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June 25, 2018

Seema Verma, 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

Submitted electronically via https://www.regulations.gov/

Subject: Fiscal Year (FY) 2019 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) Prospective Payment System Proposed Rule, CMS-1694-P

Dear Ms. Verma,

On behalf of more than 4,000 practicing neurosurgeons in the United States, the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) appreciate the opportunity to comment on the above-referenced CMS hospital inpatient prospective payment system proposed rule.

SUMMARY OF COMMENTS

PAYMENT PROVISIONS

Operating Room (O.R.) and Non-O.R. Issues

- **Percutaneous Endoscopic Excision of Brain and Cerebral Ventricles**
  - The AANS and CNS support the proposal by CMS to change the designation of 22 ICD-10-PSC codes for Percutaneous Endoscopic Excision of Brain and Cerebral Ventricles from non-O.R. designation to O.R. designation.

FY 2019 Applications for New Technology Add-On Payments

- **Sentinel® Cerebral Protection System**
  - The AANS and CNS support the request from Claret Medical, Inc. for new technology add-on payment for the Sentinel® Cerebral Protection System, as cerebral protection devices provide a significant new clinical benefit by reducing the risk of embolic shower to the brain during interventional cardiovascular procedures.

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QUALITY PROVISIONS

General

- The AANS and CNS support efforts to streamline quality measure sets and reporting requirements across programs to reduce provider burden, but request that CMS adopt a more transparent and inclusive process to inform these decisions.

Hospital IQR Program

- **SFusion Payment measure**
  - The AANS and CNS support the removal of this measure at this time but encourage CMS to continue to work with relevant clinical stakeholders to further refine this measure.
- **Hospital-Wide, All-Cause, Risk-Standardized Mortality measures**
  - The AANS and CNS do not support adoption of these measures until a thorough evaluation of the most appropriate and functional risk adjustment and stratification strategies has been conducted.
- **Hospital-Harm Opioid-Related Adverse Events Electronic measure**
  - We urge CMS to refine this measure before implementation. It should be restricted to patients with documented respiratory failure in the presence of narcotic administration, and perhaps only in the setting of transfer to a higher level of care.

Promoting Interoperability (PI) Program

- **2015 CEHRT**
  - Given the diversity of clinical practice across the nation, we oppose CMS' requirement that clinicians and hospitals adopt 2015 Edition Certified Electronic Health Record Technology (CEHRT) in 2019. We believe there are ways to incentivize movement towards the 2015 Edition without mandating its use. Similarly, we support more flexibility in the PI Programs so that providers can select measures most relevant to their practice.
- **Public Health and Clinical Data Exchange objective**
  - The AANS and CNS oppose the future removal of this objective from the PI Program. We urge CMS to adopt policies, both within and outside of this program, that further incentivize the electronic exchange of data between EHRs and clinical data registries and that recognize registries as an alternative way to harness and share data to improve quality.
- **Prescription Drug Monitoring Program (PDMP) Query and Opioid Agreement measures**
  - While the AANS and CNS appreciate the intent of these measures and support efforts to curb opioid abuse and harm, we do not believe these measures should be adopted at this time due to the ongoing lack of standards and the challenges they would present at the point of care.

RFI on Interoperability

- The AANS and CNS agree that innovative policies are needed to move the needle on interoperability and that applying pressure at the facility-level would be a more effective strategy than targeting the individual clinician-level.

- At the same time, we oppose heavy-handed mandates, such as requiring data exchange as part of the Medicare Conditions of Participation (CoP) process, due to the impact this could have on patient access.

- We urge CMS first to give ONC the opportunity to implement and evaluate policies authorized under the 21st Century Cures Act, which could potentially help to more meaningfully advance the exchange of health data.

DETAILED COMMENTS

PAYMENT PROVISIONS

Operating Room (O.R.) and Non-O.R. Issues

Percutaneous and Percutaneous Endoscopic Excision of Brain and Cerebral Ventricle

CMS has addressed several requests regarding changing the designation of specific ICD-10-PCS procedure codes from non-O.R. to O.R. procedures. We agree with CMS that the 22 procedures listed below typically require the resources of an operating room and should be designated as O.R. procedures for ICD-10-PSC and assigned to the appropriate corresponding MS-DRGs.

ICD-10-PCS Procedure Code	Code Description
00B03ZX	Excision of brain, percutaneous approach, diagnostic
00B13ZX	Excision of cerebral meninges, percutaneous approach, diagnostic
00B23ZX	Excision of dura mater, percutaneous approach, diagnostic
00B63ZX	Excision of cerebral ventricle, percutaneous approach, diagnostic
00B73ZX	Excision of cerebral hemisphere, percutaneous approach, diagnostic
00B83ZX	Excision of basal ganglia, percutaneous approach, diagnostic
00B93ZX	Excision of thalamus, percutaneous approach, diagnostic
00BA3ZX	Excision of hypothalamus, percutaneous approach, diagnostic
00BB3ZX	Excision of pons, percutaneous approach, diagnostic
00BC3ZX	Excision of cerebellum, percutaneous approach, diagnostic
00BD3ZX	Excision of medulla oblongata, percutaneous approach, diagnostic
00B04ZX	Excision of brain, percutaneous endoscopic approach, diagnostic
00B14ZX	Excision of cerebral meninges, percutaneous endoscopic approach, diagnostic
00B24ZX	Excision of dura mater, percutaneous endoscopic approach, diagnostic
00B64ZX	Excision of cerebral ventricle, percutaneous endoscopic approach, diagnostic
00B74ZX	Excision of cerebral hemisphere, percutaneous endoscopic approach, diagnostic
00B84ZX	Excision of basal ganglia, percutaneous endoscopic approach, diagnostic
00B94ZX	Excision of thalamus, percutaneous endoscopic approach, diagnostic
00BA4ZX	Excision of hypothalamus, percutaneous endoscopic approach, diagnostic
00BB4ZX	Excision of pons, percutaneous endoscopic approach, diagnostic
00BC4ZX	Excision of cerebellum, percutaneous endoscopic approach, diagnostic
00BD4ZX	Excision of medulla oblongata, percutaneous endoscopic approach, diagnostic

New Technology Add-on Payments

Sentinel® Cerebral Protection System

The AANS and CNS support the request from Claret Medical, Inc., for new technology add-on payment for the Sentinel® Cerebral Protection System. Neurosurgeons are uniquely aware of the special vulnerability of the brain to potential complications from therapies carried out in the heart as well as proximal aortic and cervical vasculature.

Currently, the endovascular device-based therapeutic options available to treat cerebral infarction are focused on large vessel occlusions, which are defined arbitrarily as occurring in cerebral arteries with a diameter of greater than 2.5 mm. As evidenced by multiple international randomized prospective trials, the rate of successful return to pre-occlusion functional status after extraction of occluding intravascular debris remains approximately 50%, even in experienced hands. For smaller strokes of embolic origin, the current standard therapy is intravenous (IV) tissue plasminogen activator (tPA), which has a much lower success rate, depending upon the type of debris and location of occlusion(s). It should be noted that post-interventional strokes are frequently ineligible for IV tPA because of fresh arterial puncture, systemic use of heparin, other concurrent invasive procedures, or other reasons.

After procedures such as transcatheter aortic valve replacement (TAVR), which may cause cerebral infarction by a "showering effect" from many small pieces of debris in addition to the release of a single large piece of thrombus or calcium, the potential for treatment success is diminished even further. The spectrum of debris is quite broad and may include thrombus; arterial, ventricular, or valvular tissue; myocardium; calcium nodules from the native valves; and foreign material from the TAVR catheter. Other than thrombus, these types of debris are most likely resistant to IV tPA and would require sophisticated mechanical intervention for their removal. Many patients are left with ischemia in multiple vascular territories, with subsequent physical, neurological, and neurocognitive deficits.

The role of filter-based cerebral protection in the field of TAVR is supported by various studies that demonstrate safe and effective entrapment and removal of both micro and macro debris caused by delivery and deployment of the TAVR system and prosthesis in heavily calcified aortas and aortic valves. By successfully trapping debris before it reaches the brain, this protective technique serves to reduce the incidence of cerebral infarction without significant additional risk or procedure time.

We strongly support the clinical benefit of the Sentinel® Cerebral Protection System in reducing the incident risk of embolic shower to the brain during interventional cardiovascular procedures. We believe that such mechanisms carry the promise of improved neurologic and functional outcomes following these life-saving procedures and support the sponsors request for new technology status.

QUALITY PROVISIONS

Hospital Quality Programs

General Comments

In accordance with its Patients Over Paperwork and Meaningful Measures initiatives, CMS proposes to eliminate a total of 19 measures (and decrease duplication for an additional 21 measures) that acute care hospitals are currently required to report across its five hospital quality and value-based purchasing programs, while still maintaining meaningful measures of hospital quality and patient safety. The AANS and CNS very much appreciate CMS taking steps to remove duplicative measures and to minimize unnecessary provider burden by proposing to focus on only the most meaningful measures. This will not only result in increased efficiencies but also improved beneficiary experiences as providers can shift their attention away from reporting mandates and focus primarily on the patient.

At the same time, we request that CMS adopt a more transparent and inclusive process for making these decisions. Prior to proposing measures for removal through rulemaking, CMS should consult with relevant clinical experts, and also seek the patient perspective, to determine whether it is appropriate to remove a measure and whether that decision could have downstream implications on patient safety and public health (e.g., topped out measures typically only reflect a small and skewed portion of the population to which they apply). CMS also must account for the value of consistency in program measure sets, keeping in mind that the provider costs associated with adapting to measure sets that are constantly changing and quality improvement efforts that are always shifting in focus.

Hospital Inpatient Quality Reporting (IQR) Program

Measures Proposed for Removal

- **Spinal Fusion Clinical Episode-Based Payment Measure (SFusion Payment)**. CMS proposes to remove this measure from the IQR program beginning with the CY 2018 reporting period/FY 2020 payment since the cost of administering the measure outweighs the benefit of its continued use. CMS believes data from this measure are already captured within the broader Hospital Medicare Spending Per Beneficiary (MSPB) measure, which will be retained in the Hospital Value-Based Purchasing (VBP) program.

  The AANS and CNS have long voiced concerns over the SFusion Payment measure and support its removal from all hospital quality reporting programs at this time. Although we appreciate CMS' previous attempts to refine this measure so that it results in a less heterogeneous patient population, we have concerns that this measure still needs to focus on more homogeneous lumbar fusion cohorts that are each held to their own separate standard. We support efforts to develop and shift to more specific episode-based payment measures and believe data from such measures can provide providers with more actionable feedback to implement targeted improvements in comparison to an overall payment measure. However, this measure still requires additional refinements before it can accurately evaluate spinal fusion resource use. Additionally, since the measure is still not tied directly with any other clinical quality measures, it does not provide a complete picture of providers' clinical effectiveness and efficiency. As a result, data derived from this measure, in its current form, may be of lower utility to patients and providers.

  In general, we also remind CMS about the overall limitations of relying on administrative datasets for measures such as this one and urge the agency to evaluate ways to incorporate better clinical data collected from registries when feasible. We also remind CMS of the critical importance of adjusting for factors such as patient socioeconomic status, obesity, tobacco use, and other population health variables that significantly impact clinical outcomes.

  While the AANS and CNS support the removal of the SFusion Payment measure at this time, our spine care experts would be happy to continue to work with CMS to further refine and test this measure for potential future reinstatement, and to ensure that the full range of clinical and potential patient factors are considered and appropriate adjustments are made. Members of the AANS and CNS are currently working with Acumen to develop a Lumbar Spinal Fusion episode-based cost measure for potential use under MIPS, which might provide insight into how to improve the facility-focused measure.

Potential New Measures

- **Hospital-Wide, All-Cause, Risk-Standardized Mortality measure.** CMS seeks feedback on the potential inclusion of this measure in the IQR. This measure derives results from 13 mutually exclusive service-line divisions, with a separate risk model for each of the service-line divisions. The surgical divisions are cancer, cardiothoracic, general, neurosurgery, and orthopedics. This measure

is being proposed as two separate measures — one that is claims-based and a hybrid version that would be electronically extracted.

The AANS and CNS view the hybrid approach to this all-cause mortality measure as a significant improvement over the claims-only version since it recognizes the value of the EHR to identify comorbidities and at least starts the process of risk standardization/stratification. Nevertheless, both measures still rely, to some degree, on claims data and the structural limitations of claims-based extraction will limit the clinical applicability of any data produced by the measure.

We are also concerned that without adequate risk-standardization, these measures could disproportionately penalize tertiary care and academic centers with disproportionately high mortality, disincentivize facilities from providing care for high-risk individuals, and reward hospitals for "cherry–picking" less risky patients and referring anything complex to safety net hospitals.

We also have concerns about the method by which CMS would stratify the data by specialty. Neurosurgery is a very large tent, and the clinical scoring systems to predict mortality are so different between the various subspecialties that it could become a heterogeneous, meaningless measure. For example, if hospital A treats 90% spine patients and a larger Hospital B receives all of A's vascular and complex brain tumor patients, how would this measure risk adjust between the spine patient and the subarachnoid hemorrhage patient? Also, would spine be considered "orthopedic surgery" or "neurosurgery"? Would brain tumors fall under "cancer" or "neurosurgery"? Because of these issues, we would recommend CMS exploring subspecialty- or condition-specific groupings for more meaningful comparisons across hospitals. At the same time, we appreciate the exclusions for intracranial injury, spinal cord injury, anoxic brain injury, the presence of metastatic disease, and hospice admission within two days of hospital admission and request that these be preserved.

The AANS and CNS agree with the Measure Application Partnership (MAP) that the hybrid version of this measure should not be considered for implementation until a thorough evaluation of the most appropriate risk adjustment and stratification strategies has been conducted and clinical and social risk factors, including the impact of socioeconomic status, are built into such models, and functional.

- **Hospital-Harm Opioid-Related Adverse Events Electronic Clinical Quality Measure.** CMS is considering a newly specified Hospital-Harm Opioid-Related Adverse Events eCQM for possible concurrent inclusion in future years of the Hospital IQR and Medicare and Medicaid Promoting Interoperability Programs. This outcome measure would assess, by hospital, the proportion of patients who had an opioid-related adverse event. The measure uses the administration of naloxone, an opioid reversal agent that has been used in a number of studies, as an indicator of opioid-related adverse respiratory events, to indicate a harm to a patient. The intent of this measure is for hospitals to track and improve their monitoring and response to patients administered opioids during hospitalization, and to avoid harm, such as respiratory depression, which can lead to brain damage and death. The measure window focuses specifically on in-hospital opioid-related adverse events, rather than opioid overdose events that happen in the community and may bring a patient into the emergency department. Thus, it is not intended to incentivize hospitals to not administer naloxone to patients who are in respiratory depression, but rather incentivize hospitals to closely monitor patients who receive opioids during their hospitalization to prevent respiratory depression. CMS also clarifies that the aim of this measure is not to identify preventability of an individual harm instance or whether each instance of harm was an error, but rather to assess the overall rate of the harm within a hospital incorporating a definition of harm that is likely to be reduced as a result of hospital best practice.

  While the AANS and CNS appreciate the intent of this measure, it is critical to note that naloxone can be used globally as one part of a resuscitation protocol, and so the fact that the drug was

administered does not necessarily mean that there was a condition of respiratory failure. ***We would advocate for refining the metric by restricting its consideration to those patients with documented respiratory failure in the presence of narcotic administration, and perhaps then only in the setting of transfer to a higher level of care***.

Promoting Interoperability

CMS proposes to rename the Hospital Medicare and Medicaid Electronic Health Record Incentive Program ("Meaningful Use") to the Promoting Interoperability (PI) Program to reflect the agency's focus on interoperability and the exchange of health information between providers and patients. Also, CMS is proposing to significantly reduce the reporting burden by eliminating the number of required measures from 16 to 6, to focus on key agency priorities (such as addressing the opioid crisis and furthering interoperability), and to move from a threshold-based scoring system to a performance-based scoring system. CMS is also proposing a 90-day reporting period for 2019 and 2020, and to require hospitals to use 2015 Edition CEHRT in 2019.

The AANS and CNS support CMS' effort to align the policies of this hospital-focused program with the clinician-focused Merit-Based Incentive Payment System (MIPS) by proposing a more reasonable 90-day reporting period, reducing the number of measures to better align with MIPS, and moving away from all-or-nothing threshold-based scoring policies. At the same time, we are concerned about CMS' proposal to require both hospitals and physicians to transition to 2015 Edition CEHRT starting in 2018, and request that CMS continue to allow providers to use either 2014 or 2015 Edition CEHRT in recognition of the large investment that providers must make when upgrading their systems — expenditures that often disproportionately impact small and rural providers. We appreciate and support the improvements that have been in the 2015 Edition CEHRT, including changes that better support electronic transmissions of information on transitions of care and third-party app compatibility. However, some of the most sophisticated neurosurgical practices continue to face challenges upgrading their systems to the 2015 Edition CEHRT, and the additional changes to measures proposed in this rule will complicate things further over at least the short term. ***We recommend that CMS not require 2015 Edition CEHRT in 2019 among hospitals or clinicians. To recognize the value of the 2015 Edition and incentivize movement in that direction, we suggest that CMS consider a policy similar to MIPS in 2018, where adoption of 2015 Edition CEHRT is not required, but instead rewarded with bonus points. If CMS insists on requiring 2015 Edition CEHRT in 2019, then we request that it at least provide flexible hardship exemptions for small, rural, critical access, and other types of facilities that are unable to upgrade at this time.***

We are also concerned that, despite the proposed changes, the program continues to rely on a rigid structure that fails to provide hospitals with the flexibility to demonstrate meaningful use of EHRs in a manner that is most relevant to that specific facility. ***For both the hospital and clinician-focused programs, we support allowing providers to select which measures to report on within an objective and how those objectives should be weighted.***

CMS discusses its intent to propose, in future rulemaking, to remove the Public Health and Clinical Data Exchange objective and measures from the PI Program no later than CY 2022. Specialty society registries already face multiple challenges in getting hospitals and EHRs to share data seamlessly and electronically, and many hospital-based registry participants still rely on time-consuming and costly manual uploads. The measures currently under this objective, including the Clinical Data Registry Reporting measure, are not ideal since they only recognize the use of registries that can electronically communicate with CEHRT, which is something that many registries still struggle with for reasons outside of their control. Nevertheless, by retaining this objective in the program, there is at least an incentive for hospitals and their EHRs to move towards improved electronic data exchange with registries. ***We oppose the future removal of the Public Health and Clinical Data Exchange objective. At the same***

time, we would support the refinement of its measures so that they continue to promote the use of registries, but better account for the barriers that registries face in trying to secure electronic data from EHRs. ***In general, we encourage CMS to simultaneously adopt policies, both within and outside of the PI Program, to further incentivize the electronic exchange of data between hospital EHRs and registries, and to recognize registries as an effective way of harnessing and sharing data in a manner that improves patient outcomes and care experiences.***

Newly Proposed Measures for the Hospital Promoting Interoperability Program

CMS also proposes to add two new opioid-focused Hospital PI measures, which would be voluntary in 2019 and required in 2020.

- ***PDMP Query Measure***. This measure evaluates whether, for opioids e-prescribed using CEHRT, the hospital uses data from CEHRT to conduct a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history prior to transmission of the prescription, except where prohibited by law. Multiple opioid prescriptions prescribed on the same date by the same hospital would not require multiple queries of the PDMP.

  Many of our members report that they are just *starting* to acquire the ability to use their EHR to interact electronically with a PDMP. Cost remains a significant factor, particularly for those who must incur the burden of manually querying the PDMP. The lack of existing EHR certification criteria related to the query of a PDMP is also problematic and likely an ongoing contributor to the widespread lack of CEHRT integration with PDMPs. As a result, many systems currently just generate a PDF report, with license agreements that actually prevent discrete data capture. ***While our members oppose additional regulatory burden, the AANS and CNS would support standards in this space to provide a more streamlined way of performing queries and allowing for data capture and documentation that supports clinical decision support and minimizes the additional work currently required of physicians and their clinical staff.*** For example, EHRs should be able to perform PDMP verification not only so this can be documented in the note, but also at the time of ordering/writing a prescription. Members whose CEHRT is already integrated with the PDMP report how much easier this makes meeting state requirements but also making well-informed decisions at the point of care. Not only does it enable system checking and enforcement for compliance (e.g., the clinician cannot sign the prescription until done), it also reminds clinicians of the importance of checking the PDMP, places the correct patient's information in front of the clinicians within the same EHR application, and avoids delays with a separate log on and query of a separate system.

  There are other ongoing challenges related to PDMP use that stem from a patchwork of state laws and adopted processes. One of the main challenges is how frequently the information is updated. If a patient receives an opioid prescription today, it may take 30 days to appear in the PDMP, depending upon the state. This significantly hampers the ability of the PDMP to provide meaningful information and is an issue that goes beyond the functionality of the system. If more emphasis is going to be placed on checking the PDMP, the accuracy and usefulness of its underlying data should also be addressed.

  Furthermore, in our specialty, our members see a number of patients that reasonably require a short course of opioids post-operation. Measures and other regulatory requirements in this space should be aimed only at safety and abuse and should not impede the efforts of physicians and clinicians to access these medications when appropriate. Also, CMS measures should not conflict with State laws regarding the number of pills prescribed that meet a local threshold for a query of the PDMP. Taking into consideration the realities of clinical practice, we also remind CMS of the importance of permitting query and reporting requirements to be fulfilled by a surgeon's delegate (e.g., resident, PA, NP) if they are the one actually doing the prescribing.

Finally, we believe this measure should limit queries of the PDMP to once during the hospital stay, which should be at discharge from the hospital, since pain control needs can change dramatically for an inpatient, requiring many changes in agents and doses. While in an ideal world, it would great if PDMP queries happened all the time for opioids, the reality is that it would pose too big of a burden at this time since standards do not yet exist to ensure PDMP-CEHRT integration across the nation.

- **Opioid Agreement Measure.** For opioids e-prescribed by the hospital using CEHRT during the EHR reporting period, if the total duration of the prescription is at least 30 cumulative days within a 6-month lookback period, this measure would evaluate whether the hospital seeks to identify the existence of a signed opioid treatment agreement and incorporates it into CEHRT. CMS recognizes that the look-back may pose challenges, which is intended to also capture opioids in patient's medication history prior to hospitalization since many hospitals do not prescribe opioids for more than a few days.

  While the AANS and CNS agree with the intent of this measure, we do not believe it should be implemented at this time due to the ongoing lack of standardization in this space. Without EHR standardization, in particular, it is unclear how the proposed measure could produce any meaningful data. For example, the patient might have an agreement, but what does the agreement say and how could that information be pulled out of a document reliably without standardization? We believe that standards in this space could help to streamline communication between providers since currently available documents are "all over the board." We would be happy to work with CMS on the future development of standards related to opioid agreements and integration with EHRs.

  We also question the overall utility of opioid agreements in the context of the post-surgical period, where defining opioid abuse is problematic. While it may be appropriate to develop an agreement with patients who request multiple refills or display any behaviors concerning for abuse, we question whether all patients should have an agreement drafted up front. This not only takes time to explain and sign but may paint pain medications negatively for all patients, including those where pain medications are appropriate. We are also not aware of any data that suggests that an up-front opioid treatment agreement with all patients actually helps reduce misuse and diversion. Creating an additional paperwork burden without a clear goal will just add to the administrative burdens that are already making daily practice challenging.

  While we appreciate the intent of both of opioid-focused measures, many of our members are still in the process of transitioning to e-prescribing for opioids and challenges remain, such as employing two means of authentication for security. The patchwork of state laws, particularly related to PDMPs, also plays a huge factor in determining requirements and workflow. ***As such, we believe that adoption of the two proposed measures at this time would be premature***. As standards are adopted over time, we would re-consider our support for the measurement of PDMP queries.

RFI on Interoperability

CMS seeks public input on how it could use the CMS health and safety standards that are required of providers participating in Medicare and Medicaid (e.g., Conditions of Participation (CoP) and Conditions for Coverage (CfC) as a way to advance the electronic exchange of information and support effective transitions of care between hospitals and community providers. Revisions to the current CMS CoPs for hospitals could include that hospitals:

- Transfer medically necessary information to another facility upon a patient transfer or discharge do so electronically;
- Electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and

- Make certain information available to patients or a specified third-party application (e.g., required discharge instructions) via electronic means if requested.

CMS will use the feedback collected to inform next steps.

The AANS and CNS agree with CMS that something more is needed to move the needle on interoperability. Our members have experienced directly the barriers to clinical data exchange that hospitals and EHR vendors continue to impose. For example, our members report that they still cannot get most hospitals to transmit DICOM® (Digital Imaging and Communications in Medicine) images to their clinics, even though this technical standard—designed to overcome interoperability issues in medical imaging — was developed in the 1980's and was fairly mature by the 1990's. Technology and standards are not always the limiting factor; financial and business decisions play a large role here, too. Hospitals systems, in particular, have incredible, but underused, power to influence interoperability. Since the hospital system is the entity contracting with the EHR vendor directly, to some degree, they can make demands on vendors and be heard. ***In general, we believe there is a much greater likelihood of driving interoperability by applying pressure to larger systems such as hospitals, rather than via programs like the Merit-Based Incentive Payment System (MIPS), that put pressure on individual physicians***.

At the same time, we have concerns about CMS mandating data exchange through the CoP process because of the significant implications this could have on a facility's ability to participate in Medicare (particularly under-resourced facilities) and the residual impact this could have on community providers, with fewer resources to adopt expensive software, and patient access to care. Despite progress made in some aspects of interoperability, electronic health information exchange (HIE) systems are still relatively immature. It remains a random assortment of proprietary interfaces which require the same EHR product at both institutions, and state-based exchanges that vary in effectiveness. And although we are getting closer to a vendor-agnostic and patient-centered system with efforts such as FHIR (Fast Healthcare Interoperability Resources), this is still a new and untested standard. As a result, there are ongoing barriers related to data exchange between providers, and between providers and patients, many of which remain outside of the provider's direct control. Neither the hospital nor the provider should be penalized for these factors.

We also do not support policies that impose a mandate on one institution that requires compliance by another institution or provider (e.g., in the case of a hospital who is held accountable for ensuring a community provider can receive the facility's data). Requiring a hospital to send electronic discharge summaries to private clinicians' offices who are unable to receive the information electronically is futile and frustrating for all providers involved.

It is our understanding that the Office of the National Coordinator (ONC) is now working to develop regulations to implement various aspects of the 21st Century Cures Act that will address interoperability, information blocking (including penalties for blocking by providers and HIT developers), and patient access to health information. ***We request that before CMS consider employing such a heavy-handed approach that it first give ONC the opportunity to implement and evaluate the impact of more innovative policies authorized under the Cures Act that could potentially help to more meaningfully advance the exchange of health data***. As these policies are implemented, we remind CMS that, at least for the near future, there will continue to be community providers that do not have the resources to incorporate the latest technologies. These providers should not be penalized by efforts to promote data exchange, nor should hospitals and other clinicians who are making a good faith effort to exchange data with these providers.

CONCLUDING REMARKS

The AANS and CNS appreciate the opportunity to comment on this proposed regulation. We look

forward to working with CMS to make improvements to the IPPS program. In the meantime, if you have any questions or need further information, please feel free to contact us.

Sincerely,

Shelly D. Timmons, MD, PhD, President
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Ashwini D. Sharan, MD, President
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