



American
Clinical Laboratory
Association

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The Honorable Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, DC 20201

Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program Proposed Rule (CMS-0033-P)

Dear Ms. Frizzera:

The American Clinical Laboratory Association ("ACLA") is pleased to have this opportunity to submit our comments on the *Medicare and Medicaid Programs; Electronic Health Record Incentive Program (the "Proposed Rule")*.¹ ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As the primary providers of clinical laboratory services throughout the country, our members commend the Centers for Medicare & Medicaid Services ("CMS") on its efforts to propose parameters for the electronic health record ("EHR") Incentive Programs in accordance with the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"), enacted as part of the American Recovery and Reinvestment Act of 2009 ("ARRA").²

ACLA's member companies provide laboratory testing for a countless number of the nation's physicians and hospitals for their Medicare and Medicaid beneficiaries. As such, laboratories interact with physicians and hospitals on a daily basis with respect to the electronic transmission of laboratory test results and orders. Therefore, although clinical laboratories are not eligible for incentive funds under the EHR Incentive Programs, laboratory information will be an integral component of a certified EHR. As an association of clinical laboratories that provides laboratory services to eligible professionals ("EPs") and eligible hospitals, we want to assist these eligible providers in satisfying the proposed meaningful use criteria. Accordingly, to the extent that the Proposed Rule sets forth meaningful use measures that specifically address laboratory orders and results, we would like to take this opportunity to comment on those measures.

¹ 75 Fed. Reg. 1844 (Jan. 13, 2010).

² For purposes of our comments, any reference to "EHRs" or "EHR technology" includes both Complete EHRs and EHR Modules, as defined in the Office of the National Coordinator's ("ONC's") *Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Interim Final Rule*, unless otherwise specified. See 75 Fed. Reg. 2014 (Jan. 13, 2010).

I. Comments on the Proposed Rule

As discussed above, we applaud CMS' efforts to implement the EHR Incentive Program. Our comments below are limited to the following meaningful use measures: (1) use of computerized physician order entry ("CPOE") and other clinical decision support tools; and (2) the incorporation of laboratory test results into the certified EHR as structured data.

A. Use of CPOE and Clinical Decision Support

As part the HITECH Act's graduated approach to the adoption of certified EHRs, CMS proposes the use of clinical decision support tools as part of Stage 1 of the meaningful use definition. Specifically, CMS proposes the use of CPOE and the implementation of clinical decision support rules.³ As we discuss in our comments on the Office of the National Coordinator's ("ONC's") Interim Final Rule, we believe that CPOE and clinical decision support should be required components of any EHR technology. The benefits to the use of clinical decision support are several. Namely, CPOE and other clinical decision support tools are able to decrease delay in order completion, reduce errors related to handwriting or transcription, allow order entry at point-of-care or off-site, provide error-checking for duplicate or incorrect doses or tests, and simplify inventory and posting of charges. Most importantly, with respect to laboratory testing, these tools allow providers to make more informed patient care decisions with respect to ordering medically necessary testing when prompted by these technologies. Ultimately, these technologies provide the ability to properly diagnose patients based on more timely laboratory testing, which results in better disease and medication management for the patient.

As such, ACLA strongly supports the use of CPOE and clinical decision support as meaningful use criteria. We urge CMS to maintain these criteria as part of its final rule for Stage 1 of the meaningful use definition.

B. Incorporation of Laboratory Test Results

CMS proposes that laboratory test results be incorporated into EHR as structured data.⁴ According to the Proposed Rule, structured data are data that have a specified data type and response categories within an electronic record or file. The measure for this criterion would require that at least 50 percent of all clinical laboratory test results ordered whose results are in a positive/negative or numerical format are incorporated in certified EHR technology as structured data.⁵

While ACLA supports the incorporation of laboratory test results into EHRs, it is unclear how the 50 percent threshold should be measured with respect to the numerator and denominator. For example, laboratories offer automated chemistry test panels ordered with a single order code, but which provide multiple numeric results (typically from two to over twenty). Does the measure

³ 75 *Fed. Reg.* at 1854-1855.

⁴ *Id.* at 1855.

⁵ *Id.* at 1862.

track one test order or, by way of illustration, 20 test results? As such, we ask that CMS provide clarity with respect to calculating this measure.

Additionally, it is unclear as to why the 50 percent threshold was selected as a threshold to demonstrate meaningful use. At best, it seems to have been chosen arbitrarily without regard to the way in which laboratory tests are, in fact, reported to the EP or eligible hospital. It is worth noting that many laboratory tests, such as anatomic pathology testing and microbiology testing are not reported as positive/negative or in numerical format. Rather, these tests are typically reported in narrative form.

II. Conclusion

In closing, we appreciate the opportunity to submit our comments on the Proposed Rule. If you have any questions or need any further information, please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink that reads "Alan Mertz". The signature is written in a cursive style with a large, stylized 'M'.

Alan Mertz