

AMERICAN ASSOCIATION OF  
NEUROLOGICAL SURGEONS

KATHLEEN T. CRAIG, *Executive Director*  
5550 Meadowbrook Drive  
Rolling Meadows, IL 60008  
Phone: 888-566-AANS  
Fax: 847-378-0600  
info@aans.org



American  
Association of  
Neurological  
Surgeons



Congress of  
Neurological  
Surgeons

CONGRESS OF  
NEUROLOGICAL SURGEONS

REGINA SHUPAK, *CEO*  
10 North Martingale Road, Suite 190  
Schaumburg, IL 60173  
Phone: 877-517-1CNS  
FAX: 847-240-0804  
info@1CNS.org

*President*  
CHRISTOPHER I. SHAFFREY, MD  
Durham, North Carolina

*President*  
GANESH RAO, MD  
Houston, Texas

June 24, 2019

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) 2020 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) Prospective Payment System Proposed Rule, CMS-1716-P**

Dear Administrator Verma,

On behalf of more than 4,000 practicing neurosurgeons in the United States, the American Association of Neurological Surgeons (AANS) and the 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**

***New Technology Add-On Payment General Issues***

- **Proposed New Technology Add-on Payment Alternative Pathway for Devices**
  - The AANS and the CNS support the agency's proposal to streamline the process for new technology add-on payment status for medical devices that receive clearance through the Food and Drug Administration (FDA) Breakthrough Devices Program.
- **Proposed Increase for New Technology Add-on Payment**
  - The AANS and the CNS support the CMS proposal to increase new technology add-on payment from 50% to 65% of the lesser of the costs of the new medical technology or the amount by which the costs of the case exceeds the standard DRG payment.
- **Request for Information (RFI) on New Technology Substantial Clinical Improvement Criterion**
  - The AANS and the CNS appreciate the agency's interest in increasing transparency and providing greater predictability for new technology add-on payment applicants.

### ***FY 2020 Applications for New Technology Add-On Payments***

- **Sentinel® Cerebral Protection System**

- The AANS and the CNS support the request from Claret Medical, Inc. for continued 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.

- **GammaTile™**

- The AANS and the CNS support the new technology application from GT Medical Technologies for the GammaTile™ brachytherapy technology for use in the treatment of patients diagnosed with brain tumors.

### **QUALITY PROVISIONS**

#### ***Hospital Inpatient Quality Reporting (IQR) Program***

- **New Opioid Measures**

- The AANS and the CNS advise against the adoption of the Safe Use of Opioids – Concurrent Prescribing electronic clinical quality measure (eCQM) due to potential unintended consequences.
- In regards to the Hospital Harm – Opioid-Related Adverse Events eCQM, the AANS and the CNS advocate for refining the measure 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, and with IV use.

- **New Readmission Measure**

- While the AANS and the CNS view the Hybrid Hospital-Wide Readmission (HWR) measure as an improvement over the claims-only version, the measure continues to rely on claims data, which will limit the clinical applicability of any data produced by the measure. Furthermore, the risk adjustment variables bear an uncertain and potentially unreliable relationship to the risk of postoperative complications in the surgical population.

#### ***Hospital Promoting Interoperability Program***

- **Existing Opioid Measures**

- In general, measures and other regulatory requirements targeting opioid use disorders should be aimed only at safety and abuse and should not impede the efforts of clinicians to access these medications when appropriate.
- The AANS and the CNS support CMS' proposal to maintain the Query of Prescription Drug Monitoring Program (PDMP) measure as optional for 2020 and to modify it to a yes/no attestation. We continue to support standards that 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.

- We support CMS' decision to remove the Verify Opioid Agreement measure from the program starting in 2020. While we agree with the intent of this measure, we do not believe it is ready for implementation at this time due to the ongoing lack of standardization in this space.

- **RFI on new NQF and CDC Opioid Quality Measures**

- The AANS and the CNS support the intent of the NQF measures but urge CMS to delay implementation of these measures until such integrated systems are more widespread.
- In regards to the CDC measures, until there are more standardized laws and systems to allow for the seamless sharing of such data, we do not believe that CMS should adopt measures that rely on PDMP data.

## **DETAILED COMMENTS**

### **PAYMENT PROVISIONS**

#### **New Technology Add-on Payment General Issues**

##### ***Proposed New Technology Add-on Payment Alternative Pathway for Devices***

The AANS and the CNS support the agency's proposal to streamline the process for new technology add-on payment status for medical devices that receive clearance through the Food and Drug Administration (FDA) Breakthrough Devices Program. As a specialty dedicated to enhancing life and ability for our patients through advances in medical technology, we appreciate efforts by CMS to reduce regulatory burden and increase the effectiveness of new technology add-on payment. This change will prevent unnecessary, duplicative paperwork for manufacturers of devices that have been designated by the FDA as providing more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

##### ***Proposed Increase for Calculation of New Technology Add-on Payment Amount***

Neurosurgery has a long tradition of excellence and innovation in patient care, often involving cutting edge devices. For that reason, we support facility payment that appropriately recognizes the cost of essential devices to increase rapid access to new and better options for care to our patients. We share the common goal of enhancing efficiency in bringing lifesaving improvements to Medicare beneficiaries and, therefore, we commend CMS for increasing new technology add-on payment. The AANS and the CNS support the CMS proposal to increase new technology add-on payment from 50% to 65% of the lesser of the costs of the new medical technology or the amount by which the costs of the case exceeds the standard DRG payment.

##### ***Request for Information (RFI) on New Technology Substantial Clinical Improvement Criterion***

We thank the agency for reaching out to help stakeholders better understand how CMS evaluates new technology applications for add-on payment. We appreciate the agency's recognition of the need for greater predictability about which applications will meet the criterion for substantial clinical improvement. As we have stated in our comments above, neurosurgery is a specialty that is highly dependent on

medical innovation. We are eager to work with the agency as it considers taking up the issue of assessing clinical advancement in future rulemaking, and we expect to be able to provide more detailed comments at that time. However, we offer the following brief observations relevant to CMS' new technology add-on payment clinical criteria based on our long-standing record of support for device innovation.

- **Broad Adoption Criteria.** CMS has requested comment on ways to define and measure "broad adoption," as part of the definition of "substantial clinical improvement." For many new technologies, particularly if they are approved through the FDA Breakthrough Devices Program or the Humanitarian Devices Exemption, adoption may be dependent on adequate reimbursement through initiatives such as the Medicare new technology add-on payment. Therefore, broad adoption should not be a barrier to receiving adequate reimbursement but, rather, the payment should be adequate to help important new treatment options reach patients who may benefit more quickly.
- **Comparison to Existing Technology Criteria.** CMS has specified that substantial improvements would be demonstrated by reference to existing technology. However, for some novel devices, such as those that come through the FDA De Novo Pathway, there may not be an existing technology for comparison. We urge the agency to consider rigorous scientific data regarding the clinical benefits of the new technology under consideration in a way that permits possible eligibility for devices that offer substantial improvement, but that may not be easily compared with a predicate device.
- **Real World Evidence Criteria.** We are pleased the agency recognizes the need to consider data other than that from prospective randomized controlled trials (RCTs) and to see a specific reference to the use of registry data. Although such real-world evidence beyond what was presented during FDA clearance may be limited for devices under consideration for the new technology add-on payments, we wish to emphasize our dedication to the development of real-world evidence for neurosurgical procedures. The neurosurgery-led NeuroPoint Alliance (NPA) registry has worked closely with the FDA and other societies on several important initiatives to explore real-world data sources and alternatives to costly and time-consuming RCTs.
- **Guidance on Types of Evidence and Study Design to Assess Clinical Improvement.** The agency has asked for feedback on the types of evidence or study designs that may be considered in evaluating substantial clinical improvement. As we note in the comments above on real-world evidence, conducting prospective RCTs may not be applicable in all situations. For implanted devices, randomization presents particular ethical and logistical difficulties by exposing patients to sham surgeries that are unlikely to provide benefit. We look forward to working with the agency as it considers new guidance on substantial clinical improvement assessment in future rulemaking that will recognize these unique aspects of device development.
- **Evidence from Subsets of Patient Populations.** CMS has asked about whether the agency should adopt a policy in regulation or sub-regulatory guidance to allow the substantial clinical improvement criterion to be met if only a small subset of beneficiaries would likely benefit from the device. We appreciate the agency's recognition of the unique needs of small subset populations of patients. For any technology, appropriate patient selection is essential to successful outcomes, and we urge the agency to maintain the flexibility to evaluate and apply add-on payment to subsets of beneficiaries.
- **Evidence from Off-label Use.** We note that the agency has provided a question about evidence regarding off-label, or "physician-directed," use of devices. The rationale for this question is somewhat unclear in the context of the RFI, and we hope that CMS will elaborate on what it is seeking on this topic in future rulemaking. The AANS and the CNS have long advocated for a wider

understanding of the importance of the safe and effective “off-label” use of medical products at the direction of physicians to improve patient care and drive innovation in clinical practice. Again, we look to the agency to provide additional information on how it envisions data from off-label use being relevant to efforts to increase transparency and predictability of substantial clinical improvement standards for new technology add-on payment.

## **New Technology Add-on Payment for Specific Devices**

### ***Sentinel® Cerebral Protection System***

The AANS and the CNS support the request from Claret Medical, Inc., for a continuation of 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 a 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). We note 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 we support the sponsor's request for a continuation of new technology status.

### ***GammaTile™***

The AANS and the CNS support the application of GT Medical Technologies for new technology add-on payment for GammaTile™ brachytherapy technology for use in the treatment of patients diagnosed with

brain tumors. The additional resources will allow surgeons to offer this new therapy to appropriately selected patients to help prevent disease progression and improve quality of life for patients with recurrent brain tumors, a devastating diagnosis. These patients often have limited treatment options, and Medicare's new technology add-on payment can help bring important innovation and hope to patients with few other alternatives for their care. Neurosurgeons are on the cutting edge of developing more effective treatments for brain tumor patients, and we urge the agency to provide funding that will allow Medicare patients and their physicians the widest range of highly individualized choices.

## QUALITY PROVISIONS

### Hospital Inpatient Quality Reporting (IQR) Program

The Hospital IQR Program is a pay-for-reporting program that reduces payments to hospitals that fail to meet program requirements.

#### *New Opioid Measures*

In this rule, CMS proposes to adopt the following two new opioid-focused measures beginning with the CY 2021 reporting period:

- [Safe Use of Opioids – Concurrent Prescribing electronic clinical quality measure \(eCQM\)](#). This process measure calculates the proportion of patients age 18 years and older prescribed two or more opioids or an opioid and a benzodiazepine concurrently at discharge from a hospital-based encounter (i.e., inpatient or emergency department [ED], including observation stays). The measure excludes patients with cancer, patients on palliative care, and patients with encounters of 120 days or longer. CMS recognizes the fact that there are instances where the concurrent prescription of a benzodiazepine and an opioid could be clinically appropriate and clarifies that the expectation would not be 0% performance. This new measure would be added to the eight available eQMs from which hospitals may choose to report to satisfy IQR requirements. Thus, hospitals would not be required to report on it.

***Although hospitals would not be required to select this measure, the AANS and the CNS are concerned about potential unintended consequences associated with it and would advise against its use.*** For example, this measure could dissuade physicians from prescribing opioids, which could result in under-treatment. It also could result in patients being inappropriately taken off benzodiazepines by physicians who do not primarily manage their care, which could lead to potential patient harm. Further, there are evidence-based spine surgery recovery protocols, which include both opioids and benzodiazepines. Although these may change over time, with a move to other muscle relaxants, there are valid clinical reasons for prescribing two drugs which have different mechanisms of action and accomplish different goals (pain relief and muscle spasm reduction). Some practices and institutions may immediately have very high rates of non-compliance. For these reasons, we would advise against the use of this measure.

- [Hospital Harm – Opioid-Related Adverse Events eCQM](#). This outcome measure assesses the proportion of patients who had an opioid-related adverse event during admission to an acute care hospital by assessing the administration of naloxone, an opioid reversal agent that has been used in several studies as an indicator of opioid-related adverse respiratory events (ORAREs). The measure focuses on in-hospital opioid-related adverse events, rather than opioid overdose events that happen in the community and may bring a patient into the ED. It specifically assesses the administration of naloxone after 24 hours from hospital arrival or during the first 24 hours after hospital arrival with

evidence of opioid administration in the hospital prior to the naloxone administration. This includes inpatient admissions that were initiated in the ED or in observational status followed by a hospital admission. Importantly, the measure excludes the use of the drug in the operating room to account for cases where naloxone is used as part of a sedation plan.

The intent of the measure is for hospitals to track and improve their monitoring and response to patients administered opioids during hospitalization, and avoid harm, such as respiratory depression, which can lead to brain damage and death. Under this proposal, this measure would be added to the eCQM measure set from which hospitals could choose to report.

As noted in our FY 2019 IPPS proposed rule comments to CMS, the AANS and the CNS appreciate the intent of this measure. However, we continue to remind CMS 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. Further, there are other reasons for administering oral naloxone in the postop period, which has little to do with opioid withdrawal. ***We would advocate for refining the measure 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, and with IV use.*** If these refinements are not made, this measure could result in clinicians withholding naloxone from patients who might need it.

### ***New Readmission Measure***

CMS also proposes to adopt a [Hybrid Hospital-Wide Readmission \(HWR\) measure](#) under the Hospital IQR program, which would rely on claims and EHR data and replace the current all-claims version of the measure. The measure would be voluntary starting in 2021 and mandatory beginning in July 2023. At the end of the proposed voluntary reporting period, CMS intends to publicly report the measure.

The CMS-developed Hybrid HWR measure, which was endorsed by the National Quality Forum (NQF) in December 2016, is designed to capture the hospital-level, risk-standardized readmission rate (RSRR) of unplanned, all-cause readmissions within 30 days of hospital discharge for any eligible condition. The target population is Medicare fee-for-service (FFS) beneficiaries who are 65 years or older and hospitalized in non-federal hospitals. The outcome is defined as unplanned readmission for any cause within 30 days of the discharge date for the index admission. Index admissions are assigned to one of five mutually exclusive specialty cohort groups consisting of related conditions or procedures:

1. Surgery/gynecology;
2. General medicine;
3. Cardiorespiratory;
4. Cardiovascular; and
5. Neurology

For each specialty cohort group, the SRR is calculated as the ratio of the number of “predicted” readmissions to the number of “expected” readmissions at a given hospital. The specialty cohort SRRs are then pooled for each hospital using a volume-weighted geometric mean to create a hospital-wide composite SRR. The composite SRR is multiplied by the national observed readmission rate to produce the RSRR.

The proposed Hybrid HWR measure adjusts both for case-mix differences (i.e., how severely ill patients are when they are admitted) as well as differences in hospitals’ service-mix (i.e., the types of conditions

that cause patients' admissions). The case-mix variables include patients' ages and comorbidities as well as laboratory test results and vital signs. The measure specifically uses 13 core clinical data elements from EHRs — seven laboratory test results (hematocrit, white blood cell count, sodium, potassium, bicarbonate, creatinine, glucose) and six vital signs (heart rate, respiratory rate, temperature, systolic blood pressure, oxygen saturation, weight). The service-mix variables include principal discharge diagnoses grouped into AHRQ Clinical Classification Software. Patient comorbidities are based on the index admission, the admission included in the measure cohort, and a full year of prior history.

The measure excludes index admissions for the following patients:

- Admitted to prospective payment system (PPS)-exempt cancer hospitals
- Without at least 30 days of post-discharge enrollment in Medicare FFS
- Discharged against medical advice
- Admitted for primary psychiatric diagnoses
- Admitted for rehabilitation
- Admitted for medical treatment of cancer

For this measure, a specified set of readmissions are planned and do not count in the readmission outcome. However, all unplanned readmissions are considered an outcome, regardless of cause.

The AANS and the CNS view the hybrid approach to this hospital-wide readmissions measure as a significant improvement over the claims-only version since it recognizes the value of clinical data in risk adjusting for a patients' severity of illness. Nevertheless, ***the measure continues to rely on claims data, and the structural limitations of claims-based extraction will limit the clinical applicability of any data produced by the measure. Furthermore, the risk adjustment by the stated case-mix variables bears an uncertain and potentially unreliable relationship to the risk of postoperative complications in the surgical population.***

### **Hospital Promoting Interoperability Program**

The Medicare Promoting Interoperability Program (formerly known as the Medicare EHR Incentive Programs, or "Meaningful Use") was established in 2011 to encourage hospitals to adopt and demonstrate meaningful use of certified electronic health record technology (CEHRT). This program is separate, but in many respects aligned with the requirements that physicians face under the Promoting Interoperability category of the Merit-Based Incentive Payment System (MIPS).

### ***Existing Opioid Measures***

Last year, CMS substantially streamlined the hospital program's measure set and scoring methodology by reducing the required measure set. CMS also adopted two *optional* measures related to e-prescribing of opioids, and noted its intent to make these measures mandatory in the future:

- [Query of Prescription Drug Monitoring Program](#) (PDMP) measure. This measure evaluates whether, for opioids e-prescribed using CEHRT, the hospital uses data from CEHRT to conduct a query of a 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.



- [Verify Opioid Treatment 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.

In this year's proposed rule, CMS discusses implementation challenges surrounding these two measures, reported by both hospitals and HIT vendors. As a result, CMS proposes to maintain the [Query of PDMP](#) measure as optional for 2020 and to require a simple "yes/no" attestation instead of the reporting of a numerator/denominator. At the same time, CMS proposes to completely remove the [Verify Opioid Treatment Agreement](#) measure from the program starting in 2020.

In regards to both measures, we remind the agency that neurosurgeons 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 clinicians to access these medications when appropriate.***

***In regards to the [Query of PDMP](#) measure, the AANS and the CNS support CMS' proposal to maintain this measure as optional and to modify it to a yes/no attestation.*** Many of our members are still 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 merely generate a PDF report, with license agreements that actually prevent discrete data capture.

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.

Given these ongoing challenges, the AANS and the CNS very much appreciate that the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018 includes new requirements and federal funding for PDMP enhancement, integration, and interoperability. We are encouraged by ONC's ongoing work to understand better the current state of policy and technical factors impacting PDMP integration across states, and its work in collaboration with the CDC to advance and scale PDMP integration with health IT systems. We are also pleased to hear that CMS plans to work closely with the DEA on future technical requirements that can better support measurement of adoption and use of electronic prescribing of controlled substances.

As CMS continues to evaluate the [Query of PDMP](#) measure, it should work to ensure that the measure does 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 doing the prescribing.

***In regards to PDMPs, in general, the AANS and the CNS continue to support standards that 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.

**In regards to the Verify Opioid Agreement measure, the AANS and the CNS support CMS' decision to remove this measure from the program. While we agree with the intent of this measure, we do not believe it is ready for implementation at this time due to the ongoing lack of standardization in this space.** Without EHR standardization, 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 also have concerns that without standardization of systems, the look-back period may pose challenges. Finally, we continue to 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, an agreement is not necessarily required for all patients. These agreements not only take time to explain and sign but may paint a negative picture of pain medications for patients where pain medications are, in fact, 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 add to the administrative burdens that are already making daily practice challenging. For these reasons, the AANS and the CNS support CMS' decision to remove this measure.

### ***New Opioid Measures***

In an effort to align the CQM reporting requirements for the Promoting Interoperability Program with similar requirements under the Hospital IQR Program, CMS also proposes to add the following two opioid-related CQMs to the Promoting Interoperability Program measure set beginning with the reporting period in CY 2021:

- [Safe Use of Opioids – Concurrent Prescribing eCQM](#)
- [Hospital Harm – Opioid-Related Adverse Events eCQM](#)

We refer CMS to our earlier comments on these measures in the context of the IQR Program.

### ***RFI on NQF and CDC Opioid Quality Measures***

CMS also seeks feedback on potentially adding existing opioid-focused measures, which are listed below, to the Hospital Promoting Interoperability Program in the future. CMS believes that the clinical actions identified within these measures can be supported by the standards and functionalities of certified health IT.

- **NQF-Endorsed Opioid Measures.** The following three NQF-endorsed quality measures, stewarded by the Pharmacy Quality Alliance (PQA), evaluate patients with prescriptions for opioids in combination with benzodiazepines, at high-dosage, or from multiple prescribers and pharmacies:

- [Use of Opioids at High Dosage in Persons Without Cancer](#) (NQF #2940). This measure evaluates the percentage of individuals  $\geq 18$  years of age who received prescriptions for opioids with an average daily dosage of  $\geq 90$  morphine milligram equivalents (MME) over  $\geq 90$  days. It excludes patients in hospice care and those with cancer.
- [Use of Opioids from Multiple Providers in Persons Without Cancer](#) (NQF #2950). This measure evaluates the percentage of individuals  $\geq 18$  years of age who received prescriptions for opioids from  $\geq 4$  prescribers and  $\geq 4$  pharmacies within  $\leq 180$  days. It excludes patients in hospice care and those with cancer.
- [Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer](#) (NQF #2951). This measure evaluates the percentage of individuals  $\geq 18$  years of age who received prescriptions for opioids with an average daily dosage of  $\geq 90$  MME over a period of  $\geq 90$  days AND who received prescriptions for opioids from  $\geq 4$  prescribers AND  $\geq 4$  pharmacies within  $\leq 180$  days. It excludes patients in hospice care and those with cancer.

To ensure accuracy, all of these measures will depend on better integration of pharmacy, PDMP, and EHR data. **We support the intent of these measures but urge CMS to delay implementation of these measures until such integrated systems are more widespread.** We are encouraged by CMS and ONC's recent proposals related to interoperability and patient data access, which would require the adoption of standards that would help to overcome current challenges. However, we urge CMS to wait until those standards are in place and well-tested before implementing these measures.

- **CDC Quality Improvement (QI) Opioid Measures.** The CDC developed 16 QI opioid measures to align with the recommendations in the [“CDC Guideline for Prescribing Opioids for Chronic Pain”](#) and to improve opioid prescribing. These measures are found in Appendix B of the CDC document [“Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain.”](#) These measures address treatment guidelines for both initial treatment practices (e.g., #2: Check PDMP Before Prescribing Opioids; #4: Evaluate Within Four Weeks of Starting Opioids) and long-term treatment and outcomes (e.g., # 11: Check PDMP Quarterly; #12: Counsel on Risks and Benefits Annually). The data sources from these measures include state PDMP data or the practice EHR data field.

We refer CMS to our earlier comments regarding ongoing challenges related to the integration of PDMPs. **Until there are more standardized laws and systems to allow for the seamless sharing of such data, we do not believe that CMS should adopt measures that rely on PDMP data.**

In the meantime, we encourage CMS to focus on practice-level strategies to help organize and improve the management and coordination of long-term opioid therapy, such as:

- Using an interdisciplinary team approach;
- Establishing practice policies and standards; and
- Using EHR and clinical data registries to track quality improvement related to opioid use and disorders.

We also encourage CMS to collaborate with its colleagues at the CDC and AHRQ on the ongoing development of electronic clinical decision support tools that can provide real-time clinical decision

support for some of the best practices included in the Implementing the CDC Prescribing Guideline document.

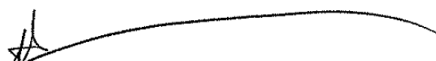
### **CONCLUDING REMARKS**

The AANS and the 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,



Christopher I. Shaffrey, MD President  
American Association of Neurological Surgeons



Ganesh Rao, MD, President  
Congress of Neurological Surgeons

### **Staff Contact for Payment Provisions**

Catherine Jeakle Hill  
Senior Manager, Regulatory Affairs  
AANS/CNS Washington Office  
25 Massachusetts Ave. NW  
Suite 610  
Washington, DC 20001  
Phone: 202-446-2026  
E-mail: [chill@neurosurgery.org](mailto:chill@neurosurgery.org)

### **Staff Contact for Quality Provisions**

Rachel Groman, MPH  
Vice President, Clinical Affairs and Quality  
Improvement  
Hart Health Strategies  
Phone: 202-729-9979 ext. 104  
Email: [rgroman@hhs.com](mailto:rgroman@hhs.com)