

February 25, 2018

Gentlemen:

I am writing to comment on the section of ***Advance Notice of Methodological Changes for Calendar Year 2019 for Medicare Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter*** which proposes regulations guiding the prescription and dispensing of opioids. I am including a case study of my wife who is dealing with intractate pain as a by-product of Adhesive Arachnoiditis.

There is no question regarding the existence of an epidemic of addictive drugs, and opioids are the substance de jour. While the proposed regulations are consistent with the current CDC Guidelines, those guidelines and the proposed regulations are likely to hurt patients suffering from intractable pain.

The CDC Guidelines are directed towards family physicians and similar health practitioners, e.g., physician's assistants, and not for board certified physicians specializing in pain management. The latter group the deals with the most complex cases, and must use their professional judgment, going outside the specifics of the guidelines when required when necessary for the treatment of their patients – sometimes prescribing large doses of opioids for an extended period of time, often in combination with a cocktail of other substances. It should also be noted that while intractable pain patients may be dependent on their drugs, they are not addicts and they cannot 'sell them on the street' without causing serious problems to themselves.

The CDC guidelines divide patients into two categories – those suffering from acute and chronic pain. The chronic pain category links together two groups – chronic pain sufferers who may have bouts of pain over an extended period, and intractable pain sufferers who have constant pain that never goes away and

frequently gets progressively worse. My concern is with protecting physicians and patients in this latter category.

Setting real or perceived limits of dosage size or frequency for these patients can have the practical effect of forcing them to be without access to their medicines for some period of time – just the opposite of the medical mandate to ‘do no harm.’ A similar point can be said about a system that lets far removed personnel in drug insurance companies manage this process.

The current panic regarding opioids is already having negative impact. Organizations such as the DEA, lacking required medical expertise, are targeting pain specialists (and their patients?). Some pain specialists are leaving this specialty. Pain patients are operating in a panic mode and starting to look for other (not necessarily sound) sources of pain relief. This situation will get worse if the current regulations are put into force without the dealing with this special case. There is a very active social media website containing details of these and other related trends.

The solution to this situation is straightforward: (1) Permit board certified pain specialists to write prescriptions for opioids going outside of specified dosage levels; (2) prohibit managers of drug plans from questioning or limiting these prescriptions; (3) require that managers of drug plans notify dispensing pharmacies that these patients have been preapproved for a period of at least one year; and (4) notify both the DOJ and the DEA that where prescriptions are written by these board certified physicians, data mining through databases such as PDMP can lead to false results injuring both physicians and their patients.

I am adding a case study based on my wife’s case, to highlight the points that I have just made. Prior to her retirement, Wendy Burnett was an Occupational Therapist – a trained, licensed and professionally certified health practitioner.

Because she is 74 and suffering from a number of medical issues, her health care is quite complex, i.e., careful oversight and coordination is required to the deal with potential drug and treatment interactions. Her journey that eventually led to our cross-country trip to see a prominent pain specialist, began in 1972 when she had an accident. As part of the diagnostics she had a myelogram that utilized Pantopaque as a contrast medium – it is now off the market and its use is prohibited. This was followed by radical spinal surgery from L1 to S1. Three years later she was able to go back to school, got a degree in Occupational Therapy, and became a Certified Hand Therapist. She ran a private practice in Manhattan

specializing in rehabilitation of the hand and upper extremity for 30 years. She had manageable episodes of pain throughout this time until she had a bout of severe Lyme disease that caused not only liver failure but also spinal meningitis. Her pain became increasingly severe. A radiologist from Weill Cornell Medical College reported seeing "clumping" of spinal nerves and probably Arachnoiditis.

She is currently working with a team of physicians from Mt Sinai Medical Center: her primary physician (a Board-certified internist, hematologist and oncologist), the chief of neurology, and a professor of pain management. Their primary goal was to control the pain. Together, they were able to help decrease the neurogenic pain with multiple drugs as well as a spinal cord stimulator implant. Her bladder was also impacted and helped with drugs, an Interstim implant, as well as Botox injections into the bladder.

Her medical team's goal was helping to control her increasing pain and her neurogenic bladder. What was not addressed was how to stop, slow down, or even reverse the destruction caused by this horrendous, progressive disease – Adhesive Arachnoiditis.

She researched multiple monographs describing the disease and found that there was nothing about treatment of this progressive disease other than palliative pain control. As a by-product of this research she also made contact with an active support group operating on social media. The name of a prominent physician kept coming up. We reviewed his work and subsequently went to a 2-day conference at which he discussed the etiology and treatment of Adhesive Arachnoiditis, including a research review showing the possible reversal of the damage done by spinal cord inflammation.

Her New York team got in contact with the physician and we started some of his recommendations. Our immediate goal was to keep her disease from progressing by controlling inflammation and re-balancing hormones. She was seen by him in July 2017, at which time she had a comprehensive 2-hour examination that included a detailed review of diagnostic procedures and treatments from the Mt. Sinai physicians. She has since seen him twice. She has spoken to him on the phone multiple times as we fine tune his protocol for her specific needs.

Her disease seems to have stabilized, thanks to the on-going efforts of her medical team. Indeed, her Mt Sinai medical team continues to follow his protocol and her pain management physician is even following his protocol in treating other Arachnoiditis patients.

The situation now gets more complicated.

The doctor is one of the foremost physicians specializing in the treatment of intractable pain patients. He has been practicing since 1975. Since that time, he has authored more than 350 peer reviewed articles, and lectured widely. He is, at the same time, controversial because he very publicly supports the use of opioids for intractable pain if they are required by the patient and carefully monitored.


Using prescription records available to them under PDMP, the DEA noted that a large number of opioid prescriptions were filled by a pharmacy and that many of these prescriptions were written by him. A DEA agent, with apparently very limited training regarding pain management, then opened a case. The agent consulted a physician that the DEA uses regularly as an expert witness -- a family physician with little or no experience treating intractable pain patients and who has made a considerable amount of money from the DEA-related expert witness fees. Using this information, the agent was able to get a search warrant that resulted in seizure of ALL records in the doctor's office and house. The warrant was exercised while the doctor was away testifying against the DEA in an unrelated case. Exercise of the warrant was of course accompanied by adverse publicity, his premises being roped off as 'crime scenes,' etc.

Needless to say, his patients are both concerned and incensed. Seizure of everything included all patient records – and hence it put patients in a position that could potentially limit their access to on-going medical treatment. Patients were not notified by the DEA that their medical records were seized and that copies could be recovered by making appropriate requests. That information was obtained by someone on the intractable pain 'support network' and provided to other patients. Since we had an appointment booked with him we made such a request. Although copies of records were sent to us, they were disorganized and they missed a CD with MRI results that had to be the basis for a follow-up request. We are assuming that what was sent to us is now complete, but we have no way to prove it since we have no access to the originals.

It goes without saying that the doctor's patients are having all of the reactions noted in the previous section of this letter. They are getting good care and they are dependent on his on-going treatment for pain control. Most interestingly, his patients have banded together to help with his defense and to raise funds to cover at least part of his legal bills.

None of this should have happened! The so-called expert witness used by the DEA has questionable pain management expertise. He is a family physician and, as far as I can tell, not only has little or no expertise treating intractable pain patients, while at the same time a significant part of his earnings come from acting as an expert witness for the DEA. Similarly, the leap from a large number of prescriptions to an accusation of malfeasance is illogical, a misuse of statistical methodology and a violation of the premise that one is innocent unless proven guilty beyond a reasonable doubt. Is this an attempt by the DEA to make political points? Is it an attempt by someone in the DEA to build his or her career? Is it just an incompetent investigation? Is it 'grandstanding' by the DEA? Who knows? The one thing that is known is that innocent people are being hurt.

Respectfully submitted.

  
Prof Mike Uretsky