June 27, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-5517-P
P.O. Box 8013
Baltimore, MD 21244-8013

DELIVERED ELECTRONICALLY

RE: Proposed Rule on Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (CMS-5517-P, RIN 0938-AS69)

Dear Administrator Slavitt:

I am submitting the attached comments on behalf of the American Clinical Laboratory Association (ACLA) in response to the April 25, 2016 proposed rule on Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (CMS-5517-P, RIN 0938-AS69). The scope of these comments is limited to issues in the Proposed Rule impacting use of electronic health records, interoperability and other health information technology issues as encountered and as viewed by clinical laboratories.

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 member laboratories appreciate the opportunity to comment on the proposed rule and would welcome working with CMS further on these initiatives.

Sincerely,

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

ATTACHMENT

ATTACHMENT: Comments of the American Clinical Laboratory Association (ACLA)

Reference: 42 CFR Parts 414 and 495
AGENCY: CMS-5517-P
RIN 0938-AS69
ACTION: Proposed rule. Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models
RELEASED: May 9, 2016
COMMENTS DUE: June 27, 2016
Submit comments electronically to http://www.regulations.gov. Follow the ''Submit a comment'' instructions.

Below are ACLA's comments on the proposed rule:

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Third, we are focused on making data more available and enabling the use of delivery. Consistent use of certified EHR technology and clinical quality measurement in managing patient populations would help lead to substantial improvements in our health care system, by allowing clinicians to track and take care of their patients throughout the care continuum and to easily and securely access electronic health information to support care when and where it is needed. … To aid in this process, we have sought feedback from the health care community through various public avenues and will seek comment through this proposed rule.
Comment: We suggest CMS formally seek input from the laboratory industry in the future, either directly, or through laboratory associations such as the American Clinical Laboratory Association (ACLA). More than 70% of medical decisions made by physicians are based on laboratory findings[1], yet labs are often not consulted regarding critical interoperability decisions. For example, CMS removed laboratory results as a Meaningful Use (MU) measure before the Lab Result Interface (LRI) interoperability standard ONC named for Meaningful Use Certification could be fully deployed. Laboratories invested significant resources developing this interface to help EHR vendors achieve MU certification but few vendors actually deployed this interface, even though they may have certified a product. Additionally, CMS's FAQ also gave vendors an 'out' stating the LRI IG named by ONC did not have to be used to meet the MU measure. (Available online: **https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/Stage2_EPCore_10_ClinicalLabTestResults.pdf**) Moving to a single laboratory result interface format nationally could have achieved monumental health care cost savings, but this is now a lost opportunity since vendors are no longer interested in implementing an LRI interface because structured lab results are considered 'topped out' as referenced Table 2-OBJECTIVES AND MEASURES IDENTIFIED BY PROVIDER TYPE THAT ARE REDUNDANT, DUPLICATIVE, OR TOPPED OUT in the *Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017* final rule.

[1] *American Society for Clinical Pathology (ASCP) Careers in Pathology and Medical Laboratory Science*, page 3.

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With respect to the use of certified EHR technology under the Medicare and Medicaid EHR Incentive Programs and the MIPS Program, effective surveillance and oversight is fundamental to providing basic confidence that such technology consistently meets applicable standards implementation specifications, and certification criteria adopted by the Secretary when it is used by eligible clinicians, EPs, eligible hospitals, and CAHs, as well as by other persons with whom eligible clinicians, EPs, eligible hospitals, and CAHs need to exchange electronic health information to comply with program requirements. The need to ensure that technology consistently meets applicable standards, implementation specifications, and certification criteria is important both at the time it is certified and on an ongoing basis when it is implemented and used in the field by eligible clinicians, EPs, eligible hospitals, and CAHs in order to meet objectives and measures under the Medicare and Medicaid EHR Incentive Program or MIPS.

Comment: There are problems with this approach now. Under Meaningful Use (MU) EHR systems are required to certify to a specific implementation guide to meet ONC certification requirements, for example, HL7 VERSION 2.5.1 IMPLEMENTATION GUIDE: S&I FRAMEWORK LAB RESULTS INTERFACE (LRI), RELEASE 1 – US REALM for laboratory results. Some EHR systems were certified, but the vendor did not implement the certified interface into production in the provider's EHR systems.

We request that "certified" systems be used in production and if not, provide a venue to report the deviation with or without anonymity.

Laboratories invested in significant development cost to upgrade laboratory systems to provide data to provider's EHR systems to meet certification requirement, in hopes of eventually achieving return on investment (ROI)/ cost savings by implementing a single interface, the LRI, with multiple vendors, vs. an expensive customized interface with each provider. Additionally, the migration of the provider base to the new interface and re-certification for CLIA, which is required every two years, is also a considerable cost to the laboratories.

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Efforts to strengthen surveillance and oversight of certified EHR technology in the field will become even more important as the types and capabilities of certified EHR technology continue to evolve and with the onset of Stage 3 of the Medicare and Medicaid EHR Incentive Programs and MIPS, which include heightened requirements for sharing electronic health information with other providers and with patients using a broad range of certified EHR technology and other health IT.

Comment:

Please clarify what happens after Meaningful Use Stage 3; how will the standards required for certified EHR technology be selected? For example, what is the relationship to standards named in the ONC Interoperability Standards Advisory (ISA)? Will ISA named standards be the basis for certification in the future?

We request CMS be more clear on how all entities; Eligible Professionals, Hospitals and Critical Access Hospitals (CAHs); using Medicare and Medicaid will align for certification as the current ruling is confusing.

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In addition, we note that ONC has clarified, in consultation with the Office for Civil Rights, that ONC–ACBs engaging in authorized surveillance of certified EHR technology under the ONC Health IT Certification Program meet the definition of a ''health oversight agency'' in the HIPAA Privacy Rule (45 CFR 164.501), and as such a health care provider is permitted to disclose protected health information (PHI) (without patient authorization and without a business associate agreement) to an ONC–ACB during the limited time and as necessary for the ONC–ACB to perform the required on-site surveillance of the certified HER technology (45 CFR 164.512(d)(1)(iii)) (80 FR 62716).[4]

Comment:

As patient engagement becomes more prevalent, we have concerns about the patient privacy with this measure.

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We believe that, at a minimum, such a demonstration would need to provide substantial assurance not only that the certified EHR technology was connected in accordance with applicable standards during the relevant EHR reporting period, but that the eligible clinician, EP, eligible hospital, or CAH acted in good faith to implement and use the certified EHR technology in a manner that supported and did not interfere with the electronic exchange of health information among health care providers and with patients to improve quality and promote care coordination. Accordingly, we are proposing that such a demonstration be made through an attestation comprising three statements related to health information exchange and information blocking, which are set forth in our proposal in this rule. We are proposing to revise the definition of a meaningful EHR user at § 495.4 and the attestation requirements at § 495.40(a)(2)(i)(I) and § 495.40(b)(2)(i)(I) to provide that, for attestations submitted on or after April 16, 2016, an EP, eligible hospital, or CAH under the Medicare and Medicaid EHR Incentive Programs must attest to this three-part attestation.

Comment:

A provider may not realize their vendor did not implement the certified laboratory result interface using CERHT that allowed their EHR product to attain certification. A good faith attestation will not resolve this issue.

Page 28172 – Second attestation statement

Second, the eligible clinician, EP, eligible hospital, or CAH would be required to attest that it implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times: connected in accordance with applicable law; compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170; implemented in a manner that allowed for timely access by patients to their electronic health information; (including the ability to view, download, and transmit this information) and implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate certified EHR technology and vendors

Comment:

Based on our experience with MU interfaces thus far, we are concerned that EC, EP, EH, and CAH may not know if their EHR system is not running a standard adopted at 45 CRF 170. Therefore, we suggest there be a methodology for trading partners, such as the laboratory, to report EHR systems deviating from required standards with or without anonymity.

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Prior to these amendments, to be treated as a meaningful EHR user, an EP, eligible hospital, or CAH had to demonstrate to the satisfaction of the Secretary that its certified EHR technology was connected during the relevant EHR reporting period in a manner that provided, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.

Comment:

"…that certified EHR technology was connected…"

Excerpt from: Eligible Professional Meaningful Use Core Measures Measure 10 of 17, Stage 2 , Date issued: November, 2014 EPCore_10_ClinicalLabTestResults. (Available online: **https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/Stage2_EPCore_10_ClinicalLabTestResults.pdf**)

Although the following standard was named: HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, (incorporated by reference in § 170.299), CMS stated: "Structured data does not need to be electronically exchanged in order to qualify for the measure of this objective. The EP is not limited to only counting structured data received via electronic exchange, but may count in the numerator all structured data entered through manual entry through typing, option selecting, scanning, or other means."

This was interpreted by some vendors to mean they were not required to use the named standard to achieve the MU measure.

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… We have also learned that updating software, training staff and changing practice workflows to accommodate new technology can take time, and that clinicians need time and flexibility to focus on the health IT activities that are most relevant to their patient population.

Comment:

This statement re: updating and deploying software/new technology also applies to laboratories required to upgrade their systems to meet EHR system's interoperability requirements. We request the similar flexibility in scheduling, with enough time to implement required changes and obtain CLIA certification before their effective date.

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(2) Advancing Care Information Performance Category Within MIPS

…We propose to emphasize performance in the objectives and measures that are the most critical and would lead to the most improvement in the use of health IT and health care quality….

Comment:

We request that CMS reconsider future objectives addressing the entire suite of laboratories interoperability standards, and deploy them in an organized, workflow perspective, working in conjunction with ONC and Laboratory Industry to recognize/name the appropriate standards and incorporate the lab workflow perspective.

We believe this approach supports CMS's goal to "…improve the use of health IT to achieve better patient outcomes, and continue to meet the vision of enhancing the use of certified EHR technology as defined under the HITECH Act."

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We anticipate that as certified health IT and related standards continue to evolve to support health information exchange, care coordination (for example, referral management), and other capabilities, we will consider updates to the certified health IT requirements for MIPS. We continue to work with the Office of the National Coordinator for Health IT to identify certified health IT that would aid clinicians in MIPS.

Comment:

Please clarify how CMS/ONC will determine the standards required for certified EHR technology in the future.

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Throughout this proposed rule, we use the terms ''certified health IT'' and ''certified EHR technology''. These terms refer to health information technologies and systems that are certified to various standards and functions under the ONC Health IT Certification Program. In general, the full range of potential technologies, functions, standards, and systems for which ONC has established certification criteria are referred to as ''certified health IT'' (See the 2015 Edition Health IT Certification Criteria final rule (80 FR 62604)). In contrast, the term ''certified EHR technology'' is a statutory and regulatory term that defines the technology that MIPS eligible clinicians and participants in Advanced APMs must use.
It is important to note that certified EHR technology is a part of the larger category of certified health IT. Therefore when discussing certified health IT in a broad and general manner; such a discussion includes both the functions included in certified EHR technology
and other additional potential functions and criteria. In other words, certified EHR technology is a subset of the broader definition of certified health IT.
''Certified health IT'' is used in two different ways within this proposed rule. The first is stated as ''certified health IT'' to identify where the text is referencing a broad range of technology that is included in the ONC Health IT Certification Program. The second use is where the term ''a certified Health IT Module'' identifies a technology or function used independently from the clinicians' EHR. An example of this second use of the term includes the certified functions leveraged by Health Information Exchange organizations, QCDRs, and public health agencies to support actions like information exchange, quality measurement, and data submission. These individual functions may also be a part of the certified EHR technology definition and may connect with the EHR, but are in these cases used independently from the clinicians' EHR systems.

Comment:

Please clarify the term "for which ONC has established certification criteria"? For example, does this mean existence of an implementation guide with conformance criteria, ONC certification plan, build out of NIST (or other) validation tool, etc. Multiple ways of certified health IT can be potentially confusing.

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In this proposed rule, we are proposing to adopt a definition of certified EHR technology at § 414.1305 for MIPS eligible clinicians that is based on the definition that applies in the EHR Incentive Programs under 42 CFR 495.4.

Comment:

We commend CMS approach to leverage work that has already accomplished or in process through the Meaningful Use ONC certification program.

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(7) Advancing Care Information Performance Category Objectives and Measures Specifications
(a) MIPS Objectives and Measures Specifications

Laboratory Orders Measure: At least one laboratory order created by the MIPS eligible clinician during the performance period is recorded using CPOE.
- Denominator: Number of laboratory orders created by the MIPS eligible clinician during the performance period.
- Numerator: The number of orders in the denominator recorded using CPOE.

Comment:

CPOE only requires the provider enter the order into the EHR and not the transmission of the order to the laboratory. We suggest that CMS consider changing the rule to require the transmission of laboratory orders to external labs and that ONC name a standard for this exchange.

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(b) Modified Stage 2 Advancing Care Information Objectives and Measures Specifications for MIPS

Laboratory Orders Measure: At least one laboratory order created by the MIPS eligible clinician during the performance period is recorded using CPOE.

- Denominator: Number of laboratory orders created by the MIPS eligible clinician during the performance period.
- Numerator: The number of orders in the denominator recorded using CPOE.

Comment:

CPOE only requires the provider enter the order into the EHR and not the transmission of the order to the laboratory. We suggest that CMS consider changing the rule to require the transmission of laboratory orders to external labs and that ONC name a standard for this exchange.

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We seek comment on the proposed definition of CEHRT for Advanced APMs and Other Payer Advanced APMs and whether the definition should be the same for both.

Comment:

We agree that there should be a single definition for CEHRT across all programs.

Page 28301

We seek comment on how requirements for the use of CEHRT within APMs could evolve to support expanded participation in organizations supporting HIEs. For instance, should CMS consider expanding in future rulemaking the CEHRT criterion for Advanced APMs to include recognition of participation with an organization providing HIE services? Would this option be likely to spur further interest among entities in partnering with organizations that provide HIE services? Should these organizations be required to adhere to specific standards that promote interoperability across health information systems? How could a potential future governance mechanism for HIE (that is, establishing a common set of standards, services, policies, and practices) be incorporated into requirements for APMs? We seek comment on these and any other issues related to advancing participation in HIEs though the use of CEHRT in APMs.

Comment:

Yes, we believe HIEs should adhere to current CEHRT standards.

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We seek comment on the proposed definition of CEHRT for Advanced APMs and Other Payer Advanced APMs and whether they should be the same for both. We seek comment on the proposed method for Other Payer APMs to meet the CEHRT use criterion.

Comment:

We agree that there should be a single definition for CEHRT across all programs.