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February 16, 2018

The Honorable Orrin G. Hatch, Chairman Committee on Finance United States Senate Washington, DC 20510 The Honorable Ron Wyden, Ranking Member Committee on Finance United States Senate Washington, DC 20510

Subject: AANS and CNS Feedback on Committee Questions Concerning Policy Recommendations to Address Opioid and Substance Use Disorders.

Dear Chairman Hatch and Ranking Member Wyden:

The American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) appreciate the opportunity to provide feedback to the Senate Finance Committee regarding opioid use disorder (OUD) and other substance use disorders (SUDs). Below are our thoughts related to six of the questions you posed in your February 2, 2018 letter:

1. How can Medicare and Medicaid payment incentives be used to promote evidence-based care for beneficiaries with chronic pain that minimizes the risk of developing OUD or other SUDs?

The incorporation of opioid contracts in the care of chronic pain patients may reduce the incidence of substance abuse disorder (SUD) and opioid diversion during treatment. By establishing a mutually agreed upon framework for continued opioid prescribing, these agreements may include goals of therapy (including long-term weaning) and mechanisms for nonjudgmental treatment in the case of misuse of opioids or other drugs of abuse. Keeping patients in a therapeutic relationship is key to minimizing abuse. However, currently there is no specific mechanism to account for the time, and effort physicians expend maintaining these contracts, including the administrative burdens of checking state drug monitoring registries. Perhaps, a new CPT code that allows a physician to be reimbursed for the time spent managing this relationship would incentivize the use of these contracts. Furthermore, with the increasing burdens being placed on pain management specialists to handle the non-procedural aspects of pain control, many of these physicians are becoming increasingly reluctant to take on "medical" pain patients who do not need interventional treatments. By providing a method for these specialists to be compensated more fairly for treating these "medical" pain patients, improved pain management care will be possible and even likely. A dedicated code may also improve tracking of the use of these agreements in clinical practice.

2. What barriers to non-pharmaceutical therapies for chronic pain currently exist in Medicare and Medicaid? How can those barriers be addressed to increase utilization of those non-pharmaceutical therapies when clinically appropriate?

The AANS and CNS support the use of non-pharmacologic (i.e., procedural and behavioral) therapies for the treatment of chronic pain when appropriate. Interventions such as neuromodulation (i.e., spinal cord stimulation, peripheral nerve stimulation, brain stimulation), nervous system ablation (destructive surgical treatments), comprehensive pain rehabilitation

clinics, and pain psychology all have been shown to decrease pain-related disability and reduce opioid use. Indeed, advanced spinal cord stimulation (SCS) technologies allow chronic pain specialists to provide increased patient satisfaction and may lower overall health care costs through fewer provider visits and less opioid medication. However, Medicare and Medicaid often deny the use of these treatments for chronic pain patients, despite substantial evidence supporting their use in addressing chronic pain. These restrictive policies only serve to encourage the use of opioids as physicians see few covered alternatives. Medicare and Medicaid should allow coverage of these non-pharmacologic therapies for chronic pain when sufficient clinical evidence (including such resources as clinical trials, prospective data registries, and/or peer-reviewed clinical practice guidelines listing the therapy as a treatment option) exists. These noncoverage determinations are often based on the fact that studies for some of these treatments are relatively small compared to those for pharmaceuticals. It is important to understand that these treatments are not utilized in the same numbers as pharmaceuticals, and large studies may not be feasible.

3. How can Medicare and Medicaid payment incentives be used to remove barriers or create incentives to ensure beneficiaries receive evidence-based prevention, screening, assessment, and treatment for OUD and other SUDs to improve patient outcomes?

Medicare and Medicaid may use payment bonuses, such as those available through the Meritbased Incentive Payment System (MIPS), to incentivize physician use of validated, evidencebased screening tools for those patients on chronic opioids to increase early identification of OUD and other SUDs. Moreover, these same payment incentives can be awarded to those physicians who adhere to guidelines issued by professional societies regarding opioid prescribing limits and referral for treatments and interventions such as addiction counseling and pain psychology evaluation.

4. Are there changes to Medicare and Medicaid prescription drug program rules that can minimize the risk of developing OUD and other SUDs to improve patient outcomes?

The AANS and CNS favor the development and implementation of a Risk Evaluation and Mitigation Strategy (REMS) tool through the FDA to facilitate the dispensing of appropriate opioid prescriptions when medically necessary. The standardized tool, which does not have to be overly complex and administratively burdensome, would be completed by the prescriber at the time the prescription is written and would accompany the prescription (either physically or electronically, as appropriate) to the pharmacy.

Every opioid prescription, regardless of the quantity of opioid prescribed, would have the REMS tool attached. This tool would allow the prescribing clinician to:

- a) specify the patient's diagnosis as appropriate for continued opioid therapy;
- specify the indication for continued opioid therapy, such as acute pain, chronic pain requiring maintenance opioid medication, acute postoperative pain, pain exacerbation requiring opioid dose escalation, or palliative care/cancer pain; and
- c) certify that the patient has either failed an appropriate non-opioid therapy prior to initiation of opioid therapy or particular non-opioid therapies (such as NSAIDs) are contraindicated.

Moreover, we suggest that Medicare and Medicaid consider funding the creation of a national Prescription Drug Monitoring Program (PDMP), which could either consist of a new national PDMP, or interlink existing state-based PDMPs. This national database would then be queried by the pharmacist before the medication is dispensed. Any red flags noted would prompt a hard stop on dispensing and a call to the prescriber from the pharmacist. This would be a more efficient method, as access to PDMP databases is not always available to prescribers at all points

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of patient care (emergency departments, walk-in clinics, satellite offices, etc.). CMS may also use this database to analyze the opioid dispensing patterns of pharmacies or providers, helping to identify those pharmacies that are dispensing inappropriately large amounts of opioids as part of diversion.

The AANS and CNS anticipate that this reasonable REMS mechanism, combined with a national PDMP, will both curb inappropriate opioid prescribing practices and preserve access to opioids to those patients who may benefit from them.

5. How can Medicare or Medicaid better prevent, identify and educate health professionals who have high prescribing patterns of opioids?

With a national PDMP, CMS will have access to the opioid prescribing characteristics of clinicians. This may then be utilized to identify those clinicians who have unusual prescribing patterns. Those prescribers identified via this screen would then be subject to a more detailed investigation of prescribing patterns. If there is no diversion involved, the clinician could be asked (in a non-punitive manner) to complete an educational course in proper opioid prescribing.

6. What can be done to improve data sharing and coordination between Medicare, Medicaid, and state initiatives, such as Prescription Drug Monitoring Programs?

As mentioned above in question number 4, the AANS and CNS favor the development and implementation of a single nationwide PDMP. This could either consist of a new federal PDMP, or a system of interlinked state-based PDMPs. If the latter is chosen, funding could be provided to help states establish PDMPs. The purpose of a national PDMP is to both prevent patients from pill shopping across state lines and to identify trends in prescribing and dispensing that could indicate diversion. Currently, a patient can obtain an opioid prescription in one state, and then immediately go across the border to another state and get a duplicate opioid prescription without triggering an alert in either state's PDMP. This situation is unacceptable and makes opioid abuse and diversion easier to camouflage.

The AANS and CNS appreciate the opportunity to provide our responses to the above-listed questions to assist the Committee in its deliberations on this important public health topic. As the committee continues to explore ways to address the opioid crisis, we are happy to meet with you to further discuss our ideas. In the meantime, thank you for considering our comments.

Sincerely,

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Alex B. Valadka, MD, President American Association of Neurological Surgeons

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