



May 23, 2016

Substance Abuse and Mental Health
Services Administration
5600 Fishers Lane, Room 13E21C
Rockville, Maryland 20857

ATTN: RIN 0930-AA22

On behalf of the more than 108,500 nationally-certified PAs (physician assistants) represented by the American Academy of PAs (AAPA), I am pleased to offer comments on the Substance Abuse and Mental Health Services Administration's (SAMHSA's) proposed rule on medication-assisted treatment (MAT) for opioid use disorders. AAPA wholeheartedly supports increased access to MAT; however, we believe increasing the number of patients to whom a physician may provide MAT is only part of the solution. ***We therefore urge SAMHSA to work with Congress to amend the Drug Addiction Treatment Act of 2000 (DATA 2000) to allow PAs to prescribe buprenorphine for the purposes of MAT.***

Additional MAT Providers are Necessary

The U.S. Department of Health and Human Services (HHS) has estimated that more than 60 Americans die from an opioid-related overdose every day. While changes have been made to curb prescription drug abuse by both healthcare providers and drug manufacturers, little impact has been made on the overall opioid abuse epidemic. Worse, it appears limiting the ability to access prescription opioids 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. SAMHSA's own data show that in 2014, 1.9 million Americans over 12 years of age were addicted to prescription painkillers and 586,000 were addicted to heroin. It is clear more must be done to combat this growing problem.

At the same time, it is crucial to remember that there are many Americans who suffer from chronic pain, for whom access to opioids and hydrocodone products are necessary to effectively manage their symptoms. The majority of patients use these drugs without incident. AAPA believes a fine line must be maintained between fighting opioid abuse and ensuring patients who are in need of pain management are able to access it. As a result, AAPA appreciates the work done by the administration and Congress to combat the abuse, diversion, and mortality associated with the misuse of opioids while still ensuring access to these medications. We also support the desire to stop opioid addiction before it starts through the use of safe prescribing practices, patient education and monitoring, and screening for potential abuse.

While administratively increasing the number of patients to whom a physician may prescribe MAT with buprenorphine is a good start, we believe it is necessary for DATA 2000 to be updated by Congress to allow PAs to provide this treatment, as well. Many areas which experience a shortage of physicians to treat opioid use disorder are rural or otherwise considered to be medically underserved. Simply allowing physicians to treat more patients may not necessarily increase access for individuals who currently lack it because there may be no physician practicing in these locations. SAMHSA quotes data in the draft rule which shows only five percent of physicians who are waived to prescribe MAT with buprenorphine to up to 100 patients are located in rural areas. Increasing the cap to 200 for this five percent would likely have a small impact, but increasing the number of providers by including PAs could make a much greater difference for individuals who lack access to a waived physician.

PA Education & Practice

PAs receive a broad medical education over approximately 27 months which consists of two parts. The didactic phase includes coursework 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.

The majority of PA programs award a master's degree. PAs must pass the Physician Assistant National Certifying Examination and be licensed by a state in order to practice. The PA profession is the only medical profession that requires a practitioner to periodically take and pass a high-stakes comprehensive exam to remain certified, which PAs must do every ten years. PAs must also complete 100 hours of continuing medical education (CME) every two years.

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.

PA Prescribing Authority & AAPA Response to the Opioid Epidemic

PAs are currently permitted to prescribe up to Schedule III controlled substances in 49 states and D.C.; 43 states and D.C. authorize PAs to prescribe Schedule II drugs. PAs frequently work with patients who struggle with opioid dependency. While some PAs may choose to 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 health 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 their own medical practices.

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. AAPA is an active partner in the Collaboration of REMS Education (CO*RE) Initiative to Address Extended Release/Long Acting (ER/LA) Opioids. Thousands of PAs have participated in the CO*RE educational activity on safely prescribing ER/LA opioid painkillers, and AAPA is pleased to be a partner among several other provider groups in continuing to create opportunities for inter-professional education in this area. AAPA also works with the National Institute on Drug Abuse (NIDA) on a CME initiative regarding pediatric substance use and the Hilton Foundation on adolescent substance abuse and the treatment of adolescent opioid addiction. Additionally, AAPA has hosted multiple online and in-person CME courses addressing opioid abuse, pain management, and safe prescribing, and plans to remain active in encouraging PAs to remain up-to-date on current best practices surrounding the responsible prescribing of opioid medications and comprehensive assistance for those who become addicted.

Finally, AAPA supports efforts to expand the use of available technology to better manage the use of opioid drugs in patients who are at risk of addiction or overdose. The Centers for Disease Control and Prevention (CDC) has stated the death rate for individuals who either overdose on opioids or experience a deadly drug interaction involving opioids has more than tripled since 2000. As a result, it is important for all prescribers to have better access to information about what medications their patients have been prescribed, particularly those who see more than one healthcare provider or who are experiencing or at

risk of addiction. One potential solution for this problem is to strengthen prescription drug monitoring programs (PDMPs). Earlier this year, Senators Richard Blumenthal (D-CT) and Dan Coats (R-IN) introduced S. 2479, the Expanding Access to Prescription Drug Monitoring Programs Act, which would encourage state PDMPs to allow PAs and nurse practitioners (NPs) to view and update their patients' prescription records. While some states allow this access, others do not – even though most states allow these practitioners to prescribe opioid drugs. AAPA supports this legislation, which would ensure PAs have all of the available information to make the best possible determinations about their patients' care and quickly spot potential abuse or diversion issues.

The Role of PAs in Treating Opioid Use Disorder

AAPA supports the use of varying types of MAT to assist individuals who are addicted to opioids. Both 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 like counseling. MAT patients have greater overall survival rates and treatment retention, and they show decreased criminal activity, allowing them to become and stay employed. Yet despite these positive outcomes, there is a public perception that MAT simply amounts to replacing one dependency with another. As a result, the stigma associated with these medications has deterred some qualified providers from seeking the ability to prescribe them. At the same time, federal laws which limit the availability of these drugs and restrict the types of providers who may prescribe and dispense them has led to a severe shortage of providers to assist patients with an opioid addiction.

Currently, PAs are authorized to prescribe and dispense three drugs used as part of MAT programs:

- **Methadone:** PAs who are employed by certified opioid treatment programs may dispense methadone and participate in the care and treatment of patients who are dependent on opioid drugs.
- **Naltrexone:** Naltrexone is available in settings outside of opioid treatment programs, and it is not a controlled substance. As such, federal laws allow any licensed provider (including PAs) to prescribe and administer this drug.
- **Naloxone:** Naloxone is not a controlled substance, but states have differing laws regarding the prescribing and dispensing of this drug. Forty-eight states currently allow PAs to prescribe naloxone, subject to licensing and educational requirements.

Despite PA presence in MAT programs, DATA 2000 prohibits PAs from prescribing one of the most useful MAT drugs – buprenorphine – for the treatment of opioid addiction, even though they are allowed to prescribe this drug or similarly scheduled drugs in nearly every state for pain management purposes. This law must be updated to ensure that patients who currently lack access to a physician who provides MAT are able to receive this lifesaving treatment.

Efforts to Update DATA 2000 & PA Concerns

Over the last several months, there have been attempts by both Congress and the administration to amend DATA 2000 and allow PAs to prescribe buprenorphine as part of MAT. These proposals include:

- **The TREAT Act (S. 1455):** The TREAT Act, introduced by Senator Edward Markey (D-MA), adds PAs to the list of providers who may prescribe buprenorphine as part of MAT. This legislation was marked up by the Senate Health, Education, Labor and Pensions (HELP) Committee in March, and the reported version of the bill incorporated changes which were favorable to PA practice, including deferring to state laws when determining whether a PA is able to prescribe MAT. AAPA supports the TREAT Act as approved by the HELP Committee because it recognizes the need to use PAs to increase access to MAT and allows CME and other learning resources offered by AAPA to be used towards meeting the educational requirements in the bill.

- **The Opioid Use Disorder Treatment Expansion and Modernization Act (H.R. 4981):** The Opioid Use Disorder Treatment Expansion and Modernization Act, introduced by Representative Larry Bucshon (R-IN), includes the same PA-friendly provisions as the TREAT Act as amended by the Senate HELP Committee, but it also includes a new provision which requires PAs who are waived to prescribe buprenorphine to work with a physician who is also waived. This is a requirement which is not seen anywhere else, in either state or federal law. For instance, the Federal Motor Carrier Safety Administration's (FMCSA's) National Registry of Certified Medical Examiners requires a PA who is certified as a medical examiner to work with a physician who is knowledgeable about occupational medicine, but it does not require that physician to also be certified. FMCSA's rationale in making this decision was based in part on the realization that such a requirement would limit the agency's ability to build the necessary workforce to address the need to certify the medical fitness of commercial drivers. We believe this argument is compelling as it relates to ensuring adequate numbers of providers who can prescribe MAT, as well. AAPA is concerned the waived physician requirement will limit the number of PAs who may become waived to prescribe buprenorphine, creating additional barriers to patient care.

H.R. 4981 was approved by the House of Representatives on May 11, 2016 and sent to the Senate as part of a package of House-passed opioid bills. A conference committee is expected to convene in the coming weeks to resolve the differences between the House and Senate approaches to the overall epidemic, during which time AAPA will be advocating for the inclusion of the MAT language from S. 1455 as approved by the Senate HELP Committee.

- **The President's FY17 Budget Request:** The administration proposed in its budget a demonstration program to gauge the feasibility of allowing PAs and NPs to prescribe buprenorphine as part of MAT. AAPA believes a demonstration program is unnecessary because the majority of PAs and NPs can already prescribe buprenorphine for the treatment of pain and other purposes, and it delays the addition of more providers to combat the opioid crisis.

AAPA Recommendations

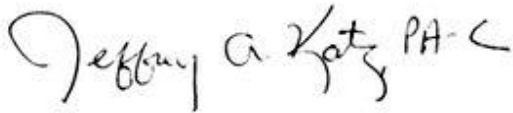
AAPA supports efforts by SAMHSA and others to increase the availability of MAT for patients who need it. However, we believe more must be done beyond increasing the patient cap for physicians. We therefore request SAMHSA encourage Congress to update DATA 2000 to include PAs as prescribers of buprenorphine as a part of MAT, with the following considerations:

- **Federal law regarding MAT should not include state scope of practice language.** Legislation which places state scope of practice language in federal statute is problematic because state laws in this space are constantly changing. To ensure continuity of patient care and access to care, it is essential that federal laws addressing prescribing authority simply defer to state laws.
- **Education requirements for PAs seeking to prescribe MAT should be reasonable and attainable.** AAPA supports language which ensures that PAs who seek a waiver to prescribe buprenorphine for MAT are fully equipped to do so. However, we believe any educational requirements above and beyond the typical PA curriculum must be reasonable and attainable. As such, it is imperative that current educational capacity and availability be analyzed and the costs to practitioners – both in terms of time and financial commitment – are not overly burdensome or unreasonable. PAs should also be treated the same way as other healthcare providers in regard to additional educational requirements.
- **PA competency for prescribing MAT should not be tied to a new federal requirement that a supervising or collaborating physician also be waived to prescribe buprenorphine for the treatment of opioid addiction.** States typically require a PA to practice within the scope of the physician with whom they work, but there is no requirement in either state or federal law which requires the physician to prove competency in an area before the PA may practice. While

this may seem like a small distinction, the ever-changing nature of state laws means this burden may become a full-on barrier to PA practice over time. Additionally, there are already too few physicians who choose to be waived to prescribe MAT, and these physicians are limited by state law in how many PAs they may oversee. Adding an extra level of physician engagement defeats the purpose of increasing the number of eligible providers and risks limiting patient access at a time when it is most needed.

AAPA is committed to combating opioid use disorder in the U.S., and we look forward to working with SAMHSA as it works to increase access to MAT. 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,

A handwritten signature in black ink that reads "Jeffrey A. Katz PA-C". The signature is written in a cursive, slightly slanted style.

Jeffrey A. Katz, PA-C, DFAAPA
President and Chair of the Board of Directors