May 31, 2016

Kana Enomoto
Principal Deputy Administrator
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Rockville, MD 20857

RE: RIN 0930-AA22: Medication Assisted Treatment for Opioid Use Disorders

Dear Ms. Enomoto:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to comment on the proposed rule titled “Medication Assisted Treatment for Opioid Use Disorders” (RIN 0930-AA22). The AANA submits comments to the proposed rule for the following areas:

- Support for Efforts that Expand Access to Treatment For Substance And Opioid Use Disorders
- Concerns Regarding Medication Assisted Treatment

Additionally, the AANA appreciates the opportunity to respond to the following agency questions:

(1) Evidence Supporting an Optimal Patient Prescribing Limit
(3) Practitioner Training for 200 Patient Limit
(4) Alternate pathways to qualify for 200-patient prescribing limit
(8) Synchronization of Renewal Request with DEA Practitioner Registration Renewal
(13) Reporting Periods
(14) Balance of Access and Safety

Background of CRNAs and the AANA
The AANA is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists, with membership that includes more than 49,000 CRNAs and student nurse anesthetists representing over 90 percent of the nurse anesthetists in the United States. CRNAs are advanced practice registered nurses (APRNs) who personally administer more than 40 million anesthetics to patients each year in the United States. CRNAs provide acute, chronic, and interventional pain management services. In some states are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities.

Based on education, training and work experience of our CRNA membership, the AANA is very aware of the risks that opioid use disorder poses for the country, and especially for healthcare professionals who work directly with highly addictive medications. By virtue of education and individual clinical experience, a CRNA possesses the necessary knowledge and skills to provide the full range of anesthesia and related care, and to employ therapeutic, physiological, pharmacological, interventional, and psychological modalities in the management and treatment of acute and chronic pain. Furthermore, because anesthesia professionals were found in the early 1980s to be five times more likely than the general population to abuse opioids due to their access, the AANA in 1983 established the Peer Assistance Advisors Committee (PAAC) to address patient and provider safety.
concerns related to impaired providers and drug abuse in the nurse anesthesia community. The PAAC is committed to educational endeavors to increase awareness of addiction, promote prevention modalities, respond to helpline calls with peer assistance, and develop evidence-based guidelines for early recognition, intervention, treatment, long-term recovery, and appropriate re-entry for anesthesia professionals struggling with substance use disorder. From these educational, clinical and professional experiences and expertise in opioid pharmacology, the AANA is developing professional practice standards for CRNAs providing anesthesia and pain care to patients addicted to opioids.

**AANA Supports Efforts that Expand Access to Treatment for Substance and Opioid Use Disorders**

The AANA supports the goal of this proposed rule which is to increase access to treatment for opioid use disorder while reducing the opportunity for diversion of the medication for unlawful use. We believe multi-faceted public and private sector initiatives are important to help address the prescription opioid and heroin epidemic. We support efforts for improving access to treatment for substance and opioid use disorders, which may include:

- Safe, responsible use of medication assisted therapy (MAT) to assist with comprehensive addiction treatment which includes close medical supervision, behavioral therapy or counseling, patient education, evaluation for individualized treatment with consideration of co-occurring disease and disorders, ability to refer patients to higher levels of care as necessary, and drug screening to minimize the risk of relapse and maximize the benefit of treatment to support the patient’s long-term recovery;\(^2\)-\(^4\);
- Expanding access to treatment of substance use disorders through the creation of specialty education and credential pathways for advanced practice professionals to enter the field of addictionology;
- Increasing patient volume per practitioner to treat opioid use disorder patients with MAT when appropriate without overburdening and hindering the ability to provide appropriate care for other patients in a comprehensive treatment program;
- Expanding availability of Naltrexone or its extended use version Vivitrol which has no abuse potential, is non-narcotic, and has no side effects that may cause impairment;
- Increased use of non-pharmacologic and non-opioid management of acute and chronic pain, such as options listed in the [AANA Chronic Pain Management Guidelines] and [American Chronic Pain Association (ACPA)];
- Nurse anesthetists providing anesthesia care and pain management services with a holistic perspective for the patient, in a manner that reduces the need for opioids intraoperatively and postoperatively.

**AANA Concerns Regarding Medication Assisted Treatment**

In the effort to mitigate the current opioid epidemic, caution is needed to prevent the misuse of buprenorphine. The AANA is concerned that medication assisted treatment would replace or not be used in combination with other important treatment modalities (e.g., counseling, drug screen) and would be used without appropriate supervision and monitoring. Some specific concerns regarding expanding buprenorphine use for MAT include:

- **Abuse Potential:** Buprenorphine (agonist) and buprenorphine with naloxone (agonist/antagonist) are classified by the Drug Enforcement Administration (DEA) as Schedule III narcotics with abuse and dependency potential.\(^7\)-\(^8\)
• **Acute Treatment:** Buprenorphine products are insufficient when used alone for any phase of treatment, but are valuable when included in the management of acute opioid withdrawal (detoxification) and for short-term treatment

• **Relapse Prevention:** There is risk of dependence, misuse and diversion when buprenorphine is used for relapse prevention.

• **Safety:** Impaired decision making, especially for individuals in safety-sensitive professions (e.g., airlines pilots, transit workers, healthcare professionals) pose public/patient safety concerns due to possible cognitive and motor impairment related to buprenorphine therapy. For those professions where vigilance and decision making are key to safety, naltrexone may be considered as an alternative to buprenorphine therapy.

**RESPONSES TO AGENCY QUESTIONS FOR COMMENT**

(1) **Evidence Supporting an Optimal Patient Prescribing Limit**
The AANA supports the increased prescribing limit to expand patient access to comprehensive treatment with appropriate oversight for each patient.

(3) **Practitioner Training for 200 Patient Limit**
The AANA believes that limiting the MAT provider qualifications to physicians may be too narrow to increase access to comprehensive treatment as the opioid epidemic continues to grow. Addictionology specialty education pathways could be developed to include advanced practice professionals (e.g., CRNAs, nurse practitioners, physician assistants, psychologists). Nurse anesthetists currently provide subspecialty care in chronic pain management using holistic approaches to minimize or reduce the use of opioids. If a pathway for addictionology education and training is available for CRNAs and other advance practice professionals, they could provide addiction treatment to expand access to care, especially for those who reside in areas where a certified medical addictionologist is unavailable (e.g., rural areas). In some states, CRNAs are the sole anesthesia providers in nearly 100 percent of rural hospitals.

(4) **Alternate Pathways to Qualify for 200-Patient Prescribing Limit**
An alternative pathway to qualify for 200-patient prescribing limit could involve supplemental education and training pathways for other advanced practice professionals as addressed in our response to question 3.

(8) **Synchronization of Renewal Request with DEA Practitioner Registration Renewal**
The AANA supports reducing practitioner burden by synchronizing the Request for Patient Limit Increase renewal with the renewal of the DEA practitioner registration, currently required every three years.

(13) **Reporting Periods**
The AANA supports standardizing the reporting process to be less burdensome and improve the ease of reporting for practitioners. Consolidating and synchronizing reporting requirements, periods and deadlines should also encourage practitioners to report standardized data that is focused on process and outcome measures.

(14) **Balance of Access and Safety**
The AANA supports advanced practice professionals (e.g., CRNAs, nurse practitioners, physician assistants) entering the field of addiction treatment through specialty education. Expanding the number of professionals who are eligible to treat opioid use disorders may provide greater access to
treatment for patients in need without overburdening physicians due to current MAT prescribing rules. An expansion of providers is envisioned to help meet the balance of access and safety to provide appropriate oversight and adjunctive therapies, such as counseling and monitoring, to avoid MAT misuse and dependency.

Recovery for individuals struggling with opioid use disorder can be improved by expanding access to participation in patient-centered, comprehensive treatment that may include short-term use of medication assisted treatment. We hope that this proposed rule will encourage broader availability of high-quality MAT by an increasing number of healthcare professionals who can provide this treatment, including CRNAs. The AANA thanks the Substance Abuse and Mental Health Services Administration and the Department of Health and Human Services for the opportunity to comment on this very important issue and is hopeful that more patients will be able to receive the life-saving addiction treatment needed. Please do not hesitate to contact Lynn Reede, DNP, MBA, CRNA, Senior Director, Professional Practice, at (847) 655-1136 or lreede@aana.com if you have any questions or comments.

Sincerely,

Juan Quintana, DNP, MHS, CRNA
AANA President

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

References