



April 7, 2022

Rochelle P. Walensky, MD, MPH
Director
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road
Atlanta, GA 30329

Re: CDC-2022-0024; Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids

Dear Director Walensky:

On behalf of the American Academy of Family Physicians (AAFP), representing more than 127,600 family physicians and medical students across the country, I write in response to the notice “Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids” published in the February 10 edition of the [Federal Register](#).

Family physicians regularly treat patients with chronic pain and are required to balance care for chronic pain with the challenges of managing opioid use and dependence. These guidelines are one important resource for family physicians to ensure opioid prescribing practices adhere to evidence-based, clinically appropriate standards.

The AAFP is committed to addressing the dual public health crises of undertreated pain and opioid misuse at both the national and local levels. To this end, the AAFP has formed a cross-commission advisory committee to address the multiple issues involved. Through its efforts with other physician and medical organizations, as well as governmental entities, the AAFP is committed to being a leader in promoting the advancement of safe pain management and opioid prescribing, and in addressing the growing burden of opioid dependence. The AAFP is also an accredited continuing medical education (CME) provider and has offered several courses for family physicians on, appropriate prescribing and pain management.

We applaud the CDC’s efforts to update the opioid prescribing guidelines and address issues in the 2016 version. The 2016 guidelines contained overly prescriptive recommendations and did not include enough consideration of patients’ unique needs and the important role of shared decision making. Even though the guidelines were developed to guide clinician decision making, these prescriptive recommendations were inappropriately used by insurers, regulatory boards, pharmacy chains, hospital systems, and other stakeholders, which resulted in unintended consequences like abrupt tapering or discontinuation of opioids.¹ The 2016 guidelines also made physicians fearful of prescribing opioids which created barriers to effective pain management for patients. The AAFP is glad that the draft guidelines clarify that they are voluntary recommendations that should be taken into consideration along with the circumstances and unique needs of each patient. Given the AAFP’s

STRONG MEDICINE FOR AMERICA

President
Sterling Ransone, MD
Deltaville, VA

President-elect
Tochi Iroku-Malize, MD
Islip, NY

Board Chair
Ada Stewart, MD
Columbia, SC

Directors
Andrew Carroll, MD, *Chandler, AZ*
Steven Furr, MD, *Jackson, AL*
Teresa Lovins, MD, *Columbus, IN*
Jennifer Brull, MD, *Plainville, KS*
Mary Campagnolo, MD, *Borderstown, NJ*
Todd Shaffer, MD, *Lee’s Summit, MO*

Gail Guerrero-Tucker, MD, *Thatcher, AZ*
Sarah Nosal, MD, *New York, NY*
Karen Smith, MD, *Raeford, NC*
Samuel Mathis, MD (New Physician Member), *Galveston, TX*
Amanda Stisher, MD (Resident Member), *Owens Cross Roads, AL*
Amy Hoffman (Student Member), *State College, PA*

Speaker
Russell Kohl, MD
Stilwell, KS

Vice Speaker
Daron Gersch, MD
Avon, MN

Executive Vice President
R. Shawn Martin
Leawood, KS

commitment to ensuring appropriate opioid prescribing practices, we appreciate the opportunity to provide additional comments on the proposed guidelines.

General Comments

The AAFP understands that opioid prescribing can be complex. However, the length of the prescribing guidelines limits the utility of the document for practicing physicians. **The AAFP recommends reducing the amount of background information, particularly that which is out of scope for the guidelines or is reviewed elsewhere.** For example, discussion around the revision process could be addressed elsewhere and repetition about what is not included in the guidelines is not necessary. Streamlining the guidelines would make them more valuable for physicians.

Additionally, many physicians already follow the CDC's 2016 version of these guidelines. Given the length of the document, it would be helpful to highlight changes included in this version. This would help physicians readily adapt to changes in prescribing guidelines. Thus, we recommend the CDC include a chart or summary of the major changes in the final version of the guidelines.

Current evidence indicates that the majority of overdoses are caused by the use of illicitly manufactured fentanyl or other drugs. The guidelines should acknowledge this more explicitly in either the "Rationale" or "Scope and Audience" sections and make appropriate recommendations for screening and referral to treatment for non-opioid substance use disorder.

Finally, the AAFP appreciates that the CDC has highlighted how historically marginalized communities and individuals have lacked a range of pain management options due to bias and structural inequities. Lack of access to other treatment options and clinical and systemic bias has resulted in pain being differentially untreated or undertreated for different populations. This callout is critical to improving clinician understanding and awareness of historical and current inequities to ensure all patients receive appropriate care. The AAFP also applauds the CDC for inclusion of patients and consumers in the guideline development process and hopes to see continued engagement with patients and consumers in the future.

Methodology and Evidence Base

The "Methods to develop the recommendations" section describes the development of Category A and B recommendations and highlights the differences between both. Category A is not defined exclusively on the evidence-base but is primarily intended to indicate an option that is applicable to most patient populations. In contrast, Category B recommendations may or may not be applicable to different patient populations and require more shared decision making between physicians and patients. Specifically, the CDC calls out that Category A recommendations are justified despite low quality evidence because of the balance between benefits and harms.

While the AAFP recognizes that recommendations are ranked as Category A because they apply to most patient populations, we are concerned that these strong recommendations are based on low quality evidence, including data from limited clinical observations or expert opinion. **The AAFP recommends the CDC provide explicit rationale for the judgements on the balance of benefits and harms that resulted in the stronger recommendation.**

As currently written, category A recommendations with limited or low-quality evidence indicate "that most patients should receive the recommended course of action". In contrast, category B recommendations with comparable or higher-quality evidence indicate "different choices will be

appropriate for different patients, requiring clinicians to help patients arrive at a decision consistent with patient values and preferences and specific clinical situations.” The AAFP has concerns that the inconsistencies between A and B recommendations creates confusion and may weaken the category A recommendations. **The AAFP recommends the CDC more clearly distinguish between A and B recommendations based on the strength and quality of the supporting evidence, in addition to careful consideration of the benefits versus harms and use consistent language throughout the guidelines.**

Recommendations

As mentioned, the AAFP appreciates the CDC’s effort to address concerns from the 2016 iteration that resulted in unintended consequences and inappropriate use by insurers, regulatory boards, and other stakeholders. The proposed revisions clearly highlight the intended audience and voluntary nature of these guidelines. To further emphasize this point, the AAFP recommends reordering the principles so that the first principle is:

“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.”

The AAFP appreciates the CDC’s efforts to prevent insurers and regulators from inappropriately interpreting the guideline as recommending any specific limits on prescribing. **However, the AAFP remains concerned that citing a 50 MME per day dosage threshold – even outside of the main recommendation statement – will continue to enable payers and legislators to interfere with clinical decision making by using this threshold to set hard limits, despite organizations like the AAFP advising against such practices.** We recognize that the available evidence indicates there are diminished returns in patient benefit in dosages greater than 50 MME per day and that this is important information to share with physicians and other prescribers. To address these competing priorities, the AAFP recommends the CDC outline how it will engage policymakers and stakeholders to remove prescribing limits and thresholds in existing laws and coverage policies and prevent the implementation of harmful limits in the future. The AAFP further recommends that CDC clarify in the final guidelines that coverage of and access to naloxone should not be limited to patients with a prescribed dosage of more than 50 MME per day.

While toxicology testing is emphasized in both the 2016 and 2022 iterations, the AAFP is concerned by revisions in the proposed guidelines that offers conflicting guidance. The 2022 guidelines recommend that clinicians consider toxicology testing to assess for prescribed medications as well as other prescriptions and non-prescribed controlled substances. CDC also states that there is no evidence that evaluated “the effectiveness of toxicology screening for risk mitigation during opioid prescribing for pain”; that such testing should not be used to dismiss patients from care, that such screening is only “potentially useful” and must be considered in context with other tools, that initial tests may be inexpensive, but confirmatory tests “can add substantial costs.” The AAFP finds this to be conflicting and anticipates confusion among clinicians who rely on these recommendations. The guideline should acknowledge past differential harms of toxicology tests and go further in advising against withholding harm reduction or medication for opioid use disorder based on toxicology tests, including for individuals who are pregnant, postpartum and parenting. The guidelines should also recommend obtaining informed consent from the patient when considering the use of urine drug testing and specifically note that urine testing should not, by itself, be a determining factor in whether to discontinue or deny care to a patient.

Finally, the AAFP applauds the CDC's inclusion of recommendations to provide or refer treatment for patients who have opioid use disorder. This is consistent with [recommendations](#) from [the AAFP](#) and other organizations. Family physicians are in an ideal position to integrate early substance use disorder (SUD) prevention services; utilize screening, brief intervention, and referral to treatment (SBIRT) for OUDs; and implement medication use for opioid use disorder (MOUD). However, selective screening programs should only be implemented if services for accurate diagnosis, effective treatment, and psychosocial supports can be offered or referred. The AAFP has consistently [advocated](#) for removal of the X-waiver for buprenorphine prescribing and will continue to work with Congress and the administration to remove barriers to effective OUD treatment.

Thank you again for the opportunity to provide comments on the CDC's draft opioid prescribing guidelines. Timely revision of guidelines is a necessary step to ensure physicians have the most up to date recommendations, and we appreciate the opportunity to provide feedback. If you have any additional questions, please contact Meredith Yinger, Manager of Regulatory Affairs, at myinger@aafp.org.

Sincerely,

A handwritten signature in black ink that reads "Ada D. Stewart, MD". The signature is written in a cursive, flowing style.

Ada D. Stewart, MD, FAAFP
Board Chair, American Academy of Family Physicians

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