



Billing Code: 4162-20 - P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: 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” - (OMB No. 0930-0369) - Revision

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 to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a “Qualifying Other Practitioner. The Notification of Intent would allow SAMHSA to determine whether other practitioners are eligible to prescribe certain approved narcotic treatment medications for the maintenance or detoxification treatment of opioid addiction.

This Notification of Intent is a result of the Comprehensive Addiction and Recovery Act (PL 114-198), which was signed into law on July 22, 2016. The law establishes criteria for nurse practitioners (NPs) and physician assistants (PAs) to qualify for a waiver to prescribe covered medications. To be eligible for a waiver, the NP or PA 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. 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.

Below are the following changes:

Use of term of “Qualifying Practitioners” (NOI Sections 1, 2, 6, and 11)

The Statute Section 823(g)(2)(B)(i) refers to both physicians and mid-level providers as “qualifying practitioners.” Therefore in order to avoid confusion and redundancy, the revised NOI refers to “other qualifying practitioners,” simply as “practitioners”.

Patient Limits (See NOI Section 6: Purpose of Notification)

Language was added allowing practitioners who have treated 30 patients for at least one year to increase their patient limit to 100. This second notification to treat 100 patients was omitted in the original NOI form.

Identification of Training Providers

The previous NOI required that the practitioner to write-in the name of training provider(s) name(s). The revised NOI allows practitioners to select training providers from a list.

The following table is the estimated hour burden:

Purpose of Submission	Number of Respondents	Responses/Respondent	Burden Hours	Total Burden Hours

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
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
Total	1,406	-	-	93

Send comments to Summer King, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57-B, Rockville, Maryland 20857, **OR** e-mail a copy to **summer.king@samhsa.hhs.gov**. Written comments should be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Summer King
Statistician

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