

organization and the rare disease(s) or condition(s) that they represent. The information provided should address the eligibility and selection criteria below.

Organizations must meet the following eligibility criteria to submit a response.

Eligibility Criteria

a. Represent a rare disease/condition as defined by law (affects fewer than 200,000 individuals in the United States).

b. Maintain a hard copy or an electronic email list of patients affected by the specific disease/condition.

c. Be willing to seek agreement by their members to share their de-identified data with the GRDR, other databases, and the research community as part of an Institutional Review Board (IRB) approved informed consent.

d. Agree to adopt the ORDR Common Data Elements and elements of the ORDR common consent form template.

e. Have a scientific or medical advisory board to assist on ethical issues of privacy human subject protection, data coding and transmission, as well as issues related to data standards, curation, coding and transmission, scientific issues related to research proposals, and other issues as needed.

Organizations that meet the eligibility criteria are asked to provide a short description of how they will address the selection criteria which are listed below. Please note that the response for each criterion has a word limit and each criterion will be weighed accordingly as indicated.

1. Have a well-defined, credible vision and purpose for establishing a registry. (300 words, weigh 30 points)

2. Have a good plan to sustain the newly established or already existing registry beyond the 2 years of the pilot project. (150 words, weigh 20 points)

3. Have, or plan to develop, a feasible system to capture patient updates of their medical information as well as updates of patients' medical information from healthcare providers. (150 words, weigh 10 points)

4. Agree to assist in the translation of their registry into multiple languages as needed to facilitate the inclusion of non-English speaking participants and appear to be capable of providing such assistance. The GRDR will use English only. (150 words, weigh 10 points)

5. Have a good plan for data verification by an individual with a medical background. (150 words, weigh 10 points)

6. Are engaged or willing to collaborate with other organizations

servicing the same or related diseases. (150 words, weigh 10 points)

7. Have a developed means of communication with the public, e.g. electronic mailing lists, newsletter, Web site and other social networking media. (150 words, weigh 5 points)

8. Have, or plan for, support to navigate both future registry activities and community outreach. (150 words, weigh 5 points)

The selection committee, comprised of individuals with medical background, patient advocacy leaders, and others, will rank the submissions from the patient groups based on the selection criteria. ORDR will make the final selections of the patient groups based on rare disease categories to achieve maximum distribution of the different rare diseases. In addition, an effort will be made to ensure that large and small patient organizations will be included, *i.e.*, half from organizations that represent a rare disease with more than 2,500 patient participants and half from organizations with less than 2,500 patient participants (based on hard copy or the electronic contact list).

This invitation and related background information will be available on the ORDR Web site <http://rarediseases.info.nih.gov/GRDR> and distributed through various communication tools. Selected organizations will be notified and their names will be posted on the ORDR Web site.

How To Submit a Response: Responses will be accepted for 30 days following publication of this notice. All responses must be submitted via the Web site at: <http://rarediseases.info.nih.gov/GRDR>. An online form will be available to submit the requested information. Submitters are requested not to exceed the number of characters indicated on the online form. Submitted information will not be considered confidential although each submission will be stored using a login and a password.

This Request for Information (RFI) notice provides information and selection criteria only. It should not be construed as a solicitation or as an obligation on the part of the Federal Government, the NIH, or the ORDR. The ORDR does not intend to make any awards to pay for the preparation of any information submitted or for the Government's use of such information.

ORDR will use the information submitted in response to this RFI at its discretion and will not provide comments to any responder's submission. However, names of patient organizations that are selected in response to this RFI will be posted on the Web site at: <http://>

rarediseases.info.nih.gov/GRDR. The ORDR may contact any responder for the sole purpose of enhancing the ORDR's understanding of the RFI submission. Respondents will receive an automated email confirmation acknowledging receipt of their response, but will not receive individualized feedback. No proprietary, classified, confidential, or sensitive information should be included in your response.

DATES: Responses to this notice must be received on or before 30 days following publication of this notice.

FOR FURTHER INFORMATION CONTACT: Yaffa Rubinstein, Ph.D., Director of Patient Resources for Clinical and Translational Research, Office of Rare Diseases Research, National Institutes of Health, 6100 Executive Boulevard, Room 3A07, Rockville, MD 20892-7518, telephone 301-402-4338, Fax 301-480-9655, Web site <http://rarediseases.info.nih.gov>.

Dated: February 1, 2012.

Thomas Insel,

Acting Director, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health.

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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 Under 21 U.S.C. 823(g)(2) (OMB No. 0930-0234)—Extension

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 practitioners (physicians) to seek and obtain waivers to prescribe certain approved narcotic treatment drugs for the treatment of opiate addiction. The legislation sets eligibility requirements and certification requirements as well as an interagency notification review process for physicians who seek waivers. The legislation was amended in 2005 to eliminate the patient limit for physicians in group practices, and in 2006, to permit certain physicians to treat up to 100 patients.

To implement these provisions, SAMHSA developed a notification form (SMA-167) that facilitates the submission and review of notifications. The form provides the information necessary to determine whether practitioners (*i.e.*, independent physicians) meet the qualifications for waivers set forth under the new law. Use of this form will enable physicians

to know they have provided all information needed to determine whether practitioners are eligible for a waiver.

However, there is no prohibition on use of other means to provide requisite information. The Secretary will convey notification information and determinations to the Drug Enforcement Administration (DEA), which will assign an identification number to qualifying practitioners; this number will be included in the practitioner’s registration under 21 U.S.C. 823(f).

Practitioners may use the form for three types of notification: (a) New, (b) immediate, and (c) to notify of their intent 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). Finally, the form may be used by physicians with waivers to certify their need and intent to treat up to 100 patients.

The form collects data on the following items: Practitioner name; state medical license number and DEA registration number; address of primary location, telephone and fax numbers; email 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 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 Locator.

Since July 2002, SAMHSA has received over 25,000 notifications and has certified almost 27,000 physicians. Fifty-nine percent of the notifications were submitted by mail or by facsimile, with approximately forty-one percent submitted through the Web based online system. Approximately 60 percent of the certified physicians have consented to disclosure on the SAMHSA Buprenorphine Physician Locator.

Respondents may submit the form electronically, through a dedicated Web page that SAMHSA will establish for the purpose, as well as via U.S. mail.

There are no changes to the forms and burden hours.

The following table summarizes the estimated annual burden for the use of this form.

Purpose of submission	Number of respondents	Responses per respondent	Burden per response (hr.)	Total burden (hrs)
Initial Application for Waiver	1,500	1	.083	125
Notification to Prescribe Immediately	50	1	.083	4
Notice to Treat up to 100 patients	500	1	.040	20
Total	2,050	—	—	149

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 8-1099, One Choke Cherry Road, Rockville, MD 20857 or email a copy to summer.king@samhsa.hhs.gov. Written comments must be received before 60 days after the date of the publication in the **Federal Register**.

Janine Denis Cook,
Chemist.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2010-0316]

National Boating Safety Advisory Council; Vacancies

AGENCY: Coast Guard, DHS.

ACTION: Request for applications.

SUMMARY: The Coast Guard seeks applications for membership on the National Boating Safety Advisory Council (NBSAC). This Council advises the Coast Guard on recreational boating safety regulations and other major boating safety matters.

DATES: Applicants should submit a cover letter and resume in time to reach the Alternate Designated Federal Officer (ADFO) on or before April 10, 2012.

ADDRESSES: Applicants should send their cover letter and resume to the following address: Commandant (CG-5422)/NBSAC, Attn: Mr. Jeff Ludwig, U.S. Coast Guard, 2100 Second St. SW., Stop 7581, Washington, DC 20593-7581. You can also call 202-372-1061; or email jeffrey.a.ludwig@uscg.mil. This notice is available in our online docket, USCG-2010-0316, at <http://www.regulations.gov>. Members of the public should not submit personal information into a docket, as it becomes public record.