Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Qualifying Other Practitioner" under 21 USC § 823(g)(2) Supporting Statement

A. Justification

1. *Circumstances of Information Collection*

The Comprehensive Addiction and Recovery Act (CARA) (PL 114-198) was signed into law on July 22, 2016. Section 303 of CARA establishes conditions under which certain practitioners may apply to be a "Qualifying Other Practitioner" under 21 USC § 823(g)(2) to prescribe certain approved narcotic treatment medications for the maintenance or detoxification treatment of opioid addiction.

The law establishes criteria for nurse practitioners (NPs) and physician assistants (PAs) to qualify for a waiver to prescribe. To be eligible for a waiver the nurse practitioner or physician assistant must: be licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain; fulfill qualification requirements in the law for training and experience; and fulfill qualification requirements in the law for appropriate supervision by a qualifying physician.

The Substance Abuse and Mental Health Services Administration (SAMHSA) has the responsibility to receive, review, approve, or deny waiver requests.

Practitioners who meet the statutory requirements will be eligible to prescribe only those opioid treatment medications that are controlled in Schedules III, IV, or V, under the Controlled Substance Act (CSA), that are specifically approved by the Food and Drug Administration (FDA) for the treatment of opioid addiction, and are not the subject of an "adverse determination." The only medications that currently fulfill these requirements are ones that contain the active ingredient buprenorphine.

The CSA establishes a set procedure for practitioners to obtain waivers to treat up to 30 patients. Interested practitioners are required to submit written notifications to the Secretary, HHS (authority delegated to the Administrator, SAMHSA). SAMHSA is required to determine whether the practitioner has met the criteria for a waiver within 45 days from the date of receipt of a notification. If SAMHSA determines the practitioner meets the legislative criteria, the Drug Enforcement Administration (DEA) is notified to assign a unique registration number to the practitioner. If SAMHSA does not respond to the practitioner within 45 days, DEA is required to release the unique identification number to the practitioner. Practitioners with approval to treat up to 30 patients may in subsequent years submit notifications to treat up to 100 provided all required criteria are met.

2. *Purpose and Use of Information*

As noted above, CARA (Attachment A) amended Section 303(g)(2) of the CSA (21 USC 823(g)(2)) to permit practitioners (NPs and PAs) to seek and obtain waivers to prescribe certain approved narcotic drugs for the treatment of opiate addiction. The law sets eligibility requirements and certification requirements as well as an interagency application process for practitioners who seek waivers.

To facilitate the processes established, SAMHSA seeks approval from OMB for the following document: "Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Qualifying Other Practitioner" under 21 USC § 823(g)(2)" form (Attachment B).

The information entered on the form will allow SAMHSA to determine whether practitioners are eligible for a waiver to prescribe certain approved narcotic treatment medications for the maintenance or detoxification treatment of opioid addiction. SAMHSA has determined that the following information would be necessary to process requests for a waiver to prescribe by qualifying practitioners:

1. Practitioner name;
2. State Health Professional License Number;
3. Professional Discipline;
4. DEA registration number;
5. Practice location information (address, telephone number, fax number, e-mail address);
5. Type of facility (FQHQ or non-FQHC);
6. Purpose of Notification (New Notification; Intent to immediately facilitate treatment of an individual; Second notification of need and intent to treat up to 100 patients);
7. Certification of use of narcotic drugs under this notification (will only use FDA approved Schedule III IV or V drugs not the subject of an adverse determination);
8. Certification of Qualifying Criteria (eligible NP or PA);
9. Certification of Qualifying Criteria (licensed to prescribe Schedule III IV or V drugs);
10. Certification of Qualifying Criteria (supervision by a qualifying physician either not required or documented if required);
11. Certification of Qualifying Criteria (training requirements completed);
12. Certification of Capacity (provide or refer patients for appropriate counseling and ancillary services);
13. Certification of Capacity (prescribe MAT drugs);
14. Certification of Maximum Patient Load (30 or 100 patients);
15. Consent (release of name address and phone number to the SAMHSA Treatment Locators);
16. Signature and date;

Processing of the Notification of Intent form by SAMHSA will conform to the existing process for evaluating waiver requests by other qualified practitioners under 21 USC § 823(g)(2).

3. *Use of Information Technology*

In addition to submissions by mail, practitioners may submit waiver notifications via an electronic version of the notification form, which is available at http://buprenorphine.samhsa.gov/pls/bwns/waiver. The dedicated Web page containing the text of the notification form has all of the fields that are found on the paper version of the form. Most practitioners access this website and submit notifications online, using an email auto-response system for signature verification.

4. *Efforts to Identify Duplication*

The law requires practitioners who wish to avail themselves of its waiver provisions to notify the Secretary of the Department of Health and Human Services. In an attempt to avoid unnecessary duplication of effort, SAMHSA has arranged to serve as a single Federal point of contact and forward notifications, including "immediate" notifications, to DEA.

With regard to the proposed reporting requirements, SAMHSA is not aware of any other public data source that would capture the information requested.

5. *Involvement of Small Entities*

Some applicants may be independent practitioners or members of small group practices that could be considered small businesses. The information being sought is the minimum needed to meet the requirements of the Drug Addiction Treatment Act of 2000 (DATA) regardless of the size of the practice. This information collection, as well as the information collection in the proposed rule, will not have a significant impact on these businesses.

6. *Consequences If Information Is Collected Less Frequently*

Without providing this information, practitioners will be unable to prescribe certain approved narcotic treatment drugs for the treatment of opiate addiction, as permitted under DATA.

7. *Consistency With the Guidelines in 5 CFR 1320.5 (d)(2)*

This information collection fully complies with 5 CFR 1320.5(d) (2).

8. *Consultation Outside the Agency*

The NOI was published in the Federal Register on November 28, 2016 (81 FR 85586).

9. *Payment to Respondents*

Respondents will not receive any payment or gifts.

10. *Assurance of Confidentiality*

There are no study subject or patient protection concerns associated with this information collection activity. The Notification of Intent includes the following statement of purpose and privacy:

> This form is intended to facilitate the implementation of the provisions of 21 USC 823(g)(2). The Secretary of Health and Human Services 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). This form may be completed and submitted electronically (including facsimile) to facilitate processing.

In addition, SAMHSA would release to the SAMHSA Buprenorphine Physician Locator only the practitioner name, address, and phone number, for those practitioners who have explicitly consented to this disclosure. The Substance Abuse Treatment Facility Locator is available at no cost on the World Wide Web <http:findtreatment.samhsa.gov> and is widely used by the members of the treatment seeking public and referring professionals. It lists more than 11,000 facilities that offer specialized drug and alcohol abuse treatment programs and provides links to many other sources of information on substance abuse. SAMHSA believes that adding the information to the Locator will assist individuals seeking opioid treatment in finding approved providers, especially in rural settings. As such, this disclosure is consistent with the legislation's goal of expanding the availability of medication-assisted treatment for opioid use disorders.

Information provided on the Notification of Intent will be provided to third parties who specialize in verification of medical credentials for health care organizations. They will receive only the minimum information needed to identify the practitioner whose credentials are to be verified. The data will be provided only under standard privacy agreements with the verifying organizations. No other use of this information by a third party will be authorized. The complete information will be used only to review and certify waiver notifications.

Built in database authentication would allow access to practitioner information only by authorized SAMHSA or SAMHSA contractor personnel. This information would also be sent to the DEA by a secure channel as necessary. Information provided by practitioners may not be changed by them, SAMHSA staff, or the system contractor. A list of practitioners with valid requests for patient limit increase may be provided to pharmacists and the registered distributor, from time to time, containing information needed to verify the practitioners' authority to prescribe the drugs covered by the request for patient limit increase. No other access would be permitted without the express permission of each practitioner.

11. *Questions of a Sensitive Nature*

There are no questions of a sensitive nature. The questions included on the application are basic items about the qualifications and licensing of practitioners.

12. *Estimate of Annualized Hour Burden*

The following table summarizes the estimated annual burden of the information collections described in this document.

Purpose of Submission	Number of respondents	Responses / Respondent	Burden/ Response (Hr.)	Total Burden (Hrs.)	Hourly Wage Cost ($)	Total Wage Cost ($)
Notification of Intent for Qualifying Other Practitioner to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Qualifying Other Practitioner" under 21 USC § 823(g)(2) – Nurse Practitioners	816	1	.066	54	$48.68	$2,268

Purpose of Submission	Number of respondents	Responses / Respondent	Burden/ Response (Hr.)	Total Burden (Hrs.)	Hourly Wage Cost ($)	Total Wage Cost ($)
Notification of Intent for Qualifying Other Practitioner to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Qualifying Other Practitioner" under 21 USC § 823(g)(2) – Physician Assistants	590	1	.066	39	$47.73	$1,861
Total	1,406	-	-	93	-	$5,649

As indicated in the chart above, SAMHSA estimates that completion of the Notification of Intent form would require .066 hours or about 4 minutes. According to the U.S. Bureau of Labor Statistics,[a] the average hourly wage for a nurse practitioner is $48.68 and for a physician assistant is $47.73.

13. *Estimates of Annualized Cost Burden to Respondents*

Completing the Notification of Intent should not require any additional costs for computer equipment or other record-keeping technology.

14. *Estimates of Annualized Cost to the Government*

SAMHSA has planned and allocated resources for the efficient and effective management and use of the information to be collected including the processing of the information in a manner, which shall enhance, where appropriate, the utility of the information to the agencies and the public.

Costs will be incurred by SAMHSA and the DEA in order to process the additional Notification of Intent forms generated by the inclusion of NPs and PAs. For purposes of analysis, and based on contractor estimates, SAMHSA estimates that it will pay a

[a] U.S. Bureau of Labor Statistics. National Occupational Employment and Wage Estimates. Retrieved from: http://www.bls.gov/oes/current/oes291171.htm and http://www.bls.gov/oes/current/oes291071.htm

contractor $100 to process each waiver. SAMHSA estimates a combined annual average of 1,406 forms, resulting in an estimated annual cost of $140,600. SAMHSA estimates that DEA will allocate the equivalent of 1 FTE at the GS-11 level to process the additional requests coming to DEA for issuance of a new DEA number designating the physician as eligible to prescribe buprenorphine for the treatment of opioid use disorder as a result of this final rule. SAMHSA estimates the associated cost is $144,238, which SAMHSA arrived at by multiplying the salary of a GS-11 employee at step 5, which is $72,219 in 2015, by two to account for overhead and benefits.

SAMHSA estimates that it would require approximately 5 minutes to review and verify each Notification of Intent form processed by our contractor. This translates into approximately 117 total hours per year including both NPs and PAs. In addition, SAMHSA estimates that it would require approximately 8 hours per year to review special cases that may require additional verification efforts. Together, the total estimated review time is approximately 125 hours. SAMHSA believes that this review would be conducted by a GS13 ($50/hour) level public health advisor within SAMHSA. Accordingly, the total SAMHSA annual cost to review these forms is approximately $6,250.

Thus, the total annual cost is estimated to be approximately $291,088.

15. Changes in Burden

Currently there are 4747 total burden hours in the OMB inventory. SAMHSA is requesting 117 additional burden hours.

16. Time Schedule, Publication, and Analysis Plan

SAMHSA would provide updated counts of waivered practitioners and their respective patient limits on a daily basis as well as to populate and regularly update the SAMHSA Behavioral Health Treatment and other service provider locators maintained by SAMHSA. SAMHSA would also use the data collected to support the activities described in #2 above as well as to inform Congressional testimony and respond to requests for information.

17. Display of Expiration Date

The expiration date for OMB approval will be displayed.

18. Exceptions to Certification Statement

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act Submissions.

Attachments

A. The Comprehensive Addiction and Recovery Act (CARA).

B. Notification of Intent for Qualifying Other Practitioner to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Qualifying Other Practitioner" under 21 USC § 823(g)(2).

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