Notification of Intent to Use Schedule III, IV, or V Controlled Medications for the Treatment of Opioid Use Disorder by a "Qualifying Physician" under 21 USC § 823(g)(2)	OMB No.: 0930-0234 Expiration Date: 01/31/2023 DATE OF SUBMISSION

Note: Notification is required by § 303(g)(2), Controlled Substances Act (21 USC § 823(g)(2)). See instructions on reverse. **For second notifications, you must complete items 6, 7, 8, 9, 10, and sign and date the form (item 12).**

1A. NAME OF PRACTITIONER (See instruction below)

1B. State Health Professional License Number Registration Number | **1C. Professional Discipline** | **1D. DEA**

2. ADDRESS OF PRIMARY PRACTICE LOCATION *(Include Zip Code) (See instruction below)*

2A. Is this practice location a Federally Qualified Health Center (FQHC) as defined under Section 1861(aa)(4)(B) of the Social Security Act (42 U.S.C. 1395x)?

Yes ☐ No ☐

3. TELEPHONE NUMBER *(Include Area Code)*

4. FAX NUMBER *(Include Area Code)*

5. EMAIL ADDRESS *(Required)*

6. PURPOSE OF NOTIFICATION (check all that apply):

☐ New Notification to treat up to 30 patients

☐ New Notification, with the intent to immediately facilitate treatment of an individual (one) patient

☐ Second notification of need and intent to treat up to 100 patients (existing 30-patient limit practitioners)

☐ New notification to treat up to 100 patients*

*NOTE: In order to treat up to 100 patients in the first year, practitioners must either hold additional credentialing as defined under 42 C.F.R. § 8.2, or provide treatment with covered medications (as such terms are defined under 42 C.F.R. § 8.2) in a qualified practice setting as described under 42 C.F.R. § 8.615.

7. CERTIFICATION OF USE OF CONTROLLED MEDICATIONS UNDER THIS NOTIFICATION

☐ When providing treatment for opioid use disorder, I certify that I will only use Schedule III, IV, or V medications or combinations of medications that have been approved by the Food and Drug Administration (FDA) for use in such treatment and that have not been the subject of an adverse determination.

8. CERTIFICATION OF QUALIFYING CRITERIA (See instructions below)

☐ SAMHSA/HHS Buprenorphine practice guideline exemption (April 2021). These practice guidelines exempt covered practitioners licensed under state law, and who possess a valid DEA registration, from certification requirements related to training, counseling, and other ancillary services (i.e., direct provision of or referral to psychosocial services).

This exemption only applies to those treating up to 30 patients at a given time. Time spent practicing under this exemption will not qualify the practitioner for a higher patient limit.

☐ **NEW NOTIFICATION -** I certify that I meet at least one of the following criteria, and am therefore, a qualifying physician:

☐ Subspecialty board certification in Addiction Psychiatry or Addiction Medicine from the American Board of Medical Specialties
☐ Addiction certification or board certification from the American Society of Addiction Medicine or American Board of Addiction Medicine
☐ Subspecialty board certification in Addiction Medicine from the American Osteopathic Association

Completion of not less than eight hours of training for the treatment and management of patients with opioid use disorder that included training on the following topics: opioid use disorder treatment

with medications ; appropriate clinical use of all medications approved by the Food and Drug Administration for the treatment of opioid use disorder; initial and periodic patient assessments (including substance use monitoring); individualized treatment planning, overdose reversal, and prevention of recurrence; counseling and recovery support services; staffing roles and considerations; and diversion control; and that was provided by the following organization(s):

Check and provide copies of documentation (e.g., certificates of completion) for all that apply.

- ☐ American Society of Addiction Medicine (ASAM)
- ☐ American Osteopathic Association (AOA)/American Osteopathic Academy of Addiction Medicine (AOAAM)
- ☐ American Academy of Addiction Psychiatry (AAAP)
- ☐ American Medical Association (AMA)
- ☐ American Psychiatric Association (APA)
- ☐ SAMHSA Providers' Clinical Support System (PCSS)

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Date and location of training (Use "Web" for city if web training was received):

DATE	CITY	STATE

☐ Participation as an investigator in one or more clinical trials leading to the approval of a controlled medication in Schedule III, IV, or V for treatment of opioid use disorder

☐ State medical licensing board-approved experience or training in the treatment and management of patients with opioid use disorder .

☐ Graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States during the last five (5) years, and during which I successfully completed a comprehensive allopathic or osteopathic medicine curriculum, or accredited medical residency, that included at least 8 hours of training on treating and managing patients with opioid use disorder that included training on the following topics: opioid use disorder treatment with medications; appropriate clinical use of all medications approved by the Food and Drug Administration for the treatment of opioid use disorder; initial and periodic patient assessments (including substance use monitoring); individualized treatment planning, overdose reversal, and prevention of recurrence; counseling and recovery support services; staffing roles and considerations; and diversion control.

Upload Board Certification or Training Documentation

File to Upload Choose Files

☐ **SECOND NOTIFICATION FOR 100 PATIENTS** - I certify that my qualifications from my initial notification request have not changed.

- ☐ Subspecialty board certification in Addiction Psychiatry or Addiction Medicine from the American Board of Medical Specialties
- ☐ Addiction certification or board certification from the American Society of Addiction Medicine or American Board of Addiction Medicine
- ☐ Subspecialty board certification in Addiction Medicine from the American Osteopathic Association
- ☐ Provide treatment with medications for opioid use disorder in a "qualified practice setting" as defined in 42 C.F.R. § 8.615

Upload Board Certification or Training Documentation

File to Upload Choose Files

☐ **NEW NOTIFICATION TO TREAT 100 PATIENTS-** I certify that I meet at least one of the following criteria and am therefore a qualifying physician:

- ☐ Subspecialty board certification in Addiction Psychiatry or Addiction Medicine from the American Board of Medical Specialties
- ☐ Addiction certification or board certification from the American Society of Addiction Medicine or American Board of Addiction Medicine

☐ Subspecialty board certification in Addiction Medicine from the American Osteopathic Association
☐ Provide treatment with medications for opioid use disorder in a "qualified practice setting" as defined in 42 C.F.R. § 8.615

9. CERTIFICATION OF CAPACITY

☐ **I certify that I have the capacity to provide patients with appropriate counseling and other appropriate ancillary services, either directly or by referral.**

☐ **I certify that I have the capacity to provide, directly or through referral, all medications approved by the FDA for the treatment of opioid use disorder, including for long-term, withdrawal management, and relapse prevention, as well as reversal of opioid-related overdose.**

10. CERTIFICATION OF MAXIMUM PATIENT LOAD (select one)

☐ **I certify that I will not exceed 30 patients for long-term opioid use disorder treatment or withdrawal management at one time.**

☐ Second Notification – I have provided treatment at the 30-patient limit for one year and need to treat up to 100 patients and **I certify that I will not exceed 100 patients for long-term opioid use disorder treatment or withdrawal management at one time** if I meet the criteria under 21 U.S.C. 823(g)(2)(B)(iii)(II)(aa)-(cc).

☐ New Notification for 100 Patients – **I will not exceed 100 patients for long-term opioid use disorder treatment or withdrawal management at one time.**

11A. CONSENT *(Read instruction 11 below before answering)*

☐ **I consent to the release of my name, primary practice address, and phone number to the SAMHSA Treatment Locators.**

☐ **I do not consent to the release of my name, primary practice address, and phone number to the SAMHSA Treatment Locators.**

11B. Do you also want to be identified on the SAMHSA Treatment Locators as providing treatment with:

1. Long-acting injectable naltrexone ☐ Yes ☐ No
2. Long-acting injectable buprenorphine ☐ Yes ☐ No

12. I certify that the information presented above is true and correct to the best of my knowledge. I certify that I will notify SAMHSA at the address below if any of the information contained on this form changes. Note: Any false, fictitious, or fraudulent statements or information presented above or misrepresentations relative thereto may violate Federal laws and could subject you to prosecution, and/or monetary penalties, and or denial, revocation, or suspension of DEA registration. (See 18 USC § 1001; 31 USC §§ 3801–3812; 21 USC § 824.)

X_____ Signature

X _____ Date

Substance Abuse and Mental Health Services Administration,
Division of Pharmacologic Therapies

Please complete online at:
http://buprenorphine.samhsa.gov/pls/bwns/waiver

For questions, please contact the Buprenorphine Help Desk at 1-866-287-2728 (1-866-BUP-CSAT) or

This form is intended to facilitate the implementation of the provisions of 21 USC § 823(g)(2). The Secretary of DHHS will use the information provided to determine whether practitioners meet the qualifications for waivers from the separate registration requirements under the Controlled Substances Act (21 USC § 823(g)(1)). If such qualifications are met, the Drug Enforcement Administration will assign an identification number to qualifying practitioners and the number will be included in the practitioner's registration under 21 USC § 823(f).

infobuprenorphine@samhsa.hhs.gov	
1. The practitioner must identify the DEA registration number issued under 21 USC § 823(f) to prescribe substances controlled in Schedules III, IV, or V.	**2**. Although practitioners may practice in multiple sites, only the primary practice address should be specified. For the practitioner to dispense the controlled medications or combinations to be used under this notification, the primary practice address listed here must be the same primary address listed in the practitioner's DEA registration under § 823(f). Practitioners may provide any additional practice locations by Using the Update Practitioner Contact Information form on SAMHSA's Buprenorphine website, http://buprenorphine.samhsa.gov/forms/update-contact-info-login.php.

6. Purpose of notification:

To provide notice to the Secretary of the United States Department of Health and Human Services of the intent to use schedule III, IV, or V controlled medications for the long-term treatment and withdrawal management of opioid use disorder consistent with 21 U.S.C. § 823(g)(2).

11. The SAMHSA Treatment Locators are accessible at http://buprenorphine.samhsa.gov/bwns_locator/ and https://findtreatment.samhsa.gov/ . The Locators list the name, practice, types of medications for opioid use disorder offered, and contact information of practitioners with DATA waivers who consent to be listed on these sites. The Treatment Locators provide links to many other sources of information on substance use. No practitioner listings on the SAMHSA Treatment Locators will be made without the express consent of the practitioner.

Privacy Act Information

Authority: Section 303 of the Controlled Substances Act of 1970 (21 USC § 823(g)(2)). Purpose: To obtain information required to determine whether a practitioner meets the requirements of 21 USC § 823(g)(2).Routine Uses: Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Relevant Licensing Boards to verify practitioners' qualifications.
B. Other federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
C. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
D. Persons registered under the Controlled Substance Act (PL 91-513) for the purpose of verifying the registration of customers and practitioners.
Effect: This form was created to facilitate the submission and review of waivers under 21 USC § 823(g)(2). This does not preclude other forms of notification.

Paperwork Reduction Act Statement

Public reporting burden for completing this form is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the completed form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0234. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to SAMHSA Reports Clearance Officer; Paperwork Reduction Project (0930-0234); 5600 Fishers Lane, **15E57B,** Rockville, MD 20857.