

November 12, 2019

Suchitra Iyer, PhD
Task Order Officer
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Iyer:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I write to provide brief comments on the *Draft Comparative Effectiveness Review*, “Opioid Treatments for Chronic Pain,” that was prepared for the Agency for Healthcare Research and Quality (AHRQ) of the U.S. Department of Health and Human Services (HHS). The AMA has two key comments on this review:

- **The AMA urges the AHRQ to clarify that the review does not support a conclusion that the epidemic of opioid-related overdose deaths is due to efforts to treat patients with chronic pain or cancer pain, or to manage pain for patients receiving hospice or palliative care.**
- **The AMA further urges the AHRQ to clarify that this review should not be used to justify or support reductions in opioid therapy for patients with acute, chronic, palliative, cancer-related or other pain when clinically indicated by the patient’s physician.**

Perhaps one of the most important passages in the report comes at the beginning in stressing that there is no substitute for individual clinical decision-making to support patients.

“This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by *individual patients*.” (emphasis added)

The HHS Pain Management Best Practices Interagency Task Force¹ has strongly recommended that patients experiencing pain need to be treated as individuals, not according to one-size-fits-all algorithms

¹ “The Task Force emphasizes the importance of individualized patient-centered care in the diagnosis and treatment of acute and chronic pain.” U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website: <https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html>

and policies that do not take individual patient's needs into account. A similar statement was made by the U.S. Centers for Disease Control and Prevention (CDC) in 2016 when it published its "CDC Guideline for Prescribing Opioids for Chronic Pain" (CDC Guideline). In that guideline, the authors plainly stated that:

The recommendations in the guideline are voluntary, rather than prescriptive standards. They are based on emerging evidence, including observational studies or randomized clinical trials with notable limitations. Clinicians should consider the circumstances and *unique needs of each patient* when providing care."² (emphasis added)

Yet, the CDC Guideline also included multiple arbitrary dosage and quantity recommendations that were consistently misapplied by state legislatures, national pharmacy chains, pharmacy benefit management companies, health insurance companies and federal agencies. The AMA warned³ that the arbitrary opioid analgesic dosage and quantity thresholds appearing in the CDC Guideline would cause unintended consequences when used to severely limit individual treatment decisions made by physicians. These unintended consequences, unfortunately, harmed many patients⁴—so much so that the CDC authors⁵ and HHS this year issued long-overdue, but greatly appreciated, clarifications that states should not use the CDC Guideline to implement an arbitrary threshold:

Unfortunately, some policies and practices purportedly derived from the guideline have in fact been inconsistent with, and often go beyond, its recommendations. A consensus panel has highlighted these inconsistencies, which include inflexible application of recommended dosage and duration thresholds and policies that encourage hard limits and abrupt tapering of drug dosages, resulting in sudden opioid discontinuation or dismissal of patients from a physician's practice. The panel also noted the potential for misapplication of the recommendations to populations outside the scope of the guideline. Such misapplication has been reported for patients with pain associated with cancer, surgical procedures, or acute sickle cell crises. There have also been reports of misapplication of the guideline's dosage thresholds to opioid agonists for treatment of opioid use disorder. Such actions are likely to result in harm to patients.

The AMA welcomed this clarification, and we are concerned that the AHRQ review may have similar unintended consequences, causing some to blame the treatment of chronic pain with opioid therapy for the increase in rates of opioid use disorder and opioid-related mortality. While the AMA does not dispute that opioid analgesic prescribing increased in the United States until approximately 2011-2012, it is not clear that rates of opioid use disorder or opioid-related mortality among chronic pain patients followed a similar trend. Furthermore, as opioid analgesic prescribing has decreased by one-third between 2013-2018, rates of opioid-related mortality have

² Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. *MMWR Recomm Rep* 2016;65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>

³ AMA Press release, AMA responds to CDC guidelines on opioids. March 15, 2016. Available at <https://www.ama-assn.org/press-center/press-releases/ama-responds-cdc-guidelines-opioids>

⁴ Beth D Darnall, David Juurlink, Robert D Kerns, Sean Mackey, et al., International Stakeholder Community of Pain Experts and Leaders Call for an Urgent Action on Forced Opioid Tapering, *Pain Medicine*, Volume 20, Issue 3, March 2019, Pages 429–433, <https://doi.org/10.1093/pm/pny228>

⁵ Deborah Dowell, M.D., M.P.H., Tamara Haegerich, Ph.D., Roger Chou, M.D. No Shortcuts to Safer Opioid Prescribing. June 13, 2019. *N Engl J Med* 2019; 380:2285-2287. DOI: 10.1056/NEJMp1904190.

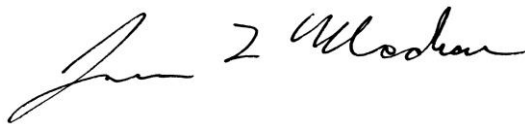
increased. Moreover, the causes of opioid-related mortality have largely shifted from opioid analgesics that may be prescribed for valid medical reasons to illegal fentanyl, fentanyl analogs and heroin.

For this reason, the AMA urges AHRQ to clarify that its report did not find that medical treatment of patients with chronic or cancer pain with prescription opioid analgesics caused the epidemic of opioid-related mortality. The AMA further urges the AHRQ to clarify that this review should not be used to justify or support reductions in opioid therapy for patients with acute, chronic, palliative, cancer-related or other pain when clinically indicated by the patient's physician.

A final suggestion is to increase the transparency about who was consulted in drafting the report. We acknowledge that AHRQ will publish the list of key informants, technical experts and peer reviewers in the final report. Waiting until the final report, however, potentially raises questions that could have been addressed—and answered—by full disclosure during this comment period. We appreciate that there are criteria for disclosing conflicts, but we would suggest that AHRQ publish the list of all those involved in any aspect of the report during the comment period to help remove any perception of potential conflict.

Thank you for your consideration of our concerns. If you have any questions, please contact Margaret Garikes, Vice President, Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD