

February 8, 2018

Anna K. Abram
Deputy Commissioner for Policy, Planning, Legislation, and Analysis
Food and Drug Administration
Attention: Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted electronically to <https://www.regulations.gov>

Re: FDA-2017-N-5897 for “Packaging, Storage, and Disposal Options to Enhance Opioid Safety-Exploring the Path Forward

Dear Deputy Commissioner Abram,

The American Nurses Association (ANA) is pleased to provide written comment to the Food and Drug Administration (FDA), regarding Docket No. FDA-2017-N-5897 for Packaging, Storage, and Disposal Options to Enhance Opioid Safety-Exploring the Path Forward. ANA is the premier organization representing the interests of the nation’s 3.6 million registered nurses (RNs) through its constituent and state nurses associations, organizational affiliates, and individual members. RNs serve in multiple direct care, care coordination, and administrative leadership roles, across the full spectrum of health care settings. RNs provide and coordinate patient care, educate patients and the public about various health conditions, and provide advice and emotional support to patients and their family members. ANA members also include those practicing in the four advanced practice registered nurse (APRN) roles: nurse practitioners, clinical nurse specialists, certified nurse-midwives and certified registered nurse anesthetists.¹ ANA is dedicated to partnering with health care consumers to improve practices, policies, delivery models, outcomes, and access across the health care continuum.

The opioid crisis, including substance use disorder (SUD) and the nurse’s role in addressing these issues, has been a top priority for ANA for over two decades. For the majority of ANA’s members, the complexity of opioid misuse will continue to be front and center as the nation grapples with changing the trajectory of this tragic epidemic. Today, over 91 Americans die every day from an opioid overdose.² In 2015, 12.5 million Americans misused opioid prescription medications, with an estimated 2.1 million misusing prescribed opioids for the first time.³ In addition, between 2000 and 2015, approximately 12,000 children or young

¹ The Consensus Model for APRN Regulation defines four APRN roles: certified nurse practitioner, clinical nurse specialist, certified nurse-midwife and certified registered nurse anesthetist. In addition to defining the four roles, the Consensus Model describes the APRN regulatory model, identifies the titles to be used, defines specialty, describes the emergence of new roles and population foci, and presents strategies for implementation.

² The Centers for Disease Control and Prevention. (2017, August 30). *Opioid Overdose, Understanding the epidemic*. Retrieved from <https://www.cdc.gov/drugoverdose/epidemic/index.html>

³ Substance Abuse and Mental Health Services Administration (SAMHSA). (2015). *Results from the 2015 national survey on drug use and health: detailed tables*. Retrieved from: [https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015.pdf](https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015.pdf)

adults annually were poisoned due to opioid ingestion. Greater than 90% of the events occurred at home and around 60% occurred in children younger than 5 years.⁴

Fueling the opioid crisis have been, in part, well-meaning attempts over time to control pain in America. Over 100 million adults living in the U.S. are suffering from common chronic pain conditions, including a reported 44% of U.S. soldiers who have returned from deployment.⁵ Chronic pain is complex and involves biological, psychological, and social factors. As such, there exist pain management strategies besides prescribing opioids to mitigate chronic pain conditions and prevent the worsening of the opioid epidemic.

ANA supports the FDA's *Opioids Action Plan* that is aimed at taking concrete steps toward reducing the impact of opioid abuse in communities across America. Moreover, ANA was pleased to participate in the two-day Packaging, Storage, and Disposal Options to Enhance Opioid Safety – Exploring the Path Forward Workshop in December 2017. Specifically, ANA encourages the FDA to align its activities with regard to prescribing, storage and disposal to all agencies and partners who are in the trenches of fighting this epidemic. Government agencies, the healthcare system, and individual stakeholders are all working with limited resources; therefore, we need to ensure that regulations are not overly burdensome and programmatic strategies are effective without creating more barriers to change the trajectory of opioid abuse.

Prescribing

ANA supports allowing providers with prescribing authority to be able to practice to the full extent of their education and license. Providers should have the authority to determine the best course of care including the ability to prescribe complementary and alternative therapies in order to treat the underlying and direct causes of pain. In addition, expanding prescribing authority to APRN and physician assistants (PAs) will assist in meeting demand for medically assisted treatment for substance use disorder.

Proper Packaging, Storage and Disposal

Policy recommendations on proper storage and disposal of opioids must support RNs, the larger health care interdisciplinary team, and community stakeholders (e.g., pharmacies and police headquarters). Current guidelines from the FDA instruct consumers of opioids and medications in general to keep medicines in a secured location out of reach and sight of children and pets.⁶ However, educational programs, storage options, and routine reinforcement through media campaigns are lacking and should be considered moving forward. Moreover, when medicines are expired or unwanted, safe disposal is vital to reduce the chance that others may misuse the unneeded medicines. The FDA recommends take-back programs through groups such as the U.S. Drug Enforcement Administration, local law enforcement, or waste management.⁷ Moreover, ANA encourages the FDA to support education on providers and patients on issues such as prompt disposal methods and return of unused medications options. If packaging changes to current distribution are being considered, the evidence based reason to change must outweigh the financial and logistical burden to

⁴ Allen, J.D., Casavant, M.J., Spiller, H.A., Chounthirath, T., Hodges, N.L., & Smith, G.A. (2017, March). Prescription opioid exposures among children and adolescents in the United States: 2000–2015. *Pediatrics* 139(4), 1-10. Retrieved from: <http://pediatrics.aappublications.org/content/pediatrics/early/2017/03/16/peds.2016-3382.full.pdf>

⁵ Institute of Medicine. (2011). *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*. Retrieved from <https://www.nap.edu/catalog/13172/relieving-pain-in-america-a-blueprint-for-transforming-prevention-care>

⁶ Food and Drug Administration (FDA). (2016, June 13). *Put Your Medicines Up and Away and Out of Sight*. Retrieved from: <https://www.cdc.gov/Features/MedicationStorage/>

⁷ FDA. (2018, January 11). *Disposal of Unused Medicines: What You Should Know*. Retrieved from: <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm>

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change. Finally, packaging changes should be considered for specific treatment courses or risk of abuse in specific populations and not be a broad stroke approach that may, in fact, create additional barriers to other populations in need.

We appreciate the opportunity to share our views with the FDA and hope to continue to work together as a partner and for nursing expertise. If you have any questions, please contact Mary Beth Bresch White, Director, ANA Health Policy, at 301.628.5022 or marybreschwhite@ana.org.

Sincerely,

A handwritten signature in cursive script that reads "Cheryl A. Peterson". The signature is written in black ink on a white background.

Cheryl Peterson, MSN, RN
Vice President for Nursing Programs

cc: Pamela Cipriano, PhD, RN, NEA-BC, FAAN, ANA President
Debbie Hatmaker, PhD, RN, FAAN, ANA Interim Chief Executive Officer