College of American Pathologists
Comments in Response To
"REBOOT: Re-examining the Strategies Needed to Successfully Adopt Health IT"
May 20, 2013

The College of American Pathologists (CAP) is pleased to comment on your white paper titled: "REBOOT: Re-examining the Strategies Needed to Successfully Adopt Health IT". We appreciate your interest in seeking feedback from physicians and other stakeholders regarding the adoption of health information technology (HIT) and in particular, concerns about the Electronic Health Record (EHR) meaningful use (MU) program and ways in which it could be improved.

The College of American Pathologists (CAP) represents 18,000 pathologists who practice clinical and/or anatomic pathology in community hospitals, independent laboratories, academic medical centers and federal and state health facilities. It is the world's largest association composed exclusively of board-certified pathologists. With extensive experience as a quality standards-setting organization, the CAP accredits more than 7,000 laboratories and enrolls as many as 23,000 laboratories in its proficiency testing programs to meet and exceed standards under the Clinical Laboratory Improvement Act of 1988 (CLIA).

The CAP has significant HIT expertise. CAP's Professional Services division offers a wide range of vocabulary, standards and other HIT strategy and implementation consulting services to providers, vendors and federal agencies. CAP has also been an active contributor to a number of Office of National Coordinator standards initiatives such as the Laboratory Results Interface (LRI) Pilots, the Laboratory Orders Interface (LOI), Electronic Delivery of Services (eDOS), and the Laboratory Reporting Tiger Team.

Pathologists have long been on the front lines of HIT, utilizing sophisticated computerized laboratory information systems and anatomic laboratory information systems, referred to as LIS and APIS respectively, or blood banking systems, to manage vast amounts of laboratory and medical data and feed the diagnosis and results of their testing in the HER for each patient. However, pathologists do not practice in the EHR. This is an important and fundamental distinction that has implications for policy and strategies relating to the pathologist role in the adoption of HIT and exchange of health information.

OVERVIEW AND KEY AREAS OF CONCERN

The CAP supports the goals of increasing interoperability and health information exchange (HIE). 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 and enabling vitally important new coordinated care models.

Laboratory testing and pathology diagnostic information are without question a key influence on health care decision making driving an estimated 70% of clinical decision making. Laboratory testing results comprise a large portion of any patient

EHR and influence a significant amount of medical spending. Therefore, laboratory data and pathologists as stewards of laboratory data are essential to progress on interoperability. As noted above, pathologists and their laboratories use LISs and APISs to support the work of analyzing patient specimens and generating test results. It is with these information systems that EHRs or enterprise-wide clinical information systems exchange laboratory and pathology data. Provision of laboratory results and orders is often a key selling point for both public and private HIEs.

While your paper addresses a wide range of concerns, for purposes of our response, we focus on three key areas of concern you've identified which have particular implications for pathology and laboratory medicine. These are:

- EHR MU Program
- Interoperability
- Patient Safety

EHR MEANINGFUL USE PROGRAM

The EHR Meaningful Use (MU) program was established as a result of passage in 2009 of the Health Information Technology and Economic and Clinical Health (HITECH) as part of the American Recovery and Reinvestment Act (ARRA). The program provides federal incentive funding to physicians who meet meaningful use standards established by the Office of the National Coordinator for Health Information Technology (ONC). This incentive funding will be phased out over time and replaced with payment penalties beginning in 2015 for physicians who are not "meaningfully using" health IT. While well intended, the Centers for Medicare and Medicaid Services (CMS), as your paper points out, has taken a "one-size-fits-all" approach to achieving meaningful use which does not account for differences in the abilities of providers to comply.

This is particularly evident for pathologists, whose medical practice is vastly different from the office-based physician upon which the MU program is based. Pathologists are responsible for diagnosing disease and ensuring patient safety through laboratory testing. They practice in independent laboratories or hospital-based facilities. Unlike primary care practitioners that have their own patient base, pathologists rarely have the type of face-to-face encounters with patients that would satisfy MU requirements. For example, pathologists don't chart a patient's vital signs, drug allergies or smoking cessation. The "hardship exception" included in the underlying statute would require every pathologist to individually apply on an annual basis to be exempt from the MU incentives and penalties. Under this exception, relief could only be extended on a year to year basis and for only five years in total. We do not consider this to be a practical or reasonable solution. CMS has indicated that pathologists will not be penalized in 2015, but there is no clarify going forward. Furthermore, under the law, pathologists meet the definition of "eligible professionals" and CMS has said it lacks the authority to more permanently address our concerns.

That's why the CAP strongly supports legislation H.R. 1309, the *Health Information Technology Reform Act* introduced by Representatives Tom Price, MD (R-GA) and Ron Kind (D-WI). The bill prevents pathologists from facing payment penalties under the EHR

MU program. In excluding pathologists from payment penalties, the bill also excludes pathologists from payment incentives. Pathologists should not be left to wonder whether they will be hit with payment reductions for requirements they can't meet as they practice their profession. At a time when providers are already facing considerable cost pressures, the threat of such penalties makes business planning difficult. Legislation is needed to remove with certainty the threat of payment reductions. We urge you to support such legislation in the Senate.

INTEROPERABILITY

Under MU, most eligible providers and hospitals will need to rely on data that pathologists and their laboratories generate to report required data. As we've noted previously, in their current operations, pathologists typically utilize LISs, APISs or blood banking systems that enable them to receive test orders, track test status, and report test results and provide interpretive reports. These test results and interpretive reports are then typically transmitted by interface to the EHR. However, MU incentive payments do not cover interface requirements for laboratories. This failure to account for the interface results in substantial costs for laboratories and creates barriers to interoperability as individual laboratories provide testing to multiple practice settings and diverse EHR systems – each of which may require a different interface. MU incentives or other funding mechanisms should cover the cost of interfaces since under MU such interfaces are essential to achieve interoperability.

As the Exchange Subcommittee of the ONC HIT Policy Committee recognized in a December 15, 2009 presentation, interfaces often cost from $5,000 to $25,000 each. Those numbers represent interfaces that do not include Computerized Physician Order Entry—which is required for laboratory orders in Stage 2 of MU. If anything, the 2009 numbers would under-estimate costs today. Adaption of the ONC Laboratory Reporting Implementation (LRI) guide as mandated by the 2014 Standards and Certification (S&C) Final Rule and the ONC Laboratory Orders Implementation (LOI) guide, likely to be mandated as part of the 2016 S&C, by converging on one standard may save costs in the long-run. In the short-run, however, these standards are just being pilot-tested (or have just completed pilot-testing.) Many laboratories will have to employ middleware to use them, thereby adding significant costs. **The CAP urges Congress to work with ONC and CMS to identify funding streams to cover the costs of laboratory interfaces, particularly for smaller laboratories.** It's also important to note there is a need for additional monies and education for laboratories and providers/EHR users on LOINC and SNOMED CT encoding and mapping of those laboratory test results.

Access to electronic patient data is essential to advancing coordinated care models, such as accountable care organizations (ACOs). As EHRs and HIEs become more common, a key role for pathologists is to design the format for laboratory results in the EHR and HIE, making the format as actionable as possible. As laboratory data stewards, pathologists in these new payment models either have taken, or are looking to take on, a leadership role in making data more accessible and more actionable by others physicians throughout the care team. For this to occur, the CAP believes that HIEs will need to be multi-directional and interoperable so that the laboratory is not just viewed

as a source of the data but instead allows:

- pathologists easy access to patient data across the patient's EHR; and
- other clinicians easy access to readable and actionable data from the laboratory.

Indeed, a CAP White Paper, *Contributions of Pathologists in Accountable Care Organizations: A Case Study* (see http://www.cap-aco_white_paper.pdf) found that key to an ACO's success is a "health information technology system that allows providers to access information about the patient across different care settings and allows for implementation of the payment and care delivery reforms." Importantly, the paper also notes that in settings with robust coordinated care and HIE, the laboratory data is used to implement population health management programs, communicate and assess the effectiveness of standardized laboratory order sets, and present laboratory results in a way that makes it easier and more efficient for the clinician to provide appropriate care to the patient.

INTEGRITY OF LABORATORY RESULTS AND PATIENT SAFETY

CAP has long been concerned about the integrity of laboratory orders and results as they move from the LIS/APIS to the EHR. Renditions of laboratory results in the EHR can be varied, lack the full intent of the originating lab results (e.g., not all of the report is displayed in the EHR due to field size constraints), and carry misinformation (e.g., units of measure are incorrect or not displayed properly). It is not clear that certification alone will lead to increased data integrity. We regularly hear stories from pathologists of dropped laboratory results or values, incorrectly displayed values and other problems, which in some cases can pose a risk to patient safety.

CAP's new white paper, *Laboratory Interoperability Best Practices: Ten Mistakes to Avoid,* released in March see: http://www.cap.org/apps/docs/committees/informatics/cap_dihit_lab_interop_final_march_2013.pdf) notes that "There are numerous examples of problems that can occur when interfacing laboratory systems to EHRs". Some of the common ones include:

- Results that are truncated
- Comments that do not display
- Results that are not accepted because the patient identifiers do not match
- Results being mapped to incorrect tests in the display
- Errors that aren't detected because interface error logs are not monitored."

The goal of increasing health information exchange is laudable but should only be done if patient safety can also be assured. Given the number of MU objectives that incorporate or depend on laboratory results, it may be desirable to have one "official source of truth in the EHR" (e.g. one official laboratory report) that is verified

by the laboratory, from which other parts of the EHR can take necessary laboratory data for clinical decision support, discharge summaries, etc.

As one avenue to ensure laboratory data integrity, ONC should explore certification or at least verification of functionality by receiving systems or by those that receive messages with laboratory results and reports to ensure modification of the message or formatting are not compromised. This includes any downstream information system receiving laboratory results or interface. Preserving report functionality and formatting including the CLIA required data elements, but also functionality for use of LOINC, SNOMED CT, reference ranges and other laboratory data by all downstream entities.

CONCLUSION

Again, thank you for the opportunity to comment. The CAP appreciates your leadership on this important topic. The goal of interoperable HIE has the potential to change and improve how health care is provided. Federal laws and regulations have a role to play, but they must be carefully designed, monitored and if necessary, adjusted over time to achieve success. We look forward to working with you, Congress, the Administration and other stakeholders to implement and improve HIT policies in the best interest of our health care system and the patients we serve.

If you have questions or need additional information, please contact Denise Bell, Director of Legislation and Political Action at 202-354-7106 or by email at dbell@cap.org