractor (MAC)-issued Demand Letters

Provider Types Affected

This article is for all physicians, providers, and suppliers who bill Medicare claims processing contractors (Carriers, Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and Medicare Administrative Contractors (MACs)).

Provider Action Needed

STOP – Impact to You

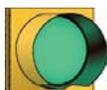
This article is based on Change Request (CR) 7436 which announces that Medicare's Recovery Auditors will no longer issue demand letters to you as of January 3, 2012.

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents. CPT only copyright 2010 American Medical Association.

**CAUTION – What You Need to Know**

Recovery Auditors will, however, submit claim adjustments to your Medicare contractor, who will perform the adjustments based on the Recovery Auditor's review, and issue an automated demand letter to you.

**GO – What You Need to Do**

See the Background and Additional Information Sections of this article for further details regarding these changes.

Background

As of January 3, 2012, the Centers for Medicare & Medicaid Services (CMS) is transferring the responsibility for issuing demand letters to providers from its Recovery Auditors to its claims processing contractors. This change was made to avoid any delays in demand letter issuance. As a result, when a Recovery Auditor finds that improper payments have been made to you, they will submit claim adjustments to your Medicare (claims processing) contractor. Your Medicare contractor will then establish receivables and issue automated demand letters for any Recovery Auditor identified overpayment. The Medicare contractor will follow the same process as is used to recover any other overpayment from you.

The Medicare contractor will then be responsible for fielding any administrative concerns you may have such as timeframes for payment recovery and the appeals process. However, the Medicare contractor will include the name of the initiating Recovery Auditor and his/her contact information in the related demand letter. You should contact that Recovery Auditor for any audit specific questions, such as their rationale for identifying the potential improper payment.

Additional Information

If you have questions, please contact your Medicare contractor at their toll-free number, which may be found at <http://www.cms.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the Centers for Medicare & Medicaid Services (CMS) website.

To see the official instruction (CR7436) issued to your Medicare contractor, see <http://www.cms.gov/Transmittals/downloads/R192FM.pdf> on the CMS website.

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COLA Update

NOVEL ACCREDITATION ACHIEVEMENT, UPDATED EDUCATIONAL PRODUCTS, LATEST LABORATORY INFORMATION

ISO Certification

Of the many accomplishments COLA has achieved over the past year, the most significant has to be obtaining ISO (International Organization for Standardization) certification. With this certification, granted in May 2011, COLA became the only health care accreditation organization deemed by CMS that is certified as meeting the ISO 9001:2008 standard.

The ISO 9001:2008 standard specifies requirements for a Quality Management System where an organization:

- Needs to demonstrate its ability to provide products and/or services that consistently meet customer needs, and consistently meet statutory and regulatory requirements;
- Aims to enhance customer satisfaction by offering a process for continual improvement, as well as by assuring conformity to customer, statutory, and regulatory requirements.¹

ISO certification is both highly coveted and difficult to achieve. The ISO registration audit included over 20 hours of observation and interviews conducted by the ISO inspector. COLA's certification covers the delivery and administration of its CLIA-approved accreditation program for medical laboratories, including on-site surveys, monitoring proficiency testing, and correcting citations through education and consultation. Every key process, from survey scheduling to conducting a COLA survey to paperwork review, was thoroughly audited.

According to Douglas Beigel, CEO of COLA, "By participating in the rigorous ISO review process, COLA has proven to the labs we serve that we are willing to engage in the same kind of thorough quality review process we perform for them. In doing so, we sharpen our ability to ensure that clinical laboratories meet the high standards doctors expect and patients deserve."²



New Learning Management System Coming Soon

COLA has been hard at work in recent months creating a new Education platform and converting courses and products to the new system. Soon you will be able to see the result of that work. You will notice a new look and feel to our websites, www.COLA.org and www.COLACentral.com, our online courses, and many of our products.

In anticipation of the new system, we reviewed all of our online courses. Revisions were made as necessary to ensure that our courses provide you with the most up-to-date information possible. In a few instances, when it was not possible to revise the course, we decided to remove it from our course menu, rather than offer you outdated information.

Over the last several months, we added to our available courses; the additions include two MLE CEexpress courses and several Webinar CEexpress editions. Please visit The COLA Store at www.COLA.org for detailed information on each course.

We are working on MORE new courses! We have used your suggestions for new course topics and expect to introduce several new courses throughout the coming year. Our LabGuides and other educational products are also currently being reviewed and revised. We will notify you as these courses and products become available.

Compliance Updates

A few COLA criteria, specifically BA-2, BA-7, M-8 and QC-24, were updated this year. Technical Bulletins about these criteria were included in the May-June, 2011 issue of *Insights*. The Bulletins are also available on www.COLA.org for COLA labs to download for free. Simply type "Technical Bulletins" in the Search window to access a copy.

This past year, technical committees within COLA began the major task of reviewing all of the criteria for needed updates and revisions. Be on the lookout for these revisions as they become available over the next several months.

>> CONTINUED ON PAGE 15

Also this past year, we created a new product to help you with your compliance needs. "Compliance Tips" focus on one or two criteria to explain them in more detail to help you understand how to meet their requirements. The March-April, 2011 *Insights* issue contains Compliance Tips for PER-3, PER-4, and PER-5 and a Compliance Tip addressing ORG-9 & 10 was included in the July-August, 2011 issue. These will be available for download after the new Education platform has been launched.

We will keep you informed of these and other upcoming changes as they happen.

Learn the Latest Laboratory Information at The Symposium

Each year, our Symposium for Clinical Laboratories continues to be our premier attraction. The most recent conference, held in Dallas in October 2011, is no exception. Here is what a few of the attendees had to say:

- First, I learned that we need to create a new QC strategy to minimize patient result risk factors. The second thing is not something that was learned but was experienced. I have never attended a COLA symposium and I experienced a feeling of "oneness" with my fellow laboratorians. This feeling has inspired me to want our laboratory to go above and beyond to achieve the best in patient testing and care.
- This symposium was my first for COLA - I am rejuvenated and very excited to get back to my lab and implement everything I learned. And, I can't wait to get back and go to COLA Central online to see what else I can learn. Also, I am impressed with the staff from COLA that are present - everyone is more than willing to help which proves the statement that COLA wants to help the laboratories be successful. Thank you.

- I loved the overall experience of feeling very important in my job field. I left the symposium wanting to definitely be the best lab employee I can be.
- Symposium was very well organized and informative. The hotel was wonderful. The food quality and selection was superb. Great Job!!!
- This is my first symposium and I hope not the last. The COLA staff has been wonderful and the hotel staff as well.
- Speakers had a passion for quality patient care.
- I was very impressed with all presenters - very qualified and well respected within the COLA and laboratory communities.
- It finally clicked on how to bring together Quality Assurance.
- COLA provides significant assistance to laboratories, assisting them in becoming and maintaining compliant with regulations.
- Always very PRACTICAL useful information and how to apply it in our facilities.
- This was my first COLA meeting and I was pleased with the opportunity to learn and interact with presenters and attendees alike.
- The lectures were energetic and informative. I liked that it was interactive with the audience and I felt free to ask questions. A lot of good information came from the lecture, but I like that we were also provided with resources to go to for help.

Our next Symposium will surely promote as much excitement! It is scheduled for April 18 - 21, 2012 at the newly renovated Tropicana Hotel in Las Vegas; remember, "What happens in Vegas, stay in your lab!" ■

>> RESOURCES CONTINUED ON PAGE 16

**COLA's
Symposium for
Clinical Laboratories!**

Las Vegas, NV | April 18-21, 2012
Newly Renovated Tropicana Las Vegas

**Early Bird Fee \$425
Expires February 1st**

**EDUCATION THAT STAYS
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SYMPOSIUM 
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The University of Wisconsin School of Medicine and Public Health and COLA thank the following companies for their financial support of the Symposium for Clinical Laboratories.

Thank you!



CONTINUED FROM PAGE 15

RESOURCES

¹International Organization for Standardization, Catalog, Products, ISO Standards; Abstract ISO 9001:2008; *last accessed November 2011*; http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=46486

²COLA, News, COLA Receives ISO Registration; *last accessed November 2011*; <http://www.cola.org/news.html?NewsID=601> ISO is an international-standard-setting body composed of representatives from various national standards organizations. ISO has developed over 18,500 International Standards on a variety of subjects; approximately 1,100 new ISO standards are published every year. For more information, visit www.iso.org.

RESOURCES

¹Public Law 111-148, 111th Congress, The Patient Protection and Affordable Care Act of 2010; <http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf> last accessed November 2011

²Federal Register; Vol. 76, No. 212; Wednesday, November 2, 2011; Rules and Regulations; 42CFR 425.20; 42Code of Federal Regulations, Part 425, Subpart A, §425.20 – Definitions; <http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27461.pdf#page=173> last accessed November 2011

³As reported by Dark Daily, many of the nation's most influential medical associations were quick to criticize the ACO rules. See: Dark Daily, "Medicare's Final Rule for Accountable Care Organizations (ACO) Draws Fire from Healthcare Provider Groups," May 31, 2011, <http://www.darkdaily.com/medicare%E2%80%99s-final-rule-for-accountable-care-organizations-aco-draws-fire-from-healthcare-provider-groups-053111> and Dark Daily "Many Hospitals and Doctors Not Happy with Federal Rules for Accountable Care Organizations (ACOs)," June 21, 2011, <http://www.darkdaily.com/many-hospitals-and-doctors-not-happy-with-federal-rules-for-accountable-care-organizations-acos-62111> last accessed November 2011

⁴American Society for Clinical Pathology's comments on the proposed ACO rules; letter to Donald M. Berwick, MD, Administrator, Centers for Medicare and Medicaid Services, June 6, 2011, <http://www.ascp.org/PDF/Advocacy/ASCP-Comments-on-Proposed-ACO-Rule.pdf> last accessed November 2011

⁵The College of American Pathologists' comments on the proposed ACO rules; letter to Donald M. Berwick, MD, MPP, Administrator, Centers for Medicare and Medicaid Services, June 3, 2011, http://www.cap.org/apps/docs/advocacy/comments/aco_proposed_rule_letter.pdf last accessed November 2011

⁶Federal Register; Vol. 76, No. 212; Wednesday, November 2, 2011; Rules and Regulations; 42CFR, Part 425; Final Rule; <http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27461.pdf#page=88> and 42Code of Federal Regulations, Part 425, Subpart F, §425.500 – Quality Performance Standards and Reporting; <http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27461.pdf#page=183> last accessed November 2011

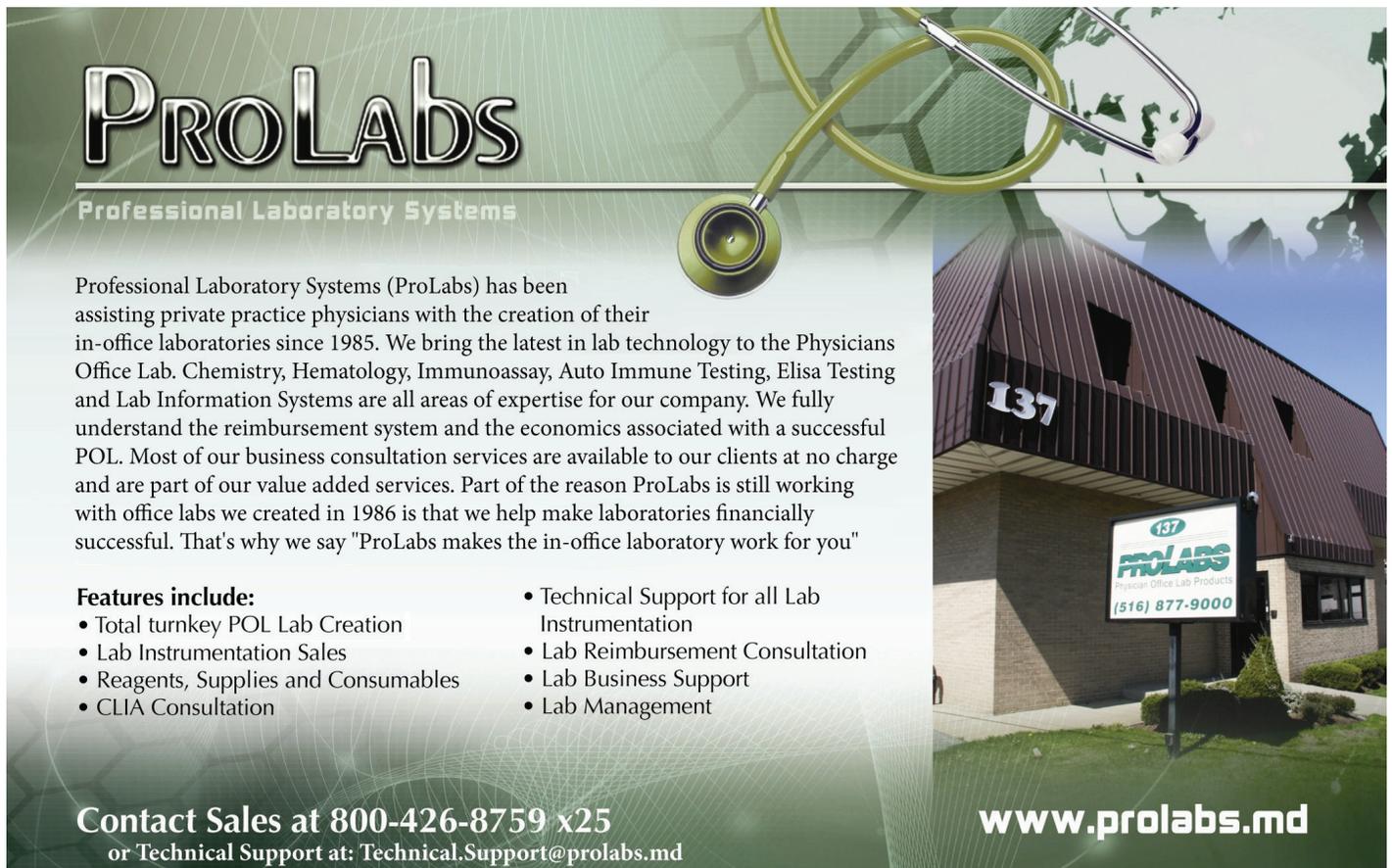
⁷The listed documents can be accessed via the following hyperlinks:

- 1) Medicare Program; Final Waivers in Connection with the Shared Savings Program: <http://frwebgate1.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=iQjMod/9/2/0&WAIAction=retrieve>
- 2) IRS Notice 2011-20: <http://www.irs.gov/pub/irs-irbs/irb11-20.pdf>
- 3) FTC & DOJ anti-trust statement: <http://www.ftc.gov/opp/aco/>

⁸Federal Register; Vol. 76, No. 212; Wednesday, November 2, 2011; Rules and Regulations; 42CFR, Part 425; Final Rule; <http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27461.pdf#page=3> last accessed November 2011

A table showing the key differences between the proposed and final rules can be viewed at this site: <http://www.cms.gov/ACO/Downloads/Appendix-ACO-Table.pdf>

⁹Federal Register; Vol. 76, No. 212; Wednesday, November 2, 2011; Rules and Regulations; 42CFR, Part 425; Final Rule; <http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27461.pdf#page=88> last accessed November 2011



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