February 16, 2018

United States Senate
Committee on Finance
Washington, D.C. 20510
opioids@finance.senate.gov.

Re: Committee's Request for Feedback on the Opioid Crisis

The Senate Finance Committee has sought comment, specifically asking how Medicare and Medicaid program incentives can be used for beneficiaries with chronic pain in ways that minimize the risk of becoming addicted to opioids. This comment discusses (1) why barriers to access for pain control for chronic intractable pain patients are misguided, and (2) how targeted regulations and physicians education is key to controlling the the risk of OUD and other SUDs.

The problem with overarching pain control guidelines, including the 2016 opioid guidelines by the CDC, is that the true intractable pain patients are swept up in the aftermath. Non-cancer chronic intractable pain patients' dosages get reduced or removed, along with everyone else's, no matter the individual patient's situation. After the CDC Guidelines were revealed, many physicians stopped prescribing opioids altogether, and even more refused to prescribe above the suggested 90 MME, no matter the previous dosage of the patient. A lot of physicians stated that they feared retribution by governmental agencies if they continued to prescribe to chronic intractable pain patients as they had before the guidelines.

A major problem with this situation is that the logic behind removing or quickly reducing opioid for stable chronic intractable pain patients is untested and unproven. There have been no prospective clinical studies to show that discontinuing opioids for currently stable pain patients helps those patients or anyone else. While slowly weaning from some of their medications under a physician's supervision could theoretically be helpful to a minority of chronic pain patients, it seriously destabilizes the vast majority, and will likely promote the use of heroin or other illegal substances. Thus, the discontinuation of pain control medication for these patients, who rely on them in order to work, and be otherwise productive, contributes directly to the decompensation of the patient. A very ill chronic pain patient will no longer be able to work, or otherwise be productive, which will lead to more individuals on disability, Medicare, and Medicaid. Thus, an expensive, vicious downward cycle develops, as more formally stable patients have their pain control medications taken away, and they join the ranks of the disabled. Meanwhile, those on disability become sicker, and rely on the governmental safety nets more and more.

To significantly lessen the risk of OUD and SUDs within the greater Medicare and Medicaid populations, without harming those patients who rely on opioids to function in their daily lives, any and all regulation must be targeted. Specifically, instead of the broad regulations and guidelines of the past few years that paint every person with an opioid prescription with one broad stroke, we suggest targeting certain aspects, such as:

- establishing a uniform physician education program,
- updating the ICD-10 codes for chronic intractable pain

- establishing a national Prescription Monitoring Program (PMP),
- requiring all prescription opiates are tagged with a unique identification number, and
- requiring and covering genetic testing for medication metabolism markers.

Taken together, these suggestions will give physicians the tools they need in order to diagnose true chronic intractable pain patients, and monitor those patients who are already receiving opioids.

We envision a uniform physician education program in the form of mandatory CME classes that would inform physicians of the steps needed to diagnose and treat intractable pain patients. Physicians could learn a guidelines for approaching newly diagnosed intractable pain patients, such as prescribing neuropathic agents and anti-inflammatories before trying opioids, running genetic testing to see how each patient metabolizes medications, and ordering targeting physical therapy for musculoskeletal pain and dysfunction. These classes could also discuss the benefits and drawbacks of alternative therapies, including acupuncture, massage, aqua therapy, etc. Physicians would also be instructed on guidelines for diagnosing chronic intractable pain.

Hand-in-hand with physician education, the suggestion to update the ICD-10 codes would eliminate uncertainty about the diagnostic criteria for chronic, intractable pain patients. Currently, the ICD-10 has approximately 100 different codes for pain. Code R52.1 purports to address chronic intractable pain; however, it is included under the heading of “Pain, unspecified,” and is the description is intermixed with that of acute pain. Also, none of these codes properly addresses the biopsychosocial aspects of chronic intractable pain. A new code or updated code for chronic intractable pain would limit any confusion between chronic and acute pain for diagnostic purposes.

A federally-mandated national PMP for would help to eliminate any abuses of the system. Currently, most states have PMPs, while the rest have enacted legislation in order to establish them. However, a system to monitor patients nationally does not yet exist, although about 40 states are voluntarily participating in PMP Interconnect, a secure communications exchange platform that facilitates the transmission of PMP data across state lines to authorized requestors. A federally-mandated system national system would combat prescription medication abuse and diversion with neighboring states, and allow CMS to monitor Medicare and Medicaid beneficiaries.

We also suggest that CMS work with the FDA to require that all prescription opioids be tagged with a unique identifier. This unique identifier would be akin to a car’s VIN number and would allow the tracing of all opioid-based prescription medications. The major cause of the influx of prescription medications to the street is diversion, most of it out the back doors of pharmacies and distributors. If every type of opioid medication had a unique identifier, governmental agencies would be able to track the patterns of diversion and shut them down. This suggestion would assist the federal government is stopping the diversion of prescription medications, which is a significant problem in the opioid crisis.

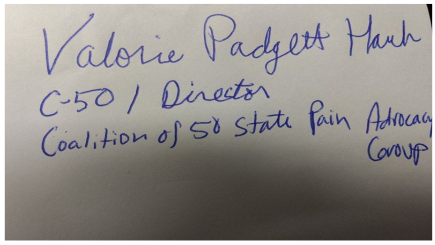
Finally, CMS should both require and cover genetic testing for medication metabolism marker. More than 75% of people have genetic variations that determine how their bodies process and use medications. Because of these genetic differences, two people can take the same dose of the same medication, but respond in very different ways. For example, a

medication might work very well for one patient, not at all for another, and causes serious side effects for a third. Especially when dealing with opioids, genetic testing is helpful to discover how quickly a patient will metabolize the medication without trial-and-error. This type of genetic testing, therefore, could assist physicians in determining the correct course of action for chronic intractable pain patients. Additionally, when a physician decides that opioids are necessary, this genetic testing will help physicians in determining what dosages are appropriate.

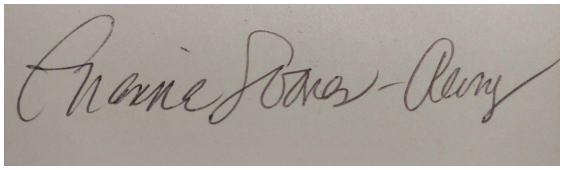
We hope that the above-referenced explanation of why overbroad legislation and regulations harms chronic intractable pain patients, and our suggestions on how to target specific legislation and regulations will assist you in your decision-making process. Thank you for your time and consideration.

Sincerely,

Amie Schaadt Knauer
Committee Member
Don't Punish Pain Nationwide Organization



Valorie Padgett Hawk
Coalition of 50 State Pain Advocacy Group



Gianna Soares
Committee Members
Don't Punish Pain Nationwide Organization

Patient Supporters:
Jan L. Shoop..Tacoma, Washington, janjonesshoop@gmail.com
Rebecca Roberts, Columbus, Indiana, mccandless.becky@yahoo.com
Inga Dawson, Hagerstown, Maryland, dld2imdrn@gmail.com
Kari Kruska- Oklahoma City, OK , kkruska@cox.net
Mary Donna Rogers-Oklahoma City, OK, bdrogers1@cox.net
Pamela Aylor, Sun City Center, Fl 33573, aylo8292@bellsouth.net
Mary Bridget Gentleman , Silver Spring, MD, Elefink2@yahoo.com
Kara Davidson, Stevensville, MD, karadavidson@live.com
Holly Davidson , Stevensville Md 21666, Hollyjack@verizon.net
Erica Moote, Marquette, MI 49855, MissEricaR@aim.com
Jenifer Markoe Eagan, MN, JMARKOE661@aol.com
Audrey Liebl, 418 Meadow Street Unit B7, Agawam, MA 01001, ethantus@gmail.com