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December 15, 2015

Andrew M. Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-3310 & 3311-FC
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 Final Rule with Comment Period

Dear Administrator Slavitt,

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), we appreciate that the Centers for Medicare & Medicaid Services (CMS) reopened the comment period for finalized policies related to Stage 3 of the Electronic Health Records (EHR) Incentive Program and are pleased to offer our comments for your consideration.

Summary of Comments/Recommendations

General Concerns

- Ongoing barriers to widespread adoption of EHR systems, including their high cost, lack of specialty-relevant functionalities and measures, and interoperability continue to impede meaningful use of these technologies.
- Moving to a uniform definition of meaningful use by 2018, regardless of specialty and participation status, perpetuates the problematic one-size-fits-all approach that has long plagued this program, and remains a barrier to meaningful participation among specialists.
- CMS' decision to dramatically increase thresholds for Stage 3 seems not only aggressive, but arbitrary given low participation rates to date and insufficient data on which to base well-informed policymaking.
- We urge CMS to recognize reporting to a Qualified Clinical Data Registry (QCDR) as satisfying the CQM component of the EHR Incentive Program.

Comments on Specific Measures

- Overall, we appreciate CMS' decision to, in some cases, finalize lower thresholds than originally proposed, to align reporting requirements, and to provide some flexibility in regards to measure choice.
- However, we continue to believe that many thresholds remain too high, especially for first time participants, and represent too substantial of a leap from the Stage 2 requirements.
- We also strongly oppose holding physicians accountable for actions outside of their direct control, especially since the EHR Incentive Program will continue to be an "all-or-nothing" penalty-only program.

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General Concerns

Ongoing Impediments to Meaningful Use of EHRs

As noted in our original comments, the AANS and CNS support the goal of a national health information infrastructure and recognize the potential value of electronic health records to improve the quality of patient care. Nevertheless, there are considerable barriers to widespread adoption of electronic health record (EHR) systems. 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.

Regarding 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 the Office of the National Coordinator (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 have ongoing concerns about CMS' decision to move toward a single, uniform definition of meaningful use (i.e. Stage 3), with which all providers would be required to comply by 2018 — regardless of their prior experience participating in the program. While we fully appreciate the agency's intent to streamline the program's requirements in order to minimize administrative complexity, this policy 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 strongly urge CMS to continue to rely on a wide assortment of menu objectives (versus a more limited set of required objectives), which would give specialists the flexibility to choose objectives and measures 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 CMS' decision to eliminate the 90-day reporting period for first-year participants in 2018. 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. 2018 should be no different, especially if CMS ultimately decides to hold all participants, regardless of previous experience, to a substantially higher bar in 2018.

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 finalized its decision 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. This approach might be reasonable if CMS opted to maintain its original phased approach to meaningful use and only required this in the latest stages. However, since CMS is requiring all professionals to comply with the same requirements in 2018, we view this policy as unreasonable and continue to 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 low participation rates have produced sufficient data to accurately guide policymaking for Stage 3. With such little program experience, CMS decision to dramatically increase thresholds for Stage 3 seems 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 more carefully study experience with prior stages of meaningful use and existing barriers to engagement before finalizing this expansion of requirements for all providers by 2018.

We also urge CMS to keep in mind that the entire physician quality reporting infrastructure is about to be overhauled with the introduction of the Merit-Based Incentive Payment System (MIPS), which is expected to first impact physicians with the 2017 reporting year and 2018 payments. Meaningful use of EHRs is one of four components that will determine physician performance-based Medicare payment adjustments under MIPS. CMS should hold off on finalizing Stage 3 policies until it has more thoughtfully considered other aspects of MIPS and how the various performance categories relate to each other. In doing so, CMS should use MIPS as an opportunity to press the reset button and re-evaluate its policies related to measuring and incentivizing meaningful use of EHRs.

Reporting of Clinical Quality Measures (CQMs)

In the final rule, CMS noted its intent to continue its policy of establishing certain CQM requirements for the Medicare EHR Incentive Program, including a common set of CQMs and specified reporting periods

for CQMs. It also finalized a policy to require electronic reporting of CQMs starting in 2018. CMS intends to address these requirements more specifically through subsequent Medicare Physician Fee Schedule rulemaking. As CMS works to craft these requirements, we strongly urge CMS to adopt a policy that allows Qualified Clinical Data Registry (QCDR) reporting to satisfy the CQM component of meaningful use. The current set of CQMs is largely primary care-focused and of little relevance to specialists. If an EP is already reporting data to a clinical data registry on the same number of quality measures as required under the CQM requirement of the EHR Incentive Program, we believe that this more than sufficiently demonstrates electronic capture of clinical quality measure data and should satisfy the CQM element of the program.

Comments on Specific Measures

Objective 1: Protect Patient Health Information

CMS finalized this measure with no changes.

> Measure: Conduct or review a security risk analysis, including addressing the security of ePHI created or maintained in CEHRT in accordance with federal requirements, and implement security updates as necessary and correct identified security deficiencies as part of the EP's risk management process.

The AANS and CNS support the general aim of this objective, but continue to strongly oppose the intended rule implementation that 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 with regards to 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

CMS finalized a lower threshold than proposed for the single measure under this objective.

> Measure: More than 60 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

The AANS and CNS appreciates that CMS' finalized a lower threshold than originally proposed for this measure. As such, more than 60 percent (rather than 80 percent) of all permissible prescriptions written by the EP must be queried for a drug formulary and transmitted electronically using certified EHR technology. Still, we request that CMS should adopt a lower threshold (such as 40 percent) for first year participants, as was finalized for those scheduled to participate in Stage 1 in 2015. As CMS notes in the rule, appropriate management of prescribed medications in both acute and chronic care patients is critical and too high of a reporting threshold could put patient safety at risk.

CMS also finalized its decision to continue to allow providers the option to include or exclude controlled substances in the denominator where such medications can be electronically prescribed. CMS clarifies that these prescriptions may be included in the definition of "permissible prescriptions" at the EP's discretion, where allowable by law. We appreciate and support CMS' clarification that this decision will remain in the control of the EP and not be mandatory for those who practice in states where it is permissible to report them electronically.

We continue to support exempting from this measure EPs who write fewer than 100 permissible prescriptions during the EHR reporting period. However, it is not completely clear whether CMS intends to count controlled substances toward the 100 "permissible prescriptions," when determining exemptions. CMS states: "We will define a permissible prescription as all drugs meeting our current

Stage 2 definition of a prescription with a modification to allow the inclusion of controlled substances where feasible and allowed by law as proposed in Stage 3 in the denominator of the measure. We will no longer distinguish between prescriptions for controlled substances and all other prescriptions, and instead will refer only to permissible prescriptions. Therefore, we are changing the measure for this objective to remove the term controlled substances from the denominator and instead changing the denominator to read 'permissible prescription.'"

The AANS and CNS believe that CMS should NOT include controlled substances as a "permissible prescription" when determining whether an EP is eligible for an exclusion based on writing fewer than 100 permissible prescriptions during the EHR reporting period. Most of our members write very few prescriptions and the prescriptions they do write are often only for controlled substances. Although an increasing number of states now permit the e-prescribing of controlled substances, these members still face significant barriers transmitting these prescriptions, including security compliance, provider authentication, pharmacy inability to electronically accept these prescriptions, and other regulatory barriers. If CMS counts controlled substances toward the 100, it will be very difficult for these providers to take advantage of this exclusion when it might be appropriate.

Objective 3: Clinical Decision Support

CMS finalized two measures for this objective, as originally proposed.

> Measure 1: The EP must implement five CDS interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period. Absent four CQMs related to a provider's scope of practice or patient population, the CDS interventions must be related to high-priority health conditions.
>
> Measure 2: The EP enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

The AANS and CNS appreciate the wide range of options provided under this finalized policy, which is particularly important for neurosurgical specialists. CMS clarifies in the final rule that EPs who are not able to identify four CQMs that apply to their scope of practice or patient population may implement CDS interventions that "they believe are related to high-priority health conditions relevant to their patient population and will be effective in improving the quality, safety or efficiency of patient care." We take this to mean that CMS will give EPs the freedom to make these determinations on an individual basis and hope that CMS will not hold EPs to any sort of validation process to confirm whether a CQM could have applied, similar to the Measures Applicability Validation (MAV) process under PQRS. CMS also notes in the rule that these high priority conditions must be determined prior to the start of the EHR reporting period in order to implement the appropriate CDS to allow for improved performance. We request that CMS further clarify whether this was intended to be a requirement, with an associated formal process for making this declaration, or whether CMS was merely making a suggestion.

CMS also clarifies that for providers linking CDS to CQM selections, they are not limited to the CQMs they choose to report for the EHR Incentive Program. Also, the same interventions do not have to be implemented for the entire EHR reporting period as long as the threshold of 5 CDS interventions (at any given time) is maintained for the duration of the EHR reporting period. Finally, CMS also clarifies that CDS need not necessarily be presented during a patient encounter. We appreciate this flexibility.

Objective 4: Computerized Provider Order Entry

CMS finalized a lower threshold than originally proposed for Measure 1 and finalized Measures 2 and 3 as proposed:

Measure 1: More than 60 percent *[rather than 80 percent, as proposed]* of medication orders created by the provider during the EHR reporting period are recorded using CPOE.

Measure 2: More than 60 percent of laboratory orders created by the provider during the EHR reporting period are recorded using CPOE.

Measure 3: More than 60 percent of diagnostic imaging orders created by the provider during the EHR reporting period are recorded using CPOE.

The AANS and CNS appreciate that CMS lowered the threshold for Measure 1 to align with the other two measures under this objective, which should help to minimize administrative complexity. However, we continue to believe that the thresholds for the remaining two measures are too high. While the threshold for Measure 1 is now consistent with the threshold finalized for Stage 2 reporting from 2015-2017, the thresholds finalized for Measures 2 and 3 in Stage 3 are ***double*** what they are for Stage 2 (i.e., 60 percent vs. 30 percent).

Objective 5: Patient Electronic Access to Health Information

CMS finalized two measures for this objective.

Measure 1: For more than 80 percent of all unique patients seen by the EP:

(1) The patient (or the patient authorized representative) is provided access to view online, download, and transmit (VDT) his or her health information within 24 hours of its availability to the EP; and
(2) The patient (or the patient authorized representative) is provided access to an ONC certified API that can be used by third-party applications or devices to provide patients (or patient authorized representatives) access to their health information, within 24 hours of its availability to the EP.

Measure 2: The provider must use clinically relevant information from certified EHR technology to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the provider.

For Measure 1, we again thank CMS for clarifying that the provider is only required to provide patient access to the information through the means outlined and that ***the patient is not required to take action in order for the provider to meet this objective***. Additionally, CMS specifically states that "this objective should not require the provider to make extraordinary efforts to assist patients in use or access of the information, but the provider must inform patients of these options, and provide sufficient guidance so that all patients could leverage this access." Nevertheless, we remain concerned that CMS finalized the 80 percent threshold for Measure 1, as proposed. This represents a substantial leap from the 2015-2017 Stage 2 requirement of 50 percent.

This higher threshold is particularly concerning given CMS' decision to finalize a policy for Stage 3 that would *require that EPs offer all four functionalities* — that is, that the patient is provided timely access to view, download, and transmit, AND access through application programming interfaces (APIs) his/her health information. During rulemaking, CMS considered an alternate proposal that would have made the API function optional. Although APIs, which enable patients to access their health information through third- party applications, may provide patients with more flexibility than in currently found in many patient portals, we do not believe that EPs should be held accountable for ensuring all four of these functionalities. EPs should have the flexibility to choose between a patient portal, API, or both options, but none of these functionalities should be *mandatory* so long as at least one is implemented (similar to how the finalized Objective 6, Measure 1 is worded below). As noted in the final rule, patient portals are already in place and widely used by patients, who might not want to change their approach to obtaining

data. Alternatively, some EPs might prefer to use APIs because they provide more flexibility and might not require as big of an investment as a "patient portal." To account for the fact that APIs and patient portals both have clear advantages and disadvantages depending on the needs of an EP's practice and patient population, we urge CMS to give EPs the choice to use either a portal or enable the functionalities of an API (or both), but not to require both. The AANS and CNS also oppose the requirement that patients could use any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT since this could pose an obstacle to continued refinement and innovation, and stymie the development of low-cost APIs by third parties.

This measure, as proposed, also originally included a 24-hour timeframe. The AANS and CNS originally commented that 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 requested that CMS consider extending this timeframe to at least 4 business days. While we still believe that EPs should have up to 4 business days (which is the standard adopted for Stage 2), we appreciate that CMS at least extended this requirement to 48 hours.

Regarding Measure 2, CMS finalized its decision to no longer allow the use of paper-based methods for capturing this measure. We once again request that CMS maintain the flexibility of allowing providers to use paper-based methods and count paper-based transactions in the measure numerator, especially for EPs who predominately work with a patient population that prefers paper-based resources or for those new to the program. Furthermore, we are concerned about the 35 percent threshold for this measure. At the very least, CMS should lower it so that it aligns with the finalized Stage 2 requirement of 10 percent for first time participants.

Objective 6: Coordination of Care through Patient Engagement

CMS finalized modified versions of all three of the following measures that fall under this objective. CMS also finalized its proposal that EPs would need to attest to all three of these measures, but only meet the thresholds for two of the three.

> Measure 1: During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) seen by the EP actively engage with the EHR made accessible by the provider and either:
> (1) view, download or transmit (DVT) to a third party their health information; or
> (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or
> (3) a combination of (1) and (2).
>
> *Threshold for 2017: The resulting percentage must be more than 5 percent.*
> *Threshold for 2018 and beyond: The resulting percentage must be more than 10 percent.*
>
> **Note: CMS originally proposed a threshold of more than 25 percent for this measure, which also originally did not include the option of using a combination of both DVT and APIs. CMS also did not originally distinguish between reporting years in regards to setting thresholds.*
>
> Measure 2: For more than 25 percent of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient or their authorized representative.
>
> *Threshold for 2017: The threshold is 5 percent.*
> *Threshold for 2018 and beyond: The threshold is 25 percent.*

**Note: CMS original proposed a threshold of 35 percent with no distinction regarding reporting year.*

Measure 3: Patient generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5 percent of all unique patients seen by the EP during the reporting period.

**Note: CMS originally proposed a threshold of more than 15 percent for this measure.*

In regards to Measures 1 and 3, 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 electronic 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 appreciate that CMS reduced the thresholds for these measures, we continue to oppose holding physicians accountable for the actions of their patients, especially since the EHR Incentive Program will continue to be an "all-or-nothing" penalty-only program under these finalized Stage 3 rules. Also, although CMS purports to adopt a phased approach by finalizing significantly lower thresholds for 2017 versus 2018, participation in Stage 3 is optional in 2017 and will only be pursued by the most advanced and well-resourced providers. Therefore, this policy does virtually nothing to assist EPs who are demonstrating meaningful use for the first time in 2018.

For Measure 1 specifically, we oppose the 10 percent threshold finalized for 2018 and instead urge CMS to adopt the requirement that it finalized for this measure for Stage 2, which is that at least one patient satisfy the VDT requirement. We strongly urge CMS to finalize this requirement for Stage 3, as well. At the very least, CMS should require that EPs, who are demonstrating meaningful use for the first time in 2018, only have to demonstrate compliance with this measure for at least one patient.

We also believe that the finalized threshold for Measure 2 is still too high since the majority of EPs will not opt to comply with Stage 3 until 2018, at which point they will be held accountable to the 25 percent threshold. We strongly urge CMS to lower the threshold for 2018 so that it is not such a major leap from the 2017 requirement of 5 percent.

Finally, regarding Measure 3, we have similar concerns about EPs being held accountable for patient actions. We also question the accuracy, timeliness and value of incorporating non-clinical or patient generated data into the EHR. While we appreciate that CMS offers a broad definition of the types of data that would satisfy this measure (e.g., advance directives, medical device data, home health monitoring data, fitness monitor data, and patient-reported outcomes data), most EHRs still have not adopted a standardized mechanism for capturing and incorporating this type of data.

Overall, we support the goal of ensuring patients have access to health information in a timely manner, but do not believe that patient action should 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. We recommend that CMS make one overall threshold for this objective, such as one patient, and allow EPs to satisfy it using any

combination of the three measures-- whether it be reporting on one measure or a combination of two or all three.

Objective 7: Health Information Exchange

CMS finalized the measures under this objective as proposed. EPs must attest to all three of these measures, but only meet the requirements of two of the three measures.

> Measure 1: For more than 50 percent of transitions of care and referrals, the EP that transitions or refers their patient to another setting of care or provider of care: (1) creates a summary of care record using certified EHR technology; and (2) electronically exchanges the summary of care record.
>
> Measure 2**:** For more than 40 percent of transitions or referrals received and patient encounters in which the EP has never before encountered the patient, the provider incorporates into the patient's record in their EHR an electronic summary of care document from a source other than the provider's EHR system.
>
> Measure 3: For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP performs clinical information reconciliation. The EP must implement clinical information reconciliation for the following three clinical information sets:
>
> (1) Medication review of the patient's medication, including the name, dosage, frequency, and route of each medication.
> (2) Medication allergy review of the patient's known allergic medications.
> (3) Current problem list review of the patient's current and active diagnoses.

While we appreciate that physicians would only have to meet the thresholds for two of the three measures under this objective and that CMS finalized exclusions that would hold harmless EPs who refer patients less than 100 times during the reporting period, we have ongoing concerns 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. If CMS maintains these measures, it should at least adopt an additional exclusion that recognizes situations where the technology is not yet installed and tested to meet this objective.

Objective 8: Public Health and Clinical Data Registry Reporting

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.

CMS made multiple modifications to these measures, as originally proposed. Instead of EPs needing to report on three of the five measures applicable to an EP, the final rule only requires that EPs successfully attest to any combination of two of the five measures. CMS also finalized its policy that EPs could report on more than one registry for Measures 4 and 5 to meet the requirements of this objective.

> Measure 1, Immunization Registry Reporting: The EP is in active engagement with a public health agency (PHA) to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

Measure 2, Syndromic Surveillance Reporting: The EP is in active engagement with a PHA to submit syndromic surveillance data from an urgent care ambulatory setting for EPs.

**Note: the original proposal required submission from "non-urgent settings."*

Measure 3, Case Reporting: The EP is in active engagement with a PHA to submit case reporting of reportable conditions.

Measure 4, Public Health Registry Reporting: The EP is in active engagement with a PHA to submit data to public health registries.

Measure 5, Clinical Data Registry Reporting: The EP is in active engagement to submit data to a clinical data registry (CDR).

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.

As such, we thank CMS for broadening the scope of this objective, as proposed, to include clinical data registries. We also thank CMS for finalizing for both Stage 2 and Stage 3, a policy that recognizes an EP's "active engagement" in a registry, rather than the previous requirement of successful "ongoing submission" of data from a CEHRT to a registry. "Active engagement" is much more flexible and includes registering with a CDR to submit data.

While we appreciate CMS responding to stakeholder concerns by lowering the requirement for this objective so that EPs only have to satisfy two out of five of the measures, this policy fails to recognize that most specialists who are engaged in registry reporting only report to a single meaningful registry. Therefore, we believe the requirement to participate in two registries is arbitrary and does not account for the realities of clinical practice. We fully support the value of registries and efforts to promote them, but EPs should only have to engage in a single registry to satisfy this objective since that is often all that is available and relevant to most specialists.

In our original comments, we also sought clarification on the exclusions proposed for clinical data registries. We questioned how CMS would determine that a provider:

- 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.

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

CMS clarified in the final rule that its definition of jurisdiction was intended to be general, and that the scope may be local, state, regional or at the national level. According to the agency, the definition will be dependent on the type of registry to which the provider is reporting. A registry that is "borderless" would be considered a registry at the national level and would be included for purposes of this measure. While we appreciate this clarification, it might be helpful (and avoid future ambiguity) if CMS defined this in terms of a registry's applicability to an EP's practice rather than framing it in terms of the registries available in one's jurisdiction

Finally, we continue to strongly support the fact that an EP could claim an exclusion for all five measures if the relevant registry is not capable of accepting the specific standards required to meet the certified EHR technology definition at the start of the EHR reporting period or has not declared readiness to accept the data at the start of such reporting period. We especially appreciate that CMS broadened the proposed exclusions for each measure under this objective so that they include a 6 month lead time for the declaration of readiness rather than requiring that registries declare readiness on the first day of the EHR reporting period (i.e., if a registry has not declared 6 months before the start of the EHR reporting period whether it will be ready by January 1 of the upcoming year for use by providers seeking to meet EHR reporting, a provider can claim an exclusion).

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 with the course of patient care, then physicians will just stop participating — despite incurring payment 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 MIPS. 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 once again comment on the Stage 3 requirements. We look forward to working with both CMS 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.

Sincerely,

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