March 15, 2018

The Honorable Kevin Brady
Chairman
Ways and Means Committee
Washington, DC 20515

The Honorable Richard Neal
Ranking Member
Ways and Means Committee
Washington, DC 20515

The Honorable Peter J. Roskam
Chairman
Ways and Means Committee
Subcommittee on Health
Washington, DC 20515

The Honorable Sander Levin
Ranking Member
Ways and Means Committee
Subcommittee on Health
Washington, DC 20515

RE: Response to the Opioid Crisis

Sent electronically (in Word format) to WMOpioidSubmissions@mail.house.gov

Dear Chairman Brady, Ranking Member Neal, Chairman Roskam, and Ranking Member Levin:

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians from thirteen specialty and subspecialty societies. The Alliance is deeply committed to improving access to specialty medical care through the advancement of sound health policy.

The undersigned members of the Alliance appreciate the opportunity to provide feedback regarding responding to the opioid crisis. Consider that every day, 46 Americans die as a result of prescription opioid overdose,[1] and the rate of heroin-related overdose deaths has seen a 6.2 fold increase since 2002.[2] In addition to these tragic figures, the nation is seeing an increase in opioid-related pediatric exposures and poisonings. There has been a distressing rise in neonatal abstinence syndrome (NAS) as a result of women being exposed to opioids during pregnancy. Misuse by older adults has also become an increasing concern. The rate of opioid-related hospital admissions has increased significantly over the last two decades across all age cohorts. Because of higher rates of substance use disorders in the current "baby boomer" cohort, illicit and non-medical drug use among older adults is expected to increase in the future. Physicians are well positioned to understand the complexities of medical and nonmedical opioid use and to lead change in safe ways that do not marginalize segments of the population through reactionary policies and actions. While many non-opioid analgesics exist and use of these should be optimized moving forward, physicians must help guide policymakers regarding the valid and necessary roles for opioids.

According to the Centers for Disease Control and Prevention (CDC), the amount of opioids prescribed in the US peaked in 2010 and then decreased each year through 2015. However, prescribing remains high and varies widely from county to county. In 2015, six times more opioids per resident were dispensed in the highest-prescribing counties than in the lowest-prescribing counties. County-level characteristics, such as rural versus urban, income level, and demographics, only explained about a third of the differences. This suggests that people receive different care depending on where they live. Healthcare providers have an important role in offering safer and more effective pain treatment.

[1] Hedegaard H, Warner M, Miniño AM. Drug overdose deaths in the United States, 1999–2016. NCHS Data Brief, no 294. Hyattsville, MD: National Center for Health Statistics. 2017/ CDC. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at http://wonder.cdc.gov

[2] https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates

Already, there are studies that suggest specialties have shown discretion in their opioid prescribing patterns, including ophthalmology[3] and spinal surgery.[4] At the same time, however, physicians must ensure that their patients have appropriate pain management.

RESPONSES TO THE REQUEST FOR INFORMATION

Overprescribing/Data Tracking

1. **Perverse Incentives in Medicare**: The Committee seeks input on perverse incentives within Medicare that spur overprescribing of opioids across all settings of care. The Committee seeks input on best practices and policies that would modify prescribing patterns to prevent opioid abuse and misuse and reduce the use of opioids in emergency departments and other outpatient settings.

Ensure quality measurement does not lead to inappropriately treating pain. The Alliance recommends that quality measures with an emphasis on opioid use focus on how well the patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. If pain can be well-controlled and function improved without the need of high doses of opioids over a long period of time, that is a good indication of patient care. Focusing on a reduction in opioid use alone, such as opioid prescriptions that exceed 90 morphine milligram equivalents (MME)/day is not an appropriate goal. Focusing on daily dose may serve as an indicator of whether a patient is at risk of overdose and should be co-prescribed naloxone, but does not provide a signal that a physician provides poor quality care. In fact, since the CDC *Guideline for Prescribing Opioids for Chronic Pain* was issued, there have been many reports of patients who have been successfully managed on opioid analgesics for long periods of time, but forced to abruptly reduce or discontinue their medication regimens with sometimes extremely adverse outcomes, including depression, loss of function, increased heroin addiction, and even suicide.

Recently, the Centers for Medicare and Medicaid Services (CMS) finalized a decision to remove the Pain Management dimension (which is derived from HCAHPS) from the scoring formula used in the Hospital Value-Based Purchasing Program, beginning with FY2018 payment adjustments. CMS also finalized alternative questions for the HCAHPS Pain Management dimension. In particular, CMS removed the following three questions:

- During this hospital stay, did you need medicine for pain?
- During this hospital stay, how often was your pain well controlled?
- During this hospital stay, how often did the hospital staff do everything they could to help you with your pain?

And replaced them with the following, which focus more on ***communication*** about pain.

- During this hospital stay, did you have any pain?
- During this hospital stay, how often did hospital staff talk with you about how much pain you had?
- During this hospital stay, how often did hospital staff talk with you about how to treat your pain?

These questions remain on the HCAHPS survey and will continue to be publicly reported on Hospital Compare, but as of now, will no longer be used for payment determinations. Therefore, the Alliance encourages CMS and Congress to examine ways in which patient satisfaction is tied to payment and such satisfaction is related to overall payment [e.g., Merit- based Incentive Payment System (MIPS) quality measures and patient satisfaction surveys or patient-reported outcome tools].

In addition, the Alliance supports additional tools for educating patients regarding the pain management expectations. Patients have been well educated on "pain as the fifth vital sign", and patient expectations rooted in this outdated teaching may not match current physician understanding of these issues.

Provide better reimbursement for managing pain. 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

[3] https://www.ncbi.nlm.nih.gov/pubmed/28983558
[4] https://www.ncbi.nlm.nih.gov/pubmed/28763410

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.

Current reimbursement policies do not recognize the critical need for lengthy, emotionally trying face-to-face discussions needed to tackle ineffective pain coping strategies. 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.

Anecdotally, several specialty physicians noted that pharmacies are currently limiting opioid prescriptions for chronic pain. Specifically, although the Drug Enforcement Agency (DEA) laws allow a 90-day prescription for opioids and the CDC recommendations allow for 90 days between visits, many pharmacies are now only dispensing opioids for 30 days, even if the prescription is for longer. Rather than simply providing the additional opioids later (to fulfill the initial prescription), the pharmacy is requiring a second prescription. This causes unnecessary visits to the doctor and extra co-pays for the patient.

Finally, pain psychology services are woefully underfunded, and there is a serious undersupply of psychologists trained in evidence-based behavioral techniques for pain management. To correct this issue, Congress would need to provide additional funding to train existing psychologists.

2. **Tools to Prevent Opioid Abuse**: The Committee seeks input on tools currently unavailable in the Medicare program that could be used to curb opioid abuse and dependence.

The Alliance strongly supports additional prevention measures. Unused medications increase the risk of non-medical use by adolescents who live in the home or by their friends. Unused medication also can be ingested by young children who are curious about what is inside the pill container. Implementing campaigns to educate the public on the importance of storing opioid medications locked and out of the reach of children and properly disposing opioid medications following the end of use can encourage these safe practices.

Support implementation of the National Pain Strategy. The National Pain Strategy (NPS) was published in 2016 but little progress has been made on implementing its core elements to improve the state of pain care in the nation. The Alliance believes that, along with comprehensive treatment of OUD, the capacity to deliver multidisciplinary treatment of pain is also necessary to reverse the nation's opioid overdose and death epidemic. The NPS calls for developing a system of patient-centered integrated pain management practices based on a biopsychosocial model of care that enables health professionals and patients to access the full spectrum of pain treatment options, and it also calls for taking steps to reduce barriers to and improve the quality of pain care for vulnerable, stigmatized, and underserved populations. NPS implementation will change the paradigm for treating pain and ensure that physicians can recommend all pain management modalities to patients and know that insurance plans will cover those treatments. When payers use high deductibles, yearly limits on treatments, and prior authorizations to delay or deny care, patients often are left with few non-opioid pain treatments. In addition, employers need to recognize that patients may require time away from work to participate in therapeutic modalities so that opioid analgesics are not the only affordable option.

Support state-based innovation. In the past two to three years, several hundred new policies have been enacted at the state and local levels to address the opioid epidemic. The Alliance strongly urges that efforts be undertaken to fully

evaluate how these new laws and policies effect access to opioids, impact pain care, or might be associated with unintended consequences. As the nation's opioid epidemic is increasingly fueled by heroin and fentanyl and other illicit, synthetic derivatives, the Alliance urges the Committee to consider how public policies focusing on opioid supply need to be balanced by policies that offer a measure of hope to those individuals and families already affected by this epidemic.

Address illicit drug use. Drug overdose is the leading cause of accidental death in the US, with 52,404 lethal drug overdoses in 2015. Opioid addiction is driving this epidemic, with 20,101 overdose deaths related to prescription pain relievers, and 12,990 overdose deaths related to heroin in 2015.[5] Strategies to deal with opioid addiction cannot solely focus on prescription opioids but must also address illicit drugs such as fentanyl, heroin, methamphetamines, and others. A comprehensive strategy that focuses on interdiction of illicit drugs is also required to fully address this epidemic.

Avoid focusing on limits for acute pain prescriptions. As part of the 2019 Medicare Advantage and Part D Advance Notice Part II and Draft Call Letter, CMS proposes two policies related to acute pain prescriptions: (1) Expecting all sponsors to implement hard formulary-level cumulative opioid safety edits at point-of-sale (POS) at the pharmacy (which can only be overridden by the sponsor) at 90 morphine milligram equivalent (MME), with a 7 days supply allowance; and (2) Implementing a supply limit for initial fills of prescription opioids (e.g., 7 days) for the treatment of acute pain with or without a daily dose maximum (e.g., 50 MME). The Alliance believes that the 90 MME limit on all acute or chronic pain patients is arbitrary. The proposed limit was derived from studies examining the risk of overdose death as it relates to the MME prescribed. While at least one study has shown that treatment of pain long-term is likely not beneficial with opioids,[6] short-term use of opioids to manage pain may still be beneficial and may require higher doses.

In addition, the seven-day limit is problematic for certain circumstances, including trauma and post-surgical acute pain management [such as major spine surgery (e.g., fusion, deformity) and joint replacement). As noted below, the CDC guidelines related to *chronic* pain, not acute pain. Specifically, the guidelines note that "[o]pioid treatment for post-surgical pain is outside the scope of this guideline. . . ." With respect to trauma, a sudden accident is not planned for and can take weeks to months to resolve in the case of major multisystem injuries. These are not chronic pain patients, but certainly three to seven days is unrealistic and inhumane to restrict appropriate pain management. There should be further work to construct a possible trauma pain management framework where you can prescribe more than seven days with added monitoring.

For these reasons, the Alliance suggests that Congress provide appropriate latitude for prescribing opioids, as outlined in H.R. 4482, the "Opioid Abuse, Deterrence, Research, and Recovery Act of 2017," sponsored by Rep. Mark Meadows (R-NC-11), Rep. James Renacci (R-OH-16), and Rep. Ted Bud (R-NC-13). This legislation amends Section 303 of the Controlled Substances Act (21 U.S.C. 823) by requiring any practitioner licensed under State law who prescribes schedule II or III controlled substances to submit to the Attorney General a certification during his or her registration and renewal that he or she will not prescribe any opioid for the initial treatment of acute pain unless the prescription is for less than seven days or falls within a State- established prescription limit. Further, this certification does not prevent a practitioner from prescribing a schedule II or III opioid that is approved by the FDA for opioid use disorder treatment, for immediate, post-operative pain relief; or for more than seven-days if the prescription aligns with a clear medical standard of care, is documented in the patient's medical record and consults the applicable State electronic health record system or prescription drug monitoring program.

Further, the inability to "call in" opioids may lead to prescriptions of large quantities to ease burdens for post-surgical care providers and their patients. One might consider the ability to write a step-wise prescription, with acceptance of verbal authorization of small quantity refills in an early postoperative period.

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[5] Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep 2016;65:1445–1452. DOI: http://dx.doi.org/10.15585/mmwr.mm655051e1

[6] https://jamanetwork.com/journals/jama/article-abstract/2673971?redirect=true

Promote industry engagement. Opioid and non-opioid options originate from pharmaceutical companies. Intravenous acetaminophen (Ofirmev®) increased in cost 229% since 2014 when it was acquired by another company.[7] This very effective medication, which allowed patients to go home pain free from outpatient surgery, was removed from the formulary of many hospitals due to cost constraints. Without industry at the table, options can be limited.

Recognize the limitations of the CDC guidelines. In March of 2016, the CDC developed and published a guideline for prescribing opioid pain medications for adults 18 years of age and older *in primary care settings*. According to the White House Commission, prescriptions by primary care clinicians account for nearly half of all dispensed opioid prescriptions, and the growth in prescribing rates among these clinicians have been above average. However, while many professional organizations encourage use of the CDC guideline, it is important to note that patients who currently use opioid medications for legitimate medical reasons are worried about the guideline being too restrictive for their physicians to properly treat them. Clinicians have added their concerns about the CDC guideline, including the time required to discuss alternative forms of pain control, the difficulty in obtaining reimbursement for alternatives, how to address opioid tapering, and concerns with the prescribing guideline for specific forms of pain. Furthermore, it is important to point out that the CDC guideline is intended for primary care clinicians, who are treating patients for chronic pain in outpatient settings, and opioid treatment for post-surgical pain is outside the scope of this guideline, having been addressed elsewhere.[8] Thus, as it relates to acute pain, more latitude in decision-making should be given to physicians that have specialized training in pain management and surgeons managing post-surgery pain.

3. **Electronic Prior Authorization**: The Committee seeks input on the value of standardizing the electronic prior authorization process and other improvements that could be made to improve coordination and prevent abuse.

Encourage electronic prescribing of controlled substances (EPCS). Drug Enforcement Agency (DEA) requirements for biometric devices limit user-friendly consumer electronics already found in physicians' offices, such as fingerprint readers on laptop computers and mobile phones, from being utilized for two-factor authentication in EPCS. This and other rules contribute to cumbersome workflows and applications which are an impediment to physician EPCS update. Encouraging EPCS uptake and interoperability of prescription drug monitoring program (PDMP) databases and electronic health records would improve the integration of controlled substance data into practice workflows and clinical decision-making. While we recognize that the DEA is not within your specific committee jurisdiction, we recommend that you urge DEA to be responsive to removing their regulatory barriers to EPCS.

4. **Prescription Drug Monitoring Program (PDMPs)**: Currently, CMS does not have access to state PDMPs. The Committee seeks input regarding state PDMP data-sharing with CMS and other health care entities. Specifically, the Committee seeks information on potential barriers to implementation.

The Alliance encourages physicians, dentists and other prescribers of controlled substances to register for and use their local prescription drug monitoring programs (PDMP) — as one tool to identify when a patient may need counseling and treatment for a substance use disorder. The trend among policymakers has been to use PDMPs to identify "doctor shoppers". This, by itself, is important, but the real work is to understand why a patient is seeking medication from multiple prescribers or dispensers — and to offer a pathway for treatment and recovery. The information in PDMPs can play a helpful role in identifying patients in need of help.

Strengthen PDMPs. Physician consultation of PDMPs has increased from 61 million inquiries in 2014 to more than 136 million in 2016. PDMPs are now functional in almost every state, and most state PDMPs can share data. To expand the use of these clinical support tools, the Alliance encourages increased research and funding to help integrate PDMPs into electronic health records and physician workflow in a meaningful, user-friendly manner. Without such PDMP integration, the administrative burden for compliance would be too difficult.

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[7] https://www.bloomberg.com/news/articles/2015-10-12/how-one-drugmaker-learned-the-consequences-of-price-increases

[8] Washington State Agency Medical Directors' Group. AMDG 2015 interagency guideline on prescribing opioids for pain. Olympia, WA: Washington State Agency Medical Directors' Group; 2015. http://www.agencymeddirectors.wa.gov/guidelines.asp

Communication and Education

1. **Beneficiary Notification**: The Committee seeks input on the types of communications that would be appropriate for notification of the adverse effects of prolonged opioid use and alternative pain management treatment options.

Patient education reportedly decreases the need for postoperative opioid medication and improves patient satisfaction. Every patient encounter is a chance to educate patients about pain management expectations, modalities of pain control, and the risks of opioid pain medications. Interdisciplinary strategies that incorporate the surgeon, pain management specialists, nurses, physical and occupational therapists, ancillary staff, families, and other patient support systems are ideal approaches to controlling patient pain while minimizing opioid use.[9]

2. **Prescriber Notification and Education**: The Committee seeks input on the best methods for provider education on the adverse effects of prolonged opioid use, clinical guidelines for alternative pain treatments, and clinical guidelines for opioid prescribing. The Committee also seeks input on effective ways to notify providers who prescribe such medicines in excess of their peers.

Enhance education of physicians and other providers. A key part of our commitment to reversing the opioid epidemic is supporting enhanced education, training and resources for physicians and other health care professionals across the continuum of medical education to ensure that they have the resources they need to make informed prescribing decisions. In 2015 and 2016, more than 118,000 physicians took educational courses related to opioid prescribing, pain management, substance use disorders, and related topics offered by national organizations as well as medical specialty and state medical societies. For instance, in partnership with CO*RE, the American Osteopathic Association (AOA) offers grants for hosting "Opioid Prescribing: Safe Practice, Changing Lives" programs. AOA affiliates can apply for a block grant to present live Category 1-A CME developed by the Collaborative for REMS Education (CO*RE).[10] In September 2017, the American Gastroenterological Association (AGA) published a new Clinical Practice Update to describe how opioids can affect diverse parts of the gastrointestinal tract. Patients can experience GI symptoms and side effects related to the intake of opioids, including opioid-induced constipation (OIC), esophageal dysmotility and delayed gastric emptying.[11] The AANS and CNS have sponsored continuing medical education courses to educate our members about the opioid epidemic, proper prescribing practices and alternative pain management strategies. The AANS/CNS certifying board is also considering incorporating opioid-related topics into our board certification and continuing certification requirements.

The Alliance strongly supports efforts to enhance education, but believes that it should occur at the state level to avoid creating confusion and unnecessary federal overlap with existing state law. In addition, while sitting in CME courses, whether mandated or voluntary, does provide some benefit, benchmarking projects should be encouraged and funded. This has been one of the criticisms that have been heard regarding opioid prescribing. Medicine is evidence-based and training should be held to that standard as well.

Treatment

1. **Opioid Treatment Programs (OTPs) and Medication Assisted Treatment (MAT)**: The Committee seeks input from providers around best practices for identification and referral to OTPs, as well as how an OTP benefit could be integrated into the Medicare fee-for-service program - whether through bundled payments or otherwise. The Committee seeks input on the types of providers that are involved in delivery of MAT, best practices to promote coordinated and managed care, and current reimbursement challenges providers face through Medicaid and commercial plans.

We must change the conversation about what it means to have a substance use disorder (SUD) and increase access to evidence-based treatments. This means putting an end to stigma, increasing access to medication-assisted treatment

[9] https://www.facs.org/~/media/files/publications/bulletin/2017/2017%20august.ashx
[10] https://www.osteopathic.org/inside-aoa/development/research-and-development/Pages/core-rems-programs.aspx
[11] http://www.gastro.org/news_items/aga-releases-new-clinical-guidance-on-opioids-in-gastroenterology

(MAT) for opioid use disorder (OUD) and supporting the expanded use of naloxone — a life-saving medication that can reverse the effects of an opioid-related overdose. People with substance use disorder deserve to be treated like any other patient with a medical disease, and specialty physicians are helping the nation understand how to do this.

Support payment incentives for treatment of OUD. Medicare and Medicaid may use payment bonuses, such as those available through the MIPS, to incentivize physician use of validated, evidence- based 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.

Support continued Medicaid coverage for treatment of OUD and pain management. Medicaid provides insurance coverage that is critical to treatment of acute pain so that it does not become chronic pain as well as treatment of mental health issues that individuals with OUD often have.

Enforce existing SUD parity laws. More resources need to be provided for enforcing the *Mental Health Parity and Addiction Equity Act*. This can be done at both the state and federal levels, but America's patients also need your leadership to encourage health insurance companies and pharmacy benefit managers (PBMs) to end the type of prior authorization, step therapy, and fail first protocols that only serve as a barrier to MAT and multimodal pain care. While some payers have already taken positive steps to remove some barriers, this epidemic requires all payers to work to ensure access to care.

2. **Alternative Options for the Treatment of Pain**: The Committee is interested in ways to effectively address pain and ideas for innovative ways to encourage multimodal treatment of pain through payment reforms or benefit changes.

Improve coverage and eliminate payment barriers for MA and Part D plans. All MA and Part D plans should eliminate barriers to multimodal treatment for pain by covering non-opioid analgesics and non-pharmacologic treatments for pain. Better coverage of these other therapeutic options could help reduce overreliance on opioid analgesics and lessen the rapidly accelerating growth in the number of Medicare patients with OUD.

In addition, the prompt review requirements imposed on the plans for prior reauthorization and step therapy have the perverse effect of producing prompt denials if the physician does not have sufficient time to provide the requested plan information. The best time to get a patient into treatment is during the appointment at the physician's office. Prior authorizations and step therapy requirements impose unnecessary administrative burdens on prescribers and unjustified access delays on patients. Plans have placed too many drug utilization management (DUM) requirements on medical practices and hurdles in front of patients' rapid access to their medications. The prescribing clinician's judgment should be accepted at the time that the prescription is initially written that the medication is needed for the patient. CMS should prohibit the use of these DUM requirements, especially for OUD treatment, and the Ways and Means Committee should urge CMS to do so.

Further, the Alliance urges Congress to examine ways to create appropriate insurance incentives for pain management. For instance, recently, a specialist reported that he had performed a procedure and opted to prescribe Celebrex (not an opioid). Unfortunately, the patient copayment was $200 – much more expensive than Percocet (an opioid). As a result, the patient called and requested the opioid prescription, which was much less expensive. Thus, the insurance companies are complicit in this epidemic by denying simple anti- inflammatory meds and forcing people into narcotics due to the differences in insurance coverage.

The Alliance supports 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. A number of high-quality, landmark studies by neurosurgeons and pain colleagues have provided clear evidence of

the effectiveness of neuromodulation. The SENZA Trial[12] reports the results of a large, prospective, randomized, controlled trial of high-frequency spinal cord stimulation (SCS) for the treatment of low back and leg pain. A follow-up study[13] demonstrates the durability of treatment effects after two years. The Accurate study[14] documents the results from a large clinical trial of dorsal root ganglion (DRG) stimulation for trunk and limb pain, while the SunBURST study[15] details the results from a large clinical trial of BURST SCS in the treatment of back and leg pain. Together, these trials represent a profound advancement in the quality of evidence supporting the use of neuromodulation in chronic pain patients. 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.

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We appreciate the opportunity to provide comments on the aforementioned issues of importance to the Alliance. Should you have any questions, please contact us at info@specialtydocs.org.

Sincerely,

American Academy of Facial Plastic & Reconstructive Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American College of Osteopathic Surgeons
American Gastroenterological Association
American Society of Plastic Surgeons
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
National Association of Spine Specialists
Society for Cardiovascular Angiography and Interventions

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[12] Kapural, L., Yu, C., Doust, M. W., Gliner, B. E., Vallejo, R., Sitzman, B. T., . . . Burgher, A. H. (2015). Novel 10-kHz high-frequency therapy (HF10 therapy) is superior to traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain. *Anesthesiology, 123*(4), 851-860.

[13] Kapural, L., Yu, C., Doust, M. W., Gliner, B. E., Vallejo, R., Sitzman, B. T., . . . Burgher, A. H. (2016). Comparison of 10-kHz high-frequency and traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain. *Neurosurgery, 79*(5), 667-677.

[14] Sinclair, C., Verrills, P., & Barnard, A. (2016). A review of spinal cord stimulation systems for chronic pain. *Journal of Pain Research, 9*, 481-492.

[15] Kapural, L., Peterson, E., Provenzano, D. A., & Staats, P. (2017). Clinical evidence for spinal cord stimulation for failed back surgery syndrome (FBSS). *Spine, 42*.