



Families for *Intractable* Pain Relief

March 5, 2018

Seema Verma, Administrator
Center for Medicare and Medicaid Services

Re: CMS-2017-0163

Subject: Comments on Proposed Policy to Implement Formulary-Level Cumulative Opioid Safety Edits at Point-of-Sale (POS) at 90 MMED

We, Kristen Ogden and Ingrid Hollis, are the co-founders of Families for Intractable Pain Relief (FIPR), an advocacy group established to observe, monitor, and take action in regard to political, legislative, regulatory, and research developments that may affect our family members' access to necessary and appropriate medical care. Our group is comprised of severe intractable pain patients and their family members. FIPR's goals are:

- (1) To raise awareness of severe intractable pain and the challenges faced by those who suffer from it; and
- (2) To advocate for access to standard and non-standard pain therapies to treat severe intractable pain, including opioids and non-opioid pain medications, hormones, anti-inflammatory agents, and adjuvant treatments as appropriate.

FIPR strongly opposes the proposed policies that will implement hard edits on opioid prescriptions at or above 90 mg MED that can only be overridden by insurance companies. This proposal will, if implemented, deny effective analgesia to millions of seniors, and poor and disabled citizens. These changes will, without doubt, damage and deny care to large numbers of the 1.6 million patients presently estimated by CMS to receive daily opioid pain treatment above 90 mg MED. Prescribing is already over-regulated and, as a result, harm is being caused to hundreds of thousands of stable patients who have already been forcibly tapered to doses below therapeutic levels.

While the proposed policy is supposedly intended to ensure compliance with the CDC guideline recommended ceilings, this notion is blatantly false, as the guideline does not recommend that these thresholds be used as targets for non-consensual dose reduction for patients who are already prescribed a higher dose of opioids. The guideline recommends benefit risk assessment for patients at or above the 90 mg MED threshold but absolutely does not endorse forced reduction of doses for stable patients. The Guideline was developed and put forth as voluntary opioid prescribing recommendations for primary care

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physicians to aid them in effective use of opioid pain medications and does not, in any of its recommendations, seek or support involuntary tapering of long-term stable patients already benefiting from opioid doses above the 90 MME threshold. Also, the CDC guideline failed to take into account genetic variants that cause some pain patients to be ultra-rapid or poor metabolizers of opioid pain medications. The proposed hard edits will no doubt have disastrous impact on hundreds of thousands of patients who presently benefit from opioid therapy, but at considerably higher doses than 90 mg MED.

The proposed process to obtain an exception to the hard edit in order to extend initial prescriptions beyond seven days is guaranteed to doom patients through bureaucratic failure. It is highly doubtful that such a process can be implemented and carried out in a timely, efficient manner, thus harming patients and burdening doctors unnecessarily. The extra workload on doctors is unreasonable and may drive even more pain practitioners away from the practice of treating pain.

On January 30, 2018, FIPR co-founder Kristen Ogden gave a presentation on behalf of FIPR at FDA's Public Hearing on Policies for Opioid Prescribing Intervention. A major thrust of her presentation was that, in the recent and continuing media frenzy about the so-called opioid epidemic, the very existence of severe intractable pain as a long-term disease state has been silently denied. The pain patients who comprise our membership are "invisible" to the media, to elected officials, and to healthcare policy-makers. The conversation about the opioid epidemic, about reducing harms associated with opioids, and about preventing opioid-related deaths NEVER acknowledges the existence of people like our family members. At best, any discussion in media coverage, Congressional committee meetings, or regulatory agency deliberations may offer a "throw-away line" that, of course, policy would never intend to harm those who live with chronic pain and have legitimate need for medication. The "invisible" state of intractable pain patients is actually not a new phenomenon, but the current opiophobic environment has served to obliterate any view of these patients to an even greater extent than in the past. CMS should step back and consider whether there is any compelling evidence to conclude that very high doses of opioid medications are never helpful as a last resort means of relieving long-term ongoing severe constant pain. We believe there is no such evidence. As previously stated, the CDC guideline does not endorse forced tapering to 90 mg MED of stable patients, so we see absolutely no basis for the implementation of hard edits at all, much less hard edits that can be overridden only by insurance companies. Who would this practice benefit? Certainly not chronic pain patients. From our perspective, the only beneficiaries for such policy are, in fact, the insurance companies that get out of paying for necessary medications. This is ugly policy that demonstrates no concern whatsoever for the well-being of patients.

Like the CDC guideline, there is no mechanism proposed in this policy to monitor and evaluate patient outcomes, thus almost guaranteeing that the likely unintended consequences will indeed take place and will not soon, if ever, be effectively assessed or addressed. The proposed opioid medication caps via hard edits will cause great harm to millions of responsible citizens for a long time to come.

As stated, on January 30, 2018, Kristen Ogden had the opportunity to speak on behalf of FIPR at FDA's Opioid Policy Steering Committee Public Hearing on Opioid Prescribing Interventions. She chose to speak specifically about intractable pain and the challenges patients face and to address the importance of continued access to opioids, often in high doses, to this subset of chronic pain patients. We have attached the hearing agenda and a copy of Kristen's presentation to this letter. We are also providing below a link to

the webcast recording and urge reviewers of these comments to take time to view the 8-minute presentation. When the page loads, click on session 1. Kristen's presentation begins about 27 minutes into the session. If reviewers can read or view it, they may get a better feeling for what FIPR is saying about intractable pain and the treatment needs of this subset of chronic pain patients.

<https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm583543.htm>

Among the key points made in the presentation are the following. When we speak of intractable pain, we are talking about a severe, constant pain that is not curable by any known means, causes adverse biologic effects on the body's cardiovascular, hormone, and neurological systems, and leads to a bed- or house-bound state and early death if not adequately treated. Effective analgesia for these patients can normalize physiologic and mental function and enable the patients to independently carry out activities of daily living to the maximum extent possible and to enjoy a greatly improved quality of life.

Characteristics of intractable pain include:

- Constant, excruciating, 24/7 pain
- Elevated blood pressure and pulse rate
- Poor sleep and reduced food intake
- Physical and mental incapacitation
- Underlying cause incurable, not removable
- Endocrine and immune system abnormalities
- Elevated serum inflammatory and neuroinflammatory markers

Severe intractable pain may lead to death from stroke, cardiac arrest, or adrenal failure if untreated or undertreated. The cause of severe intractable pain can be thought of as two-fold:

- The initial injury or disease is severe enough to cause pathologic transformation of microglial cells in the spinal cord and/or brain. This activation of microglial cells causes neuroinflammation and the constancy of pain. This process is referred to as "centralization" and the result is Central Pain Syndrome.
- Only the most serious diseases or conditions are severe enough to cause centralization. Among these are:
 - o Adhesive arachnoiditis
 - o Reflex sympathetic dystrophy
 - o Post-viral neuropathy/encephalopathy
 - o Traumatic brain injury
 - o Genetic diseases such as Ehlers-Danlos Syndrome and Marfan Syndrome

Why is it necessary and appropriate to treat intractable pain? Medical management of intractable pain can enable a patient's overall condition to be stabilized, while the underlying causes are identified and treatments are attempted. Effective medical management of intractable pain can be accomplished without undue risk of such adverse outcomes as overdose, addiction, or death.

We will also state here, the following oft-held misconceptions about those who suffer from intractable pain:

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- Intractable pain patients are NOT addicts
- Intractable pain patients do NOT fit the definition of Substance Use Disorder
- Intractable pain patients on high-dose opioids are NOT likely to overdose or die from their prescribed medications or to become addicted
- Intractable pain patients on opioids do NOT get high, do NOT appear drugged or incapacitated, and are NOT impaired by their medications

In addition, intractable pain patients on high-dose opioids:

- Do NOT engage in drug-seeking behaviors
- Are NOT drug diverters or drug traffickers
- Would NEVER sell or give away their medications
- ARE helped by their high dose pain medications
- CAN remain on stable high opioid doses for years
- ARE able, with doses sufficient to control and manage their pain, to regain function, enjoy participation in life, and achieve greatly improved quality of life
- ARE able to again become functional family members and productive citizens
- ARE enabled, not disabled, by opioid pain medications

Many of our members are affected by genetic variants that limit the body's ability to metabolize opioid medications. This fact explains why many members require higher than usual dosages and supports our contention that the risk factors for these patients is lower than among the general population. That said, we certainly agree that there are risks associated with the use of opioid pain medications, but in the case of our patient population, these risks are often greatly outweighed by the benefits. In our experience, severe intractable pain patients for whom high dose opioids are being considered are informed of the risks and required to acknowledge their acceptance of these risks in writing prior to the medications being prescribed. Many of our members report they have been stable on the same very high doses for many years with substantially improved function, greatly improved quality of life, and no adverse outcomes. Family members of these patients confirm these reports and believe the patients should continue their high-dose regimens as long as cure of the underlying disease conditions is not possible. There is no one-size-fits-all patient or treatment plan for pain. Implementation of hard edits that will, in effect, serve as absolute medication caps will bring catastrophic impacts upon our patient members. The proposed policies are totally unacceptable.

While the dosages and outcomes experienced by our members are not documented in specific published studies conducted in randomized controlled trials, we assert to you that our patient members really do exist and have enjoyed greatly enhanced lives, although still ill, as compared to their lives prior to medical management with high-dose opioid analgesics. As stated, our group is comprised exclusively of intractable pain patients and their family members. The patients for whom we advocate are not hypothetical, unknown, nameless persons. They are either our members themselves, or they are beloved wives, husbands, sons, daughters, and parents of our group members. Intractable pain patients who clearly experience great benefit from opioid therapy at doses above 90 mg MED are known individuals who actively participate in our advocacy efforts. The names of more than 30 FIPR member advocates, both patients and family members, are listed at the end of this letter. Our patient members are indeed outliers,

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but nevertheless real people! Despite continuing efforts to render our patients and our families invisible, we exist, we are real, and we demand to be acknowledged.

Thank you for the opportunity to comment.

Sincerely,

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Attachments as stated

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