



**American Hospital
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May 27, 2015

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS-3310-P, Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 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 Centers for Medicare & Medicaid Services' (CMS) proposed rule defining "meaningful use" of electronic health records (EHRs) for Stage 3 of the Medicare and Medicaid EHR Incentive Programs.

Hospitals strongly support the long-term goal of the EHR incentive programs, and they have been working diligently to implement new health information technology to improve the quality and coordination of care for patients. **While the Stage 3 proposals offer promising ideas that could further health information exchange and support greater patient engagement, we do not yet have sufficient experience at Stage 2 to be confident that the proposals for Stage 3 are feasible and appropriate.** In addition, the standards and information exchange structures needed to support many of the Stage 3 requirements are not yet mature enough to be included in regulation. Furthermore, Stage 3 proposals such as relying on third-party applications to access sensitive patient data in EHRs may be a successful mechanism for the exchange of patient data information, but they raise important questions about patient privacy and information security that must be carefully considered.

Therefore, the AHA urges CMS to refrain from finalizing a Stage 3 meaningful use rule at this time. Instead, the agency should evaluate the experience in Stage 2 while accelerating the availability of mature standards and the infrastructure needed for efficient and effective health information exchange.

For most hospitals and the vast majority of physicians, 2015 will be the first year at Stage 2 of meaningful use. The transition to new technology supporting Stage 2 has been a challenge for



Andrew Slavitt
May 27, 2015
Page 2 of 11

providers due to lack of vendor readiness, mandates to use untested standards, insufficient infrastructure to meet requirements to share information and compressed timelines. It also has proved extremely expensive – the AHA estimates that between 2010 and 2013 hospitals collectively spent \$47 billion each year on information technology. We greatly appreciate the changes CMS has proposed in a separate modification rule for 2015 to 2017 that would accommodate some of the challenges, such as a shorter reporting period in 2015. However, the need for those changes in the middle of a program year underlines the importance of ensuring that policies are feasible before they are finalized in regulation.

Our detailed comments (attached) elaborate on the need to learn from Stage 2 and build the infrastructure and standards needed to meet today's meaningful use requirements before finalizing Stage 3 requirements. In addition, we provide detailed comments on the proposed changes to the structure, objectives and measures proposed for Stage 3 meaningful use.

Thank you again for the opportunity to comment. If you have any questions, please contact me or Diane Jones, senior associate director of policy, at (202) 626-2305 or djones@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President

Attachment

LEARN FROM STAGE 2 OF MEANINGFUL USE BEFORE MOVING TO STAGE 3

Learn from the Experience in Stage 2. The majority of hospitals and nearly all physicians are in their first year of Stage 2 using 2014 Edition certified EHRs. According to CMS, only 38 percent of hospitals and 11 percent of physicians registered for the EHR incentive programs met Stage 2 in 2014. In addition, some hospitals and many physicians have not begun participating in meaningful use. Furthermore, given the challenges of Stage 2, CMS has proposed much-needed flexibilities for the current reporting year. The AHA greatly appreciates that flexibility and believes that CMS must evaluate whether the changes it will finalize later this year lead to stability at Stage 2. This is critical before transitioning to Stage 3.

Finally, based on CMS data and input from the hospital and health system field, it is clear that we do not yet have sufficiently mature standards and a robust health information exchange infrastructure to fully support current information exchange requirements, let alone the important new information exchange objectives contemplated in the Stage 3 proposed rule.

Prioritize the Development of Health Information Exchange Infrastructure before Finalizing Stage 3. America's hospitals strongly support the creation of an efficient and effective infrastructure for health information exchange that facilitates the delivery of high-quality, patient-centered care across health care settings. Today, an increasing confluence of pressures to share information to support care exists. These are driven in part by the EHR incentive programs and initiatives to reduce hospital readmissions and adopt new models of care. The Medicare Access and CHIP Reauthorization Act of 2015 declares interoperability of EHRs a national objective and establishes an expectation that the country will achieve widespread interoperability by December 31, 2018. However, the current infrastructure for health information exchange needs significant improvements if we are to achieve that goal.

Hospitals and health systems report that EHRs purchased during the past five years do not easily share information, and we lack efficient and affordable networks to connect providers. The cost of the many interfaces needed to connect systems and new transaction fees for information exchange do not represent a sustainable model for widespread sharing of health information. **CMS should work with the Office of the National Coordinator for Health Information Technology (ONC) and the private sector to develop the infrastructure needed to effectively and efficiently meet the Stage 2 requirements before finalizing requirements for Stage 3.**

Refine and Strengthen the Standards Required to Meet Meaningful Use Today. Experience to date in the meaningful use program underscores the need for ensuring that standards and technology are sufficiently mature before they become mandated for use. The current EHR incentive programs mandate the use of certified EHRs that incorporate draft standards to support program requirements, including the exchange of health information among clinicians and the format of the content exchanged. Inconsistency in the implementation of the standards by vendors has led to confusion and limited provider success in meeting today's regulatory requirements for information exchange. For example, Stage 2 of meaningful use established a reliance on the "direct protocol," a new standard to support the sharing of information. As a

result of inconsistent implementation among EHR vendors, the ability to use the direct protocol standard to enable information exchange varies. For example, providers are required to use the consolidated clinical data architecture (C-CDA) standard to send patient care summaries in a structured template. However, the C-CDA has proved difficult to use and has not met clinical needs to share pertinent information to support care.

Given the significant investments made to date, the AHA recommends that the current capabilities of the 2014 Edition certified EHRs be the starting point for the focused effort to develop the robust interoperability infrastructure. We also recommend that CMS work with ONC on initiatives to close the gap between standards development and standards implementation. We recommend CMS start with standards currently in use in Stage 2, such as the direct protocol and the C-CDA. CMS and ONC can then help narrow the disparity between the standard as developed and the expectations for the standard in use. These steps would maximize successful provider use of the standard in their certified EHR. At the same time, new standards to support future goals, such as application program interfaces (APIs), can be developed, piloted and refined before being required for use. In addition, important policy questions can be addressed, such as how to accurately identify patients to ensure that accurate information is shared, how to ensure privacy of information shared through third-party applications, and how to maintain the security of systems while accepting new forms of external data in the EHR. The AHA is committed to working with our federal partners to achieve our shared goals of a health information ecosystem that supports efficient and effective information exchange.

PROPOSALS FOR STAGE 3 OF MEANINGFUL USE OF EHRs

This section includes our detailed comments on the proposals for Stage 3 of meaningful use. We begin with comments on proposed changes to the structure of the program, followed by comments on the specific requirements.

STRUCTURAL CHANGES TO THE EHR INCENTIVE PROGRAMS

The AHA believes that structural changes to the EHR incentive programs should reflect prior program experience and should support safe and orderly transitions from one stage of meaningful use to the next stage.

Reporting period. The AHA supports the move from fiscal year to calendar year reporting for hospitals beginning in 2017. However, a full year of reporting for the first year of Stage 3, as proposed in the rule, is unrealistic. **The AHA strongly recommends a reporting period of any 90 days in the first year of a new stage, including Stage 3.** The first year of Stage 1 and Stage 2 offered a 90-day reporting period, which proved to be essential to supporting a safe and orderly transition to use of new technology. In addition, new entrants to the program should continue to have a 90-day reporting period in their first year of participation. Providers new to

the program need time to install and learn to use technology before beginning their first reporting period.

Consolidation at Stage 3. The AHA recommends that CMS permit providers to remain in each stage of meaningful use for three years. Sufficient time must be allowed for hospitals to update, implement and optimize the new technology in order to support performance at a high level. In the proposed rule, some hospitals that begin meaningful use participation in 2015, 2016 or 2017 would be expected to move swiftly through Stages 1 and 2, as well as from a 2014 certified EHR to a 2015 certified EHR. Some providers would even be expected to begin their participation in the program at Stage 3. Experience to date suggests that this is an unrealistic expectation. Therefore, we believe that a provider should be required to start Stage 3 after they have been at Stage 2 for three years. For example, hospitals that first meet Stage 2 in 2015 would be expected to be at Stage 3 in 2018. Those who first meet Stage 2 in 2016, however, would not be required to be at Stage 3 until 2019. However, providers should be allowed to attest to a higher stage of meaningful use, if they so choose.

Stage 3 Start Date. Offering an optional year for Stage 3 in 2017 is unlikely to mitigate the challenge of provider readiness to begin Stage 3 in 2018. CMS proposes to allow providers to choose to begin Stage 3 on January 1, 2017. All providers would be required to begin Stage 3 on January 1, 2018, regardless of their stage of meaningful use in the preceding year. CMS states that this optional year would ease timeline challenges for adoption of new technology. However, the EHR development and certification cycle to date has required a minimum of 18 months from the time of the release of new meaningful use rules to the start of the new stage, as recommended by the Health IT Standards Committee. Once hospitals receive the updated EHR software, the experience to date indicates that up to an additional 19 months is required to safely and successfully implement the new technology. This process includes time for software assessment; installation, implementation and training for staff that will use the systems; time to build up to the performance metrics required by meaningful use; and time to capture actual data in a reporting period. Furthermore, the alignment of reporting periods for all program participants may increase the possibility that certified EHRs supporting both eligible hospitals (EHs) and eligible professionals (EPs) are likely to be presented for certification simultaneously, leading to delays.

Given the expected release this fall of a final rule for the EHR incentive programs and the corresponding release of a final rule for the 2015 Edition Health Information Technology Certification Criteria, it is unlikely that providers will have newly certified EHRs and be ready to begin a full year reporting period starting January 1, 2017. Rather, it is more likely that the past experience – vendor delays and the prospect of penalties for providers, despite their best efforts at complying with the regulatory requirements – would be repeated. As noted in our overall comments, CMS must evaluate experience in Stage 2, while accelerating the availability of mature standards and the infrastructure needed for efficient and effective health information exchange before finalizing rules for Stage 3, including the start date.

Attestation Period. The AHA recommends that CMS finalize a data submission period of 120 days rather than the 60 day submission period proposed. Aligning the reporting period for EHs and EPs to a calendar year also aligns the data collection and reporting period for meaningful use and for CMS clinical quality measure reporting. However, an aligned 60-day submission period would likely present submission issues for program participants and for CMS. Experience to date with the separate data submission period for EHs and EPs indicates that both EHs and EPs are challenged to submit their data due to capacity issues with CMS's attestation system. Indeed, CMS has extended on multiple occasions the attestation period beyond 60 days to accommodate the volume of reports being submitted.

Meaningful Use Data Set. The AHA opposes use of a new data set for Stage 3 – the Common Clinical Data Set. Providers are working to become proficient with the Stage 2 Meaningful Use Data Set, and the AHA encourages CMS to support the current requirement before adding additional data requirements. The additional data fields that are incorporated into the proposed Stage 3 Common Clinical Data Set would involve significant effort to implement and transition the data elements necessary to support the standard summary of care record. Currently, providers do not have the technology to capture all the proposed data elements associated with the requirement. For example, capturing unique device identifier (UDI) data would be a new requirement for Stage 3. However, the transition to the UDI has just begun and will not be complete until 2020. It will be a complex transition, as there are three separate agencies that use different standards to create the UDI, which can be as long as 75 characters. In addition to accommodating multiple UDI formats, EHRs also will need to accept the data from different forms of automated ID technology (such as a barcode or radio frequency identification tag). At the same time, hospitals are learning how best to use the UDI and change operations to accommodate it. The AHA supports the deployment of the UDI because of the safety and efficient benefits it will bring. However, working through the standards development and implementation issues to support effective use of the UDI is a precursor to including the UDI as a data element in the common clinical data set.

Quality Reporting. The AHA strongly supports the long-term goal of using EHRs to streamline and reduce the burden of quality reporting while increasing access to real-time information to improve care. **However, required electronic submission of electronic clinical quality measures (eCQMs) for a full year in 2018, as proposed in the rule, is an unrealistic goal.** Experience to date indicates that eCQMs have required hospitals to expend considerable effort to modify how data are captured and the locations in the EHR where data is captured, but they have not yet resulted in measurement data that are comparable across measurement methodologies. eCQMs must be valid, reliable and feasible to report. Additionally, the EHR vendors should be required to modify their products to support the annually updated eCQM specifications.

The AHA recommends that CMS continue the eCQM validation pilot, initiated in 2015, to ensure that a diverse group of hospitals and EHRs are participating, and make the findings public so that all stakeholders can learn about the challenges associated with achieving validity, reliability and feasibility of eCQMs. In addition, we recommend that CMS and ONC continue their work with multiple stakeholders on improvements to eCQMs, including the process for annual updates to eCQMs, the testing infrastructure for eCQMs,

the ability of vendors to support the updates to eQOMs (which often occur more frequently than EHR certification), and the communication of the strategy for the use of eQOMs in meaningful use and other CMS programs. The AHA is engaged in this work and is committed to continued participation.

PROPOSED STAGE 3 OBJECTIVES AND MEASURES

CMS proposes to create a set of eight objectives for all providers for Stage 3 and eliminate the use of core and menu objectives. The agency believes this would simplify reporting requirements and reduce program complexity, confusion and concerns. EHs would be required to report on 21 measures. **While this proposal appears to simplify the program, it actually would increase program requirements by adopting higher thresholds for performance and introducing challenging new requirements.** We provide specific comments below on the proposed changes to certain objectives and the measures EHs, critical access hospitals (CAHs) and EPs are required to meet within those objectives. In several places, we note that CMS is making the success of providers contingent on the actions of others that are beyond the providers' control. We believe this is unfair, and make recommendations that hold providers accountable only for those things they can control, such as having the technology in place.

Objective 1, Protect Patient Health Information. The rule proposes to maintain the previously finalized Stage 2 objective that providers protect electronic protected health information (ePHI) created or maintained by a certified EHR through the implementation of appropriate technical safeguards. The measure requires conducting or reviewing annually a security risk analysis to assess whether the provider's technical, administrative and physical safeguards and risk management strategies are sufficient to reduce potential risks and vulnerabilities to the confidentiality, availability and integrity of ePHI. **The AHA supports the stability in the measure specification and the clarification that the requirement of this measure is narrower than what is necessary to satisfy the requirements of the Health Information Portability and Accountability Act (HIPAA).**

Objective 2, Electronic Prescribing. Electronic prescribing of discharge prescriptions by EHs and CAHs was an optional menu item in Stage 2 with a measure threshold of 10 percent. The AHA has long recommended that when an item moves from being optional to being required it should have the same threshold. This is because optional objectives will have limited actual use by providers, and experience in the clinical environment should precede an increase in provider requirements for performance. Therefore, **the AHA opposes the proposed Stage 3 increase in the electronic prescribing threshold and recommends that the threshold stay at 10 percent.**

Objective 3, Clinical Decision Support (CDS). For Stage 3, the rule proposes to continue the Stage 2 objective that EHs, CAHs and EPs implement CDS interventions focused on high-priority conditions. CMS proposes two measures to meet the objective. The first measure requires five CDS interventions related to five or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. The second measure requires EHs, CAHs and EPs to enable and implement the functionality for drug-drug and drug-allergy

interaction checks for the entire EHR reporting period. **The AHA recommends removing the tie between CDS and clinical quality measures in favor of high-priority safety and quality improvement objectives of the hospital.** This would better allow hospitals to use EHRs to meet their quality improvement goals and remove the measurement burden of tracking the links between CDS and clinical quality measure. It also would give hospitals the flexibility to start and stop their use of specific CDS tools in accordance with their unique quality improvement activities, rather than to be in compliance with regulatory requirements. We also continue to have concerns about the second measure, requiring EHs, CAHs and EPs enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period. For the second measure, **the AHA recommends removing the “entire EHR reporting period” from the measure specifications to limit unnecessary measurement burden.**

Objective 4, Computerized Provider Order Entry (CPOE). For Stage 3, the rule proposes to maintain the CPOE objective that providers use a computer or mobile device to record and enter clinical orders in a structured format. Three measures are proposed to meet this objective: 80 percent of all medication orders are recorded using CPOE; 60 percent of all lab orders are recorded using CPOE; and 60 percent of all diagnostic imaging orders be recorded using CPOE. **The AHA supports the continuation of the three measures with higher thresholds for Stage 3.**

Objective 5, Patient Electronic Access to Health Information. For Stage 3, the rule proposes to continue the use of patient portals to facilitate patients’ ability to view, download or transmit (VDT) their health information electronically, but increases the threshold from 50 to 80 percent and shortens the timeframe to within 24 hours of the information available to the provider. CMS also proposes the use of ONC-certified APIs to facilitate patient electronic access. **The AHA opposes the acceleration of the timeframe – from 36 hours to 24 hours – for the provider to give access to a patient to VDT or access the information through an API as it would present operational challenges to hospitals.** The AHA recognizes the potential future use of APIs to facilitate information exchange. However, the standards to support the use of APIs are still under development and are not yet mature enough to be included in regulation.

Measure two proposes to increase the electronic provision of patient-specific educational resources for more than 35 percent of unique patients. **The proposed threshold presents a very high bar above the Stage 2 threshold of 10 percent and is not supported by any evidence that this is the optimal level to achieve better health outcomes. Additionally, the AHA believes that successful patient engagement must use a full array of mechanisms that support patient preference in the manner of engagement, whether in-person, electronically or through paper-based materials.**

Objective 6, Coordination of Care through Patient Engagement. The AHA strongly supports the goal of this objective, but recommends changes to the specific measures. For Stage 3, CMS proposes to create a new objective to use certified EHRs to engage with patients or their authorized representatives in the coordination of care. The first of the three measures proposes to require more than 25 percent of patients use the patient portal or use an ONC-certified API. In 2014, hospitals cited the engagement of patients with the patient portal as one of the most

difficult of the Stage 2 criteria to meet, and CMS data on the performance of EHs and CAHs on this measure for Stage 2 underscored this point. In response, CMS included a proposal in the 2015 EHR modifications rule to retain the current requirement to provide patients with online access to their health information and demonstrate it has been used by at least one patient, rather than requiring that 5 percent of patients use the patient portal. **The AHA appreciates and strongly supports this approach to measuring the EHR patient portal. We urge CMS to continue the approach of requiring providers to ensure that functionality is enabled in Stage 3.** The AHA continues to encourage all EHs and CAHs to engage their patients through all of the mechanisms that the patients may prefer, whether in person, by telephone, electronically, or via other means. As patients should have the ability to exercise their preferred method of engagement, we believe that it is unfair to hold providers accountable if patients select a means of engaging their provider other than through the use of the EHR portal or in the future, through an ONC-certified API.

The second measure proposes that for more than 35 percent of patients or the patient's authorized representative, the EHR would be used to send a secure message to the patient or used in response to a secure message sent by the patient. **The AHA believes that this measure should be applicable to EPs as a patient following an acute care visit is more likely to access information through a primary care provider than from the hospital directly. In addition, we believe it is appropriate to measure the provider's use of the secure messaging but not the patient's responsiveness or utilization of this technology. We believe that patients should be able to choose the mechanism supporting their engagement with their provider.**

The third measure proposes to require inclusion of patient-generated data for more than 15 percent of unique patients in the EHR. This measure raises questions about the readiness of standards to technically support this proposal. Additionally, the readiness of standards to support the validation of the data and the ability to match the data to the correct patient record are unknown at this time. The issue of medical liability for the provider recipient of the patient-generated data has not been addressed in order to support a path for the inclusion of patient-generated data. While ONC may support the maturation of standards that support the transmission of patient-generated data, **the AHA believes it is premature to propose that providers use certified EHR functionality to support receipt of patient-generated data from 15 percent of all unique patients.**

CMS proposes the use of APIs in support of the patient electronic access to health information and the coordination of care objectives, yet the standards for APIs are currently immature. The use of APIs holds promise, but we lack evidence on the readiness of the approach in any clinical setting. We also lack insight on the number of different EHR vendors engaged in the API standards development work. Experience indicates that there is a distinction between a draft standard for trial use and a mature standard with implementation specificity that providers can expect vendors to adhere to. Stakeholders are working to develop a standard and implementation specifications for APIs that would be used by EHR vendors, and CMS should continue to collaborate with ONC on these and other efforts to develop mature standards that may be able to support health information exchange requirements. The development, testing and trial use of a

standard used in technology should precede the standard's inclusion and use in federal regulation.

Additionally, new technology approaches that engage third parties in the exchange of data between patients and providers must be supported within the context of the existing HIPAA framework. Third parties, including developers of applications that receive, aggregate and transmit data must be covered by the same HIPAA requirements as other business associates of providers. Finally, we have significant concerns that the introduction of APIs could introduce security risks to providers' health information systems. Hospitals are part of the nation's critical infrastructure and are responsible for keeping systems as secure as possible. They must proceed carefully when introducing new technologies that touch their system. **While the AHA supports the concept of using APIs to share data, it is premature to require their use by providers in meaningful use because of the lack of standards maturity, the security risks they pose and the significant policy questions that must be addressed.** CMS should recognize that the absence of a patient matching solution remains problematic to accelerating health information exchange.

Objective 7, Health Information Exchange. The AHA supports the goals of the health information exchange objective. However, we have significant concerns that the standards and information exchange infrastructure are not yet sufficiently mature to support the specific measures proposed. CMS proposes to require providers to create electronically and send electronically a summary of care document for more than 50 percent of transitions of care and referrals, up from the 10 percent required in electronic exchange of a summary of care record in Stage 2. CMS reported that in 2014 the lowest quartile of hospitals reached a 19 percent threshold and the highest quartile reached 48 percent, suggesting that an increase to 50 percent is unreasonable. In addition to examining the threshold data, the AHA recommends that CMS study the hospital experience to understand the level of effort required to achieve the 2014 threshold. Additionally, the higher threshold should not be proposed in advance of a more robust health information exchange infrastructure. We recommend that CMS evaluate the use of current health information exchange mechanisms.

Objective 8, Public Health Registry Reporting. The AHA supports the proposed change in the requirement that EHs, CAHs and EPs are in "active engagement" with a public health registry or clinical registry rather than the Stage 2 requirement for an "ongoing submission" of data to meet the public health objective. We also support the three-part criteria proposed to assess the active engagement:

- Completing registration to submit data with a public health agency (PHA) or clinical data repository (CDR) within 60 days after the start of the EHR reporting period;
- In the process of testing and validating electronic submission of data to a PHA or CDR; or
- Electronically submitting data generated through clinical processes involving patient care to a PHA or CDR.

The proposed six measures in support of the public health registry reporting requirement give an appearance of flexibility, but they will require hospitals to exhaust multiple reporting options in order to claim an exemption for a given measure. This represents a significant increase in the reporting burden. **Until the state public health and registry reporting infrastructure are able to meet the readiness assumed in this proposal, the AHA recommends retaining the existing Stage 2 requirements for public health reporting. The AHA recommends that the Department of Health and Human Services (HHS) focus its work on the readiness of public health departments to accept data in accordance with the standards supported by the certified EHRs.** The standard that is used by public health should be consistent so that providers are not required to submit the same data via multiple formats to every state or local public health department. **Additionally, HHS should require that any registry that an EH is required to send data to must be certified to accept the data.** The additional time also would support the ability of EHRs to support the more advanced reporting requirements proposed for Stage 3. For example, we do not believe that EHR technology would be sufficiently mature in 2018 to support the bi-directional data exchange between a provider's EHR and a state or local immunization registry.