Wright, Kevin (Finance)

From: Kelly Merrill <painalliances@gmail.com>
Sent: Friday, February 16, 2018 6:41 PM
To: opioids,

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United States Senate
Committee on Finance
Washington, D.C. 20510

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, whether for stubborn lower back pain or a rare, degenerative, incurable, pain-generating disease.

When the 2016 "voluntary" CDC Guidelines (the "Guidelines") were revealed, they were intended as a guide for primary care physicians. However, the Guidelines caused great upheaval and massive suffering as doctors, including pain management physicians, either stopped prescribing whatsoever, refused to prescribe above the suggested 90 MME or abandoned patients altogether; regardless of their previous, least effective dosages for treating chronic, intractable pain. There is a great deal of fear in the community on the part of both physicians and patients. Many physicians fear government retribution for any prescribing of opioids, regardless of medical necessity.

Quickly reducing or stopping previously effective opioids therapies to treat chronic, severe and persistent pain is unproven and dangerous. In practice, doing so has caused untold harm to the pain community. In fact, the Veteran's Administration revealed something the pain community has been talking about for years; that a reduction opioid pain-relieving therapies has not resulted in a decrease in mortality rates, but instead an increase in suicide mortality.

There have been no prospective clinical studies to show that discontinuing opioids for currently stable pain patients helps those patients or anyone else. While physician-monitored downward titrations on opioids may be helpful to small percentage of chronic pain patients for the sake of downward titration itself, this practice seriously destabilizes the vast majority.

Pain is not an inconvenience or the result of a weak-willed person. Unmitigated, pathological, severe, intractable pain is dangerous. It is physiologically damaging to every system of the body. Opioid pain-relievers are, at the present time, the best offense we have to retain functionality and prevent further damage.

Discontinuing those medications means patients will be pushed to the brink; suicide, pain-induced dementia or dangerous street drugs and an early grave their only options.

Further, these measures are economically nonsensical and contribute directly to the decompensation of the patient and lead to more individuals on disability, Medicare, and Medicaid. Thus, an expensive, vicious downward cycle develops, as 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 governmental safety nets more and more.

Specifically, instead of the broad regulations, we suggest the following specific measures:

- 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 intractable pain patients, and monitor those patients who are already receiving opioids.

We support the establishment of 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. Such education should include medication management, including 1st-, 2nd- and 3rd-tier therapies, beginning with non steroidal anti-inflammatory and neuropathic drugs, progressing to weak opiates and then utilizing synthetic opioids for severe, persistent pain.

Education should cover genetic testing to determine how patients metabolize opioids. There are 15-fold variations in the way patients metabolize opioids. In addition, such education should include scientifically-backed information regarding the pro's and con's of interventional and alternative therapies. .

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 tracking of all opioid-based prescription medications. and allow DEA to detect patterns of diversion and shut them down.

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 variables, there is a 15-fold variation in the way people metabolize opioids. Genetic testing will help physicians determine what dosages are appropriate.

Broad-sweeping legislation and regulations harm chronic intractable pain patients. Please use our suggestions to assist you in your decision-making process. And contact me at 207-650-8863 if you have any questions.

Thank you for your time and consideration.

Sincerely,

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-Kelly F. Merrill
Executive Director
Chronic Pain Advocacy Alliance