To Whom It May Concern:

The American Association of Nurse Anesthetists (AANA) is the professional association for nearly 48,000 Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists, representing over 90 percent of the nurse anesthetists in the United States. The AANA welcomes the opportunity to submit comments regarding the U.S. Food and Drug Administration (FDA) notice of a public meeting and request for comments, “Exploring Naloxone Uptake and Use” (80 Fed. Reg. 28621, May 19, 2015).

The AANA supports the increased public availability of naloxone to treat opioid-related overdoses and encourages public education and awareness initiatives to effectively recognize an opioid overdose, initiate an emergency response, and administer live-saving treatment.

The AANA shares the FDA’s concern regarding the alarming death rate of overdose from both prescription opioids and heroin.\(^1\) Witnessed or suspected opioid overdoses can be reversed when a bystander is able to administer naloxone and call for emergency medical care.\(^2\) Though not a substitute for emergency medical care, naloxone is an effective antagonist when administered immediately to reverse an opioid-related drug overdose.

Making this life-saving drug more widely available to the public has opportunity to decrease the number of deaths attributed to prescription and illicit opioid use. U.S. and international health organizations recommend providing naloxone kits to individuals who may witness an opioid overdose; to patients in substance use treatment programs; to persons leaving prison and jail; and as a component of responsible opioid prescribing.\(^2,3,4\) Naloxone, as a pure opioid antagonist that displaces narcotics at the opioid receptor sites, does not have potential for abuse and does not cause adverse effects in persons who have not taken opioids. Naloxone may reverse dependency and cause excess sympathetic nervous system response related to withdrawal.

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The AANA advocates for continued public education and awareness initiatives to teach individuals how to recognize opioid abuse and overdose, initiate the emergency response system, and administer naloxone along with other life-saving measures. Members of the public may lack formal medical knowledge and training, but may be first to identify a family member, friend, or acquaintance who has overdosed on opioids. A number of states have addressed the opioid overdose epidemic by removing legal consequences against individuals who act in good faith and administer naloxone to individuals who are suspected of opioid overdose. Increasing the availability of naloxone in communities may reach underserved and at risk populations that may have difficulty obtaining a prescription for naloxone.

Naloxone education should also extend to clinicians who prescribe opioids, treat high-risk patients, or provide addiction treatment. Working collaboratively with the patient, their family, or caregiver to identify substance abuse, understand the risks and complications of opioid overdose, and provide access to emergency overdose management, which includes naloxone, may be critical to saving a patient’s life. Patients, their families, or caregivers should also be aware of community-based drug treatment and education programs which they can turn to for help.

Combating opioid abuse, dependence, and overdose is the goal of the Department of Health and Human Services (HHS) evidence-based opioid initiative with a focus on three priority areas: to inform opioid prescribing practices, increase the use of naloxone, and expand the use of medication-assisted treatment of opioid use disorder. AANA encourages the FDA to continue to partner with HHS, other stakeholder agencies, professional associations, such as the AANA, and public health and patient advocacy organizations to develop a comprehensive strategy addressing barriers to naloxone access. Removing barriers to naloxone availability and affordability and providing education for those who may witness opioid overdose is an important part of a strategy to decrease the rate of opioid-related deaths in the U.S.

We thank you for the opportunity to comment and further partner with the FDA on this important public health issue. Please do not hesitate to contact Lynn Reede, CRNA, DNP, MBA, Senior Director, Professional Practice, at (847) 655-1136 or lreede@aana.com if you have any questions or comments.

Sincerely,

Sharon Pearce, CRNA, MSN
AANA President

cc: Wanda O. Wilson, CRNA, PhD, AANA Executive Director/Chief Executive Officer
    Lynn Reede, CRNA, DNP, MBA, Senior Director, Professional Practice

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