



**Association of  
American Medical Colleges**  
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399  
T 202 828 0400 F 202 828 1125  
www.aamc.org

*Via Electronic Submission ([www.regulations.gov](http://www.regulations.gov))*

May 29, 2015

Mr. Andrew Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Acting Administrator Slavitt:

***Re: Medicare and Medicaid Programs: Electronic Health Record (EHR) Incentive Program-  
Stage 3 Proposed Rule, File Code CMS-3310-P***

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS' or the Agency's) Proposed Rule entitled *Medicare and Medicaid Programs: Electronic Health Record Incentive Program-Stage 3*. 80 FR 16732-16804 (March 30, 2015). The AAMC is a not-for-profit association representing all 141 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems, and 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, and 115,000 resident physicians.

The AAMC commends CMS for the Agency's efforts in streamlining and simplifying many of the meaningful use requirements across hospitals and eligible professionals (EPs); however, the Association is concerned that the significant expansions and changes in the Stage 3 proposed rule represent an overly optimistic view of the capabilities of many providers and vendors, are based on the experience of a small number of early attestors to Stage 2, and do not provide enough flexibility to new providers or to hospitals and EPs who wish to upgrade their systems. If the proposed rule were finalized without significant revisions, many hospitals and EPs would be unable to become Stage 3 meaningful users and would face penalties. The AAMC supports a slow and steady expansion of meaningful use and quality requirements that are designed to support the considerable efforts that hospitals and EPs are taking to improve patient care through many avenues, including the use of electronic health records (EHRs).

### **CMS Should Delay Finalizing Stage 3 Both to Obtain More Experience with Stage 2 and Determine How Meaningful Use Will Be Incorporated into the Merit-based Incentive Payment System (MIPS)**

The AAMC recognizes that, as promised in the Meaningful Use Stages 1 and 2 rules, and as envisioned by Congress in incorporating the EHR Incentive Program into the American Recovery and Reinvestment Act, CMS is moving eligible hospitals (EHs) and (EPs) toward increased use of EHRs and a health care system that embraces interoperability. Some AAMC members are leaders in EHR adoption and use, while others are working diligently toward implementing their widespread use. The benefits of EHRs are well understood, especially as essential tools for improving patient care and managing population health. Yet, our members also appreciate the many challenges involved, particularly in complex academic environments that encompass clinical care, research, and teaching.

Furthermore, as you know, recent legislation calls for changes to meaningful use for physicians in the coming years. Specifically, the Medicare Access and CHIP Reauthorization Act of 2015 directs HHS to create a Merit-based Incentive Payment System (MIPS) that combines meaningful use with the existing Physician Value-based Modifier and Physician Quality Reporting System programs. To ensure coordination across programs and avoid duplicative or contradictory policies, we urge CMS to delay finalizing Stage 3 until the MIPS program has been designed. While MIPS only applies to EPs, it is important to keep the meaningful use requirements for hospitals and physicians aligned.

There are still many lessons to be learned from Stage 2, given that 2015 is the first year most providers will be meeting the Stage 2 requirements. According to the latest data from CMS, only 38 percent of hospitals and 11 percent of physicians registered for the EHR incentive programs met Stage 2 in 2014 (presentation to HIT policy committee, March 2015). In the spirit of a learning system, we believe that Stage 3 requirements, including the higher thresholds and more robust requirements for technology, should be built on evaluation of experience in Stage 2 by all providers, and not just those that are among the first adopters.

Our commitment to the successful use of EHRs and electronic exchange of health information remains strong. We believe that providing additional time for maturation of implemented technology and optimization to support meaningful use and other regulatory requirements is the right policy to keep all stakeholders focused on the activities that will support better quality care for patients and for populations.

#### **KEY RECOMMENDATIONS**

- Delay implementation of Stage 3 until sufficient experience with Stage 2 is reported and evaluated
- Coordinate implementation of Stage 3 with the MIPS program

- Finalize the proposal to align the hospital reporting period with the calendar year (CY), but only beginning in 2017
- Do not finalize the proposal that all providers be required to meet meaningful use Stage 3 in 2018, and provide additional flexibility for 90-day reporting periods
- Provide a group reporting option for EPs
- Do not finalize the proposal prohibiting paper-based formats from counting for certain measures
- Reconsider the significantly increased thresholds for a number of measures until more data is available from Stage 2
- Do not finalize the proposal to make electronic submission of clinical quality measures (CQMs) mandatory

## **ISSUES WITH THE STRUCTURE OF THE MEANINGFUL USE PROGRAM**

### **Aligning Hospital Reporting Period with Calendar Year**

In the Meaningful Use Stage 3 rule, CMS proposes to change the definitions of “EHR reporting period” and “EHR reporting period for a payment adjustment year” such that, beginning in CY 2017, the EHR reporting period would be a full calendar year. Under the current definition, eligible hospitals report on a federal fiscal year (FY) basis.

The AAMC supports aligning the hospital reporting period with the CY reporting period currently in use for EPs. However, as the Association will note in comments on the rule modifying Meaningful Use for 2015-2017, CMS should *not* implement mandatory CY reporting for eligible hospitals *prior to* CY 2017. Instead, for FYs 2015 and 2016, CMS should grant hospitals the option of choosing whether to report on a federal FY or CY basis. Hospitals have already made reporting plans and fiscal projections for these years. CMS should consider these years as an appropriate period of transition to calendar-year reporting.

Additionally, the AAMC urges CMS to clarify in the final rule whether and how a shift to CY reporting would affect an eligible hospital’s payment or penalty period. Final EHR payments for eligible hospitals are based on the 12-month cost reporting period for the hospital FY that starts after the beginning of the payment year. Therefore, during the transition in reporting period from FY to CY, hospitals with FYs beginning October 1 would benefit from an explanation as to which cost reporting period will be affected by which reporting period.

### **Requiring a Full-Year Reporting Period Each Year Beginning in 2016**

The AAMC strongly opposes the proposal to eliminate the 90-day EHR reporting period currently in place for new meaningful users beginning in 2017. CMS proposes to require a full CY EHR reporting period for all providers except for those in a first payment year who are eligible for the Medicaid EHR Incentive Program, who would remain eligible for a 90-day reporting period.

Since the Meaningful Use program began, CMS has consistently offered the flexibility of a 90-day reporting period for providers entering a new stage of meaningful use – and for good reason. A provider’s first year at a new stage of meaningful use necessarily comes with both technological and operational challenges, and the penalty stakes under this program are high. The AAMC also is concerned about vendor readiness issues, particularly in light of the fact that CMS is proposing to require *all* providers to attest to Meaningful Use Stage 3 at the same time in CY 2018.

Even in later years, when it may be appropriate to require a full year of reporting, the AAMC urges CMS to define “one full CY” with flexibility (i.e. less than 365 days), given that every EHR system has occasional downtime in the course of a year.

### **Requiring Stage 3 for All Providers in 2018**

The AAMC opposes the plan to require *all* providers to meet meaningful use Stage 3 requirements in 2018. This proposal changes the Agency’s prior plan to permit meaningful users who, by 2018, had not spent two years in either Stage 1 or Stage 2, to remain in that stage for a second year before transitioning to Stage 3.

As noted above, the AAMC urges CMS to delay Stage 3 implementation in its entirety, particularly given the lack of data on experience with Stage 2 and the fact that the MIPS program has not yet been designed. If the Agency decides to move forward to Stage 3 in 2018, however, the Association strongly opposes requiring all providers to meet the Stage 3 requirements that year. The AAMC acknowledges CMS’ attempt to move all providers toward common reporting requirements in the 2015-2017 modifications proposed rule. Nonetheless, all providers should have the benefit of progressing toward the more challenging Stage 3 requirements in a gradual and phased manner. Under CMS’ proposal, the very providers for whom meaningful use proves to be the most challenging will be forced to comply with the most difficult standards at the fastest pace. CMS has numerous ways the Agency could maintain alignment, while still recognizing the needs of new providers, such as: shortening the reporting period, providing more flexibility in the number of measures that have to be reported, or reducing the thresholds for the measures for later adopters.

### **Permitting Stage 3 as an Option in 2017**

CMS proposes that Stage 3 be optional for providers in 2017 and requests comment on whether to permit providers who are prepared to transition to Stage 3 by 2017 the option of doing so. As noted above, the AAMC urges CMS to delay Stage 3 implementation in its entirety. If, however, the Agency decides to move forward in finalizing a Stage 3 rule this year, AAMC supports the proposal to make Stage 3 an option in 2017 for providers who are prepared to advance to that stage. Having a cohort of early adopters advance to Stage 3 in 2017 could help identify issues or barriers before Stage 3 becomes required for all other providers the following year.

## **Hardship Exemptions**

As the EHR Incentive Program transitions from incentives to penalties, the AAMC strongly encourages CMS to consider additional hardship exemption categories, including providing an option for a provider who is on leave for all or part of a year for research or personal reasons to be automatically exempted from penalties.

## **Group Reporting Option for EPs**

While hospitals are measured at the organizational level, EPs are measured at the individual level. Measurement becomes complicated as providers change organizations. As the EHR Incentive Program shifts to penalties and the new MIPS program is designed, the AAMC recommends that CMS develop an EHR group reporting option that allows groups to document that their organization is meaningfully using an EHR system.

## **OVERARCHING ISSUES RELATED TO OBJECTIVES AND MEASURES**

While the AAMC has concerns about the feasibility and structure of some specific measures, the Association generally supports CMS' efforts to simplify and align the reporting objectives and requirements for hospitals and EPs and to remove redundant measures. The following outlines AAMC comments on the overarching proposals related to the objectives and measures.

### **Eliminating "Topped-Out" Measures**

The AAMC supports CMS' approach to eliminating "topped-out" measures. CMS proposes to eliminate from the meaningful use program certain "topped out" measures for which performance among providers is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. Under the Agency's proposal, CMS will evaluate whether a measure is topped out using the following criteria: (1) statistically indistinguishable performance at the 75<sup>th</sup> and 99<sup>th</sup> percentile, and (2) performance distribution curves at the 25<sup>th</sup>, 50<sup>th</sup>, and 75<sup>th</sup> percentiles as compared to the required measure threshold.

### **Eliminating the Option to Include Paper-Based Formats for Certain Objectives and Measures**

The AAMC strongly objects to the proposal that paper-based formats (e.g., print, fax, mail) would not be required or permitted for the purpose of meeting Stage 3 meaningful use objectives and measures, even though it was permitted for Stages 1 and 2. Despite the "strides that providers have made in the use of Certified Electronic Health Record Technology (CEHRT)" that CMS discusses, many patients still have a preference for paper-based versions of documents such as clinical summaries and educational materials. Providers who fully meet patient

preferences by supplying these materials in a paper-based format should be given credit under the meaningful use program for engaging with patients in ways the patients prefer.

### **Including Patient-Authorized Representatives in Numerators of Certain Objectives**

The AAMC supports the proposal to include patient-authorized representatives in the numerator of the Coordination of Care through Patient Engagement and Patient Electronic Access objectives, in the same way the patient is included in the numerator. In the proposed rule, CMS acknowledges that patients often consult with and rely on trusted family members and other caregivers to help coordinate their care, understand health information, and make health care decisions. The AAMC appreciates CMS' recognition of the important role patient-authorized representatives play in managing patient care.

### **ISSUES RELATED TO SPECIFIC OBJECTIVES AND MEASURES**

CMS proposes to realign the meaningful use measures into eight objectives. The first four objectives are similar to existing Stage 2 measures; while the last four focus on exchanging and interfacing electronically with data.

#### **Objective 1: Protect Electronic Health Information**

The AAMC agrees with the importance of protecting electronic health information and supports retaining a measure for a risk analysis.

#### **Objective 2: Electronic Prescribing**

CMS proposes separate requirements for EPs and hospitals. For EPs, CMS proposes to increase the threshold for e-prescribing from 50 percent or more to 80 percent. For hospitals, CMS proposes to make the measure mandatory (previously it was a menu option), to remove the requirement to e-prescribe for refills, and to increase the threshold to 25 percent.

The AAMC opposes the requirement to increase the thresholds for hospitals and EPs. In the proposed rule, CMS states that the Agency selected the 80 percent threshold for EPs, because the median performance is 89 percent for Stage 1 and 92 percent for Stage 2. However, the AAMC believes that the median is not the most relevant rate to consider. Rather, CMS should be evaluating those hospitals and EPs that are below the median to see if there are barriers to reporting. For example, some pharmacies do not accept eRx and, again, some patients prefer paper.

The AAMC is also opposed to the proposed threshold increase for hospitals, which are shifting from a menu set measure to a core measure and should have time to gain experience with eRx before facing an increased threshold. AAMC supports the recommendation to remove refill prescriptions from the requirement.

### **Objective 3: Clinical Decision Support**

The two measures under clinical decision support (CDS) have not changed from Stage 2, other than that CMS clarified the definition of CDS. AAMC agrees with the proposed broader definitions for CDS.

### **Objective 4: Computerized Provider Order Entry**

The AAMC is concerned about proposed increases to laboratory and diagnostic imaging – going from 30 percent in Stage 2 to 60 percent in Stage 3. There are two reasons to urge caution. First, CMS has very limited experience with providers reporting Stage 2. Second, CMS is broadening the application of the requirement from radiology orders only to encompass diagnostic imaging orders. Such a change should come with a lower threshold.

The Computerized Physician Order Entry (CPOE) requirement calls for orders to be entered by licensed health care providers or certified medical assistants. However, as will be explained, some medical residents fall into neither category. For example, in Utah residents are not provided with any license—relying instead on the supervision requirements of an approved residency program and the hospital’s by-laws—until they have completed a portion of their residency. Residents in these states would be prevented by CMS from entering orders despite the fact that doing so is a necessary part of their training and is part of the established workflow. The Association also asks CMS to explicitly recognize that residents in approved residency programs are qualified to enter CPOE.

### **Objective 5: Patient Electronic Access to Health Information**

While the AAMC remains firmly committed to providing patients access to their electronic data, the Association believes the measures related to patient electronic access to health information need to be revised. The purpose of the objective is to provide patients with timely access to information related to their care. Providers support giving patients access to their health information and are required to do so under the Health Insurance Portability and Accountability Act. However, the measures under this objective are flawed in several ways including the following:

- Requiring EPs and hospitals to provide access to patient information within 24 hours is unrealistic at this time. The Stage 2 requirement is for EPs to provide access within four business days and for hospitals to provide access within 36 hours of discharge. The 2015-2017 modifications proposed rule retains the current stage 2 requirements and should remain in effect until a sufficient number of EPs and hospitals successfully attest to this measure and there is ample evidence that moving to 24 hours is reasonably achievable

- The threshold for using clinically relevant information from CEHRT to identify and provide access to patient-specific educational resources should remain at the current Stage 2 and 2015-17 modifications level of more than 10 percent of patients. Providers also must be allowed to count both paper and electronic communication, depending on the patient's preference. While the AAMC recognizes CMS' desire to encourage providers to increase the use of electronic information, what must remain of utmost importance is the best way to get patients information in a format that they will use. Just as EPs and hospitals must respect patients treatment choices, so too must they be permitted to respect the patient's choice of the most usable format for the information without fear of penalty. Additionally, EPs and hospitals should continue to be allowed to count that information whether or not it is in electronic form. If providers move ahead of patients' preferences, the danger is that patients will not access or use any of the information that is made available

### **Objective 6: Coordination of Care through Patient Engagement**

The AAMC continues to object to measures that require actions by the patient, because providers have no ability to control those actions. This objective focuses on encouraging the use of EHR functionality for secure dialogue and efficient communication between providers, care team members, and patients. Each of the three measures in this objective requires a significant number of patients to access information through electronic means as follows:

- Measure 1: More than 25 percent of patients must download or transmit their health information to a third party
- Measure 2: More than 35 percent of patients must be sent secure message electronically
- Measure 3: Provider must incorporate patient-generated health data from a non-clinical setting into the EHR for more than 15 percent of patients

All measures represent a significant increase from the current requirement that more than 5 percent of patients be sent a secure message, and also from the proposed 2015-2017 modifications which require only a yes/no attestation that the EP has fully enabled the CEHRT's capability for patients to send and receive a secure electronic message. Meeting the Stage 2 measure has been a struggle, and there is no evidence that hospitals or EPs will be prepared to meet these higher thresholds. Should CMS finalize these measures, the AAMC strongly opposes the large increases in the thresholds.

Furthermore, the AAMC urges CMS not to apply Measures 2 and 3 to hospitals, as patients are unlikely to actively engage with hospitals about their health concerns after discharge, nor are they likely to send or receive messages from them regarding their health information. Even when a patient receives care at a hospital, their engagement on these issues is through their physicians or other providers, not through the hospital.



The AAMC and our members have many concerns about Measure 3, which requires that patient-generated health data or data from a non-clinical setting be incorporated into the CEHRT. CMS has asked for feedback on a number of issues, all which must be resolved before this measure is adopted. AAMC members have voiced a number of concerns, including the following:

- In many electronic systems, patients access health information through a portal. It is unclear how patients would submit data when many portals do not yet possess that functionality. Related concerns include:
  - While the technology exists in many forms to gather data from patients, the ability to integrate this information into a CEHRT remains immature
  - CMS must ensure that the definition of patient-generated data is consistent with the interface technology supported by vendors
  - It is unclear how providers would best incorporate external data into clinical workflows. There is potential for patients to enter overwhelming amounts of data into the record, and each type of data would likely need a specific workflow build
  - There must be an understanding of the medico-legal risks to an institution or an EP if this information is incorporated into a medical record. For example, if the provider fails to pick up on a health issue that could potentially be identified through patient-submitted data, would the provider incur liability?
  - Among some patient populations, there are significant problems with health literacy levels. The ability of the CEHRT to make this functionality available in the patient's preferred language is also a concern

### **Objective 7: Health Information Exchange**

This objective seeks to ensure that a summary of care document is transmitted or captured electronically and incorporated into the EHR for patients seeking care among different providers, and to encourage reconciliation of health information for the patient. The three measures apply to EPs and hospitals and are as follows:

- Measure 1: For more than 50 percent of transitions of care and referrals to another care setting or provider, a summary of care must be created and electronically exchanged using CEHRT
- Measure 2: For more than 40 percent of new patient encounters, an electronic summary of care document from a source other than the provider's EHR system must be incorporated into the patient's EHR
- Measure 3: For more than 80 percent of transitions of care or referrals for new patients, a clinical information reconciliation must be performed

The AAMC urges CMS not to finalize the proposed thresholds, as they are far too aggressive. CMS also should modify Measures 2 and 3 so that they make no distinction between new patients and established patients, as the burden of tracking this information is enormous.

## **Objective 8: Public Health Reporting**

Objective 8 focuses on the importance of the ongoing lines of communication that should exist between providers and public health agencies and between providers and clinical data registries. The Agency proposes to measure this activity by requiring hospitals and EPs to report to a variety of registries and/or public health agencies.

This objective is very challenging for a number of reasons, including that not all public health departments can receive data, and qualifying for an exception requires that all measures be exhausted. It also must be noted that Measure 1 calls for bidirectional data exchange, but the technology for this type of data exchange remains immature.

This objective is especially challenging for faculty practice plans, which typically have many more specialists than primary care physicians. Issues identified by AAMC members include:

- CMS needs to provide additional clarity regarding the definition of a clinical data registry. In addition, CMS should release a list of approved or recommended registries that meet these criteria.
- For a large group practice, CMS should allow all physicians to attest to the measure as long as the group participates as an organization in the selected registries. For example, if each physician were required to participate, one AAMC member estimates that it would have to set up 50 or more registry feeds, which is administratively burdensome and costly.
- Reporting frequently occurs through primary care specialties, but faculty practice plans typically have a large number of specialists. Specialty registries cover a limited patient base and therefore would work for only a limited number of specialty physicians.

## **ISSUES RELATED TO CLINICAL QUALITY MEASURES (CQM)**

### **Mandatory Electronic Submission**

The AAMC strongly opposes the proposal that providers participating in the EHR Incentive Program be required to electronically report clinical quality measures (eCQM) starting in CY 2018. The AAMC appreciates CMS' goal of transitioning towards greater electronic reporting of clinical data and overall further alignment between CQM reporting and hospital and EP quality reporting; however, the Association strongly believes that a mandatory electronic data reporting requirement is impractical and unworkable at this time. The AAMC continues to have serious feasibility and validity concerns with the use of electronic measures and urges CMS to take a more stepwise approach to implementing such an expansive and burdensome requirement at a time when providers are sufficiently prepared to meet it.

Major teaching hospitals and faculty practices, leaders in EHR implementation, face serious roadblocks to electronic data submission. Through discussions with our member institutions, we

have heard that the process to map the necessary data elements to the appropriate Quality Reporting Data Architecture (QRDA) format requires considerable resources and is a significant burden on staff. We have also heard reports that data vendors are not properly equipped to collect and transmit such data through the CMS portal. Additionally, the mandatory eCQM requirement forces hospitals and EPs to have the correct version of specifications, something that is in the control of EHR vendors, not providers. These roadblocks to satisfactory reporting also extend beyond the providers' capabilities. On May 22, 2015, CMS distributed a communication to hospitals through its inpatient listserv that the eCQM Receiving System had experienced two new errors:

- The Submission Summary, Detail, and Performance Feedback Reports contained improper data and had been disabled, and
- The CMS measures engine is not counting some QRDA Category 1 release files accurately and will not be fixed until July 2015.

All nascent reporting systems experience such glitches at a much higher rate than more established processes. Maintaining a voluntary e-measure submission process ensures that such problems are limited only to those reporting eCQMs, who are also typically better equipped to adapt to such issues as they arise. To address all of these concerns, the AAMC strongly recommends that the Agency reach out to EHR vendors, hospital quality staff, and other affected stakeholders to identify underlying structural problems and barriers to reporting these measures.

In addition to the feasibility concerns, AAMC member institutions have reported that e-measure output does not match that of similar chart-abstracted data. Before any electronic submission requirement is enacted, CMS must ensure that a robust validation process is in place and should establish a process for hospitals to review their data and correct any errors.

In the interim, the AAMC urges CMS to continue to allow reporting of CQMs via attestation, until these barriers to electronic submission are addressed. While mandatory electronic submission of CQMs is premature, we encourage the Agency to take additional action to further align the EHR Incentive Program with other hospital and EP program requirements.

### **Updated CQM Reporting Requirement through Annual Rulemaking**

The AAMC supports the proposal to address changes to CQM reporting requirements for hospitals and EPs through the Inpatient Prospective Payment System and Physician Fee Schedule annual rulemaking cycle. Including CQM in these programs allows the Agency and hospital and physician stakeholders to analyze all reporting requirements holistically. CMS should consider, however, the time it takes for vendors to develop and for providers to implement any necessary changes.

Acting Administrator Slavitt

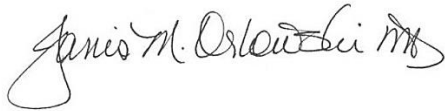
May 29, 2015

Page 12

**CONCLUSION**

Thank you for the opportunity to present our views. If you have any questions concerning these comments, please feel free to contact Ivy Baer, at [ibaer@aamc.org](mailto:ibaer@aamc.org) or at 202-828-0499.

Sincerely,

A handwritten signature in black ink that reads "Janis M. Orlowski MD". The signature is written in a cursive, flowing style.

Janis M. Orlowski, MD, MACP  
Chief Health Care Officer  
AAMC

cc: Ivy Baer, AAMC  
Lori Mihalich-Levin, AAMC  
Scott Wetzel, AAMC  
Mary Wheatley, AAMC