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**Re: Docket no: CMS-2017-0163-0007**

**Qualifications:**

I am an attorney and counselor-at-law whose professional practice is primarily devoted to healthcare, particularly representing individuals with complex healthcare needs. My training includes extensive graduate coursework in public health at Boston University's School of Public Health. I serve as healthcare agent, pursuant to Massachusetts General Law Chapter 210D, for several elderly, dual-eligible principals whose physicians have determined they are not competent to make their own healthcare decisions. As part of my fiduciary duties in this practice area, I regularly select Part C / Part D plans for my principals. I also represent patients in complex health insurance appeals for denials of coverage of medically necessary prescription medication; I have extensive experience representing patients before Part D and Part C plans and their Pharmacy Benefit Managers.

**CMS proposes:**

- requiring Medicare plan sponsors implement a hard edit triggered when a Medicare beneficiary reaches or exceeds 90 MME per day;
- requiring Medicare plan sponsors implement a soft edit when a Medicare beneficiary tries to fill what CMS calls "duplicative" long-acting opioid prescriptions; and
- adding a flag for gabapentin/pregabalin and opioid co-administration to OMS

These policies would burden, disrupt, and deny beneficiaries access to medically necessary drug regimens. Furthermore, these proposed steps would not improve patient safety, decrease risk of substance use disorder ("SUD"), or decrease morbidity and mortality from SUD.

## **A 90 MME Per Day Hard Edit Will Harm Patients And Is Arbitrary And Capricious**

In explaining its rationale for the 90 MME per day limit, CMS relies on the CDC Guidelines for Prescribing Opioids for Chronic Pain, writing in relevant part, "...the OMS criteria incorporate a 90 morphine milligram equivalent (MME) threshold cited in the CDC Guidelines, which was developed by experts as the level that prescribers should generally avoid reaching with their patients."

### **CMS is cherry-picking from the CDC Guidelines in an arbitrary and capricious manner.**

CMS misunderstands the CDC Guidelines in a way that runs counter to the evidence before it. In actual fact, Recommendation 5, the recommendation having to do with the 90 MME/day threshold, of the CDC Guidelines reads:

When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to  $\geq 50$  morphine milligram equivalents (MME)/day, and should avoid increasing dosage to  $\geq 90$  MME/day or carefully justify a decision to titrate dosage to  $\geq 90$  MME/day [emphasis added]

CMS does not account for the "or" that is plainly part of Recommendation 5. That failure to account for the alternative explicitly provided for in Recommendation 5 runs counter to the very evidence before CMS that the agency is citing as its rationale for the 90 MME threshold. CMS also ignores the overarching thrust of the guidelines; decisions relative to opioid analgesic therapy should be made on an individual basis, taking into account all of the clinically relevant factors that pertain to a particular patient. By imposing a one-size-fits-all rule on the basis of the CDC Guidelines, CMS is failing to consider an important aspect of the problem of safe prescribing and, in so doing, the agency's proposed actions would run counter to the evidence, i.e. the CDC Guidelines, it purports to rely upon.

### **CMS is ignoring other very important aspects of the problem.**

#### **Patient-to-patient variability and expert disagreement about conversion ratios**

On the record before the agency, CMS must be aware that the proposed 90 MME per day limit does not address patient-to-patient variability in opioid equianalgesic doses because expert Hospice and Palliative Medicine and Pain Management clinicians have submitted comments

raising the issue. Likewise, CMS must be aware that the proposed 90 MME per day limit does not address the difference of opinion among experts for conversion ratios between opioid analgesics. Both patient-to-patient variability and disputed conversion ratios are vital components of any 90 MME per day ban. First, the simple medical fact is that 90 MME will provide less pain relief to some patients than others, even holding all else constant. That is a vital fact to consider when imposing an arbitrary numerical cutoff. Second, the lack of expert consensus on conversion ratios between opioid analgesics means that confusion will be created in among clinicians as they attempt to comply with the agency's proposed dose cutoff. CMS has failed to even consider these vital aspects of setting a cutoff dosage, and how they might burden patients access to medically necessary medications.

**Cancer, hospice, palliative, and sickle cell patients are not protected**

CMS fails to protect cancer, hospice, palliative, sickle cell and other patients. On the record before the agency, CMS must be aware that sickle cell disease disproportionately impacts African-American patients. There is no mention of protecting sickle cell patients from the horrendous pain of a sickle cell crisis. This arbitrary and capricious disregard for sickle cell patients must not proceed.

Many of these patients, and others, are established on opioid therapy above 90 MME per day to good effect. CMS proposes a seven day window during which Medicare's denial of their claims can be dealt with. Seven days is wholly inadequate to resolve prior authorization issues. Abrupt discontinuation is incredibly dangerous and must not be allowed to occur. Physicians, pharmacists, and plan sponsors will be overwhelmed with administrative work to clear those patients who need 90 MME per day or more. Furthermore, as CMS admits, plan sponsors have failed to adequately protect patients with regard to medically necessary opioid prescriptions. CMS failing to address that important aspect of the problem is, again, arbitrary and capricious.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Matt BC".

Matthew B. Cortland, Esq.