

requirement by submitting a notice of intent (NOI), with specific statutorily required certifications, to the Substance Abuse and Mental Health Services Administration (SAMHSA) within HHS. *Id.* at § 823(g)(2)(B). Once SAMHSA approves the waiver request and notifies the Drug Enforcement Administration (DEA) of that approval, DEA issues an X-waiver identification number authorizing that practitioner to treat OUD patients with buprenorphine.

In order to be qualified for a waiver under current law, a practitioner must satisfy certain certification requirements related to training, counseling, and other ancillary services (*i.e.*, psychosocial services) that are codified under 21 U.S.C. 823(g)(2)(B)(i)–(ii). The Secretary of HHS has determined that these requirements represent a perceived barrier to prescribing buprenorphine in the United States. The Secretary of HHS, in consultation with DEA, the Administrator of the Substance Abuse and Mental Health Services Administration,<sup>1</sup> the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, may create exemptions from the certification requirements under 21 U.S.C. 823(g)(2) by issuing practice guidelines pursuant to 21 U.S.C. 823(g)(2)(H)(i)(II). Therefore, pursuant to this authority, HHS hereby issues the following practice guidelines exemption:

1. With respect to the prescription of medications that are covered under 21 U.S.C. 823(g)(2)(C), such as buprenorphine, practitioners licensed under state law, and who possesses a valid DEA registration under 21 U.S.C. 823(f), may become exempt from the certification requirements related to training, counseling, and other ancillary services (*i.e.*, psychosocial services) under 21 U.S.C. 823(g)(2)(B)(i)–(ii). Consistent with the applicable statute, practitioners who meet the above conditions must submit an NOI in accordance with current procedures in order to be covered under this exemption and receive a waiver. However, if a practitioner selects a patient limit of 30 in the NOI, the practitioner will not need to certify as to the training, counseling, or other ancillary services requirements listed under 21 U.S.C. 823(g)(2)(B)(i)–(ii).

2. This exemption applies to practitioners, as defined in these Guidelines, who are state licensed and DEA registered.

3. Practitioners utilizing this exemption are limited to treating no more than 30 patients at any one time. Time spent practicing under this exemption will not qualify the practitioner for a higher patient limit under 21 U.S.C. 823(g)(2)(B)(iii).

4. Physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives are required to be supervised by, or work in collaboration with, a DEA registered physician if required by State law to work in collaboration with, or under the supervision of, a physician when prescribing medications for the treatment of opioid use disorder.

5. Practitioners who do not wish to practice under this exemption and its attendant 30 patient limit may seek a waiver under 21 U.S.C. 823(g)(2) per established protocols. This means that such practitioners must submit an NOI that includes all of the certifications under 21 U.S.C. 823(g)(2)(B)(i)–(iii), and qualify for a higher patient limit through one of the methods identified in 21 U.S.C. 823(g)(2)(B)(iii). More information about how to treat more than 30 patients may be found here (<https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner>).

6. This exemption applies only to the prescription of Schedule III, IV, and V drugs or combinations of such drugs, covered under 21 U.S.C. 823(g)(2)(C), such as buprenorphine. It does not apply to the prescribing, dispensing, or the use of Schedule II medications, such as methadone, for the treatment of opioid use disorders.

7. Practitioners utilizing this exemption may only treat patients who are located in states where those practitioners are licensed to treat patients unless the practitioner is an employee or contractor of a department or agency of the United States who is acting in the scope of such employment or contract, and registered under 21 U.S.C. 823(f) in any State, or is using the registration of a hospital or clinic operated by a department or agency of the United States a registered under Section 823(f). The requirements in (4) also do not apply to such employees.

#### *Recommendations Around Training, Education, and Psychosocial Treatment*

1. Recognizing the importance of practitioner education and training around the provision of comprehensive care for patients with OUD, practitioners treating patients under the exemption provided by these Practice Guidelines are strongly encouraged to

utilize the HHS Buprenorphine Quick Start Guide.

2. Given the multiple challenges often faced by individuals with substance-use disorder and the high rate of psychiatric comorbidity, and evidence that psychosocial treatment may improve outcomes of treatment compliance and retention, practitioners practicing under this exemption are encouraged to provide access to psychosocial services, such as counseling, or other ancillary services, or refer as appropriate to licensed behavioral health practitioners in their communities.

3. Recognizing that substance-use disorder education is not yet uniformly integrated into medical education, colleges of medicine and residency training programs for nurses and physician assistants are strongly encouraged to develop or to continue implementing comprehensive training in substance-use disorder diagnosis and management as a component of their core, required curriculum. The SAMHSA Providers Clinical Support System may be used as a resource for technical assistance. (<https://pcssnow.org/>)

The Department, along with federal partners monitoring diversion and enforcement like DEA, will assess impact and make formal recommendations to the Secretary of Health and Human Services on whether the guideline should be continued, discontinued, or modified.

Approved: April 26, 2021.

**Xavier Becerra,**

*Secretary of Health and Human Services.*

[FR Doc. 2021-08961 Filed 4-27-21; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NICHD.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the Eunice Kennedy Shriver National Institute of Child Health & Human

<sup>1</sup> The head of the Substance Abuse and Mental Health Services Administration is known as the Assistant Secretary for Mental Health and Substance Use following the 21st Century Cures Act (Pub. L. No: 114-255).

Development, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, NICHHD.

*Date:* June 4, 2021.

*Time:* 10:00 a.m. to 5:00 p.m.

*Agenda:* A report by the Acting Scientific Director, NICHHD, on the status of the NICHHD Division of Intramural Research; current organizational structure; to review and evaluate personnel qualifications and performance, and competence of individual investigators.

*Place:* National Institutes of Health, 31 Center Drive, Bethesda, MD 20892 (Video-Assisted Meeting).

*Contact Person:* Mary C. Dasso, Ph.D., Acting Scientific Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 9000 Rockville Pike, Building 31A, Room 2A46 Bethesda, MD 20892, (301) 594-5984, [dassom@mail.nih.gov](mailto:dassom@mail.nih.gov).

Information is also available on the Institute's/Center's home page: <https://www.nichd.nih.gov/about/meetings/Pages/index.aspx>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: April 23, 2021.

**Ronald J. Livingston, Jr.,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2021-0047]

#### Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625-0043

**AGENCY:** Coast Guard, DHS.

**ACTION:** Thirty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of

information: 1625-0043, Ports and Waterways Safety; without change.

Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

**DATES:** You may submit comments to the Coast Guard and OIRA on or before May 28, 2021.

**ADDRESSES:** Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket number [USCG-2021-0047]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>.

Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

A copy of the ICR is available through the docket on the internet at <https://www.regulations.gov>. Additionally, copies are available from: Commandant (CG-6P), ATTN: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, STOP 7710, Washington, DC 20593-7710.

**FOR FURTHER INFORMATION CONTACT:** A.L. Craig, Office of Privacy Management, telephone 202-475-3528, or fax 202-372-8405, for questions on these documents.

#### SUPPLEMENTARY INFORMATION:

#### Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of

information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG-2021-0047], and must be received by May 28, 2021.

#### Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION**

**CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments to the Coast Guard will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the <https://www.reginfo.gov>, comment-submission web page. OIRA posts its decisions on ICRs online at <https://www.reginfo.gov/public/do/PRAMain> after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625-0043.

#### Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (86 FR 10329, February 19, 2021) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

#### Information Collection Request

*Title:* Ports and Waterways Safety.