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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 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 (Pub. L. 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:

Address of Practice Location (NOI Item 2 and Instructions Section)

The newly revised instructions in Section 2 now acknowledge that practitioners may practice at multiple practice locations, but may only list a practice location address that matches their DEA registration practice site. Furthermore, the revised section provides a link where practitioners may add additional practice sites.

Use of term of “Other Qualifying Practitioners” (See NOI Items 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 Instructions Section refers to “other qualifying practitioners,” simply as “practitioners.”

Use of term of “Supervisory Physician or Collaborative Physician” (NOI Item 8)

The third and fourth criteria in this section created confusion regarding the relationship with a qualifying physician since providers are required to be supervised by OR work with a collaborative physician, but not both. Therefore, the word “and” was replaced by “or”.

Patient Limits (Item 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.

Use of term of “Qualifying Physician” (NOI Item 8)

The Controlled Substance Act (CSA) requires that NPs and PAs be supervised (or collaborate with) a “qualifying physician” when required by state law to work with a supervising physician (see 21 USC 823(g)(2)(G)(iv)(III)). SAMHSA added a footnote with a definition of the term “qualifying physician” means in the context of the NOI. The term “qualifying physician” is specifically defined under 21 USC 823(g)(2)(G)(ii).

Certification of Qualifying Criteria (NOI Item 8)

The law specifically authorizes NPs and PAs as eligible to apply to be a “Qualifying Other Practitioner.” However, the proposed Notification of Intent form asks applicants to certify that they are either an “advanced practice nurse or physician assistant.” This difference in terminology was considered confusing to potential applicants. SAMHSA revised the first attestation in Certification of Qualifying Criteria to read “I certify that I am either a nurse practitioner or physician assistant who satisfies the definition of a ‘qualifying other practitioner.’”

Identification of Training Providers (NOI Item 8)

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 all applicable training providers from a drop down list.

Certification of Capacity (NOI Item 9)

The second attestation in this section was missing a verb. SAMHSA corrected this error to reflect the statutory language requiring qualifying practitioners to attest to the capacity to provide *directly or by referral*.

Certification of Maximum Patient Load (NOI Item 10)

It was clarified that the second option regarding increasing patient load to 100 refers to a second notifications (as specified in the analogous NOI form for physicians).

Privacy Act Information

This section noted that medical specialty societies be used to verify practitioner credentials. The revised NOI replaced the words “medical specialty societies” with “relevant licensing boards to verify practitioners’ qualifications.”

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

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, DC 20503.

Summer King,

Statistician.

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