

JANUARY / FEBRUARY '12

COLA'S

# inSights

## INTO *Documentation*

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## FROM THE CHAIR

You don't have to be in Laboratory Medicine very long before you hear the axiom "If it's not documented, it's not done." This can be understood to have two different meanings. The first is that the action is not finished until the paperwork is completed. The second is that if the action is not documented, it is as if the action never happened.

The second meaning is why documentation is such an important aspect of laboratory medicine; it provides evidence of the actions you took to complete a task. It doesn't matter how well the work is performed, if there is no record documenting it. If there is no documentation, the work was not done. Surveyors depend on documentation to understand what has happened in your laboratory. From looking at your paperwork alone, they should be able to clearly see what happened with a particular patient, a specific specimen, or an individual investigation.

Documentation also helps prevent errors and unnecessary duplication. Laboratory personnel need documented requests to ensure they perform the correct laboratory tests. Clinicians rely on laboratory reports to accurately assess their patients' conditions. If action steps are recorded as they are completed, you will not have to repeat actions your coworkers have already finished.

This issue of *Insights* focuses on documentation since it is so vital to laboratory operations.

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



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# QSE: Documents and Records

Quality Management Systems (QMS) is a systematic approach to quality management with a focus on error prevention and efficiency. The goal of QMS is to take quality and effectiveness to a higher level of performance. The Quality System Essentials (QSEs) work together to comprise a quality management system; they support the path of workflow; and form the foundation of the laboratory's operations.

The QSE: Documents and Records focuses on your laboratory's policy, process, and procedure documents and the records that are generated when performing laboratory activities.

## Definitions

**Documents** are communications that guide the work to be performed; they express the intention for and the implementation of various activities; and may be written or generated electronically. Policies, processes, procedures, instructions, and forms are all examples of documents.

**Records** describe what happened; they provide evidence of the work performed; and they detail the results achieved. Instrument print-outs, and completed maintenance logs, QC charts and graphs, and patient demographic forms are just a few examples of records.

## Document Types

Document types can be categorized according to a document hierarchy: policies provide a broad overview, processes narrow the view, and procedures further refine the view.

**Policies** are broad statements that declare the desires and intentions of your laboratory's leadership. They set expectations and communicate rules and guidelines. They may address business concepts, safety concerns, testing requirements, or other similar "big picture" items. Examples of policy statements include:

- "Laboratory XYZ does not routinely offer refunds for services rendered; however, special requests may be considered on a case-by-case basis."
- "Hospital ABC provides lab coats and disposable gloves for use by all laboratory employees. Additional protective gear, such as face shields, safety glasses, face masks, etc., will be provided when appropriate."
- "Proficiency Testing (PT) shall be performed on all analytes, whether regulated or non-regulated, whenever possible."

The policy would expand on the broad statement, but would not include specific process or procedural details.

**Processes** provide some details since they describe the sequence of activities performed by different departments, positions, or roles to reach a desired, defined endpoint or outcome (who does what when).

**Documents convey information or instructions. They can be written policies, processes, procedures, instructions, or forms.**

**Records show evidence of completion of an activity or task. They contain specific details about the activity or task.**

**A form is a document; a completed form is a record.**

Flowcharts and/or tables are routinely used to illustrate processes. Figure 1 shows a process flowchart depicting how a patient travels through a physician's office. As you can see, the flowchart depicts interactions between several different departments and positions. Note that the activities and interactions are listed, but specific details of these activities are excluded.

## Procedures

Activity details constitute the components of procedures. **Procedures** are step-by-step instructions for a particular role/position to perform a specific task. They answer the question, "How do I perform this activity?"

While the step-by-step instructions are the main part of a procedure, they do not constitute the entire procedure. According to the Clinical and Laboratory Standards Institute (CLSI), the following sections are commonly included in procedure documents:

- Title
- Purpose or Principle
- Process Flowchart or Table (if applicable)
- Procedure Instructions

**>> CONTINUED ON PAGE 4**

**QSE: DOCUMENTS AND RECORDS**

- Related Documents
- References
- Appendixes or Attachments
- Author(s) and Approval Signature(s)

Several other sections can also be included in procedures dependent upon which phase (pre-analytic, analytic, post-analytic) of the path of workflow is addressed. The following information can be included when applicable:

- Patient preparation
- Specimen collection and handling
- Specimen and/or reagent storage
- Safety precautions
- Necessary supplies and equipment
- Calibration and maintenance
- Quality Control requirements
- Result calculation and interpretation
- Reference ranges
- Reporting results and critical values
- Archiving results and test reports
- Document retention

This information can be organized in its own self-titled sections or incorporated into broader sections that address similar topics.

**Forms**

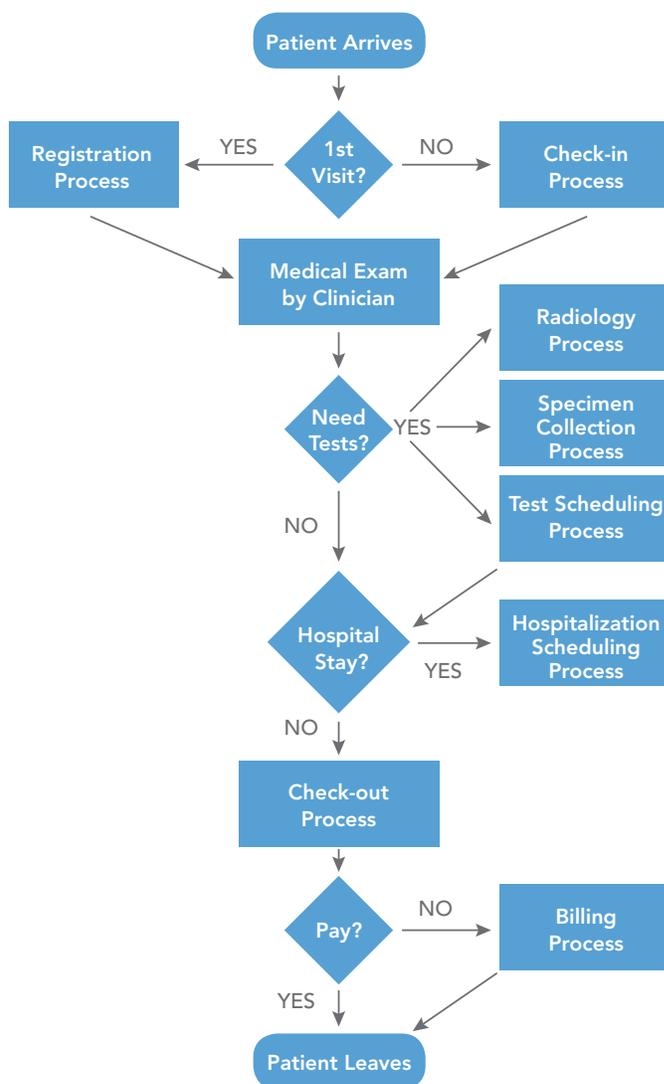
The final type of document this article will address is the “form.” Forms are customizable blank templates used to capture specific information, and can be electronic or paper in nature. Forms should include at least the following:

- Title – to describe the form’s purpose
  - Laboratory name and location
  - Effective date
  - Fields – to record information
- Examples include:
- Date information is added
  - Time – when appropriate
  - Initials or other identifier of the person completing the form
  - Results, interpretations, reference ranges
  - Patient demographics (name, sex, age, etc.)

Naturally, the specific information requested varies according to the purpose of the form. Patient demographics would not be necessary on equipment maintenance logs just as control lot numbers are not needed on test requisitions. When information is added to complete a form, the form becomes a record. Retention requirements vary depending on the type of record created.

Forms (whether documents or records) and all other laboratory documents should be tracked and maintained through a document management system. This is discussed further in the Document Management article on page 5 in this issue of *Insights*. ■

Figure 1 – Process Flowchart



RESOURCES:

<sup>1</sup>Clinical and Laboratory Standards Institute, *Laboratory Documents: Development and Control; Approved Guideline – Fifth Edition*, GP2-A5, Vol. 26 Number 12, release date: 03.01.2008

# Document Management

Every laboratory produces documents and records. They form the heart of the laboratory's Quality Management System. Therefore, document management should be routine in every laboratory; but what exactly is document management?

Document Management, also known as Document Control, is a means to protect the value, relevance, and quality of documents and to enhance their usefulness. It is a way to monitor and maintain the development, approval, issue, change, distribution, maintenance, use, retention, security, and disposal of laboratory documents and records.<sup>1</sup>

Using a document management system will help ensure that you do not waste resources distributing non-essential information. The system will help you ensure that valid information is kept up-to-date and is distributed only to those who need it. The system also provides for proper storage of information which can be used to improve current practices and/or investigate problems.

A successful document control system begins with defining your document control policies and processes.<sup>2</sup> Procedures to support the policies and processes should be written next. They should not be cumbersome, but should be detailed enough to provide clear direction as to how documents should be prepared and maintained.

There are several packaged systems available that utilize automated document preparation, tracking, and storage techniques, but document management systems can be created and/or modified to fit your specific needs. When choosing a document management system, be sure the system can be adapted to your needs. You do not want the system to dictate your document control policies and processes.

Regardless of whether you purchase or create a system, certain characteristics should be included in all document management systems. The main goal is to control the creation, approval, and review of documents. To do this, the system should include several different features:

- Document identification
- Periodic review of documents
- Revision of approved documents
- Distribution of documents
- Archiving and retention of obsolete documents
- Document Master Index organization and maintenance
- Document Master File organization and maintenance



## Document Identification

Naming or titling a document is not the only component of document identification. In fact, several items should be included to allow for proper identification. Your facility's name should be included on each document to verify that it is indeed an official document of your laboratory. The version should be noted by an edition, revision, or version number and its effective date. This helps ensure that the most current version is in use. The current page number and the total number of pages should be listed to ensure that single pages are not lost.

If you decide it is necessary, other identifying information, such as the following, can be included:

- Identification number and/or code
- Name of the author, editor, authorizer, owner, and/or reviewer
- Whether the document is classified, confidential, proprietary, etc.
- Copyright information

**>> CONTINUED ON PAGE 6**

### **Review and Revision**

All documents should be reviewed periodically and revised as needed. Through this process, which should be clearly defined in your procedures, the reviewer can ensure that the information presented in the document is current, accurate, and complete.

Many facilities use a “document change request form” so the information collected is standardized and consistent for all document revisions. At a minimum, the reviewer’s name and the date of the document review should be listed along with the requested changes.

The reviewer should mark the requested changes so they can be easily identified. This will help expedite the document approval process, and allow inspections, surveys, internal audits, and future document reviews to be accomplished more easily. The changes can be identified by underlining, bolding, or similar technique; a page listing all the changes can be added to the document; or a combination of techniques can be used.

When the revisions are approved, the revised document should be differentiated from the original by changing the version, edition, or revision number/code. The date that the revised document is implemented should also be recorded.

Document revisions often impact other documents. Be sure to assess the impact that the revisions have on other areas of your facility and initiate the corresponding changes to the appropriate documents.

Document revisions impact personnel as well. Staff should be notified of document changes; steps should be taken to ensure that they understand the changes; and when applicable, staff should be trained on how the changes affect their work. The revisions are complete when all of these steps are documented.

### **Document Distribution, Storage, and Retention**

All personnel should know where to find official documents and should trust that these locations will have the most current versions of those documents. Your document management system

should have some mechanism of listing these locations so documents stored there can be replaced as they are revised. If personnel are able to print documents to keep at their work stations, the document management system should be able to send a notification message to personnel when documents are revised to prevent the inadvertent use or distribution of obsolete documents.

Obsolete documents as well as earlier versions of current documents must be retained for at least two years. Longer retention times may be needed as defined by Federal, State, and local regulations and/or your facility’s protocols. Your document management system should provide a means of electronic storage or a record of the physical location of stored hard copies. One way to accomplish this is through the use of a Master File and Master Index.

### **Master File and Master Index**

The Master File contains the current version and all obsolete, previous versions of each of your documents. Each document has its own Master File, which is the document’s historic record, from its inception to its present status.

The Master Index is an extended “Table of Contents” that lists all of the Master Files, and the locations of all official documents.

Your document management system must be capable of organizing the Master Index and the Master Files. Your procedures should outline how the Master Files will be maintained, and who is responsible for this maintenance.

### **Summary**

A Document Management / Document Control system can be tailored to fit your needs. Begin by writing your policies, processes, and procedures; then look for systems to help you manage and control them. By using a document management system, you can ensure that accurate and complete information is distributed to those who need it, and that it will be available to correct problems and improve current practices. ■

#### RESOURCES:

<sup>1</sup>Dick, David and Bine, Kathy, *Documentation Management for Dummies*, originally published in the July/August 2003 issue of *The Nor’easter*, Northern New England Chapter of the Society for Technical Communication; <http://www.ebstc.org/newsletter/0304/reprint1.htm>; last accessed February 2012

<sup>2</sup>Refer to “QSE: Documents and Records” on page 3 of this issue of *Insights* for a discussion on policies, processes, and procedures.

# HHS announces intent to delay ICD-10 compliance date<sup>1</sup>

As part of President Obama's commitment to reducing regulatory burden, Health and Human Services Secretary Kathleen G. Sebelius today (February 16, 2012) announced that HHS will initiate a process to postpone the date by which certain health care entities have to comply with International Classification of Diseases, 10th Edition diagnosis and procedure codes (ICD-10).

The final rule adopting ICD-10 as a standard was published in January 2009 and set a compliance date of October 1, 2013 – a delay of two years from the compliance date initially specified in the 2008 proposed rule. HHS will announce a new compliance date moving forward.

"ICD-10 codes are important to many positive improvements in our health care system," said HHS Secretary Kathleen Sebelius. "We have heard from many in the provider community who have concerns about the administrative burdens they face in the years ahead. We are committing to work with the provider community to reexamine the pace at which HHS and the nation implement these important improvements to our health care system."

ICD-10 codes provide more robust and specific data that will help improve patient care and enable the exchange of our health care data with that of the rest of the world that has long been using ICD-10. Entities covered under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) will be required to use the ICD-10 diagnostic and procedure codes.

## RESOURCES:

<sup>1</sup>United States Department of Health & Human Services, Newsroom, news release: *HHS announces intent to delay ICD-10 compliance date*; for immediate release: February 16, 2012; last accessed February 2012; <http://www.hhs.gov/news/press/2012pres/02/20120216a.html>



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# Select Sessions at the COLA Symposium in Las Vegas

SYMPOSIUM FOR CLINICAL LABORATORIES

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On **Thursday, April 19, from 2:00pm to 3:30pm**, an exciting and informative professional development session will be presented by **Edward J. Peterson, Jr, MBA, MT(ASCP)**.

Mr. Peterson is currently the Executive Director of the Department of Pathology and Laboratory Medicine for WellStar Health System, and Site Director for the Laboratories at WellStar Kennestone Hospital in Marietta, GA. At the system level, he is responsible for operations of a five hospital system in the areas of Laboratory Information Systems, Outreach, Point of Care, Quality Management, Performance Improvement, and Education. At the hospital level he is responsible for the day-to-day operations of the Department of Pathology and Laboratory Medicine in a 633 bed not-for-profit organization with 200 laboratory employees.

Mr. Peterson is also an Assistant Professor at the University of Medicine and Dentistry of New Jersey, Department of Clinical Laboratory Sciences, where he co-teaches an on-line course on Healthcare Regulations & Laboratory Management. He is a member of CLMA and ASCLS and has held various leadership positions on state, regional, and national levels of ASCLS. He is currently the Chair of the Lab Administration Scientific Assembly of ASCLS and President of ASCLS Georgia.

## Professional Development

### Clinical Ladders: A Tool for Professional Development, Employee Retention and Recruitment

(1.5 P.A.C.E.® or AAFP Prescribed Credits)

Recruitment and retention of qualified laboratory staff is a daily challenge. The Clinical Ladder program has proven to be a tool to address this challenge. The program provides professional advancement and personal growth opportunities above and beyond normal job requirements that will serve to benefit the laboratory, the organization, and the employee.

#### Learning Objectives

- Discuss how to start and develop a Clinical Ladder program
- Discuss the goals of the Clinical Ladder program, including professional and personal development, clinical skills enhancement, and benefit to the organization
- Identify the essential elements of the program that will help you obtain management approval for the program

On **Friday, April 20, from 1:00pm to 2:30pm**, an exciting and informative allergy session will be presented by **Vivian Saper, MD, FAAAAI**.

Dr. Saper is a practicing allergist who has a longstanding appointment as part of the teaching faculty at Stanford University Medical Center. After pediatrics residency at Stanford University, Dr. Saper entered private practice in pediatrics. She returned for fellowship training to UCSF Medical Center and Stanford University. She holds subspecialty certifications in Allergy, Asthma and Immunology as well as in Pediatric Rheumatology.

## Allergy

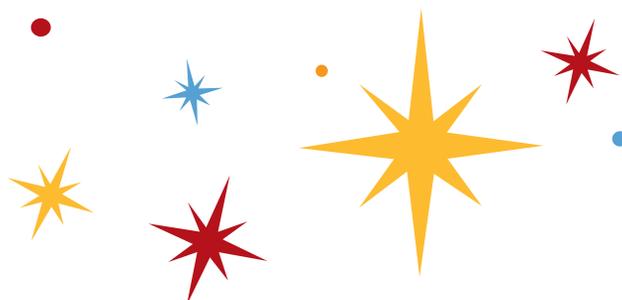
### So Many Allergy Tests, So Hard to Choose

(1.5 P.A.C.E.® credits)

With hundreds of allergen specific in-vitro IgE tests available on the market, it can be a chore to decipher which tests suit your clientele's needs. Participants in this session will learn about allergen specific IgE tests from both a laboratory and a clinical view. By gaining an understanding of the test itself and the associated allergic conditions, selecting the appropriate test offerings will be easier. Topics covered include atopic medical conditions, variables important to the clinical significance of a specific IgE determination for these conditions, and an opportunity to see and even try the initial predicate device, a prick skin test.

#### Learning Objectives

- Understand allergen specific IgE test methodology
- Gain an understanding of how in-vitro tests relate to skin tests
- Decide which allergy tests are useful for specific medical conditions
- Understand the current limitations and strengths of these important test offerings



On **Thursday, April 19 and Friday, April 20**, we will present these sessions that are of special interest to nurses, medical assistants and phlebotomists involved in point-of-care testing.

**Point-of-Care  
Testing**

**To Test or Not to Test?** (1.5 P.A.C.E.<sup>®</sup> or AAFP Prescribed Credits)

**Presented by Nancy Anderson, MMSc,  
on Thursday from 10:30am to 12:00pm.**

*Ms. Anderson is the Chief of the Laboratory Practice Standards Branch of the Division of Laboratory Science and Standards at the CDC.*

Forethought, planning, and preparation are critical when making decisions to begin testing or when adding a new test to the menu in a laboratory, physician office, or other point-of-care location. It is important to carefully weigh the potential benefits in light of the issues to be considered. During this session, Ms. Anderson will discuss recent testing trends and the benefits of testing in physician offices and point-of-care settings. She will also review considerations pertaining to management responsibility for testing and the regulatory and physical requirements for testing. Last, she will briefly cover test selection, personnel training and assessment, the importance of following the manufacturer's instructions for testing, and quality assurance.

**Point-of-Care  
Testing**

**Competent to Collect?** (1.5 P.A.C.E.<sup>®</sup> or AAFP Prescribed Credits)

**Presented by Lisa O. Ballance, BS, MT(ASCP), CLC(AMT),  
on Thursday from 2:00pm to 3:30pm.**

*Ms. Ballance is the Director of Online Education for the Center for Phlebotomy Education, Inc.*

Assessing the competence of your phlebotomy personnel is good risk management; it identifies gaps in training and can improve sample quality. CLSI's revised venipuncture standard will be discussed and used as a basis for a competency assessment plan. Elements of a competency assessment plan, who should be assessed, and assessment methods will be discussed, so you can develop an assessment program for collector competence.

**Point-of-Care  
Testing**

**POCT: Issues and Answers** (1.5 P.A.C.E.<sup>®</sup> or AAFP Prescribed Credits)

**Presented by Toni Clinton, PhD(BLCD), MT(ASCP),  
on Friday from 1:00pm to 2:30pm.**

*Dr. Clinton is the General Manager of the University of Tennessee Medical Center Laboratory in Knoxville, TN.*

Point of Care Testing (POCT) is used routinely in a number of healthcare settings. The values obtained are used to not only help determine patient compliance with specific care regimens, but they are also used to alter medications. What are the advantages / disadvantages of this practice? Are the results the same as those determined in a more standard clinical laboratory setting? What does it mean if the results vary? Real-life examples of troubleshooting and corrective action plans will be provided. Good laboratory practices for both point of care and traditional test methods will be discussed.

**Go to [www.cola.org/?page\\_id=541](http://www.cola.org/?page_id=541) today to see all of the great sessions and to register for the conference!**



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

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FOR CLINICAL LABORATORIES



# Secretary Sebelius announces next stage for providers adopting electronic health records<sup>1</sup>

Health and Human Services Secretary Kathleen Sebelius today (February 24, 2012) announced the next steps for providers who are using electronic health record (EHR) technology and receiving incentive payments from Medicare and Medicaid. These proposed rules, from the Centers for Medicaid & Medicare Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC), will govern stage 2 of the Medicare and Medicaid Electronic Health Record Incentive Programs.

“We know that broader adoption of electronic health records can save our health care system money, save time for doctors and hospitals, and save lives,” said Secretary Sebelius. “We have seen great success and momentum as we’ve taken the first steps toward adoption of this critical technology. As we move into the next stage, we are encouraging even more providers to participate and support more coordinated, patient-centered care.”

Under the Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the American Recovery and Reinvestment Act of 2009, eligible health care professionals and hospitals can qualify for Medicare and Medicaid incentive payments when they adopt certified EHR technology and use it in a meaningful way. What is considered “meaningful use” is evolving in three stages:

- Stage 1 (which began in 2011 and remains the starting point for all providers): “meaningful use” consists of transferring data to EHRs and being able to share information, including electronic copies and visit summaries for patients.
- Stage 2 (to be implemented in 2014 under the proposed rule): “meaningful use” includes new standards such as online access for patients to their health information, and electronic health information exchange between providers.
- Stage 3 (expected to be implemented in 2016): “meaningful use” includes demonstrating that the quality of health care has been improved.

CMS’s proposed rule specifies the stage 2 criteria that eligible providers must meet in order to qualify for Medicare and/or Medicaid EHR incentive payments. It also specifies Medicare payment adjustments that, beginning in 2015, providers will face if they fail to demonstrate meaningful use of certified EHR technology and fail to meet other program participation requirements. In a November 2011 “We Can’t Wait” announcement (<http://www.hhs.gov/news/press/2011pres/11/20111130a.html>), the Department outlined plans to provide an additional year for providers who attested to meaningful use in 2011. Under today’s proposed rule, stage 1 has been extended an additional year, allowing providers to attest to stage 2 in 2014, instead of in 2013. The proposed rule announced by ONC identifies standards and criteria for the certification of EHR technology, so eligible professionals and hospitals can be sure that the systems they adopt are capable of performing the required functions to demonstrate either stage of meaningful use that would be in effect starting in 2014.

“Through the Medicare and Medicaid EHR Incentive Programs, we’ve seen incredible progress as over 43,000 providers have received \$3.1 billion to help make the transition to electronic health records,” said CMS Acting Administrator Marilyn Tavenner. “There is great momentum as the number of providers adopting this technology grows every month. Today’s announcement will help ensure broad participation and success of the program, as we move toward full adoption of this money-saving and life-saving technology.”

“The proposed rules for stage 2 for meaningful use and updated certification criteria largely reflect the recommendations from the Health IT Policy and Standards Committees, the federal advisory committees that operate through a transparent process with broad public input from all key stakeholders. Their recommendations emphasized the desire to increase health information exchange, increase patient and family engagement, and better align reporting requirements with other HHS programs,” said Farzad Mostashari, MD, ScM, National Coordinator for Health Information Technology. “The proposed rules announced today will continue down the path stage 1 established by focusing on value-added ways in which EHR systems can help providers deliver care which is more coordinated, safer, patient-centered, and efficient.”

The number of hospitals using EHRs has more than doubled in the last two years from 16 to 35 percent between 2009 and 2011. Eighty-five percent of hospitals now report that by 2015 they intend to take advantage of the incentive payments.

A technical fact sheet on CMS’s proposed rule is available at [http://www.cms.gov/apps/media/fact\\_sheets.asp](http://www.cms.gov/apps/media/fact_sheets.asp).

A technical fact sheet on ONC’s standards and certification criteria proposed rule is available at <http://www.healthit.gov/policy-research>.

The proposed rules announced today may be viewed at [www.ofr.gov/inspection.aspx](http://www.ofr.gov/inspection.aspx).

Comments are due 60 days after publication in the Federal Register. ■

## RESOURCES:

<sup>1</sup> United States Department of Health & Human Services, Newsroom, news release: *Secretary Sebelius announces next stage for providers adopting electronic health records*; for immediate release: February 24, 2012; last accessed February 2012; <http://www.hhs.gov/news/press/2012pres/02/20120224a.html>

## COLA *Compliance Tip* *Blackout Dates*

*Focus:* COLA Policy concerning Blackout Dates for survey scheduling.

**Your laboratory will be allowed up to 10 blackout dates (not date ranges) per survey cycle.**

See below for timing of blackout date submission.

In order to ensure that all of our COLA accredited laboratories receive biennial on-site surveys on time, we are providing you with the following guidance regarding blackout dates.

A “blackout date” is defined as a date on which the laboratory cannot accommodate a survey; therefore, COLA will make every attempt to avoid scheduling a survey on those dates.

Your laboratory will be allowed up to 10 blackout dates each two (2) year survey cycle. **Please note that these are individual dates, not date ranges.** For example, if your laboratory director will be on vacation for five (5) business days, if requested as blackout dates, this will be counted as five (5) blackout dates, **not** as one (1) blackout date.

1. Blackout dates must be submitted to COLA within the following time frames:
  - a. **As soon as possible** following the date of your enrollment with COLA, if you have not had a COLA survey yet; or
  - b. **No later than** 20 months from the date of your last COLA survey;
2. You may submit blackout dates to COLA by:
  - a. Utilizing COLAcentral™ at [www.COLAcentral.com](http://www.COLAcentral.com)
  - b. Faxing COLA at 410 381-8611
  - c. Calling COLA at 800 981-9883
  - d. Emailing COLA at [info@cola.org](mailto:info@cola.org)

Be sure to include your COLA ID number on all correspondence.

*Please note:*

*COLA cannot provide more than two (2) weeks notice for a scheduled survey, and in certain situations, will conduct unannounced surveys.*

***Submit your blackout dates through COLAcentral!***

1. Log on to [www.COLAcentral.com](http://www.COLAcentral.com)
2. Go to the Management / Compliance Tab
3. Choose “Lab Information”
4. Choose “Blackout Dates”
5. Enter your blackout dates for the coming survey cycle