



To: FDA

RE: [FDA-2023-D-1987](#) (Psychedelic Drugs: Considerations for Clinical Investigations; Draft Guidance for Industry)

From: Organization of Psychedelic and Entheogenic Nurses (OPENurses)

Date: July 21, 2023

To Whom it May Concern:

We, the Organization of Psychedelic and Entheogenic Nurses (OPENurses), are writing to address the proposed guidance FDA-2023-D-1987 (Psychedelic Drugs: Considerations for Clinical Investigations; Draft Guidance for Industry).

Nurses represent the largest group of health care workers, with 3.8 million nurses who are vital links for providing access to high-quality care across the country. OPENurses represents the largest group of nurses engaged in, practicing, and researching psychedelic therapies, and works to advocate for best practices that serve and protect patients undergoing psychedelic therapy.

We are commenting today to express our concerns about the limited roles that will be afforded Registered Nurses (RN) and Advanced Practice Registered Nurses (APRN) under this proposed guidance. Restricting access to a broad scope of nurses is a disservice to patients because it limits their ability to safely access these potentially life saving treatments.

While we are pleased to see Psychiatric Nurse Practitioners (PMHNP) among the list of professionals who would qualify as *lead monitors*, the guidance as it is currently written leaves out several important groups who could serve as highly skilled and safe psychedelic monitors.

For lead monitors, we suggest this guidance be broadened to include *Advanced Practice Registered Nurses (APRN)* to the list of Licensed Independent Practitioners who can serve as lead monitors. This would ideally include and not be limited to, the aforementioned Psychiatric/Mental Health Nurse Practitioners (PMHNP) in addition to other key APRN's such as Oncology Nurse Practitioners, Adult/Geriatric Nurse Practitioners (who may be working on palliative care studies), and Certified Registered Nurse Anesthetists (who often administer ketamine). It is worth noting that the guidance currently would permit not only psychiatrists, but

“other physicians” to serve in this role. As such, we advise that the guidance should read “Psychiatric Nurse Practitioners and other Advanced Practice Registered Nurses.”

Additionally, and importantly, we are writing to advocate for the inclusion of non-psychiatric nurses with the appropriate psychedelic education and training to be included as *assistant monitors* during therapy sessions involving psychedelic substances. The current language would exclude the vast majority of nurses due to the requirements for a bachelor’s degree and 1+ years of experience in a licensed mental healthcare setting. About 30% of Registered Nurses in the United States are trained at an Associates Degree in Nursing (ADN) level as opposed to a Bachelor’s Degree level, yet both groups of nurses hold a Registered Nurse license.

Additionally, only about 4% of RN’s work in Psychiatric/Mental Health (APNA, *Expanding Mental Health Care Services in America*, 2019). Many nurses who work in fields where mental health concerns are often present, such as hospice, palliative care, oncology, emergency room, addiction medicine, critical care, labor & delivery, primary care, and anesthesiology would not be able to serve as assistant monitors under the proposed guidance because their experience would not be in a “licensed mental healthcare setting”.

Emotional, mental, and social support of patients is a basic skill of all nurses, who, per the National Council of State Boards of Nursing must “provide and direct nursing care that promotes and supports the emotional, mental and social well-being of the client experiencing stressful events as well as clients with acute or chronic mental illness.”

It would be a significant loss to both patients and the nursing field, if nurses, particularly those with extensive relevant experience, are unable to become assistant monitors.

As such, we propose the following revision: “An assistant monitor with a bachelor’s degree or a licensed registered nurse. Assistant monitors should have at least 1 year of clinical experience in a licensed healthcare setting.”

As the field of psychedelic-assisted therapy continues to show promise in the treatment of various mental health conditions, it is essential to leverage the unique skill sets and expertise of nurses to enhance patient safety and care. We firmly believe that allowing nurses to serve as assistant monitors would greatly contribute to the quality of care and accessibility of psychedelic-assisted treatments for patients in need. Additionally, nurses were among the professionals involved in the psychedelic research trials that were conducted in the 1950’s and 1960’s (Parley, K 1964), so there is precedent for their inclusion in the field.

Nurses are very familiar with altered states of consciousness, as they frequently care for patients in various states of awareness and perception such as following anesthesia, trauma, childbirth, psychosis, substance use, or in the time leading up to death. This exposure enables them to effectively navigate complex situations and support individuals before, during, and following psychedelic experiences. Their expertise in assessing and monitoring patients’ physical and psychological well-being, along with their knowledge of drug interactions and side

effect management, will help ensure the safety and comfort of patients throughout the medicine sessions. Nurses are well-equipped to recognize abnormal or concerning presentations which might require medical intervention and/or emergency communication. This will be especially important as psychedelic research begins to include patients with greater medical complexity, as these patients have historically been excluded from early trials, but will need to be studied to understand the safety risks of Psychedelic Assisted Therapy (PAT) in a more representative population. Furthermore, appropriate, therapeutic touch, a practice within the scope of nursing, can provide additional comfort, support, and safety to patients during their psychedelic treatment.

The skills of nurses complement those of the therapists who will be the lead monitors. Nurses are highly skilled professionals who are trained to administer medicine, monitor vital signs, and respond to adverse medical experiences, all of which are critical to safe psychedelic care. Additionally, nurses excel in providing compassionate and holistic care to individuals across a range of physical, spiritual, and emotional challenges. Their extensive experience being *with* patients during difficult and often prolonged experiences makes them well-equipped to support individuals during psychedelic treatment sessions. The listening skills, physical care, and compassionate presence that are intrinsic in a nurse's DNA can greatly enhance the therapeutic alliance and create a supportive environment for patients throughout the treatment process.

Affordability and accessibility are critical factors in ensuring widespread implementation of psychedelic-assisted treatments. Nurses are known for their cost-effectiveness in healthcare delivery, and their involvement as assistant monitors can help reduce treatment costs. By leveraging the existing infrastructure and resources within healthcare settings, the integration of nurses into multidisciplinary psychedelic therapy teams can make these treatments more affordable, ultimately increasing their accessibility to a broader patient population.

It is key to acknowledge the importance of diversity in this modality of care. Patients often establish enhanced therapeutic alliances with facilitators who share similar backgrounds and/or life experiences. Nurses, coming from diverse backgrounds themselves, can foster a deep sense of trust and understanding with patients, thereby augmenting the therapeutic rapport and overall treatment outcomes. By including nurses as monitors, we can ensure a more inclusive and culturally sensitive approach to psychedelic therapy.

Lastly, nurses consistently rank among the most trusted and ethical professionals. Their commitment to patient-centered care and their unwavering dedication to ensuring informed consent and promoting the safety and well-being of their patients are widely recognized. Nurses are outstanding advocates and educators and are capable of being a unique and reliable multi-faceted resource for patients and their loved ones throughout the preparation, dosing, and integration phases of these sessions. A recent UC Berkeley survey showed that this trust of nurses extended to psychedelic treatments, with 76% of respondents stating that they felt that nurses were “very trustworthy” or “somewhat trustworthy” sources of information about psychedelics, higher than any other profession.

In conclusion, we strongly urge the FDA to consider the invaluable contributions that non-psychiatric nurses can make in the field of psychedelic-assisted therapy and adjust the guidelines accordingly. Their unique skill sets, extensive clinical experience, and compassionate nature make them ideal professionals to serve as monitors during therapy sessions. They will undoubtedly enhance patient care, promote safety, foster trust, increase accessibility, and ultimately contribute to the success of this very promising modality of care.

To summarize our recommendations, we encourage you to make the following changes:

- Lead monitors: “Psychiatric Nurse Practitioners *and other Advanced Practice Registered Nurses,*”
- Assistant monitors: “*An assistant monitor with a bachelor’s degree or a licensed registered nurse. Assistant monitors should have at least 1 year of clinical experience in a licensed healthcare setting.”*

Thank you for your time and attention to this matter. We appreciate your meticulous work on these guidelines and trust that you will consider our feedback as you finalize them. Please do not hesitate to contact us if you would like any additional information.

Sincerely,

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References:

American Association of Nurse Practitioners (nd). NP Fact Sheet, Accessed July 20, 2023 from <https://www.aanp.org/about/all-about-nps/np-fact-sheet>

American Psychiatric Nurses Association (2019) Expanding Mental Health Care Services in America - The Pivotal Role of Psychiatric Mental Health Nurses. Accessed July, 2023 from https://www.apna.org/wp-content/uploads/2021/03/Expanding_Mental_Health_Care_Services_in_America-The_Pivotal_Role_of_Psychiatric-Mental_Health_Nurses_04_19.pdf

Parley K. (1964). Supporting the Patient on LSD Day. *The American Journal of Nursing*, 64, 80–82.

Pollan M, Khan I, West T (2023) The UC Berkeley Psychedelics Survey. Accessed July 21, 2023 from <https://docs.google.com/presentation/d/1B6LBXa4QLyPnlqxYvnWvx3Y3j29KJB5X/edit?usp=sharing&oid=108654425957029718050&rtpof=true&sd=true>