

October 11, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma:

On behalf of the Protecting Access to Pain Relief (PAPR) Coalition, please find written comments in response to the Request for Information (RFI) entitled “Request for Information for the Development of a CMS Action Plan to Prevent Opioid Addiction and Enhance Access to Medication-Assisted Treatment.” The PAPR Coalition is a multi-stakeholder group of 17 public health organizations whose mission is to support continued access to and choice of appropriate over-the-counter (OTC) pain relief, including acetaminophen, as part of a patient’s comprehensive pain management plan, including for use as alternatives to opioids (www.paprcoalition.com). Collectively, our Coalition reaches millions of healthcare professionals, people living with pain, patients managing chronic disease, and concerned citizens. Our combined communications and engagement platforms have proven to be a powerful resource with the demonstrated capacity to educate and mobilize Americans on complex and timely public health issues.

Currently, chronic pain affects an estimated 50 million U.S. adults, and as many as 19.6 million of those adults experience high-impact chronic pain that interferes with daily life or work activities.¹ Because of its near ubiquity nationwide, pain presents a significant public health problem in the U.S. An Institute of Medicine report found that pain costs our society at least \$560-\$635 billion annually (equal to about \$2,000 per person) in lost wages and compensation for disability days.² In addition, the costs of care associated with chronic pain, which include diagnostic tests, physical therapy, medications, and medication management, can be extremely burdensome on both patients and the healthcare system as a whole. A 2015 study of a large U.S. health integrated delivery system indicated that treating chronic pain costs approximately \$32,000 per patient per year, with an annual average of nearly 19 outpatient visits and five imaging tests per patient.³

We agree with the statement by HHS Secretary Alex Azar and Assistant Secretary Adm. Brett Giroir that “[A]s we combat the opioid crisis, we cannot forget that pain is a real problem... We

¹ Dahlhamer J. et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults - United States, 2016. *Morbidity and Mortality Weekly Report (MMWR)*. 2018; 67(36):1001-1006.

² Institute of Medicine Report from the Committee on Advancing Pain Research, Care, and Education: *Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education and Research*. The National Academies Press, 2011.

³ Park PW et al. Cost burden of chronic pain patients in a large integrated delivery system in the United States. *Pain Practice*. November 2016; 16(8):1001-1011.

must do a better job of securing for them safe, effective options for managing pain.”⁴ Recent research has shown that non-opioid pharmacologic alternatives have been shown to be as effective, if not more effective, than opioids in treating chronic pain over time.⁵ The Coalition believes policy makers should take additional steps to educate health care providers and patients about the important role of OTC pain medication as part of a safe and responsible pain management plan.

OTC pain relief – including use of acetaminophen – is often a medically necessary and cost effective way for patients to manage pain. In addition to lower costs, for many patients, such as those suffering from osteoporosis and end stage renal disease, OTC pain relief represents the safest medically recommended means of alleviating pain. It is important for Americans to have access to and choice of the appropriate OTC pain relief to match their pain profile and comorbidities.

Moreover, while we know that there are numerous safe and effective pharmacologic – including OTC medicines – and non-pharmacologic pain relief options on the market and available to patients, the incorporation of these therapies into a comprehensive pain management policy is not universal. In fact, comprehensive training in the development and execution of pain management plans for patients is frequently left out of graduate medical education curricula and current practice.⁶ In large part, these issues stem from inconsistent and disparate federal guidelines for pain management despite a large body of evidence that can inform a series universal best practices within the U.S. health care system. The Centers for Medicare and Medicaid Services (CMS) can have a wide-ranging influence on how Americans seek treatment for pain, and has the ability to serve in both a policy development and educational roles for millions of Americans that utilize the Medicare and Medicaid programs.

In general, the PAPER Coalition is supportive of payment schemes that increase access to safe and effective pain management alternatives, especially structures that promote equity for coverage of nonopioid alternatives to pain relief for the patients that need them. This includes coverage options that maximize the ability of physicians and non-physicians providers, such as nurse practitioners, physician assistants, pharmacists, etc., to provide comprehensive pain management to the patients that need them and for out-of-pocket expense for the patient to be negligible or free. These policies should apply to both pharmacologic and non-pharmacologic OTC medications in order to present patients with a full array of options that provide safe and effective alternatives to opioid medications, especially for chronic pain patients.

CMS is in a unique position to be able to further education and outreach given the expanse of its payment programs to millions of individuals across all 50 states. In addition, we encourage CMS to collect and disseminate data regarding chronic pain in patients so that targeted resources may

⁴ Azar A and BP Giroir. While fighting the opioid epidemic, don't forget those who are suffering from pain. Department of Health and Human Services. 1 June 2018. <https://www.hhs.gov/blog/2018/06/01/dont-forget-those-who-are-suffering-from-pain.html>.

⁵ Krebs EE et al. Effect opioid vs. nonopioid medications on pain-related function in patients with chronic back pain or hip or knee osteoarthritis pain: The SPACE randomized clinical trial. *Journal of the American Medical Association*. 2018; 319(9):872-882.

⁶ Mezei L and BB Murinson. Pain education in North American medical schools. *J Pain*. December 2011; 12(12):1199-1208.

be developed that are targeted to special populations, including and especially those suffering from nonneuropathic, noncancer pain. The PAPR Coalition was an active stakeholder of HHS' Pain Management Best Practices Inter-Agency Task Force and appreciated the federal government's efforts to coordinate activities to deliver a comprehensive set of federal best practices to agencies, healthcare professionals, and patients alike. The Coalition supports the continuation of federal coordination on these issues and encourages CMS to coordinate with other agencies within and outside of HHS to ensure that barriers, including payment barriers, are removed so that patients have access to and choice of safe and effective pharmacologic and nonpharmacologic pain relief options appropriate for their condition.

The PAPR Coalition collectively has numerous resources for educating patients about the safe use of medications for the treatment of pain and engages numerous populations, including the aged, in ways to utilize nonopioid alternatives, both pharmacologic and nonpharmacologic, to treat chronic pain. We look forward to serving as a partner to the agency as it develops new outreach mechanisms to Medicare and Medicaid enrollees regarding safe and effective pain management.

Thank you for your attention to these important issues and for your work to fulfill the intent of the *SUPPORT Act*. Should you have any questions about this submission, please contact me (michael.werner@hklaw.com) or Joel Roberson (joel.roberson@hklaw.com).

Sincerely,



Michael Werner

On Behalf of the PAPR Coalition