CMS Comments 2018

On behalf of and all those Medicare beneficiaries who have major medical problems that require ongoing pain management, please do not enact changes for opioid prescribing that could negatively impact their quality of life and ongoing health issues. Undertreated pain in the disabled and elderly populations can affect not only their ability to perform activities of daily living, but can pose grave dangers to their health, including death, from side effects of untreated pain such as increased blood pressure, heart rate and increased cardiac strain. The potential efficacy of opioid medications in chronic pain management is well established. From Cochrane reviews to policy statements from the Mayo Clinic, there is medical value here. The under-treatment of pain among the elderly is already a problem, and the opioid crisis is impacting cancer pain care and hospice care, too. **Opioid medications are best left as a last option for treatment, after all other methods fail, but are still a very important and timely last option.**

         We strongly object to the government's continued interference in the medical care of intractable pain patients. We believe that patients and their doctors should be making the decisions about their healthcare, not the federal government partnered with insurance companies.

         We strongly oppose the Centers for Medicare adopting the March 2016 Centers for Disease Control Guideline for Prescribing Opioids for Chronic Pain. The proposal that “all sponsors implement hard formulary-level cumulative opioid safety edits at point-of-sale (POS) at the pharmacy (which can only be overridden by the sponsor) at 90MME- the dose ceiling recommended by the CDC. This will give pharmacies and insurance carriers the right to over-ride the physicians prescription which is based on the physician’s knowledge of individual conditions and medical necessity, not an arbitrary number of MME’s, and will result in the pharmacy refusing to fill prescriptions. Not only is this number of MME’s arbitrary and unscientific, it excludes those outlier’s, who by no fault of their own, have different rates of metabolism of many types of medications. It will cause unneeded suffering and increased pain in a population already struggling with on-going and intractable health conditions.

There is no hard science to recommend a standard dosage of medication for all patients. The negative results of the CDC Guidelines are quite clearly presenting themselves:

— **Patients who have long been successfully managed on high doses** **of opioids are being outright deserted**, in many cases without withdrawal assistance or oversight, and uniformly without access to effective alternative means for maintaining the quality and functionality of their lives.

-- Nowhere in the CDC Guideline are **genetic factors acknowledged which create wide variability in opioid metabolism.** This variation directly contradicts most of the dose limit rationale embedded in the CDC Guideline.

— Many among those deserted are **lapsing into disability, losing their ability to sustain former employment** or family relationships that have benefited from treatment of pain with opioids.

— Some patients have already committed **suicide, overcome by agony imposed on them by their physicians due to removal of adequate analgesia.**  More are likely to suicide as this

crisis continues and deepens.

—  Although **opioid-related deaths** are a serious public health issue, they are for the most part **not being caused by drugs prescribed to legitimate pain patients.**

—  **The CDC Guidelines were originally phrased as advisory for general practitioners and subject to tailoring for each individual patient — not mandatory** for all physicians or applied as a one-size-fits-all restrictive edict.  If made mandatory, the 90 MMED upper limit on opioid dose levels will effectively destroy the lives of many tens of thousands of chronic pain patients who have been maintained at stable doses above 100 MMED (often above 400 MMED) for years.

The 2017 CDC Annual Surveillance Report of Drug-Related Risks and Outcome clearly states that "Prescription opioid pain relievers were formerly driving the crisis, but by 2015 they shared equal measure with heroin, synthetic opioids other than methadone (mostly illicit fentanyl), and—increasingly— cocaine and methamphetamines.” So, while securing the prescription opioids against theft or diversion remains an important issue, pain management which includes opioid medications for people with major disorders who either cannot use other medications or are not gaining good relief is also important.

It again is abundantly clear that private medical decisions are best left between a treating doctor and the patient. It is our hope that CMS reach more reasonable prescribing practices for a group of people who are in general at very low risk of medication abuse or addiction and who are already enduring or at high risk of developing painful medical conditions.

Sincerely,

Dr. and Ms. Hollis