May 4, 2012

American Clinical Laboratory Association

Ms. Marilyn Tavenner, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-0044-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

RE: RIN 0938-AQ84: Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2

Dear Ms. Tavenner:

The American Clinical Laboratory Association ("ACLA") appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS's") Proposed Rule, "Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2" ("Proposed Rule").[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of millions of clinical diagnostic laboratory services for Medicare beneficiaries and Medicaid recipients each year, ACLA member companies will be impacted directly by the Proposed Rule.

I. Summary of ACLA's Comments

ACLA urges CMS to ensure that the final regulations it promulgates for the Electronic Health Record Incentive Program for Stage 2 are consistent with other regulations, such as those issued by the Office of the National Coordinator for Health Information Technology ("ONC") for electronic health record ("EHR") certification, regulations that implement the Clinical Laboratory Improvement Amendments ("CLIA"), and Medicare claims review requirements. Also, CMS must give careful consideration to how pathologists differ from other physicians in their day-to-day practices and use its authority to exempt pathologists from payment adjustments currently scheduled to begin in 2015. Finally, we urge CMS to amend certain proposed objectives and associated measures to clarify which onces do and do not pertain to laboratories and laboratory information systems (which may capture and store some of the same information as EHRs).

II. Substantive Comments

A. CMS must be mindful of the programming burdens laboratories already face.

CMS, along with other agencies, must be mindful of the myriad regulatory initiatives being implemented within a very short two-to-three year window and the programming burdens faced by laboratories and other health care providers. In addition to the "meaningful use" requirements embodied in this Proposed Rule, providers are facing the conversion to ICD-10 diagnosis codes in 2014 and the Version 5010 standard for electronic health care transactions, among other major

[1] Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2, 77 Fed. Reg. 13,698 (Mar. 7, 2012).

changes. Each of these initiatives requires a tremendous resource commitment to design a compliant program, test it, possibly redesign the system, implement it across an enterprise, and conduct training on how to use it properly. It would be helpful for CMS to work with other entities issuing mandates and deadlines that require significant programming overhauls and re-trainings to prioritize the changes and to stagger them such that providers can manage the cascade of requirements. Doing so would allow all providers to implement the directives more efficiently and effectively and to obtain the intended objectives.

B. CMS and the Office of the National Coordinator must align their rules on "Meaningful Use Stage 2" and "EHR Standards and Certification Criteria" and they must be consistent with other regulatory requirements.

We urge CMS and ONC to coordinate closely as each promulgates final rules on the EHR Incentive Program for Stage 2 and the EHR Certification Criteria, 2014 Edition. (ACLA has submitted comments on the ONC's proposed rule separately.) ONC has made efforts to align its certification criteria with the Stage 2 meaningful use objectives, which is encouraging, but it also raises the possibility of unintended inconsistencies between the two rules, based on comments each agency receives and responds to. We hope that, prior to release of the final rules, the agencies thoroughly review the final rules and identify and address both inconsistencies in the rules and any ambiguities that are likely to be confusing to stakeholders. Additionally, the final rules must be consistent with other regulatory requirements, such as CLIA and implementing regulations.

C. Pathologists should be exempt from meaningful use payment adjustments.

ACLA believes strongly that pathologists should be exempt from payment adjustments for failure to meet meaningful use requirements and that such an exemption should be as broad as possible. ACLA publicly supports legislation currently before Congress, the Health Information Technology Reform Act, which would exclude pathologists from payment adjustments and incentives under the EHR Incentive Program, and we urge CMS to support the legislation, as well.[2] However, in the event that the legislation is not passed into law, ACLA urges CMS to accomplish through regulation what the legislation would accomplish in statute.

Section 1848(a)(7)(B) of the Social Security Act permits the Secretary of Health and Human Services ("the Secretary") to exempt from meaningful use payment adjustments an eligible professional ("EP"), on a case-by-case basis, if the Secretary determines that compliance with the requirements for being a meaningful EHR user would result in a significant hardship.[3] CMS is soliciting comments on the appropriateness of granting exceptions for EPs who lack face-to-face interaction with patients, lack follow-up with patients, and lack control over the availability of Certified EHR Technology at a practice location.[4] It also seeks comment on the timeframe such an exception should cover and whether such exceptions "should apply to individual EPs or across-the-board based on specialty or other groupings that generally meet the appropriate criteria."[5]

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[2] H.R. 4066, 112th Cong. (2012), *available at*: http://thomas.loc.gov/cgi-bin/query/z?c112:H.R.4066:.
[3] 42 U.S.C. § 1395w-4(a)(7)(B).
[4] 77 Fed. Reg. 13,770.
[5] *Id*. at 13,771.

Pathologists should not be penalized for failure to meet objectives that, because of the nature of the practice of pathology, are virtually impossible for them to meet. It would be especially unjust for pathologists to be subject to a payment adjustment when pathologists would not seek or qualify for incentives through the EHR Incentive Program. Meaningful use standards are inapplicable to the practice of pathology for a number of reasons. As CMS noted in the Proposed Rule's preamble, pathologists generally do not have face-to-face or consultative interaction with patients whose specimens they test, and instead they typically submit reports to other physicians who review the results with patients.[6] Similarly, a pathologist rarely has follow-up with a patient after a physician reviews results with the patient. Finally, pathologists generally do not have control over the availability of CEHRT at a practice location because pathologists are utilized as "referral physicians" and in many instances operate from an entirely separate facility. Since they operate independently, they do not make decisions regarding the availability of CEHRT.

Pathologists' medical records already are generated, transmitted, received, and stored in integrated laboratory information systems. Transitioning to another, less efficient records system just to avoid meaningful use payment adjustments would be wasteful and counterproductive.

ACLA urges CMS to exempt pathologists for as long as possible from payment adjustments. CMS states in the preamble that it is considering providing a time-limited two year payment adjustment exception for EPs who meet the above criteria, which would allow it to consider the exemption in future rulemaking on the EHR Incentive Program. An alternative, it says, is to provide such an exception with no specific time limit, although it notes that "by statute, no individual EP can receive an exception for more than five years."[7] CMS should adopt a five year exemption for pathologists since the practice of pathology is not likely to change significantly any time soon, and this may provide enough time for a legislative solution to amend the statutory definition of "eligible professional" to exclude pathologists, or to eliminate the exception's time limit.

D. The Computerized Provider Order Entry objective should be consistent with current Medicare claims review requirements for written orders.

At the outset, we wish to reiterate our strong support for the use of CPOE as meaningful use criterion, as CPOE decreases delay in order completion, reduces errors resulting from transcription, and allows order entry at point-of-care or off-site. However, ACLA is concerned that the proposed objective for Computerized Provider Order Entry ("CPOE"), which CMS intends to extend to laboratory orders for Stage 2, may be inconsistent in some respects with current Medicare claims review requirements for laboratory orders.

CMS proposes this objective, carried over from the meaningful use Stage 1 objectives: "Use [CPOE] 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 to create the first record of the order."[8] Laboratory and radiology orders were not included in the Stage 1 objective. CMS says that the CPOE function must be used "to create the

[6] *Id*.
[7] *Id*.
[8] *Id*. at 13,708.

first record of any type for the order" and that "[I]n a practice, this means the originating provider (the provider whose judgment creates the order) must personally use the CPOE function, verbally communicate the order to someone else who will use the CPOE function, or give an electronic or written order that must not be retained in any way once the CPOE function has been utilized."[9] CMS also says that "each provider must make the decision of whether a record of an order is part of the patient's medical record."[10]

CMS continues, saying "This is a meaningful use requirement and does not affect any other legal or regulatory requirements as to what constitutes a patient's health record or order,"[11] but ACLA is concerned about the practical realities of how this objective may intersect with claims reviews for laboratory orders and with signature requirements. We want to be certain that CPOE modules used to create laboratory orders are capable of showing that a particular physician ordered a lab test and that the modules contain enough information to satisfy claims reviewers. Current Medicare claims review regulations require the entity submitting a claim for laboratory services to be able to produce "documentation of the order for the service billed (including information sufficient to enable CMS to identify and contact the ordering physician or nonphysician practitioner)."[12] If a laboratory cannot produce such documentation, CMS will ask the ordering physician or non-physician practitioner to identify the order, or it will request the part of the beneficiary's medical record relevant to the claim, and it may deny the claim without sufficient documentation. However, CMS states that it is up to the ordering provider whether a record of a laboratory order is part of the beneficiary's medical record, and furthermore, if the physician communicates the order to someone else who uses the CPOE function, such an electronic or written order "must not be retained in any way once the CPOE function has been utilized."[13] This may leave laboratories in the position of having claims denied for laboratory services ordered using CPOE if orders are not entered personally by the physician and/or medical records have been purged of other information about the order.

ACLA encourages CMS to ensure there is consistency between this CPOE objective and other Medicare requirements designed to demonstrate that a particular physician ordered a particular lab service.

E. The lab results objective may be too aggressive and raises some questions.

CMS proposes to move from the Stage 1 menu objective set to the Stage 2 core objective set the objective that clinical laboratory test results are incorporated into CEHRT as structured data.[14] It also proposes to increase the threshold to "more than 55 percent" from "more than 40 percent" in Stage 1. CMS acknowledges that the HIT Policy Committee did not recommend an increase in the threshold for this measure, but it says its "initial data on Stage 1 of meaningful use shows high compliance with this measure for those providers individually selecting the objective from the menu

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[9] *Id*. at 13,709.
[10] 77 Fed. Reg. 13,709.
[11] *Id*.
[12] 42 C.F.R. § 410.32(d)(3)(i).
[13] 77 Fed. Reg. at 13,709.
[14] *Id*. at 13,717.

set."[15] CMS fails to consider that providers who successfully reported on this measure in Stage 1 may have been a self-selecting group of those who could meet the objective easily and that simultaneously moving this objective to the core set and raising the threshold may be too aggressive for most providers. ACLA recommends that CMS either move this objective to the core set without raising the threshold amount, or leave the objective in the menu set and raise the threshold amount, but not both.

The proposed denominator for the measure could be problematic for some laboratory tests. CMS proposes that the denominator should be the "number of lab tests ordered during the EHR reporting period…whose results are expressed in a positive or negative affirmation or as a number."[16] Some tests are organ- or disease-related panels ordered together and whose results are returned together. Also, laboratories oftentimes offer automated chemistry test panels ordered with a single order code but that provide multiple numeric results. It is unclear how tests ordered and returned in panels can be distinguished from individual tests whose results are returned as a positive or negative affirmation or as a number, for purposes of determining the denominator. Additionally, ACLA would like to confirm that pathology results, which may have a numerical component, would not be included in this denominator.

F. The summary of care objective should not apply to laboratories.

ACLA seeks to confirm that the summary of care objective would not apply to laboratories.[17] This proposed objective, moved from the menu objective set to the core objective set, would require that an "EP who…refers [a] patient to another provider of care provides a summary of care record for each…referral." Based on purpose of the summary of care record and on the fields required to be included in the summary of care record, we do not believe that CMS intended to include referrals to laboratories for testing, and we ask CMS to confirm that this is the case.[18]

G. CMS should clarify certain aspects of its public health objectives.

Certain aspects of the public health objectives need clarification. ACLA requests that CMS clarify that the capability to submit information to public health registries applies to certified EHRs, not to laboratory information systems. We agree that submission of electronic reportable laboratory results to public health agencies should be included in a certified EHR's capabilities, "except where prohibited, and in accordance with applicable law and practice," and it is important that CMS make this clear throughout its discussion of the objectives.[19] EHRs are capable of capturing details not relevant to laboratory tests, and it must be clear that this objective and its associated measure applies only to certified EHRs. This is clearer in the preamble language than in the proposed

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[15] *Id*.
[16] *Id*.
[17] *Id.* at 13,722.
[18] As proposed, the fields include patient name; referring provider's name and contact information; procedures; relevant past diagnoses; laboratory tests results; vital signs (height, weight, blood pressure, BMI, growth charts); smoking status; demographic information (preferred language, gender, race, ethnicity, date of birth); care plan field, including goals and instructions; and any additional known care team members beyond the referring or transitioning provider and the receiving provider. *Id*.
[19] *Id*. at 13,726.

regulation language itself. The preamble language describing the measure reads "Successful ongoing submission of electronic reportable laboratory results from Certified EHR Technology to a public health agency for the entire EHR reporting period,"[20] whereas the proposed regulation reads "Beginning in 2013, capability to submit electronic data on reportable (as required by state and local law) lab results to public health agencies and actual submission except where prohibited according to applicable law and practices."[21] It must be clearer that the measure applies to such submission from a certified EHR, not from another system such as a laboratory information system.

H. Imaging Results objective should not apply to laboratory tests (other than pathology) that can be returned as images.

CMS should clarify that the menu set objective pertaining to imaging results does not pertain to non-pathology laboratory tests that can be returned as an image.[22] "Imaging results" needs to be defined more clearly. It is not clear whether, if a lab test can obtain an image, it automatically is considered to return an "imaging result." Diagnostic tests may include an image, but they may not be ordered as an image by the physician. For example, bone marrow analysis has textual results and image results, and graphs on a laboratory report may be considered "imaging results." ACLA requests a clearer definition of "imaging result" to understand what results are and are not included in this proposed objective. It may be that CMS intended for radiology images to be accessible through CEHRTs, in which case the objective should be more specific to radiology. It also is important to know whether a certified EHR must maintain a copy of all imaging results. These files can be quite large and impact the performance of EHRs.

I. CMS should encourage interim rulemaking on transport standards if it is warranted.

CMS mentions ONC's proposed approach for adopting additional transport standards through interim final rulemaking with comment.[23] ACLA supports this approach. Although we encourage CMS and other agencies to be mindful of the many programming requirements facing laboratories and other providers – and to permit ample time between deadlines so that providers can implement new systems properly – we would welcome so-called "off-cycle rulemaking" regarding a transport standard if the proposed transport standard would be less expensive and more flexible for providers.

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[20] *Id*.
[21] *Id*. at 13,817.
[22] *See id.* at 13,726.
[23] *Id*. at 13,724.

III. Conclusion

Thank you for your consideration of ACLA's comments and suggestions.

Sincerely,

Alan Mertz, President
ACLA