April 11, 2022

Rochelle P. Walensky, MD, MPH Director Centers for Disease Control and Prevention 4770 Buford Highway NE Mailstop S106-9 Atlanta, GA 30341

Attn: Docket No. CDC-2022-0024

Dear Dr. Walensky:

On behalf of the more than 168,000 osteopathic physicians (DOs) and osteopathic medical students represented by the American Osteopathic Association and undersigned specialty and state osteopathic associations and the patients they serve, we write to express our appreciation for the work of the Centers for Disease Control and Prevention (CDC) to develop new opioid prescribing guidelines that will improve how patients' pain is treated and address the misuse and abuse of opioids. These comments are submitted to help build upon the CDC's efforts and further improve patient care.

DOs take a "whole-person" approach to patient care by focusing on prevention and care coordination as keys to maintaining health. This is demonstrated in all specialties and practice settings, including when caring for patients' pain. Based on this perspective, our organizations appreciate the more individualized, patient-centered approach taken in the proposed 2022 guidelines.

While we support many of the changes and recommendations in the proposed 2022 guidelines, we ask the CDC to rescind the 2016 prescribing guidelines and issue the 2022 guidelines as new rather than as an update. This approach is needed based on how the 2016 guidelines were interpreted and used. It has been widely documented that there was variation in how the CDC's 2016 guidelines were interpreted, with some states, licensing boards, and pharmacists often misapplying those guidelines to the detriment of patients and their clinicians.

According to the National Conference of State Legislatures, 33 states had enacted legislation with some type of limit, guidance or requirement related to opioid prescribing by October 2018.¹ Using the 2016 CDC guidelines, states codified in statute the number of days an opioid prescription could be filled for. A seven-day limit is most common, with six states limiting prescriptions to five days or less. Some states also set dosage limits (morphine milligram equivalents, or MMEs). This had a negative impact on patients and their clinicians and harmed patient access to adequate pain management. As a result, over the past several years, physicians

¹ <u>Prescribing Policies: States Confront Opioid Overdose Epidemic.</u> <u>https://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx</u>

have been flagged and excluded from national pharmacy programs, and even investigated and sanctioned by licensing boards simply based on arbitrary dosage limits.

Our organizations also want to express our strong support for the removal of arbitrary MME dosage thresholds from the guidelines. However, we disagree with the distinction made in Recommendations #1 and #2 between acute and chronic pain. Treating clinicians should consider the risks and benefits of opioid therapy regardless of whether a patient's pain is acute or chronic. The distinction between whether pain is acute or chronic does not account for the severity of the pain or other factors that need to be factored in as part of patient-centered medical decision-making.

We recognize that the pathophysiology of acute and chronic pain is different and that opioids are lower on the list of safe treatment options. However, patients suffering from chronic pain should have their pain effectively managed just as someone with acute pain from a fracture or kidney stone should. In some instances, the recommendations seem vague and ambiguous; at other points, the language on acute and chronic pain comes across as redundant or even contradictory. We ask that they be edited appropriately to provide greater clarity to patients and prescribers.

We are also strongly supportive of the CDC's recognition of the role of nonpharmacologic and integrative therapies in treating pain and acknowledging limitations on insurance coverage in recommendation #1. It is important to highlight the beneficial role that improved access to nonpharmacologic treatment modalities has in reducing the use of opioids while managing patients' pain. However, greater emphasis on addressing the need to remove barriers to patient access to evidence-based treatments is needed.

For example, osteopathic manipulative treatment (OMT), uniquely offered by osteopathic physicians, has been shown in numerous studies to provide significant relief to patients experiencing chronic low back pain. A systematic review of literature on the use of OMT to treat chronic and acute nonspecific low back pain published in 2014 found that patients experienced both pain relief and functional improvement following treatment with OMT². Prior to the analysis published in 2014, a systematic review of randomized control trials conducted by Licciardone et al. similarly found that OMT significantly reduced low back pain in trials of OMT compared to active treatment or placebo control, and OMT compared to no treatment control³. Despite evidence demonstrating the efficacy of OMT, there are significant gaps in coverage and payment for these services. We ask that the CDC include a recommendation supporting coverage for OMT and other nonpharmacologic treatments that improve access to pain care and reduce reliance on opioids and other pharmacologic treatments.

As noted above, DOs take a whole-person approach to patient care. Whether relating to the risk of addiction posed by opioids, the challenges patients have coping with chronic pain, or preexisting behavioral or substance use diagnoses that patients may have, collaborative care improves patient outcomes by increasing access to behavioral and mental health, and substance use disorder treatment. The CDC's 2022 prescribing guidelines should encourage the use of

³ Licciardone et al. "Osteopathic manipulative treatment for low back pain: a systematic review and meta-analysis of randomized controlled trials." BMC Musculoskeletal Disord. 2005; 6: 43. Published online 2005 Aug 4.

² Franke et al. "Osteopathic manipulative treatment for nonspecific low back pain: a systematic review and metaanalysis". BMC Musculoskelet Disord. 2014 Aug 30;15:286.

collaborative care and other evidence-based models of integrative care to help facilitate care for patients with overlapping diagnoses. These models also include provider directed medical care (PDMC) for complex cases, telemedicine, and remote patient monitoring (RPM).

Additionally, it is important to note that while many states enacted legislation based on the 2016 CDC guidelines that set arbitrary prescribing limits for opioids, there was no corresponding effort to promote or facilitate medication-assisted-treatment (MAT), such as buprenorphine and methadone. In fact, physicians in some states have reported that prescribing MAT can result in a physician being flagged by a state's prescription drug monitoring program (PDMP) as potentially demonstrating problematic prescribing patterns.

The 2016 guidelines negatively affected all layers of the U.S. healthcare system. Misinterpretation and misapplication have occurred across all sectors, and interprofessional relationships have been strained. One example of this is the way some pharmacists have misinterpreted and misused the 2016 CDC guidelines, which has hindered patient adherence to treatment plans. There are examples of both corporate decisions impacting pharmacy practices as well as individual pharmacists denying patient prescriptions not just for pain medication, but also for buprenorphine based on PDMP or non-specific concerns. These pharmacy practices harm patients' pain treatment as well as those patients being treated for opioid use disorder (OUD).

Countless patients and physicians have been burdened by erroneous denials of service based on misguided interpretations of the 2016 guidelines. While diversions have been down, overdoses have gone up. The 2022 guidelines need to address the misuse of the 2016 guidelines serving as the basis for denials of service to patients in need of treatment.

The elimination of arbitrary prescribing caps in the 2022 guidelines will help address some of these issues, but further action is needed. This issue is another example of why the 2016 guidelines should be rescinded, and not just updated. Additionally, these issues show why education and guidance for pharmacists is also important. Pharmacists must be trained not just to look for signs of diversion or other abuses, but also to avoid stigmatizing patients being treated for pain or OUD.

Our organizations are grateful for the thoughtful approach taken by the CDC on the 2022 opioid prescribing guidelines and appreciates the opportunity to submit comments. We look forward to working collaboratively to disseminate information on the final guidelines and improve opioid prescribing and pain care for patients.

Sincerely,

American Osteopathic Association

American Academy of Osteopathy

American College of Osteopathic Internists

American College of Osteopathic Neurologists and Psychiatrists

American College of Osteopathic Obstetricians and Gynecologists

American Osteopathic Academy of Addiction Medicine

American Osteopathic Association of Physical Medicine and Rehabilitation

American Osteopathic College of Anesthesiologists

Connecticut Osteopathic Medical Society

Florida Osteopathic Medical Association

Georgia Osteopathic Medical Association

Illinois Osteopathic Medical Society

Indiana Osteopathic Association

Iowa Osteopathic Medical Society

Louisiana Osteopathic Medical Association

Massachusetts Osteopathic Society

Michigan Osteopathic Association

Minnesota Osteopathic Medical Society

Missouri Association of Osteopathic Physicians and Surgeons

North Carolina Osteopathic Medical Association

Ohio Osteopathic Association

Osteopathic Physicians and Surgeons of Oregon

Rhode Island Society of Osteopathic Physicians and Surgeons

Tennessee Osteopathic Medical Association

Texas Osteopathic Medical Association

Virginia Osteopathic Medical Association

Washington Osteopathic Medical Association