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May 29, 2015

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

Submitted via http://www.regulations.gov

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

Dear Administrator Slavitt,

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS),we appreciate the opportunity to comment on proposals for Stage 3 of the Electronic Health Records (EHR) Incentive Program.

Ongoing Impediments to Meaningful Use of EHRs

The AANS and CNS support the goal of a national health information infrastructure and recognize the potential value of EHRs to improve the quality of patient care. Nevertheless, there are considerable barriers to widespread adoption of EHRs. These include, among others, high cost, lack of functionality (especially for specialists, which require much more tailored EHR systems), lack of relevant measures in the incentive program, and interoperability challenges. Physicians, their practices, and their EHR needs are not homogenous. Many specialists have adopted EHRs into their practice, but still choose not to participate in the EHR Incentive Program due to a lack of relevant measures. Furthermore, many EHR products do not work in a way that meets their patient's needs, and many meaningful use measures do not result in the collection of data that is important to those providing specialty care.

Adding to these challenges is the fact that EHR vendors are often inclined to avoid the added expense of extensive customization, focusing on building models solely based on program requirements. This results in systems that only collect information on a limited set of measures that are not applicable to all specialties, which decreases the value of the products on the market for specialists. Even in situations where custom models can be built for specialists, the costs are often prohibitive.

In terms of interoperability, problems persist not just between physician practices and hospital systems, but also between EHR systems and clinical data registries. We believe that CMS and ONC can, and should, play a greater role in facilitating the use of clinical data registries by encouraging the development of standards for sharing/transmitting data between EHRs and registries. Presently,

practices are forced to manually enter data into a registry because no streamlined process exists and because of the proprietary nature of EHR products. This is particularly challenging for solo and small practices, which do not necessarily have the resources to hire additional staff for data entry; thus preventing many from participating in registries.

Finally, to date, the EHR Incentive Program has put the onus of adoption and interoperability on the wrong parties. Rather than requiring EHR vendors to meet such standards, medical providers are tasked with the burden of paying to integrate their EHR systems through costly and regular updates or periodic changes in EHR systems and products.

Lack of Program Flexibility

In light of these ongoing obstacles, we are disappointed that for Stage 3, CMS proposes to move toward a single, uniform definition of meaningful use, by which all providers would be required to adhere by 2018 — regardless of their prior participation in the program. While we fully appreciate the agency's intent to streamline the program's requirements in order to minimize administrative complexity, this proposal perpetuates the problematic one-size-fits-all approach that has long plagued this program, and remains a barrier to meaningful participation among specialists. Instead, the AANS and CNS urge CMS to rely on a wider assortment of menu objectives (versus a more limited set of required objectives), which would give specialists the flexibility to choose those elements that are most appropriate for their practice and most relevant to their patient population. We believe this would result in more meaningful participation and ultimately, encourage more widespread adoption of EHRs in a manner that truly impacts quality.

Moving to a uniform definition of meaningful use by 2018 also fails to recognize the varying circumstances of providers, some of which have less experience with adoption and meaningful use of EHRs. Since the program's inception, first-year participants were held to a lower bar than those with more experience. Many professionals have not yet adopted a federally certified EHR and may not do so until 2018 or beyond due to the significant investment of time and resources. As such, we urge CMS to preserve what has traditionally been a more staged approach to meaningful use. This approach would include varying sets of requirements depending on the eligible professional's (EP) level of experience, and encourages a more gradual approach to achieving more advanced uses of EHR technology to improve care.

Similarly, we oppose the proposed elimination of the 90-day reporting period for first-year participants. Traditionally, all new participants to the program have been given the option to report for a 90-day period to allow them to get acclimated to the program. This exception should be extended into the future, rather than requiring all EPs to attest to meaningful use for a full year beginning in 2017. Continuous reporting over an entire year would place an undue burden on EPs and their practices, especially since manual data abstraction will remain the only mode of reporting for the foreseeable future.

Flexibility is also lacking on two other important fronts. We continue to have concerns about the program's ongoing all-or-nothing approach under which even providers who have fully committed to meaningful use are penalized and unrecognized for their investment if they fail any single objective. This is a major disincentive to physicians, especially specialists who already have major concerns about the relevance of this program. Flexibility is also lacking in regards to hardship exemptions, which fail to recognize those who are unable to upgrade from earlier editions to EHR technology certified to the 2015 edition. We, therefore, urge CMS to provide exemptions for those who have

previously adopted certified EHRs, but do not have the resources or capacity to upgrade to the 2015 edition by 2018.

Finally, CMS proposes to discontinue the policy of allowing providers to print, fax, mail, or otherwise produce a paper document and manually count these actions to include in a measures calculation for Stage 3. If CMS instead chose to maintain its original phased approach to meaningful use and only required this in the latest stage, this approach would be reasonable. However, since CMS is requiring all professionals to comply with the same requirements in 2018, we view this proposal as unreasonable and request an exception for those in their initial year(s) of reporting.

Lack of Knowledge to Guide Future Policymaking

We remind CMS that only a small fraction of EPs have been able to satisfy Stage 2 to date and that about one-half of EPs still have not participated in the program at all. We question whether these participation rates have produced sufficient data to accurately guide CMS in policy-setting for Stage 3. For example, we question the accuracy of the agency's determination that certain measures have "topped out" when this assessment is based on program years when less than half of all EPs participated in the program. Other proposals to dramatically increase measure thresholds seem not only aggressive, but arbitrary. Making changes to the program too quickly, and without a sufficient evidence base, could result in misguided policies that further discourage specialist engagement and erode the quality of patient care. We urge CMS to study more carefully prior stages of meaningful use and existing barriers to engagement before finalizing this expansion of requirements for all providers by 2018.

Comments on Specific Measures

Objective 1: Protect Patient Health Information

Proposed Objective: Protect ePHI created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

The AANS and CNS support the general idea of this objective, but strongly oppose the implementation insofar as it burdens the EP with performance of a security analysis and threat analysis that is not within the expected scope of expertise of the EP and would, therefore, not be expected to yield workable results. As there is considerable redundancy with the requirements EPs have to fulfill regarding compliance with the HIPAA Security Rule, we recommend that CMS accept compliance with the HIPAA Security Rule as fulfillment of meaningful use Objective 1.

Objective 2: Electronic Prescribing

Proposed Objective: EPs must generate and transmit permissible prescriptions electronically, and EHs and CAHs must generate and transmit permissible discharge prescriptions electronically.

The AANS and CNS support this objective as far as the continued exclusion of OTC medications are concerned. However, we are opposed to language — which we interpret as mandatory — inclusion of controlled substances in states where e-prescribing such substances is permissible. We request clarification on whether controlled substances are part of the group of "permissible prescriptions" when determining EPs who should be excluded from this measure based on low prescription volumes. We recommend that inclusion of controlled substances under this definition be made optional.

Objective 3: Clinical Decision Support

Proposed Objective: Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

The AANS and CNS appreciate the wide range of options provided under this proposal, which is particularly important for neurosurgical specialists. We would encourage CMS to allow EPs to select and develop CDS implementations that are tied to existing CQM in a reasonable way and not linked too stringently in order to foster innovation in this area.

Objective 4: Computerized Provider Order Entry

Proposed Objective: Use CPOE for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

The AANS and CNS support measure 1 of this objective, but have significant concerns about measure 2 and 3 of the objective since a significant number of outpatient laboratories and imaging centers do not support "e-ordering" and there is currently no infrastructure set-up to allow for this on a large scale. Requiring this at the current time would probably distort competition and increase healthcare delivery costs for laboratory and imaging charges for beneficiaries due to the need to defray necessary investments over a short time period.

Objective 5: Patient Electronic Access to Health Information

Proposed Objective: The EP, EH, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.

The AANS and CNS are pleased with the clarification that EPs are required to provide reasonable patient access to such information, but would not be penalized should patients opt not to view their PHI. However, we are concerned about the requirement to provide the patient with such information within 24 hours of its availability to the provider. This time frame does not account for situations where pathology or radiology reports come back with concerning findings that lack a clinical correlation or require counseling by the EP. It also does not account for reports made available immediately prior to the weekend. We request that CMS consider extending this timeframe to at least 4 business days.

The AANS and CNS also oppose the requirement that an "ONC-certified" API must be used since the certification process for the rapidly changing field of patient portals will be seen as an obstacle to continued refinement and innovation and is in direct conflict with CMS' expectation that third party developers will create low-cost APIs.

Objective 6: Coordination of Care through Patient Engagement

Proposed Objective: Use communication functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

The AANS and CNS continue to strongly oppose measures that hold physicians accountable for actions that are outside of their direct control, such as actions taken (or not taken) by the patient. This has been a longstanding concern of the provider community, due to a physician's lack of control over how a patient chooses to interact with an electronic interface and what a patient decides to do once given access to electronic data. This may be especially problematic for practices whose patient populations consist mainly of older adults or other populations who may not have access to or familiarity with the internet or other electronnic formats, or simply may not want to receive their health information in an electronic format. Direct patient action measures also present unique challenges to providers who primarily treat acute cases and may not necessarily have an ongoing relationship with the patient, as do some chronic care providers.

While we support the goal of ensuring patients have access to health information in a timely manner, patient action should not be a determinant of whether a physician satisfies a measure. Physicians should only be held accountable for actions that are within their direct control, such as making health information accessible to patients when feasible. Accountability should not be judged based on the patient's use or decision to access such data.

Objective 7: Health Information Exchange

Proposed Objective: The EP, EH, or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.

While we appreciate that CMS has proposed a number of exceptions and that that physicians would only have to meet the thresholds for two of the three measures under this objective, we are concerned that this objective will be too challenging for physicians to satisfy. Rather than focusing efforts on moving more data, we recommend that CMS focus on furthering functional interoperability.

Objective 8: Public Health and Clinical Data Registry Reporting

Proposed Objective: The EP, EH, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

The AANS and CNS continue to strongly support the expanded use of specialty registries as part of federal quality programs. Specialty registries may be useful in helping to streamline the exchange of health information for quality improvement and patient safety purposes, and measures from these registries are often more relevant, clinically appropriate, and actionable for specialists. Registries require a significant investment of resources, and it often takes several years of data collection, and analysis, before improvement in practice can be documented. However, we believe that aligning registry participation with the EHR Incentive Program is one way to help facilitate strategic health information exchange and more focused quality improvement while reducing the reporting burden on the physician community. Allowing specialists to participate through registries that are validated, relevant, and developed and run by specialists will increase, and result in more meaningful, participation in these programs.

We appreciate that the Stage 3 rule places greater emphasis on clinical data registries. However, we remind CMS that a single registry is often all that is both relevant and available to a neurosurgeon

and should be sufficient to satisfy the objective related to registry use. We do appreciate that CMS proposes exclusions for situations in which 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;
- 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; or
- 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.

However, we remind CMS that clinical data registries are typically national in scope and virtually "borderless." Therefore, we recommend that CMS remove the reference to "jurisdictions" to ensure that physicians can fully take advantage of these exclusions as appropriate.

Where feasible, we also encourage CMS to recognize the important quality data collected by these clinical data registries as a surrogate for the Clinical Quality Measure (CQM) requirement. The current list of available CQMs is mostly primary care focused and of little relevance to specialists. If a clinical registry is already collecting data on the same number of quality measures as required under the EHR Incentive Program, we believe this more than sufficiently demonstrates electronic capture of clinical quality measure data and should satisfy the CQM element of the program.

Concluding Remarks

The AANS and CNS support the intent of meaningful use, but believe the program is sliding down a slippery slope of unsustainability. If the program continues to become more difficult and expensive with which to comply, more irrelevant to daily practice, and more disruptive to patient care, then physicians will just stop participating — regardless of penalties.

To make EHR adoption more relevant and meaningful, CMS and ONC must first make interoperability a top priority, since sharing health information across EHRs and with registries is essential to reducing costs, improving efficiency and quality, and increasing patient safety. CMS also must make the EHR Incentive Program more flexible for specialists, such as surgeons, who may not be able to satisfy all of the current objectives and measures of the program. This is especially critical if CMS is going to maintain the all-or-nothing nature of the program, where failure to satisfy even one measure results in an automatic penalty. CMS should give providers more flexibility to choose reporting options that are most relevant to their practice by emphasizing menu options over core requirements. Finally, CMS and ONC must streamline reporting requirements both within the EHR Incentive Program and among other federal quality reporting programs, and provide physicians with the tools needed to more easily navigate this increasingly complex maze of reporting requirements.

While CMS states that Stage 3 will be the final stage of the EHR Incentive Program, EHR meaningful use will remain a significant component of the Medicare Incentive Payment System (MIPS), recently mandated by the Medicare Access and CHIP Reauthorization Act of 2015. To that end, we urge CMS to work more closely with the specialty provider community to develop meaningful use criteria that facilitate the use of health information technology to achieve improvements to specialty patient care. Simultaneously, we urge CMS to work closely with the ONC to develop certification criteria that would prompt EHR vendors to address significant shortcomings in currently available products for specialists and the patients that we serve.

The AANS and CNS appreciate the opportunity to comment on this proposed regulation. We look forward to working with both CMS and ONC to make improvements to the EHR Incentive Program and to work toward the overall goal of a nationwide interoperable HIT infrastructure that improves patient quality. In the meantime, if you have any questions or need further information, please feel free to contact us.

Sincerely,

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American Association of Neurological Surgeons

Nathan R. Selden, MD, PhD, President
Congress of Neurological Surgeons

cc: Karen DeSalvo, MD, MPH, MSc, National Coordinator
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