



College of American Pathologists

Testimony of

David L. Booker, MD, FCAP
Governor, College of American Pathologists

Before the

Meaningful Use Workgroup of the
Health Information Technology Policy Committee

May 13, 2011

College of American Pathologists
1350 I Street, NW, Suite 590
Washington, DC 20005
(202) 354-7100
(202) 354-7155 – fax
(800) 392-9994
www.cap.org

Dear Chairman Tang, Co-Chairman Hripcsak, Meaningful Use Workgroup Members:

The College of American Pathologists appreciates the opportunity to testify on the important issue of “Meaningful Use and EHR Support of Specialists in Patient Care, including Clinical Decision Support.” We will first address the general issue of pathologists and our use of electronic systems; proceed to discuss how that interacts at a very high-level with the Meaningful Use rules –both Stage 1 and your draft Stage 2 recommendations -- and then move to answer the questions that are the focus of today’s session. We have structured our testimony in this fashion because in many ways these issues are inter-related, and it is difficult to address one without the other.

The CAP is a national medical specialty society representing more than 17,000 physicians who practice anatomic and/or clinical pathology. CAP members practice medicine in clinical laboratories, academic medical centers, research laboratories, community hospitals and federal and state health facilities. The CAP has significant HIT expertise. CAP is the original creator of SNOMED Clinical Terms® (SNOMED CT®), and CAP STS continues to develop and maintain SNOMED CT.

PATHOLOGISTS, ELECTRONIC RECORDS AND MEANINGFUL USE

The CAP supports the goals of Meaningful Use (MU) to raise the bar and encourage the national adoption and use of electronic health record (EHR) systems by physicians and hospitals. The CAP believes that the widespread adoption of interoperable EHR systems will improve health care quality and increase the efficiency of care, benefiting physicians, patients and payers alike.

Pathology was one of the earliest specialties to embrace health information technology (HIT). Pathologists and their laboratories have long relied on sophisticated computerized laboratory information systems (LIS's) in order to support the work of analyzing patient specimens and generating test results, and it is with these LISs that EHRs or enterprise-wide clinical information systems exchange laboratory and pathology data. If the idea behind MU is to incent adoption of the appropriate electronic clinical system, such an incentive is unneeded in pathology given essentially universal adoption of LIS's and related HIT in pathology practice and laboratories.

Further, since pathologists generally do not currently directly use EHRs to input data, pathologists, regardless of practice setting, cannot meet the MU Stage 1 requirement to maintain 80% of patient records in certified EHRs. Additionally, even when pathologists -- for example, in large integrated systems -- do use EHRs, they do *not* generally have control over purchasing, implementing, and maintaining them. Even in these large systems wherein a minority of pathologists is engaged, their use of EHR's is limited usually to reading information and inputting laboratory data, comments thereon, and consultations. In fact, in some cases pathologists do not have full access to the EHR to the detriment of patient care, compromising their ability to advise on appropriate test selection and resultant follow-up care.

The majority of the Stage 1 and draft recommended Stages 2-3 objectives are outside the scope of pathology practice, as are the Clinical Quality Measures (CQMs) for Stage 1. While several Stage 1 objectives have exclusions that pathologists could use, others do not (e.g. recording demographic data as structured information including identifying the patient's primary language); this is difficult if the physician does not have contact with the patient or access to the full EHR. To take another example, the Stage 1 objective “Implement drug-drug/drug-allergy

tests"¹ is similarly outside of pathologists' scope of practice and the data would be unavailable in an LIS. The MU requirements focus on primary care physicians and secondarily on "office-based physicians" to use the terminology of ONC. The MU rules as currently written are fundamentally not applicable to pathology. Perversely however, according to the CMS Final Stage 1 rule, pathologists qualify as Eligible Providers (EPs). Few, if any, would meet the regulatory definition of "hospital-based," and they are therefore bound by the MU requirements. Specifically, most pathologists are excluded from the 'hospital-based' exception because they provide services to non-hospitalized patients, outpatient centers, and ambulatory surgery centers that constitute 10% or more of their services. Pathologists, by virtue of their practice as described above, cannot qualify for MU incentives, but would qualify for penalties. Therefore, we urge the HITPC Meaningful Use Workgroup to recommend that pathologists be exempt from the MU penalties that begin in 2015.

Even though pathologists cannot generally qualify as Meaningful Users in their own right, we intend to use our unique expertise to help other physician and health care providers meet the MU requirements, particularly those related to recording laboratory results as structured data, reporting for public health purposes, and CPOE.

It is for this reason that CAP is a founding member of the Lab Interoperability Cooperative (LIC) (see www.labinteroperabilitycoop.org), which is recruiting hospitals to participate in a program that will electronically connect hospital laboratories with public health agencies in order to facilitate such reporting for MU and public health purposes. Establishing this connection will enable hundreds of hospitals to engage in electronic reporting that helps public health officials act more rapidly and efficiently to control disease. Funded by a grant from the Centers for Disease Control and Prevention, the LIC includes participation from the American Hospital Association and Surescripts in addition to CAP. During the two-year grant period, the LIC will recruit, educate and connect to the appropriate public health agencies a minimum of 500 hospital labs. By engaging hospital labs and their LIS's, which handle the majority of lab tests in the United States, the LIC represents a unique opportunity to advance lab interoperability with public health agencies and the nation's health care system overall. The LIC will provide the necessary educational and technical assistance to enable those hospital labs selected to participate in the program to begin electronically transmitting lab results.

HOW CAN EHRs FACILITATE SPECIALTY CARE OF INDIVIDUAL PATIENTS, INCLUDING USE OF CLINICAL DECISION SUPPORT?

To answer this question, it is important to recognize -- as noted above -- that pathologists do *not* generally use EHRs; they use LIS's and related systems. Put another way, the pathologist work space is the LIS; pathologists build information into the LIS, not the EHR. This significantly affects the data provided to the ordering physician. Physicians document in EHRs what they observe about patients; pathologists are a key source of data to the EHR. In many cases, decision support in EHRs depends on LIS data fields. Many quality measures --including 12 of the 38 MU Clinical Quality Measures in Stage 1 -- depend on the robust functionality of laboratory data (e.g. HgbA1C in diabetics). Not all the data pathologists receive from running a test moves to the EHR system, only the test results and interpretation do. Pathologists, however, can provide semantic and technical standards to assist EHRs to provider decision support to EHR users.

¹ The proposed draft related Stage 2 objective is "Employ drug-drug interaction checking and drug allergy checking on appropriate evidence-based interactions."

It is therefore essential that the data *that do* move to the EHR --laboratory results --are captured and displayed appropriately. Laboratory results are more than just numbers, and laboratory data in EHR systems must be an accurate representation of what is reported from the laboratory or patient safety issues could arise. EHR systems vary widely in their capability for effective and appropriate presentation of laboratory data. CAP and its member pathologists can attest to many instances of inadequate or poorly designed display of laboratory results in EHR systems that would (at best) be inconveniences and (at worst) present significant risk for misinterpretation by the health care provider and cause harm to the patients. Examples of the types of laboratory testing that may require unique considerations in data display (including beyond simply presenting simple numerical data such as chemistry and hematology data) include:

- Microbiology
- Blood bank/transfusion medicine
- Molecular pathology and genetic testing
- Interpretive testing that combines numerical results with interpretive text, e.g., coagulation panel interpretation, and serum protein electrophoresis
- Anatomic pathology, including surgical pathology, autopsy pathology, and cytopathology

Elements of laboratory reports that may be prone to suboptimal handling in EHR systems include:

- Reference ranges (normal ranges)
- Reflex test orders and results
- Interim reporting and amended results
- Sequential results reported on different dates
- Results that fall into "indeterminate" states between normal and abnormal values
- Misleading report formats
- Corrected result reporting and documentation
- Explanatory footnotes or comments
- Issuance of recent practice guideline or best practice changes and additional observations, interpretations and assessment based on test results, specific patient history and clinical presentations
- Proper identification of name and address of the performing laboratory, particularly in cases where more than one laboratory provides results to the EHR

While standards exist for messaging (HL7) and nomenclature (SNOMED and LOINC), standards for the stored structure of lab data itself are more nebulous, especially outside the realm of routine general labs. Further, the possible enumerated range that is valid for a specific field may not be a part of either the HL7 message or the coded representation. For example, a molecular test may be reported as "Positive" or "Negative" 99% of the time, but what are the standards for defining what to report when the test is limited due to technical or sample issues? "Unsatisfactory", "Limited", "Could not complete" also become necessary choices for clear communication. Should these be in upper case or lower case? In black type or red type? Font size? For instance, results that may appear binary are not necessarily so. Alternatively, a molecular test for a specific mutation may be correctly resulted as "positive" which would properly be interpreted as "negative" for the reason to order the test (e.g., KRAS mutation and chemotherapy sensitivity). Even though the assay result might be binary, which would be the "abnormal" result? Further, many seeming binary test results are not truly binary (e.g. dip-stick urinalysis; microbiology tests and contaminating organisms can affect body fluid tests).

CAP is pleased to work with other stakeholders on numerous standards-related efforts both in the private sector and through the ONC S&I Framework laboratory results interface initiative to address some of these critical issues.

How Do You Currently Support Decision Making in Your Practice?

Pathologists use decision support in a number of ways, such as the use of rules to generate interpretative comments on complex laboratory results and algorithms to automate reflex testing. Pathologists oversee the creation of rules that determine critical test results that must be immediately communicated to other physicians in life-threatening situations and “flags” that ensure that results that are out of normal range are more effectively displayed in LIS’s and EHRs. Pathologists incorporate practice guidelines and protocols, such as the CAP Cancer Protocols, into their reporting systems to ensure standardized reporting of cancer results to physicians and cancer registries. Pathologists also create rules in their LIS’s to ensure that appropriate quality control is followed on specimens, including peer review and expert consultation. Pathologists use these tools themselves to optimize test selection and interpretation and offer them to their physician colleagues through their LIS’s to assist them in ordering and interpreting laboratory tests.

Pathologists desire additional and more sophisticated HIT tools for decision support. This will require incentives for EHR and LIS vendors to support this enhanced functionality, greatly improved interoperability between LIS and EHR systems, and actions to guarantee all physicians involved in patient care – including pathologists – full access to the EHR.

Key illustrative but not exhaustive examples of decision supports in pathology are:

- The ASCO/CAP *HER2* guidelines (see http://www.cap.org/apps/docs/committees/immunohistochemistry/summary_of_recommendations.pdf) and the ASCO/CAP ER/PR guidelines (see http://www.cap.org/apps/docs/laboratory_accreditation/summary_of_recommendations.pdf) are semantic standards for testing for predictive markers that are crucial for the treatment of breast cancer. These guidelines are essential to improving the accuracy of these tests, the results of which determine whether costly treatments with significant side-effects are given or withheld from breast cancer patients, and as such have a significant impact on the cost and quality of care for large numbers of patients. These guidelines are supported by documented clinical evidence, and algorithms have been developed that can serve as the basis for decision support in electronic systems. Similar guidelines are in development for other diseases, such as lung cancer and colon cancer. Pathologists need support to see that systems vendors create clinical decision support functionality to support these standards.
- CAP has created standardized cancer protocols known as cancer checklists. These are required for the American College of Surgeons’ (ACOS) accreditation of cancer centers because they specify how cancer tissues should be examined in order to provide the necessary information to report and stage the cancer so that patients can be appropriately treated after surgical resection. The cancer checklists are the standard for reporting pathology results for cancer patients and are the foundation of tumor registries. CAP has converted checklists to electronic form. The protocols for the electronic Cancer Checklists (eCCs) are rooted in evidence-based medicine and generally require evidence of level III-2 or higher (e.g. randomized or pseudo-randomized trial, a prospective cohort study or a comparative study that includes a

concurrent control group) before a data element is mandated for inclusion. The electronic version enables a synoptic format –well-structured summarizations of these finding) where items are entered as discrete data elements and are retrievable that way.

- HPV testing -- the American Society for Colposcopy and Cervical Pathology consensus conference guidelines for the management of women with cervical cytological abnormalities and cervical intraepithelial neoplasia. These create rules for LIS searches for patient identification to ensure appropriate patient follow-up and treatment.
- Transfusion guidelines that address patient safety and ensure that scarce supplies of blood are allocated appropriately. For instance, a July 31, 2011 study in the journal *Pediatrics* (see <http://pediatrics.aappublications.org/cgi/content/abstract/peds.2010-3252v1>) found that clinical-decision support reminders placed into electronic medical records (EMR) systems can stop physicians from ordering unnecessary treatments for hospitalized patients. The researchers-- found that the pop-ups alerts saved the children's hospital studied 460 unnecessary red blood cell transfusions and \$165,000 in one year. At the same time, the reminders did not detract from patients undergoing transfusions who needed them. The data that these reminders were based on all came from LIS's and pathologists in the blood bank would have been essential to determining when flags should show in the EMR.

How Does Your Specialty Generate New Knowledge (e.g. Clinical Guidelines)?

Pathologists benefit from a wide range of tools to help them apply and assess new knowledge. A key generator is the CAP Center for Pathology and Laboratory Quality (The Center), launched in 2009, that develops evidence and consensus-based practice guidelines and white papers focused on patient care outcomes. Specifically, the Center works to ensure quality in diagnostic medicine, its linkage with patient outcomes, and the role of the pathologist in improving quality and contributing to patient care. Most of these guidelines are developed in partnership with other relevant medical societies. (See http://www.cap.org/apps/docs/membership/transformation/new/center_index.html). The Center generates white papers and clinical practice guidelines. The CAP is a member of the Guideline International Network (GIN), a global network, comprised of 93 organizations and 77 individual members representing 45 countries from all continents. The network supports evidence-based health care and improved health outcomes by reducing inappropriate variation throughout the world. CAP generates other knowledge tools such as:

- *Perspectives on Emerging Technology (POET)* reports --These reports are developed by the CAP Technology Assessment Committee (TAC) and are designed to provide pathologists with a high-level summary of a particular emerging technology that is likely to impact their practice in the reasonable future. Its format includes a one-page summary plus select reference (e.g., peer-reviewed articles, for further information and research.)
- *LAP Checklists* - The CAP Laboratory Accreditation Program (LAP) is an internationally and CMS- recognized program and the only one of its kind that utilizes teams of practicing laboratory professionals as inspectors. Designed to exceed regulatory compliance with CLIA, the program helps laboratories achieve the highest standards of excellence to positively impact patient care. The program is based on rigorous accreditation standards that are translated into detailed and focused checklist requirements. The checklists, which provide a quality practice blueprint for laboratories to follow, are used by the inspection teams as a guide to assess the overall management and operation of the laboratory. Checklists are also available in electronic formats through CAP eLab Solutions. Monitoring of laboratory performance on guideline specific

elements (cancer protocol elements, ER/PR and HER2 testing) is included in appropriate checklists with specific thresholds for performance on key elements.

- Q-Probes: CAP also has long published Q-PROBES (See http://www.cap.org/apps/cap.portal?_nfpb=true&cntvwrPtlf_actionOverride=%2Fportlet%2FcontentViewer%2Fshow&_windowLabel=cntvwrPtlf&cntvwrPtlf%7BactionForm.contentTypeReference%7D=q_probes%2Fqprobes_desc.html&_state=maximized&_pageLabel=cntvwr) Q-PROBES are an external peer-comparison program that addresses process-, outcome-, and structure-oriented quality assurance issues in laboratories. They establish benchmarks through external database comparisons and compare individual laboratory performance in order to establish laboratory goals and improve performance.
- Q-Tracks: Q-TRACKS monitors reach beyond the testing phase to evaluate the quality of processes both within and beyond the laboratory that can impact test results and patient outcomes. Each Q-TRACKS monitor provides a quarterly Performance Management Report package that helps identify improvement opportunities and monitor the effectiveness of changes implemented over time. Examples of Q-Tracks topics include patient identification accuracy; blood culture contamination; test turnaround. (For more information on Q-Probes/Q-tracks and other CAP quality management tools see http://www.cap.org/apps/docs/proficiency_testing/qmt_catalog/2011_qmt_catalog.pdf)
- CAP Cancer Checklists (discussed above)
- Anti-coagulation Monitoring -- The hospital medical staff Pharmacy & Therapeutics Committee perform anticoagulation monitoring and dosage adjustment according to a protocol that is well defined and known to the medical staff that can be an order by a physician for their patient(s) on anticoagulants if they wish and turns the task of reviewing the lab results over to a pharmacist to make an indicated adjustment in anticoagulant dosage within limits. This is an important example of care coordination using laboratory data that serves to enhance patient safety.

In addition to the quality tools/new evidence tools cited above, various CAP committees also publish other tools that generate or assimilate new knowledge into practice. To cite just one example, in July 2010, the CAP Coagulation Committee released "An Algorithmic Approach to Hemostasis Testing," based on the committee's work. (See http://www.cap.org/apps/cap.portal?_nfpb=true&cntvwrPtlf_actionOverride=%2Fportlets%2FcontentViewer%2Fshow&_windowLabel=cntvwrPtlf&cntvwrPtlf%7BactionForm.contentTypeReference%7D=cap_press%2Fpubs_hemostasis_testing.html&_state=maximized&_pageLabel=cntvwr.) The book is an illustrated reference text and practical guide for pathologists and laboratories engaged in hemostasis testing.

How Do You Disseminate This New Knowledge Among Your Specialty?

As indicated in the response to the previous question, pathologists have a wide range of knowledge at their fingertips. Because almost all pathologists practice in CLIA-regulated laboratories and most choose to adhere to even higher standards (e.g. CAP accreditation), the accreditation process requires that pathologists keep up with new standards in laboratory medicine. Like other physicians, pathologists face continuing medical education (CME) requirements and use CME courses –both online and in-person – to acquire new knowledge. The laboratory inspection process and laboratory proficiency testing are other tools. CAP like most other specialties publishes a peer-review journal, *Archives of Pathology*, as well as a widely read monthly newsletter, *CAP Today*, that serve to inform members of new knowledge. Other pathology societies such as the U.S. & Canadian Academy of Pathology, the American Society of Clinical Pathology and various subspecialty groups also offer CME, publish journals and/or

other publications. CAP is Accreditation Council for Continuing Medical Education (ACCME) certified to deliver CME qualifying education for pathologists.

CAP has created guideline specific educational programs in breast cancer to deliver specific education to pathologists concerning the guideline elements. The course, called Breast Predictive Factor Testing is a series of nine courses, six of which are online and three of which are live followed by a comprehensive examination, practical assessment and certificate of completion. This advanced educational program provided specific education to give pathologists the necessary tools to change practice in their hospital or other settings to improve the outcome for breast cancer patients.

In addition, CAP is one of the cooperating societies of the American Board of Pathology that provides Maintenance of Competency (MOC) based education for board certified pathologists as required of all board certified physicians by the American Board of Medical Specialties. CAP has developed a robust curriculum across all areas of pathology to train pathologists in specific practical ways to deliver quality health care to patients, using metrics, practice analysis tools, communication skills and professional training opportunities.

Beyond education of its members and accreditation and proficiency testing customers, CAP also publishes consumer education resources that could be provided to patients through EHR or PHR links, thereby advancing the MU goal of engaging patients and families in their care. These are www.mybiopsy.org and www.MyHealthTestReminder.org. The former explains in layman's terms what a pathology report for specific cancers means. The latter is an e-mail service that reminds patients when they are due for a variety of screening tests.

How Do You Incorporate New Knowledge into EHRs (e.g. partnership with EHR manufacturing)?

The CAP has a number of projects both ongoing and in the nascent stages to address the lack of standards for transactions between the EHR and LIS. As noted above, LIS's provide data to EHRs that they would not have. If interfaces were better, a wealth of alert flags with varying alert levels could be developed that could among other things address, at least in part, alert fatigue. The inadequacy of standards for interfaces between LIS's and EHR's is a significant barrier to the sharing of lab data and will require improved standards and additional resources to assist in the creation of interfaces that will be required to realize many MU goals. Below is a sample of the CAP projects that address the question of incorporating new information into EHRs. In many cases, the focus of these projects is standards, as it is standards that often guide vendors:

- *Barcoding*: CAP is helping to coordinate and inform various standards-related organizations that have a stake in ensuring that lab specimens are identified and tracked properly.
- *Electronic Cancer Checklists*: CAP works with a number of vendors to incorporate the eCancer Checklists in LIS systems.
- *Anatomic Pathology*: The CAP has leadership and engagement roles in the Health Level Seven International and Integrating the Healthcare Enterprise Anatomic Pathology Work Groups. These groups have been collaborating to offer the clinical domain and informatics expertise to define so-called "Structured Reports" that would increase the interoperability, quality, and re-use of Anatomic Pathology reports.
- *Descriptions of EHR-Laboratory interchanges*: The CAP has taken on the role as Secretariat for Integrating the Healthcare Enterprise Laboratory domain, providing financial and staff resources that will help the group clarify the exchange of information between laboratories and EHR systems.
- *Molecular Pathology*: The CAP has taken on a leadership role at the International Pathology and Laboratory Medicine (IPaLM) Special Interest Group. This group has been working to

identify gaps that exist in medical concept nomenclatures which are necessary for codifying the genomic content and molecular pathology-related concepts in an electronic medical record. Without the ability to codify the findings revealed by the use of new and powerful instruments for examining tissues at the molecular level, health care information exchange will be hindered, and clinicians will be burdened by the lack of uniformity in the rendering of molecular pathology findings.

CONCLUSION

Pathologists are leaders in the use of HIT, but their records are LIS's and related systems, not EHRs. MU requirements and certification rules needs to recognize that not all physicians' primary electronic record systems are EHRs. Pathologists are the experts on the use of LIS's and apply evidence-based tools to it to assess the data contained therein and move necessary data to EHRs for the benefits of ordering physicians, other members of the care team and the patient. As standards for such data in the EHR are developed, pathologists can play a key role in assuring that this laboratory data translates to EHRs appropriately.