May 29, 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 – Stage 3", CMS-3310-P (RIN 09380-AS26), 42 CFR 495, March 30, 2015 (80 FR 16732)

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 – Stage 3" (CMS-3310-P (RIN 09380-AS26)), as published in the *Federal Register* on March 30, 2015 (80 FR 16732).

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

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Comments by the American Clinical Laboratory Association (ACLA) on the Proposed Rule, "Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 3", CMS-3310-P (RIN 09380-AS26), 42 CFR 495, March 30, 2015 (80 FR 16732)

FR Page	ACLA Comment
16737	**FR Section or Text:** "For this Stage 3 proposed rule, we seek to streamline the criteria for meaningful use. We intend to do this by— • "Creating a single stage of meaningful use objectives and measures (Stage 3), which would be optional for all providers in 2017 and mandatory for all providers in 2018; • "Allowing providers flexible options for 2017; • "Changing the EHR reporting period to a full calendar year for all providers; and • "Aligning with other CMS quality reporting programs using certified health IT such as PQRS and Hospital IQR for clinical quality measurement." **ACLA Comment:** ACLA strongly supports CMS changes to streamline the criteria for Meaningful Use.
16739	**FR Section or Text:** "(b) EHR Reporting Period "… "Provide for greater flexibility, stress testing, and Quality Assurance (QA) of systems before deployment." **ACLA Comment:** In line with improved Quality Assurance provision, ACLA suggests CMS consider funding pilots for Implementation Guides and subsequent version updates prior to mandating a particular version of an Implementation Guide. Currently, innovators who may elect to pilot an early release are, in effect, penalized if the pilot results in a subsequent update to the Implementation Guide as they must re-develop and re-deploy software. Further, EHR vendors are resistant to implement draft standards until they have been field tested. Funding for pilots would help alleviate this resistance and speed the process.
16739	"Calendar Year Reporting "We are proposing to change the definitions of ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year'' under § 495.4 for EPs, eligible hospitals, and CAHs such that the EHR reporting period would be one full calendar year, with a limited exception under the Medicaid EHR Incentive Program for providers demonstrating meaningful use for the first time as discussed later in this FR Section and in FR Section II.A.2.b. of this proposed rule. This would allow for the full alignment of the EHR reporting timeline for the meaningful use objectives and associated measures and the CQMs, and align the timing of reporting by EPs, eligible hospitals, and CAHs. We propose this change would apply beginning in CY 2017."

FR Page	ACLA Comment
	ACLA Comment: ACLA strongly supports CMS changes to streamline the criteria for Meaningful Use.
16741	"The requirements state: "The objectives that address these requirements are integral to the foundational goals of the program, which would be undermined if providers were allowed to fail to meet these objectives and still be considered meaningful EHR users. For these reasons, we intend to continue to require providers to meet the objectives and measures of meaningful use as required for the program, rather than allowing providers to fail any two objectives of their choice or making all objectives menu objectives." "(a) Topped Out Objectives and Measures "In other contexts and CMS programs, CQMs are regularly evaluated to determine whether they have ''topped out,'' which means generally that measure performance among providers is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made." **ACLA Comment:** ACLA notes that the transmission and incorporation of laboratory data is not listed as an Objective/Measure for Meaningful Use in 2017 and Subsequent Years. Further, based on the April 15, 2015 MU3 NPRM publication, even though an EHR is certified for MU 1 and 2 requirements for the transmission and incorporation of laboratory data, we find no requirement for providers to attest that they actually use this functionality in their certified EHR if they have not previously attested to MU1 or MU2. The absence of this requirement would be a significant step backwards in interoperability as there would not be any incentive for providers to support electronic interfaces between laboratories and EHRs and, therefore, ACLA urges CMS to require the attestation that an EHR includes the functionality to transmit and incorporate laboratory data.
16747	"Objective 2: Electronic Prescribing "Proposed Objective: EPs must generate and transmit permissible prescriptions electronically, and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx). "… While the EP performance rate across all years and stages of participation indicate wide spread adoption, with the *median rate at 89 percent for Stage 1 and 92 percent for Stage 2* [3], we believe continued support of this objective is warranted to support the continued development of the ePrescribing marketplace." (*emphasis added*) **ACLA Comment:** This seems to contradict their other defined reasons for 'Topped Out" noted on page 16741. While we agree that eRX should continue to be a measure due to its importance in the healthcare continuum, we feel the proposal for the inclusion of Structured Lab Results as a topped out measure in the CMS 42 CFR Part 495 Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Modifications to Meaningful Use in 2015 Through 2017; Proposed Rule would also provide the same importance. ACLA will respond accordingly in that publication's public comments.

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	For reference from page 16741: "(a) Topped Out Objectives and Measures "In other contexts and CMS programs, CQMs are regularly evaluated to determine whether they have ''topped out,'' which means generally that measure performance among providers is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made."
16750	"Objective 4: Computerized Provider Order Entry "Proposed Objective: Use computerized provider order entry (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. "Note for reference: We propose to continue to define CPOE as the provider's use of computer assistance to directly enter clinical 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." **ACLA Comment:** ACLA agrees with inclusion of diagnostic imaging for a broader definition.
16752 16753	"The Stage 1 and Stage 2 final rules included a number of objectives focused on increasing patient access to *health information* and supporting provider and patient communication." (*emphasis added*) "Proposed Objective: The EP, eligible hospital, 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." (*emphasis added*) **ACLA Comment:** ACLA requests a clarification of the definition and boundaries of "health information". The definition of what type of "health information" patients will have access to should be included in the rule, specifically defining access to laboratory and diagnostic imaging results. Additionally, the proposal for availability of lab test results to patients within 24hrs of the result's availability could impact the clinical care for the patient if results are seen by the patient prior to the provider's availability to review them, especially during non-business days and for abnormal results. ACLA urges CMS to include consideration of scenarios where consultation with the provider on the results of laboratory tests is critical to interpreting the results and guaranteeing the welfare and best outcomes for the patient.
16752	**FR Section or Text:** "Proposed Measure 2: To calculate the percentage, CMS and ONC have worked together to define the following for this measure: *"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.

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	"Numerator: The number of orders in the denominator recorded using CPOE. *"Threshold:* The resulting percentage must be more than 60 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." **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? Additionally, could a laboratory panel or profile test be 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
16758 16759 16760	**FR Section or Text:** "Objective 7: Health Information Exchange "… *"…summary of care* documents… *"…* Laboratory test results." **ACLA Comment:** ACLA encourages CMS to retain a requirement for laboratory result reporting using the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Draft Standard for Trial Use, Release 2, US Realm ("LRI Release 2"), referenced in the ONC 2015 Edition proposed rule [§ 170.315(b)(5) *Transmission of laboratory test reports*], for all patients. While the LRI Release 1 Implementation Guide was required for EHR Certification under Meaningful Use Stage 2, several certified EHR system vendors have already requested laboratories to deviate from the LRI Release 1 requirements, which requires a customized interface. This defeats the cost saving goals of Meaningful Use by increasing costs for customized interfaces. Further, LRI Release 2 cited in the ONC 2015 edition has been harmonized with other S&I Framework Laboratory Implementation Guides to create a full suite of laboratory – EHR interoperability specifications. Laboratory test results are required for the EHR System's Summary of Care Record in MU3 Objective 7, therefore maintaining a consistent information exchange requirement for the laboratory result sent from the laboratory to the EHR system, which becomes the source of the Summary of Care Record laboratory test result, is necessary.

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16762-16764	**FR Section or Text:** "Objective 8: Public Health and "Clinical Data Registry Reporting "… "Proposed Measures: We are proposing a total of six possible measures for this objective. EPs would be required to choose from measures 1 through 5, and would be required to successfully attest to any combination of three measures. Eligible hospitals and CAHs would be required to choose from measures one through six, and would be required to successfully attest to any combination of four measures. The measures are as shown in Table 5. 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. …

TABLE 5—MEASURES FOR OBJECTIVE 8: PUBLIC HEALTH AND CLINICAL DATA REGISTRY REPORTING OBJECTIVE

Measure	Maximum times measure can count towards objective for EP	Maximum times measure can count towards objective for eligible hospital or CAH
Measure 1—Immunization Registry Reporting	1	1
Measure 2—Syndromic Surveillance Reporting	1	1
Measure 3—Case Reporting	1	1
Measure 4—Public Health Registry Reporting*	3	4
Measure 5—Clinical Data Registry Reporting**	3	4
Measure 6—Electronic Reportable Laboratory Results	N/A	1

* EPs, eligible hospitals, and CAHs may choose to report to more than one public health registry to meet the number of measures required to meet the objective.
** EPs, eligible hospitals, and CAHs may choose to report to more than one clinical data registry to meet the number of measures required to meet the objective.

16766	"Measure 6—Electronic Reportable Laboratory Result Reporting: The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results. This measure is available to eligible hospitals and CAHs only. Electronic reportable laboratory result reporting to PHAs is required for eligible hospitals and CAHs in Stage 2 (77 FR 54021). We propose to retain this measure for Stage 3 to promote the exchange of laboratory results between eligible hospitals/CAHs and PHAs for improved timeliness, reduction of manual data entry errors, and more complete information. *Exclusion for Measure 6:* Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure if the eligible hospital 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 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 eligible hospital or CAH at the start of the EHR reporting period." **ACLA Comment:** ACLA suggests citing the later version of the electronic lab reporting 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.

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16766	**FR Section or Text:** "We support ONC's intent to promote standardized and interoperable exchange of public health data across the country. Therefore, to meet all of the measures within this public health objective EPs, eligible hospitals, and CAHs must use CEHRT as we propose to define it under § 495.4 in this proposed rule and use the standards included in the 2015 Edition proposed rule published elsewhere in this edition of the **Federal Register**. We anticipate that as new public health registries and clinical data registries are created, ONC and CMS will work with the public health community and clinical specialty societies to develop ONC-certified electronic reporting standards for those registries so that providers have the option to count participation in those registries under the measures of this objective. ONC will look to adopt such standards, as appropriate, in future rules published by ONC. We welcome public comment on these proposals." **ACLA Comment:** ACLA supports collaboration between CMS, CDC, and ONC to promote standardized and interoperable exchange of public health data nationally, versus state specific requirements whenever possible.
16767	**FR Section or Text:** "II. Provisions of the Proposed Regulations *"A. Meaningful Use Requirements, Objectives and Measures* "2. Certified EHR Technology (CEHRT) Requirements Certified EHR technology is defined for the Medicare and Medicaid EHR Incentive Programs at 42 CFR 495.4, which references ONC's definition of CEHRT under 45 CFR 170.102. The definition establishes the requirements for EHR technology that must be used by providers to meet the meaningful use objectives and measures. "… "Under the proposed new approach, we would establish through rulemaking for the EHR Incentive Programs (either with stand-alone rulemaking or through other vehicles such as the annual Medicare payment rules) the compliance dates by which providers must use EHR technology certified to a particular edition of certification criteria to meet the CEHRT definition, which would be reflected in our regulations under 42 CFR part 495 rather than ONC's regulations under 45 CFR part 170." **ACLA Comment:** ACLA strongly supports the statement by CMS that CEHRT is expected to use the technology they were certified for.
16772	**FR Section or Text:** "6. Electronic Reporting of CQMs As previously stated in the Medicare and Medicaid EHR Incentive Programs "Stage 2 final rule (77 FR 54051 through 54053), CQM data submitted by EPs, eligible hospitals, and CAHs are required to be captured, calculated and reported using certified EHR technology. We received numerous questions from stakeholders expressing confusion over what it means to capture data in certified EHR technology. Specifically, stakeholders question whether they may manually abstract data into the EHR from a patient's chart.

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	"We do not consider the manual abstraction of data from the EHR to be capturing the data using certified EHR technology. We believe that electronic information interfaced or electronically transmitted from non-certified EHR technology, such as lab information systems, automated blood pressure cuffs, and electronic scales, into the certified EHR, would satisfy the ''capture'' requirement, as long as that data is visible to providers in the EHR." **ACLA Comment:** The laboratory industry (i.e. "lab information systems") is inspected every two years to validate that a laboratory's systems and processes meet the requirements of the Clinical Laboratory Improvement Amendments (CLIA). A CLIA inspection is an unannounced inspection, so the laboratory must be inspection ready at all times. CMS has deemed the College of American Pathologists (CAP) as an appropriate third party inspector for this CLIA Certification process and CAP includes an inspection of the procedures that a laboratory follows to validate that electronic interfaces between the Lab system and the system used by the physician and/or the hospital. Necessary procedures include periodic follow-up review of these interfaces that is more precisely defined by the CAP Lab Accreditation (a more in-depth certification) by stating it should be accomplished every two years. With this level of inspection already in place, we concur with CMS's statement that "…electronic information interfaced or electronically transmitted from non-certified EHR technology, such as lab information systems into the certified EHR, would satisfy the ''capture'' requirement…" ACLA suggests that CLIA needs to be expanded to support electronic formats and encourage CMS to work with CAP, ONC and other accrediting agencies to appropriately address overlapping certification requirements.
16795 16796	**FR Section or Text:** "PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM **…** "A. Adding the definition for ""*Application-program interface (API)*". "… "§ 495.4 Definitions. "* * * * * *"Application-program interface (API)* means a set of programming protocols Established for multiple purposes. APIs may be enabled by a provider or provider organization to provide the patient with access to their health information through a third-party application with more flexibility than often found in many current ''patient portals.''" **ACLA Comment:** ACLA supports API's predefined by standards. For the laboratory industry ACLA, HL7 or the S&I Framework should be involved as developers for API standards for lab results, orders, etc.

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16788 16789	FYI / Typo: **ACLA Comment:** Page 16788 has "b. Regulatory Flexibility Analysis and Small Entities". Under that on page 16789 section "b" has sub sections (1) and (2). Following subsection "b. Small Rural Hospitals" should be "c. Small Rural Hospitals", and so forth: ("c. unfounded mandates" becomes "d. unfounded mandates) and ("d. Federalism" becomes "e. Federalism")
16762 to 16763	**FR Section or Text:** "Objective 8: Public Health and Clinical Data Registry Reporting […] "Cancer registries" **ACLA Comment:** ACLA laboratories follow the Standards for cancer data reporting as provided by NAACCR (North American Association of Central Cancer Registries (www.naaccr.org)). CDC supports laboratories efforts to conform to the *NAACCR HL7 E-Path Version 2.3.1 Specification and Implementation Guide*. Laboratories can include the required LOINC and SNOMED codes in the current HL7 format. ACLA suggests CMS/ONC publish mappings from the currently used NAACCR format to any new cited standards, e.g. the proposed rule referenced Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), Release 1.0 and Implementation specifications. HL7 Implementation Guide for CDA © Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1. This approach may enable EHR Systems to support the proposed new standards using existing NAACCR formatted messages from laboratories.