December 28, 2017

U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Submitted Electronically

RE: Docket No. FDA-2017-N-5608; Opioid Policy Steering Committee; Establishment of a Public Docket, Request for Comments

On behalf of the more than 115,000 PAs (physician assistants) throughout the United States, the American Academy of PAs (AAPA) welcomes the opportunity to submit comments to the Food and Drug Administration (FDA) regarding the current epidemic of opioid abuse and addiction, and potential steps that the FDA might consider in responding to this crisis.

As the FDA is well aware, the abuse, diversion, morbidity, and mortality associated with the opioid epidemic are devastating families and communities across the U.S. According to the Centers for Disease Control and Prevention (CDC), the most recent data estimates that 142 Americans die every day from a drug overdose, with the overall number of opioid overdoses in America having quadrupled since 1999.

As the crisis has grown, the capacity to provide treatment is not meeting the demand for services. PAs are part of the solution to this problem, and any initiatives to address the opioid crisis are more likely to succeed if the considerable abilities of PAs are fully utilized.

AAPA supports initiatives to stop opioid addiction before it occurs through the use of safe prescribing practices, patient monitoring, and screening for potential abuse. We also believe the current epidemic will not improve without enlisting the help of additional providers to treat those who are already addicted. Therefore, AAPA supports initiatives to increase access to treatment for opioid addiction, both traditional therapy and medication-assisted treatment (MAT), as well as proposals to strengthen provider training in the areas of pain management, safe prescribing practices, and treatment of patients who are already struggling with addiction.

PA Education and Practice

PAs are one of three healthcare professionals, including physicians and nurse practitioners, who provide primary medical care in the United States. Many dedicated PAs have long been involved in the fight against the opioid crisis that is currently gripping our nation, practicing in specialties such as addiction medicine, behavioral health and emergency medicine.

PA programs provide a broad medical education over approximately 27 continuous months (approximately three academic years), consisting of two parts. The didactic phase includes coursework

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in anatomy, physiology, biochemistry, pharmacology, physical diagnosis, behavioral sciences, and medical ethics. This is followed by the clinical phase, which includes rotations in medical and surgical disciplines such as family medicine, internal medicine, general surgery, pediatrics, obstetrics and gynecology, emergency medicine, and psychiatry. Due to these demanding rotation requirements, PA students will have completed at least 2,000 hours of supervised clinical practice in various settings and locations by graduation, with the overwhelming majority of PA programs awarding a master's degree.

PAs practice and prescribe medication in all 50 states, the District of Columbia, and all U.S. territories with the exception of Puerto Rico. They manage the full scope of patient care, often handling patients with multiple comorbidities. In their normal course of work, PAs conduct physical exams, order and interpret tests, diagnose and treat illnesses, assist in surgery, and counsel on preventative healthcare. The rigorous education and clinical training of PAs enables them to be fully qualified and equipped to manage the treatment of patients with opioid addiction.

PAs currently have the authority to prescribe up to Schedule III controlled substances needed by their patients in 49 states and D.C.; 46 states and D.C. authorize PAs to prescribe Schedule II medications. In some states, PAs have been authorized to prescribe controlled medications for more than 30 years. Once granted, no state has ever rescinded PA authority to prescribe controlled medications. There has been no record of increased liability or malpractice claims due to PA prescribing of scheduled drugs, and professional liability insurers have not increased premiums when PAs have been granted authority to prescribe controlled medications.

PAs frequently work with patients who struggle with opioid dependency. While many PAs specialize in addiction medicine, there are also approximately 30,000 PAs practicing as primary care providers on the "front lines" of patient care in hospitals, private practices, community health centers, rural health clinics, non-federally qualified public or community health clinics, prisons, behavioral healthcare facilities, and free clinics, where they commonly encounter patients who present with or are at risk of opioid addiction. This care is especially critical in rural and medically-underserved areas, where PAs may serve as the only primary care clinician or in areas where PAs own and serve their own medical practices.

Requirements for Prescriber Education

While the majority of patients who use prescribed opioid medications to treat acute or chronic pain do so without incident, many become dependent on them over time. According to the National Institute on Drug Abuse (NIDA), opioid drugs are responsible for more accidental deaths than any other type of drug.

As changes have been made to curb prescription drug abuse at all levels, these changes have to date had little impact on ending the overall epidemic. It appears that limiting the ability to access these drugs in some cases 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.

AAPA believes a fine line must be maintained between fighting opioid abuse and ensuring 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.

Mandating prescriber education initiatives at the federal level would likely run into issues dealing with the patchwork of state and local laws that already govern provider practices throughout the United States. Additionally, mandating these initiatives at the federal level would run the risk of imposing regulatory burdens that are not based on evidence-based research on healthcare providers or best medical practices, creating barriers to care for patients who require treatment.

AAPA recommends encouraging all providers who commonly prescribe opioids to obtain continuing medical education (CME) designed to prevent and treat prescription drug abuse among their patients with chronic pain. AAPA does not believe creating requirements for additional prescriber education, or setting a mandatory CME threshold, will necessarily lead to better healthcare outcomes in the fight against the opioid epidemic, and might in fact create unnecessary barriers to care for patients in need of treatment.

AAPA has been proactive in ensuring PAs have access to CME and other coursework related to safely prescribing opioid medications, as well as the screening, prevention, and management of prescription drug misuse, and supports initiatives that will provide access to more education opportunities to providers in these areas. This educational content is easily available and offered to PAs online through https://cme.aapa.org/opioidrems.aspx. In 2017 alone, AAPA has provided CME in this space to over 2,500 PAs.

Reducing Barriers to Medication-Assisted Treatment (MAT)

Both the Substance Abuse and Mental Health Services Administration (SAMHSA) and NIDA have found that individuals who are addicted to opioids often fare better if they have access to MAT, as well as traditional therapies. MAT patients have greater overall survival rates and treatment retention, and they show decreased criminal activity, allowing them to become and stay employed. PAs are qualified to provide this treatment to patients and must be included as part of the solution.

In spite of the large amount of evidence showing the positive outcomes associated with MAT programs, there is often a public perception that MAT simply amounts to replacing one dependency with another. As a result, there are often commercial, regulatory and statutory barriers to providers seeking to provide MAT, and patients seeking access to this treatment. AAPA supports removing non-evidence based restrictions on the type of providers who can provide MAT for opioid-addicted patients. Additionally, AAPA strongly supports initiatives to expand access to MAT programs for patients who need treatment for opioid addiction.

Since the passage of the Comprehensive Addiction and Recovery Act (CARA) of 2016, AAPA has partnered with the American Society of Addiction Medicine (ASAM) and the American Association of Nurse Practitioners (AANP) to offer free online training courses that will allow PAs to receive a waiver to prescribe buprenorphine for the treatment of opioid addiction. As of September 19, 2017, 1,606 PAs nationwide have registered for this training, and 773 PAs have completed this training and received their waiver.

While PAs have been eager to undertake this additional education in order to better treat their patients struggling with opioid addiction, there are several barriers that prevent PAs from practicing to the full extent of their training. PAs, along with NPs, are required to complete 24 hours of training to be waiver-

eligible, while physicians are only required to complete 8 hours. This disparity is not based on educational curriculum already received or on any best medical practice or evidence-based policy.

In order to receive a waiver to prescribe buprenorphine after completing this training, PAs and NPs are currently required to have their supervising or collaborating physician be “waiver eligible.” This requirement has the potential to restrict access to treatment for those suffering from opioid addiction.

PAs and NPs who have completed the 24 hours of training, work with a “waiver eligible” supervising or collaborating provider, and received a waiver to prescribe buprenorphine are only allowed to treat up to 30 patients during their first year under this program. The cap can be raised to 100 after the prescriber has been waivered for one year. This cap has the potential to lead to practitioners that reach their cap having to turn away patients who are seeking treatment for opioid addiction.

Regarding any other initiatives that FDA may consider to combat the opioid epidemic, AAPA supports working with all relevant healthcare provider groups in order to ensure actions undertaken are supported by evidence-based science and are consistent with the best medical practices.

AAPA very much appreciates the work Commissioner Gottlieb and the FDA are doing to combat the opioid epidemic in our nation, and we look forward to working with the FDA and all relevant actors to treat this issue. Please do not hesitate to contact Tate Heuer, AAPA Vice President, Federal Advocacy, at 571-319-4338 or theuer@aapa.org, with any questions.

Sincerely,

L. Gail Curtis, PA-C, DFAAPA
President and Chair of the Board