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SEPTEMBER / OCTOBER '10

INSIGHTS

MEANINGFUL USE OF EHR

The American Recovery and Reinvestment Act (ARRA), a broad economic stimulus package also known as the Recovery Act, was passed in February 2009. The purposes of the act are, among others, "to preserve and create jobs and promote economic recovery, and to provide investments needed to increase economic efficiency by spurring technological advances in science and health."[1] Effects of the Recovery Act can be felt in federal government agencies from the US Department of Agriculture to the US Department of Transportation, Housing and Urban Development, and almost every department in between.

Many of the ARRA programs are managed by the US Department of Health and Human Services (HHS). (See http://www.hhs.gov/recovery/overview/index.html for a complete listing of HHS Recovery Act programs.) According to HHS, "Broad use of HIT (Health Information Technology) has the potential to improve health care quality, prevent medical errors, increase the efficiency of care provision and reduce unnecessary health care costs, increase administrative efficiencies, decrease paperwork, expand access to affordable care, and improve population health."[2] The expectation is that the use of HIT can improve patient safety and quality of care while decreasing overall costs through increased efficiency. Because of this, the HITECH Act (Health Information Technology for Economic and Clinical Health Act) was included as part of ARRA. HITECH is one of the programs that HHS oversees and is also the focus of this article.

HITECH aims to accomplish its goals by promoting not only the adoption, but also the "meaningful use" of electronic health record (EHR) technologies by eligible professionals (EPs) and hospitals. There are "three main components of meaningful use:

- The use of a certified EHR in a meaningful manner (e.g.: e-Prescribing);
- The use of certified EHR technology for electronic exchange of health information to improve quality of health care; and
- The use of certified EHR technology to submit clinical quality and other measures."[3]

Ensuring that EHR technology is certified falls to the EHR vendors. They must ensure that the systems meet the federal certification standards, which were established "to enhance the interoperability, functionality, utility, and security of health information technology."[4] There was a concerted effort to align the final rules for the certification standards with the final Stage One Meaningful Use objectives and measures. Both sets of final rules were published in July 2010 and the first certified systems are expected to be available by Fall 2010.

EHR Incentive Program

The HITECH Act uses incentives and penalties to encourage meaningful use of EHR technology. The incentives will be implemented in three stages over a period of five years. The penalties begin in 2015, if EHR meaningful use has not been demonstrated by then. There are different rules for Medicare, Medicaid, hospitals and EPs, but this article will concentrate on the Medicare program for EPs.

Eligible professionals under the Medicare incentive program include:

- Doctors of medicine or osteopathy
- Doctors of dental surgery or dental medicine
- Doctors of podiatric medicine
- Doctors of optometry
- Chiropractors

Hospital-based EPs, i.e. EPs who provide 90% or more of their services in either a hospital inpatient and/or emergency room setting, are not eligible for the incentives. Specialists are eligible if they meet one of the above criteria.

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FROM THE CHAIR

Much of the current healthcare news focuses on the EHR Incentive Program. The final rules for Stage One were published this summer. The final rules for the certification of EHR systems, also published this summer, were followed by announcements of approved certifying agencies. Questions, discussions and misperceptions accompanied the announcements.

In this issue of *Insights*, we want to provide you with facts to answer your questions and dispel your misperceptions. The first article provides an overview of the Incentive Program and its origins in the HITECH Act. The next article describes how HITECH and CLIA interact. The final article on the subject details how COLA can help with your laboratory documentation.

The Incentive Program is certainly a hot topic, but it is not the only news on the healthcare scene. This issue also includes a letter from the CDC's Laboratory Outreach and Communication System (LOCS) that addresses guidelines for specific testing for sexually transmitted diseases.

By way of *Insights*, the Symposium for Clinical Laboratories and our websites, **www.COLA.org** and **www.COLAcentral.com**, we do our best to keep you apprised of the latest updates in laboratory medicine. You can also contact us whenever you have questions and/or comments.

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

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However, according to the ASCP (American Society for Clinical Pathology), it will be difficult for pathologists, and other specialists, to meet all of the incentive requirements.[5]

The incentives are based on individual providers, not on practices. Therefore, it would be possible for a practice with five providers to receive five incentive payments per year. However, a single individual may receive only one incentive payment per year, regardless of the number of practices or locations where he/she provides services.

The Final Rules for Stage One[6], published in July 2010, list the requirements for demonstrating meaningful use to qualify for the incentives. They are divided into:

- A Core Set of 15 requirements
- A Menu Set of 10 requirements
- Clinical Quality Measures (CQM), which are further divided into
  - A Core Set of three requirements
  - An Alternate Core Set of three requirements
  - Additional Set of 38 CQMs.

To qualify for incentives, EPs must meet all 15 of the Core Set requirements, five of the ten requirements from the Menu Set, all three of the requirements listed under the CQM Core Set (or Alternate Core Set) and three of the 38 Additional Set CQMs. The majority of the requirements that directly affect the laboratory are listed as CQMs; however, there are several others that indirectly relate to the laboratory and the Laboratory Information System (LIS).*

The Centers for Medicare and Medicaid Services (CMS), an HHS agency, oversees the EHR Incentive Program. All of the requirements, the payment schedule and the most up-to-date information can be found on their website: http://www.cms.gov/ehrincentiveprograms/01_overview.asp?.

Demonstrating EHR meaningful use, by meeting the requirements, results in a scaled monetary payout for the eligible professional. The maximum incentive available is $44,000, paid over a five year period. However, to obtain the maximum amount, time constraints must be met. EPs who enroll and meet requirements in 2011 and 2012 are the only ones that can

** The next article in this issue of Insights delves deeper into how HITECH affects the medical laboratory.*

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receive the maximum incentive. Incentive payments decrease for those beginning in 2013 or 2014. No incentives will be paid after 2016.

Table 1 shows the incentives based on the first year of enrollment in the program.

The first row represents the first calendar year that EPs receive payment, while the other rows show the amount of the incentive they receive that year, if they continue to meet requirements.

Timeline

The first EHR certifying agencies were named in September 2010. It follows that the first certified EHR systems are expected to become available later in the fall of 2010.

Eligible professionals may begin registering for the incentive program in January 2011. Then, beginning in April 2011, CMS will accept attestation statements from EPs that they are meeting the meaningful use requirements. The first incentive payments are expected to be issued in May 2011. In 2012, CMS will phase out the attestation period by requiring the electronic submission of CQMs. Subsequently, other requirements will have to be submitted electronically by the EHR system, but that timeline has yet to be established. 2015 marks the beginning of the penalty phase for those that are not meaningful users of EHR by then, and the final Medicare incentive payments will be made in 2016.

Stage One of the meaningful use requirements is geared toward the capture and sharing of pertinent data. Stage Two, scheduled to begin in 2013, focuses on advanced clinical processes. The final stage, due in 2015, concentrates on improved outcomes. There is speculation that all of the Stage One Menu Set requirements will become Core Set requirements during the second and third stages, but the rules for Stage Two and Stage Three have not been proposed yet.

This was intended as a general overview of HITECH and EHR meaningful use with emphasis on the EHR Medicare Incentive Program for EPs. As stated earlier, hospitals and those receiving incentives through Medicaid have different requirements. Please check the resources listed in this article and in the footnotes for more details on these programs. These resources will also help you stay abreast of the most up-to-date information available.

1 The American Recovery and Reinvestment Act of 2009; http://fdsys.gpo.gov/fdsys/pkg/BILLS-111hr1ENR/pdf/BILLS-111hr1ENR.pdf
2 Office of the National Coordinator (ONC), US Department of Health and Human Services (HHS): http://healthit.hhs.gov/
3 Centers for Medicare and Medicaid Services; EHR Incentive Program; Meaningful Use http://www.cms.gov/EHRIncentivePrograms/35_Meaningful_Use.asp#TopOfPage
4 45CFR Part 170. Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule: http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf
5 CMS Final EHR Meaningful Use Rule Disappoints; Pathologists May Face Penalties; ePolicy News, The American Society for Clinical Pathology; 01 Aug 2010: http://www.ascp.org/HomePageContent/ePolicyNews/ePolicy-News--August-1-2010.aspx
6 42CFR Parts 412, 413, 422 et al. Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule: http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf

	CY 2011	CY 2012	CY 2013	CY 2014	CY 2015 *and later*
CY 2011	$18,000				
CY 2012	$12,000	$18,000			
CY 2013	$8,000	$12,000	$15,000		
CY 2014	$4,000	$8,000	$12,000	$12,000	
CY 2015	$2,000	$4,000	$8,000	$8,000	$0
CY 2016		$2,000	$4,000	$4,000	$0
TOTAL	$44,000	$44,000	$39,000	$24,000	$0

Table 1 Medicare Incentive Program

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HITECH AND THE MEDICAL LABORATORY

Since the publication of the final rules for Stage One of the EHR (electronic health record) Incentive Program, there has been a lot of discussion resulting in a fair amount of confusion as to how medical laboratories will be affected. This article's intent is to clear some of the confusion and dispel some of the associated rumors.

As outlined in the leading article in this issue of *Insights*, the focus of the HITECH Act (Health Information Technology for Economic and Clinical Health Act) is hospitals and eligible professionals (EPs), not medical laboratories. The majority of the HITECH Act addresses the EHR Incentive Program which concentrates on the adoption, implementation and upgrading of EHR technology and its meaningful use.

According to the American Society for Clinical Pathology (ASCP)[1], pathologists, laboratories, and other specialty physicians may have difficulty meeting the Stage One rules for showing meaningful use of EHR technology. ASCP stated that the rules "focus on primary care and require reporting patient information that the pathologist or laboratory would not likely possess. ... In its comments on the proposed rule, ASCP urged that pathologists be exempted from the HIT [Health Information Technology] functionality measures and the clinical care measures. ASCP argued that, given the reliance of other physicians on pathology and laboratory information, pathologists and laboratories providing information electronically to their clients should be deemed as meeting the rule's reporting requirements." The Centers for Medicare and Medicaid Services (CMS) did not change these requirements in the final rules. However, ASCP is continuing to study the final rules and is working with the American Medical Association and others to continue to address its concerns.

EHR Technology

HITECH may or may not impact your laboratory. The Act lists specific tasks that a system must perform before it can be called an EHR system. Since a Laboratory Information System (LIS) does not perform these tasks, an LIS is not the same as an EHR system[2]. This means that you do not have to reconfigure your LIS to meet the HITECH objectives. Although to take advantage of the Incentive Program, you must have an EHR system and use it in a meaningful way. If you also have an LIS, you have to ensure adequate and effective communication (integration) between the two systems. Since the privacy of protected health information (PHI) is still a concern, you will also have to confirm that laboratory orders will be received from, and results will be available to, only the appropriate healthcare providers. This may be a complicated endeavor if you work in a hospital or reference laboratory, since you may be interfacing with several different EHR systems used by several different EPs. If your laboratory does not use an LIS, integration between the LIS and EHR will obviously not be an issue. You will, however, have to determine how laboratory data will be inputted to the EHR.

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Integration may be the largest concern laboratories have to face as a result of the HITECH Act, but it is not the only one. Other issues include maintaining the safety and security of patient information, and ensuring the integrity of the LIS and the EHR system. Many issues will depend on the particular technology in use; therefore, whenever possible, laboratory personnel should be included when EHR and/or LIS options are being considered. Work closely with the LIS and EHR vendors to ensure you acquire the best systems to meet your needs.

CLIA and HITECH

The HITECH Act does not supersede, but rather complements, many existing federal laws and regulations. When the HITECH rules were developed, a coordinated approach was used to work within the established framework of HIPAA (Health Information Portability and Accountability Act), CLIA (Clinical Laboratory Improvement Amendments), PHSA (Public Health Service Act), and other acts. Unfortunately, this approach did not stop misperceptions of conflicts between the regulations from arising. The remainder of the article will clarify some perceived conflicts between CLIA and HITECH.

CLIA regulations DO NOT stipulate that laboratories have to maintain both a paper and an electronic copy of patient records. Nor do they state that test results must be saved in the identical format as the original report. They DO require that specific information be included in laboratory test reports and that this information must be transmitted accurately, reliably, confidentially, and in a timely manner. The regulations DO NOT require that a specific format be used to generate or transmit these reports. Although, when electronic reports are utilized, CMS DOES encourage the use of LOINC and HL7 (recognized vocabulary and transmission standards) since they facilitate accuracy and support the EHR certification standards. Again, these are NOT required. (See Table 1 for applicable CLIA regulations; §493.1105, §493.1241 and §493.1291.)[3]

Some interpret section §493.1291(f)3 of the CLIA regulations as not allowing the release of test results to an HIE (Health Information Exchange), which is defined as "electronic mobilization of healthcare information across multiple organizations within a community, state, or region."[4]

However, according to the latest revision of the Interpretive Guidelines for Laboratories and Laboratory Services,[5] if the HIE (or another agent) is listed on the test request or if the authorized person* lists the HIE or other agent as a designee, laboratory results can be sent directly to the HIE or agent. An agent is an individual or entity legally acting on behalf of the authorized person to receive test results.

A future goal of HITECH is that EHR will allow patients to become more involved in their own care. This may include the release of healthcare information directly to patients. However, some perceive that CLIA prohibits this. They cite section §493.1291(f) again as proof that CLIA does not allow patients to receive their test results directly. However, this is actually dependent on State law. Unless expressly prohibited by State law, patients may be able to receive their test results by qualifying as "authorized persons," or as "individuals responsible for using test results." They may also be able to receive their results if, at the time the order is placed, the ordering individual requests that a copy of the results be sent to the patient. Check with the regulatory agency within your state to verify your state's law.

Finally, laboratory personnel, including surveyors, are not responsible for ensuring that EHRs meet the federal certification and privacy standards.[5] EHR vendors must ensure that their systems meet these standards, which allow for the meaningful use of the EHR system. As stated earlier, your LIS is a separate system and is not subject to the HITECH certification criteria for EHR technology.

Even though CLIA, HITECH and other regulations aim to improve patient safety and quality of care, they are separate regulations which achieve these goals in different ways. All applicable regulations will continue to be considered as future rules are published.

** An "authorized person" means an individual authorized under state law to order tests or receive test results, or both.[5]*

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Table 1 Regulations for Test Ordering and Result Reporting; Clinical Laboratory Improvement Amendments (CLIA)

§493,1105 (a)	Standard: Retention Requirements	The laboratory must retain its records and, as applicable, slides, blocks, and tissues as follows: 1. Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. 6. Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting.
§493,1241 (a)	Standard: Test Request	The laboratory must have a written or electronic request for patient testing from an authorized person.
§493,1241 (c)	Standard: Test Request	The laboratory must ensure the test requisition solicits the following information: 1. The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. 2. The patient's name or unique patient identifier. 3. The sex and age or date of birth of the patient. 4. The test(s) to be performed. 5. The source of the specimen, when appropriate. 6. The date and, if appropriate, time of specimen collection. 7. For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. 8. Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.
§493,1291 (a)	Standard: Test Report	The laboratory must have adequate manual or electronic systems in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: 1. Results reported from calculated data. 2. Results and patient-specific data electronically reported to network or interfaced systems. 3. Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.
§493,1291 (f)	Standard: Test Report	Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.
§493,1291 (k)	Standard: Test Report	When errors in the reported patient test results are detected, the laboratory must do the following: 1. Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. 2. Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.

Current CLIA Regulations; http://wwwn.cdc.gov/clia/regs/toc.aspx

1 American Society for Clinical Pathology; ePolicy News; August 1, 2010: http://www.ascp.org/HomePageContent/ePolicyNews/ePolicy-News--August-1-2010.aspx

2 45 CFR Part 170. Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule: http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf

3 Centers for Disease Control and Prevention (CDC); listing of current CLIA regulations: http://wwwn.cdc.gov/clia/regs/subpart_k.aspx#493.1291

4 Judy Yost, MA, MT; "The Electronic Exchange of Information – CLIA & EHRs and CLIA Personnel Requirements", Continuing Education session; COLA Symposium for Clinical Laboratories, September 29 – October 2, 2010, Scottsdale, AZ. *Ms. Yost is the Director of the Division of Laboratory Services of the Centers for Medicare and Medicaid Services*

5 Centers for Medicare & Medicaid Services (CMS); "Surveying Facilities that Use Electronic Health Records (EHR)"; memorandum; March 1, 2010: http://www.cms.gov/SurveyCertificationGenInfo/downloads/SCLetter10-12.pdf

HITECH AND COLACENTRAL

COLA does not design Electronic Health Records (EHR) or Laboratory Information Systems (LIS), but we can help you manage your laboratory documentation. This is an essential first step in meeting some of the requirements of the EHR Incentive Program. Since many CLIA regulations address documentation and record retention, COLA can help you meet these requirements as well.

COLAcentral, our web portal, is the newest mechanism we use to help you. Much of the information needed for accreditation can be submitted and updated directly online. General laboratory information and personnel data as well as facts about your tests and test systems can all be submitted through COLAcentral. Many of the records specific to your laboratory can be scanned and uploaded to be stored in your own secure Document Repository. Having one location to store laboratory documentation allows you to manage and track official versions across one or multiple laboratory sites.

Whether you have one or several laboratory locations, COLAcentral is a useful tool to monitor your laboratory's survey and proficiency testing results, to track your equipment inventory and maintenance and to update your tests and test systems.

Laboratory information is an essential part of a patient's health record. It is essential to provide documentation to ensure that laboratory information is accurate. Make COLAcentral an essential way to manage and monitor your laboratory information. Allow us to bring visibility to the critical areas of your operations by providing you with the tools you need to succeed.

A LETTER FROM THE CENTERS FOR DISEASE CONTROL & PREVENTION (CDC)

Dear Colleague:

I am writing to ask all laboratory directors to review their procedure to be certain that they are following the manufacturer's guidelines for interpreting and reporting *Chlamydia trachomatis* and *Neisseria gonorrhoeae* nucleic acid amplification tests (NAATs). We have learned that some laboratories have been retesting specimens that were initially read out as "low positive", when this outcome is among the possible test readouts, and reporting those test results as "negative" if they do not confirm, whereas the manufacturer's instructions consider these results to be presumptive evidence of infection. Retesting was intended to address the lower predictive value of low-positive results; however when discordant results are reported as "negative," some infected patients may go untreated. Asymptomatic infections can lead to pelvic inflammatory disease and infertility.

If your laboratory has been retesting low-positives and reporting them as negative if they don't confirm, then you should notify the health care provider of any test results that were misinterpreted during at least the past 2 years. Health care providers should be directed to notify patients who have not been treated or retested and offer those patients the opportunity to be retested.

Yours truly,

Kevin Fenton, MD, PhD, FFPH
Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

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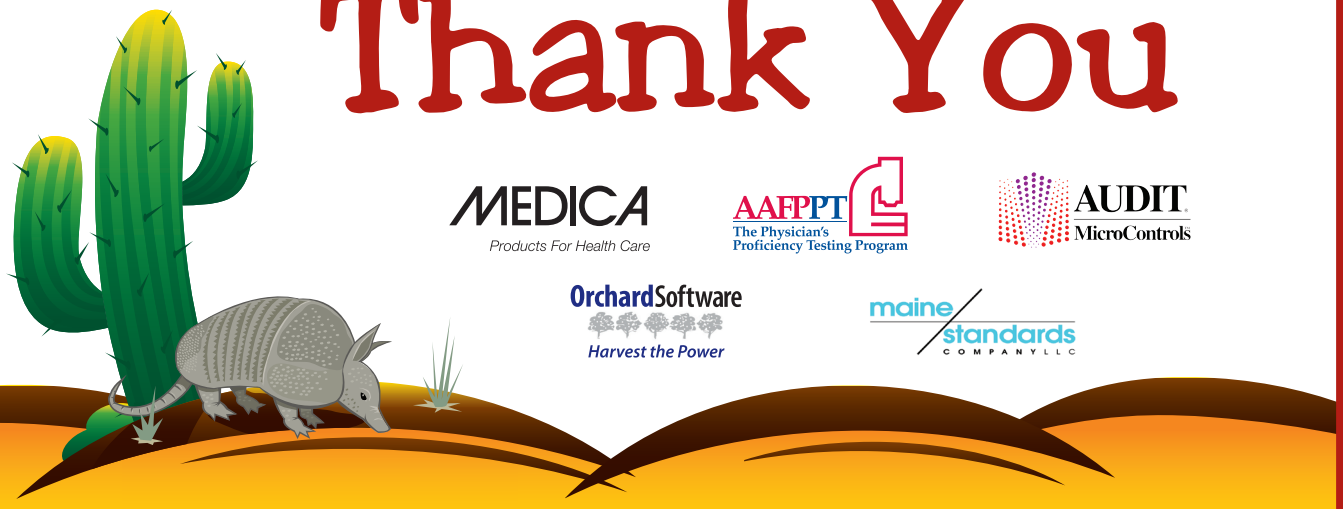

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