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April 1, 2019

Vanila M. Singh, MD
Chief Medical Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary of Health
200 Independence Avenue, SW
Washington DC 20201

SUBJECT: HHS–OS–2018–0027; Request for Public Comments on the Pain Management Best Practices Inter-Agency Task Force Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations

Dear Dr. Singh:

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), we appreciate the opportunity to comment on the above-referenced report. We are generally in agreement with the conclusions of the report, which we believe are solidly grounded in evidence and a recognition of real-world medical practice. We thank the Task Force for its thorough and thoughtful analysis and recommendations to address our nations opioid epidemic and to offer realistic options for patients living with pain. The AANS and the CNS believe that the report supports our view that reasonable mechanisms can be created to curb inappropriate opioid prescribing practices while still preserving access to opioids to those patients who would likely benefit from them. In addition, we commend the Task Force for its recognition of promising new and existing non-opioid therapies, including devices, to treat pain and for its backing of adequate reimbursement for pain care.

Comments on Specific Recommendations

Section 2.1.1 Acute Pain General Comments. The AANS and the CNS support the Task Force recommendations to mitigate opioid exposure in the perioperative period and the emphasis on individualized treatment as the primary goal of acute pain management. We agree with efforts to encourage appropriate reimbursement for pain psychology services to help identify issues that lead to opioid problems and poor surgical results. Ultimately, the surgeon and the patient must weigh the risks and benefits of acute pain control for an individual patient.

Section 2.1.1 Acute Pain, Gaps 2, Recommendations 2a and 2b. The AANS and the CNS believe that post-operative pain treatment varies based on the type of procedure and the individual needs and preferences of the patient. We appreciate the recognition that not every surgical procedure is the same, and many patients are not opioid naïve at the time of surgery. We acknowledge the recommendation for the development of acute pain management guidelines for common surgical procedures and trauma management but, as mentioned above and as the Task Force recommendation recognizes, it is very important to avoid unintended negative consequences for recommendations that are taken as hard and fast rules. The development of condition-specific treatment algorithms to guide physicians should not interfere with the goal of an individualized approach for common pain syndromes. Any guideline should allow for the flexibility to tailor treatment to the needs of an individual patient.

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Section 2.2 Medications. The AANS and the CNS appreciate the Task Force support for reimbursement for non-opioid medications. Sometimes non-opioid medications such as pregabalin are inadequately reimbursed or not covered at all. In addition, we agree with the conclusion that a limiting ceiling for opioid prescribing is problematic. Finally, we appreciate the Task Force recognition that some patient populations may be restricted from using certain medication and that some medications may interfere with the healing process for certain procedures. For example, nonsteroidal anti-inflammatory drugs (NSAIDS) interfere with bone growth and are contraindicated for spinal fusion procedures.

Section 2.2.1.1 Prescription Drug Monitoring Programs (PDMPs). We are pleased to see that the draft report is in keeping with neurosurgery's call to integrate interoperability of PDMPs with Electronic Health Record (EHR) workflows to make checking the PDMP easier for the prescriber and our strong support to develop interoperability between PDMPs across state lines. We agree with all the recommendations in this section.

Section 2.2.2 Access to Naloxone. The AANS and the CNS support the Task Force recommendations regarding access to naloxone to save lives from overdose and the need for further naloxone co-dispensing education and research into the most effective and safe method of dispensing it.

Section 2.4 Interventional Procedures. We appreciate the Task Force's recognition of high-quality evidence for neuromodulation, including spinal stimulation, new waveforms, and spinal infusion pumps and the recognition regarding difficulty with insurance coverage for these procedures. This is an area of growth and innovation for chronic pain treatment. Spinal cord stimulation and dorsal root ganglion stimulation, collectively, have five level-1 studies demonstrating their efficacy in low-back and lower extremity pain. Peripheral nerve stimulation has gained popularity and effectiveness with the recognition of peripheral nerve entrapments, increased use of ultrasound, and improvement in technology. There are now multiple level-1 studies and multiple level-2 studies demonstrating that noninvasive vagus nerve stimulation can be effective in ameliorating pain in various types of cluster headaches and migraines without requiring a surgical procedure or implant. The AANS and the CNS concur with the statements in the report regarding the use of neuromodulation and thank the Task Force for highlighting these important and effective devices to address pain.

In addition, we concur with the comments regarding intrathecal pumps. As the report highlights, because there are opioid receptors on the spinal cord and at specific areas of the brain, small doses of opioids in the spinal fluid can provide significant analgesia at much lower doses than oral opioids. Implanted intrathecal pumps with catheters in the spinal fluid can supply medication continuously, and they have been used for cancer as well as noncancer pain. Again, we appreciate the recognition of pain pumps as an important option for appropriately selected patients.

Finally, we note that the report mentions vertebral augmentation to stabilize the spine to treat painful refractory vertebral compression fractures. The treatment of chronic pain and acute post-operative pain are important competencies for neurosurgeons, and our specialty is one of constant innovation to address pain associated with conditions of the brain and spine.

Section 2.4 Interventional Procedures, Gap 3. One area of the report that we would like to address is the method of identifying physicians who are appropriately trained as pain specialists. The AANS and the CNS urge the Task Force to add the American Board of Neurological Surgery (ABNS) to the list in the draft report of accrediting organizations. ABNS certification encompasses the neurosurgical treatment of both acute and chronic pain with ablative, neuromodulatory and reconstructive procedures and the ABNS should be on the list of accrediting organizations.

Section 2.4.1 Perioperative Management of Chronic Pain Patients. We agree that perioperative pain management in chronic pain patients presents unique challenges, particularly for patients with opioid

tolerance or those vulnerable to opioid-associated risks. Patients on long-term opioid therapy can be more complicated to manage in the perioperative period compared with patients who are opioid naive. Considerations for managing these patients include the use of multimodal approaches, including consideration of devices, as well as preoperative consultation and planning.

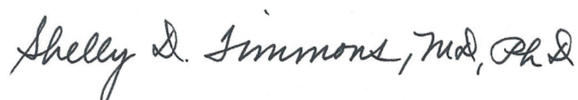
Section 2.7 Special Populations. The AANS and the CNS appreciate the Task Force recognition of the need for special consideration for vulnerable populations such as chronic pain patients needing aggressive pain management, pediatric patients, geriatric patients, pregnant patients, etc. In particular, we urge consideration of the fragility of older adults and efforts to further research into the use of neuromodulation for this population.

Section 4 Review of the CDC Guideline. The AANS and the CNS strongly support the recommendations in this section regarding the Centers for Disease Control (CDC) guideline. We are particularly supportive of recommendations to avoid strict ceiling doses of opioids. Impositions of 90 morphine milligram equivalents (MME) per day limits and hard stops on opioid prescriptions, such as 3-7 day limits, caused significant concern for patients following major surgery. The draft report recognizes that the 2016 CDC opioid prescribing guidelines have had unintended consequences, resulting in severely time-limited opioid prescriptions and forced tapering of chronic pain patients off their stable, effective opioid regimen. We appreciate the Task Force reassessment of these guidelines and recognition of the need for flexibility and consideration of individual patient needs.

Conclusion

Thank you for the opportunity to provide our comments on the Task Force draft report. It offers an excellent assessment of the current literature and a comprehensive list of recommendations that show a genuine recognition of the concerns of practicing physicians and patients. We look forward to seeing the final report, and we are eager to assist the Task Force in the important work of advocating for the care of patients in pain.

Sincerely,



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