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April 16, 2014

Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODW
8701 Morrisette Drive
Springfield, Virginia 22152

RE: Docket No. DEA-389

On behalf of the more than 95,000 physician assistants (PAs) represented by the American Academy of Physician Assistants (AAPA), AAPA is pleased to submit the following comments in response to the Drug Enforcement Administration's (DEA's) proposed rule, "Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II" (Federal Register Volume 79, Number 39/ February 27, 2014).

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 estimates 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 does not suggest limiting access to opioids, but rather recommends a comprehensive strategy of public education, research, data collection, and advanced educational preparation of healthcare professionals to confront pain prevention and management.

AAPA opposes the proposed rule to reschedule hydrocodone combination products from Schedule III to Schedule II. AAPA is skeptical whether rescheduling the drugs will alter significantly their diversion and abuse. However, rescheduling the drugs will most certainly limit access to individuals who may benefit from their appropriate use by limiting the healthcare professionals who can prescribe them, particularly in rural and other medically underserved communities where a PA may be the only available prescribing provider. The imposition of additional barriers associated with Schedule II drugs, such as the inability to phone in prescriptions or refill the prescription, will create additional burdens for all patients who rely on hydrocodone combination products to manage chronic pain. Attempts to curb the abuse and diversion of drugs should not be made at the expense of limiting access to and creating additional burdens for patients for whom hydrocodone products are clinically appropriate to manage their pain.

PAs and Prescriptive Authority

All PAs must graduate from PA educational programs accredited by the Accreditation Review Commission on Education for the Physician Assistant. The mean duration of PA educational programs is 26 months. Ninety-one percent of PA educational programs offer a master's degree.

PA programs require an average 75 hours of formal classroom instruction in pharmacology. Additionally, PA students receive instruction in pharmacology during clinical medicine coursework and clinical clerkships. The mean amount of total instruction in clinical medicine is 577.6 hours, and the average length of required clerkships is 52 weeks. A significant percentage of time is focused on patient management, including pharmacotherapeutics. Educational content on prescription drug abuse is offered through pharmacotherapeutic, behavioral health, and ethics courses.

All states, the District of Columbia, and all U.S. territories (with the exception of Puerto Rico, which does not yet authorize PA practice) authorize PAs to prescribe medication. PAs may prescribe Schedule II medications in all but 13 states. There is no clinically supportable reason why PAs should not be authorized to prescribe all legal medications, including opioids.

The Need for a Multi-Faceted Approach to Opioid Abuse & Diversion

There is a great amount of national attention focused on the opioid abuse epidemic. Policymakers agree the solution to this problem requires enhanced patient and provider education on the addictive properties of certain controlled substances, increased public awareness on the overall financial and cultural cost of opioid addiction, and enforcement of existing laws to prosecute all involved in drug diversion, including health professionals who abuse their prescribing authority. Simply reclassifying hydrocodone combination products to Schedule II is not likely to affect the epidemic, particularly in light of the continued abuse and diversion of oxycodone products, already classified as Schedule II drugs.

Recent studies of “problem prescribers” also point to the need for a multi-faceted response. A 2012 investigation conducted by the Los Angeles Times found that drugs prescribed by physicians, all Schedule II prescribers, caused or contributed to almost half of the deaths in Southern California caused by overdose of prescription drugs.¹ Using data from the National Survey on Drug Use and Health from 2008 to 2011, the Centers for Disease Control and Prevention (CDC) released a report this year that indicated similar findings – high risk opioid users continue to obtain prescriptions from doctors.² In response, the CDC recommends authorities better utilize prescription drug monitoring programs to identify and address problem prescribers.³

The implementation of best practices in working with patients to prevent and treat prescription drug abuse also works. As reported in the March 31, 2014 BNA Health Care Policy Report, Washington state has reduced narcotics prescriptions by almost 25% among its Medicaid population and has decreased the rate of narcotic death overdose through the use of seven best practices.⁴ Expanded use of best practices in prescribing and monitoring the use of pain medication is also integral to a comprehensive policy to confront prescription drug misuse and diversion.

¹ Girion, Lisa, and Glover, Scott. Doctors are top source of prescription drugs for chronic abusers. *Los Angeles Times*. March 3, 2014.

² Baublatt, J.A., et al. High-Risk Use by Patients Prescribed Opioids for Pain and Its Role in Overdose Deaths. *Journal of the American Medical Association*. March 3, 2014.

³ Girion, Lisa, and Glover, Scott. Doctors are top source of prescription drugs for chronic abusers. *Los Angeles Times*. March 3, 2014.

⁴ State Cuts Medicaid Patients' ER Usage by Implementing Series of Best Practices. *BNA's Health Care Policy Report*. March 31, 2014; 22(13)-521.

AAPA Educational Response to Prescription Drug Abuse Epidemic

AAPA believes education for opioid prescribers is essential to addressing prescription drug abuse and has used multiple opportunities to provide educational tools for PAs. Following a 2012 meeting with the White House Office of National Drug Control Policy, AAPA initiated a plan of action to educate PAs regarding the FDA's extended-release/long-acting opioid Risk Evaluation and Mitigation Strategy (REMS) project to develop best practices on prescription drug abuse prevention and treatment.

In direct cooperation with multiple professional and related organizations with extensive interest in pain care as its partners, AAPA helped create the Collaborative on REMS Education (CO*RE) and is poised to make significant contribution in pain education. CO*RE recently received approval from the REMS Program Committee (RPC) for its national initiative to support educational activities addressing the public health crisis surrounding the use, abuse, diversion and overdose associated with extended-release/long-acting opioids.

AAPA has launched education activities on prescription drug abuse at state chapter meetings, specialty meetings, the AAPA Annual Conference, and online. Most recently, AAPA announced two new free continuing medical education (CME) programs designed to help PAs prevent and treat prescription drug abuse among their patient populations with chronic pain. The CME programs are offered live on AAPA's online Learning Central, both supported by the National Institute on Drug Abuse –

- the Safe Prescribing for Pain module demonstrates skills necessary to screen for and prevent drug abuse in patients with pain
- the Managing Pain Patients who Abuse Rx Drugs module highlights the symptoms and prevalence of opioid addiction and dependence in patients with chronic pain. It also outlines the steps PAs can take to screen for, prevent, and treat these conditions.

Expanding PAs' Ability to Provide Addictions Treatment

AAPA believes the prescription drug epidemic requires greater utilization of qualified healthcare providers in the treatment of opioid addiction, including PAs. Unfortunately several barriers limit PAs' ability to provide desperately needed care for individuals abusing prescription drugs. For example,

- PAs may prescribe buprenorphine for the treatment of pain, but PAs may not prescribe the same drug for the treatment of opioid addiction. AAPA recommends that the Drug Addiction and Treatment Act of 2000 be amended to allow PAs who complete certification training to obtain a DEA waiver to prescribe and dispense buprenorphine for opioid addiction (in states where PAs are permitted to prescribe Schedule III, IV, and V medications).
- Last year the Substance Abuse and Mental Health Services Administration (SAMHSA) released draft guidelines for opioid treatment programs (OTPs) that allow PAs to assess, diagnose, and admit patients into OTPs. AAPA recommends that the draft SAMHSA guidelines be adopted.
- PAs provide the full range of healthcare services to military members and their families. However, TRI CARE does not recognize PAs as behavioral healthcare professionals. AAPA recommends that TRI CARE regulations be updated to recognize PAs as behavioral healthcare professionals.
- The Medicaid statute does not require the program to utilize PAs. Accordingly, state program directors often pick and choose which medical care services PAs may provide – often not care related to behavioral health and, specifically, addiction medicine. AAPA recommends that legislation be passed to require all Medicaid programs to consistently utilize PAs to the top of their education, experience, and license.

Also key to the overall strategy in confronting prescription drug abuse is the use of naloxone, known to save lives of those who have overdosed on opioids. In 2012 the AAPA House of

Delegates passed policy to endorse the prescribing and distribution of naloxone for secondary administration to opiate addicted patients to prevent opiate overdose. AAPA supports the establishment of naloxone prescribing programs.

Reclassification of Hydrocodone Combination Products is not the Answer

The abuse of prescription drugs is a serious problem. Clearly we can all do more – from eliminating unnecessary barriers to the quality medical care provided by PAs, to additional education, research, and data reporting regarding prevention and treatment. Rescheduling hydrocodone products from Schedule III to II will not have an impact on problem prescribers of hydrocodone products or decrease the abuse of opioids, but it will negatively impact patients who require the medication to manage severe chronic pain. Reclassification would also negatively affect PAs, who are not shown to be problem prescribers, in the 13 states where PAs are not yet authorized to prescribe Schedule II medications. For these reasons, we strongly recommend the DEA not move forward in revising the classification of hydrocodone combination products.

AAPA looks forward to working with the DEA and other stakeholders to develop a comprehensive strategy to confront the complex problem of prescription drug abuse and diversion. Please do not hesitate to contact Sandy Harding, AAPA senior director of advocacy, at sharding@aapa.org for additional information on AAPA's comments.

Sincerely,



Lawrence Herman, PA-C, MPA
AAPA president