

December 28, 2017

Anna K. Abram
Deputy Commissioner for Policy, Planning, Legislation, and Analysis
Food and Drug Administration (FDA)
5630 Fishers Lan, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2017-N-5608 - Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments (82 Fed. Reg. 45597, September 29, 2017)

Dear Commissioner Abram:

The American Association of Nurse Practitioners (AANP) is the largest full-service national professional membership organization for nurse practitioners (NPs), which represents the more than 234,000 nurse practitioners across the country. We thank you for the opportunity to comment and look forward to working with the FDA Opioid Policy Steering Committee to combat the opioid epidemic.

As you may know, nurse practitioners are advanced practice registered nurses (APRNs) who are prepared at the masters or doctoral level to provide primary, acute, chronic and specialty care to patients of all ages and walks of life. Daily practice includes: assessment, ordering, performing, supervising and interpreting diagnostic and laboratory tests, making diagnoses, initiating and managing treatment including prescribing medication (as well as non-pharmacologic treatments), coordination of care, counseling, and educating patients and their families and communities. They practice in nearly every health care setting including clinics, hospitals, VA and Indian Health Care facilities, emergency rooms, urgent care sites, private physician or NP practices (both managed and owned by NPs), nursing homes, schools, colleges, retail clinics, public health departments, nurse managed clinics, homeless clinics, and home health.

Nurse Practitioners (NPs) are educated in pharmacologic, pathophysiologic, psychologic and sociologic aspects of pain treatment that includes the diagnosis and treatment of patients with addictive diseases including those acquired from overdosing with opioids and other schedule drugs. The pharmacodynamics, therapeutics and management of controlled drugs including opioids is a part of both baccalaureate nursing education and graduate advanced practice nursing education. NPs hold prescriptive authority in all 50 states and the District of Columbia and have been providing high quality health care to patients for over half a century. With the passage of CARA in 2016, nurse practitioners were authorized to prescribe medication-assisted therapies (MATs) after taking the necessary training and obtaining the required DEA waiver to do so.

In this request for comment the FDA identified three focus areas: 1) assessing benefit and risk in the opioids setting; 2) steps to promote proper prescribing and dispensing; and 3) requirements for provider education. We will address each of these areas, as well as the general request for feedback. We look forward to continued work with the FDA to battle the opioid epidemic.

I. Assessing Benefit and Risk in the Opioids Setting

When assessing the benefits and risk of opioids the FDA must consider how guidelines can be adapted for individual responses to pain and the varying pain thresholds that patients have. While abuse and misuse are very serious concerns, there is also the concern that guidelines that are too strict may prevent a non-abusing patient who needs opioid pain management from obtaining medically necessary medication. Clinicians who provide pain management to patients, including nurse practitioners, should be included in the development of any guidelines to strike this balance.

II. Steps to Promote Proper Prescribing and Dispensing

The FDA requested feedback regarding the addition of recommended duration of treatment for specific types of patient needs to opioid product labeling. In addition, the FDA should work with prescriber groups to develop expert guidelines on proper prescribing. We should note the two are not mutually exclusive, and any recommendations for the duration of treatment should involve significant input from healthcare providers, including nurse practitioners. Healthcare providers are in the best position to understand the nuanced needs of their patients and develop recommendations that consider the various conditions that a patient may experience.

Guidelines that the FDA develops in conjunction with the provider community should include considerations of opioid selection and adverse reaction, periodic review and monitoring of patients through screening tools such as SBIRT (Screening, Brief Intervention, and Referral to Treatment) and consultation with prescription-drug monitoring programs prior to prescribing. These recommendations should also include exceptions for certain chronic pain sufferers such as hospice patients and patients with cancer pain.

The FDA should also consider prescribing guidelines that include patient self-management and non-pharmacologic treatments of pain. Many providers have difficulty prescribing non-pharmacologic pain treatments due to a lack of available options. Since many insurers base their coverage criteria on FDA policies, incorporating alternatives to opioids such as physical therapy and massage therapy in prescription recommendations will help increase their availability.

III. Requirements for Provider Education

AANP is a strong advocate for provider education and since 2013 has educated more than 24,000 nurse practitioners on the safe prescribing of opioids for pain management, which includes the CDC guidelines. To aid in the fight against the disease of addiction, AANP is a partner with the Collaborative on REMS Education (CO*RE), 11 interdisciplinary organizations working together to improve pain management and prevent adverse outcomes. AANP has collaborated with the American Society of Addiction Medicine (ASAM) to provide the required 24-hour education/training described in CARA authorizing NPs to prescribe buprenorphine and other medications for the treatment of Opioid Use Disorder (OUD). As of November 30, 2017, AANP has provided this training to 3,954 nurse practitioners.

AANP works closely with the Substance Abuse and Mental Health Services Administration (SAMHSA). In May 2016 AANP joined other state and national organizations as members of the Coalition to Stop Opioid Overdose, a coalition dedicated to advancing legislation and regulatory policies to address the opioid public health crisis. AANP has worked closely with the U.S. Surgeon General to discuss best practices in addressing the opioid epidemic. AANP has worked with the National Institute on Drug Abuse (NIDA) and is currently participating in a grant from NIDA to create and provide education on adolescent substance abuse.

In addition to working and collaborating with other organizations, AANP has provided many and varied communications to both members and nonmembers of our organization related to the safe treatment of pain and substance use disorder. AANP has focused on safe opioid prescribing and pain management by offering courses, workshops and seminars at all three of our annual conferences. Additionally, AANP has provided resources such as live webinars addressing the opioid crisis, continuing education activities and online courses, including the 24-hour waiver course for NPs to prescribe Buprenorphine and other medications for opioid use disorders.

If the FDA decides to adopt mandatory education for opioid prescribing it is important that the content and educational requirements are consistent for all providers, regardless of licensure. Collaboration with key stakeholders at the local, state and federal levels is important for developing consistency among educational programs to reduce duplication or conflicting requirements. The FDA should ensure that educational requirements can be met at no cost to the provider to lessen provider burden and promote widespread adoption of educational opportunities. It is essential that the FDA work with all stakeholders to develop adaptive learning options that allow providers to demonstrate existing knowledge and focus on areas where they have less knowledge or experience.

IV. Additional Matters for Consideration

We cannot stress enough the importance of including all qualified providers and removing barriers that inhibit a provider's ability to provide the best care to their patients. The opioid epidemic requires an all hands-on deck response, and as the FDA develops regulations to combat the opioid epidemic it is important that the regulations are inclusive of all providers, including nurse practitioners.

The FDA should continue to educate the public through public awareness campaigns focused on the scope of the opioid epidemic and the risk of taking opioids. Part of this campaign should involve educating the public on alternative pain management options. We also encourage the FDA to continue to take steps that allow for easier disposal of unused medications to facilitate the removal of excess opioids from circulation in the community.

As the FDA works to eradicate this epidemic, AANP must to be actively involved. We look forward to working together to ensure our patients gain access to treatment they so desperately need. Should you have comments or questions, please direct them to MaryAnne Sapio, V.P. Federal Government Affairs, msapio@aanp.org, 703-740-2529.

Sincerely,

David Hebert
Chief Executive Officer