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May 7, 2012

Marilyn B. Tavenner, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Subject: Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2; CMS-0044-P; RIN 0938-AQ8

Dear Ms. Tavenner:

On behalf of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), we appreciate the opportunity to provide comments on the proposed *Medicare and Medicaid Electronic Health Records Stage 2* program*.* Neurosurgeons are currently working towards adopting and incorporating electronic health records (EHR) into their practices to improve quality of care, provider workflow, patient safety and efficiency. However, stringent, overly ambitious incentive program requirements and the inability of specialists to tailor the program to their practice will hinder widespread adoption of health information technology by neurosurgeons. Finalizing a program that allows for flexibility and for physicians to adopt objectives and measures that enhance and meet the needs of their practice will result in the desired result of extensive use of technology to advance the country's health care system.

Neurosurgery understands that the legislation requires Meaningful Use of EHRs, but it provides for broad discretion in regards to implementation and program requirements. In addition, we recognize that the widespread and proper use of HIT will help transform health care by facilitating health information exchange, reducing inefficiencies, and improving quality of care, but to achieve the intended outcome financial incentives must be associated with realistic and practical measures to support the use of EHRs. Onerous measures and aggressive thresholds will not.

In the April issue of *Health Affairs,* Hsiao, et al[1] highlight that the Center for Medicare and Medicaid Services (CMS) estimated in 2010 that 36 percent of Medicare-eligible professionals and 15–47 percent of Medicaid-eligible professionals would demonstrate meaningful use in 2011. However, their survey results show much lower adoption of Stage 1 Meaningful Use at 11 percent when 51 percent indicated they intended to apply. It is evident that the low adoption rate is due to the overly burdensome program reporting requirements and physicians EHRs not having the capabilities to meet Meaningful Use. Most likely, the adoption numbers will decline if CMS moves forward with the proposed Stage 2 requirements.

[1] Hsiao Chun Ju, et al. Most Physicians Were Eligible For Federal Incentives In 2011, But Few Had EHR Systems That Met Meaningful-Use Criteria. *Health Affairs.* No. 5 (2012).

The following is a summary of our recommendations for Stage 2 Meaningful Use:

1. We strongly believe reasonable exclusions need to be maintained and included so that a physician can opt out of the measure if the measure has little relevance or does not enhance a physician's routine practice.
2. Measures that require reliance on a third party must be removed, such as requiring patients to access their health information online.
3. We urge CMS to limit the number of measures in the core set, expand the number of measures in the menu set and develop appropriate exclusions for each measure. If an increase in the threshold percentage of a measure is warranted, then the increase for Stage 2 should be no more than 10 percent. In addition, allowing physicians to opt-out of a certain number of measures to encourage more physician participation.
4. We oppose CMS' proposal to back-date the meaningful use reporting requirements under the penalty program so that a physician would face the 2015 penalty based on 2013 or 2014 data.
5. We recommend that the thresholds for CPOE and similar measures that cannot be met due to the lack of bidirectional health information exchanges be significantly lowered. We urge CMS to allow CPOE entry to be expanded to include non-licensed health care professionals.
6. CMS' proposal to require that electronic prescriptions be sent to pharmacies outside the EP's organization in order to count towards meeting this measure is unreasonable. We recommend that electronic prescriptions sent to pharmacies within and outside the EP's organization count towards meeting this measure.
7. We are supportive of allowing physicians to achieve the vital sign measure by either collecting blood pressure or height/weight. The proposal allows specialties that may not generally perform or have a need for the objective to maintain their workflow.
8. Neurosurgery does not support the clinical decision support (CDS) measure as proposed since implementing five CDS interventions will be difficult for neurosurgery to meet. Most EHRs do not have a neurosurgery template or module so there is no way for neurosurgeons to determine the interventions to be presented through EHR technology. Physicians should only have to attest to implementing no more than 2 CDS support rules.
9. We do not support the requirement that physicians send reminders to patients seen 24 months prior to the beginning of the EHR reporting period. This is a challenging requirement for neurosurgery because neurosurgeons do not provide "preventive care" so often services are one-time consultative visits. We recommend that the measure include an exclusion for physicians who do not routinely send reminders to their patients given the type of care that they provide.
10. We advise CMS to move away from any measure that requires modular certification.
11. We strongly recommend that the turnaround time for providing clinical summaries remain at three business days.
12. We do not support requiring physicians to identify EHR technology used by another physician or health care provider that they are transitioning or referring their patient to. It places a tremendous administrative burden on physicians to research what systems other providers are using, whether these systems are interoperable and influences referral patterns.
13. We strongly support the use of registries and recommend that registries be defined in the broadest terms.
14. Neurosurgery is concerned with the proposed clinical quality measures (CQM) options and the number of CQMs required to successfully achieve Meaningful Use. Requiring physicians to report on 12 CQMs is unrealistic and undermines the intent of quality improvement. Neurosurgery recommends that CMS expand the measures to include more measures included in PQRS and for physicians to not have to report on core measures or measures within a specific domain.
15. We support the establishment of an appeals process for the Meaningful Use program; however, we urge CMS to provide physicians with at least 180 days to file an appeal after receiving actual notice of determination(s) that are subject to appeal at all levels of appeal.

General Concerns and Recommendations on the Meaningful Use Program

Neurosurgery is supportive of a staged approach to the Meaningful Use incentive program, but the approach must take into account the current technological realties and the additional financial and administrative costs that will be incurred by physician participation in the incentive program. **We strongly believe reasonable exclusions need to be maintained and included so that a physician can opt out of the measure if the measure has little relevance or does not enhance a physician's routine practice**. If exclusion(s) (in both the core and menu sets) apply to a physician, then the exclusion should count towards meeting the program requirements. In addition, it is unreasonable to expect physicians to meet all 20 measures plus clinical quality measure reporting to prove that they are a meaningful user of a certified EHR. As the overall proposal stands, it will force neurosurgeons to practice primary care medicine to meet Stage 2 requirements, which is inappropriate when treating patients with neurosurgical conditions. Furthermore, high thresholds to meet objectives must be avoided, especially for measures that are not part of routine practice or due to the lack of available, well-tested tools or bidirectional health information exchange. **Measures that require reliance on a third party must also be removed.** For example, patient's accessing patient portal, labs reporting test results.

Proposed new measures should be initially placed in the menu set for Stage 2. Many of these proposed new measures require further definition, enhancement, workflow redesign and significant increased cost. Requiring mandatory adherence to a new feature will result in low achievement, especially in small physician practices that do not have the internal staff or resources to absorb the additional software and training costs.

Physicians should have an opportunity during the attestation process to explain any difficulties they had in meeting meaningful use measures and should be able to opt-out of meeting three measures at minimum, and still be eligible to receive incentives or be able to avoid penalties. The focus of Stage 2 meaningful use should be on quality not quantity. In summary, **we urge CMS to limit the number of measures in the core set and expand the number of measures in the menu set, and develop appropriate exclusions for each measure.** If an increase in the threshold percentage of a measure is warranted, then the increase for Stage 2 should be **no more** than 10 percent. In addition, allowing physicians to opt-out of a certain number of measures (e.g., three or more) is the type of flexibility needed in the meaningful use program that would encourage more physician participation and increase participation rates.

Proposed Penalty Year

We oppose CMS' proposal to back-date the meaningful use reporting requirements under the penalty program so that a physician would face the 2015 penalty based on 2013 or 2014 data. A number of exemption categories should be established and the exemptions should apply for five calendar years to minimize filing burdens and to allow time for CMS to reassess program requirements and timelines. If the participation rates are low and/or too many physicians are applying for exemptions, then significant changes need to be made to the meaningful use program requirements in the penalty phase, and exemption categories may need to be revised and additional ones developed.

Evaluation of Core Objectives for Stage 2 of Meaningful Use

- *CPOE: Use CPOE for medication, laboratory and radiology orders directly entered by any licensed health care professional who can enter orders into the medical record per State, local and professional guidelines to create the first record of the order*

We recommend that the proposed high threshold requirements for computerized physician order entry (CPOE), incorporating lab test results and similar measures be reduced. For example, requiring physicians to enter into their EHRs at least one medication and one lab or radiology order for 60 percent of their unique patients who have at least one such order, will require physicians to expend significant time and resources to manually gather information that spans both electronic and paper-based systems. In the case of referrals, it is typical for specialists and independent labs to require their own paper form to be completed by the referring/ ordering physician. Therefore, entering the order electronically through CPOE would then need to be followed up with a manual process involving a paper form. Until there is a bidirectional exchange of data and robust decision support, we do not believe the value of CPOE can be fully realized just through manual entry of most orders. Jumping from 30 percent compliance in Stage 1 to 60 percent compliance in Stage 2 is too high a bar too soon. **We recommend that the thresholds for CPOE and similar measures that cannot be met due to the lack of bidirectional health information exchanges be significantly lowered.**

We urge CMS to allow CPOE entry to be expanded to include non-licensed health care professionals. Routine practice is for a person other than the ordering healthcare professional to input the details of the CPOE and ultimately the physician signs off or approves. Not allowing a non-licensed health care professional to enter the order will slow down practice work flow and lead to a delay in orders.

- *e-Prescribing: Generate and transmit permissible prescriptions electronically Measure: More than 65% of all permissible prescriptions written by the Eligible Professional (EP) are compared to at least one drug formulary and transmitted electronically using Certified EHR Technology*

Neurosurgery believes the threshold to adhere to this measure is too high, especially for a specialty that prescribes a large amount of narcotics. We understand that narcotics are excluded from meeting the objective since some state laws prohibit the electronic transmission, but this leads to neurosurgeons moving between work flows. Often it is easier for a practice to stay with writing paper prescriptions to avoid switching systems. It is difficult to go between e-prescribing for non-narcotics and print for narcotics.

We have also heard from practices that they have had difficulty with meeting the Stage 1 threshold at 40 percent because patients are demanding a printed copy as they file their prescriptions by mail order; even when the practice explains that some mail orders can take e-prescribed prescriptions they still want the printed copy. **The increased threshold from 40 percent to 65 percent is too large for Neurosurgery given all the drugs the specialty cannot electronically prescribe.**

CMS' proposal to require that electronic prescriptions be sent to pharmacies outside the EP's organization in order to count towards meeting this measure is unreasonable. We recommend that electronic prescriptions sent to pharmacies within and outside the EP's organization count towards meeting this measure.

While we support exclusions for this measure including the one proposed by CMS that would allow EPs to be excluded from this measure if no pharmacies within 25 miles of an EP's practice location at the start of his/her EHR reporting period accept electronic prescriptions, we believe a broader exclusion category should also be established. We recommend that CMS establish an additional exclusion category that is broad enough to cover physicians who cannot meet the e-prescribing threshold requirement due to their individual hardship. For example, one for physicians who are unable to meet the threshold requirement due to issuing a large volume of mail-order prescriptions. The exclusion should also apply to physicians who mainly prescribe controlled substances. Challenges still remain on the e-prescribing of controlled substances including more restrictive state

laws and the lack of widespread availability of health IT products both for physicians and pharmacies that include the functionalities required by the Drug Enforcement Agency's (DEA) regulations for the e-prescribing of controlled substances. Until the many challenges associated with e-prescribing referenced above are resolved, the threshold for the e-prescribing measure should be no higher than 50 percent and EPs should have the discretion (not be required) to review the drug formulary, if it is readily available in Stage 2. A broad exclusion category for physicians who cannot meet the e-prescribing threshold requirement due to their individual hardship should also be established.

- *EP Core Measure 3: More than 80 percent of all unique patients seen by the EP during the EHR reporting period have demographics recorded as structured data.*

  Neurosurgery is supportive of this measure, but the increased threshold and proposed addition of demographic information is too burdensome. We support the inclusion of the recording of gender identity and/or sexual orientation, disability status, occupational demographics, etc., **as optional** information for physicians to record given that the capturing of this data is important for quality of care purposes for the appropriate specialties. Given the significant amount of information that physicians are being required to record under the meaningful use program, we urge CMS to provide as much flexibility as possible so that physicians have the discretion to record information that they believe is relevant to the care that they provide to their patients.

  We are hearing from practices in states that have tough immigration laws, like Arizona, that the patient feels the practice is being too intrusive by asking for this information. Patients feel the practice is invading their privacy and questioning them on what they are going to do with the data. Therefore, to include the additional data points will be very difficult to obtain and meet the proposed threshold. **To address this issue, we are proposing CMS include an exclusion to allow for practices to opt-out of recording the information, if they feel uncomfortable collecting demographics or the patient declines to provide.**

- *EP Core Measure 4: More than 80 percent of all unique patients seen by the EP during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.*

  Recording vital signs belongs in the clinical quality measure set; not the core health IT measure set. **The vital sign measure should be included in Table 8 within the clinical quality measure requirement for EPs to select from.** We strongly support the use of health IT to improve public health goals, however, requiring physicians to attest to and/or report on metrics that are not clinically relevant to them and their patients, or to every encounter with a patient, does not help improve quality or practice workflow.

  We are also supportive of allowing for physicians to achieve this measure by either collecting blood pressure or height/weight. The proposal allows for specialties that may not generally perform or have a need for the objective to maintain their workflow.

- *EP Core Measure 5: More than 80 percent of all unique patients 13 years old or older seen by the EP during the EHR reporting period have smoking status recorded as structured data.*

  Recording smoking status belongs in the clinical quality measure set; not the core health IT measure set. The smoking status measure should be included in Table 8 within the clinical quality measure requirement for EPs to select from. We strongly support the use of health IT to improve public health goals, however, requiring physicians to attest to and/or report on every encounter with a patient, does not help improve quality or practice workflow.

- *EP Core Measure 6: 1. Implement 5 clinical decision support interventions related to 5 or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period, and 2. The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.*

  Neurosurgery does not support the objective as proposed. Implementing five clinical decision support (CDS) interventions will be difficult for neurosurgery to meet. Most EHRs do not have a neurosurgery template or module so there is no way for neurosurgeons to determine the interventions to be presented through EHR technology. For example, in a tertiary care spine practice, there are NO decision support interventions that are appropriate. Appropriate rules must be derived from scientific evidence, much like measure development, and consensus. Once the clinical decision support rules are created, they then have to be incorporated into EHRs and this process, which takes time for vendors to implement and for physician offices to understand. Physicians should not be forced to implement low level CDS just to meet the objective. It will lead to alert fatigue and not enhance clinical practice.

  CMS' proposal that requires physicians to implement a total of 5 clinical decision support interventions is highly burdensome given the financial and administrative costs associated with clinical decision support systems. CMS should thoroughly evaluate clinical decision support prior to making any major modifications to the Stage 1 requirements on clinical decision support. Moreover, the requirement to implement 5 clinical decision support interventions related to five or more clinical quality measures would be challenging for certain specialists and sub-specialists who may not need to implement so many clinical decision support interventions for their particular patient populations given the specific type of care that they provide. **EPs should only have to attest to implementing no more than 2 clinical decision support rules during the reporting period for Stage 2.**

  In regards to the second part of the objective that requires the EP to enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period, physicians should be provided with the flexibility to use their judgment regarding where to set the threshold setting. For physicians that do not actively participate in patient pharmacy management, the drug/drug interaction is irrelevant. **We recommend, however, that an exclusion category be established for this second component for specialists who neither routinely prescribe nor actively participate in patient pharmacy management.**

- *EP Core Measure 7: More than 55 percent of all clinical lab tests results ordered by the EP during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in Certified EHR Technology as structured data.*

  Neurosurgery is supportive of incorporating lab tests into the EHR, but **we are not supportive of making this measure mandatory and the increased threshold. The threshold needs to be maintained at 40 percent or maintained as a menu objective.** For specialties that are not lab intensive, requiring the EHR to incorporate lab modules will be costly and burdensome. It will also require the implementation of several laboratory interfaces due to the requirements of insurance. Each health plan has its own preferred labs. We believe that until such time that all laboratory service providers are obliged to follow an interface and transport standard for sending results to EHR systems, and EHR vendors are required as part of their certification criteria to be able to successfully accept such test results into the EHR system, the measure cannot be mandatory and the threshold lowered to 40 percent. The measure is too aggressive and burdensome for physicians due to the required expertise, and cost of setting up functioning electronic laboratory interfaces. If the measure

stands as proposed, it would mean manual data entry processes required to meet the measure which is far too costly, burdensome, and error-prone, with potential risks to patient safety and quality.

Customized interfaces between an EHR and lab systems (which are predominantly hospital-based) do not exist on a widespread basis today, and even when they are technically feasible they are difficult and costly for physician practices to implement, test, and maintain. The incorporation of clinical lab results into EHRs as structured data is dependent on the EHR vendor and the laboratory, not just the physician's use of the EHR.

Physicians and their staffs should not be expected to key in lab results simply because there is no ability for the lab to send these results directly to the EHR. It is incumbent upon the Office of the National Coordinator (ONC) to ensure the interoperability of EHR systems and advocate for the inclusion of expectations of laboratory service providers to follow a single standard that EHR vendors can adopt so that laboratory result interfaces can be easily created by EHR vendors and offered at little to no additional cost to physicians and other EPs who use their products.

- *EP Core Measure 8: Generate at least one report listing patients of the EP with a specific condition.*

  Neurosurgery is supportive of this measure. Physicians should have the discretion as the type of lists that are relevant to their practice and patient population.

- *EP Core Measure 9: More than 10 percent of all unique patients who have had an office visit with the EP within the 24 months prior to the beginning of the EHR reporting period were sent a reminder, per patient preference.*

  We support CMS' proposed measure for sending reminders to patients, but are concerned that the measure as written is inappropriately inflexible for many specialists, especially neurosurgeons. We support EPs utilizing this electronic capability as part of their daily work process, and believe that for Stage 2, EPs should have the discretion to issue reminders in a variety of ways. However, the Stage 2 measure should be flexible enough to allow for reminders to be provided via phone calls, voice mail messages, emails, printed reminder notices provided after the initial visit, etc. Physicians should have the flexibility to implement method(s) that work best for the physician practice and the patient. CMS should not be dictating how a practice reminds patients of office visits.

  We do not support the requirement that physicians only focus the sending of reminders to patients seen 24 months prior to the beginning of the EHR reporting period. This would be a challenging requirement for certain specialties and sub-specialists, especially neurosurgery. Neurosurgery does not, for example, provide "preventive care" so often services are one-time consultative visits; therefore, there is no need to send a reminder to the patient for a follow-up visit. **We recommend that the measure include an exclusion for physicians who do not routinely send reminders to their patients given the type of care that they provide.** This proposed measure is another example of where more flexibility is needed to accommodate varying physician practices. Physicians should have the flexibility to send reminders to patients, regardless of the date of their previous visit, and should be excluded from this measure if they do not typically send reminders.

- *EP Core Measure 10: 1. More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within four business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information, and 2. More than 10 percent of all unique patients seen by the EP during the EHR*

reporting period (or their authorized representatives) view, download, or transmit to a third party their health information.

Neurosurgery opposes the 50 percent threshold and the 4 day turnaround time proposed by CMS and we strongly oppose the second component of the measure that holds the physician accountable for patient compliance/non-compliance. Practices who have patient portals have indicated that their patients are not using the feature or requesting records in an electronic form. It is costly for a practice to invest in this feature and to upload all the data.

CMS needs to evaluate the reasonableness and burdensome nature of the four business day turnaround time required by this measure, prior to moving this Stage 1 menu measure to the core set. Physicians already follow standards for communicating medical information to patients and know best how the patient will accept and react to the information, etc. Therefore, physicians should have the ability to make these decisions based on the physician-patient relationship.

Implementing a patient portal to enable the secure, exchange of health information with patients is costly from both a financial and administrative standpoint. Obtaining a patient portal for an EHR system can be costly, and a physician practice would have to dedicate staff resources to managing the patient portal and patient communications. They must also ensure that the portal is compliant with HIPAA privacy and security requirements. The volume of patient information that has to be made available within four business days for the entire calendar year would be extraordinary for most practices and their staff to manage. This rigid measure does not take into account the realities of running a practice. Technological glitches, staffing shortages due to vacations, holidays, and other unforeseen circumstances occur throughout the calendar year and could cause a delay in providing the patient information within four business days. Such understandable delays could result in the physician not meeting this one measure, which would result in the physician not receiving incentives or ending up with a financial penalty. **Given the short timeframe associated with this proposed measure, we recommend that this measure be retained in the menu set and that the threshold requirement be no higher than 20 (not 50) percent.**

Neurosurgery strongly opposes the second portion of the measure due to adherence being outside the physician's control and is reliant on the patient. The demand that 10 percent of patients actually access their online health information is something physicians should not bear the risk of being penalized for since it is an independent and potentially appropriate decision made by the patient. Requiring EPs to compel patients to access their health records is not appropriate. **We strongly recommend that any measures that require adherence from a party other than the physician, including this proposed measure, be removed from the meaningful use program.**

We also advise CMS to move away from any measure that requires modular certification. CMS has indicated at HIT Policy Committee presentations that patient portal features will not be required as part of overall certification. Not requiring a feature to be part of overall certification is confusing to EPs and EPs may potentially be misled by vendors due to vendors indicating that their product is Meaningful Use certified and not realizing it omits requirements.

- *EP Core Measure 11: Clinical summaries provided to patients within 24 hours for more than 50 percent of office visits.*

Neurosurgery is supportive of physicians providing patients with clinical summaries, but the 24 hour timeline is not realistic. Turn-around time for dictations may require greater than 24 hours of time and will be difficult to reach, unless the summary is not reconciled and will likely be useless summation complied solely from the EHR. Care plans and complete dictation in a surgical practice usually

happen after the patient leaves and the chart note is completed. Solo and small practices do not have IT departments or IT experts readily available to them 24/7 to fix technological issues that may arise. Even in hospitals, IT support is markedly limited outside of the traditional 9-to-5 business week. Technological glitches, staffing shortages due to vacations, holidays, and other unforeseen circumstances occur throughout the calendar year and could cause a delay in providing clinical summaries within 24 hours. Such delays could result in the physician not meeting the measure, and not receiving incentives or ending up with a financial penalty.

We do support CMS' proposal to allow the EP to select any modality (e.g., online, CD, USB) as their electronic option, and CMS' proposal that the physician does not have to accommodate requests for different modalities. Physicians should also be allowed to provide printed summaries generated from their EHRs to their patients. This type of flexibility would accommodate Medicare patients who prefer printed summaries if they do not use or have access to computers.

We are also concerned with CMS' proposal that every physician produce 20 items to be included in the clinical summary, including administrative related information that a physician may only retain in his/her practice management system, in order to meet this measure. Moreover, detailed information in 20 categories is more information than a patient routinely needs and risks confusing them with conflicting or excessive information. This proposal is too burdensome and overly prescriptive. **Therefore, we strongly recommend that the turnaround time for providing clinical summaries remain at three business days, flexibility be provided on clinical summary content, and the threshold requirement should be no more than 20 (not 50) percent.**

We also seek clarification on the literacy level and how is this determined? Tailoring each summary to a patient's literacy level is an additional burden on the EP.

- *EP Core Measure 12: Patient-specific education resources identified by Certified EHR Technology are provided to patients for more than 10 percent of all office visits by the EP.*

  Educating the patient on the treatment or disease for the encounter is important, but it should be at the discretion of the EP to determine which resources are best suited for the patient and if they are needed. The EHR should not be dictating the resources the physician chooses to provide to the patient. The addition of this feature will be an additional cost to the provider as educational resources associated with the EHR are typically add-on features.

- *EP Core Measure 13: The EP performs medication reconciliation for more than 65 percent of transitions of care in which the patient is transitioned into the care of the EP.*

  Neurosurgery is supportive of the measure but seeks clarification. CMS needs to define transition of care and setting of care. Also, as a specialty heavily based on referral, what is the neurosurgeon's responsibility for medications that they do not prescribe? What is the liability of the specialist if they are provided incorrect or inaccurate information from the patient?

- *EP Core Measure 14: 1. The EP that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 65 percent of transitions of care and referrals and 2. The EP that transitions or refers their patient to another setting of care or provider of care electronically transmits a summary of care record using Certified EHR Technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender for more than 10 percent of transitions of care and referrals.*

We support providing a summary care record for transitions of care and referral but recommend that this measure continue to be listed in the menu set for Stage 2 and the threshold requirement remain at no more than 50 percent. We do not support, however, the second component of the measure which requires physicians to identify EHR technology used by another physician or health care provider that they are transitioning or referring their patient to. The second component of the measure places a tremendous administrative burden on physicians to research what systems other providers are using and whether these systems are interoperable. Physicians also have no control over market adoption. There are areas of the country, such as Philadelphia where large institutions in the immediate area are using the same EHR product. Regional Extension Centers (REC) may even exacerbate the problem since RECs only recommend products that participate in their program. The measure may also force physicians to only refer to colleagues participating in the EHR program, outside their institution or practice in order to meet this measure.

CMS also needs to better define what a transition of care is and when a referral requires the summary.

- *EP Core Measure 15: Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period.*

  In general we are supportive of this measure for testing, **we do not believe it should be a core measure and instead it should be moved to the menu set.** Interfaces with immunization registries and public health agencies do not readily exist. This measure also places a tremendous burden on physicians to research whether immunization registries or information systems in their jurisdiction are capable of accepting electronic immunization data.

  We also seek clarification on whether practices that offer staff flu immunizations and do not otherwise provide immunizations to their patients would be subject to report flu immunizations?

- *EP Core Measure 17: A secure message was sent using the electronic messaging function of Certified EHR Technology by more than 10 percent of unique patients seen during the EHR reporting period.*

  We do not support this measure as a core measure, and recommend that the measure be placed in the menu set for Stage 2, and that it be modified so that the messaging is from the physician, not the patient. First, because this is a proposed new measure, it is by definition untested and should therefore be placed in the menu set for Stage 2. We also have significant concerns with a proposed measure requiring physicians to email their patients. Not all patient populations feel comfortable using the internet or have access to patient resources. In addition, if a patient is undergoing care from multiple physicians, will patients have to send secure messages to each physician for the physician to meet the objective? An unintended consequence of promoting that patients send electronic messages to their physicians is that patients who may find themselves in a life-threatening situation may turn to email as a means of communicating with their physician, rather than attempting to immediately access their physician through the use of a telephone or pager or dialing 911.

  Furthermore, we are concerned that the proposed measure is basing the physician's success for meeting the measure on patient compliance. Physicians cannot force a patient to use secure messaging. In addition, many certified EHR systems today enable a physician to send an unsecure e-mail message to the patient indicating to the patient that s/he should log into a secure portal to

access their health information. A physician could not meet this measure as written using existing EHRs given that the original email to the patient is not through secure messaging. Another point of concern is that physicians who bill Medicare are not reimbursed under current payment policies for email communications with patients. **Physicians should not be forced to provide services that are not covered or non-billable under Medicare.**

Evaluation of Menu Set Measures for Stage 2

- *EP Menu Measure 1: More than 40 percent of all scans and tests whose result is one or more images ordered by the EP during the EHR reporting period are accessible through Certified EHR Technology.*

  Neurosurgery understands the intent of the measure, but for a first time measure the 40 percent threshold is too high. The pure volume of data that will be required to be stored for radiology orders requires tripling practices storage serves to hold all the data images. **We also do not support CMS' proposal that 10 percent of all scans and tests whose result is one or more images ordered by the EP during the EHR reporting period and accessible through Certified EHR Technology be exchanged with another provider of care.** The images that are created may not be accessible due to the system of the EP or other health care provider who creates the images. It would be burdensome for the ordering EP to figure out which other providers have the ability to receive the images electronically since secure health information exchanges and interfaces do not readily exist. Furthermore, in neurosurgery often there is not another physician involved in the care so the necessity to exchange is not there.

- *EP Menu Measure 2: More than 20 percent of all unique patients seen by the EP during the EHR reporting period have a structured data entry for one or more first-degree relatives.*

  Given that this proposed measure is a new measure for Stage 2, we agree that this measure should be located in the menu set of measures.

- *EP Menu Measure 3: Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period.*

  While we generally support this measure in the Stage 2 menu set for testing, **we do not support requiring ongoing submissions as a condition to meet this measure.** Very few public health agencies are currently accepting syndromic surveillance data from physicians. Interfaces with registries and public health agencies are a work in progress.

- *EP Menu Measure 4: Successful ongoing submission of cancer case information from Certified EHR Technology to a cancer registry for the entire EHR reporting period.*
  EP Menu Measure 5: Successful ongoing submission of specific case information from Certified EHR Technology to a specialized registry for the entire EHR reporting period.

  We strongly support the use of registries. Clinical data registries are valuable tools that support evidence development, performance assessment, comparative effectiveness studies, and the adoption of new treatments into routine clinical practice. **Therefore, we recommend that registries be defined in the broadest terms for these measures in the Stage 2 menu set**. Registries can provide high-quality evidence on par with randomized clinical trials while offering the added value of documenting patient experiences in everyday clinical practice rather than under strict eligibility and treatment protocols. Regularly observing patient responses to treatment can provide important insights into which healthcare strategies work best in actual practice.

Neurosurgery, through its clinical data registry program, the NeuroPoint Alliance (NPA), has recently launched The National Neurosurgery Quality and Outcomes Database (N^2QOD). This resource will allow any U.S. neurosurgeon or orthopedic spine surgeon, practice group, or hospital system to contribute to and access aggregate quality and outcomes data through a centralized, nationally coordinated clinical registry. The primary goals of this registry are to:

1) Establish risk-adjusted national benchmarks for the cost and quality of common neurosurgical procedures.
2) Allow practice groups and hospitals to analyze their individual morbidity and clinical outcomes in real-time and, in doing so, facilitate the development of new care initiatives.
3) Generate both quality and efficiency data to support claims made to public and private payers.
4) Demonstrate the comparative clinical effectiveness of neurosurgical procedures.
5) Facilitate the conduct of essential multicenter trials and other cooperative clinical studies.

We are presently conducting a pilot registry involving approximately 40 leading practice groups from all regions of the United States, including academic and private groups in both rural and urban settings. The primary aim of this 12-month pilot is to demonstrate the feasibility of collecting high-quality, validated, aggregate practice data on a national scale. NPA has initiated the registry effort with a lumbar spine module because of the pressing need expressed by many groups around the country for outcomes data in this practice area. Furthermore, N^2QOD is the first and only national registry in the U.S. assessing one-year quality of life after surgical treatment. As the registry grows, we will be adding additional subspecialty modules to evaluate care in the areas of cerebrovascular, trauma, tumor, pain and functional neurosurgery.

The current spine portion of the registry project, called the National Spine Surgery Quality and Outcomes Database (S^2QOD), has been developed in conjunction with several national spine-care stakeholders including multidisciplinary spine care providers, patient advocacy organizations, payer groups, employers, quality care researchers and epidemiologists. This comprehensive quality project will be conducted jointly with orthopedic spine groups. The S^2QOD contains a number of unique and important structural features, including clinical variables that allow for appropriate risk adjustment and patient-reported outcomes and utilization metrics along with longitudinal follow up, the latter of which will allow for determination of the sustainability of treatment effects. Through longitudinal follow-up, the S^2QOD has the capability and intent to assess effectiveness of care. Collecting and reporting on validated outcomes that are important to, and reported by, the patient, such as pain, quality of life, function, and satisfaction, will enhance the information gleaned through this effort.

Proposed Clinical Quality Measures (CQMs) for EPs Beginning with CY 2014

Neurosurgery is concerned with the proposed clinical quality measures (CQM) options and the number of CQMs required to successfully achieve Meaningful Use. Requiring physicians to report on 12 CQMs is unrealistic and undermines the intent of quality improvement. If a practice would like to make meaningful change in their practice they must do so incrementally and focus on one area at a time. Many of the measures are heavily weighted towards primary care and preventive medicine, which would make it difficult for specialties, like neurosurgery to find 12 CQMs to track. Many physicians will be forced to report zero values for many of the measures, which significantly undercuts the utility of this process.

We are also concerned with the options proposed, 1a and 1b. Under 1a, it would be extremely difficult for neurosurgeons to identify and report 12 relevant measures to their practice and even more difficult to find a measure in each of the six domains since the measures in several of the domains are very limited.

Option 1b, would pose even more of a challenge because there are not 11 core CQMs applicable to neurosurgery. Neurosurgeons would be forced to report zero values or report on measures that are not fully relevant.

Neurosurgery recommends that CMS expand the measures to include more measures included in Physician Quality Reporting System (PQRS) and for physicians not to have to report on core measures or measures within a specific domain.

Option 2

As an alternative to Option 1a or 1b, CMS is proposing option 2 for physicians that participate in both PQRS and EHR Meaningful Use programs. Under the proposed option 2, physicians would report CQMs under the PQRS EHR reporting option to satisfy the CQM reporting requirement in Meaningful Use. Neurosurgery is concerned with this option due to the lack of relevant and limited specialty measures in the PQRS EHR reporting option. The measures are heavily weighted towards primary care and cannot be reported on by most specialists. Neurosurgery is supportive of alignment between the two programs, but advises CMS to put forward an option that works for most specialists and include a more robust set of measures to report on, as well as include measure groups. We caution CMS to move forward with expanding the option to include PQRS GPRO measures, due to the lack of relevant measures under that option as well. By expanding option 2, physicians would not have to report on separate measures in order to satisfy PQRS and Meaningful Use CQM requirements. Measure alignment is key to achieving widespread adoption.

Time Periods for Reporting CQMs

We support CMS' proposal to allow EPs to report CQMs through attestation during Stage 1 of the meaningful use program. We also urge CMS to continue to allow EPs to report CQMs through attestation during Stage 2. This flexibility is critical due to the complexity of the program and measure specifications.

Meaningful Use Penalty Phase and Exemptions

We strongly oppose the "backdating" of performance periods for any penalty program. Although the law requires penalties under Stage 2 of the Medicare/Medicaid Meaningful Use EHR program to begin in 2015, CMS is proposing that EPs who do not successfully meet meaningful use requirements in 2013 or by October 1, 2014 (for EPs who demonstrate meaningful use for the first time in CY 2014), will face a penalty starting on January 1, 2015. CMS is essentially pushing up deadlines for participation by up to two years due largely to its own data processing limitations. This back-dating policy will subject a significant number of physicians to financial penalties and slow down the adoption and implementation rates of EHRs. **Different deadlines for submitting data under the meaningful use, PQRS and value-based modifier programs, will be extremely burdensome and confusing for physicians. We urge CMS to align these data submission deadlines moving forward.**

Neurosurgery is supportive of CMS' proposed exemption categories, but recommends that the following additional exemption categories be included:

- Exemption for a physician who successfully participates in the meaningful use program from PQRS penalties. The ACA calls for the integration of the clinical quality measure reporting under the PQRS and meaningful use programs. This exemption category would be an opportunity to synchronize the meaningful use and PQRS programs by exempting physicians from a penalty under the PQRS

program if they successfully participate in the meaningful use program by reporting on CQMs in accordance with the meaningful use program requirements;

- Exemption for a physician who successfully met Stage 1 requirements in 2013, 2014, or in 2015. Physicians should not be penalized if they are making a good faith effort to meet meaningful use measures;

- Exemption for a physician who is using his/her certified EHR product(s), but is only able to meet 50 percent of the meaningful use measures because collecting data, electronically exchanging information, and/or running reports has proven to be difficult due to EHR product design and/or malfunctions, lack of vendor support, etc.;

- Exemption for a physician whose EHR loses its certification status or is not upgraded to meet certification criteria;

- A broad exemption category for physicians to allow for physicians to apply for a hardship exemption based on their individual circumstances. For example, physicians who are not hospital-based but believe that they would not be able to meet most of the measures because they do not see patients or are usually on the receiving end of orders (e.g., pathologists) or for those physicians for whom house calls are a component of their practice should be able to apply for an exemption under this broad category. Another example applicable under the broad exemption category would be for solo or small physician practices that attempted to meet Stage 1or Stage 2 meaningful use measures, but were not able to meet all of the meaningful use measures because they faced challenges (e.g., staffing issues, reimbursement delays or administrative burdens caused by HIPAA transition(s)); and

- Exemption for physicians who are currently eligible for Social Security benefits or will be eligible for Social Security benefits by 2014. It would be economically burdensome for physicians who intend to retire in the next several years to purchase, install, and meaningfully use an EHR. We are also concerned that many of these physicians may decide to close their Medicare fee-for-service panels or opt out of Medicare to avoid penalties during the end stage of their clinical careers, which would adversely affect access to care for our nation's elderly and disabled. Physicians who are currently eligible for Social Security retirement benefits or will be eligible for Social Security retirement benefits by 2014 should have the opportunity to apply for an exemption from the meaningful use program penalties.

Appeals Process

We support the establishment of an appeals process for the Meaningful Use program; however, **we urge CMS to provide physicians with 180 days to file an appeal after receiving actual notice of determination(s) that are subject to appeal at all levels of appeal.** It takes a significant amount of resources and time to collect all the required information to file an appeal.

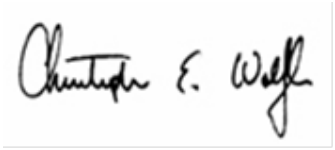
CMS also proposed to allow physicians up to seven calendar days to comply with the request for supporting documentation. Neurosurgery does not support the extremely short turnaround time proposed by CMS. We urge CMS to allow physicians at the minimum 30 days to comply with the request for supporting documentation.

Conclusion

The AANS and CNS thank CMS for the opportunity to comment and welcome the opportunity to work with CMS and ONC to ensure the final Stage 2 Meaningful Use regulation is applicable to neurosurgery.

By working together, the program can advance EHR adoption and ensure successful neurosurgery participation in the Medicare and Medicaid EHR meaningful use programs.

Sincerely,



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