Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction under 21 USC § 823(g)(2)

Supporting Statement

A. Justification

1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting a revision from the Office of Management and Budget (OMB) for approval of the Notification of Intent (NOI) to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Physician", "Qualifying Other Practitioner" and "Qualifying Practitioners for a Patient Limit of 275". The Notification of Intent would allow SAMHSA to obtain additional data information. This data collection is approved under OMB No. 0930-0234 which expires on January 31, 2020 and OMB No. 0930-0369 which expires August 31, 2020. The collection of these revised data forms are currently approved under the Paperwork Reduction Act Public Health Emergency Waiver on August 21, 2019 due to the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act.

Under OMB No. 0930-0234 there are currently three forms. SAMHSA will be adding an additional form that is currently approved under OMB No. 0930-0369 that will be merged and be approved under OMB No. (0930-0234).

The four forms that will be revised: (1) Physicians for 30 and 100 patient limit (Attachment A); and (2) Qualifying Other Practitioners for 30 and 100 patient limit (Attachment B); and (3) 275 patient limit for all Qualifying Practitioners (Attachment C); and (4) Practitioner Reporting Form (Attachment D).

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.

Since July 2002, SAMHSA has received over 99,958 notifications and has certified over 77,742 practitioners. Approximately 55 percent (42,726) of the certified practitioners have consented to disclose their contact information at the SAMHSA Buprenorphine Physician Locator, while 45 percent (35,016) have not consented. Respondents may submit an electronic NOI form through a dedicated Web page that SAMHSA established

for this purpose and which may be found at https://buprenorphine.samhsa.gov/forms/select-practitioner-type.php.

The Controlled Substances Act establishes a set procedure for practitioners to obtain waivers to treat up to 30, 100 and 275 patients. Interested practitioners are required to submit written notifications to the Secretary, HHS (authority delegated to the Assistant Secretary, 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.

The SUPPORT Act (Section 3201(d)) expands the definition of "qualifying other practitioner" enabling Clinical Nurse Specialists, Certified Registered Nurse Anesthetists, and Certified Nurse Midwives (CNSs, CRNAs, and CNMs) to apply for a Drug Addiction Treatment Act of 2000 (DATA)waiver until October 1, 2023.

The SUPPORT Act (Section 3201) also allows qualified practitioners (i.e. MDs, DOs, NPs, PAs, CNSs, CRNAs, and CNMs) who are board certified in addiction medicine or addiction psychiatry, -or- practitioners who provide MAT in a qualified practice setting, to start treating up to 100 patients in the first year of MAT practice (as defined in 42 CFR 8.2) with a waiver.

Further, the SUPPORT Act extends the ability to treat up to 275 patients to "qualifying other practitioners" (i.e., NPs, PAs, CNSs, CRNAs, and CNMs) if they have a waiver to treat up 100 patients for at least one year and provide medication-assisted 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.

Section 3202 of the SUPPORT Act also expands how physicians could qualify for a waiver. Under the statute now, physicians can qualify for a waiver if they have received at least 8 hours of training on treating and managing opiate-dependent patients, as listed in the statute if the physician graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States during the 5-year period immediately preceding the date on which the physician submits to SAMHSA.

Section 8.635 of 42 CFR indicates reporting requirements for practitioners whose request for patient limit increase was approved. All practitioners whose request for patient limit increase was approved under § 8.625 must submit to SAMHSA annually a report along with documentation and data, as requested by SAMHSA, to demonstrate compliance with applicable provisions in §§ 8.610, 8.620, and 8.630.

Finally, SAMHSA requests the collection of additional information (i.e., types of long-acting medication-assisted treatment offered) on three of the forms. The collection of

additional information will allow SAMHSA through its Locators to direct persons seeking treatment to practitioners who offer long-acting medication-assisted treatment options. Waiver of the PRA will allow SAMHSA to revise these forms quickly and provide them to practitioners seeking a waiver so that they can begin treating patients with opioid use disorder (OUD) as soon as the other requirements are met.

2. Purpose and Use of Information

As noted above, SAMHSA seeks approval from OMB for the attached documents.

The information entered on these forms 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. Below is the breakdown by form.

The Notification of Intent (NOI) to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Physician"

1A. Name of Practitioner;
1B. State Health Professional License Number;
1C. Professional Discipline/Specialty;
1D. DEA registration number;
2 Address of Primary Practice location;
2A. Type of facility Federally Qualified Health Center or non- Federally Qualified Health Center (FQHQ or non-FQHC);
3. Telephone number;
4. Fax number;
5. E-mail address;
6. Purpose of Notification (New Notification to treat up to 30 patients; New Notification with the Intent to immediately facilitate treatment of an individual; Second notification of need and intent to treat up to 100 patients; New notification 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;
9. Certification of Capacity (provide or refer patients for appropriate counseling and ancillary services); and (prescribe MAT drugs);
10. Certification of Maximum Patient Load (30 or 100);
11A. Consent (release of name 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; Long Acting Injectable, Naltrexone, Long Acting Injectable Buprenorphine; and Long Acting Implantable Buprenorphine
12. Signature and date.

The Notification of Intent (NOI) to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Qualifying Other Practitioner"

1A. Name of Practitioner;
1B. State Health Professional License Number;
1C. Professional Discipline/Specialty;
1D. DEA registration number;
2 Address of Primary Practice location;
2A. Type of facility Federally Qualified Health Center or non- Federally Qualified Health Center (FQHQ or non-FQHC);
3. Telephone number;
4. Fax number;
5. E-mail address;
6. Purpose of Notification (New Notification to treat up to 30 patients; New Notification with the Intent to immediately facilitate treatment of an individual patient; Second notification of need and intent to treat up to 100 patients; New notification 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;
9. Certification of Capacity (provide or refer patients for appropriate counseling and ancillary services); and (prescribe MAT drugs);
10. Certification of Maximum Patient Load (30 or 100);
11A. Consent (release of name 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; Long Acting Injectable, Naltrexone, Long Acting Injectable Buprenorphine; and Long Acting Implantable Buprenorphine
12. Signature and date.

The Notification of Intent (NOI) to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Qualifying Practitioners for a Patient Limit of 275"

1A. Name of Practitioner;
1B. State Health Professional License Number;
1C. Professional Discipline/Specialty;
1D. DEA registration number;
2 Address of Primary Practice location;

2A. Type of facility Federally Qualified Health Center or non- Federally Qualified Health Center (FQHQ or non-FQHC);
3. Telephone number;
4. Fax number;
5. E-mail address;
6. Purpose of Notification (New Notification; Renewal Notification; Emergency Situation Notification);
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;
9. Certification of Capacity (provide or refer patients for appropriate counseling and ancillary services); and (prescribe MAT drugs);
10. Certification of Maximum Patient Load (275);
11A. Consent (release of name 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; Long Acting Injectable, Naltrexone, Long Acting Injectable Buprenorphine; and Long Acting Implantable Buprenorphine
12. Signature and date.

Practitioner Reporting Form

1. Name of Practitioner;
2. State Health Professional License Number;
3. Specialty;
4. DEA registration number;
5. Address of Primary Practice location;
6. Telephone number;
7. Fax number;
8. E-mail address;
9. This report covers the 12-month period beginning and ending
10a. How many patients were prescribed or dispensed covered medications during each month of the preceding 12 months: 8. Certification of Qualifying Criteria;
10b. Certification of Capacity (provide or refer patients for appropriate counseling and ancillary services); and (prescribe MAT drugs);
10c. Indicate the number of patients who were prescribed or dispensed covered medications during each month of the preceding 12 months and also were referred for behavioral health services to another entity through an established formal agreement.
11. Check each of the elements included in the practitioner's diversion control plan (a) random clinical drug testing (b) routine clinical drug testing (c) random patient recall visits for covered medication counts (d) provision of information to patients about proper medication storage, including not sharing medication (e) prescription drug monitoring program (PDMP) or other central repository of prescribing and dispensing record queries

12. Under your diversion control plan, under which circumstances do you check the PDMP or other central repository? Check all that apply (At every patient visit, On first visit, According to a schedule such as quarterly, Based on clinical assessment of risk and other.
13. Any other elements of the diversion control plan not already described (e.g. implants, misuse deterrent packaging such as timed single dose dispensing packaging, and disposal);
14. 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).

Changes

Attachment A: The Notification of Intent (NOI) to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Physician"

1E. Do you work for the US Military, Veterans Administration, or Indian Health Service?
Question was removed.

2A Is this location a Federally Qualified Health Center (FQHC)
SAMHSA spelled out the words Federal Qualified Health Center for clarity.

6. Purpose of Notification
Added option New Notification to treat up to 100 patients. Also capitalized the "N" in the words Notification. Additionally, added a noted stating, "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 medication-assisted 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."

8. Certification of Qualifying Criteria
Addiction Medicine was added to two of the options.

Under the list of certificates of completion, added SAMHSA Providers' Clinical Support System the acronym PCSS was added.

Added the following option for universities: "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 opioid-dependent patients that included training on the following topics: opioid maintenance and detoxification; appropriate clinical use of all drugs 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 relapse prevention; counseling and recovery support services; staffing roles and considerations; and diversion control."

Under Second Notification For 100 Patients, 4 types of board certifications were added.
☐ 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 medication-assisted treatment in a "qualified practice setting" as defined in 42 C.F.R. § 8.615

Under New Notification To Treat 100 Patients, this is a whole new section.
☐ 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 medication-assisted treatment in a "qualified practice setting" as defined in 42 C.F.R. § 8.615

9. Certification of Capacity
Added this option, "I certify that I have the capacity to provide, directly or through referral, all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention."

11.B Do you also want to be identified on the SAMHSA Treatment Locators as providing treatment with: Long Acting Injectable, Naltrexone, Long Acting Injectable Buprenorphine; and Long Acting Implantable Buprenorphine?
SAMHSA added this question.

Attachment B: The Notification of Intent (NOI) to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Qualifying Other Practitioner"

1E. Do you work for the US Military, Veterans Administration, or Indian Health Service?
Question was removed.

2.A Is this location a Federally Qualified Health Center (FQHC)
SAMHSA spelled out the words Federal Qualified Health Center for clarity.

6. Purpose of Notification
Added option New Notification to treat up to 100 patients. Also capitalized the "N" in the words Notification. Additionally, added a noted stating, "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 medication-assisted 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."

8. Certification of Qualifying Criteria
Added New Notification Statement Option: "NEW NOTIFICATION- I certify that I am either a clinical nurse specialist, certified registered nurse anesthetist or certified nurse midwife who satisfies the definition of a "qualifying other practitioner" under 21 U.S.C. § 823(g)(2)(G)(iv), as amended by the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018, and I am aware that clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives, will be included in the definition of a "qualifying other practitioner" under 21 U.S.C. § 823(g)(2)(G)(iv) until October 1, 2023."

Added a New Notification Option, "NEW NOTIFICATION TO TREAT 100 PATIENTS - I certify that I provide medication-assisted 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."

10. Certification of Maximum Patient Load
Added Option for New Notification, "New Notification for 100 patients for maintenance or detoxification treatment at one time."

11.B Do you also want to be identified on the SAMHSA Treatment Locators as providing treatment with: Long Acting Injectable, Naltrexone, Long Acting Injectable Buprenorphine; and Long Acting Implantable Buprenorphine?
SAMHSA added this question

Attachment C: The Notification of Intent (NOI) to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Qualifying Practitioners for a Patient Limit of 275"

2.A Is this location a Federally Qualified Health Center (FQHC)
SAMHSA spelled out the words Federal Qualified Health Center for clarity.

11.B Do you also want to be identified on the SAMHSA Treatment Locators as providing treatment with: Long Acting Injectable, Naltrexone, Long Acting Injectable Buprenorphine; and Long Acting Implantable Buprenorphine
SAMHSA added this question

Attachment D:

There are no changes to this form

3. *Use of Information Technology*

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. 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 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 60-Day Notice was published in the Federal Register on October 2, 2019 (84 FR 52521). No comments were received.

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 Practitioner Locator only the practitioner name, address, and phone number, for those practitioners who have explicitly consented to this disclosure. The SAMHSA Treatment Facility Locator is available at no cost on the World Wide Web https://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator or https://findtreatment.samhsa.gov) and is widely used by the members of the treatment community seeking public and referring professionals. It lists more than 43,773 practitioners and 3,321 facilities that prescribe buprenorphine for treatment. 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.

42 CFR Citation	**Purpose of Submission**	**Estimated Number of respondents**	**Responses/Respondent**	**Burden/ Response (Hr.)**	**Total Burden (Hrs.)**	**Hourly Wage Cost ($)**	**Total Wage Cost ($)**
	Notification of Intent	1,500	1	0.083	125	$101.63	$12,653
	Notification to Prescribe Immediately	50	1	0.083	4	$101.63	$422
	Notice to Treat up to 100 patients	500	1	0.04	20	$101.63	$2,033
	Notice to Treat up to 275 patients	800	1	0.081	65	$101.63	$6,606
	Subtotal	**2,850**	**-**	**-**	**214**	**-**	**$21,713**
Burden Associated with the Final Rule That Increased the Patient Limit							
8.620 (a)-(c)	Request for Patient Limit Increase*	517	1	0.5	259	$101.63	$26,271
	Request for Patient Limit Increase*	517	1	0.5	259	$52.90	$13,675
	Request for Patient Limit Increase*	517	1	0.5	259	$52.13	$13,476
8.64	Renewal Request for	260	1	0.5	130	$101.63	$13,212

	a Patient Limit Increase*						
	Renewal Request for a Patient Limit Increase*	260	1	0.5	130	$52.90	$6,877
	Renewal Request for a Patient Limit Increase*	260	1	0.5	130	$52.13	$6,777
8.655	Request for a Temporary Patient Increase for an Emergency*	10	1	3	30	$101.63	$3,049
	Request for a Temporary Patient Increase for an Emergency*	10	1	3	30	$52.90	$1,587
	Request for a Temporary Patient Increase for an Emergency*	10	1	3	30	$52.13	$1,564
	Subtotal	**2,361**	**-**	**-**	**1,256**	**-**	**$86,487**
New Burden Associated with the Final Rule That Outlined the Reporting Requirements							
8.635	Practitioner Reporting Form*	1,350	1	3	4050	$101.63	$411,602
	"Qualifying Other Practitioner" under 21 USC § 823(g)(2) – Nurse Practitioners	816	1	0.066	54	$52.90	$2,849
	"Qualifying Other Practitioner"	590	1	0.066	39	$52.13	$2,030

	under 21 USC § 823(g)(2) – Physician Assistants						
	"Qualifying Other Practitioner" under 21 USC § 823(g)(2) – Certified Nurse Specialists	590	1	0.066	39	$35.36	$1,377
	"Qualifying Other Practitioner" under 21 USC § 823(g)(2) – Certified Nurse Mid-Wives	590	1	0.066	39	$51.40	$2,002
	"Qualifying Other Practitioner" under 21 USC § 823(g)(2) – Certified Registered Nurse Anesthetists	590	1	0.066	39	$84.03	$3,272
	Sub Total	**4,526**		-	**4260**	-	**$423,131**
	Total Burden	**6,561**	-	-	**5,519**		**$531,331**

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 2018 average hourly wage for a physician is $101.63, nurse practitioner is $52.90, certified nurse specialist $35.36, certified nurse mid-wife $51.40, certified registered nurse anesthetists $84.03, and physician assistants $52.13.

[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

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, PAs, CNS, CNMs, and CRNAs. For purposes of analysis, and based on contractor estimates, SAMHSA estimates that it will pay a contractor $100 to process each waiver. SAMHSA estimates a combined annual average of 6,561 forms, resulting in an estimated annual cost of $656,100. 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 $162,362 which SAMHSA arrived at by multiplying the salary of a GS-11 employee at step 6, which is $81,181 in 2019, 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 547 total hours per year including both NPs, PAs, CNS, CNMs, and CRNAs. 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 555 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 $27,750.

Thus, the total annual cost is estimated to be approximately $821,237.

15. Changes in Burden

Currently there are 4,751 burden hours in the OMB inventory. SAMHSA is requesting 5,519 hours. The increase of 768 hours are due to a program change of the following: 1) the 117 hours are for the addition of three nurse specialty occupations and 2) the 651 hours are because of the expansion of the patient limit to 275 for all practitioners.

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.

B. Statistical Methods

Statistical methods are not employed in this data collection.

Attachments

A. The Notification of Intent (NOI) to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Physician"

B. The Notification of Intent (NOI) to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Qualifying Other Practitioner"

C. The Notification of Intent (NOI) to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a "Qualifying Practitioners for a Patient Limit of 275"

D. Practitioner Reporting Form