March 2, 2015

Senate Committee on Finance
Attn. Editorial and Document Section
Rm. SD-219
Dirksen Senate Office Bldg.
Washington, DC 20510-6200

RE: Examining the Opioid Epidemic: Challenges and Opportunities**;** hearing held 2/23/2016

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

On behalf of the American Academy of Pain Management, and with the full support of the undersigned organizations, this letter is in response to the Committee's hearing held on February 23, 2016 entitled "Examining the Opioid Epidemic: Challenges and Opportunities." Collectively, we recognize the challenges involved in addressing two major public health crises, namely, inadequate treatment for pain, and prescription medication abuse, and to that end, have been heavily involved in both national and state-level efforts to address both health concerns. We thank you for addressing these issues, and respectfully offer the following list of possible ways that the Centers for Medicare & Medicaid Services (CMS) could address these dual issues in a balanced and thoughtful approach that aims to improve care for those with pain and other chronic conditions while improving safety for all Americans.

To date, policy solutions to address the opioid crisis have focused on opioid misuse, focusing on prescription practices and treatments for people *after* they have become addicted to opioids. These issues are important and deserve attention; however, a long-term solution to the opioid epidemic will fall short unless policies are broadened to address the underlying public health crisis of chronic pain. Policy solutions to reduce the supply of opioids, will not by themselves end this crisis – we must also address why there is a demand for the use of addictive medications in the treatment of chronic pain at all. This was highlighted in the last month by the President declining to endorse a sweeping proposal by our nation's governors to limit the amount of opioid medication that doctors can prescribe, saying such a policy would be unfair to rural Americans who don't have easy access to integrated pain care or addiction treatment programs.

The country's current state of pain care, research, education and prevention is woefully inadequate, as highlighted by the 2011 Institute of Medicine study, *Relieving Pain in America*. The study found that more than 100 million American adults suffer from chronic pain, at a cost of approximately $600 billion annually in direct medical expenses and lost productivity. Yet, our federal agencies continue to invest poorly in chronic pain research, which averaged just 4 cents per patient in 2015. The result is that the field of chronic pain treatment is 'strikingly deficient' of high-quality evidence to assess benefits and risks, according to the Food and Drug Administration, leaving clinicians with little evidence for making informed decisions for effective treatment for patients' chronic pain. It is extremely common for patients to spend months to years consulting multiple clinicians and experimenting with a host of treatments to find solutions that will help to reduce painful symptoms without intolerable side effects.

Prescription medications play a crucial role in treating and curing illness, alleviating pain, and improving quality of life for millions of Americans. Unfortunately, these medications can also be abused—and policies to address this abuse often adversely impact those who truly require these medications in order to live full, healthy, and productive lives. A balance is necessary to ensure that individuals who legitimately need prescription medications for pain and other conditions receive them, but that such medications are not diverted for improper purposes. The following suggestions provide a balanced response to both epidemics: chronic pain and prescription medication abuse.

<u>Opportunities to Reduce Prescription Medication Misuse, Abuse, and Diversion while Improving Care: Eleven Recommendations</u>

1. **In order to provide methods and measures to guide progress towards achieving improved prevention and management of pain in the United States, CMS should fund research that evaluates longitudinal pain outcomes among Medicare, Medicaid, and other beneficiaries.** A core responsibility of public health agencies is assessing the significance of health problems in the population. At present, data are needed on the prevalence, onset, course, impact, and outcomes for most common chronic pain conditions in order to guide policies and initiatives of federal and state governments, and of health care organizations and insurers. Improvement in data methods and measures will 1) guide efforts to reduce the burden of chronic pain through more accurate estimates of the prevalence and impact, 2) provide standard methods for analysis of electronic health care data related to pain treatment, and 3) develop a system of metrics for tracking changes in pain prevalence, impact, treatment, and costs over time that will enable assessment of progress, evaluation of the effectiveness of interventions at the population health level. This is one of the key long-term recommendations of the National Pain Strategy, which was developed by six federal agencies and more than 80 well-respected experts from the medical-scientific, public, private, federal, patient, and advocacy communities, under the direction of the Department of Health and Human Services. If we are to adequately address prescription overdose deaths and substance use disorder in America, we <u>must not</u> ignore the millions of people who need better pain care. We <u>must</u> develop safer and more effective ways to treat pain. Given the availability of de-identified medical data through electronic medical records, CMS has the opportunity to further this goal by funding longitudinal studies that examine the use of non-pharmacological treatments by Medicare receipts, and the impact of those treatments on subsequent care.

2. **The Center for Medicare & Medicaid Innovation (CMMI) should be required to set aside certain funds to establish demonstration projects related to interdisciplinary and integrated pain care**. An example of a demonstration project highlighting the benefits of integrative care can be found in Colorado. Since 2009, the Colorado Department of Health Care Policy and Financing has been tasked with creating and evaluating a Home and Community Based Services Waiver for the Persons with Spinal Cord Injury (SCI Waiver) Pilot Program. According to the department, there are initial signs of positive trends regarding cost-saving, but without additional research, larger sample sizes, and changes to the evaluation methodology, the evidence remains anecdotal. Personal stories from participants include describing minimal use or complete abstinence from previously used medications for pain, due to the addition of massage, acupuncture, and chiropractic care. The department is in support of the renewal of the SCI Waiver and believes that additional time combined with waiver modifications will significantly improve the data available; further, with additional program experience and some modifications to the evaluation methodology, future reports will provide more insight and actionable recommendations regarding the SCI Waiver program and its benefits.[1] Colorado's legislature agreed to continue support of this promising pilot program with the passage of CO SB 11 (2015), extending the repeal date of the pilot program to 2020. CMMI could greatly improve the outcomes of this study and many more like it, and thus improve health care and cost-savings, by funding additional, and larger, demonstration projects measuring the impact of the type of integrated pain care called for by the 2011 IOM report and the draft National Pain Strategy.

3. **CMS should allow a greater number of physical and occupational therapy sessions annually, and should allow patients to access physical and occupational therapy without first acquiring a referral or prior authorization.** Physical and occupational therapies are extraordinarily effective at preventing and treating musculoskeletal pain syndromes, in particular, and chronic pain conditions in general. Medicare's coverage for these therapies is inadequate in terms of the number of sessions covered, and requires that a physician serve as a gatekeeper. Physical and occupational therapists are highly-trained professionals who are capable of evaluating a patient's likelihood of benefitting from the treatments they offer. Requiring a gatekeeping appointment with a physician or a prior authorization process only delays a patient's access to treatment and, in some cases, may deny that patient access to an effective and cost-effective treatment that minimizes the need for opioid analgesics. Removing those barriers seems to us to be a logical step.

4. **CMS should provide total reimbursement—and collect long-term efficacy and cost data—for at least the following five non-pharmacologic treatments: chiropractic and osteopathic manipulation, acupuncture, massage therapy, biofeedback, and yoga.** Nearly every recent effort to reduce prescriptions of opioid analgesic medications has been accompanied by a provision which urges the use of alternative treatments to treat pain. However, many people cannot access these treatments due to lack of insurance coverage. This is true for Medicare, which provides only limited coverage for chiropractic and osteopathic manipulations from the list above. These five key treatments are recognized by the Department of Defense and the Veterans Health Administration as effective treatments for chronic pain, are included in the DoD/VHA pain management guidelines, and are covered services in DoD/VHA facilities.

5. **CMS should provide reimbursement to providers of behavioral health services for the prevention, treatment, or management of physical health problems.** As noted above, many efforts to reduce prescriptions of opioid analgesic medications have been accompanied by language that urges the use of alternative treatments to treat pain. Behavioral health care providers are well-equipped to teach patients skills and techniques in how to better manage and cope with pain; however, these practitioners are often not reimbursed for their services when they use proper diagnoses and Current Procedural Terminology (CPT) codes. We urge that CMS be required to reimburse these practitioners for these services utilizing the behavior assessment and intervention reimbursements codes 96150 to 96154, or their successor codes, under the CPT coding system.

6. **Medical residencies funded by Medicare and Medicaid should include adequate content on pain and substance abuse.** Pain consistently ranks as the top reason that people visit a health care provider, and undertreated and mistreated acute pain often causes patients to develop chronic pain. Yet, most health care providers have received little to no formal education in pain management. Substance use disorders also are relatively common, and coverage of that topic in medical training is likewise lacking. The 2011 Institute of Medicine (IOM) report, *Relieving Pain in America*, documented that the median medical school content on pain management is only nine hours, while a recent survey of medical schools by the Association of American Medical Colleges found a median of only five hours dedicated to substance use disorders. Through its support of medical residencies, CMS has the unique opportunity to provide the health care providers of tomorrow with tools that will help them to properly and effectively treat pain *and* reduce substance abuse and overdose deaths as they treat patients over the course of their careers, producing hugely positive effects on the public welfare.

7. **To improve education for providers already in practice, CMS should require completion of the three hour Risk Evaluation and Mitigation Strategy (REMS) program related to extended release and long-acting opioid analgesic medications as a condition of participation in Medicare.** While the Food and Drug Administration (FDA) mandated that 3 hour REMS courses be offered to prescribers a number of years ago, there was no corresponding mandate for prescribers to take the REMS course. Consequently, completion rates have been low. These REMS courses have the potential to arm health care providers with much needed strategies for preventing and addressing substance abuse, but they cannot do so if no one is taking them. This effort to educate prescribers would be simple to implement for three reasons: (1) the REMS programs have already been developed and implemented; (2) CMS is in the same department as FDA, which oversees REMS programs; and (3) this requirement could be implemented by a change in rules and regulations, and would not require legislation. The other mechanism that has been discussed as a means of mandating REMS education is linking REMS completion to Drug Enforcement Administration (DEA) registration renewal, but doing that would require legislation and would involve a law enforcement agency in the regulation of medical education, a change that would be unprecedented and, we believe, inappropriate.

8. **Medicare should contact known prescribers and dispensers in the event that a patient overdoses on *any* controlled substance.** It recently came to light that in nearly all cases in which a patient has experienced an opioid-related overdose, patients were, shortly thereafter,

given additional prescriptions for opioid analgesic medications. This is due, in large part, to the fact that prescribers were completely unaware that the overdose event had occurred. While overdoses can occur for numerous reasons, some having nothing to do with substance abuse, it is vital that the overdose victim's health care provider is made aware of an overdose to enable completion of a thorough evaluation of the patient and any necessary adjustments to the patient's treatment plan to address the underlying reasons for the overdose event. It would also be important to ascertain the substance(s) that led to the overdose to determine if these were licit or illicit so proper treatment could be determined and initiated. Medicare, by virtue of its coverage of medical services, should be able to identify these events and alert healthcare professionals who are providing care for these patients.

9. **When a prescriber writes a prescription for a controlled substance for a Medicare or Medicaid patient, they should be required to check the prescription monitoring program (PMP) prior to writing the initial prescription and regularly thereafter, at least annually.** We routinely advocate for the regular use of PMPs by prescribers and dispensers, as they have the ability to be extremely valuable healthcare delivery tools. As healthcare delivery tools, PMPs can provide three benefits: (1) Reassurance that patients are using controlled substances as prescribed, allowing providers to prescribe and dispense as needed with less anxiety; (2) Identification of behaviors suggestive of a substance abuse problem, leading providers to more thoroughly assess patients and obtain appropriate treatment where indicated; and (3) Provision of a complete record of a patient's controlled substance prescribing history, enhancing patient safety by enabling a provider to avoid potentially deadly combinations of medications.[2] To best achieve all of these objectives, heath care providers must be provided with an understanding of the full spectrum of controlled substances a patient is taking, as far more medications than just opioid analgesics and benzodiazepines can have serious side effects, potential for abuse, and interactions with one another. If PMPs provide prescribers and dispensers with comprehensive information, and if providers check the PMP upon each initial visit from a patient, they should essentially be able to put a stop to simultaneous prescribing by multiple providers. The periodic checks that we suggest for ongoing patients will help to ensure that patients with legitimate medical needs for controlled substances continue to use their medication safely and effectively and that no medications, potentially prescribed by multiple providers, will negatively interact with one another.

10. **Medicare Part D should consider implementing a policy similar to that proposed in New York Assembly Bill 8601 (2016), which provides that the initial prescription or dispensing of a controlled substance for acute pain shall be limited to a small supply (7 days, for example), but then goes on to prohibit the imposition of an additional health insurance copayment if a subsequent prescription is issued for an aggregate of not more than a 30 day supply of such controlled substance.** Anecdotally, we hear stories about people who only use a few, if any, of their prescribed opioids during an acute pain episode. We believe that in acute pain scenarios, dispensing fewer pills initially, with an option to fill the rest if needed, would allow people with pain to have access to needed medications, while also addressing the problems associated with an abundance of unneeded medications that can be potentially diverted. What's more, in theory, this would save insurers a great deal of money by only providing the number of pills needed to address serious acute pain. However, we admit that this proposal is a bit of a work

around, as 21 C.F.R. §1306.13 does not allow for any partial fills of controlled substance prescriptions, which is why this proposal contemplates *two* prescriptions. Ideally, we would urge the DEA to change this regulation so as to allow for partial fills of controlled substance prescriptions.

11. **CMS should research post-operative pain and opioid use in order to identify how many pills are actually being used and are needed by this population.** This could be done (1) through direct grants to researchers; or (2) as a part of the scope of work for Medicare Quality Improvement Organizations. As with acute traumatic pain, we often hear of post-operative patients being prescribed large amounts of opioid analgesic medications that they do not, ultimately, end up needing. Unfortunately, we currently have no way of knowing how much medication these patients are taking, and for how long they are needed, after the patients are released from the hospital. Studies would help to determine if post-operative patients, or more specifically, *which* post-operative patients, may be good candidates for smaller initial prescriptions of pain relieving medications.

The undersigned stakeholders view these suggestions as vital components of a comprehensive approach to addressing the intertwined public health crises of undertreated pain and prescription medication abuse.

Sincerely yours,

American Academy of Pain Management
Chronic Pain Research Alliance
Foundation for Peripheral Neuropathy
Global Healthy Living Foundation
International Pain Foundation
Interstitial Cystitis Association
PAINS Project
Reflex Sympathetic Dystrophy Syndrome Association
The Pain Connection
TMJ Association
US Pain Foundation

[1] Department of Health Care Policy & Financing. *Summary of the Second Annual Evaluation Report for HCBS-SCI Waiver*. 2014. Print.
[2] Twillman, R., PAINS Project. 2013. *Prescription Monitoring Programs*. (Policy brief 2). Retrieved from http://www.painsproject.org/wp/wp-content/uploads/2014/04/pains_policy_brief_2.pdf