June 15, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

DELIVERED ELECTRONICALLY

RE: Comments on the Proposed Rule, "Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Modifications to Meaningful Use in 2015 through 2017", CMS-3311-P (RIN 0938-AS58), 42 CFR 495, April 15, 2015 (80 FR 20346)

Dear Administrator Slavitt:

I am submitting the attached comments on behalf of the American Clinical Laboratory Association (ACLA) in response to the Proposed Rule, "Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Modifications to Meaningful Use in 2015 through 2017", CMS-3311-P (RIN 0938-AS58), 42 CFR 495, April 15, 2015 (80 FR 20346).

ACLA is a not-for-profit association representing the nation's leading providers of clinical laboratory services, including local, regional, and national laboratories. Our diverse membership represents a broad array of clinical laboratories, including national independent labs, reference labs, esoteric labs, hospital labs, and nursing home laboratories.

ACLA, again, appreciates the opportunity to comment on the Electronic Health Record Incentive Program. If there are any questions regarding the above comments, please do not hesitate to contact us by phone at (202) 637-9466 or via e-mail at tsparkman@acla.com.

Sincerely,

Thomas B Sparkman, RPh, MPP, JD
Vice President, Government Relations

ATTACHMENT: ACLA Comments

Comment Item: CMS/HHS Proposed Rule, "Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Modifications to Meaningful Use in 2015 Through 2017", RIN 0938-AS58, 80 Fed. Reg. 20346, April 15, 2015

ATTACHMENT: ALCA Comments regarding the proposed rule, "Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Modifications to Meaningful Use in 2015 through 2017", CMS-3311-P (RIN 0938-AS58), 42 CFR 495, April 15, 2015 (80 FR 20346).

Page	Comment
20354	"For 2015 only, we are proposing to change the definition of ''EHR reporting period'' at § 495.4 for EPs, eligible hospitals, and CAHs such that the EHR reporting period in 2015 would be any continuous 90-day period within the calendar year. We intend this change to allow providers adequate time to plan for any necessary changes to their implementation of meaningful use required in order to accommodate the changes outlined in this proposed rule. We further believe this change is responsive to provider and stakeholder feedback received through correspondence, public forums, and public comment, which requested that we allow a 90-day EHR reporting period in 2015 in order to provide flexibility for continuing difficulties providers are experiencing with successful implementation of EHR technology certified to the 2014 Edition… "We propose that for an EHR reporting period in 2015, eligible professionals may select an EHR reporting period of any continuous 90-day period from January 1, 2015 through December 31, 2015; while eligible hospitals and CAHs may select an EHR reporting period of any continuous 90-day period from October 1, 2014 through December 31,2015. This is intended to accommodate the shift from reporting based on the federal fiscal year to the calendar year for eligible hospitals and CAHs. "…However, for all returning participants that have successfully demonstrated meaningful use in a prior year, the EHR reporting period would be a full calendar year from January 1, 2016 through December 31, 2016. In 2017, the EHR reporting period would be 1 full calendar year for all providers, as proposed in the Stage 3 proposed rule (80 FR 16739)." **ACLA Comment:** ACLA strongly supports CMS changes to allow adequate planning time for the EHR reporting period in 2015 by allowing a 90-day continuous reporting period for attestation. Additionally we'd like to recommend the 90-day reporting period carry into 2016 due to competing objectives such as ICD-10, PQRS, in addition to Meaningful Use.

20355

"Redundant, Duplicative or Topped Out Objectives and Measures"

TABLE 3—OBJECTIVES AND MEASURES IDENTIFIED BY PROVIDER TYPE WHICH ARE REDUNDANT, DUPLICATIVE OR TOPPED OUT

Provider type	Objectives and measures	
Eligible Professional	Record Demographics	42 CFR §495.6 (j)(3)(i) and (ii).
	Record Vital Signs	42 CFR §495.6 (j)(4)(i) and (ii).
	Record Smoking Status	42 CFR §495.6 (j)(5)(i) and (ii).
	Clinical Summaries	42 CFR §495.6 (j)(11)(i) and (ii).
	Structured Lab Results	42 CFR §495.6 (j)(7)(i) and (ii).
	Patient List	42 CFR §495.6 (j)(8)(i) and (ii).
	Patient Reminders	42 CFR §495.6 (j)(9)(i) and (ii).
	Summary of Care	42 CFR §495.6 (j)(14)(i) and (ii).
	Measure 1—Any Method	
	Measure 3—Test	
	Electronic Notes	42 CFR §495.6 (j)(9)(i) and (ii).
	Imaging Results	42 CFR §495.6 (k)(6)(i) and (ii).
	Family Health History	42 CFR §495.6 (k)(2)(i) and (ii).
Eligible Hospital/CAH	Record Demographics	42 CFR §495.6 (l)(2)(i) and (ii).
	Record Vital Signs	42 CFR §495.6 (l)(3)(i) and (ii).
	Record Smoking Status	42 CFR §495.6 (l)(4)(i) and (ii).
	Structured Lab Results	42 CFR §495.6 (l)(6)(i) and (ii).
	Patient List	42 CFR §495.6 (l)(7)(i) and (ii).
	Summary of Care	42 CFR §495.6 (l)(11)(i) and (ii).
	Measure 1—Any Method	
	Measure 3—Test	
	eMAR	42 CFR §495.6 (l)(16)(i) and (ii).
	Advanced Directives	42 CFR §495.6 (m)(1)(i) and (ii).
	Electronic Notes	42 CFR §495.6 (m)(2)(i) and (ii).
	Imaging Results	42 CFR §495.6 (m)(2)(i) and (ii).
	Family Health History	42 CFR §495.6 (m)(3)(i) and (ii).
	Structure Labs to Ambulatory Providers	42 CFR §495.6 (m)(6)(i) and (ii).

ACLA Comment:

ACLA is concerned that while the intent is for providers to continue conducting these measures, if they are no longer required for Meaningful Use attestation, they may discontinue conducting these measures based on their current workflows and time demands.

ACLA is specifically concerned about the removal of Structured Lab Results. As previously noted for ACLA comments on Meaningful Use 3 NPRM, certain EHR vendors are able to support the LRI for ONC certification, but not necessarily incorporating the LRI IG within the providers interface. The benefits of structured lab results are vast, including support of Clinical Decision Support and common standards across various

	EHR vendors and labs to improve the implementation bottlenecks with the current laboratory results interface process. Because of this, ACLA does not believe that the current state of Structured Lab Results falls into the Redundant, Duplicative or Topped Out Measure presumptions since the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface (LRI IG) is still not widely adopted. The efforts within the S&I Framework volunteer community to support standardization and harmonization would extend into the LOI IG, eDOS, and ELR and further dampen their implementation at the local provider level.
20357	• "Patient Action To View, Download, or Transmit Health Information "++ Remove the 5 percent threshold for Measure 2 from the EP Stage 2 Patient Electronic Access (VDT) objective. Instead require that at least 1 patient seen by the provider during the EHR reporting period views, downloads, or transmits his or her health information to a third party. This would demonstrate the capability is fully enabled and workflows to support the action have been established by the provider. "++ Remove the 5 percent threshold for Measure 2 from the eligible hospital and CAH Stage 2 Patient Electronic Access (VDT) objective. Instead require that at least 1 patient discharged from the hospital during the EHR reporting period views, downloads, or transmits his or her health information to a third party. This would demonstrate the capability is fully enabled and workflows to support the action have been established by the provider." **ACLA Comment:** ACLA agrees the 5 percent thresholds should be removed and adjusted as suggested in the proposed rule.
20370	"Since "Eligible Professional .... CPOE ..... • *Measure 2:* More than 30 percent of laboratory"" (emphasis added) **ACLA Comment:** The utilization of different tables for "Eligible Professional" (EP) and "Eligible Hospital/CAH" (EH/CAH) is confusing in that the same measures for both categories (EP and EH/CAH) are repeated in each table. ACLA suggests restricting the EP measures in EP table and EH/CAH measures in EH/CAH table.
20372	"Since "Eligible Hospital/CAH ... CPOE .....• *Measure 2:* More than 30 percent of laboratory"" (emphasis added) **ACLA Comment:** The utilization of different tables for "Eligible Professional" (EP) and "Eligible Hospital/CAH" (EH/CAH) is confusing in that the same measures for both categories (EP and EH/CAH) are repeated in each table. ACLA suggests restricting the EP measures in EP table and EH/CAH measures in EH/CAH table.

20353	**Section or Text:** "(a) Calendar Year Reporting Beginning in 2015 Beginning in 2015, we are proposing to change the definition of ''EHR reporting period'' at § 495.4 for EPs, eligible hospitals, and CAHs such that the EHR reporting period would begin and end in relation to a calendar year." **ACLA Comment:** ACLA strongly supports CMS changes to streamline the reporting for Meaningful Use by moving to Calendar year reporting.
20359	**Section or Text:** *"Proposed Objective:* Use computerized provider order entry for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local, and professional guidelines. We define CPOE as entailing the provider's use of computer assistance to directly enter medical orders (for example, medications, consultations with other providers, laboratory services, imaging studies, and other auxiliary services) from a computer or mobile device. The order is then documented or captured in a digital, structured, and computable format for use in improving safety and efficiency of the ordering process. CPOE improves quality and safety by allowing clinical decision support at the point of the order and therefore influences the initial order decision. CPOE improves safety and efficiency by automating aspects of the ordering process to reduce the possibility of communication and other errors. "… • *"Measure 2:* More than 30 percent of laboratory orders created by the EP or by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry. "… "We propose to retain the three measures of this current Stage 2 objective to calculate a percentage threshold for all three types of orders: Medication, laboratory, and radiology. We propose to retain exclusionary criteria for those providers who so infrequently issue an order type that it is not practical to implement CPOE for that order type. To calculate the percentage, CMS and ONC have worked together to define the following for this objective: "… • *"Measure 2:* "Denominator: Number of laboratory orders created by the EP or authorized providers in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period. Numerator: The number of orders in the denominator recorded using CPOE. Threshold: The resulting percentage must be more than 30 percent in order for an EP, eligible hospital or CAH to meet this measure. Exclusion: Any EP who writes fewer than 100 laboratory orders during the EHR reporting period. "… *Alternate Exclusion for Measure 2:* "Provider may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015." (emphasis added)

	ACLA Comment: ACLA recommends clarification defining what constitutes an "order". For example, is an order equivalent to a single transaction OR does each order code in the single transaction represent an individual order? Is a laboratory panel/profile test counted as one order? Please clarify how the following laboratory order scenarios will be counted: • Test - with one result component, such as a glucose test (1 order, 1 result) • Panel – one order code with greater than one result code, for example a Metabolic Panel contains multiple results including: BUN/Creatinine Ratio (calculated), Calcium, Carbon Dioxide, Chloride, Creatinine with GFR Estimated, Glucose, Potassium, Sodium, Urea Nitrogen (BUN) • Profile – comprised of multiple tests or panels
20356	**Section or Text:** "Therefore, we propose that the structure of meaningful use for 2015 through 2017 would be 9 required objectives for EPs using the Stage 2 objectives for EPs with alternate exclusions and specifications for Stage 1 providers in 2015. We propose that the structure of meaningful use for 2015 through 2017 would be 8 required objectives for eligible hospitals and CAHs using the Stage 2 objectives for eligible hospitals and CAHs with alternate exclusions and specifications for Stage 1 providers and some stage 2 providers in 2015. In addition, EPs would be required to report on a total of 2 measures from the public health reporting objective or meet the criteria for exclusion from up to 5 measures, and eligible hospitals and CAHs would be required to report on a total of 3 measures from the public health reporting objective or meet the criteria for exclusion from up to 6 measures. "TABLE 4—CURRENT STAGE STRUCTURE, RETAINED OBJECTIVES, AND PROPOSED STRUCTURE" **ACLA Comment:** ACLA strongly supports CMS changes to streamline the reporting for Meaningful Use by specifying core and public health objectives and eliminating menu options for 2015 through 2017.
20366	**Section or Text:** "j. Public Health and Clinical Data Registry (CDR) Reporting" **ACLA Comment:** ACLA supports collaboration between CMS, CDC, and ONC to promote standardized and interoperable exchange of public health data nationally, vs. State specific requirements whenever possible. To improve information exchange, we suggest citing the later version of the electronic reportable laboratory implementation guide that defines additional constraints designed to work with the other S&I Framework Laboratory Implementation Guides: HL7 Version 2.5.1 IG: Electronic Lab Reporting to Public Health, DSTU R2 - US Realm, published November 2013.