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Senate Committee on Finance
219 Dirksen Senate Office Bldg.
Washington, DC 20510-6200

RE: Comments on Opioids Misuse and Improved Pain Management

Dear Chairman Hatch, Ranking Member Wyden, and Honorable Members of the Committee:

On behalf of The North American Neuromodulation Society (NANS), thank you for soliciting comments on policy recommendations to address the root causes of the opioid abuse crisis and improve pain management for Medicare and Medicaid beneficiaries. NANS' interventional pain specialist members support multidisciplinary and multimodal approaches to pain management, including neuromodulation, which involves direct stimulation of the nervous system with electrical signals, and other evidence-based pain therapies. Combatting the opioid misuse crisis will take a multi-pronged approach and will not be successful without providing patients with better access to, and options for, the treatment of pain. Such policies should improve models of pain care, modify reimbursement strategies, and promote patient and provider awareness about evidence-based opioid treatment alternatives.

As practicing pain specialists on the front-line of this public health crisis, we applaud your focus on improving pain management options as an alternative to opioid management. Pain is a debilitating problem with enormous individual and societal costs. Unfortunately, pain is often misunderstood and/or undiagnosed despite being the most common reason Americans access the health care system; pain is the number one cause of disability in this country, and impacts tens of millions of people each day. Interventional pain specialists are highly specialized physicians who are dedicated to diagnosing and treating chronic pain using precise targeted therapies to treat and reduce pain in a safe, appropriate and clinically effective manner. Advances in medical technology allow for the treatment of painful conditions using advanced technologies such as fluoroscopically guided injections, spinal cord stimulation (SCS) and radiofrequency ablation (RFA) to name a few (there are multiple other non-pharmacological FDA approved treatments which are available for patients today). These interventional pain management (IPM) therapies reduce pain, improve function and have a significant opioid sparing potential.

To date, policy solutions have primarily focused on restricting prescription practices to reduce exposure to opioids, abuse and diversion, as well as treatments for people who have become addicted to opioids. As Congress begins another legislative push to craft policies to combat the crisis, the time is right to expand that focus to advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain while reducing opioid related harms. By promoting these non-pharmacological therapies, we can prevent millions of patients from having to rely on opioid type medications to relieve their systems; in our experience most patients just want relief by any means and would rather it not be with pills. The physician members of NANS stand ready to assist you with this worthy endeavor and encourage the Committee to hold a pain-specific hearing examining pain care best practices, breaking down barriers to non-opioid treatments and what the federal government is doing to advance pain management as part of their opioid alternative strategy. NANS further recommends that Congress include a section in any proposed opioid legislation which promotes the use of these high level pain management strategies.

Again, we thank you for addressing these issues and respectfully offer the following feedback to the questions proposed on ways that Congress could address opioid misuse and improve pain management strategies in a balanced and thoughtful approach that improves care and safety for all Americans.

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 OUDs or SUDSs?

- Describe and promote the multiple other non-pharmacological therapies available to treat chronic pain including physical therapy (and other manual therapies), psychological counselling, surgery, and interventional pain management (IPM) therapies.
- Effectively direct patients, through patient and physician education, to specialists that are appropriately trained in comprehensive, multimodal, pharmacologic and nonpharmacologic pain management strategies; chronic pain patients require care by individuals specializing in pain management
- Requiring mandatory physician training for **all providers** that will be prescribing opioid therapy. In individuals that are on chronic opioid therapy, CMS could require those patients on greater than 50 mg. MEQ to be managed by a board-certified pain physician or at a minimum require consultation with a physician that is adequately fellowship trained in pain medicine.
- Payment incentives can be created for proper opioid management in the care of chronic pain patients through the clinical practice improvement activities scoring section of Merit-Based Incentive Payment System (MIPS) in the MACRA legislation.

IPM has the distinct advantage of being able to provide both diagnosis of the specific cause of pain while also helping to reduce the level of pain and improve function, these therapies are truly opioid sparing (i.e.- reduce or eliminate the need for opioids). IPM therapies have grown in frequency in the past, and in retrospect, this may have been criticized inappropriately. In response, government. and private carriers launched extensive efforts, in the form of restrictive

coverage policies, to control usage. While some aspects of this were beneficial, some policies went too far and negatively impacted patient care. These now restricted interventional pain treatment options are oftentimes our best tools to limit the use of opioids in chronic pain patients. As a result restrictive coverage policies, the use of IPM therapies has leveled off while the incidence of substance abuse has increased exponentially.

The opioid epidemic has demonstrated to everyone that pain management is complex and the treatment strategies utilized require appropriate physician education, vigilance, and training. Currently in the United States, primary care physicians, internal medicine and family medicine physicians prescribe greater amounts of opioids than fellowship trained pain management physicians (1). While much has occurred in training physicians related to opioid prescribing, the most predominant change that will result in reducing the risk of developing OUDs and SUD's is requiring mandatory physician training for **all providers** that will be prescribing opioid therapy.

In addition, as cost data is incorporated into the MIPS, it needs to be recognized that individuals with chronic pain often require chronic treatment strategies and close follow-up care. Physicians should not be penalized for providing appropriate and vigilant follow-up care. Cost calculation data should take into account the fact that the patients may require multiple comprehensive visits. In addition, for patients that are on chronic opioid therapy, proper management requires an appropriate compliance program to ensure effectiveness and limit abuse, diversion and aberrant behaviors. This may require monthly visits that could lead to an elevation or poor performance in the cost calculation for healthcare providers providing appropriate care to these individuals. Strategies in the cost calculation need to ensure that when appropriate pain care is provided, these physicians are not penalized under the MIPS scoring system.

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

- Restrictive coverage policies which limit or prevent the use of certain IPM therapies (nonpharmaceutical management) for chronic pain management.
- For some therapies current reimbursement levels are below the cost of providing care leading physicians to not offer that therapy.
- Poor use of physician resources due to high administrative burdens

Often coverage policies are developed and enforced by insurance carriers, including Medicare and Medicaid, that are overly restrictive to nonpharmaceutical therapies for chronic pain management even though these treatments have been demonstrated to be effective in clinical trials. Although numerous therapies can be named, two such non-implantable therapies that have been shown to be clinically effective in both improving pain control and function include genicular nerve radiofrequency for knee pain originating from osteoarthritis and sacroiliac joint radiofrequency for pain originating from the sacroiliac joint. Both of these therapies have coverage and reimbursement challenges that often make it impossible to employ. Even when Medicare covers one of these treatments, often Medicare Advantage Plans and Medicaid will not.

Multiple nonpharmaceutical therapies have great promise in providing effective pain control, reducing and eliminating opioid use. For example, a recent study examining opioid usage

demonstrated that spinal cord stimulation, a treatment use to treat back and leg pain and neuropathic pain, has the ability to effectively reduce opioid use in specific patient populations. In addition, as nonpharmaceutical therapies are encouraged for chronic pain that have been demonstrated to be clinically effective, physicians should not be penalized via reduced reimbursement when growth occurs in these interventions when appropriately employed in a multimodal pain treatment plans. The cost of the drug epidemic is far greater than the cost of these effective and safe nonpharmacological therapies.

Another major concern for practicing physicians today is the significant amount of time and resources that is required for interactions with insurance plans for such daily practice tasks as authorizations, claim processing and billing (including with Medicare Advantage Plans). This is all time that is lost from actual patient care. Casalino et al.(3) estimated that when the time of interaction with insurance companies was converted into dollars that the national time cost estimate to practices of interactions with plans is at least $23 billion to $31 billion each year. It was also estimated that nursing staff spends on average 13.1 hours per week on authorizations when covering a single physician. The time spent on authorizations is time that is taken away from the most important aspect of healthcare, patient care. The administrative burdens placed on practices has also led to significant healthcare professional burnout which negatively affects patient care.

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

- Study requirements are often unrealistic and lead to high quality and effective treatments being underutilized.
- Misinterpretation of literature by biased panels intent on restricting care to save money. This is short sighted because the opioid abuse it has created is far more costly.
- Clinical trials are expensive and often require industry support, this research should not be automatically discarded as biased.
- Ensure continued coverage and reimbursement for urine drug screening which is paramount for providers to properly monitor their patients.

The most significant barrier that needs to be addressed is the study and research requirements for nonpharmaceutical therapies to be accepted as covered benefits. First, although randomized control trials (RCTs) can be helpful in proving efficacy of therapies, other study designs should be considered when determining safety and efficacy of therapies. The assumption held by the National Institutes of Health, the Food and Drug Administration and others insurance carriers that RCTs are the gold standard for determining efficacy is oftentimes restrictive, overly burdensome, and misguided. Randomized control trials have limitations that should be acknowledged, including applicability to real world patients. Evidence based medicine should rely on a diverse base of evidence that can originate from other data sources including prospective studies, qualitative data reports, comparative effectiveness studies, and epidemiological data.

All too frequently the literature is misinterpreted to deny coverage for specific treatments; beauty is in the eyes of the beholder. A properly done review by a group of non-biased medical experts

practicing within the field (i.e. – a medical society) can find merit with a particular therapy only to have a biased insurance carrier paid review committee deny coverage for the same treatment. Similar bias exists in numerous Medicare intermediary coverage policies where IPM treatments are overly restricted. This tactic has been used by many states including Washington, Oregon, and most recently California to deny very good opioid sparing interventional pain therapies such as spinal cord stimulation and spinal drug delivery systems (in WA and OR to all state employees, Medicaid recipients and workers compensation beneficiaries and in CA to all workers compensation patients). Many of the organizations promoting these negative coverage policies do so for a financial incentive at the expense of hard working Americans.

The government simply cannot afford to fund all the studies that are necessary. Both industry and non-industry research will be required to continue to examine alternatives to opioid therapy. While we agree that evidence is important, many of the therapies that we want to offer to our patients are available 3 or 4 years earlier in other parts of the world. In addition once these treatments receive FDA approval this still does not mean they will be covered by government or private payers. Frequently novel and excellent treatments are developed, receive FDA approval, only to disappear because of lack of coverage.

Medicare and Medicaid can ensure that payment structures remain viable for medical treatment strategies required to prevent, screen and assess for OUD and SUD. Proper opioid management requires patient monitoring in order to ensure safety and we must find ways to continue covering testing such as urine drug monitoring to ensure patient compliance. Recent proposed cuts would have a devastating effect on physician's ability to provide proper testing. While CMS reduced the cuts for next year it remains unclear what they will do with future proposed cuts.

4. **Are there changes to Medicare and Medicaid prescription drug program rules that can minimize the risk of developing OUD and SUDs while promoting efficient access to appropriate prescriptions?**

- Require mandatory opioid prescribing education for **any provider** prescribing to patients within the Medicare and Medicaid systems. When prescribed and managed properly, opioids can be used safely; it requires training of both the physician and the patient.
- Set a limit of 50 mg MEQ that can be prescribed chronically by a non-board-certified pain physician before consultation with a pain expert is required.

Many pain physicians are becoming increasingly concerned about the discriminatory insurance practices as it relates to opioid management and so we are glad that you asked this question as we are concerned for legitimate pain patients; the pendulum is beginning to swing too far the other direction and so we urge care in how you approach setting restrictive policies. In our opinion it is better to allow a properly trained physician to make these medical decisions. Our first recommendation is to require mandatory opioid prescribing education for **any provider** prescribing to patients within the Medicare and Medicaid systems, education will eliminate most of the problems as most physicians want to do the right thing. We must be careful not to punish and discriminate against those that may require controlled substances for their pain as we cannot cure all conditions with our treatments and for many patient's opioids may be there only viable option. When prescribed and managed properly, opioids can be used safely; it requires training of both the physician and the patient. As an example, limiting chronic pain pts to 7 days of

medications will require a patient to visit the pharmacy 52 times per year, we would never do that to someone getting medication for asthma, high blood pressure or diabetes and it is not fair to do that to patients suffering from chronic pain and whom have followed physician orders and have never abused or misused their medications. While we recognize this will be controversial and difficult to implement by setting a limit of 50 mg MEQ that can be prescribed chronically by a non-board-certified pain physician before consultation with a pain expert is required will help ensure that patients are receiving safe proper pain care. One of the biggest challenges faced by practicing interventional pain management physicians today are the patients that show up on our door already on ridiculously high dosages of medications (excessively exceeding 50 mg MEQ) that we then have to wean before we can even contemplate proceeding with more specific disease-oriented treatment. Often times, earlier treatments with appropriate nonopioid forms of pain control should have be implemented prior to considering these dosages of opioids.

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

- Mandatory provider education
- Require the use of the PDMP

As we have said repeatedly mandatory physician education to prescribe opioids should be tied to DEA licensure and that can only be done by congress (based on our conversations with DEA). The PDMP can be used by states to identify high volume prescribers, and for those who lack the proper training credentials (board certification in pain management), this should lead to investigation and when necessary, requirement for additional training and/or loss of licensure in egregious cases. The DEA should be allowed to prosecute distributers who fail to report obvious aberrations in dispensing patterns.

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

- Ensure that all 50 states have compatibility so that doctors can check PDMP's across state lines.
- Require all states develop interoperability by a specific date i.e. -1/1/19, through small grants, which would help speed this process.

When the initial legislation for NASPER was proposed it was for a federal program because of the importance of having this state interoperability in this highly mobile world of today, unfortunately we ended up with s state based program. While many states have coordinated their programs already, many still have not.

7. What best practices employed by states through innovative Medicaid policies or the private sector can be enhanced through federal efforts or incorporated into Medicare?

- Connecticut - A 7 day limit of medication **for acute pain**, a requirement that a provider must check the PDMP when writing a patients first prescription and every 3 months thereafter (Note; Chronic pain patients can receive a 30 day supply of medications with proper documentation in the chart as to why it is indicated).

- Florida -Mandatory physician training

8. What human services efforts (including specific programs or funding design models) appear to be effective in preventing or mitigating adverse impacts from OUD or SUD in children and families?

- Better education of our youth, they are smart and can understand when presented with the facts in a proper format.
- Look at alternative programs to *DARE*.

The most important things we can do as a society is educate our youth as to the perils of using controlled substances when not under a physician's direction. Current programs such as *DARE* have not worked and need to be replaced with a different and modern approach to educate our youth. We attached a link to a video of the *Wake-Up* program, an alternative program developed by a board-certified pain physician that relies on education of our youth rather than the use of scare tactics (*DARE* is taught typically by the police). This program could be offered in high schools, colleges and in many areas where substance abuse is now evident in the middle school, the program should be adopted to fit this group. The program is designed to be taught by local volunteer physicians in the community.

https://youtu.be/v-FwLkeEP_0

Sincerely,

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