



American Association of  
**NURSE ANESTHESIOLOGY**

August 24, 2023

Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852  
Docket number: [FDA-2023-D-1987](#)

To Whom It May Concern,

The undersigned organizations welcome the opportunity to comment on the draft guidance entitled “Psychedelic Drugs: Considerations for Clinical Investigations.” The American Association of Nurse Anesthesiology and the American Nurses Association represent the interests of the nation's millions of registered nurses and advanced practice registered nurses.

Use of psychedelic drugs in the treatment of medical conditions such as psychiatric disorder and substance use disorders, is an emerging practice for CRNA’s and the AANA and ANA understand the importance of designing comprehensive and sound clinical studies so the results can be interpretable and meet the substantial evidence standard to establish effectiveness. CRNAs possess a strong foundation in nursing, critical care, anesthesia delivery, pain management, advanced physiology/pathophysiology, pharmacology, and advanced physical assessment - all of which are critical to safely delivering patient care when integrating new technologies or drugs. In addition to their extensive anesthesia experience, many CRNAs also provide medically necessary services within their scope of practice and standards of nurse anesthesia practice in the fields of mental health, pain management and substance use disorder treatments. In addition to their clinical expertise, CRNAs serve as educators and researchers. Many CRNAs lead studies and research on various topics, including pain management, the science of anesthesia, mental health and substance use disorders, health policy, education and other clinical issues and are well versed on effective and proper research methods, quality improvement, and emerging technologies to optimize patient outcomes.<sup>1</sup>

All this experience permits CRNAs to be well positioned to serve as leaders in studies. Therefore, we request that CRNAs are included as those provider types who are allowed to serve as lead monitor on all

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<sup>1</sup> AANA CRNA Scope of Practice,  
[https://issuu.com/aanapublishing/docs/scope\\_of\\_nurse\\_anesthesia\\_practice\\_2.23?fr=sNDg2MDU2NDxMjU](https://issuu.com/aanapublishing/docs/scope_of_nurse_anesthesia_practice_2.23?fr=sNDg2MDU2NDxMjU)

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studies. Restricting access to a broad scope of nurses is a disservice to patients to access these treatments. CRNAs play a critical role by ensuring proper anesthesia services management which can make a tremendous difference in terms of improving patient flow, patient safety, and cost savings. CRNAs are involved in every aspect of anesthesia services and work in many types of facilities and also provide acute, chronic, and interventional pain management services. In some states they are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities. CRNAs have been on the front lines of developing novel non-opioid based treatments for both chronic and acute pain and the AANA supports maximum flexibility in allowing pain treatment plans that rely on the clinical judgment of the practitioner directing care.

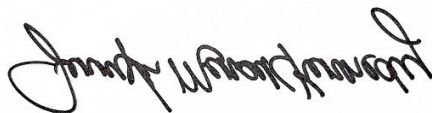
In the mental health arena, CRNAs are educated and trained to administer ketamine both for sedation and general anesthesia, chronic pain management and also ketamine infusion therapy and related modalities for psychiatric disorders and chronic pain. Ketamine infusion clinics are becoming more available, and this therapy has been shown to have antidepressive properties and is increasingly becoming used to treat psychiatric disorders, including major depressive disorder (MDD), bipolar disorder, treatment-resistant depression, and post-traumatic stress disorder (PTSD). The AANA supports a patient-centered, interdisciplinary approach to managing patients who suffer from psychiatric disorders and may benefit from ketamine infusion therapy. As with all clinical practice, CRNAs practice in accordance with professional ethics, scope and standards of practice, sound professional judgment, available evidence, interests of the patient, and applicable law. When administering ketamine for the treatment of psychiatric disorders, CRNAs collaborate with healthcare professionals whose practice includes focusing on and diagnosing psychiatric disorders within their professional and state scope of practice.<sup>2</sup>

We urge the agency to consider the invaluable contributions that CRNAs can make as the lead monitor for studies, and they should be included on the list of healthcare professionals who serve in this role. The AANA appreciates the opportunity to comment on this guidance. Should you have any questions regarding our comments, please feel free to contact Randi Gold, AANA Senior Associate Director, Federal Regulatory and Payment Policy at 202-741-9082 or [rgold@aana.com](mailto:rgold@aana.com).

Sincerely,



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AANA President



Jennifer Mensik Kennedy, Ph. D., MBA, RN, NEA-BC, FAAN  
ANA President

cc: William Bruce, MBA, CAE, AANA Chief Executive Officer  
Ingrida Lusic, AANA Chief Advocacy Officer  
Randi Gold, MPP, AANA Senior Associate Director Federal Regulatory and Payment Policy

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<sup>2</sup> AANA and APNA Joint Position Statement on Ketamine Infusion Therapy for Psychiatric Disorders (2019), <https://issuu.com/aanapublishing/docs/apna-aana-joint-statement-on-ketamine?fr=sY2VIZjU2NDAxMjU>