

My comment is related to Part D Opioid Overutilization Policy, which begins on page 203.

I'm a 61 year old female on SSDI from multiple back surgeries and chronic pain. I have severe DDD, Ehlers Danlos (EDS) hyper mobility, pseudoclaudication, stenosis, and osteoarthritis in most of my joints due to the EDS. I also suffer from adjacent segment disease as a direct result of all of my previous back fusions. My lower spine is fused from L2 to S1 and both of my SI joints. My neurosurgeon says he has no doubt my L1 will also eventually fail and at that point he will most likely have to fuse me from T10 down. Currently, access to pain medications (albeit a limited amount due to the current opioid hysteria), is the only thing that allows me to have any quality of life.

Prior to my first double fusion in 2008, when my intermittent back pain became chronic in 2003, I tried every available procedure to address my pain. I had already been using chiropractic care since my early 20's but I also tried prolotherapy, acupuncture, massage, injections, radio frequency ablation - almost anything but voodoo - to address my pain. Opioids were the only thing that helped. Prior to my first double fusion I was on about 200MME's a day. A year after the surgery when I felt I no longer needed them, I requested I be weaned off, a process that took 7 months. But as typical with fusions, my L3 began to fail barely 3 years later and it was added to my fusion in 2012. My SI joint was also fused in 2012 (a decision I greatly regret). Barely 2 1/2 years later my L2 started to fail but I had it fused before it was entirely medically necessary because I was having a difficult time having my pain adequately addressed with pain medications as the war against opiates was full on. I had hoped that fusing L2 would provide me some relief. It did but it was short lived. Now my L1 is failing but I am unable to receive adequate doses of pain medication due to the opioid hysteria that is currently occurring in this country.

My first issue with this proposed regulation change is allowing insurance companies to be the final determiner in allowing doses of opioids above 90MME rather than the patient's doctor! It should NOT be the insurance companies decision on what dose is adequate and correct for individual patients, that should be a decision only the physician, who knows the patient, should be making. How dare you give insurance companies a greater say over our health than our own private physicians. I've had my DNA tested and I have anomalies on my CYP450 enzyme, which is consistent with those of us who also have EDS. I am an intermediate metabolizer which means for some classes of drugs I actually need more than the average dose to gain the same benefit, although this science is not known by all doctors. Which leads to my 2nd concern.

Limiting the dose of opioids to below 90 MME is irresponsible and down right cruel to those of us living with chronic painful conditions. Just like we would never set caps on the dose of insulin, heart medication or any other medication, setting a top limit on opioids does not address the differences in metabolism, length of time on opioids so the need to increase dose to maintain benefit, and to provide a decent quality of life.

People with chronic, intractable pain have become the target in the opioid war even though we are NOT the problem. The only increased deaths among chronic pain patients are those who've chosen to commit suicide rather than continue experiencing the torture of losing the one medication that provides relief.

There is now more than enough documentation showing that scripts for opioids have been dramatically decreasing over the past several years and yet the deaths due to OD's continue to increase. And that is because they are not due to prescription opioids but to illegal heroin laced with fentanyl. There are 5 times as many deaths due to preventable medical error (which the

CDC lists as the 3rd cause of death) than there are from opioids yet no one talks about that. Where is the outrage to over 250,000 Americans dying each year from preventable medical error? Or deaths cause by alcohol and/or tobacco use and yet we are not targeting those products.

And while CMS is going to try to reduce the risk of unintended consequences and allow a 7-day supply, do you realize the harm that would cause to those of us who live in rural communities? I live in rural western Montana, in a town of 550 people that doesn't even have a pharmacy. My doctor is over 70 miles away, one way. And for those living in eastern Montana the miles are far greater. If someone is suffering from chronic back pain, driving is one of the hardest tasks. These rules would cause a unfair burden on those of us who live in rural communities. The same would be true for the proposed limit of a 7-day supply for acute, short term pain or pain from surgery.

While I feel for the families of those who've lost someone due to OD'ing on opioids, punishing those of us with chronic, intractable pain is not the right solution. Nor is giving insurance companies the right to make final decisions and not our doctors! Of course the insurance companies will say no.

And if there is such concern then why is Medicare/Medicaid not covering the costs of other treatments to help with chronic pain?

And while the big push is to have everyone just practice mindfulness and breathe their pain away, as a long term practitioner, I can speak to that.

I started meditating in 1976! I started practicing Theravadan Buddhism (Vipassana), which is often also called mindfulness in 1987. I've been on several 10 day silent retreats where we are in sitting or walking meditation from 6am until about 10pm, except for a dharma talk after dinner. I was also dealing with chronic pain prior to my first double fusion when I was attending these silent retreats and guess what? I still needed to take my pain medication! While it did remove my awareness away from my pain some while meditating, it's pretty impractical to think people can spend every waking hour meditating. The important point to note is that while there was some relief during meditation practice, it did not carry over during non meditation. And as a long term meditator, if I wasn't receiving the benefits that the folks from PROP like Andrew Kolodny, Gary Franklin, Jane Ballantyne, etal promote, do you really believe someone who's never practiced before is really going to receive great enough benefits to allow for them to reduce their reliance on pain medications?

We need to leave the decision between doctor and patient what works best for them for their particular condition. We are not going to solve the current overdose deaths due to heroin and/or fentanyl by limiting access to pain medications to those suffering from a painful, intractable condition. All these rules do is torture pain patients even more. The use of prescription monitoring programs have all but eliminated doctor shopping and the majority of so called "pill mills" have been shut down. Making chronic, intractable pain patients the target will do nothing to solve the OD's but will continue to increase the number of suicides by chronic pain patients who've been forced tapered off the one medication that provides relief.