American Pharmacists Association®
Improving medication use. Advancing patient care.
APhA

January 13, 2016

[Submitted electronically to opioidcomments@cdc.gov]

Tom Frieden, MD, MPH
Director, Centers for Disease Control and Prevention
Debra Houry, MD, MPH
Director, National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, Georgia 30329-4027

RE: Docket No. CDC-2015-0112; Draft CDC Opioid Prescribing Guideline for Chronic Pain

Dear Dr. Frieden and Dr. Houry:

The American Pharmacists Association ("APhA") appreciates the opportunity to provide our perspective on the Centers for Disease Control and Prevention's ("CDC's") draft Opioid Prescribing Guideline for Chronic Pain (the "Guideline"). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians' offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

APhA is committed to working with the CDC and other health professionals and stakeholders to identify ways to curb opioid misuse and abuse. We believe solutions will require the unified efforts of many diverse stakeholders, including health care professionals, patients and caregivers, community-based organizations, and federal, state, and local governments. Thus, we appreciate CDC's decision to seek public comment before finalizing the Draft Opioid Prescribing Guideline. Overall, APhA supports the Guideline as being an important step to address and improve opioid prescribing; however, we have some concerns and offer suggestions to improve the Guideline. Additionally, as the Guideline is finalized, it is important that CDC continue to recognize the need for "patients to have access to safer, more effective chronic pain treatment" and to remember the millions of patients with chronic pain in need of legitimate access to appropriate prescription pain medications.

Our members support strategies to promote safe and effective medication use and to minimize the risks of adverse effects, including misuse and dependence. The Institute of Medicine (IOM) estimates that there are 100 million Americans living with chronic pain—a number that does not

include the additional 46 million individuals the CDC itself estimates suffer from acute pain due to surgery. Given the sheer number of Americans impacted, policy changes that could directly or indirectly restrict legitimate patient access to prescription drugs for pain will have far-reaching consequences. Thus, any approach must provide safeguards to ensure patient access to medically-necessary treatment, including pain treatment that includes opioids. Below we have highlighted issues related to evidence, incorporating a team-based approach, lowest-effective dose, prescription drug monitoring programs, disposal, and education.

I. Evidence

While APhA strongly supports efforts to combat the abuse and misuse of prescription opioids, guidelines for prescribing and managing opioids must be based on the best available scientific evidence. In the Guideline, CDC's recommendations rely on type 3 evidence (confidence in the effect is limited and the true effect might be substantially different from the estimate of the effect) and type 4 evidence (very little confidence in the effect estimate, and the true effective is likely to be substantially different from the estimate of the effect). APhA acknowledges the lack of evidence on this topic, specifically the lack of type 1 and 2 evidence, and considers the evidence CDC relied upon to be the best available. However, we strongly encourage CDC to regularly revise the Guideline as more robust and reliable evidence is presented.

II. CDC Must Revise the Guideline to Incorporate a Team-Based Approach to Care

APhA's greatest concern regarding the Guideline is that it fails to include a team-based approach to care. Patients with chronic pain often need an integrated, interdisciplinary team approach to managing their pain. As drafted, the Guideline focuses solely on the prescriber-patient relationship, fails to make recommendations that encourage a primary care physician to work collaboratively with members of the patient's care team, and does not utilize the expertise of other health care professionals, including pharmacists. As a result of this omission, patient care and the Guideline's goals[1] to improve communication, improve the safe and effectiveness of pain treatment, and reduce the risks associate with long-term opioid therapy will not be optimized unless it is revised.

According to Starfield (1992), a patient care team is comprised of a group of diverse clinicians that regularly communicate with each other regarding a patient and participate in that patient's care.[2] Other research has demonstrated that incorporating pharmacists on care teams involved in direct

[1] Centers for Disease Control and Prevention, CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016 (stating that the "guideline is intended to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including abuse, dependence, overdose, and death.")

[2] Starfield B. Primary care: concept, evaluation, and policy. New York: Oxford University Press; 1992

patient care improves medication adherence, patient knowledge, outcomes, and quality-of-life.[3,4,5,6] Pharmacists bring value to pain management and appropriate use of opioids through their unique understanding of prescription medications and regular contact with patients. Physicians and pharmacists can collaborate in a team-based care model to better and more comprehensively promote appropriate opioid use and to work toward prescription drug abuse prevention.

In addition, community pharmacists have a legal corresponding responsibility to ensure that prescriptions for controlled substances, including opioids, are dispensed for a legitimate medical purpose.[7,8] Encouraging physician-pharmacist collaboration in the Guideline would lead to more coordinated patient care in the appropriate use of opiates. Based on this information, APhA urges the CDC to modify the Guideline to clearly integrate a team-based approach to care that includes pharmacists. Below are comments and suggestions to integrate such an approach.

a. Patient Treatment Goals and Discontinuation Plans Should Be Made Available to the Patient's other Providers, including Pharmacists

The Guideline should be revised to encourage providers to share a patient's treatment goals with pharmacists, and other members of the care team. Recommendation 2 notes that providers should establish treatment goals with patients, but does not suggest collaboration with other members of the patient's care team when developing and implementing treatment goals. Also, Recommendation 7 notes that providers should work with patients to reduce opioid dosage and to discontinue opioids. The impact of both of these recommendations would be significantly improved if pharmacists had access to treatment goals to reinforce them when interfacing with patients.

Pharmacists serve a critical role in the continuum of patient care. They possess extensive medication expertise and can serve as a resource in medication dosing, opioid conversion, and tapering and discontinuation of medication. Pharmacists in community settings see patients often and if the patient utilizes one pharmacy, the pharmacist has a comprehensive picture of all the medications the patient is taking and potential for adverse effects from multiple medication regimens. Based on these potential benefits, APhA urges CDC to revise Recommendation 2 to encourage prescribers to share treatment goals with the patient's providers, including their pharmacist leading to more coordinated care.

---

[3] *See,* Chisholm-Burns, M.A., Kim Lee, J., Spivey, C.A., Slack, M., Herrier, R.N., Hall-Lipsy, E., Graff Zivin, J., Abraham, I., Palmer, J., Martin, J.R., Kramer, S.S. & Wunz T. (2010). US Pharmacists' Effect as Team Members on Patient Care: Systematic Review and Meta-Analyses, *Medical Care,* 48(1), 923-933.

[4] *See also,* Hunt, J.S., Siemienczuk, Pape G., Rozenfeld, Y., MacKay J., LeBlanc, B.H. & Touchette, D. (2008). A Randomized Controlled Trial of Team-Based Care: Impact of Physician-Pharmacist Collaboration on Uncontrolled Hypertension, *Journal of General Internal Medicine,* 23(12). 1966-1972.

[5] *See also,* Carter, B.L., Rogers, M., Daly, J., Shimin, Z., & James, P.A. (2009). The Potency of Team-Based Care Interventions for Hypertension, Journal of the American Medical Association: Internal Medicine, 169(10), 1748-1755.

[6] *See also,* DeBar, L.L., Kindler, L., Keefe, F.J. Green, C.A., Smith, D.H., Deyo, R.A., Ames, K. & Feldstein, A. (2012). A primary care-based interdisciplinary team approach to the treatment of chronic pain utilizing a pragmatic clinical trials framework, *Translational Behavioral Medicine,* 2(4), 523-530.

[7] 21 C.F.R. § 1306.04(a)

[8] *See,* National Association of Boards of Pharmacy, American Academy of Family Physicians, American College of Emergency Physicians, American Medical Association, American Osteopathic Association, American Society of Anesthesiologists, American Society of Health-System Pharmacists, Cardinal Health, CVS Health, Healthcare Distribution Management Association, National Association of Chain Drug Stores, National Community Pharmacists Association, Pharmaceutical Care Management Association, Purdue Pharma L.P., Rite Aid & Walgreen Co. (2015). Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances

b. Pharmacists Can Play a Crucial Role in Educating Patients and Managing Opioid Therapy

CDC should consider revising the Guideline to address how providers can work with pharmacists in managing opioid therapy. Recommendations 3 and 7 provides specific timeframes related to communicating to and monitoring patients receiving opioid therapy. Although APhA is not commenting regarding the sufficiency of these timeframes, we believe that pharmacists, who often see patients at least one a month, can help educate and monitor patients, thereby limiting risk of opioid abuse.

As one of the most accessible members of a health care team and medication experts, pharmacists can help providers manage opioid therapy. Pharmacists are accessible providers who are able to provide and reinforce patient education on the risks and benefits associated with taking prescription drugs with a potential for abuse. Pharmacists also advise patients on drug-drug interactions, review medication dosages for appropriateness, and have the ability to more frequently observe behaviors that may be of concern. In addition, the vast majority of states allow providers to engage in collaborative practice agreements with pharmacists for certain services, such as medication therapy management. Some pharmacists in team-based care settings are engaged in pain management with prescribing authority for opioid therapy working with physicians under collaborative practice agreements. Thus, APhA encourages CDC to expand recommendations 3 and 7 to include additional methods primary care physicians can use to facilitate appropriate use of opioids, such as engaging services provided by pharmacists to educate and monitor patients beyond provider-patient meetings.

III. CDC Should Clarify that Lowest Effective Dose Needs to Be Patient-Specific

Although APhA agrees with Recommendation 5 that advises prescribing the lowest effective dose when starting an opioid, we are concerned that providers may interpret lowest effective dose to mean the lowest starting dose on the product's labeling. APhA's members expressed concern that for patients who have previously been on opioids, the lowest effective dose may be much higher than the lowest available dose, thus preventing patients from receiving adequate pain treatment. Therefore, we ask that CDC clarify that lowest-effective dose may not be the lowest available dose, and that the lowest-effective dose be patient-specific.

IV. Improvements to Prescription Drug Monitoring Programs

APhA strongly supports better collaboration and communication between pharmacists and physicians to identify potential substance abuse problems and consequently, the intent of Recommendation 9 that providers use prescription drug monitoring programs (PDMPs). PDMPs represent one tool that helps prescribers and pharmacists to identify and prevent drug misuse, abuse, and/or diversion. APhA supports strategies to integrate state PDMPs to allow health care professionals to access information across state lines in a seamless manner with their workflow. However, to be effective, APhA recommends some needed changes.

APhA recommends that in the first bullet of Recommendation 9, CDC replace and/or remove "pharmacist" to prevent the Guideline from conveying the only health professional who makes errors in PDMPs is the pharmacist. It's likely that information errors in PDMPs are caused by human error at

various entry points. APhA urges CDC to replace "pharmacist" with a general term, such health care practitioner.

In addition, APhA believes that the Guideline should advise physicians to use electronic prescribing (i.e. e-prescribing) of opiates to combat prescription drug abuse, misuse and diversion, and to further develop a mechanism to share meaningful information electronically with the pharmacist. . The direct transmission of a prescription using e-prescribing standards and technology reduces the potential for hard copy prescriptions in the patients' possession to be altered, forged, reproduced, or otherwise misused for unlawful purposes. Additionally, the capability for standardized interoperable information exchange of critical clinical information via structured electronic documents between pharmacists and prescribers is important to having meaningful systems to combat prescription drug abuse and misuse while decreasing heavy administrative burdens on busy health care professionals.

Lastly, APhA supports strategies to integrate state PDMPs to allow health care professionals to access information across state lines in a seamless manner with their workflow.

V. Disposal

APhA supports CDC's recommendation to discuss storage and disposal of unused opioids with patients before starting and during opioid therapy, but believes that additional guidance and support is needed on appropriate disposal of opioids. For example, our members have expressed concern that there are not enough take-back events or facilities willing to accept unused medications, and the current DEA requirements for community pharmacies to serve as disposal sites are very cumbersome to implement, creating a barrier for patients' safe disposal. Thus, APhA believes CDC should consider developing additional guidance and support regarding storage and disposal of unused opioids.

VI. Enhance Health Care Professionals' Education on Prescription Drug Abuse

APhA supports comprehensive efforts to educate health care professionals, including prescribers and pharmacists about prescription drug abuse, mechanisms to prevent it and how to address abuse with patients. The training should incorporate ways to identify patients susceptible to addiction, and behaviors of addiction, abuse, misuse or diversion. The training should also educate health care professionals on various ways prescription drugs are diverted, and the different ways abusers are manipulating and administering the drugs. Additionally, materials should be developed to help health care professionals identify treatment options available to patients. APhA member feedback identified that pharmacists are often unaware of treatment services available, including local DATA-waived physicians and other support services, such as Narcotics Anonymous. The same may be true for primary care physicians. CDC may also consider develop materials detailing treatment options at the local level.

Thank you for your leadership and work on this issue. We look forward to supporting your efforts and working with you as the Guideline is refined. If you have any questions please contact, Jenna Ventresca, Associate Director for Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO