May 29, 2015

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services
Attention: CMS–3310–P, Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3

Dear Administrator Slavitt:

The Heart Rhythm Society (HRS) appreciates the opportunity to comment on CMS' proposals related to Stage 3 of the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program and associated Meaningful Use (MU) criteria. HRS is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients, and the primary information source for heart rhythm disorders. We represent more than 5,300 specialists in cardiac pacing and electrophysiology, including physicians, scientists and their support personnel, who perform electrophysiology studies and curative catheter ablations to diagnose, treat and prevent cardiac arrhythmias.

Overarching Comments on the Move to Stage 3

HRS remains committed to improving the quality and efficiency of heart rhythm care through the adoption and meaningful use of health information technologies. This is an exciting time for electrophysiologists (EPs), in part due to CMS' efforts to advance electronic health records (EHRs), as well as efforts by the EP community to advance interoperability standards for various implantable cardiac and heart rhythm devices and other EP procedures that support improved the quality of EP performance, patient care and remote monitoring, and clinical research.

Success of CMS' efforts are evidenced in a recent data brief from the Office of the National Coordinator for Health IT (ONC), *ONC Data Brief, No. 16, Adoption of Electronic Health Record Systems among U.S. Non-federal Acute Care Hospitals: 2008-2013,* which found that hospital adoption of EHR systems has increased more than five-fold since 2008, and that 9 in 10 hospitals possessed a certified EHR technology in 2013, increasing 29% since 2011.[1] Similarly, a data brief from the National Centers for Healthcare Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC) in its *NCHS Data Brief, Number 143, January 2014, Use and Characteristics of Electronic Health Record Systems Among Office-based Physician Practices; United States, 2001-2013,* shows that 78% of office-based physicians used any type of electronic health record (EHR) system in 2013. The data brief also notes that, in 2013, 69% of office-based physicians reported that they intended to participate (i.e., they planned to apply or already had applied) in "meaningful use" incentives.

[1] http://www.healthit.gov/sites/default/files/oncdatabrief16.pdf

Despite the positive momentum, we question the value of the current meaningful use criteria for heart rhythm care. For clarity, consider the excerpt below by two practicing EPs, Drs. Raman Mitra and Michael Mirro, who describe the role EHRs could play in a managing a serious, resource-intensive heart rhythm condition – atrial fibrillation – which consumes a significant proportion of Medicare spending on heart disease:

> *"As ablation for atrial fibrillation improves in both efficacy and safety, we may see a short-term paradoxical increase in the cost of treating such patients with increased use of ablation, and the true long-term economic benefits may not be seen unless such patients are followed for a decade or more in properly designed registries that would reflect whether reductions in arrhythmia, hospitalizations, strokes, heart failure, and death translate into lesser economic burden of this disease. This is certainly an area where well-designed EHRs can help in obtaining such long-term data. Unfortunately, even current EHRs that are geared toward primary care physicians will require significant sophisticated enhancements and customization to accurately track more complex disease management in fields like cardiology."*[2]

We continue to believe that the meaningful use criteria do not address the needs of patients with heart rhythm disorders or our physician members caring for them. We do not yet have data on how specialty providers have been impacted by prior stages of meaningful. This is hampering efforts to plot a new course for an improved EHR program. Patient safety and usability concerns have not been fully addressed, leaving providers without an appropriate level of confidence in available systems. Interoperability standards, critical to the success of advanced health information exchange in Stage 3 must be identified, mandated and incorporated in certification criteria. A single governing body is needed by stakeholders to serve as the authority on data element definitions and interoperability standards. EHRs and other data repositories must then be required to meet these standards so that data may be entered once and then used for multiple purposes. Without clear guidance and organization for data element definitions and interoperability standards, patients will not be able to receive the benefits of improved health care delivery and outcomes that a robust health information infrastructure would provide.

Given the recent enactment of the *Medicare Access and CHIP Reauthorization Act of 2015* and despite CMS' proposal that Stage 3 will be the final stage of the EHR Incentive Program, we understand that CMS will continue to evaluate providers' meaningful use of certified EHRs, to include encouraging the use of such systems for reporting quality measures, with respect to 2019 and each subsequent year.[3] To that end, we urge CMS to work more closely with the specialty provider community, including EPs, to develop meaningful use criteria that facilitates the use of health information technology to achieve substantive improvements in the delivery of quality heart rhythm care, consistent with our previous comments. Subsequent to that, we urge CMS to work closely with ONC on developing certification criteria that would prompt EHR vendors to address significant shortcomings in currently available products for our specialty and patients we serve. Both of these requests are consistent with existing initiatives within the Department of Health and Human Services, including the Million Hearts Initiative.

Finally, we urge CMS to encourage ONC to immediately address interoperability. We have previously requested ONC to incorporate profiles developed by the cardiology community through Integrating the Healthcare Enterprise (IHE) into its voluntary certification criteria to help support interoperability in

[2] http://www.eplabdigest.com/articles/Keeping-Meaningful-Use-Becoming-Meaningless-Abuse-Cardiology-Electrophysiology-Perspective
[3] http://www.gpo.gov/fdsys/pkg/BILLS-114hr2enr/pdf/BILLS-114hr2enr.pdf

heart rhythm and cardiac care. Cardiology has worked collectively with EHR vendors and Cardiac Rhythm Management (CRM) manufactures, as well as federal agencies, including the US Food and Drug Administration (FDA), to develop IHE profiles covering a wide range of use cases for multiple cardiac conditions. However, it is our understanding that EHR vendors, given their own resource challenges, are limited in their ability to incorporate these profiles, as finance managers are strict about modifications unless they are included in the certification criteria, ad therefore viewed as "mandatory." We will continue to encourage ONC to incorporate these profiles in its voluntary certification criteria, similar to other IHE profiles that have been adopted by the agency. It would be helpful if CMS could include meaningful use criteria that would require the functionality enabled by the profiles in the EP clinical space, which would encourage ONC to incorporate this into its certification criteria and EHR vendors to adopt these profiles, as well.

Comments on Specific Objectives and Measures

Patient Electronic Access to Health Information

Regarding Measure 1, we urge CMS to allow providers to choose between Option 1 and 2, rather than requiring both.

Coordination of Care through Patient Engagement

We are disappointed that CMS' proposal continues to require patient action in order for the provider to meet this objective. This has been a longstanding concern of the provider community, and we are frustrated that CMS has failed to revise the requirements consistent with our requests. It is impossible for physicians to control whether a patient engages in their care using health information technology, regardless of how simple the provider makes this activity for his or her patients. Furthermore, the threshold for the measures in this objective are very challenging, despite CMS' proposed flexibility on meeting the threshold in only 2 of 3 measures. We urge CMS to reconsider making patient action a determinant of provider quality.

Health Information Exchange (HIE)

While the overall meaningful use criteria are overly aggressive or irrelevant for the majority of our members, we are pleased that CMS has included capturing of the FDA's Unique Device Identifier (UDI) in a patient medical record and the inclusion of that data field within the Common Clinical Data Set (CCDS) requirements for the summary of care documents. This is a critical issue for EPs and their patients, and represents a key step toward improving the quality of care and ensuring patient safety associated with medical devices.

Nonetheless, we are concerned that the requirements do not go far enough; that is, there is no requirement that providers capture this information *at the point of care*. We urge CMS to revise its criteria to require collection of UDI at the point of care in the final rule for Stage 3. We also urge CMS to consider making UDI data collection in other federal regulatory requirements, such as Medicare's Conditions of Participation (CoPs) and Conditions for Coverage (CfCs). Incorporating UDI collection requirements into Medicare's CoPs and CfCs would facilitate more complete and collection of this data by other providers that utilize medical devices, but are not covered under the EHR incentive program, including ambulatory surgery centers (ASC).

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Thank you for considering our comments and concerns related to Stage 3 of the EHR Incentive Program.

We look forward to engaging in a dialogue with you about these issues, including how best to address them for heart rhythm clinicians and patients. Should you have any questions, please contact Isabelle LeBlanc, HRS's Manager of Health Policy, at ileblanc@hrsonline.org.

Sincerely,

David Slotwiner, MD
Chair, Health Policy Committee