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[Submitted electronically via www.regulations.gov and opioids@cdc.gov]

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National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway NE
Mailstop S106-9
Atlanta, GA 30341

Attn: Docket No. CDC-2022-0024

RE: Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids

Dear Ms. Greenspan:

The American Pharmacists Association (APhA) is pleased to submit our comments to the Centers for Disease Control and Prevention (CDC) in strong support of the proposed opioid prescribing guideline titled Clinical Practice Guideline for Prescribing Opioids, published in the Federal Register on February 10, 2022 (87 FR 7838).

Founded in 1852, APhA is the largest association of pharmacists in the United States representing the entire pharmacy profession. APhA members practice in community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

Pharmacists are important providers on the patient's health care team and play a critical role in the use of medications for the treatment of acute, subacute, and chronic pain in the following situations, among others:

- Caring for patients with acute, subacute, and chronic pain, and/or substance use disorder (SUD) and opioid use disorder (OUD) including prescribing medications, as authorized;
- Providing medication management services, including opioid tapering services;

- Dispensing, and educating patients about opioid and non-opioid pain medications, including risks and safe storage and disposal;
- Educating patients about nonpharmacologic therapies;
- Aiding in harm reduction efforts by furnishing the opioid overdose reversal agent naloxone; and
- Participating in syringe services programs (SSPs), including providing non-prescription sterile syringes (NPSS) to people who inject drugs (PWID) in order to prevent the transmission of bloodborne pathogens such as HIV and hepatitis C virus (HCV).

Accordingly, APhA was pleased to see CDC's proposed clinical practice guideline for prescribing opioids, an update to the *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*. From the addition of “clinical practice guideline,” in the title to the expanded focus on acute, subacute, and chronic pain, the 2022 proposed guideline effectively promotes an individualized, person-centered approach to pain management that centers on shared decision-making between the patient, family, and caregivers and the clinicians on the patient's team. While the 2016 opioid prescribing guideline was well-intentioned, dosage thresholds from its recommendations were incorporated into laws, regulations, and policies that resulted in unintended consequences for patients, such as inappropriate tapering, patient abandonment, and other care access issues.¹ APhA commends CDC on the thorough process used in the guideline update, as well as the clarity of purpose and practical information provided for clinicians.

APhA's comments on the proposed guideline were informed by input from practicing pharmacist members involved in the delivery of pain management services and dispensing of opioid prescriptions, including feedback received during two sessions at APhA's recent Annual Meeting in San Antonio, TX. APhA submits the following comments for consideration:

Overarching Comments:

- APhA appreciates the tone and balance of the proposed guideline and supports its strong emphasis on effective individualized pain care provided by primary care clinicians focused on goals for pain, function, and quality of life. The clarity and emphasis regarding what the proposed guideline “is” (a clinical tool for clinicians), and what it “is not” (e.g., an inflexible standard of care or applicable to sickle cell disease

¹ Dowell, D., Haegerich, T., & Chou, R. (2019). No Shortcuts to Safer Opioid Prescribing. *N Engl J Med*, 380(24), 2285-2287. doi:10.1056/NEJMp1904190

related pain, cancer pain, palliative care or end of life care) will be helpful in application of the guideline once released.

- APhA supports the expanded scope of the proposed guideline to include acute, subacute, and chronic pain. By presenting guidelines for the treatment of pain across the spectrum, including the use of opioids, clinicians are provided a more holistic view of various treatment and management options, including considerations for managing risks of opioids and other therapies.

5 Guiding Principles to Inform Implementation of the Proposed Guideline

The proposed guideline includes five guiding principles to be applied in the implementation of the guideline. APhA supports the addition of these five principles and encourages CDC to promote them broadly, as they provide a strong foundation for effective pain care and are likely to help in avoiding misapplication of the guideline.

1. Acute, subacute, and chronic pain need to be appropriately and effectively treated independent of whether opioids are part of a treatment regimen.
2. Recommendations are voluntary and are intended to support, not supplant, individualized, person-centered care. Flexibility to meet the care needs and the clinical circumstances of a specific patient are paramount.
3. A multimodal and multidisciplinary approach to pain management attending to the physical health, behavioral health, long-term services and supports, and expected health outcomes and well-being needs of each person is critical.
4. Special attention should be given to avoid misapplying this updated clinical practice guideline beyond its intended use or implementing policies purportedly derived from it that might lead to unintended consequences for patients.
5. Clinicians, practices, health systems, and payers should vigilantly attend to health inequities, provide culturally and linguistically appropriate communication, and ensure access to an appropriate, affordable, diversified, coordinated, and effective nonpharmacologic and pharmacologic pain management regimen for all persons.

Principle #3:

APhA supports the multimodal, multidisciplinary approach to pain management featured in this principle and the 12 recommendations. As stated throughout the proposed guideline, there are many barriers to a multimodal, multidisciplinary pain care approach including access to providers and services, and lack of coverage and payment for those services. APhA members expressed concerns that until these barriers are effectively addressed, it will be difficult to achieve widespread access to multimodal, multidisciplinary pain care. APhA encourages CDC to collaborate with other agencies, including the Centers for Medicare and Medicaid Services (CMS), and external stakeholders to provide evidence-based information and highlight gaps in access to care and coverage in an effort to mainstream multimodal, multidisciplinary pain care services.

Principle #5:

APhA is very encouraged to see the important focus on health equity and social determinants of health, including a focus on addressing stigma, in this principle and throughout the guideline. Pharmacists are highly accessible providers who are well-positioned to contribute expertise and needed services, aligned with this proposed guideline, in underserved and disadvantaged communities.

CDC recommendations for prescribing opioids for outpatients with pain outside of sickle cell disease-related pain management, cancer pain treatment, palliative care, and end-of-life care

The proposed guideline contains 12 recommendations grouped into four areas:

- 1) Determining whether or not to initiate opioids for pain;
- 2) Opioid selection and dosage;
- 3) Opioid duration and follow-up; and
- 4) Assessing risk and addressing potential harms of opioid use.

APhA received positive feedback from our members on the organization of the guideline, including the four areas under which the recommendations were placed. The addition of implementation considerations for each recommendation is appreciated and supported. The following comments are focused on the recommendations in the proposed guideline:

Recommendation #4, page 98:

APhA strongly supports the removal of dosage and duration thresholds at the recommendation level, and the placement of these thresholds as benchmarks in the supporting text with clarifying language to guide clinical decision-making.

As stated earlier, opioid dosage and duration thresholds have been incorporated into laws, regulations, and policies that may be difficult to reverse and have the potential to impact effective implementation of the proposed guideline. APhA's members have reported patients who have been abandoned by providers and experienced rapid tapering related to these laws, regulations, and policies. Our members have also experienced challenges in ordering and supplying medications based on morphine milligram equivalents (MME) restrictions. APhA has concerns that if laws, regulations, and policies focused on opioid dosage and duration thresholds are not changed, barriers to effective pain care will continue and urges CDC to engage in collaborative interagency, state, and health plan efforts to effect changes in alignment with the proposed guideline. A priority is working with the Drug Enforcement Administration (DEA) to view opioid use for pain through a different lens and address barriers to opioid pain treatments for those who need them. Actions could include issuing position statements that focus on optimized pain care while remaining in good standing with the law.

Recommendation #8, page 125, Implementation Considerations, lines 3031-33:

- *Naloxone co-prescribing can be facilitated by clinics or practices with resources to provide naloxone training and by collaborative practice models with pharmacists or through statewide protocols or standing orders for naloxone at pharmacies.*

APhA appreciates the recognition of pharmacists' roles in provision of the life-saving opioid overdose reversal agent, naloxone. Pharmacists' authority to furnish naloxone through pharmacies extends beyond standing orders to statewide protocols in many states. To reflect this, APhA recommends that this bullet be edited as indicated, **in red**, above.

Conclusion

Thank you for the opportunity to provide these comments in support of CDC's proposed Clinical Practice Guideline for Opioid Prescribing. Pharmacists play a vital role in providing pain management services in various healthcare settings, and can be further optimized in contributing to multimodal, multidisciplinary pain care. APhA looks forward to the release of the guideline and would welcome the opportunity to work with CDC on educational and informational resources for pharmacists. If you have any questions or require additional information, please contact me at ibernstein@aphanet.org or by phone at 202-429-7533.

Sincerely,



Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice and Government Affairs