American Society of Anesthesiologists®

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February 16, 2018

via email: opioids@finance.senate.gov

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

Dear Chairman Hatch and Ranking Member Wyden:

On behalf of the American Society for Anesthesiologists (ASA) and our 52,000 members, we are pleased to submit our response to the Senate Finance Committee's (the "Committee") recent request for suggestions on how the Medicare and Medicaid programs can better address the opioid epidemic. We appreciate the Committee's interest in this critical issue and look forward to serving as a resource for Committee members as the discussion evolves.

Physician anesthesiologists have a critical role in combating the opioid epidemic.

Physician anesthesiologists' role in the delivery of care makes these specialists integral to reducing opioid use throughout the perioperative period and upon discharge. They have a unique understanding of the intricacies of short-term pain management (e.g. following a surgical procedure or acute injury) and effective non-opioid alternative treatment strategies. Additionally, a subset of the ASA membership specializes in long-term pain management (e.g. a chronic condition).

Physician anesthesiologists partner with patients and families to manage expectations around pain treatment, educate patients on the safe use, storage and disposal of opioids, and the prevention of opioid misuse and abuse post discharge. ASA recommends that all patients on high daily doses of opioids undergo evaluation by a board-certified pain physician with additional addictionology consultation if needed.

The *2017 National Pain Strategy*, published by the National Institutes of Health (NIH), states, "Chronic pain is a biopsychosocial condition that often requires integrated, multimodal, and interdisciplinary treatment, all components of which should be evidence-based."[1] ASA supports this approach, and our recommendations are based upon a comprehensive, clinically-driven care protocol. Patients experiencing pain should have timely access to patient-centered care that meets their needs, but appropriate prescribing and treatment behavior must be equally paramount. Physician anesthesiologists and other clinicians

[1] Department of Health and Human Services: National Pain Strategy: A Comprehensive Population Health Strategy for Pain. Available at: https://iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf Accessed on 2/14/18.

caring for these patients must have access to the timely research and evidence-based treatment options to address patients' health care needs in a safe and effective manner.

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

Proper clinical guidelines along with appropriate payment incentives are key to promoting desired behavior from health care providers. ASA urges Congress to consider multiple approaches to align payment incentives with evidence-based care, including:

Utilization of MIPS and AAPMs

Utilization of the Merit-based Incentive Payment System (MIPS) and the Advanced Alternative Payment Models (AAPMs) implemented under MACRA's Quality Payment Program (QPP) supports the provision of appropriate, high-quality treatment of pain for Medicare beneficiaries. Clinicians are investing significant resources to successfully participate in these programs, and the development of new incentives and performance measurement tools presents a unique opportunity to address the risks and concerns associated with opioid use. ASA urges Congress to find ways to leverage the existing infrastructure of these programs to promote and encourage evidence-based care for patients with acute and chronic pain. For example, the Centers for Medicare & Medicaid Services (CMS) could focus on appropriate pain medicine and management practices with special attention to proper opioid prescribing and methods of minimizing opioid use in patients with pain conditions when assessing and approving quality measures, improvement activities and the use of health information technology objectives under MIPS.

Programs to Support Models of Care that Minimize Opioids

ASA recommends that Congress direct CMS or another federal entity to develop a grant program to explore the creation of innovative programs that encourage opioid sparing techniques in the hospital and surgical setting.

ASA has created the Perioperative Surgical Home ("PSH") learning collaborative, a learning collaborative exploring a new patient-centered model designed to improve health, the delivery of health care and to reduce the cost of care. The PSH is implemented through shared decision-making and seamless continuity of care for the surgical patient, from the decision for surgery through recovery, discharge and beyond. The idea is that a well-coordinated and well-integrated PSH model can more consistently and effectively guide the patient through the entire surgical continuum. The goals of the PSH are aligned with the goals of AAPMs and MIPS and should be recognized as an opportunity to address the opioid epidemic.

In the PSH model, physician anesthesiologists and surgeons are positioned to develop, implement, and coordinate a comprehensive perioperative analgesic plan, which begins with the formal preoperative patient assessment and continues throughout the post discharge, convalescence period. Specifically, safe and effective perioperative pain management should include a plan of care that is tailored to the individual patient, presence of a chronic pain condition and preoperative use of opioids, and the specific surgical procedure—with evidence-based, multimodal analgesia. A patient-tailored, opioid-sparing, multimodal analgesic regimen has been effectively defined and consistently applied in reported PSH models.[2] The PSH holds great potential for having an impact on patients by addressing risks for opioid misuse, abuse and addiction. A grant program would support these efforts on a wide-scale and enable implementation of safer pain management practices across the care continuum.

[2] Vetter, R. Thomas, Kain, N. Zeev, Role of the Perioperative Surgical Home in Optimizing the Perioperative Use of Opioids, International Anesthesia Research Society, 2017.

Implement Quality Measure Development Funding Initiative

In May 2017, CMS announced that it will award up to $30 million in grant funding to clinical specialty societies, clinical professional organizations and independent research organizations to develop quality measures under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).[3] The application process for this funding has been delayed multiple times since the original announcement and the estimated project start date is now August 1, 2018, although applications have yet to be released. ASA urges Congress to direct CMS to move forward with this important quality measure development funding initiative that will contribute to supporting the provision of evidence-based care for patients with chronic pain. Quality measures seek to track the degree to which evidence-based treatment guidelines are followed, where indicated, and assess the results of that care. The use of quality measurement helps strengthen accountability and supports performance improvement initiatives at numerous levels. An increase in measures in this area will help support the provision of evidence-based care for pain management services.

The ASA and American Society of Regional Anesthesia and Pain Medicine (ASRA) partnered in 2017 to develop chronic and acute pain measures for physicians and their practices to use. These measures include Safe Opioid Prescribing Practices and Multimodal Pain Management and are available for eligible clinicians to report via our Qualified Clinical Data Registry (QCDR). We were disappointed that CMS did not accept our measure on patient education related to proper disposal of opioids. In the future, we hope that pain medicine physicians and others will use these measures to improve quality care and to effectively address the opioid crisis.

Coverage and Payment Strategies

Coverage and payment policies must be appropriately designed for critical services that support pain treatment therapies and substance use disorders (SUDs). Payment and coverage policies should ensure that appropriate medical examinations of patients are being performed and adequate assessment of opioid risks are addressed prior to initiation of treatment. This includes risk stratification using risk tools, such as the Opioid Risk Tools and the Screener and Opioid Assessment for Patients in Pain—Revised (SOAPP-R) and/or referral to an addiction psychologist or psychiatrist to quantify risk. The Medicare program should recognize the value and worth of these services; referrals to these providers should be covered services to help ensure that patients get the care they need. Periodic assessment of function and risk of developing opioid use disorder (OUD) should be assessed through tools such as the Current Opioid Misuse Measure (COMM). Periodic documentation of these interventions should be tied to incentive-based pay. Finally, regular drug screening should be covered for Medicare/Medicaid beneficiaries with confirmatory tests.

Coverage for alternative and interventional therapies that can be effective in treating chronic pain is often hindered by the current CMS evidence threshold requiring three randomized clinical trials (RCTs). ASA urges Congress to direct CMS to lower this threshold and require less than three RCTs. It is challenging to conduct an RCT in chronic pain because there are several confounding factors and therefore, not all interventional procedures can have 3 RCTs as required. For example, many patients with chronic pain suffer from depression and this can impact the studies' outcomes. Additionally, it is difficult to measure changes or improvements in patients' pain because there is no perfect pain score measure. In fact, pain is subjective in nature and thus, there is variability. In studies examining chronic pain interventions, physicians must use indirect measures such as quality of life. Improving Medicare and Medicaid coverage of reasonably effective treatments that do not require the use of opioids (or promote the use of lower doses) would be very beneficial to combatting the opioid crisis by making more treatment options available to patients. However, it is worth noting that the clinical evidence base for some of these

[3] Medicare Access and CHIP Reauthorization Act (MACRA) Funding Opportunity: Measure Development for the Quality Payment Program ; Grants.gov; .go https://www.grants.gov/web/grants/search-grants.html?keywords=macra; accessed on 2-14-18.

alternative treatments is not as strong as it should be in some cases. As such, CMS should also work with the clinical and academic communities to support additional research to identify and establish the evidence base necessary to facilitate coverage of these therapies across payers.

Further, as a multimodal approach to pain treatment becomes more prevalent, the utilization of interventional procedures will increase, and that utilization should not be considered as sole grounds for identifying the services as being potentially misvalued and subject to review and decreased valuation under the Medicare Physician Fee Schedule. ASA points out that the values associated with interlaminar epidural injections were significantly reduced in recent years. We would ask that CMS be directed to re-consider its stance in regard to these services and take into account the savings they provide in overall spending - not only due to their effectiveness but also how their use can contribute to solving the opioid crisis.

Implementation of National Prescription Drug Monitoring Program

ASA could support the implementation of a national prescription drug monitoring program (PDMP) under certain circumstances. Such a program could reduce unnecessary or inappropriate opioid prescribing as well as facilitate consistent reporting and tracking across the country. Almost every state has its own PDMP but they differ significantly from one state to another, and there are marked differences in how states set up agreements with other states to share the data. Another significant problem is a lack of physician access to information about what prescriptions patients have filled in other states. A national PDMP or providers participating in the Medicare program could address many of the shortcomings of the various state PDMPs and create a uniform resource that avoids gaps in care or information that could lead to prescription drug abuse or ineffective monitoring. If a national PDMP is established, Congress should ensure that clinicians are not overburdened by reporting to both a state and national registry.

Public/Private Education Initiatives

Congress should support public/private initiatives to educate hospitals and physician practices on clinical guidelines and best practices for opioid pain management. This approach would encourage more responsible prescribing behavior in both hospitals and physician practices, as well as reduce the number of unused opioids in American communities and households. This should entail a grant program specifically supporting and targeting the perioperative setting and opioid sparing techniques, as statistics have shown that many individuals experience problems with misuse or addiction following a surgical procedure or through diversion of prescription opioids stemming from a surgical procedure.

Because of the unique role they play in the process of care, physician anesthesiologists can be critical in these partnerships. ASA is currently collaborating with Premier, Inc. and their network of hospitals in a nationwide opioid safety pilot to reduce harm associated with the use of opioids in patients undergoing certain high-volume surgical procedures (hip, knee, and colectomy). The project, which is being executed through CMS's Hospital Improvement Innovation Networks (HIIN), involves implementing evidence-based pain management practices to measurably reduce opioid-use during and after surgery. As part of the pilot, ASA physician-members are providing education to the participating hospitals on these practices, including multimodal approaches to pain management, with the goal of reducing the overall number of opioids prescribed to patients receiving these surgeries. This is just one example of the type of public-private partnerships that can facilitate effective dissemination of the clinical information necessary to combat patient abuse of opioids and opioid addiction.

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?

ASA is pleased to see that the Committee is exploring non-pharmaceutical treatments for chronic pain, a critical issue in the fight against opioid misuse, abuse and addiction. According to data from the 2012 National Health Interview Survey (NHIS), 11.2 percent of American adults (25.3 million people) have experienced some form of pain every day for the past three months. ASA strongly believes that increased coverage must be coupled with increased funding for research. It is only through significant, dedicated and focused resources committed to this area that we can gain a better understanding of the appropriate and more effective treatment of chronic pain.

Under the current Medicare and Medicaid coverage polices, patients may receive a relatively low-cost opioid prescription as opposed to other effective treatment options because opioid products are typically covered by Medicare, Medicaid and most health plans. Recent clinical evidence indicates that non-pharmaceutical and alternative therapies— such as acupuncture, radiofrequency ablation and neuromodulation— can be safe and effective treatment methods in certain circumstances and would be more available to patients if covered by Medicare and Medicaid.

ASA supports increased patient access to multimodal, multi-disciplinary pain management, including safe and effective opioid prescribing. A comprehensive, patient-centered approach to pain management may also include interventional therapies (e.g. epidural steroid injections, radiofrequency ablation, and neuromodulation), which are key non-opioid therapies for the treatment of chronic pain and have been shown to reduce and eliminate pain, improve function, decrease reliance on opioids, and for some patients eliminate the need for surgery. Our pain management experts have reported that when spinal neuromodulation is performed by physicians trained to perform these procedures, the average opioid reduction for chronic pain patients is approximately 70 percent after one year.

In ASA members' experience, Medicare and Medicaid are still denying many instances of non-opioid alternatives (*e.g.* chiropractic therapy, acupuncture, biofeedback, nerve blocks, and neurostimulators) when such care could provide benefit to these patients.

To address these barriers, ASA recommends:

- increased coverage for alternative therapies and interventional pain management, (one example is median nerve radiofrequency ablation, which entails lesioning of certain nerves that supply joints like the sacroiliac joint, knee, and shoulder);
- increased research funding for alternative therapies and interventional pain management; and
- increased funding at NIH for non-opioid therapies, including a dedicated funding stream for chronic pain.

Congress recently recognized the importance of pain research by passing the "STOP Pain Act" as Section 108 of the CARA legislation in the last Congress. That provision recognizes the work already underway through the Interagency Pain Research Coordinating Committee ("IPRCC") at NIH, the National Pain Strategy released last year, and the recently released Federal Pain Research Strategy, all which support prioritization of pain research studies. The essential next step is to provide adequate funding, and we urge the Committee and other members of Congress to work towards finding a continued funding mechanism for this important initiative.

Support for pain research funding has suffered for many reasons, principal among them being the lack of a dedicated institute or center at NIH. Consequently, pain-related grants are spread across various institutes and centers, not one of which has pain as its highest priority. In recent years, and with strong support from Congress, NIH has developed important infrastructure to coordinate and prioritize these separate funding streams. This includes, in addition to the IPRCC, the NIH Pain Consortium and an Office of Pain Policy. As the Committee focuses on promotion of evidence-based practice and related incentives, it is critically important that additional support and effort be targeted towards developing a consistent, well-established body of evidence that can better inform care protocols and clinical guidelines. Well-informed physicians acting upon clinical evidence and professional judgment are more than capable of furnishing safe, effective pain treatments and management. Artificial prescribing limits and other policies that inhibit a physician's ability to practice safe, effective and high-quality medicine are not necessary to ensure adherence to evidence-based guidelines and, in fact, may prevent a physician from adequately addressing a patient's unique clinical needs.

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

Physician education on opioid prescribing and best practices for pain management, as well as on substance use and addiction can have a real, positive impact on addressing the opioid epidemic. A recent report by the American Medical Association (AMA) Opioid Task Force, of which ASA is a member, found that opioid prescriptions continue to decline nationwide. The report also notes that nearly all 50 states have naloxone access laws, more physicians are educated on safe opioid prescribing than ever before, use in PDMPs has increased, and the number of physicians certified to provide office-based medication-assisted treatment for opioid use disorders has also increased.[4] These trends are a good sign of progress, but more work needs to be done.

Effective physician education is reinforced throughout the continuum of medical education, including residency training, clinical experiences, and continuing education for practicing physicians. ASA supports vigorous efforts to improve education across the health care professions in both pain management and substance abuse prevention and treatment. Professional education and training must assure clinical competence in pain care, including, but certainly not limited to, the prescribing of controlled substances. Clinicians must be trained and demonstrate competencies in pain, controlled substance prescribing and substance abuse prevention.

While training, education and licensure are managed at the state level, there are federal initiatives that can help support and guide clinician training and best practices. The Food and Drug Administration (FDA)'s Risk Evaluation and Mitigation ("REMS") program, NIH's Centers of Excellence in Pain Education ("CoEPEs") grant program, and the Center for Disease Control's Guideline for Prescribing Opioids for Chronic Pain all support increased professional competency. The FDA is already in the process of significantly revising its REMS training materials to better reflect pain management, by expanding the classes of drugs that are covered, and supporting training of non-physician professionals involved in pain management in clinical settings. Congress should ensure that these initiatives are appropriately funded and prioritized.

Another effort that can be supported by CMS might include partnering with the national professional and medical societies to develop educational materials and guidelines on opioid prescribing, non-opioid alternatives, pain management and substance abuse prevention and treatment. Specifically, a grant

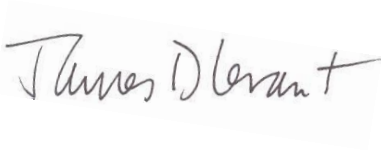
[4] AMA Opioid Task Force Progress Report: Physicians' progress to reverse the nation's opioid epidemic, April 2017, available https://www.ama-assn.org/sites/default/files/media-browser/public/physicians/patient-care/opioid-task-force-progress-report.pdf, accessed 2/14/2018.

program that supports collaboration and consensus among the medical specialties and societies would increase participation and consistency in continuing education.

ASA recommends that any educational initiative be targeted at all prescribers and even other health care providers, not just opioid prescribers. For example, since 2013, ASA has been a member of the Controlled Substances Stakeholders' Coalition, which was formed to recognize the shared responsibility of physicians and other prescribers and pharmacists to ensure all controlled substances are prescribed and dispensed for a legitimate medical purpose. The coalition meets annually and works together to develop resources. In 2014, the coalition developed a consensus document that details the challenges faced by all involved, highlighting red flag warning signs for physicians and pharmacists to detect diversion, misuse, and abuse of controlled substance medications, and identifying aberrant behavior indicators. ASA also believes that initiatives focused only on opioid prescribing or only on Schedule II drugs, and that permit prescribers to avoid education by simply opting out of prescribing certain drugs, would likely lead to the prescribing of other controlled substances that have abuse potential. Therefore, it is important that such unintended consequences be taken into consideration in developing any educational initiative.

Thank you for your leadership in addressing the opioid epidemic in communities across the nation. We appreciate the opportunity to provide our suggestions as the Finance Committee continues its critically important work on this issue. Please do not hesitate to contact ASA Pain Medicine and Federal Affairs Manager, Ashley Walton, J.D., via email at a.walton@asahq.org or by telephone at (202) 289-2222 if we can be of further assistance. Thank you again for your leadership on this critical issue facing our country.

Sincerely,



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