

March 15, 2018

U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: 2019 Medicare Advantage and Part D Advance Notice Part II and Draft Call Letter

In its 2019 Medicare Advantage and Part D Advance Notice Part II and Draft Call Letter, CMS has proposed to enhance OMS to flag beneficiaries using potentiator drugs in combination with prescription opioids; to administer a soft point-of-sale (POS) safety edit for beneficiaries with prescriptions for both opioids and benzodiazepines; to implement a hard POS edit, which can only be overridden by both prior authorization requested by the prescriber and approval by the sponsor, of cumulative opioid prescriptions at 90 morphine milligram equivalent (MME), with a 7 days supply allowance; to implement a 7-day supply for the treatment of acute pain; and to administer a soft POS safety edit for beneficiaries with multiple long-acting opioids. For the reasons below, these proposals should be abandoned.

A. The Proposals Override the Discretion of Prescribers

The problem with these types of overarching pain control guidelines is that chronic intractable pain patients have their dosages reduced or removed without any regard for the individual patient's situation, illness, genetic profile, or responses to medications. For these reasons, and because every patient is unique, physicians should have ultimate discretion on prescribing medication to their patients. 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 intractable pain patients as they had before the guidelines.

Physicians should have ultimate discretion over the prescribing of medication. Physicians, by the nature of their occupation, have a personal relationship with the patient, and know so much more about a patient's conditions, contraindications, allergies, and genetic markers than a paper-pushing bureaucracy ever possibly could. Medicine is part art; it cannot be performed solely on paper. Medicine is also not a one-size-fits-all proposition. However, this is exactly what the policy-makers at CMS are proposing. CMS's proposal will take discretion away from physicians in treating chronic pain patients, and force patients to involuntarily taper from their current dose of pain medication. Many of these chronic intractable pain patients will have their medication abruptly reduced or stopped entirely, as seen in the wake of the CDC Guidelines for Prescribing Opioids for Chronic Pain (March 2016).

The drastic decreasing or termination of pain control is leading to the development of an expensive, vicious downward cycle, with tragic outcomes. As more formally stable patients

have their pain control medications taken away, they join the ranks of the disabled. Meanwhile, those on disability become sicker, and rely on the governmental safety nets more and more. Suicide is the ultimate tragedy. The chronic pain community is extremely close-knit, and we are aware when we lose one of our own. While statistics on attempted and completed suicides due to withdrawn medications have not yet been compiled, anecdotally, the situation is not uncommon. (E.g. Slate, "Some People Still Need Opioids," Aug 17 2017). What we do know is that the suicide rate among those with chronic pain is double that of people without chronic pain, and it is very plausible that approximately 20,000 individuals with chronic pain commit suicide each year. ("Chronic Pain and the Risk of Suicide," Judy Foreman, Psychology Today, Nov 24 2015).

If CMS does not find it appropriate to completely remove the 90 MME hard edit, then it should deem those chronic intractable pain patients who have prescriptions for over 90 MME as "legacies" and automatically exempt from the hard edit. As CMS has proposed, patients who are above the 90 MME would depend on obtaining prior authorization from the prescriber and approval by the sponsor to continue their medications as prescribed. However, as described above, physicians currently fear governmental agencies; they do not want to make any waves, nor will they want to appeal to them. And most sponsors are wont to deny these claims. Additionally, this "exemption" process is yet another obstacle chronic intractable pain patients have to surmount in order to receive appropriate care. These patients are already required to go to their physicians every 30 days for a new (paper) prescription, and physically take that prescription to the pharmacy, and then hope the pharmacist on duty will fill it. Most pain patients are also subjected to drug testing every month. Forcing these patients into yet another fight for their medication, using up what little energy they have, seems at best poor policy, and at worst, inhumane.

With the above said, chronic pain patients above 90 MME should also be deemed exempt because the forcible significant weaning of those who are and have been on a stable dose of opioids is never recommended. (See, "Opioid Crisis, Patients Pushed to the Brink," Markian Hawryluk, The Bulletin, June 2 2017). Even the CDC did not recommend this type of approach. "At the National Rx Drug Abuse & Heroin Summit in Atlanta in April, Dr. Deborah Dowell, a CDC senior medical adviser and coauthor of the guidelines, said that approach was not the authors' intent. 'We do hear stories about people being involuntarily taken off opioids,' she said. 'We specifically advise against that in the guidelines.' Patients should be tapered off medications slowly, she said, at a rate of 10 percent per week, even slower for those who have been on their medications long term. For many medications, a large sudden drop in dose can have dangerous effects." (Hawryluk). Since these proposals will only give a 7-day hold-over dose to a patient waiting for their exemption, an exemption that very well may never be granted or may take much longer than 7 days, this process puts all chronic intractable pain patients at risk for these dangerous effects from sudden drops in their medication dosages. (See "Are Prescription Opioids Driving the Opioid Crisis? Assumptions vs Facts" Mark Edmund Rose, Pain Medicine, Dec 27 2017). To prevent serious illness, injury, and death, CMS should make chronic intractable pain patients who have prescriptions above 90 MME automatically exempt.

B. The Proposals Are Inherently Irrational

CMS states that its end goal from these proposals is to address the “public health emergency,” meaning the current crisis involving overdoses of opioid-based medications. However, as explained below, the means by which CMS has suggested to meet the end goal are not rationally related to each other.

Currently, approximately 44 million people receive Medicare benefits. However, in the preamble to these proposals, it was stated that the 90 MME hard edit would affect 35,053-319,133 beneficiaries. That number was increased to “almost 1.6 million beneficiaries” in the draft call letter. Though the jump in numbers does seem questionable, we will calculate based upon the higher given estimates. Using the high estimate from the preamble, this works out to about 0.7% of Medicare beneficiaries; the number from the draft call letter works out to about 3.6%. Although a precise number of US pharmacies is not available, a conservative estimate of 82,000 will be used. (See <http://www.skainfo.com/databases/pharmacy-data>). This means that, on average, 19 Medicare beneficiaries may trigger the hard edit at each pharmacy. This is such a small percentage of each pharmacy’s total population as to be nearly insignificant, especially when the proposal will necessitate extra work, training of staff, and the expenditure of money on computer software and/or upgrades by all pharmacies in order to comply. Once the numbers are run, this proposal becomes *prima facie* irrational.

The substances that are causing the vast majority of the overdoses are not going to be affected by these proposals. Illicit fentanyl and heroin cause the most of the overdoses in the US (see below). Opioid analgesic prescribing and associated overdose deaths both peaked around 2011 and are in long-term decline; the sharp overdose increase recorded in 2014 was driven by illicit fentanyl and heroin. (See “Are Prescription Opioids Driving the Opioid Crisis? Assumptions vs Facts” Mark Edmund Rose, Pain Medicine, Dec 27 2017). These illicit substances are not coming through physician offices; instead, they are being illegally imported into the United States through various methods. The vast majority of the illicit fentanyl (at least since the mid- to late- 2000s) is arriving in the US from China via our own US Postal Service. (E.g. Reuters, “China’s illegal opioids enter U.S. through Postal Service gaps: probe” Jan 24 2018). A year-long investigation by a Senate homeland security and government affairs investigations subcommittee found US-based buyers have easy access to purchase fentanyl, often in relatively large quantities, through the internet. (The Guardian, “Chinese labs use mail to send opioid fentanyl into US, Senate report finds,” Jan 24 2018). Further, the National Institute on Drug Abuse stipulates that “[t]he...category [of non-methadone synthetics] is dominated by illicit fentanyl overdose.” (National Institute on Drug Abuse, “Opioid Overdoses,” Revised Sept 2017). Thus, the proposed policies would have no effect on “the public health emergency.”

Both the preamble to the proposed regulations and the regulations themselves state that the 90 MME cutoff would have exempted beneficiaries, including those with cancer, those in

long-term care, and those in hospice. CMS is attempting to draw bright lines among and in between sick patients. This is a job for treating physicians, not for bureaucracy. CMS should not be making the determination that someone with a tumor should be able to obtain over 90 MME without a fight, while someone incapacitated with Multiple Sclerosis must fight the bureaucracy in order to get the pain relief s/he needs. Thus, the government bureaucracy is denying care to some ill patients, while granting it immediately to others, without consideration of how sick the patients are, or how much pain they are in, but only the diagnostic code given to such patient.

Because there is such a wide range in the dose levels among people using opioids long term, many doctors agree limits like 90 MME are completely arbitrary. No studies have been done showing that 90 MME is the ideal safe, yet effective, dose. While physicians acknowledge that opioid prescribing should be limited, they also agree that the policy must be applied where it makes sense. Targeting all patients with blunt instruments like dose limits is likely to compound the negative consequences of the epidemic. Further, due to genetic differences between humans, any black line limit is arbitrary. This is a concept that is consistently ignored by governmental agencies. "Patients with chronic pain who require high doses of opioids to achieve pain relief show exceptionally high rates of defects of the cytochrome P450 (CYP450) enzyme system compared with the general population." ("Need for High Opioid Dose Linked to CYP450," Nancy A. Melville, Sept 25 2012).

Further, the proposal specifically states that after triggering a hard edit, a patient can receive a 7-day supply of medication, but would then have to obtain a new prescription for amounts beyond the 7-day supply. It not reasonable or feasible to expect chronic pain patients to visit both their physician, for a new prescription, and their pharmacy twice in a single month (once for the 7-day supply, and then once for their 30-day supply). As the name makes clear, these are patients with chronic, intractable pain. They struggle to perform basic daily tasks. Many cannot drive, public transportation is not available for many of these patients, or simply not accommodating for their lack of mobility/wheelchairs/rollators, and a paid ride is simply out of their budget. Most live below the poverty line, making the copayment and possible co-insurance for extra doctor's appointments and extra prescriptions per month well out of reach for them. A similar, yet worse, situation is true for acute pain patients, who, under this proposal, must obtain a new prescription from their physician, and have it filled at the pharmacy every 7 days.

With all the above taken into account, the means by which CMS is attempting to curb the opioid overdose problem are irrational, and do not come close to getting to the actual sources of the problem.

C. The Studies and Statistic Cited are Flawed

The CDC statistics that were cited as a basis for the CDC Guideline for Opioid Prescribing and are used as the foundation for these proposals are flawed. Contrary to CDC claims, the rate of opioid prescribing is dropping. Data from the CDC indicate that between 2010

and 2015, the amount of opioids prescribed in the United States actually decreased by more than 18%, with a 13.1% decrease reported between 2012 and 2015 alone. Survey data also suggest that more than half of physicians in the United States have reduced their opioid prescribing, with nearly 10% having stopped prescribing opioids altogether. Data from the state indicate that every state (with the exception of Florida) and the District of Columbia reported a decrease in the number of opioid prescriptions written between 2015 and 2016. Consequently, there is little doubt that the amount of opioids being prescribed is decreasing dramatically, so it would be disingenuous to suggest otherwise.

Moreover, in a study several years ago, a research team purposely excluded chronic pain patients with prior drug abuse and addiction from their data, and found that only 0.19 percent of the patients developed abuse and addiction to opioids. (See “What Percentage of Chronic Nonmalignant Pain Patients Exposed to Chronic Opioid Analgesic Therapy Develop Abuse/Addiction and/or Aberrant Drug-Related Behaviors? A Structured Evidence-Based Review,” Fishbain, et al., *Pain Medicine*, Oct 2 2007). Among patients with non-cancer, chronic intractable pain, a review of international medical research by the Cochrane Library, a highly regarded database of systemic clinical reviews, found that treatment with long-term, high-dose opioids produced addiction rates of less than 1 percent. (See “Opioids for long-term treatment of noncancer pain,” Noble, et al., *Cochrane*, Jan 20 2010). Thus, dependency is not addiction; chronic intractable pain patients are not causing the addiction problem.

Furthermore, the number of overdoses caused solely by prescription opioids was miscalculated by the CDC and its advisors. The “60,000 drug overdose deaths” is a widely-known and used statistic. However, “drug overdose deaths” is now standard jargon used to characterize fatalities from all drugs of all sorts, anticoagulants, antidepressants, aspirin, cocaine, etc. All opioids overdose deaths together (including heroin) equals about 30,000. (See National Institute on Drug Abuse, “Opioid Overdoses,” Revised Sept 2017). The number of deaths from prescription opioids—the target of the current crusade— was about 17,000. (See CDC, “Vital Statistic Rapid Release, Provisional Drug Overdose Death Counts,” Revised Feb 2019 and “Opioid Abuse,” Dixon, et al., *Medscape*, Dec 22 2017). But this 17,000 number includes overdose deaths that are frequently the result of combination with other medications. In 2015, almost half (7,500) of the overdose deaths from opioids also involved benzodiazepines. (See National Institute on Drug Abuse, “Opioid Overdoses,” Revised Sept 2017). When you include other drugs that are taken with opioids, especially alcohol and cocaine, it can reasonably be assumed that the number of deaths from opioid pills alone will be much, much lower. The concern is this: for the CDC to suggest that more than 15,000 died in that year from “prescription opioids” when a closer examination of the data indicates that illicit opioids and/or polypharmacy were involved is not only inaccurate, it is disingenuous. (See, “Pain management, prescription opioid mortality, and the CDC: is the devil in the data?,” Schatman, et al., *Journal of Pain Research*, 2017). It can negatively impact patients who are well-managed on long-term opioid therapies and have no effective safe alternatives, and health care providers seeking to relieve suffering.

Further, the proponents of these proposals and of similar ones always point to the fact that people who are currently addicted to heroin and other street drugs, synthetic and/or semi-synthetic, got their start by taking doctor-prescribed opioid medications. However, this is another inaccuracy. Many who are addicted begin by stealing and/or purchasing illegally diverted prescription drugs. (See, e.g. "Patterns of Prescription Medication Diversion Among Drug Dealers," Rigg, et al., Jan 1 2013; "Prescription for Disaster: How Teens Abuse Medicine," Drug Enforcement Agency, Aug 2012). The article most cited for the concept of prescription-drug-users-to-heroin-addicts is a 2-page question-and-answer summary by Bridget M Kuehn in JAMA. ("Driven by Prescription Drug Abuse, Heroin Use Increases Among Suburban and Rural Whites," Vol 312, No. 2, July 9 2014). However, this article actually never states that people were legally given prescription drugs, and goes on to explain that the reason for the switch to heroin was due to price and availability of the prescription drugs. These are the same reason cited in the Riggs article dealing with diverted drugs. If these people had been obtaining the prescription drugs legally, neither of these "problems" should have been an issue. Thus, the underpinnings of the argument that legally obtained prescription medications caused the current epidemic are false.

These CMS proposal are based upon the 2016 CDC Guidelines. However, the Guidelines show both bias and lack of accountability. What began with prescribing guidelines created in secrecy, evolved to the use of statistical data and public statements that failed to capture not only the complexity of the problem but also the distinction between licit and illicit opioids and their relationship to the alarming increase in unintentional overdose. For instance, when its members were eventually identified after being kept secret by the CDC until leaked, many were concerned that the group's composition was not balanced and had an inherent bias against the use of prescription opioids to treat pain. (See "Dysfunction, Lobbying, and Conflict of Interest in the Debate Over Opioids," S. McCoy. Inside Sources. Oct 15 2015.) After allegations of unlawful behavior by the CDC during the creation of the guideline were made, Congress forced the CDC to have a 30 day open comment period. (Congress.gov. Comprehensive Addiction and Recovery Act of 2016. Available at: <https://www.congress.gov/bill/114th-congress/senate-bill/524/text>.) Although the new open comment period yielded several thousand comments in the Federal Register, there was little change between the draft guideline and the final guidelines. With all of the above taken into account, CMS cannot base new proposals on flawed data.

D. Conclusion

The logic this CMS proposal is completely untested, unproven, and unsupportable. 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 will seriously destabilize the vast majority, and would likely promote the use of heroin or other drugs. In effect, pain patients currently taking opioids long-term have become involuntary participants in an experiment, with their lives at stake.

Sincerely,

A handwritten signature in black ink that reads "Amie Schaadt Knauer". The script is cursive and fluid, with the first name "Amie" starting with a capital 'A' and the last name "Knauer" ending with a stylized flourish.

Amie Schaadt Knauer
Committee Member
Coalition of 50 State Pain Advocacy Groups

