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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:

Established in 1943, the AAAAI is a professional organization with more than 6,700 members in the United States, Canada and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases. We appreciate the opportunity to comment on policies outlined for Stage 3 of the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program and associated Meaningful Use (MU) criteria.

General Comments on the Move to Stage 3

Health information technologies (health IT), including electronic health records (EHRs), clinical data registries (CDRs) and clinical decision support tools (CDS), are redefining how care is delivered and received, and poised to improve health care quality and outcomes as they continue to evolve. We encourage and support clinical practice innovations that use health IT in a meaningful way. However, since the inception of the EHR program, we have questioned the relevancy and value of the meaningful use criteria to A/I specialists, and the sufficiency of current certification standards in regards to facilitating meaningful use objectives and achieving true interoperability. Despite the phase-out of the EHR Incentive Program after Stage 3, "meaningful use" of EHRs will be a key component in the Merit-based Incentive Payment System (MIPS), one of the new Medicare physician payment pathways authorized under the recently enacted *Medicare Access and CHIP Reauthorization Act (MACRA)*. Therefore, we urge CMS to work more closely with A/I physicians to improve their ability to demonstrate meaningful use in Stage 3 and beyond.

In the sections below, we provide both general and detailed comments on specific proposals for Stage 3 of meaningful use.

(continued)

Uniform Definition for Meaningful Use

AAAAI appreciates CMS' proposal to create a single, uniform definition of meaningful use that all providers would be required to adhere to by 2018, which is intended to streamline the programs requirements and further align reporting requirements across federal programs that rely on certified EHR technology, and to ultimately minimize administrative complexity by proposing a single set of objectives and measures. Nonetheless, this proposal perpetuates the one-size-fits-all approach that has long plagued this program.

Current and proposed objectives and measures are almost exclusively focused on primary care, which puts A/I specialists at a disadvantage in qualifying under the program. Granted, a single, more streamlined set of objectives may reduce complexity, but it also further limits the applicability of the objectives across specialties, practice types, and patient populations. We urge CMS to offer physicians multiples means by which they can satisfy program objectives and goals. Eligible professionals should have the flexibility to choose from an assortment of measures in each of the relevant domains that are most appropriate for their practice and patient population. We invite CMS to work with AAAAI on a list of appropriate metrics for each of the eight objectives in the programs.

Increasing Thresholds

The EHR Incentive Program was intended to follow a staged process that gradually encouraged providers to work towards more advanced uses of EHR technology. Like many other specialists, many A/I physicians have not been able to satisfy Stage 2 requirements. CMS' proposals to dramatically increase the measure thresholds for most of the objectives in Stage 3 could result in misguided policies that further discourage provider engagement. This is particularly true for measures where patient action is the primary determinant of provider success in meeting certain objectives. We urge CMS to reconsider finalizing this expansion of requirements for all providers by 2018.

Hardship Exemptions

The EHR Incentive Program relies on an all-or-nothing approach where even providers who have truly committed to meaningful use and may have achieved a significant percentage of the objectives, are penalized and unrecognized for their investment. In fact, some providers who achieved meaningful use, but failed to properly attest because of confusion about the process, are being penalized. This is a major disincentive to providers, who should be recognized for various levels of commitment. We are also concerned about the limitations of existing hardship exemptions, especially their failure to recognize those who are unable to upgrade from earlier editions to EHR technology certified to the 2015 edition. We appreciate that CMS proposes to maintain current hardship exemptions, including for those who lack internet access or other barriers to obtain HIT infrastructure; those who are new to practice; and those who have limited control over decisions related to HIT adoption. However, we do not feel these exemptions account for those who have previously adopted certified EHRs, but do not have the resources or capacity to upgrade to the 2015 edition by 2018. We feel this proposed rule moves further away from the original goals of the program. We urge CMS to consider additional hardship categories, including those who are nearing retirement, and those who can demonstrate meeting meaningful use, but were unsuccessful in their attempt to attest.

(continued)

Specific Comments Related to Proposed Stage 3 Objectives and Measures

Objective 1: Protect Patient Health Information

Requiring professionals to conduct or review a security risk analysis is a reasonable metric, and one that AAAAI supports. As CMS notes in the rule, the requirement of this proposed measure is narrower than what is required to satisfy the security risk analysis requirements entities must already comply with under the HIPAA Security Rule. Nonetheless, physician practices, primarily those that are small, continue to face challenges in meeting this requirement, as evidenced in recent payment audits of the EHR Incentive Program. While the Office of the National Coordinator for Health Information Technology (ONC) and the Office of Civil Rights (OCR) have collaborated to provide physician practices with tools to assist with their security risk assessment, many practices do not employ in-house information technology (IT) staff, nor do their office staff have proper training in IT security protocols.

To address these concerns, AAAAI urges CMS to collaborate with its federal agency partners to develop more robust guidance for physician offices on conducting security risk assessments; provide data on common security risk failures in physician practices, large and small; and, provide enhanced technical assistance and support on HIT security. These efforts would go a long way toward helping secure protected health information and ensure providers are not penalized for failing to meet meaningful use on this metric alone.

Objective 2: E-Prescribing

In line with our aforementioned comments, we are concerned with CMS' proposal to increase the threshold for this measure from the current Stage 2 requirement of 50%, to more than 80%. This shift is too dramatic and an especially high bar for first-year participants. We recommend that CMS maintain the Stage 2 threshold for all participants, or at a minimum, maintain the 50% threshold for first-year participants.

Objective 3: Clinical Decision Support

We appreciate CMS' efforts to improve this measure, and support CMS' proposal that if none of the available CQMs apply, the provider may apply a CDS intervention that he or she believes will be effective in improving the quality, safety, or efficiency of patient care in their practice. Nonetheless, many A/I physicians remain concerned about their ability to meet this objective.

First, there are few relevant CQMs for A/I conditions for which a CDS intervention is currently available, making the threshold of 5 CDS interventions extremely challenging. Second, A/I physicians have found that existing CDS programs do not include relevant interventions to their specialty, whether tied to a CQM, or not, further exacerbating their concern. Finally, A/I physicians are confused about the process by which they would develop, on their own, electronic CDS interventions, especially since they are not trained in such activities. We note there is limited guidance on this subject from trade associations representing EHR vendors, however, these materials are not official publications of, or endorsed by, CMS or other federal agencies, therefore, it is unclear whether a practice following such guidance would have CDS measures that hold up in an audit situation.

AAAAI seeks guidance and clarification on how physician practices would be able to meet this measure if their EHR vendor does not offer CDS with relevant or applicable interventions to A/I, or if the EHR vendor would only develop such CDS interventions for an additional fee. In addition, we urge CMS to provide guidance on how physicians can meet this objective, including technical assistance on how to develop CDS interventions at the practice-level.

We also seek assurance from CMS that providers truly have the freedom to select a CDS intervention that may not be tied to a specific CQM. We are concerned that CMS would target these individuals for further analyses to validate whether a CQM could have applied, similar to what it does under the PQRS Measures Applicability Validation (MAV) process.

Objective 4: Use of CPOE

We sincerely appreciate CMS' clarification in the proposed rule that orders entered by any licensed healthcare professional, credentialed medical assistant (by a credentialing body other than the employer), and certain other medical staff members with appropriate credentialing and training, would count toward this objective. We urge CMS to codify this language in the final rule. However, as noted above, we are concerned with the significant increases in the thresholds for the measures associated with this objective, particularly for new participants. We urge CMS to maintain the lower thresholds from Stage 2 of the program.

Objective 5: Patient Electronic Access to Health Information

Patient engagement is integral to A/I clinical practice and a key component of established clinical guidelines for many A/I conditions. In fact, A/I care cannot be successful without involvement of the patient. For example, patients must be engaged to ensure success with their asthma action plan, allergy, and immunotherapy care. For patients with primary immune deficiency (PID) diseases, tracking of reactions to immunotherapy treatments and other sickness or illness can make the difference between life and death. Patients under care and treatment for a variety of A/I conditions are frequently required to maintain various logs, such as a food diary or allergy list (including medication allergies), as well as complete surveys about progress or set-backs related to their A/I diagnoses.

A/I physicians support CMS' efforts to engaging patients in their healthcare. In particular, we are supportive of and encouraged by the proposal to include application programming interfaces (API) as a means to connect and engage with patients and meet the measures associated with this objective. Our members have faced many technological challenges with existing "patient portals," most of which center on exorbitant costs associated with maintaining these portals via the EHR vendor. APIs will offer patient and providers alike a variety of means by which engagement can take place, and at no additional cost.

Despite our encouragement with the proposed modifications, we remain concerned that the 80% threshold for Measure 1 is too high, and urge CMS to maintain a threshold of 50%. For measure 2, we urge CMS to maintain the 10% threshold vs. the proposed increase to 35%. In addition, we do not believe that providers should be required to satisfy both options for Measure 1, given they are similar in intent.

In addition, we oppose CMS' proposal to decrease patient wait time for the availability of information from 4 business days to within 24 hours of the office visit or of the information becoming available to the provider. We are concerned that this does not take into account visits that may happen immediately prior to the start of a weekend or outside of normal business hours. Additionally, we believe a false sense of urgency is created for patients to receive routine healthcare information. We note that patients are notified about important changes in their health information, such as critical lab values, within 24 hours of those data being available to the A/I physician, but ensuring other routine data are made available to the patient in an electronic format with such urgency does nothing to improve the quality or cost of patient care. As a result, we urge CMS to increase this timeframe and to define it terms of business days.

Finally, we urge CMS to reconsider requiring providers to meet both measures associated with this objective. We believe it is more appropriate at this stage of the program to allow providers a choice in meeting either Measure 1 or Measure 2.

Objective 6: Coordination of Care through Patient Engagement

Again, we are deeply committed to engaging patients in their care, as this is a critical component of A/I care. However, we are concerned that CMS' proposal continues to require patient action in order for the provider to meet this objective. While it is understandable to require providers to make data accessible to patients in a timely manner, patient action related to that data should not be a determinant of provider quality. Providers should only be held *accountable* for actions within their *direct control*. We strongly oppose CMS' proposal to increase the threshold for Measure 1 from 5% to 25%.

Regarding Measure 2, we appreciate CMS' proposal to include in the measure numerator situations where providers communicate with other care team members using the secure messaging function, and the patient is engaged in the message and has the ability to be an active participant in the conversation between care providers. This would give providers in different practice situations more flexibility to use secure messaging in a manner that is most relevant to their patients.

We appreciate that CMS offers a broad definition of the types of data that would satisfy Measure 3 (e.g., advance directives, medical device data, home health monitoring data, fitness monitor data, and patient-reported outcomes data), as there are multiple ways in which A/I physician may collect data such as peak-flow readings, food diaries and asthma action plan information, as discussed in the aforementioned objective. However, we urge CMS to limit the denominator to patients with whom the provider has an ongoing relationship, and not just those who are seen once during a performance period.

Finally, we recommend that CMS only require that a provider to attest to two out of three of these measures.

Objective 7: Health Information Exchange

We urge CMS to clarify how transitions of care/referrals to specialists are counted, as this remains an area where A/I physicians are confused. In addition, we support CMS' decision to revise this objective for Stage 3 to allow the inclusion of transitions of care and referrals in which the recipient provider may already have access to the medical record maintained in the referring provider's CEHRT, as long as the providers have different billing identities within the EHR Incentive Program and the initiating provider actually sends a summary of care document (versus the receiving provider simply accessing the patient's health information).

Objective 8: Public Health and Clinical Data Registry Reporting

While CMS has broadened the scope of this objective to include clinical data registries and proposes to allow participation in more than one clinical data registry to count towards this objective, the reality is that most specialists who are engage in registry reporting only report to as single comprehensive and meaningful registry. We also note there may be significant costs to the provider associated with participating in or reporting through a clinical data registry, which may limit the provider to only being able to fund reporting to one registry. As such, we believe the requirement to participate in three registries is too high and unwarranted. While we recognize the value of registries and support efforts to promote them, we urge CMS to lower the threshold on this objective so that providers are only requires to satisfy 1 of the 5 measures.

Should CMS not finalize our request, we seek clarification on the currently proposed exclusions for clinical data registries. Specifically, we seek clarity on the following:

- How will CMS determine that a physician does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period?;
- How will CMS determine if a physician operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period?; and
- How will CMS determine if a physician operates in a jurisdiction where no clinical data registry for which the EP is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period?

Since an increasing number of clinical data registries are national in scope and essentially “borderless,” it is unclear how CMS would define a provider’s “jurisdiction.” We appreciate CMS providing as much clarity to these questions as possible, should a reduction in the number of registries to which a provider must report cannot be reduced.

Finally, and while perhaps outside the scope of CMS’ jurisdiction, we continue to worry about the ability of clinical data registries to be interoperable with EHR systems. CMS should encourage ONC to facilitate the development of standards to foster this activity on a more robust level.

Other Concerns

Patient safety remains a high priority for A/I physicians. We are concerned that there are no formal or structured mechanisms in places for A/I physicians to report HIT-related patient safety events, nor assurances that identified patient safety hazards will be adequately addressed in a timely fashion. For those A/I physicians practicing in hospital and academic institutions, we urge CMS to modify its Conditions of Participation (CoP) related to a hospital’s quality assessment and performance improvement (QAPI) activities. QAPI programs are already required to address adverse patient events, however CMS has not clarified that HIT-related adverse patient events are to be included. CMS should work with the Center for Clinical Standards and Quality (CCSQ) to improve the Medicare CoPs to ensure patient safety events associated with HIT and EHR products are addressed appropriately, and in a timely fashion, at no cost.

For A/I physicians in private practice that have secured CEHRT independent from a hospital system, an HIT patient safety reporting program should be established.

HIT-related patient safety events that are collected should be made public and disseminated to other users to prevent further patient harm.

CMS should also work with its agency counterparts at the Office of the National Coordinator (ONC) to ensure that, as part of the 2015 Certification Criteria, patient-safety reporting and appropriate resolution of such identified issues, are addressed appropriately, and in a timely fashion, at no cost to the provider. Any software updates resulting from identified HIT-related patient safety events should be made available to all users at no charge.

Conclusion

A/I specialists are seeing a slow, but steady, increase in EHR adoption across the country, and a realization of the value of certain EHR capabilities. However, there remain a host of concerns about interoperability, usability and patient safety, not to mention requirements for which we do not have direct control over the outcome. Physicians and other health professionals should not be held accountable to an increasingly higher and less flexible bar that simultaneously includes steeper penalties and little pressure on the EHR industry to develop products that support truly meaningful use of health IT.

The EHR Incentive Program is well intended, and has the potential to realize many positive benefits, but in its current and proposed form results in significant unintended consequences. We urge CMS to invest in processes and tools that make achievement of the criteria not simply easier, but more relevant and meaningful.

We appreciate the opportunity to provide comments on the aforementioned issues of importance to our members. Should you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@aaaai.org or (414) 272-6071.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Lemanske, Jr.", with a stylized flourish at the end.

Robert F. Lemanske, Jr., MD FAAAAI
AAAAI President