March 3, 2017

Dear Acting Director Tudor:

As health professionals, we write to register strong objection to opioid-related provisions of the CMS Advance Notice of February 1, 2017, concerning Medicare Part C and D pharmacy benefit plans. We believe these changes misconstrue the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain, which some of us helped to develop. As a result, these changes pose serious risks to some patients who currently receive opioids. All persons signing this letter are physicians, or doctoral-level clinicians. Many of us are clinicians with expertise in addiction medicine (signified "A" next to signature), or pain medicine ("P"). Persons among us who assisted the Centers for Disease Control and Prevention (CDC) in developing or reviewing the Guideline are designated "C". All of us share a commitment to promoting safety with regard to opioids, to enhancing access to addiction treatment, and to caring humanely for patients with pain.

Our understanding of the CMS plan is guided by review of the Advance notice pages 145 to 150, supplemented by additional Q&A with CMS, personal observation of the environment of care for patients with chronic pain, and participation in a wide range of institutional initiatives focused on promoting opioid safety.

Our strong suggestion is that CMS not advance this initiative at this time, and that CMS carefully revisit the premises upon which this plan was developed. While CMS has avowed its intention to "align with" the 2016 CDC Guideline, many of many of the actions proposed in the Advance Notice undermine aspects of the Guideline and could pose a threat to patients.

Mechanisms proposed by CMS emphasize payer-mandated opioid dosage controls, using both hard and soft edits at the point of sale. A hard edit (recommended for 200 MME) means that a patient's prescription will not be filled unless a successful prior authorization takes place between payer, pharmacist and doctor. A soft edit could, in principle, be overridden by a pharmacist. However, the criteria for such overrides are unknown and many payers have elected to impose hard edits as a way of staying one step ahead of CMS policy. Mechanisms for overcoming payment denial are often adversarial, and subject to delay.

Broadly, these payer controls are at odds with the underlying purpose of a Guideline, which the CDC's Dr. Debra Houry described as "not a rule, regulation or a law…It is not intended to take away physician discretion or decision-making." The Guideline sought to provide clinical guidance for physicians making individualized clinical decisions. Emphasis on individualized assessment of risk and benefit is key to understanding CDC Guideline Recommendations 1, 2 and 3. The past year has shown that payer-based controls can undermine individualized decision making, with Pharmacy Benefits Plans acting in ways that stymie patient-centered care.

These concerns may translate into a risk to patients who currently receive opioids for pain, particularly patients who are stable on doses above the thresholds of 90 or 200 Morphine Milligrams Equivalent (MME). The CMS plan will accelerate a widely-reported pattern of involuntary dose tapering or termination. Denials and adversarial challenges by Pharmacy Benefit Plans, in service of CMS policy, tend to force inexpert clinicians to enact involuntary opioid termination or tapering on otherwise-stable patients. As a commercial pharmacist with a primary pain/addiction practice wrote to one of us "I have seen many patients similar to the ones you have posted about forced to taper (because the insurance will deny the PA and appeal and only approve x dose of opioid). The patient goes from working and having a quality of life to being bed ridden and suffering in pain. It is horrible what is happening to pain patients as the pendulum is swinging."

Nowhere in the CDC Guideline did CDC experts suggest that patients be "forced to taper", even though the Guideline recommended caution in regard to key dosage thresholds. While some small studies do report favorable outcomes from voluntary opioid tapers carried out by experts, there exist no data to justify involuntary dose tapering carried out by clinicians lacking expertise. And worse, there are a rising number of reports of patient harms, including suicide and death (summarized here).

All of us signing this letter understand that Prior Authorization mechanisms are frequently slow, adversarial and problematic. In the extreme, CMS mandates will cause previously stable patients to suffer acute withdrawal with or without medical complications, including death, as reported in a recent issue of JAMA. This chain of events would be the result of CMS initiatives that we believe are in tension with the spirit and the letter of the CDC Guideline.

Finally we note that there is no plan from CMS, either in its Advance Notice or in its 2017 Opioid Strategy to take the action recommended by the Opioid Guideline Workgroup convened to advise CDC's Board of Scientific Counselors. That Workgroup recommended that implementation of the CDC Guideline be monitored for "unintended consequences." Despite the array of anecdotal reports of adverse effects, a plan for systematic monitoring does not appear in the CMS Opioid Misuse Strategy of January, 2017. A recently-published commentary noted that one failure of the Joint Commission's Pain as a Fifth Vital Sign campaign was a failure to track adverse effects of an initiative derived from excess enthusiasm and weak data. We urge CMS not to repeat this error. People's lives are in the balance.

With this letter we speak as professionals. We urge you not to advance this initiative at this time, and to carefully revisit the premises upon which this CMS plan was built.

This letter includes 83 signatories. Four had formal roles assisting the Centers for Disease Control and Prevention in development of the 2016 CDC Guideline; 60 hold academic appointments. Most have expertise in addiction or pain. **Disclaimer:** Views expressed here are those of the signers alone, and do not represent formal positions of any employing or affiliated organization, university, or United States Federal Agency. Names were collected individually by Dr. Stefan G. Kertesz, MD, MSc.

(A): Addiction Professional
(P): Pain Professional
(C): Assisted the CDC in Opioid Guideline Development as Reviewer, Core Expert, or Author

Names of signatories are withheld as Dr. Kertesz did not obtain permission from the signatories to release them. The government may choose to release all received comments at its discretion.