



April 24, 2020

Virginia Mackay-Smith
Acting Director
Center for Delivery, Organization and Markets
Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857

Dear Acting Director Mackay-Smith:

On behalf of the Protecting Access to Pain Relief (PAPR) Coalition, please find written comments in response to the Request for Information (RFI) related to the Agency for Healthcare Research and Quality (AHRQ)'s "Opioid Management in Older Adults" project. The PAPR Coalition is a multi-stakeholder group of 18 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. The Coalition is strongly supportive of efforts to increase knowledge and resources around pain management for older Americans, including through developing comprehensive graduate medical education on pain management, encouraging the development of a multi-disciplinary approach to pain management utilizing non-opioid alternatives where appropriate, expanding payment schemes to improve access to appropriate pain management options, increasing research into novel pain management practices, and encouraging additional federal coordination on pain management policies.

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

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.

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 Department of Health and Human Services (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 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 healthcare providers and patients, especially those in older populations, 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 older adult 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 of universal best practices within the U.S. healthcare system. HHS, as well as other federal healthcare agencies, 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 role for millions of older Americans that utilize, among others, the Medicare and Medicaid programs. The PAPR Coalition supports additional efforts for HHS to work with stakeholders in the medical

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.

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.

community to develop continuing medical education and other tools to ensure that health practitioners across the nation are comfortable consulting with their patients about their comprehensive and tailored pain management plans.

The PAPR Coalition strongly supports the use of a multidisciplinary approach that utilizes non-opioid alternatives such as OTC analgesics in older populations. The use of non-opioid alternatives in this population expands access and lowers barriers to safe and effective pain relief by potentially reducing physician office visits in between regular and necessary evaluations. Further, the use of non-opioid alternatives is crucial for this population, which is frequently more susceptible to both respiratory depression and reduced medication clearance related to decreased renal function. Finally, educational materials should be tailored to this population to enhance the safe use of OTC pain relief options, which includes ensuring comprehension of safe-use information for these pain relief options to maximize both safety and treatment effectiveness. This is particularly true considering that many patients may be limited in their choice of OTC pain relief alternatives. For example, millions of Americans, including older patients, are contraindicated for non-steroidal anti-inflammatory drugs (NSAIDs) and thus require additional education on other pharmacologic alternatives, such as acetaminophen, or non-pharmacologic alternatives.

The PAPR Coalition is also supportive of payment schemes in the Medicare, Medicaid, and commercial payment programs that increase access to safe and effective pain management alternatives, especially structures that promote equity for coverage of non-opioid alternatives to pain relief for the patients that need them. This includes coverage options that maximize the ability of physicians and non-physician providers, such as nurse practitioners, physician assistants, pharmacists, etc., to provide comprehensive pain management to the patients that need them, especially considering the wide range of caregivers providing treatment and care to older populations, and for out-of-pocket expense for the patient to be negligible or free. These policies should apply to both pharmacologic OTC medications and non-pharmacologic alternatives 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.

The PAPR Coalition also encourages HHS and others to collect and disseminate data regarding chronic pain in patients so that specific resources may be developed that are targeted to special populations, including and especially older populations, suffering from non-neuropathic, non-cancer pain. This includes making investments in additional research to generate data on novel pain management options. For instance, there have been recent calls for data and research on new approaches combining both pharmacologic and non-pharmacologic – rehabilitation or exercise – pain management interventions that could be successful in managing pain in older populations.⁷ Additional research in this and other promising approaches is needed to inform guidelines that are easily interpreted by older populations.

Finally, 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

⁷ Federal Pain Research Strategy. Interagency Pain Research Coordinating Committee. National Institutes of Health. 12 Dec. 2018.
https://www.iprcc.nih.gov/sites/default/files/iprcc/FPRS_Research_Recommendations_Final_508C.pdf.

activities to deliver a comprehensive set of evidence-based federal best practices to agencies, healthcare professionals, and patients alike. The Coalition supports the continuation of federal coordination on these issues and encourages other agencies within and outside of HHS to ensure that barriers are removed so that older patients have access to and choice of safe and effective pharmacologic and non-pharmacologic 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 those over the age of 65, in ways to utilize non-opioid alternatives, both pharmacologic and non-pharmacologic, to treat chronic pain. We look forward to serving as a partner to AHRQ as it develops new outreach mechanisms regarding safe and effective pain management.

Thank you for your attention to these important issues. Should you have any questions about this submission, please contact me (michael.werner@hklaw.com) or Joel Roberson (joel.roberson@hklaw.com).

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Werner".

Michael Werner

On Behalf of the PAPR Coalition