

1 March 2018

Demetrios Kouzoukas
Principal Deputy Administrator and
Director Center for Medicare

Submitted electronically

RE: Centers for Medicare Medicaid Services (CMS) Other: [Advance Notice of Methodological Changes for Calendar Year \(CY\) 2019 for Medicare Advantage \(MA\) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter](#) Docket ID: CMS-2017-0163

Dear Mr. Kouzoukas:

I am writing from the viewpoint, of what is becoming the quickly neglected group, of the intractable pain patient. I suffer from the incurable disease Lumbo-sacral adhesive arachnoiditis (AA).

I am disappointed in the question being posed by Medicare. No where do you ask, "How do we continue to help people suffering from intractable pain, who have taken the appropriate steps up the ladder to opioid use?" "What and how do we help physicians to understand that there is no known opioid ceiling; that weight, height, metabolic issues and pain tolerance in general differs among each individual causing people to need very small amounts of opioids to ultra-high opioids for management of intractable pain?"¹ "Is there enough palliative care

available for those patients that suffer from serious diseases such as adhesive arachnoiditis? Most importantly, “Are the deaths from opioids being reported in such a way to intentionally tell the story that the CDC wants told or the TRUTH?” Statistics have changed due to definitions. In some states, such as Illinois, no matter the true cause, “the state’s death certificate data categorize any death in which even an iota of a prescription opioid (or a nonpharmaceutical fentanyl product) is found as a “prescription opioid death”. ”²

<https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/why-some-patients-require-high-dose-opioid-therapy>

2

<https://www.dovepress.com/pain-management-prescription-opioid-mortality-and-the-cdc-is-the-devil-peer-reviewed-article-JPR>

I know that the Opioid Policy Steering Committee (OPSC) is also working on some of these same questions and the results of the final CARA law will dictate even what Medicare (CMS) will be able to do about illicit abusers and the many people who are truly suffering from intractable pain whether from adhesive arachnoiditis to cancer, to the “treatment for any serious illness that requires excellent management of pain or other distressing symptoms.”

From *Lumbo-Sacral Adhesive Arachnoiditis: A Review*,

*“Treatment of arachnoiditis There is no cure for arachnoiditis, and no hope of remissions due to natural healing of the diseased subarachnoid tissues and cauda equina. Palliation is achieved to some degree by the use of pain-relieving drugs, by decreasing mobility, and by increasingly long periods of sitting or lying flat.” “Conclusion The relentless and progressive pain syndrome of arachnoiditis is taxing to the patient's morale. In many instances doctors, relatives, and friends fail to realize that the pain can be as bad as terminal cancer, without the prospect of death to end the suffering. Well-meaning enquiries as to whether there is any improvement with the implication that there must inevitably be improvement, 'since it is not cancer', are distressing to the patient. There are sympathetic doctors, relatives, and friends who expect the patient to be brave, stoical, and cheerful. In the end the patient yearns for less exhortation and more compassion. Compassion is an important consequence of comprehension of the existence and nature of arachnoiditis.”*³

Suggestion 1: The CDC Opioid Guidelines have the exception for palliative care.” For this guideline, palliative care is defined in a manner consistent with that of the Institute of Medicine as care that provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness. Palliative care can begin early in the course of treatment for any serious illness that requires excellent management of pain or other distressing symptoms”.⁴ I feel strongly that the FDA should make sure that every medical provider from general medicine to pain medicine (PM) providers, insurers, pharmacists, etc. ***all understand what exactly palliative care is and when it is time to admit that palliative care is the answer.*** Why are PM doctors trying to force epidural steroid injections onto patients inflicted with AA? When if educated on AA, doctors would know this will make the

3

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1292616/pdf/jrsocmed00137-0076.pdf>

4

<https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

condition worse. With the exception of very gentle stretching, and as much motion as possible for as long as the patient can still walk, is all that is appropriate for AA patients. Everything else severely irritates this horrific disease. ***Palliative care doctors have to be allowed to treat each individual patient as needed, without fear of prosecution, or the palliative care and hospice care exceptions in the CDC recommendations mean nothing. I was counting on this to help me but the palliative care organizations around Daytona Beach, Florida do not have enough staff and are unable to take on anyone but cancer patients. So, the exceptions, for which my disease clearly qualifies, will leave me in a position to suffer until I die or to commit suicide to stop the suffering. Doctors are now afraid of going to jail and therefore will not provide the needed treatment and if your rules go into effect, the doctor's hands will be bound even if they had been willing to treat the patient as they deemed appropriately knowing their patient.***⁵

Back in 1980, I was rushed to emergency surgery after a myelogram when the dye could not exit the body. I had many more back surgeries as I had premature degenerative disc disease, my internal organs did not keep up with the growth of my body, resulting in a very taut spinal cord. I managed my pain very well on Darvocet N-100. I took 1-6 daily for 25 years except the year I tried to go to college. Sitting and walking proved too much and I was talking upwards of 12-15 Darvocet N-100, resulting in a gastric ulcer.

I had been in the military system and my doctor all through high school retired. When I returned to clinic, a new doctor told me that I needed to learn to live in pain and that there was no way I could become a doctor, my dream from age 8. I left his clinic appointment with my father, knowing that I could never live in the pain I was in daily. I had saved a bottle of 10/325 Percocet for just such a situation. I returned to college and very shortly after returning decided it was time to end the pain once and for all. I took 72 Percocet in the quad at school. I made sure I had no identification on myself. I went to the student union to call the suicide prevention number from a payphone to tell them that when my body is found, to tell my parents that I loved them and that I could not live in the pain I was in. Unfortunately, a friend ran into me before the phone call and talked for more than 10 minutes. So, my plan to call suicide prevention and then get out into a field, where I could not be found, failed. I got too tired shortly after exiting the student union and tried to hide behind some bushes. I woke up for many people, then I guess I didn't as a rescue squad was transporting me to the local hospital. At the hospital they wanted to know what

I took. I refused to tell them until 4 hours had passed, as I had read that was the point of no return.

Once I told the ER doctor, *he immediately called me a liar stating I would be dead had I consumed what I said I had*. He did not start any treatment for all the time awaiting the toxicology reports. When they finally came through, about another hour later, he felt badly for not believing me and tried to make the reversal as painless as possible by placing in a nasal-gastric tube. This way I was not forced to drink charcoal nor the rotten egg smelling stuff for the Tylenol. **I tell you this story for two reasons.** One, I was such a rapid metabolizer that I only slept very briefly the whole time, I remained conscious upon any questioning, so the doctors did not treat as an opioid overdose until the proof came to them. Two, afterwards I was told by every doctor I saw, that I need never attempt suicide again as there will always be people willing to give the opioids needed to manage my pain. My dad found the only doctor in Washington, DC area claiming to be a Pain Specialist in the early 1990's, he was a psychiatrist. He put me on anti-depressants, which at the time, no one realized, I was experiencing the "Black Box Warning" reactions of each and every antidepressant on which he put me. I ended up very suicidal for mental reasons caused by the antidepressants instead of the pain. The mental pain created by these antidepressants was unbearable and almost destroyed my family. But, one day I realized that I was so much worse off and I quit the antidepressants cold turkey. Within 10 days, I was back to just pain control with 1-6 Darvocet N-100. I ended up metabolizing Percocet (oxycodone) very rapidly and it appears that the antidepressants did not process quickly and essentially became toxic to me within about two weeks. Insurances spent well over \$1,000,000 in just under two years with multiple psychiatric hospitalizations due to my reaction to antidepressants.

Suggestion two: A way to handle addiction and meet the needs of intractable pain patients is through genetic testing. Genelex laboratories provides genetic testing to help determine the best medications for an individual's needs.⁶ According to their own information, most insurances now cover this testing. Genelex now has a contract with Veterans Affairs⁷ and when patients say they are not getting sufficient pain relief, testing should be done to find out if there is indeed a medical reason, as in my case. I spent five years in horrendous pain. The only thing keeping me going was still the hope of finding the answer and repairing it. Instead when I was finally diagnosed in the clinical setting of AA,

6

<http://genelex.com/physicians/>

7

<https://www.onlineprnews.com/news/672909-1457971327-united-states-department-of-veterans-affairs-awards-genelex-federal-supply-schedule-contract.html>

by Forest Tennant, MD, DPH, he also used Genelex labs and “YouScript” to find out that I required high to ultra-high opioids to get any relief. There are also tests for the DRD2 gene and other genes, to be released in the near future, to help determine the addictive risks of different substances.⁸ This would be the best way to help understand the illicit drug user and the legal prescription needing patient. Both the intractable pain patient needs the proper opioids to allow the best possible quality of life, as equally the addictive person needs the best care to overcome the addiction. Addiction is an illness just as adhesive arachnoiditis is an illness **But Medicare (CMS) cannot punish one group, people suffering from intractable pain for the sake of drug abusers!**

Suggestion3: I think it is reasonable to dispense Naloxone with all opioid patients, more for people who get into drugs to abuse, not for the patients. In my home, we have no children and my mother keeps all my opioids in her living space so that I do not forget having taken something and accidentally take it again. I dole out my daily allowance at the beginning of the day. My fentanyl patches are kept in my Mom’s room and the date for each patch appears every three days on the calendar. My Mom gives those to me on the day they are due. The better controlled my pain, the better I can manage my own pain medications. ***But when my pain was not controlled, I could never remember taking medications. I have very little memory of the first two years when my pain was basically under NO control despite being up as high as 450 MME.*** I got some relief from my second surgery: the pedicle subtraction osteotomy, I finally got a little relief in the taut spine. I ceased waking up screaming several times a night after that surgery I believe that the medication for the month should both be divided and hidden well in the event of a robbery. This way hopefully one does not lose it all. We also have naloxone just in case someone were to get hold of medications they should not have. But in my home, it is my mother who is my caretaker and me. Lock boxes would just be a severe hinderance in my house and I believe that if you have small children, one just needs to keep them high and out of reach. A tween or teen intent on getting high and stealing medication is going to know exactly what to steal and break into. People who choose to intentionally abuse their body with illicit items will not let a lockbox stop them. **A lock box is a fool’s protection!** I find it appalling the way that the intractable pain patient is treated. We have been relegated to second class citizens. We require Pain Management doctors to force patients to sign into contracts. **This is the ONLY medical condition were the patient is both treated as a criminal and found guilty of an offense without due process.** The fact that as a country we have the ability to

provide pain relief but are now so unwilling to do so, especially for people like me, who require high doses of opioids is placing the United States into the category of possible cruel and inhuman torture:

Denial of pain relief

86. The Special Rapporteur calls upon all States to:

- (a) Adopt a human rights-based approach to drug control as a matter of priority to prevent the continuing violations of rights stemming from the current approaches to curtailing supply and demand (A/65/255, para. 48). Ensure that national drug control laws recognize the indispensable nature of narcotic and psychotropic drugs for the relief of pain and suffering; review national legislation and administrative procedures to guarantee adequate availability of those medicines for legitimate medical uses;
- (b) Ensure full access to palliative care and overcome current regulatory, educational and attitudinal obstacles that restrict availability to essential palliative care medications, especially oral morphine. States should devise and implement policies that promote widespread understanding about the therapeutic usefulness of controlled substances and their rational use;
- (c) Develop and integrate palliative care into the public health system by including it in all national health plans and policies, curricula and training programmes and developing the necessary standards, guidelines and clinical protocols.

Suggestion4: Medicare (CMS) is suggesting bringing the following into the 2019 rules: including evaluating the addition of mental health, substance use disorder, and chronic kidney disease conditions in the risk adjustment model and making adjustments to take into account the number of conditions an individual beneficiary may have. All patients suffering from pain should be treated and treated to their body's pain needs. There is no flat MME that will work for everyone. **Patients should be educated about kidney failure and other risks but the ultimate decision should be up to the patient in consult with their physician, not the insurer.** A doctor does not need to send a patient home with 60 Percocet 5/325 for a thumb pinning surgery, but at the same time sending someone home with 4 tablets after cutting the tendons in their hand and refusing extra medicine when the family member calls stating that the patient is screaming should not be denied extra medication. Pain is very tricky. Some people can stand quite a lot through training of their minds, such as Special Forces. But meditation does not work for everybody. For me, it is a sure way to raise my blood pressure! **Medicare (CMS) has to resist the temptation of a one size fits all mentality for every type surgery or procedure.** Giving a starting point is fine, but recognizing that the pain still needs to be treated on an individual basis is crucial before pain

becomes centralized. Once pain is centralized, the battle is much harder to win but instead you just have to hope to give that person the best possible quality of life.⁹

Suggestion5: Pain Education is important, but it is necessary for the Federal Drug Administration, the Drug Enforcement Agency, the Department of Justice as well as the members of the medical establishment to become educated on drug necessities and drug abuse. It is amazing how fast the pendulum has swung in the other direction in just two years. You will note from many of the comments submitted, that fear of suffering in extreme pain is being constantly noted by individuals in intractable pain. People saying that without proper opioids, they will either be murdered by the federal government by proxy (leaving suicide as the only option to relieve the pain) or they will play Russian roulette with illicit drugs. So, it seems to me a very easy call. **Patients in severe pain should be told the likelihood of diminishing their lives with long term opioids but the choice should be theirs and theirs alone.** When I was 16, I told my parents then, I would rather die at age 25 and have 9 years without significant pain then to live to be 50, suffering the whole time. This country has no issues with letting people who are dying be treated the way they want and in fact, we now have states, to which we can freely move to. and be assisted with death. But we put a condition on this. The condition doesn't care about who is suffering the most but rather are you likely to die within 6 months to up to a year. There is something insanely wrong that we think it to be inhumane to make and watch our pet suffer but yet we, as a society, have come to believe that unless you have cancer, you should be forced to suffer. It is time to realize that there is indeed a fate worse than cancer and death. It is to be alive fully aware of your body killing you cell by cell, atom by atom, ion by ion. This is what my disease feels like when not controlled. I require a minimum of 860 MME to a high of 1260 MME daily just to be willing to stay alive to be company to my mother of 73 years. I cannot sit (therefore cannot drive). I cannot walk but about 6 driveways with a walker and at a snail's pace. I cannot shower but once a week as it sets off a flare. I cannot clean as my body has lost its' thermostat. I have a very limited quality of life and that is my mother. For if she were not here to take care of me and to be a companion, I would have no reason to go on with the little bit of life I get to enjoy. Without the opioid levels that my body requires, even my mother knows and approves of my death, as seeing me suffer is worse than losing me to death. If the OPSC cannot establish palliative care programs where doctors, without fear of prosecution or persecution, can treat me as my internist

(providing palliative care) before the CARA laws are finalized, then OPSC, Medicare (CMS) along with all the other people who think they know more about my life and the worth of my life, will be responsible for the suffering and my ultimate death! I will die! The question will be will I die from natural causes with palliative care, by being tortured to death or by being forced into suicide. It seems as if the ultimate decision will lay with the OPSC in setting up the final rules of Public law 114-198, but these Medicare (CMS) rules are jumping the gun before the laws have been written. This should at most be changes that ONLY occur if they align with the final law as written. Putting on artificial limits, that in the past doctors knew to be dependent on many different factors, is a fool's task and a risk to the intractable pain patient's needs. Please do not put senior's lives into the hands of the insurer for final decisions! Doctors go through years of training and just because a group of doctors got up on their soap box, they have totally misrepresented the true intractable pain patient. The doctors from PROP have their opinion and have persuaded the press and therefore legislators, which in turn has cause these proposed changes. Yet much of the studies that PROP utilized were poor and that true opioid abuse disorder is not very prevalent. A study in The British Medical Journal, where they tracked for 665,000 opioid-naïve post-surgical patients, between 2008 and 2016. Only 0.6% were later diagnosed with Opioid Abuse Disorder (OAD). And less than 1% of patients renewed their prescriptions after 13 weeks.¹⁰

Sincerely,

Kimberly Comfort

K
i
m
b
e
r
l
y

¹⁰ <https://morningconsult.com/opinions/do-alternatives-to-opioids-really-exist/>

C
o
m
f
o