COLLEGE of AMERICAN PATHOLOGISTS

May 29, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-3310-P
P.O. Box 8013
Baltimore, MD 21244-8013

The College of American Pathologists (CAP) appreciates the opportunity to comment on the HHS Notice of Proposed Rulemaking (NPRM) entitled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program –Stage 3." The CAP is a medical society serving 18,000 physician members and the global laboratory community. It is the world's largest association composed exclusively of board-certified pathologists and is the worldwide leader in laboratory quality assurance. The CAP advocates accountable, high-quality, and cost-effective patient care. The CAP's Laboratory Accreditation Program is responsible for accrediting more than 7,000 clinical laboratories worldwide. The CAP has significant HIT expertise. Since the acquisition of SNOMED CT® by the International Health Terminology Standards Development Organisation (IHTSDO) the CAP Professional Services division has continued to develop and maintain SNOMED CT under contract to the IHTSDO. The division also offers a wide range of vocabulary, standards and other HIT strategy and implementation consulting services to providers, vendors and federal agencies.

INTRODUCTION:

The CAP supports the goals of Meaningful Use (MU) to advance national health care system improvement goals through the 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 and enabling vitally important new coordinated care models.

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 (LISs) 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 LISs and related HIT in pathology practice and laboratories.

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

The CAP understands that CMS wrote MU rules largely to incent office-based providers, particularly primary care physicians and hospitals to adopt certified EHRs. Therefore, it is not surprising that the majority of the Stage 1, Stage 2, and proposed Stages 3 objectives are outside the scope of pathology practice. While some proposed Stage 3 objectives have exclusions that pathologists could use, others do not.

The CAP appreciates the continuation of the hardship exception finalized in the CMS final rule for MU Stage 2 that grants automatic relief for pathologists based on their Provider Enrollment, Chain and Ownership System (PECOS) specialty code. Recognizing that ARRA statutorily limits CMS to providing no more than five years of relief, we strongly encourage that CMS grant this relief for the full five years with continuation beyond 2016. As this is the last stage of MU, we also seek clarification as to where CMS will publish additional guidance for the hardship exceptions.

The CAP's comments below address the timeline for Stage 3, the MU objectives, the clinical quality measures, and the payment adjustments.

TIMEFRAME FOR STAGE 3

The CAP supports the optional demonstration of Stage 3 beginning in 2017. 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. It is extremely time-consuming and expensive to set up and test interfaces between LISs and certified EHRs. Pathologists directing laboratories will be working to support hospitals and EPs meet MU. At the same time, pathologists are facing declining reimbursement and the threat of penalties from various Medicare programs in addition to the EHR incentive program (e.g. PQRS, value-based modifier, etc.) While an optional year is likely to be inadequate, it provides at least a start.

MEANINGFUL USE (MU) REQUIREMENTS

CERTIFIED EHRs

The CAP is commenting separately to ONC on its NPRM on the next version of certified EHR criteria. However, we wish to emphasize that while the majority of pathologists have viewing access to an EHR, the clinical systems they use are LISs, APISs (Anatomic Pathology Information Systems) and blood banking systems. Unlike other physician specialties, medical records of pathologists are already generated, transmitted, received and stored in integrated laboratory information systems. Therefore, no matter

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

what the objectives are, pathologists cannot meet MU, since they generally do not directly use EHRs.

Additionally, even when pathologists -- for example, in large integrated systems -- *do* access EHRs, they do *not* generally have control over purchasing, implementing, and maintaining them. Even in these large systems wherein minorities of pathologists are engaged, their use of EHRs is limited usually to reading information and inputting *laboratory* data, comments thereon, and consultations.

Further, ONC is proposing voluntary certification of Health IT, including LISs. We would like clarification whether this is for MU or non-MU certification. It is vital that the pathology community be involved in efforts to develop any such criteria and that any such program be voluntary. We have included similar comments in our response to ONC in the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications NPRM. The CAP welcomes the opportunity to provide pathology expert resources to aid in the development of certification criteria most meaningful for LISs.

OBJECTIVES

While we appreciate CMS' proposal to create a single set of 8 objectives for MU that would be optional beginning in calendar year 2017 and required in 2018, we do not think it is appropriate to have increased thresholds over similar Stage 1 and 2 measures. We believe it is important to allow providers the option to demonstrate Stage 3 beginning in 2017 before it is required in 2018.

While we have concerns about the applicability of most of the objectives to pathology, pathologists and their laboratories are critical to the achievement of many of the enumerated objectives (e.g. public health reporting, clinical decision support tools, etc.) by other EPs and hospitals.

The CAP has annotated Table 6 in the NPRM, which lists the proposed Stage 3 objectives, by adding a column that lists CMS proposed exclusions and a column with the CAP comment on the objectives. We note that there are several overlapping themes to our concerns with these objectives:

- The objective is written from the perspective of the ordering provider, not the physician receiving the order and performing or directing the activities ordered (e.g. pathologist/radiologist.)

- Pathologists engage in the activity covered by the objective but maintain and transmit the information relevant to that objective in LISs, which have greater relevant clinical functionality to pathologists than certified EHRs.
- The objective is outside the control of the pathologist.
- The activity referenced by the objective is outside the scope of pathologists' usual practice and interaction with patients.
- The pathologist is dependent on another EP for the information.

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

COLLEGE of AMERICAN PATHOLOGISTS

STAGE 3 MEANINGFUL USE OBJECTIVES AND ASSOCIATED MEASURES

Note: *Table 6 in the CMS NPRM; first two and last two columns added*

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
1	**Protect Patient Health Information**	Protect electronic protected health information (ePHI) created or maintained by the certified EHR technology (CEHRT) through the implementation of appropriate technical, administrative, and physical safeguards.	Protect electronic protected health information (ePHI) created or maintained by the certified EHR technology (CEHRT) through the implementation of appropriate technical, administrative, and physical safeguards.	Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.	None	Pathologists cannot generally meet this objective because they do not utilize EHRs. Pathologists utilize an LIS, not the EHR and are not involved in the activities and security policies of EHRs.
2	**Electronic Prescribing (eRx)**	Generate and transmit permissible prescriptions electronically (eRx).	Generate and transmit permissible prescriptions electronically (eRx).	**EP Measure:** More than **80 percent** of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT. **EH Measure:** More than **25 percent** of hospital discharge	**EP:** Any EP who: (1) writes fewer than 100 permissible prescriptions during the EHR reporting period; or (2) does not have a pharmacy within their organization and there are no pharmacies that accept electronic prescriptions within10	Medication reconciliation is outside the scope of pathology practice. Pathologists, however, oversee and are generally responsible for the laboratory testing that underpins the ability to practice genomic medicine

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
				medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.	miles of the EP's practice location at the start of his or her EHR reporting period. **EH:** Any EH or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their EHR reporting period.	and can contribute to decision support efforts on the appropriateness of a given medication given differing patient subpopulations.
3	**Clinical Decision Support (CDS)**	Implement CDS interventions focused on improving performance on high-priority health conditions.	Implement CDS interventions focused on improving performance on high-priority health conditions.	**Must meet both measures** **Measure 1**: The EP, EH, or CAH must implement **five** clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period. Absent four CQMs related to an EP, EH, or CAH's scope of practice or patient population, the clinical decision support interventions must be	**Measure 2:** For the second measure, any EP who writes fewer than 100 medication orders during the EHR reporting period.	Pathologists cannot generally meet this objective. While there are eight pathology PQRS measures, no CQMs to date are relevant to pathologists' scope of practice. Any CDS pathologists use would not be found in the EHR.

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
				related to high-priority health conditions. **Measure 2**: The EP, EH, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.		
4	**Computerized Provider Order Entry (CPOE)**	Use CPOE for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.	Use CPOE for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.	**Must meet all three measures** **Measure 1**: More than **80 percent** of medication orders created by the EP or authorized providers of the EH's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry; **Measure 2**: More than **60 percent** of laboratory orders created by the EP or authorized providers of the EH's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using	**Measure 1:** Any EP who writes fewer than 100 medication orders during the EHR reporting period. **Measure 2:** Any EP who writes fewer than 100 laboratory orders during the EHR reporting period. **Measure 3:** Any EP who writes fewer than 100 diagnostic imaging orders during the EHR reporting period.	This objective is written from the perspective of the EP placing the order, not the EP performing or supervising the ordered service. Pathologist-generated orders and reflex tests per protocols would not be included in the certified EHR, but in the LIS (and is out of scope for the S&I Lab Order Interface). We would urge the measure threshold not be increased from 30% as indicated in the Stage 2 Final Rule to 60% for Stage 3 for laboratory

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
				computerized provider order entry; and **Measure 3**: More than **60 percent** of diagnostic imaging orders created by the EP or authorized providers of the EH's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.		orders.
5	**Patient Electronic Access to Health Information**	The EP provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.	The EH or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.	**Must meet both measures** **Measure 1**: For more than **80 percent** of all unique patients seen by the EP or discharged from the EH or CAH inpatient or emergency department (POS 21 or 23): <u>Option 1:</u> The patient (or patient-authorized representative) is provided access to view online, download, and transmit their health information within **24 hours** of its availability	**Measure 1, Exclusions:** • An EP may exclude from the measure if they have no office visits during the EHR reporting period. • Any EP, EH, or CAH that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps	This objective is outside of pathologists' usual scope of practice. Pathologists have no control as to whether patients are given the required access to the EHR to which LIS-generated information is transmitted. This objective should be placed on the system of care as a whole rather than on a

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
				to the provider; **or** <u>Option 2:</u> The patient (or patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information, within **24 hours** of its availability to the provider. **Measure 2**: The EP, EH or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than **35 percent** of unique patients seen by the EP or discharged from the EH or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.	broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measure. **Measure 2, Exclusions:** • An EP may exclude from the measure if they have no office visits during the EHR reporting period. • Any EP, EH, or CAH that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first	provider-by-provider basis given that patients are often interested in their entire record of care. In the case of pathologists, the pathologist EP would in many cases only have access to laboratory data and not the other health information of interest to the patient. Pathologists could benefit from the exclusion as they generally do not have office visits. (*Note: A small percentage of pathologists do generate E&M services, defined by CPT as an office or other outpatient visit. Pathologist evaluations for apheresis, for example, would qualify as "other outpatient visit" not as an office visit.*)

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
					day of the EHR reporting period may exclude the measure.	
6	**Coordination of Care through Patient Engagement**	Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.	Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.	**Must attest to the numerator and denominator for all three measures but only required to meet the threshold for 2 out of the 3 measures.** **Measure 1:** During the EHR reporting period, more than **25 percent** of all unique patients seen by the EP or discharged from the EH or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider. An EP, EH or CAH may meet the measure by **either:** Option 1: More than **25 percent** of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the EH or CAH inpatient or	**Measure 1 (either option):** • Any EP who has no office visits during the EHR reporting period may exclude from the measure. • Any EP, EH or CAH that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure. **Measure 2:** • Any EP who has no office visits	This objective is generally outside the scope of pathology practice as direct patient contact is the exception rather than the rule in pathology. Pathologists do not conduct office visits, although as discussed above in instances they may generate other E&M codes, and would benefit from the exclusion. Further, we would caution against the dangers of unsupervised (and possibly unstructured) incorporation (e.g. scanning) of patient-generated information into an institution's EHR. The data may not

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
				emergency department (POS 21 or 23) during the EHR reporting period view, download or transmit to a third party their health information; **or** <u>Option 2:</u> More than **25 percent** of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the EH or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period access their health information through the use of an ONC-certified API that can be used by third-party applications or devices. **Measure 2:** For more than **35 percent** of all unique patients seen by the EP or discharged from the EH or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of	during the EHR reporting period may exclude from the measure. • Any EP, EH, or CAH that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure. **Measure 3:** • Any EP who has no office visits during the EHR reporting period may exclude from the measure. • Any EP, EH, or CAH that conducts 50 percent or more of his or her patient encounters	mesh well with local reporting standards, resulting in misinterpretation by a physician. Also, the results may simply be wrong or in conflict with local EHR data. To prevent potential misinterpretation, patient-generated data entered into the EHR must be clearly identified as such and preferably set apart from provider-generated data. One potential solution would be the addition of disclaimers that made clear to the treating physician when data was patient-reported or acquired separately from the laboratory origination source, information accuracy and completeness must be retained across the parties that exchange data as the data flows from the originator (e.g.

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
				CEHRT to the patient (or the patient's authorized representatives), or in response to a secure message sent by the patient (or the patient's authorized representative). **Measure 3:** Patient-generated health data or data from a non-clinical setting is incorporated into the certified EHR technology for more than **15 percent** of all unique patients seen by the EP or discharged by the EH or CAH during the EHR reporting period.	in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.	patients, other provider or other laboratory) to the transporting system/intermediary (e.g. portal or health information exchange) to the receiving systems that manage and present patient information for clinical decisions and care. We recommend that this meta data be included in the CEHRT as a certification criterion. In addition, patient-generated information, even if it is a laboratory result not sent directly to the CEHRT, should be able to be sent as a pdf or some sort of non-discreet data elements. Doing so would be another way to ensure that discreet data items sent from a CLIA-certified laboratory are not confused

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
						with other, potentially less reliable or accurate information.
7	**Health Information Exchange (HIE)**	The EP provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.	The EH or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.	**Must attest to the numerator and denominator for all three measures but only required to meet the threshold for 2 out of the 3 measures.** **Measure 1:** For more than **50 percent** of transitions of care and referrals, the EP, EH or CAH that transitions or refers their patient to another setting of care or provider of care: (1) creates a summary of care record using CEHRT; **and** (2) electronically exchanges the summary of care record. **Measure 2:** For more than **40 percent** of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, EH or CAH incorporates into the patient's EHR an	**Measure 1:** • An EP neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period. • Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measures. • Any EH or CAH operating in a location that does not have 50	Pathologists do not engage in transfers of care from one setting to another. Pathologists write reports for other physicians/EP with laboratory results including anatomic pathology results. CAP believes that this report writing is not what is intended by the term “referral of care”. Pathologists cannot generally meet the objective. Medication reconciliation is outside the scope of pathology practice. Pathologists practice in the LIS, not in the EHR where this care coordination is supposed to take place.

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
				electronic summary of care document from a source other than the provider's EHR system. **Measure 3:** For more than **80 percent** of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, EH, or CAH performs a clinical information reconciliation. The provider would perform reconciliations for the following three clinical information sets: • Medication. Review of the patient's medication, including the name, dosage, frequency, and route of each medication. • Medication allergy. Review of the patient's known allergic medications. • Current Problem list. Review of the patient's current and active diagnoses.	percent or more of its housing units with 4Mbps availability according to the latest information available from the FCC at the start of the EHR reporting period. **Measure 2:** • Any EP, EH or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure. • Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps	Pathologists have no control over their ability to access the EHR to provide or receive the required information.

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
					broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measures. • Any EH or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps availability according to the latest information available from the FCC at the start of the EHR reporting period. **Measure 3:** • Any EP, EH or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer	

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
					than 100 during the EHR reporting period is excluded from this measure. • Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measure. • Any EH or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps availability according to the latest information available from the FCC at the start of the EHR reporting	

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
					period.	
8	**Public Health and Clinical Data Registry Reporting**	The EP is in *active engagement* with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.	The EH or CAH is in *active engagement* with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.	**EP must choose from measures 1 through 5 and successfully attest to any combination of three measures** **EHs and CAHs must choose from measures 1 through 6, and would be required to successfully attest to any combination of four measures**. The measures are as shown in **Table 5 (below).** As noted, measures four and five for Public Health Registry Reporting and Clinical Data Registry Reporting may be counted more than once if more than one Public Health Registry or Clinical Data Registry is available. **Measure 1 – Immunization Registry Reporting:** The EP, EH, or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories	**Measure 1:** Any EP, EH, or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the EP, EH, or CAH: (1) does not administer any immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or immunization information system during the EHR reporting period; (2) operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no immunization registry or immunization	Pathologists would benefit from the exclusion as immunization administration is generally outside the scope of pathologist practice.

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
				from the public health immunization registry/immunization information system (IIS). **Measure 2 – Syndromic Surveillance Reporting**: The EP, EH, or CAH is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting for EPs, or an emergency or urgent care department for EH's and CAHs (POS 23). **Measure 3 - Case Reporting**: The EP, EH, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions. **Measure 4 - Public Health Registry Reporting**: The EP, EH, or CAH is in active engagement with a public health agency to submit data to public health registries. **Measure 5 – Clinical Data Registry Reporting:**	information system has declared readiness to receive immunization data at the start of the EHR reporting period. **Exclusion for EPs for Measure 2:** Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the EP: (1) does not treat or diagnose or directly treat any disease or condition associated with a syndromic surveillance system in their jurisdiction; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from EPs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no	Laboratories play a key role for antibiotic sensitivities in the hospital and community. Clear and detailed specifications to recognize candidate records for syndromic surveillance data submission must be identified, built, and the appropriate data populated accurately in the EHR systems before this will be fully effective and reliable.

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
				The EP, EH, or CAH is in active engagement to submit data to a clinical data registry. **Measure 6 – Electronic Reportable Laboratory Result Reporting:** The EH or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results. This measure is available to EH's and CAHs only.	public health agency has declared readiness to receive syndromic surveillance data from EPs at the start of the EHR reporting period. **Exclusion for EHs/CAHs for Measure 2:** Any EH or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the EH or CAH: (1) does not have an emergency or urgent care department; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from EH or CAHs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency	

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
					has declared readiness to receive syndromic surveillance data from EHs or CAHs at the start of the EHR reporting period. **Measure 3:** Any EP, EH, or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the EP, EH, or CAH: (1) does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no	

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
					public health agency has declared readiness to receive electronic case reporting data at the start of the EHR reporting period. **Measure 4:** Any EP, EH, or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure if the EP, EH, or CAH: (1) does not diagnose or directly treat any disease or condition associated with a public health registry in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a	

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
					jurisdiction where no public health registry for which the EP, EH, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period. **Measure 5:** Any EP, EH, or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure if the EP, EH, or CAH: (1) does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the	

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
					CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no clinical data registry for which the EP, EH, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period. **Measure 6:** Any EH or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure if the EH or CAH: (1) does not perform or order laboratory tests that are reportable in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of accepting the specific ELR standards	

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

#	OBJECTIVE NAME	OBJECTIVES – ELIGIBLE PROFESSIONALS	OBJECTIVES – ELIGIBLE HOSPITALS/CAHs	MEASURES	EXCLUSIONS	CAP COMMENTS
					required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from an EH or CAH at the start of the EHR reporting period.	

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

COMMENTS ON SPECIFIC OBJECTIVES

Objective 3: Clinical Decision Support

We comment in regards to the CMS statement: “In alignment with the HHS National Quality Strategy goals, providers are encouraged to implement CDS related to quality measurement and improvement goals on the following areas: Appropriateness of diagnostic orders or procedures such as labs, diagnostic imaging, genetic testing, pharmacogenetic and pharmacogenomic test result support or other diagnostic testing.” We caution that to enable clinical decision support for complex laboratory testing, subject matter expertise in conjunction with robust data analytics may be required. Even where data has been analyzed by expert groups (e.g. Bethesda reporting for cervicovaginal cytology), significant laboratory/pathology subject matter expertise is required for proper implementation. The CAP would be interested in assisting with development of CDS content for accurate, optimal, and appropriate laboratory ordering and result interpretation.

Objective 5: Patient Electronic Access to Health Information

CAP seeks clarification of the following statement in the proposed rule: “we further propose to decrease patient wait time for the availability of information to within 24 hours of the office visit or of the information becoming available to the provider for potential inclusion in the case of lab or other test results which require sufficient time for processing and returning results.” We are unclear of the intent of the phrase: “or of the information becoming available to the provider for potential inclusion in the case of lab or other test results which require sufficient time for processing and returning results.” We specifically request clarification on the value of provider annotation of laboratory results and how best to manage release of complex multipart or sequential testing.

Objective 7: Health Information Exchange

We concur with CMS regarding the paragraph below on inclusion of all vs. a partial set of laboratory data and clinical notes. We ask that CMS recognize that EHR information overload serves to obfuscate information relevant to a particular care episode. Rather than inclusion or exclusion of relevant data, categorization of data using a mechanism to “tag” content would permit more efficient meaningful use of voluminous data sent over a HIE. The CAP welcomes the opportunity to provide pathology expertise to help define how to appropriately tag laboratory and pathology data sets for more efficient use (e.g. microbiology, chemistry, oncology, hematology, etc):

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

"Similarly, for Stage 3 we have received comments from stakeholders and through public forums and correspondence on the potential of allowing only clinically relevant laboratory test results and clinical notes (rather than all laboratory tests results and clinical notes) in the summary of care document for purposes of meeting the objective. We believe that while there may be a benefit and efficiency to be gained in the potential to limit laboratory test results or clinical notes to those most relevant for a patient's care; a single definition of clinical relevance may not be appropriate for all providers, all settings, or all individual patient diagnosis. Furthermore, we note that should a reasonable limitation around a concept of ''clinical relevance'' be added; a provider must still have the CEHRT functionality to include and send all labs or clinical notes. Therefore, we defer to provider discretion on the circumstances and cases wherein a limitation around clinical relevance may be beneficial and note that such a limitation would be incumbent on the provider to define and develop in partnership with their health IT developer as best fits their organizational needs and patient population. We specify that while the provider has the discretion to define the relevant clinical notes or relevant laboratory results to send as part of the summary of care record, providers must be able to provide all clinical notes or laboratory results through an electronic transmission of a summary of care document if that level of detail is subsequently requested by a provider receiving a transition of care or referral or the patient is transitioning to another setting of care. We note that this proposal would apply for lab results, clinical notes, problem lists, and the care plan within the summary of care document."

CLINICAL QUALITY MEASURES (CQMs)

CMS is not proposing changes to the reporting requirements for CQMs for achievement of MU. Reporting CQMs is impossible for the vast majority of pathologists. We appreciate the CMS proposal to align the reporting period of CQMs with the Physician Quality Reporting System (PQRS) reporting period and to align measures with the PQRS measures. However, currently while pathologists have eight quality measures in the CMS Physician Quality Reporting System (PQRS), pathologists generally use their LISs and billing systems to generate this data and do not routinely utilize an EHR. All of the current PQRS pathology measures can only be reported via claims and cannot be submitted and satisfactorily reported as CQMs under the PQRS EHR reporting option. Furthermore, while many of the CQMs rely on laboratory and pathologist data such as blood tests and cancer diagnosis and staging, none of the CQMs are applicable to pathologists' scope of practice and the eight pathology-specific PQRS measures are not included. The CAP supports the six domains of the National Quality Strategy upon which the measures are based and offers extensive services to

laboratories for quality improvement. However, for all the reasons stated, pathologists cannot submit CQMs in any of the specified domains.

The CAP appreciates that CMS has previously stated that if there is no data for CQMs that the EP must report zero denominators, but because this requirement too is linked to the use of certified EHRs, this exception is not relevant to pathology.

PAYMENT ADJUSTMENTS

As stated above, we appreciate the continuation of the hardship exception finalized in the CMS final rule for MU Stage 2 that grants automatic relief for pathologists based on their Provider Enrollment, Chain and Ownership System (PECOS) specialty code. Recognizing that ARRA statutorily limits CMS to providing no more than five years of relief, we strongly encourage that CMS grant this relief for the full five years with continuation beyond 2016. As this is the last stage of MU, we also seek clarification as to where CMS will publish additional guidance for the hardship exceptions.

We also urge CMS to finalize the proposal to maintain the four categories of exceptions based on the following and especially the last referring to a lack of face-to-face interaction with patients, a lack of follow-up with patients, and a lack of control over the availability of Certified EHR technology at their practice locality:

- The lack of availability of internet access or barriers to obtain IT infrastructure.
- A time-limited exception for newly practicing EPs or new hospitals that would not otherwise be able to avoid payment adjustments.
- Unforeseen circumstances such as natural disasters that would be handled on a case-by-case basis.
- (EP only) exceptions due to a combination of clinical features limiting a provider's interaction with patients or, if the EP practices at multiple locations, lack of control over the availability of CEHRT at practice locations constituting 50 percent or more of their encounters.

Congress has also recognized that current quality programs, including meaningful use, do not reflect the way non-patient facing providers practice medicine. Therefore, Congress included language in the recently enacted Medicare Access and CHIP Reauthorization Act (MACRA), Public Law 114-10, that gave the Secretary of HHS the authority to develop measures and alternatives that reflect the way non-patient facing providers, like pathologists, practice medicine. Given this new authority and as this proposed rule was published before enactment of

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

MACRA, we ask that CMS detail what process it will undertake to develop those measures, within the EHR MU program, for providers that have no face-to-face interaction with patients. Additionally, we ask that CMS detail how this non-patient facing language will influence its rule making on the EHR MU program generally.

While meeting the requirements of the EHR Incentive Program is not always impossible for pathologists, it is unduly burdensome given the current state of commercially available EHRs particularly compared to standalone specialty system products, certification of technology appropriate for these specialties, workflow challenges, nature of the patient relationship, and patient data needs. Moreover, pathologists are often subject to the capabilities and resources of the hospital facilities in which a significant number of them work or contract with. Whenever those facilities are not proactive partners in enabling all onsite (including contracted) physicians to meet MU via adequate data collection, certified EHR technology access, and technical support, the barrier to compliance is significantly higher and often impossible to overcome. As a result of these barriers only a small minority of physicians with the relevant pathology PECOS designations have attested to meaningful use.

While some pathologists do have occasional direct contact with patients (e.g. for the performance of fine needle aspiration; bone marrow aspiration and core biopsy; and apheresis procedures --plasmapheresis, leukopheresis, apheresis collection of blood products, etc. in the blood bank), it is generally a time-limited event. As indicated above, a significant barrier to pathologist achievement of MU is that pathologists have little control over whether there is Certified EHR technology at their practice location. Even when pathologists -- for example, in large integrated systems -- *do* access EHRs, they do not generally have control over purchasing, implementing, and maintaining them. Another hurdle is that the vast majority of the objectives are outside the scope of pathology practice.

We are aware that according to publicly available data posted on www.data.gov that a very small number of pathologists have attested to MU. According to CAP's analysis of the data, as of June 2014, only 38 pathologists had attested to MU in all three years of the program and only 366 had EVER attested. We believe that the fact that hardly any pathologists have attested supports our contention that the vast majority of pathologists cannot meet MU. We do not know the specific fact basis for any pathologists who have attested. However, it *may* be that those few pathologists who have attested to MU may be because they are part of larger practice organizations, the leaders of whom may be making practice-wide attestations on behalf of all of their physicians, including their pathologists. The CAP welcomes the opportunity to provide pathology expert resources to aid in the

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org

development of measures to incentivize meaningful use and interoperability of laboratory data.

CONCLUSION

The CAP appreciates the opportunity to comment on this important rulemaking. We look forward to working with CMS to not only address the pathologists MU concerns, but also to use MU to advance interoperable EHRs to improve care for our patients. Should you have any questions on our comments, please contact Loveleen Singh, Assistant Director, Economic & Regulatory Affairs at (202) 354-7133 or via email at Lsingh@cap.org.

College of American Pathologists
t: 800-392-9994 ext. 7133
f: 202-354-8133
Lsingh@cap.org
1350 I Street, NW, #590
Washington, DC 20005
800-392-9994 | cap.org