Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opioid Use Disorder 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 approval from the Office of Management and Budget (OMB) for a revision to include the reporting requirements for practitioners who increase their patient limit to 275 as a result of 42 CFR Part 8, "Medication Assisted Treatment for Opioid Use Disorders."

The Controlled Substances Act (CSA), as amended by the Drug Addiction Treatment Act of 2000 (DATA), establishes (21 USC § 823(g)(2)) conditions under which certain practitioners (physicians) may prescribe certain approved narcotic treatment medications for the maintenance or detoxification treatment of opioid addiction.

The legislation establishes criteria for waivers and a procedure for practitioners who are interested in waivers to obtain a unique Drug Enforcement Administration (DEA) identification number. To be eligible for a waiver the practitioner must: be a licensed physician; be registered by DEA; fulfill qualification requirements in the law for training and experience; and make written certifications relating to the capacity to provide ancillary services and maximum patient loads (currently no more than 30 patients).

Without the waivers provided under the new law, practitioners would have to seek and obtain the separate registration required under 21 USC 823(g)(1). Attachment A is a copy of 21 USC § 823(g)(2).

As authorized by the statute at 21 U.S.C. 823(g)(2)(B)(iii), the Substance Abuse and Mental Health Services Administration (SAMHSA) issued a final rule on July 8, 2016 to increase access to medication-assisted treatment (MAT) with buprenorphine in the office-based setting as authorized under 21 U.S.C. 823(g)(2). The final rule increases the highest available patient limit for qualified practitioners to receive a waiver from 100 to 275.

Practitioners authorized to treat up to 275 patients under 21 U.S.C. 823(g)(2) are required to meet infrastructure and capacity requirements that exceed those required for the lower limits, including information collections as described below. The incremental increase from 100 to 275 patients would attach additional criteria and responsibilities to practitioners who would be able to treat up to 275 patients with the specific aims of ensuring quality of care and minimizing diversion.

The final rule also created an option for an increased patient limit for practitioners responding to emergency situations that require immediate, increased access to MAT pharmacotherapies.

SAMHSA has the responsibility to receive, review, approve, or deny waiver requests.

The CSA establishes a set procedure for practitioners to obtain waivers to treat up to 100 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, 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.

Under the rule, SAMHSA must determine whether the practitioner has met the criteria for a waiver within 45 days from the date of receipt of a notification. If SAMHSA were to determine that the practitioner met the regulatory criteria, SAMHSA would thereafter notify the practitioner who requested the patient limit increase, and the DEA. A practitioner's approval to treat up to 275 patients under this section would extend for a term not to exceed 3 years. This term would be renewable.

In addition to the final rule to increase the patient limit to 275, SAMHSA issued a final rule on September 27, 2016 regarding reporting requirements for practitioners who possess a waiver to prescribe buprenorphine to up to 275 patients. SAMHSA has created a form that practitioners will need to complete and either mail to SAMHSA or submit electronically. Public comment will be solicited on the form which asks about: 1) The number of patients who were prescribed or dispensed covered medications during each month of the preceding 12 month period; 2) The number of patients who were prescribed or dispensed covered medications during each month of the preceding 12 month period and (i) Received behavioral health services, as defined in section 8.2 of the rule, from the prescribing practitioner; or (ii) Were referred by the prescribing practitioner for behavioral health services to another entity through an established formal agreement ; 3) The elements included in the practitioner's diversion control plan, such as: (i) Random clinical drug testing; (ii) Routine clinical drug testing; (iii) Random patient recall visits for covered medication counts; (iv) Prescription drug monitoring program (PDMP) or other central repository of prescribing and dispensing record queries and if so, the number of queries performed in the preceding 12 months and the circumstances of such queries (as requested by SAMHSA); (v) Provision of information to patients about proper medication storage; and (vi) Any other elements of the diversion control plan not already described.

2. *Purpose and Use of Information*

As noted above, DATA amended the Controlled Substances Act (21 USC 823(g)(2)) to permit practitioners (physicians) to seek and obtain waivers to prescribe certain approved narcotic drugs for the treatment of opiate addiction. The legislation sets eligibility requirements and certification requirements as well as an interagency application process for physicians who seek waivers.

To facilitate the processes established in the rule, SAMHSA seeks approval from OMB for the following documents: "Request For Patient Limit Increase Under 42 C.F.R. 8.620" form (Attachment B), and patient notice (Attachment C).

The Request for Patient Limit Increase is separate from the already approved "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)" (Attachment D) which allows practitioners to get a waiver to treat up to 100 patients. The form () will have to be completed and submitted to SAMHSA.

The information entered on the form will allow SAMHSA to determine whether practitioners are eligible for a patient limit increase of 275. The Request for Patient Limit Increase form is limited to two sets of items: attestation of the qualifications for a patient limit increase of 275 set forth in 42 CFR 8.620; and only such additional information as is required to validate the statements made on the form regarding the notifying physician's state medical licensure, and medical board certification and/or training/experience. SAMHSA has determined that the following information would be necessary to process requests for patient limit increase of 275:

1. Practitioner name;
2. State medical license number;
3. Medical Specialty
4. DEA registration number;
5. Service location information (address, telephone number, fax number, e-mail address);
5. Type of facility (FQHQ or non-FQHC);
6. Attestation of qualifying criteria for a patient limit increase of 275;
7. Attestation of intent to treat up to and not exceed 275 patients at one time;
8. Attestation that the practitioner would adhere to national recognized evidence-based guidelines for the treatment of patients with opioid use disorders;
9. Attestation that the practitioner would provide patients with necessary behavioral health services or establish formal agreement with another entity to provide behavioral health services;
10. Attestation that the practitioner would 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;
11. Attestation that the practitioner would use patient data to inform the improvement of outcomes;
12. Attestation that the practitioner would adhere to a diversion control plan to manage the covered medications and reduce the possibility of diversion of covered medications from legitimate treatment use;
13. Attestation that the practitioner has 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 § 8.2;

14. Attestation that the practitioner would notify all patients above the 100 patient level, in the event that the request for the higher patient limit is not renewed or is denied, that the practitioner would no longer be able to provide MAT services using buprenorphine to them and make every effort to transfer patients to other addiction treatment;
15. Attestation that when requesting an emergency increase to 275 patients, the practitioner is practicing in an emergency situation as defined in 42 CFR 8.2 and 8.655;
16. Attestation that when requesting an emergency increase to 275 patients, the practitioner would not exceed his or her current patient limit until notified by SAMHSA;
17. Attestation that when requesting an emergency increase to 275 patients, the practitioner the practitioner would not exceed his or her 200 patients for maintenance or detoxification treatment at one time;
18. Attestation that when requesting an emergency increase to 275 patients, the practitioner may only practice at the higher limit for a period not to exceed 6 months unless such approval is extended under 42 CFR 8.655(d);
19. Attestation that the practitioner would use only those schedule III, IV, or V drugs or combinations that have been approved by the FDA for use in maintenance or detoxification treatment and that have not been the subject of an adverse determination;

Practitioners would use the form for three types of requests for patient limit increase to 275: (a) new, (b) renewal, and (c) emergency situation request for patient limit increase to treat up to 275 patients. Under "new" requests, practitioners would make their initial request for a patient limit increase to 275 to SAMHSA. "Emergency Situation" requests for a patient limit increase to 275 would inform SAMHSA of a practitioner's desire to prescribe immediately to facilitate continuity of care for patients whose care might otherwise be abruptly terminated due to an emergency situation. "Renewal" notifications would inform SAMHSA of a physician's intent to continue treating up to 275 patients.

SAMHSA will be developing a system for receiving, storing, reviewing, and verifying the information submitted with the requests for patient limit increase to 275.

Practitioners will be submitting requests for patient limit increase to 275 to SAMHSA. SAMHSA would then forward them to a designated contractor who would, as an initial step, send an acknowledgment letter to the applicant physician. The contractor would then verify physician credentials by contacting DEA (through SAMHSA), State Medical Boards (through a subcontractor or directly as necessary), medical specialty societies (to confirm training and experience status), and other entities as appropriate. The contractor would forward reports on each applicant to SAMHSA where staff would review and approve or deny each request. If additional information were needed to determine qualifications, the applicant would receive an "incomplete" letter. If it is determined that the physician meets the requirements under the proposed rule, the physician would receive an approval letter. The letter would explain the status of their request for a patient limit increase, and provide contact information. .

SAMHSA would use the collected information to gauge the overall quality of care provided under the final rule; inform development of technical assistance and guidance to federal, state, and private partners and stakeholders regarding access to treatment, resources utilization, and outcomes; assess internal program monitoring and evaluation; and generate reports on agency activities and public summary reports.

Practitioners who do not renew their Request for Patient Limit Increase must notify all patients above the 100 patient limit that the practitioner will no longer be able to provide medication-assisted services using covered medications and make every effort to transfer patients to other addiction treatment. The Patient Notice is a model notice to guide practitioners in this situation when they notify their patients.

Practitioners who have been approved for the request for patient limit increase would also be required to submit annually to SAMHSA a reporting form. To facilitate this process SAMHSA seeks approval from OMB for the practitioner reporting form (Attachment I).

SAMHSA would use the collected information to assure compliance with 42 CFR Part 8 Subpart F.

3. *Use of Information Technology*

In addition to submissions by mail, physicians may submit waiver notifications via an electronic version of the notification form, which is available at www.buprenorphine.samhsa.gov. 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 physicians access this website and submit notifications online, using an email auto-response system for signature verification.

Under the final rule, physicians would be able to submit a request for a patient limit increase to 275 via an electronic version of the notification form, which also would be available at www.buprenorphine.samhsa.gov.

SAMHSA would accept electronic notifications, and SAMHSA would convert the proposed system to the Department-wide standard once it is available.

SAMHSA would accept electronic submission of annual reports.

4. *Efforts to Identify Duplication*

The law requires physicians 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. SAMHSA is not aware of any other public data source that would capture the information requested in the reporting requirements.

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 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, physicians will be unable to prescribe certain approved narcotic treatment drugs for the treatment of opiate addiction, as permitted under the Drug Addiction Treatment Act of 2000. All physicians who wish to prescribe the narcotic treatment drugs included under this statute for up to 100 patients must submit a notification. Under the rule, those wishing to treat up to 275 patients would have to submit a request for patient limit increase. Additionally, if the reporting requirements information is not collected, SAMHSA will not be able to assure compliance with 42 CFR Part 8 Subpart F.

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 NPRM that increased the patient limit was published in the Federal Register on March 30, 2016 (81 FR 17639) - (Attachment E).

The Final Rule that increased the patient limit was published in the Federal Register on July 8, 2016 (81 FR 44712) - (Attachment F).

The Supplemental NPRM that outlined reporting requirements was published in the Federal Register on July 8, 2016 (81 FR 44576) – (Attachment G)

The Final Rule that outlined reporting requirements was published in the Federal Register on September 27, 2016 (81 FR 66191) – (Attachment H)

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)). 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).

The proposed Request for Patient Limit Increase also will include this language.

In addition, SAMHSA would release to the SAMHSA Buprenorphine Physician Locator only the physician name, address, and phone number, for those physicians 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. While this disclosure may not be necessary for the implementation of DATA or the patient limit increase to 275, 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 and proposed rule's goal of expanding the availability of medication-assisted treatment for opioid use disorders.

Information provided on the Notification of Intent and the proposed Request for Patient Limit Increase 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. To the extent provided by law, no other access would be permitted without the express permission of each practitioner.

The practitioner reporting form includes the following statement of purpose and privacy:

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:

- Medical specialty societies to verify practitioner qualifications.
- Other federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
- State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
- 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.

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 practicing physicians. The questions included on the practitioner reporting form are about service provision.

12. *Estimate of Annualized Hour Burden*

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

Current burden							
42 CFR Citation	Purpose of Submission	Number of respondents	Responses/Respondent	Burden/ Response (Hr.)	Total Burden (Hrs.)	Hourly Wage Cost ($)	Total Wage Cost ($)
	Notification of Intent	1,500	1	.083	125	$73.00	$9,125
	Notification to Prescribe Immediately	50	1	.083	4	$73.00	$304
	Notice to Treat up to 100 patients	500	1	.040	20	$73.00	$1,460
	Subtotal	**2,050**	-	-	**149**	-	**$10,889**
Burden Associated with the Final Rule That Increased the Patient Limit							
8.620	Request for	517	1	.5	259	$93.74	$24,232

(a)-(c)	Patient Limit Increase*						
8.12 (c) (2)	Diversion Control Plan*	517	1	.5	259	$93.74	$24,232
8.640	Renewal Request for a Patient Limit Increase*	1	1	.5	.5	$93.74	$47
8.645	Patient Notice*	1	1	3	3	$93.74	$281
8.655	Request for a Temporary Patient Increase for an Emergency*	10	1	3	30	$64.47	$1,934
	Subtotal	**1,046**	**-**	**-**	**552**	**-**	**$50,726**
New Burden Associated with the Final Rule That Outlined the Reporting Requirements							
8.635	Practitioner Reporting Form*	1,350	1	3	4,050	$64.47	$261,104
	Total Burden	**4,446**	-	-	**4,751**		**$ 322,719**

* Provision in the final rule.

As indicated in the chart above, SAMHSA estimates that completion of the Request for Patient Limit Increase form (for initial and renewal) would require .5 hours or about 30 minutes. SAMHSA estimates that completion of the form for emergency situations would require 3 hours or 180 minutes. Additionally, SAMHSA estimates that adherence to a diversion control plan would require .5 hours or 30 minutes and that distribution of patient notices would take 3 hours or 180 minutes. Finally, SAMHSA estimates that the annual practitioner reporting form would require 3 hours. According to the U.S. Bureau of Labor Statistics,[a] the average hourly wage for a physician is $93.74.

13. *Estimates of Annualized Cost Burden to Respondents*

Completing the Notification of Intent and the proposed Request for Patient Limit Increase should not require any additional costs for computer equipment or other record-keeping technology. The reporting requirements would have some associated capital costs if practitioners choose to adjust IT systems to facilitate recordkeeping.

14. *Estimates of Annualized Cost to the Government*

[a] U.S. Bureau of Labor Statistics. National Occupational Employment and Wage Estimates. Retrieved from: http://www.bls.gov/oes/current/oes_nat.htm#29-0000.

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.

SAMHSA estimates that it would require approximately 10 minutes to review and verify each request for patient limit increase form processed by our contractor, and recommended for a patient limit increase to 275. This translates into approximately 200 hours per year. In addition, SAMHSA estimates that it would require approximately 50 hours per year to review special cases that may require additional verification efforts. Together, the total estimated review time is approximately 250 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 $12,500.

As discussed above, a request for patient limit increase processing and verification system would be developed and would be maintained by a contractor under a task-order contract that includes provision for other activities to support implementation of the patient limit increase to 200. The estimated cost of the patient limit increase processing and verification system for the three-year life of the contract would be $2,250,000 or an annualized cost of $750,000 per year over the potential three-year term of the contract if all option years are exercised. This would include general management costs that can be attributed to the increase patient limit request processing and verification activity.

Thus, the total annual cost is estimated to be approximately $762,500.

SAMHSA estimates that it would require a new FTE for SAMHSA to review the reporting requirements form processed, analyze the data and contact the practitioners for any issues such as not meeting the reporting requirements or sending an alert when the practitioner is approaching the expiration of their waiver. This translates into a full-time position. SAMHSA believes that this review would be conducted by a GS13 level public health advisor within SAMHSA. Accordingly, the total SAMHSA annual cost to review this form and coordinate all works pertinent to it will be approximately $92,000

Additionally, the reporting requirements form would be developed and maintained by a contractor under a task-order contract. Additionally, the information on the reporting requirements form will be maintained in a data collection system that serves as a repository for all of the collected form data. The contractor and SAMHSA staff will have access to this system when data analysis is needed. The estimated cost of developing, maintaining, and reviewing the reporting requirements form for the 5-year life of the contract would be $1,000,000, or an annual cost of $200,000 per year over the potential 5-year term of the contract if all option years are exercised. This includes general management costs that can be attributed to reviewing the reporting requirements form for accuracy and completeness, as well as maintaining a data collection system.

Thus, the total annual cost associated with the reporting requirements is estimated to be approximately $292,000.

The total annual cost associated with all information collection will be $1,054,500.

15. *Changes in Burden*

Currently there are 701 total burden hours in the OMB inventory. SAMHSA is requesting 4,751 total burden hours. The increase of 4,050 burden hours is due to a program change of the reporting requirements form (1,350 respondents and 4,050 hours).

16. *Time Schedule, Publication, and Analysis Plan*

SAMHSA would provide updated counts of waiver 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 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. 21 USC § 823(g)(2).

B. Request for Patient Limit Increase Form

C. Patient Notice

D. 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)Patient Notice

E. Notice of Proposed Rulemaking – published on March 30, 2016

F. Final Rule – published on July 8, 2016

G. Supplemental Notice of Proposed Rulemaking – published on July 8, 2016

H. Final Rule – published on September 27, 2016

I. Reporting Requirements Form