| **Notification of Intent to Use Schedule III, IV, or V Medications for the Treatment of Opioid Use Disorders of Opioid Use Disorder by a "Qualifying Practitioners" under 21 USC § 823(g)(2) for a Patient Limit of 275** | OMB No.: 0930-0234<br><br>Expiration Date: 01/31/2023<br>DATE OF SUBMISSION |
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Note: Notification is required by § 303(g)(2), Controlled Substances Act (21 USC § 823(g)(2)). See instructions on reverse. **PLEASE DON'T FORGET TO SIGN AND DATE THIS FORM (ITEM 12)**

**1A. NAME OF PRACTITIONER** (See instruction below)

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

| **2. ADDRESS OF PRIMARY PRACTICE LOCATION** *(Include Zip Code) (See instruction 2 below)*<br><br>**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)?**<br><br>Yes No | **3.TELEPHONE NUMBER** *(Include Area Code)*<br><br>**4.FAX NUMBER** *(Include Area Code)*<br><br>**5.EMAIL ADDRESS** *(Required)* |
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**6. PURPOSE OF NOTIFICATION** (See note below) New Notification

Renewal Notification

Emergency Situation

Notification

*Note: In order to treat up to 275 patients, practitioners must have a waiver to treat up to 100 patients for at least one year and 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 instruction below)**

8A. Please answer the following for increase to 275 patients

8A1. I certify that I meet one of the following criteria and am therefore a qualifying practitioner. (Check and provide copies of the documentation that apply):

I certify that I meet all the requirements to treat up to **275** patients as specified in **42 CFR 8.610(a)** as a practitioner with **additional credentialing** (i.e., 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; or subspecialty board certification in Addiction Medicine from the American Osteopathic Association).

**Upload Board Certification Documentation**

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**OR-**

I certify that I meet the qualifying criteria and have the capacity to meet all the requirements to treat up to **275** patients as specified in **42 CFR 8.610 (a) and (b)(2)** in a **Qualified Practice Setting as defined** in **42 CFR 8.615** that: provides professional coverage for patient medical emergencies during hours when the practitioner's practice is closed; provides case-management services; uses health information technology systems; is registered for the State prescription monitoring program where operational and in accordance with Federal and State law; and accepts third-party payment for costs in providing health services.

8A2. I certify that I intend to treat up to 275 patients and I certify that I will not exceed 275 for long-term treatment of opioid use disorder or withdrawal management at one time.

8A3. I certify that I will adhere to nationally recognized evidence-based guidelines for the treatment of patients with opioid use disorders.

8A4. I certify that I will provide patients with necessary behavioral health services as defined in § 8.2 or through an established formal agreement with another entity to provide behavioral health services.

8A5. I certify that I will provide appropriate releases of information in accordance with Federal and State laws and regulations, including the Health Information Portability and Accountability Act Privacy Rule and Part 2 of this chapter, if applicable, to permit the coordination of care with behavioral health, medical, and other service practitioners.

8A6. I certify that I will use patient data to inform the improvement of outcomes.

8A7. I certify that I will adhere to the diversion control plan to manage the covered medications and reduce the possibility of diversion of covered medications from legitimate treatment use.

8A8. I certify that I have considered how to assure continuous access to care in the event of practitioner incapacity or an emergency situation that would impact a patient's access to care as defined in 42 CFR § 8.2.

8A9. I certify that I will notify all patients above the 100-patient level, in the event that the higher patient limit is not renewed or is denied, that the practitioner will no longer be able to provide treatment with buprenorphine to them and make every effort to transfer patients to other addiction treatment.

**8B. Please Answer the following to request an Emergency Increase to 275 patients**

8B1. ☐ I certify that I am practicing in an emergency situation as defined in 42 CFR 8.2 and 8.655 (documentation attached). 8B2. ☐ I certify that I understand that I may not exceed my current limit until notified by SAMHSA.

8B3. ☐ I certify that I understand that once approved for the higher limit, I may only practice at the higher limit for a period not to exceed six months unless such approval is extended under 42 CFR 8.655(d).

**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 Food and Drug Administration 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**

☐ I certify that I will not exceed 275 patients for long-term treatment of opioid use disorder 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**_____ **X**_____

**Signature** **Date**

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

**Please complete online at:**

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

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| **http://buprenorphine.samhsa.gov/pls/bwns/waiver**<br><br>**For questions, please contact the Buprenorphine Help Desk at 1-866-287-2728 (1-866-BUP-CSAT) or info buprenorphine@samhsa.hhs.gov** | 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). |
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| **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 treatment of opioid use disorders consistent with 21 U.S.C. § 823(g)(2).

**11.** The SAMHSA Treatment Locator Websites are accessible at http://buprenorphine.samhsa.gov/bwns_locator/ and https://findtreatment.samhsa.gov/ . The Websites list the name, primary practice address, 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 Locator Websites provide links to many other sources of information on substance use. No practitioner listings on the SAMHSA Treatment Locator Websites will be made without the express consent of the practitioner.

| **Privacy Act Information** | **Paperwork Reduction Act Statement** |
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| 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:<br>A. Relevant Licensing Boards to verify practitioners' qualifications.<br>B. Other federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.<br>C. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.<br>D. Persons registered under the Controlled Substance Act (PL 91-513) for the purpose of verifying the registration of customers and practitioners.<br>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. | 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 |