



March 16, 2018

Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

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

Re: Opioid Policy Steering Committee: Prescribing Intervention – Exploring a Strategy for Implementation;
Public Hearing; Request for Comments [FDA-2017-N-6502]

Dear Commissioner Gottlieb,

The American Nurses Association (ANA) is pleased to provide written comment to the Food and Drug Administration (FDA), regarding Docket No. FDA-2017-N-6502 for Opioid Policy Steering Committee: Prescribing Intervention – Exploring a Strategy for Implementation. ANA is cautious to support arbitrary threshold drug amounts for opioid analgesic prescriptions above which prescribers would be required to provide additional documentation of medical necessity. ANA supports the Agency considering additional measures intended to improve the safety of patient storage and handling of opioid analgesics.

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

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>

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 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 work in fighting this epidemic. Specifically, ANA encourages the FDA to align its activities with regard to prescription, 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.

ANA is cautious to support arbitrary threshold drug amounts for opioid analgesic prescriptions above which prescribers would be required to provide additional documentation of medical necessity.

ANA is guarded against supporting additional steps in the workflow of prescribers. Clinicians already face tremendous reporting burdens through the course of their workflows. Having to justify dosage and reason for patients that need a prescription greater than an arbitrary number defined, will only lead to more burden on clinicians. Furthermore, prior to implementing the additional documentation measure, FDA should ensure that this additional process step does not cause a delay in care for any patient population. If the proposed documentation measure is passed, EHR vendors, clinicians, pharmacies, and government agencies need to come together to work on interoperability, privacy, and safety.

Moreover, ANA is cautious to suggest or support a threshold drug amount for opioid analgesic prescriptions because of the potential to seriously undermine the ability to individualize pain management plans for patients with chronic pain. Prior to setting an arbitrary threshold that requires an increased burden on a prescriber, the FDA should work with its partners to review concurrent increases in pain complaints, as well as push for third party payment for non-opioid pain management strategies; such strategies include Complementary and Alternative Medicine (CAM). In conjunction, consensus and evidence based de-escalation guidelines should be implemented to minimize abrupt changes in patient's pain management. We do, however, support the underlying rationale and intent to prevent excess unused pills into communities.

In addition to review of thresholds, ANA also recommends strong review of barriers to practitioner desired opioid prescribing in acute pain settings. These would include allowing for flexibility in prescribing in quantities of 1-5 pills, rather than larger quantities mandated by reimbursement patterns. As part of review of prescribers, the Dental and Veterinary communities should be active partners in the dialogue. Finally, ANA

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)

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>

supports allowing providers with prescriptive 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 patient care, including the ability to prescribe complementary and alternative therapies in order to treat the underlying and direct causes of pain. In addition, expanding prescriptive authority to APRNs and PAs will assist in meeting demand for medically assisted treatment for SUD.

ANA supports the Agency considering additional measures intended to improve the safety of patient storage and handling of opioid analgesics.

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 consistent, nation-wide 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 Such take back opportunities should be offered frequently and in a non-punitive manner. Furthermore, 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 change.

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 me at 301.628.5022 or marybreschwhite@ana.org.

Sincerely,



Mary Beth Bresch White
Director, Health Policy

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

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>

