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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Project: Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction Under 21 U.S.C. 823(g)(2) (OMB No. 0930–0234 and OMB No. 0930-0369) – Revision

The Drug Addiction Treatment Act of 2000 ("DATA," Pub. L. 106–310) amended the Controlled Substances Act (21 U.S.C. 823(g)(2)) to permit qualifying practitioners to seek and obtain waivers to prescribe certain approved narcotic treatment drugs for the treatment of opiate addiction. The legislation set eligibility requirements and certification requirements as well as an interagency notification review process for practitioners who seek waivers. To implement these provisions, SAMHSA developed Notification of Intent Forms that facilitate the submission and review of notifications. The forms provide the information necessary to determine whether practitioners meets the qualifications for waivers set forth under the law at the 30-, 100-, and 275- patient limits. This includes the annual reporting requirements for practitioners with

waivers for a 275 patient limit. On October 24, 2018, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Pub. L. 115-71) was signed into law. Sections 3201 – 3202 of the SUPPORT Act made several amendments to the Controlled Substances Act regarding office-based opioid treatment that affords practitioners greater flexibility in the provision of medication-assisted treatment (MAT). The SUPPORT Act 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. It 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 CFR 8.2) in a qualified practice setting as described under 42 CFR 8.615. Finally, 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. In order to expedite the new provisions of the

SUPPORT Act, SAMHSA sought and received a Public Health Emergency Paperwork Reduction Act Waiver. Practitioners may use the form for four types of notifications: (a) New Notification to treat up to 30 patients; (b) New Notification, with the intent to immediately facilitate treatment of an individual (one) patient; (c) Second notification of need and intent to treat up to 100 patients; and (d) New notification to treat up to 100 patients. Under "new" notifications, practitioners may make their initial waiver requests to SAMHSA. "Immediate" notifications inform SAMHSA and the Attorney General of a practitioner's intent to prescribe immediately to facilitate the treatment of an individual (one) patient under 21 U.S.C. 823(g)(2)(E)(ii). The form collects data on the following items: Practitioner name; state medical license number; medical specialty; and DEA registration number; address of primary practice location, telephone and fax numbers; e-mail address; name and address of group practice; group practice employer identification number; names and DEA registration numbers of group practitioners; purpose of notification: new, immediate, or renewal; certification of qualifying criteria for treatment and management of opiate dependent patients; certification of capacity to provide directly or refer patients for appropriate counseling and other appropriate ancillary services; certification of maximum patient load, certification to use only those drug products that meet the criteria in the law. The form also notifies practitioners of Privacy Act considerations, and permits practitioners to expressly consent to disclose limited information to the SAMHSA Buprenorphine Physician and Behavioral Health Treatment Services locators. The following table summarizes the estimated annual burden for the use of this form.

42 CFR Citation	**Purpose of Submission**	**Estimated Number of respondents**	**Responses/Respondent**	**Burden/ Response (Hr.)**	**Total Burden (Hrs.)**

	Notification of Intent	1,500	1	0.083	125
	Notification to Prescribe Immediately	50	1	0.083	4
	Notice to Treat up to 100 patients	500	1	0.04	20
	Notice to Treat up to 275 patients	800	1	1	65
	Subtotal	**2,850**	**-**	**-**	**214**
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
	Request for Patient Limit Increase*	517	1	0.5	259
	Request for Patient Limit Increase*	517	1	0.5	259
8.64	Renewal Request for a Patient Limit Increase*	260	1	0.5	130
	Renewal Request for a Patient Limit Increase*	260	1	0.5	130
	Renewal Request for a Patient Limit Increase*	260	1	0.5	130
8.655	Request for a Temporary Patient Increase for an Emergency*	10	1	3	30

	Request for a Temporary Patient Increase for an Emergency*	10	1	3	30
	Request for a Temporary Patient Increase for an Emergency*	10	1	3	30
	Subtotal	**2,361**	**-**	**-**	**1,256**
New Burden Associated with the Final Rule That Outlined the Reporting Requirements					
8.635	Practitioner Reporting Form*	1,350	1	3	4050
	"Qualifying Other Practitioner" under 21 USC § 823(g)(2) – Nurse Practitioners	816	1	0.066	54
	"Qualifying Other Practitioner" under 21 USC § 823(g)(2) – Physician Assistants	590	1	0.066	39
	"Qualifying Other Practitioner" under 21 USC § 823(g)(2) – Certified Nurse Specialists	590	1	0.066	39

	"Qualifying Other Practitioner" under 21 USC § 823(g)(2) – Certified Nurse Mid-Wives	590	1	0.066	39
	"Qualifying Other Practitioner" under 21 USC § 823(g)(2) – Certified Registered Nurse Anesthetists	590	1	0.066	39
	Sub Total	**4,526**		-	**4260**
	Total Burden	**6,561**	-	-	**5,519**

Written comments and recommendations concerning the proposed information collection should be sent by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via e-mail to: OIRA_Submission@omb.eop.gov. Although commenters are encouraged to send their comments via e-mail, commenters may also fax their comments to: 202-395-7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, D.C. 20503.

Summer King,

Statistician.

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