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

RE: Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Modifications to Meaningful Use in 2015 Through 2017 [CMS-3311-P]

Dear Acting Administrator Slavitt:

The American College of Cardiology (ACC) is pleased to submit comments on the proposed rule, *Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Modifications to Meaningful Use in 2015 Through 2017* [CMS-3311-P]. The ACC is a 49,000-member medical society that is the professional home for the entire cardiovascular care team. The mission of the College is to transform cardiovascular care and improve heart health. The ACC leads in the formation of health policy, standards and guidelines. The College operates national registries to measure and improve care, provides professional medical education, promotes cardiovascular research and bestows credentials on cardiovascular specialists who meet stringent qualifications. The *Journal of the American College of Cardiology* (JACC), which publishes peer-reviewed research on all aspects of cardiovascular disease, is the most widely read cardiovascular journal worldwide. JACC is ranked No. 1 among cardiovascular journals worldwide for its scientific impact. We appreciate the opportunity to respond to the government's proposal.

Key recommendations:
The ACC is a long-time supporter of EHR adoption as a driver of improved patient care quality. Because impeded health information exchange can negatively affect the quality of patient care as much as continued reliance on paper records, the ACC recommends that the Centers for Medicare and Medicaid Services (CMS):
• Issue a final rule as quickly as possible
• Adopt the proposed 90-day reporting period for 2015
• Grant participants as much flexibility as is feasible by expanding hardship exemptions
• Provide a 90-day reporting period option for first time meaningful users in 2016 and 2017 and for participants reporting to a new stage of the program
• Reconsider the constricting requirements of the Public Health Objective

Overall, the College applauds the Administration for proposing a number of changes which aim to remedy the concerns stakeholders have been voicing about the Meaningful Use (MU) program as of late. These proposals will allow providers the opportunity to achieve the levels of meaningful use of EHRs in the 2015-2017 reporting years that they have worked towards since joining the program along with those who are just joining the program. The modifications proposed lay a framework for progress towards a program

structure that allows for the broad adoption and improved use of health IT leading to interoperable health information exchange.

Of the utmost importance is the need to issue a final rule as quickly as possible due to the timing of this proposed rule. There are many decisions that need to be made based on the deadlines for implementing the proposed objectives and measures of Stage 1 and Stage 2. To help facilitate the decision-making process**, the ACC urges the Centers for Medicare and Medicaid Services (CMS) to finalize this rule in an expeditious fashion**. By the time a final rule is issued, it will be August or September, not long before the end of the participation window for program participants. CMS must act quickly to provide EPs and EHs with as much information as possible, so they can assess their options with a degree of certainty.

The ACC is extremely relieved to see CMS' response to our July 11, 2014 and December 15, 2014 letters, where we called for the 2015 reporting period to be reduced from a full year to 90 days to reflect the time of transition providers find themselves in. Given the difficulties that providers experienced in 2014, and continue to experience in 2015, along with the inability of many EPs and EHs to meet the requirements for Stage 2 in 2014, **the ACC strongly supports the proposed change and hopes the 90-day reporting period proposed is an indicator that CMS recognizes that 2015 is also a transitional year**. The shortened reporting period would afford EPs and EHs additional time to develop the external relationships required to achieve some of the objectives and measures, while also allowing for additional training time, workflow adjustments and the other components of EHR implementation that affect the quality of patient care. EHRs have tremendous potential to assist in improving the quality of patient care, but only if adopted and implemented properly. Improper EHR implementation can be as bad as or worse than not implementing an EHR for patient care, so it is crucial that it is done properly and not rushed. Penalizing EPs and EHs that have done everything they can do to meet the requirements, and yet, are unable to do so would only send the wrong message and punish them for actions beyond their control.

While the College greatly appreciates the shortened reporting period proposed for 2015, we remain unconvinced that significant numbers of EPs and EHs will be able to meet the subsequent proposed revisions to Stage 2 objectives and measures for a full year in 2016 or 2017. Thus, **the ACC recommends that CMS continue to allow first-time meaningful users the ability to attest with any continuous 90-day EHR reporting period in calendar years 2016 and 2017.** Providers should not continue to be punished for not being among the first-adopters of EHRs and should in turn be provided an adequate chance to begin their journey towards achieving meaningful use. **The College also recommends that CMS extend the 90-day reporting option to any program participant in their first year of a new stage.**

Furthermore, the College urges CMS to broaden the hardship exemptions available to program participants. This would include the adoption of a hardship exemption for providers switching EHR vendors, an exemption for providers experiencing ICD-10 conversion issues, and an exemption allowing providers to take a 90-day reprieve during any program year for upgrades, planned downtown, bug fixes related to new technology or optimizing the use of new technology within new workflows. It is of great concern to the College that switching program requirements for 2015 mid-year will create confusion and added difficulty for physicians who have begun discussions for acquisitions of new technologies along with the related workflow changes implemented to meet current measures. This coupled with the value-based payment program, the Physician Quality Reporting System, the ICD-10 implementation and the pending Merit-Based Incentive Payments System (MIPS) rollout further complicate reporting requirements

Despite the request for additional hardship exemptions, **the College recognizes and appreciates the Administration's efforts to reduce program complexities by streamlining the MU requirements.** The ACC supports the proposal to consolidate the program requirements and in turn provide a path where physicians can foresee achieving the lofty Stage 3 objectives proposed in the *Federal Register* on March 30 of this year. This includes supporting the elimination of the distinction between core and menu objectives, alignment of the reporting period across all program participants, and the removal of attestation requirements tied to measures that are redundant, duplicative, or topped out. The College's providers who are program participants have continued to struggle when navigating the complex structure and requirements and the College portends that the proposed establishment of a single, aligned reporting period for providers based on the calendar year, will indeed assist the providers somewhat in understanding which 12 month reporting period pertains to them and can allow the participants to more easily consult with others and to receive applicable guidance when progressing through the program.

Given the complexities associated with the current EHR Incentive program structure and the additional workload it will impose on providers to attain the proposed program changes**, the ACC supports CMS' proposal of a later attestation deadline to accommodate the effective date of the final rule**. When considered altogether, EPs and EHs are facing a long and complex process to implement not only new 2014 Edition CEHRT, but also new Stage 1 and Stage 2 requirements. In conjunction with this proposal, **the ACC respectfully but resolutely requests that the Administration provide widespread education on the possible ramifications of this change given that new participants may be subject to a payment adjustment on claims submitted prior to attestation.**

A critical component to the success of the EHR incentive program is physician participation. The CMS have launched extensive physician education campaigns to encourage physician adoption of EHRs, and the ACC applauds these efforts. However, this process is not complete. As suggested, CMS will need to continue physician outreach and education programs as they unveil these critical modifications of the program at such a late phase in the reporting year. The CMS must be prepared to provide continuous education on these modified stages, recognizing that physicians will choose to adopt and implement EHRs at different points in time. **The ACC urges CMS to work closely with the physician community to ensure that the educational materials address all of the potential questions and concerns.** As representatives of the parties directly affected by the incentive program, physician organizations such as the ACC are best suited for assisting CMS in preparing these materials and disseminating them to physicians.

Objectives & Measures

It continues to be of concern to the College that the proposal further requires all program participants to meet the advanced objectives proposed. Consolidation of previously individual objectives ignores the multiplier effect that occurs when combining requirements. The operational burden of a given objective is not equal to the sum of the individual components of that objective. Instead, it is a compounded burden – the burden related to each of the individual components, plus the effect of the compound objective. A compound objective does not eliminate the burden associated with the individual components. While the program structure has long been overly complex, combining all participants onto the same stage will not automatically result in continued program success. **Because of the increased demands proposed, the College urges CMS to discontinue the pass-fail approach of the EHR Program and transition to assessing achievement on a sliding scale so participants can be provided credit for partially meeting performance thresholds.**

In this case, it is also worrisome that providers have already been working in the existing program's construct and they would be provided insufficient time to be educated on changes provided in the final rule. Interjecting changes at this time could yield unintended consequences and severely jeopardize providers' abilities to successfully participate. **Given the different structured proposed for 2015 and 2016, the ACC suggests that for 2015, the program keep the current Stage 1 and Stage 2 measures while still adopting the 90-day reporting period and modifications to patient electronic access, secure messaging, and summary of care objectives and in turn making the public health objective optional. For 2016 and 2017, the College suggests adopting the proposed modified version of Stage 2 along with our proposed extension of 90-day reporting periods for first time meaningful users and those participating at a new stage, and our proposed expansion of hardship exemptions.**

Protect Electronic Health Information

The ACC supports the continued inclusion of Protect Electronic Health Information as a required objective including the requirement to perform security risk analyses. The College suggests that CMS establish an educational campaign to help physicians better secure and protect patient information in a digital world to reduce the likelihood of breaches. This would help program participants to better understand the importance and utility of the administrative, physical, and technical safeguards which are required to be implemented.

Clinical Decision Support (CDS)

The College supports this objective as it is proposed. CDS can assist physicians in many ways. It is important to significantly increase clinical decision support (CDS) in EHRs as it relates to clinical data registry reporting. Not only is it important to give prompts to providers about appropriate lack of compliance with performance measures, but also to give them the functionality to order or change medications, laboratory tests, and diagnostic imaging studies within that same tool.

Computerized Provider Order Entry (CPOE)

In the proposed rule the Agency clearly recognizes that medical orders are frequently given verbally by physicians, rather than directly entered into a patient's medical record. This, in many ways, is due to the need for a direct action to occur as a result of the order. Left alone in the medical record, it may end up ignored or forgotten. When given verbally to another individual, the physician can be assured that a follow-up action will occur. The individual who receives the order is the one who takes those next steps and would be in the best position to enter the order into the medical record, whether the record is on paper or electronic. Additionally, there are many demands on a physician's time, and the patient is not always best served if the physician has to stop what he or she is doing to physically enter the order into the electronic record, especially if it will have to also be handwritten or called into someone else. In some settings, CPOE may not easily fit into the workflow, especially as the first record of the order in the patient's medical record. CPOE may interfere with the ability of patients to conduct price comparisons for imaging or lab tests ordered by physicians if they are required to immediately inform the physician where they intend to have those tests performed. **Given this, the ACC urges CMS to allow scribes and other non-licensed personnel to physically enter an order into the EHR, rather than requiring it be done by licensed personnel.**

Electronic Prescribing (eRx)

The ACC has long acknowledged the benefits of e-prescribing and encouraged cardiovascular specialists to adopt this technology. In order to continuously advance the MU program's goals, ACC members have voiced that it would be ideal to have medications prescribed flow automatically to clinical data registry fields that correspond to the medication in question. For example, a patient that is discharged after a myocardial infarction (with coronary artery disease)

on aspirin, a P2Y12 inhibitor, beta blocker, angiotensin-converting enzyme (ACE) inhibitor, and high intensity statin, it would be highly beneficial to have data fields automatically populated.

Summary of Care

The College is encouraged by CMS' proposed change to this objective. Simplifying this objective to allow for the creation of the document within CERHT along with electronic transmission of the document and thus removing the requirement that the document be transmitted in a specific manner allows for the industry to build upon the work that has already occurred in this sphere. **Although various methods of electronic transmission exist, the ACC agrees that this will help reduce interface costs charged by vendors to transfer data and thus supports the proposed requirement of this objective.**

Patient Specific Education

The ACC supports the continued inclusion of Patient Specific Education Resources as a required objective. In order to fully participate in making decisions pertaining to their own care, patients must be sufficiently educated regarding their disease or condition and various treatment options. For this requirement to improve patient care, the patient-education resources must be relevant to the individual patient and the specialty of the treating physician. General educational resources, such as information on the importance of annual flu shots, are less helpful and do little to educate patients regarding their own health. It is critical that the materials provided are at appropriate literacy and cultural competency levels for individual patients. **The ACC urges CMS to work with medical specialty societies such as ACC and educational material vendors to identify materials appropriate for these purposes.** The ACC is firmly committed to the provision of such materials to assist communications between patients and physicians.

In 2008, as a result of the ACC's commitment to patient-centered care and response to the lack of accurate, authoritative patient resources related to cardiovascular disease, the College launched CardioSmart.org, a patient-facing website providing educational materials on cardiovascular disease and associated conditions along with relevant therapies and treatment options. Cardiovascular specialists are encouraged to direct their patients to these resources, where they can also find mobile apps and online programs to help them live more fully with their condition. The CardioSmart.org website incorporates interactive information and tools to better engage patients in understanding their health and working with their cardiac care team. It is also the primary dissemination point for ACC's shared decision making tools, which offer evidence-based decision aids to help patients better understand their preferences for care in light of the risks and benefits associated with their care options. The ACC has also partnered with a number of patient advocacy organizations to expand its reach for content dissemination so that patients throughout the United States have more effective and higher quality conversations with their physicians and participate more actively in their care.

In addition to the website, the CardioSmart brand also hosts a text messaging service for which patients can register to receive text messages with practical tips, advice and reminders to prevent heart disease and to stop smoking. The ACC has also developed a CardioSmart app, a virtual anatomical model of the heart, available for iPad users, to assist cardiovascular specialists in educating patients about their condition at the point of care. There are a number of medical specialty societies that have developed patient-facing websites and educational materials. **The ACC urges CMS to work with physician organizations and EHR vendors to ensure that patients are receiving accurate educational materials pertaining to their individual needs and concerns.**

Medication Reconciliation

The ACC believes the proposed measure exclusion for EPs and EHs is appropriate, and we support the continued inclusion of Medication Reconciliation as a required objective.

Patient Electronic Access (VDT)

While the ACC continues to reject any requirements that place accountability for patient behavior beyond what a clinician or healthcare provider can control, the College strongly supports the right of patients to have access to their health information in a timely fashion and understands the importance of ensuring that patients understand their diagnoses and conditions. The ACC would caution the increase of thresholds for this objective, though, as the program matures. This is due to the inability of physicians to force patients to enroll in their online portal, and thus their inability to transmit a patient's information electronically until the patient has enrolled in the portal. Those who already have portals have experienced difficulties enticing patients to enroll in them. Thus, what will occur is that organizations that can afford to do so will hire staff whose sole job will be to sit in the lobby or waiting room and sign patients into their electronic records. Of course, if patients will not even enroll in the portal, the likelihood of them actually using it to access their information is fairly slim. As the health IT industry continues discussions of how best to engage the patient through technology, the College calls upon CMS to think more innovatively around the concept of patient engagement, how to differentiate between those that do it well and those who do not, and how to incentivize low-tech groups.

In order to engage a broader audience, the ACC would suggest that CMS expand the opportunities to engage beyond the patient portal and view/download/transmit construct provided; leverage ONC's privacy toolkit to unlock data that was previously difficult to obtain due to unnavigable privacy laws and guidelines; and increase the usability of patient engagement tools.

Secure Messaging

The College supports and applauds the change to this objective and the continued inclusion of Secure Messaging as a required objective for EPs. Physicians cannot continue to be held responsible for their patients' decisions regarding preferred methods of communicating with their physicians and their office staff so the modification to lower the threshold so patients need only be provided access is highly desirable for the College.

Public Health and Clinical Data Registry Reporting

Clinical Data Registry Reporting remains challenging in 2015. There is a scarcity of specialty registries available for EP to report to and their number and affordability needs to increase. While ACC's Pinnacle is a well-developed registry for cardiology, even at this time directly reporting through the EHR is not supported with any vendor. It is likely that by the end of the year prevalent vendors such as Epic may permit direct registry population. That being said, we would caution CMS on the timeline for this required objective. Given that reporting remains challenging and can act as a barrier to participation, mandating participation can cause an unprecedented surge in registry enrollment which on the surface seems like a good problem to have. However, the time necessary from engaging an appropriate registry, to executing a contract, to achieving active engagement, is by no means an expeditious process.

Before finalizing this requirement **we would strongly urge CMS to consider the many months it can take to finalize agreements and the time it will take for registries to adapt to this influx, again, preventing providers from being penalized for actions outside of their control**. Furthermore, this mandates an increased number of requirements without addressing how a physician, who is reporting through a CDR, may receive credit for MU quality requirements and PQRS. While we appreciate and are supportive of CMS allowing physicians to meet some of their MU requirements through these population and public health activities, we believe the mandate is premature. **The ACC recommends CMS make the requirement for PHA or CDR reporting optional in 2015-2017 given the lack of notice for this new**

requirement. Again, we do not disagree with the approach, but we also do not believe it will be easily implemented with such little time between finalization and the beginning of the last 90-day reporting period, October 1, 2015. Additionally, the College is encouraged by CMS' proposed removal of the prior "ongoing submission" requirement and replacing it with an "active engagement" requirement.

Although CMS proposes exclusions for each PHA/CDR measure, the ACC does not feel that these exceptions are sufficient for this new requirement. For example, the proposed exclusion pathways associated with the measure and the requirement for bi-directional exchange for immunizations registries go beyond what current Stage 2 requires. This is a concern because such capabilities are not currently available in most certified EHR vendor systems, and the bi-directional functionality was not required in the 2014 Edition certification criteria for public health reporting. Therefore, the College asks that the final rule specify that bi-directional messaging be postponed to MU Stage 3.

However difficult CDR integration into the MU program may be, the ACC and its members are committed to furnishing high quality care to patients diagnosed with cardiovascular diseases or conditions. One of the best ways to do this is through the collection of data using specialized registries. **The ACC applauds CMS and ONC for including reporting to public health and/or clinical data registries as one of the objectives**. We believe this objective should seek to ensure that physicians participate in registries that are truly committed to increasing the quality of patient care. **To that end, the ACC recommends that CMS include registries that meet the following specifics in the proposed centralized repository of national, state, and local PHA and CDR readiness:**

- Demonstrate an adequate organizational structure that is multifunctional, unbiased, HIPAA-compliant and representative of relevant parties
- Employ evidence-based science with standardized data elements and definitions that are developed with input and consensus among national experts, then made publicly available and used for national benchmarking purposes
- Include built-in rigorous data quality procedures to ensure accuracy by providing training and education, conducting auditing, developing completeness requirements, and requiring the entry of consecutive patients
- Offer timely support services and training to participating sites, including best practices on incorporating data collection into their workflow

Cardiovascular specialists have been among the most prominent supporters of registries. Through the use of registries, much has been learned about cardiovascular care. Studies of data gathered from cardiovascular registries have been used to identify strategies for improving the quality of care for cardiovascular patients. For many years, the National Cardiovascular Data Registry® (NCDR®) has been focused on the collection of data from hospitals. Data abstractors input the information into the registry from hospital records. This requires additional time and resources on the part of participating hospitals, but they also gain the quality and benchmarking data that they would not otherwise be able to obtain.

Certified EHR Technology (CEHRT)

CMS proposes no further changes to the definition of CEHRT in this proposed rule and they reiterate that providers must use EHR technology certified to the 2014 Edition for an EHR reporting period in 2015, an approach with which the ACC agrees.

Clinical Quality Measurement (CQM)

The ACC supports CMS' proposals relating the clinical quality measurement including maintaining the existing requirements established in earlier rulemaking for the reporting of CQMs, including requirements for 9 CQMs covering at least 3 National Quality Strategy (NQS)

domains for EPs and 16 CQMs covering at least 3 NQS domains for hospitals. CMS also proposes a 90-day reporting period for CQMs for all providers. CMS adds that it would be acceptable for a provider to use a continuous 90-day reporting period for CQMs even if it is different from their continuous 90-day EHR reporting period for the meaningful use objectives and measures if that provider is reporting via attestation. CMS says professionals seeking to participate in multiple programs with a single electronic submission, such as PQRS and MU, would be required to submit a full calendar year of CQM data using the 2014 electronic specifications for CQMs for a reporting period in 2015.

Conclusion

The ACC believes the Administration should be commended on their efforts to adjust the EHR Incentive Program in response to the wide-ranging issues stakeholders have voiced to them. Providing the appropriate modifications to a program this far into the reporting year is not an easy feat and the College recognizes the amount of thought and work that went into the development of this proposal. The College appreciates the opportunity to furnish input on this important issue and looks forward to the prompt issuance of the final rules. We would welcome the opportunity to discuss this and other relevant issues with CMS. Please direct any questions or concerns to Julie Brown at (202) 375-6351 or jbrown2@acc.org.

Sincerely,

Kim Allan Williams, Sr., MD, FACC, FAHA, FASNC
President