January 11, 2016

National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway NE
Mailstop F-63
Atlanta, Georgia 30341

ATTN: Docket CDC-2015-0112

On behalf of the more than 104,000 nationally certified PAs (physician assistants) represented by the American Academy of PAs (AAPA), I am pleased to offer comments on the Centers for Disease Control's (CDC's) *Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain*. Although AAPA supports utilization of many of the best practices in prescribing opioids that are contained in the guideline, AAPA has concerns with several aspects of the guideline and offers the following recommendations:

- PAs are one of three healthcare professionals, including physicians and nurse practitioners, who provide primary medical care in the U.S. AAPA recommends the guideline acknowledge the role of all primary care providers, including PAs, as well as their role as prescribers of opioids for the management of chronic pain. AAPA believes it would be a mistake if the guideline failed to include all primary care providers who may prescribe opioids for pain.
- AAPA disagrees with the guideline's premise that non-pharmacological and alternative non-opioid pharmacologic therapies are presumed to be the preferred treatment for chronic pain. Decisions regarding therapeutic options and management for pain should be determined using best practices and evidence-based guidelines on a case-by-case basis. Further, AAPA is concerned that the "voluntary" guideline may be viewed as mandatory by medical practices and by the Drug Enforcement Administration, frightening patients and healthcare professionals alike, and leading to under treatment of pain. Accordingly, AAPA recommends that the guideline makes clear that clinicians have the full range of therapeutic options for pain, including opioids, when appropriate.
- By exempting patients who are undergoing treatment for cancer from the guideline, CDC appears to place greater legitimacy on pain caused by cancer and cancer treatment, as opposed to pain created by other conditions or disability. AAPA recommends that all patients with pain be equally evaluated and receive clinically indicated care.
- Background information accompanying the proposed guideline states that primary care providers report insufficient training in prescribing opioids. AAPA recommends that the guideline address this issue by encouraging all primary care providers who prescribe opioids to obtain continuing medical education (CME) designed to prevent and treat prescription drug abuse among their patients with chronic pain. CME is offered by AAPA and other healthcare organizations through the Collaboration of REMS Education (CO*RE) Initiative to Address Extended Release/Long Active Opioids. Since 2013 CO*RE and its partner organizations have educated more than 110,000 prescribing clinicians across the country and plan to educate an additional 25,000 to 35,000 in 2016. With its collective communication channels, CO*RE estimates that it has brought awareness of opioid misuse and abuse to over a million healthcare professionals across the country.
- The preamble to the CDC Guideline notes extensive consultation with selected medical and federal agency stakeholders in the development of the guideline. However, involvement of patients appears to have been limited to a webinar. AAPA recommends that the comment period on the CDC Guideline be extended to ensure feedback from all stakeholders, particularly patients.

AAPA wholeheartedly supports utilization of best practices in prescribing opioids for the treatment of pain and has for several years been an active partner in the CO*RE Initiative to Address Extended Release/Long Active Opioids. Additionally, AAPA is working with the National Institute on Drug Abuse (NIDA) on a CME initiative regarding pediatric substance use and the Hilton Foundation on adolescent substance use and the treatment of adolescent opioid addiction. All of these initiatives educate PAs on best practices in the evaluation and management of opioids. While many of the educational components of AAPA's CME initiatives are contained in the CDC Guideline and we support these efforts, we are very concerned that other language in the guideline will create unnecessary confusion, burden, and potential harm for the millions of American who legitimately rely on opioid products to manage chronic pain.

AAPA acknowledges the abuse, diversion, morbidity and mortality associated with the misuse of prescription drugs, particularly opioids, are devastating families and communities across our nation. AAPA is also concerned that many Americans suffer chronic pain, for which access to opioids and hydrocodone products are necessary to safely and effectively manage their pain. In its 2011 report, *Relieving Pain in America*, the Institute of Medicine (IOM) states that the level of pain experienced by Americans is a human and economic crisis. The IOM estimated that over 100 million Americans suffer from chronic pain alone, and pain costs the U.S. $635 billion each year in medical treatment and lost productivity. The report did not suggest limiting access to opioids, but rather recommended a comprehensive strategy of public education, research, data collection, and advanced educational preparation of healthcare professionals to confront pain prevention and management.

While the majority of patients who use opioid medications to treat acute or chronic pain do so without incident, many become dependent on them over time. According to NIDA, opioid drugs are responsible for more accidental deaths than any other type of drug. While changes have been made to curb prescription drug abuse at all levels, they have had little impact on the overall epidemic. Worse, it appears that limiting the ability to access these drugs has led to a dangerous, unintended consequence: it has become cheaper and easier for many individuals who are dependent on opioids to turn to heroin to achieve similar effects. As a result, the U.S. saw a 39% increase in the number of deaths due to heroin abuse between 2012 and 2013, and a recent NIDA report cited a 2012 study which found that 86% of "young, urban injection drug users" had first abused prescription opioid medications.

AAPA believes that a fine line must be maintained between fighting opioid abuse and ensuring that patients who need opioids for pain management are able to access them. As such, AAPA supports efforts to stop opioid addiction before it occurs through the use of safe prescribing practices, patient monitoring, and screening for potential abuse. Additionally, AAPA asserts that the current epidemic will not improve without enlisting the help of additional providers to treat those who are already addicted through medication-assisted treatment (MAT).

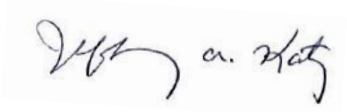
According to the Substance Abuse and Mental Health Services Administration, MAT, used in conjunction with traditional therapies, has been proven to increase patient survival and retention in treatment, decrease criminal activity, and better allow patients to become and stay employed. Unfortunately, the stigma associated with these medications has deterred qualified providers from seeking the ability to prescribe them. At the same time, current federal laws that limit the availability of the drugs and restrict the types of providers who may prescribe and dispense them – particularly, buprenorphine – has led to a severe shortage of providers available to assist patients with opioid addiction. In fact, a recent study published in the *American Journal of Public Health* found that in 2012, an estimated 2.3 million Americans either abused or were dependent on opioids, while the capacity for treatment programs offering MAT was only 1.4 million. Meanwhile, according to the Department of Health and Human Services, more than 60 Americans die from an opioid-related overdose every day. It is clear that additional qualified clinicians, including PAs, are necessary to combat this growing epidemic.

PAs are currently permitted to prescribe up to Schedule III controlled substances in all 50 states and D.C.; 41 states and D.C. also allow PAs to prescribe Schedule II drugs. While PAs are able to prescribe Schedule III buprenorphine to their patients for pain management, the Drug Addiction Treatment Act of 2000 (DATA 2000) does not allow PAs to prescribe this medication for the treatment of opioid addiction. ***In light of the enormity of opioid addiction and the shortage of physicians specializing in mental health and addiction medicine, AAPA strongly believes that DATA 2000 must be updated to permit PAs to prescribe buprenorphine to treat opioid addiction in states where they are already permitted to prescribe it for other purposes.***

PAs commonly work with patients who struggle with opioid dependency. While some PAs may choose to specialize in addiction medicine, there are also over 32,000 PAs working at hospitals, community health centers, rural health clinics, non-federally qualified public or community health clinics, and free clinics. A significant number of PAs are working on the “front lines” of patient care and recognize the complexity of the opioid epidemic.

AAPA is committed to finding ways to assist in combatting opioid addiction in the U.S., and we look forward to working with CDC as it finalizes its guideline. We strongly encourage CDC to remove language in the guideline that stigmatizes the use of opioids to manage severe chronic pain and to enlist the aid of AAPA and the CO*RE Collaboration for REMS Education to educate primary care providers to safely treat patients experiencing chronic pain with opioids while protecting against misuse and abuse. Please do not hesitate to contact Sandy Harding, AAPA senior director of federal advocacy, at 571-319-4338 or sharding@aapa.org with any questions.

Sincerely,



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