



June 2, 2015

Submitted Electronically

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-3311-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Modifications to Meaningful Use in 2015 through 2017; Proposed Rule

Dear Mr. Slavitt:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the proposed changes to the requirements for the Medicare and Medicaid Electronic Health Records (EHR) Incentive Program for 2015 through 2017. The proposed rule provides significant flexibilities in the reporting period and the definition of meaningful use that are needed for the program to succeed. The AHA has concerns, however, about the scope of proposed change in the middle of a program year, which could cause confusion and increase burden for hospitals, particularly for those new to the program. Based on data from the Centers for Medicare & Medicaid Services (CMS), about half of physicians and 15 percent of hospitals have yet to attest to meaningful use.

The AHA greatly appreciates the shorter, 90-day reporting period CMS has proposed for eligible hospitals, critical access hospitals, and physicians and other eligible professionals (EPs) in 2015. We strongly urge CMS to finalize as quickly as possible the shorter reporting period and other proposals to provide greater flexibility in meeting the challenging meaningful use Stage 2 requirements. Even if the rule is finalized by August 1, providers have very little time to understand the changes, work with their vendors, and ensure that they meet the revised requirements.



As discussed in our detailed comments that follow, we recommend that CMS:

- Allow hospitals to choose whether to report on a fiscal or calendar year basis for 2015 and 2016 before moving to mandatory calendar year reporting in 2017;
- Open the attestation window for 2015 no later than Aug. 1, 2015;
- Finalize the proposed changes to meaningful use objectives that provide greater flexibility for hospitals and other providers, including changes to the patient electronic access, summary of care and secure messaging objectives; and
- Refrain from making any changes to the meaningful use objectives and measures that make achieving meaningful use Stage 2 more difficult, such as accelerating the date by which a new provider must meet Stage 2, making e-prescribing of discharge medications mandatory, or adding new public health reporting measures.

Hospitals' commitment to the success of the meaningful use program remains strong. However, according to data presented by CMS at the March 10 meeting of the Health IT Policy Committee, providers are still struggling to meet Stage 2. Specifically, while 85 percent of hospitals registered for the meaningful use program successfully attested to meaningful use in fiscal year (FY) 2014, only 38 percent of hospitals attested to Stage 2. Among EPs, the latest data indicate that only 41 percent had successfully attested to meaningful use as of March 1, and only a small share – 11 percent – had attested to Stage 2. The vast majority of hospitals, and many EPs, however, will be expected to attest to Stage 2 for the 2015 program year. Clearly, providers continue to face challenges complying with complex program rules and using certified EHRs that do not share data easily.

Our comments generally support proposed changes that increase the odds of program success and encourage the agency to refrain from finalizing provisions that could hinder providers' efforts. The meaningful use program must succeed so that we can build on the tremendous adoption of EHRs over the past five years, and use EHRs to support care improvements, patient engagement and new models of care. According to the most recent AHA survey data, hospitals experienced a five-fold increase in EHR use between 2010 and 2014 – an unprecedented growth that was spurred, in great part, by the meaningful use program.

Modifications to the meaningful use program also should be considered in light of the significant payment penalties for noncompliance. According to the inpatient prospective payment system (PPS) proposed rule for FY 2016, inpatient PPS hospitals that missed meaningful use in 2014 would receive a cut to their Medicare inpatient payments of 1.35 percent. Penalties would be larger in FY 2017 and later years, as they would go from being equal to half of the market-basket increase to being equal to three-fourths of the market-basket increase.

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We appreciate the opportunity to comment on this important proposed rule. If you have any questions or need further information, please contact Chantal Worzala, director of policy, at cworzala@aha.org or 202-626-2313.

Sincerely,

/s/

Rick Pollack Executive Vice President

American Hospital Association (AHA) Detailed Comments

Congress established the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program in the American Recovery and Reinvestment Act of 2009 to provide needed funds to accelerate the widespread adoption and use of EHRs to improve health and health care. We share these goals, and America's hospitals have invested tremendous financial and human resources to make them reality. Hospitals also work every day to ensure adequate privacy and security for patients and their health information.

Meaningful use began in 2011, with Stage 1 requirements. Stage 2 began in 2014, and represented a significant increase in requirements for providers. Due to challenges with Stage 2, the Centers for Medicare & Medicaid Services (CMS) offered limited flexibility for reporting in 2014 that allowed providers to attest to either Stage 1 or Stage 2 in 2014. Beginning in 2015, the vast majority of hospitals and many eligible professionals (EPs) are required to be at Stage 2. Experience in the field has indicated that 2015 also is a transition year to new technology and the complex Stage 2 rules for a number of reasons:

- Vendor delays and implementation issues have limited hospitals' ability to meet Stage 2 requirements. Hospitals are finding that 2014 Edition Certified EHRs do not work as expected and require significant and expensive patches or work-arounds. The biggest problems have been with the "transitions of care" and "patient portal" requirements.
- 2014 Edition Certified EHRs do not share data easily, either within the hospital or across care settings. They are not, generally speaking, interoperable. In addition, many areas of the country do not have efficient and affordable information exchange networks in place.
- The meaningful use program holds hospitals accountable for events outside their control. For example, to meet the transitions of care requirement, a hospital must find other providers ready to receive information in the manner required by the government. Yet post-acute care providers are not part of the meaningful use program, and many physicians have yet to implement their 2014 Edition EHRs.

The AHA is pleased that CMS has proposed changes to alleviate some of the challenges faced in Stage 2.

CHANGES TO THE REPORTING PERIOD

The proposed rule includes two changes to the meaningful use reporting period for hospitals and critical access hospitals (CAHs) in 2015 – a shorter reporting period and a shift from reporting on the fiscal year (FY) to reporting on the calendar year (CY). Taken together, the changes would shift the reporting period from a full fiscal year to any continuous 90-day period between Oct. 1, 2014 and Dec. 31, 2015. In 2016 and 2017, hospitals and CAHs continuing in the program would be expected to report on a full calendar year. The switch to calendar year

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reporting for hospitals and CAHs is meant to align their reporting with EP reporting, and with quality reporting under other Medicare payment systems.

The AHA urges CMS to finalize the shorter, 90-day reporting period for 2015. However, we believe that hospitals and CAHs should be able to choose whether to report on a fiscal or calendar year basis in 2015 and 2016.

The Medicare EHR Incentive Program will continue to pay incentives in FYs 2015 and 2016. Hospitals and CAHs already have included these promised incentives in their budgets for the coming years. The move to calendar year reporting effectively delays payment of those incentives for at least three months, causing financial and budgeting challenges, especially for hospitals that use the calendar year for budgeting. These hospitals assumed that they could attest at the end of the fiscal year and receive their incentive payments by the end of the calendar year. The impact on finances will be most significant in 2015 because the proposed rule was released well after budgets were developed for this year. However, budgeting for 2016 also will be impacted. Therefore, we recommend that CMS adopt a transitional policy allowing hospitals to choose to report on either a fiscal or calendar year basis in 2015 and 2016. Beginning in 2017, all hospitals would report on a calendar year basis.

ATTESTATION WINDOW

As a consequence of the move to a calendar year reporting period for hospitals, CMS proposes to change the attestation window for 2015 reporting to Jan. 1, 2016 through Feb. 29, 2016. Further, to accommodate the significant changes proposed for 2015, CMS proposes to delay any attestations for 2015 until Jan. 1, 2016 or later. Thus, even hospitals that choose Oct. 1 to Dec. 31, 2014 as their reporting period would not be able to attest until Jan. 1, 2016 at the earliest. The AHA strongly urges CMS to open the attestation window as quickly as possible, but no later than Aug. 1, 2015. This is necessary to treat hospitals fairly, especially those first attesting in 2015.

The proposed delay in attestation would cause financial challenges for hospitals that have already budgeted expecting to receive incentives in the fall. In addition, the AHA has heard concerns from member hospitals that are attesting to meaningful use for the first time in 2015, based on the 90-day reporting period that current rules allow for new participants to the program. These hospitals should have been able to attest as early as Jan. 1, 2015, but have not been able to because CMS has closed down the system. These hospitals counted on receiving incentives based on the rules currently in place. While we understand the need for CMS to update its attestation systems to comply with any finalized changes to the program, it is unfair to delay incentive payments to hospitals that were operating under the current rules.

Furthermore, CMS proposes to change the reporting period used to assess penalties from the fiscal year to the calendar year. In the long term, this alignment makes sense. In the short term, however, it creates significant and unfair challenges for hospitals that first attest to meaningful use in 2015. Under current rules, a hospital that first participates in meaningful use in FY 2015 must attest by July 1, 2015 to avoid a payment penalty in FY 2016. With the proposed delay in

attestation, however, it would not be possible for these hospitals to attest by that date. Consequently, CMS proposes to apply the FY 2016 penalties to inpatient prospective payment system (PPS) hospitals that have never participated in meaningful use beginning Oct. 1, 2015; suspend the penalties once the hospital has attested successfully; and subsequently reprocess claims and reconcile any penalties previously assessed. This proposal would create significant financial hardship for hospitals that first meet meaningful use in 2015 by applying undeserved penalties equal to an estimated 1.35 percent of all inpatient PPS payments. It also would create operational challenges for both the hospitals and CMS to re-process claims. If, however, CMS opened the attestation window by Aug. 1, 2015, the agency could identify these hospitals more quickly, and limit both the time that penalties might be assessed and the number of claims to reprocess.

FLEXIBILITY IN MEANINGFUL USE REQUIREMENTS

The AHA greatly appreciates the specific proposed changes to meaningful use objectives and measures that would create more flexibility for providers in meeting the modified version of Stage 2 and strongly urges CMS to finalize them as proposed. Hospitals have found the current set of requirements to be overly prescriptive and difficult to meet. This is particularly true of those items that hold providers accountable for the actions of others that are beyond their control. The changes in the proposed rule would go a long way toward easing those challenges, while still keeping hospitals on track to deploy advanced EHR functions that support improved care and engaged patients.

Specifically, the AHA supports the proposals to:

- Remove objectives and measures from Stage 2 that CMS believes are "redundant, duplicative or topped out;"
- Change the measures for patient electronic access;
- Change the requirements for the summary of care objective; and
- Change the requirement for secure messaging (EP only).

Objectives for Removal. CMS proposes to remove 11 hospital objectives and two hospital measures from Stage 2 that it believes are "redundant, duplicative or topped out." For EPs, CMS proposes to remove 10 objectives and two measures, most of which overlap with the hospital objectives proposed for removal. While the AHA supports removal of these objectives to simplify the meaningful use requirements, we note that many of these items would still be part of the meaningful use program because they are fundamental pieces of other objectives. For example, CMS proposes to remove collection of problem lists as a separate objective, but problem lists would be expected to be available through the patient portal.

Patient Electronic Access. The AHA greatly appreciates the proposed changes to this objective and strongly urges CMS to finalize them as proposed. The AHA also encourages all hospitals to continue to actively engage patients through whichever channels patients prefer, whether in person, by telephone, electronically or via other means. In response to the concerns of hospitals and physicians, CMS proposes to change the requirements on patient

engagement for 2015 to 2017. Under the proposed rule, the current requirement to provide patients online access to their health information would remain. However, the requirement that 5 percent of patients use the patient portal would be modified to at least one patient using the portal. We agree with CMS that this change would ensure the capability is enabled while giving providers and patients more time to incorporate these tools into the care process. The proposal also would not hold providers accountable if patients choose not to use the portal technology. In many acute care cases, such as a broken arm or a hospitalization for pneumonia, it may well make more sense for patients to access information through their primary care provider, who coordinates all of their care, rather than from the hospital directly. Furthermore, as currently constructed, the program encourages the proliferation of portals across providers, rather than a consolidation of results and information in one place.

Summary of Care. The AHA appreciates the proposed changes to the summary of care objective, which has been challenging for hospitals to meet, and urges CMS to finalize them. CMS proposes to rename and modify the specifications for the transitions of care objective in the following ways:

- Remove the current Stage 2 requirement that a summary of care document be sent for 50 percent of transitions and referrals (which could include fax and paper copies), referred to in the rule as Measure 1.
- Keep the requirement that the hospital, CAH or EP send the summary of care electronically for 10 percent of transitions and referrals.
- Remove the requirement to send at least one summary of care record to a provider that uses a different EHR vendor.
- Remove any requirements on the specific methods used to electronically send the summary of care document, such as specifying the use of a certified EHR to do so.

We also note that the preamble to the proposed rule does not include a discussion of the data that must be included in the summary of care document, while previous rulemaking did include specific requirements.

The AHA supports removing Measure 1, which has created significant challenges for providers across the country because of the large volume of summary of care documents that have been faxed and mailed to physician offices not yet able to receive them electronically.

We also support providing more flexibility in the type of technology that can be used to electronically share the summary of care. While the Direct protocol currently required under meaningful use will likely continue to be used in many instances, it is not the only means providers have at their disposal. Providers also may use another form of secure email or the services of a health information exchange to share information with the next provider of care. Importantly, the use of alternative mechanisms to share data also will be helpful in sharing a summary of care document with post-acute and other providers of care that are not part of the meaningful use program, and may not have Direct capability enabled. For many hospitals, 30 percent of patients, or more, may be discharged to a post-acute setting. Furthermore, some health

systems are moving to a model of shared access to a common data set, rather than transactions that send data from one location to another. This approach is more efficient and prevents issues of data duplication and possible mixing of records through poor patient matching. We believe that all of these forms of information sharing, including providing access through a shared record, should count toward the 10 percent threshold.

We interpret the lack of detail on the data to be included in the summary of care document to mean that CMS would allow physicians and other providers discretion to determine the summary of care content that is relevant for the next provider of care to receive. We strongly support this direction and ask CMS to clarify this issue in the final rule. We note that the highly prescriptive information requirements contained in the current rules have led to summary of care documents that were 30 or even 50 pages long. Experience in the field indicates that those summaries are not helpful, and may be harmful, because the relevant information is hard to separate from the large pool of data currently required to be in the summary of care.

Secure Messaging (EP only). The AHA supports CMS's proposal to modify the Stage 2 secure messaging objective for EPs to have secure messaging capabilities fully enabled so that patients can send and receive messages electronically. The AHA believes that all providers should actively engage patients through whichever channels patients prefer, whether in person, by telephone, electronically or via other means. Under current rules, the measure is to have a secure message sent using the secure messaging function of certified EHR technology by more that 5 percent of unique patients seen by the EP (or their authorized representatives) during the reporting period. By fully enabling the capability, EPs are ensuring their patients have the ability to send secure messages. Under this proposal, however, EPs would no longer be held accountable if patients choose not to use that form of communication.

PROPOSALS THAT WOULD MAKE MEANINGFUL USE MORE DIFFICULT OR COMPLICATED

The proposed rule contains several provisions that would make it more difficult for providers to meet meaningful use. Some of those changes would apply to all providers, while others would accelerate the requirements on providers new to the program. The AHA strongly urges CMS to refrain from finalizing proposals that increase the difficulty of meeting meaningful use Stage 2 for all hospitals, including those new to the program.

Consolidation at Stage 2. CMS proposes to create a single, modified Stage 2 definition that all providers would have to meet. For 2015 only, CMS proposes to afford providers meant to be at Stage 1 the option to attest to the Stage 1 objective and measure specifications for all of the objectives of meaningful use that it has retained. For example, these providers would have to implement only one clinical decision support tool (Stage 1 requirement), rather than five (Stage 2 requirement). For objectives that did not exist in Stage 1, these providers would have an exclusion in 2015. For example, these providers would have an exclusion from the transitions of care objective because Stage 1 does not have a similar objective. In 2016 and later, however, CMS would require all providers to meet the same requirements, regardless of when they first enter the program.

The AHA opposes the requirement that all providers meet all of the modified Stage 2 requirements in 2016 and later years. We strongly recommend that CMS keep the alternate specifications and exceptions it proposes for 2015 available to providers meant to be at Stage 1 in 2016 and 2017. From the very beginning, CMS has taken a staged approach to meaningful use, recognizing that adoption of EHRs is challenging and not all functionality can be adopted at once. We recognize, however, the simplicity for CMS of maintaining a single set of criteria. Maintaining the alternate specifications and exceptions in 2016 and 2017 would allow CMS to simplify the overall structure of the program, while also providing more recent entrants to the meaningful use program the same progression through the stages of meaningful use as those who entered earlier. Many of these more recent entrants are likely to be smaller and more financially challenged providers that would have trouble with an accelerated pace.

e-Prescribing. Under previously finalized rules for Stage 2, e-prescribing of discharge medications was a menu item. In this rule, CMS proposes to require it for all hospitals, with the same threshold of 10 percent of hospital discharge medication orders for permissible prescriptions being queried against a drug formulary and transmitted electronically using a certified EHR. CMS proposes to exclude hospitals from this measure in 2015 only if they did not intend to choose e-prescribing as a menu item. The AHA strongly urges CMS to extend that exclusion into 2016 for all hospitals that did not intend to choose e-prescribing as a menu option. At best, there will be five months between when this rule is finalized and Jan. 1, 2016. This is far too short a time period for hospitals to make all of the needed changes to implement e-prescribing of discharge prescriptions, which includes purchasing and updating technology, training both clinical and pharmacy staff, educating discharged patients on how e-prescribing will work, and making arrangements with local pharmacies, among other things.

Public Health Reporting. The AHA has significant concerns with CMS's proposals to modify the public health objective by adding new public health measures for hospitals and changing the immunization measure. Specifically, the agency proposes to add new measures for case reporting, reporting to public health registries and reporting to clinical data registries, as well as changing the immunization measure to involve bidirectional information exchange; that is, both reporting to the registry and receiving forecasts and other information from the registry. These items were not included in the previously finalized Stage 2 rules, and were not, therefore, anticipated by hospitals. Consequently, these reporting activities are likely not supported by the Certified EHR deployed by a given hospital. Furthermore, we note that the ability of public health departments to maintain registries other than immunization registries and to accept electronic case reports is highly variable. Finally, current certification requirements do not include bidirectional exchange with immunization registries; thus, hospitals do not have the capability to conduct bidirectional exchange.

The AHA supports CMS's proposal to introduce the concept of "active engagement" with a public health agency or clinical data registry, which provides much needed clarification of the type of activity that meets meaningful use requirements. The proposed definition includes:

• Registering to submit data within 60 days after the start of the EHR reporting period;

- Being in the process of testing and validating electronic submission of data; or
- Electronically submitting production data.

We note that the need for this clarification is symptomatic of the lack of readiness of public health agencies to receive data electronically from all of those who are required to submit it under meaningful use. Therefore, we urge CMS to focus first on supporting public health departments in building out their capability before adding new reporting requirements on providers.

Finally, the AHA is concerned that, if CMS chooses to add new public health reporting options, it would greatly increase burden on hospitals. On its face, the idea of adding new options and allowing hospitals to report on three of the six measures would add flexibility to the program. However, CMS also proposes that an exclusion for a measure would not count toward the total of three measures that must be met by a hospital. For example, if a hospital qualifies for an exclusion on one measure, the hospital would still need to meet three of the remaining measures. If a hospital qualifies for four or more exclusions, however, the hospital could meet the objective by meeting the two remaining measures and taking one of its four exclusions. This proposal places tremendous burden on the hospital to investigate and exhaust all possible reporting options, and adds uncertainty about compliance with a program that contains significant penalties for noncompliance. Therefore, we urge CMS to include only those three public health reporting options for hospitals that have the same measure specifications and exceptions that were previously finalized for Stage 2.

We also recommend that CMS work with other federal agencies to create a single website for providers that lists all public health departments and registries that can accept electronic reports according to the Office of the National Coordinator for Health IT's standards, and provides information about their readiness to accept provider registrations, engage in testing and validation of electronic submission of data, and receive production data electronically.

Definition of a Hospital-based EP. Under the meaningful use program, hospital-based EPs are not eligible for incentive payments or subject to payment penalties. The current definition considers EPs to be hospital-based if they furnish 90 percent or more of their covered professional services in sites (places) of service identified as an inpatient hospital (POS 21) or emergency room (POS 23) setting in the year preceding the payment year.

The AHA believes that it is appropriate to include the outpatient hospital setting (POS 22) in the definition of a hospital-based EP. Certain physician specialties, such as pathologists and radiologists, and even some hospitalists, have reported challenges with the existing definition. A change in the definition of hospital-based would provide more clarity for these physicians, many of whom provide specialized services that are not easy to translate into the meaningful use requirements. To provide an adequate transition period, the AHA recommends that CMS change its definition beginning with the 2017 payment year.