ENDOCRINE SOCIETY
Hormone Science to Health

May 28, 2015

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

Re: 45 CFR Part 170 Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3; 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications; Proposed Rules

Dear Mr. Slavitt:

On behalf of the Endocrine Society, thank you for considering our comments on the proposed changes to the Medicare and Medicaid Electronic Health Record Incentive Programs (Meaningful Use) for Stage 3. The Endocrine Society represents over 19,000 endocrinologists who care for patients with endocrine diseases and conduct research to identify new cures and treatments. Many of our members participate in the Meaningful Use Program with the goal of improving the quality of care that they provide to their patients.

The Endocrine Society appreciates the modifications that CMS has proposed for implementation in Stage 3 to a) provide greater flexibility to eligible professionals (EPs), b) align clinical quality measures (CQMs) with other quality programs, and c) focus objectives on the advanced use of EHRs. However, the Society remains concerned with the aggressive timeline for implementation of Stage 3, and the proposed performance thresholds for patient engagement, patient electronic access to health information, and health information exchange. Specific comments on these provisions are outlined below.

Flexibility in Objective Requirements
CMS has proposed to allow EPs greater flexibility in determining which measures to meet in the Care Coordination through Patient Engagement, Public Health and Clinical Data Registry Reporting, and Health Information Exchange. Although an EP must report the numerator and denominator for each measure within these objectives, they are allowed to choose two of the three measures for which they must meet the performance thresholds. **Although the Society remains concerned about the pass/fail nature of the eight primary objectives, we are pleased that CMS has provided flexibility within the objectives in recognition that all**

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measures may not apply to an EP's practice. We urge CMS to incorporate this flexibility into the remaining five objectives to eliminate the strict pass/fail nature of the program.

Alignment of Clinical Quality Measures (CQM)
In the Proposed Rule, CMS has indicated an interest in aligning clinical quality measures across Federal quality improvement programs. It is CMS' intent to move to yearly quality measure updates and better align the Meaningful Use quality measures with the Physician Quality Reporting System (PQRS). EPs have numerous requirements that they must meet for the PQRS, Meaningful Use, and Value Based Modifier programs. The reporting burden is significant and requires clinical staff time that reduces available time to spend on patient care and coordination. **The Society is supportive of efforts by CMS to align the requirements for these programs to reduce the impact on practices and patients.**

Focus on Advanced Objectives
CMS has stressed that the rationale for many of the changes to Stage 3 have been proposed with the goal of realizing the full potential of EHRs. As a result, many of the changes to the objectives focus on eliminating measures that are "topped out" or redundant. As federal quality improvement programs have evolved, endocrinologists have expressed concern that they must "check a box" to meet program requirements that often do not achieve the goal of improving the quality of care that they provide. By removing these more basic requirements, such as measuring height and weight, EPs will be allowed to focus on objectives that will have a truly transformational effect on their practice. **The Society is supportive of a focus on advanced objectives. However, as discussed below, we remain concerned about the aggressive timeframe that EPs face to avoid penalties.**

Stage 3 Implementation Timeline
CMS proposes to require that all EPs, regardless of when they begin participation in Meaningful Use, meet Stage 3 requirements in 2018. While the proposed changes will ease the complexity of meeting the Meaningful Use requirements for some EPs, the Endocrine Society continues to believe that EPs are being asked to meet challenging criteria on an aggressive timeline. **While we appreciate that CMS has chosen to implement Stage 3 in 2018 rather than October 1, 2016 as previously proposed, we urge CMS to provide greater flexibility in when EPs must meet Stage 3 requirements.** Penalizing EPs for failing to meet Stage 3 requirements while they are still adapting to the requirements of Stage 1 or 2 will take away valuable resources that are needed to build the capacity to meet Stage 3.

Patient Electronic Access to Health Information and *Coordination of Care Through Patient Engagement Objectives*
CMS proposes to focus on encouraging the use of EHR functionality for secure dialogue and efficient communication between providers, care team members, and patients about their care

and health status, as well as important health information such as preventive and coordinated care planning. Through this objective, EPs will be required to meet the threshold for two out of three measures, which will increase significantly from Stage 2 requirements.

The Society supports the communication of health information to patients and caregivers through electronic means, but has signficiant concerns about the increase in requirements over Stage 2. For instance, requiring 25 percent of an EP's patients to access the patient portal (Objective 6, Measure 2) is unrealistic when many practices are struggling to reach the 5 percent threshold required under Stage 2. While EPs can take necessary steps to make the experience of accessing the patient portal one of value to the patient, there is only so much an EP can do to draw the patient to the portal. Many clinicians tend to populations of patients (e.g. older patients, patients with multiple comorbidities, patients whose English proficiency is limited, etc) whose internet access/computer skills will not allow them to access secure portals. We appreciate that CMS has provided an exclusion for the lack of internet connectivity in some rural communities, but this does not account for a patient population that may lack the skills or equipment to access the internet. It is unrealistic to penalize EPs for factors that are outside of their control. **Therefore, we recommend that CMS reduced the proposed threshold from 25 percent to 10 percent.** While this is still an increase from the current Stage 2 threshold of 5 percent, it is a more reasonable target for most EPs. Should the majority of EPs meet this goal in subsequent years, CMS could consider increasing the threshold to 25 percent.

Furthermore, high-quality patient-specific educational resources may not be available for less common medical conditions, placing subspecialists who focus on treatment of these diseases at a disadvantage. Consequently these high thresholds may result in EPs providing information to patients simply to meet the requirements (e.g. of Objective 5, Measure 2) rather than providing meaningful value to the patient, which would not lead to patient engagement in the way envisioned by CMS. Forcing EPs to encourage patients to participate in activities for their own (providers) monetary gain creates clear conflicts of interest and makes for an unappealing precedent. **We recommend that CMS reduce the proposed threshold for Obejctive 5, Measure 2 from 35 percent to 20 percent.** As mentioned previously, should the majority of EPs meet this goal in subsequent years, CMS could consider increasing the threshold to 35 percent.

Health Information Exchange

The Society is further concerned that provider performance on Objective 7 (Health Information Exchange) is highly dependent on the providers / healthcare organizations with whom they routinely share patients. Measure 1 in particular requires that the summary of care be electronically exchanged with the referring provider or a hospital. If the referring provider or a hospital does not have appropriate systems in place – someting entirely out of an EP's control –

meeting Measure 1 is impossible. **The Society therefore recommends that the threshold on Objective 7 Measure 1 be decreased substantially from 50 percent to 20 percent.**

The Society would like to express a concern about the complexity of the clinical reconciliation measure (Objective 7, Measure 3). In its current form, a reconciliation is required with every patient transition. While clinically prudent, this requirement is difficult to operationalize because EHR data does not reflect many of the patient transitions (for example, outside of an integrated healthcare system, it is impossible to tell from the EHR that a patient was recently discharged from a hospital). **We therefore recommend that clinical reconciliation measure be limited to the patients who are new for the EP (a condition that can be easily identified in the EHR data).**

Additional Comments
Below, the Society provides comments on several areas where CMS has sought stakeholder input:

1) We agree with the CMS proposal to allow EPs who are ready to attest to Stage 3 requirements in 2017 to do so. However, based on the provider experience to date, many EPs will likely be unable to meet this target. As such, we support CMS' decision to defer the start of universal Stage 3 requirements to 2018. We encourage CMS to reevaluate the requirement that all EPs, regardless of when they began participation in Meaningful Use, be required to meet Stage 3 requirements in 2018.
2) We agree with the CMS proposal to continue to allow, but not require, EPs to limit computerized physician order entry (CPOE) measures to those patients whose records are maintained using Certified Electronic Health Record Technology (CEHRT). This flexibility will further enable EPs with varying logistical and organizational circumstances to work towards achieving Meaningful Use.
3) We recommend that for Objective 2, Electronic Prescribing, inclusion of over-the-counter medications should be an option to allow EPs to choose an attestation approach that better reflects their practice requirements. For the same reason, we also agree with the CMS proposal to make inclusion of Schedule II – VI substances optional for this Objective.
4) We recommend that EPs be allowed to choose whether to implement View, Download, Transmit *or* API functionality to satisfy Objective 5. Requirement for providers to implement both functionalities would place undue burden on practices, while experience with these functionalities is insufficient to demonstrate a clear benefit to the patients of having both available.
5) With respect to Objective 6, Measure 3 (Patient-Generated Data), we recommend that EPs be allowed to choose whether patient-generated data has to be verified or automatically incorporated into the CEHRT. A wide variety of patient-generated data may be submitted to CEHRT under this Objective, with different degrees of reliability, and therefore some may require verification and others will not. For the same reason, EPs should not be required to

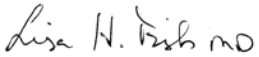
make a uniform decision across their entire practice about whether patient-generated data will be automatically incorporated or require verification, because the same variation of data sources may be found within individual providers, and even within individual patients.

6) In a further comment regarding Objective 6, Measure 3 we recommend that EPs **not** be required to have structured fields in the EHR for patient-generated data. While this would be ideal, the wide variety of patient-generated data categories will likely preclude CEHRT vendors from creating appropriate structured fields for all possible data categories in time for Stage 3 attestation deadline.
7) We recommend that provenance of the patient-generated data always be recorded in CEHRT. More detailed information (e.g. whether the data was actually entered by the patient, by their guardian, generated by a patient-owned device, etc.) on the provenance of data should be left up to the EP (and will depend on CEHRT functionality).
8) We agree with the CMS proposal for Objective 6, Measure 3 that this measure should be limited to patients with whom the provider had multiple (> 1) encounters during the reporting period. It is difficult to expect patients with whom the provider does not have an established relationship to enter data into the provider's CEHRT.
9) We recommend that at this time Objective 6, Measure 3 remain undivided into sub-measures to minimize high complexity of the existing reporting requirements.
10) We recommend that for the purpose of Objective 7, Measures 1 and 2 EPs be allowed to transmit summary of care using any electronic means rather than requiring utilization of a nationwide health information network to be established by the Office of the National Coordinator (ONC). Setting up a functioning nationwide health information network is a technically and logistically challenging. It is uncertain whether it will be completed prior to the 2018 onset of Stage 3 requirements to allow the CEHRT vendors to implement required functionality and EPs to adopt it in their clinical workflow.
11) We recommend that EPs be allowed to choose whether to perform clinical reconciliation (Objective 7, Measure 3) automatically or manually, as this is likely to be dependent on the specific EP's patient population and clinical workflow.
12) We propose that the staff qualification requirements established for the CPOE Objective not be applied to clinical reconciliation (Objective 7, Measure 3). While orders entered for the patient directly affect patient care and therefore is necessary that individuals entering them be qualified to do so "per state, local, and professional guidelines", performing clinical reconciliation does not bear the same degree of patient safety implications. Relaxing staff requirements in this manner will decrease the costs of providing care – an important consideration in today's economic climate.
13) We agree with the CMS proposal to allow EPs to choose 2 out of 3 clinical information reconciliation datasets relevant to their practice for Objective 7, Measure 3 to maintain maximum flexibility to accommodate different practice patterns.

The Endocrine Society and its members support the ultimate goal of improving quality of care through the use of health IT, but believe that penalizing physicians who are unable to meet the Meaningful Use requirements despite their best efforts is counterproductive. We appreciate CMS' efforts to ease the reporting burden through changes such as those in the proposed rule, but we encourage administrators to analyze the entire program for feasibility and effectiveness in reaching the goals of the program.

Thank you for considering our comments, and for the work that CMS has done to engage the physician community in advancing the EHR Incentive Program. We look forward to the release of the Final Rule and helping our members to fully engage in the program. Should you have questions on our comments, please contact Stephanie Kutler, Director of Quality Improvement, at skutler@endocrine.org.

Sincerely,



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