

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: April 13, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-08992 Filed 4-18-16; 8:45 am]

BILLING CODE 4140-01-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: Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Dependence—42 CFR part 8 (OMB No. 0930-0206) and Opioid Treatment Programs (OTPs)—Revision

42 CFR part 8 establishes a certification program managed by SAMHSA's Center for Substance Abuse Treatment (CSAT). The regulation requires that Opioid Treatment Programs (OTPs) be certified. "Certification" is the process by which SAMHSA determines that an OTP is qualified to provide opioid treatment under the Federal opioid treatment standards established by the Secretary of Health and Human Services. To become certified, an OTP must be accredited by a SAMHSA-approved accreditation body. The regulation also provides standards for such services as individualized treatment planning, increased medical supervision, and assessment of patient outcomes. This submission seeks continued approval of the information collection requirements in the regulation and of the forms used in implementing the regulation.

SAMHSA currently has approval for the Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR 8.11 (Form SMA-162); the Application for Approval as Accreditation Body Under 42 CFR 8.3(b) (Form SMA-163); and the Exception Request and Record of Justification Under 42 CFR 8.12 (Form SMA-168), which may be used by physicians when there is a patient care situation in which the physician must make a treatment decision that differs from the treatment regimen required by the regulation. Form SMA-168 is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions.

SAMHSA believes that the recordkeeping requirements in the regulation are customary and usual practices within the medical and rehabilitative communities and has not calculated a response burden for them. The recordkeeping requirements set forth in 42 CFR 8.4, 8.11, and 8.12 include maintenance of the following: 5-year retention by accreditation bodies of certain records pertaining to accreditation, and documentation by an OTP of the following: A patient's medical examination when admitted to treatment, a patient's history, a

treatment plan, any prenatal support provided to the patient, justification of unusually large initial doses, changes in a patient's dosage schedule, justification of unusually large daily doses, the rationale for decreasing a patient's clinic attendance, and documentation of physiologic dependence.

The rule also includes requirements that OTPs and accreditation organizations disclose information. For example, 42 CFR 8.12(e)(1) requires that a physician explain the facts concerning the use of opioid drug treatment to each patient. This type of disclosure is considered to be consistent with the common medical practice and is not considered an additional burden. Further, the rule requires, under Sec. 8.4(i)(1) that accreditation organizations shall make public their fee structure; this type of disclosure is standard business practice and is not considered a burden.

A number of changes have been made to the forms. Forms have been reworded for clarification, updated with current SAMHSA mailing and web-submission information, and a few additional fields have been provided for clarity and for providers to best explain their services (e.g., expanding the former global patient census in the SMA-162 to request patient census by drug type—methadone, buprenorphine, naltrexone, or other) and the needs of their patients (e.g., including urinalysis results on the SMA-168 and adding "weather crisis" as a standard option for physician justification of the requested exception). Amendments also include the removal of information pertaining to faxing the forms to SAMHSA, as this is no longer an acceptable form of submission. The burden hours have increased slightly (by 28% or approximately 639 hours) due to an increase in the number of facilities accredited and certified by SAMHSA since the previous submissions of these forms. The forms are available online with a unique feature for both the SMA-162 and SMA-168 that pre-populates certain information within the form. This in turn reduces the program's time spent filling out the forms as well as the staff time spent on processing it.

The tables that follow summarize the annual reporting burden associated with the regulation, including burden associated with the forms.

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR ACCREDITATION BODIES

| 42 CFR citation | Purpose | Number of respondents | Responses/respondent | Total responses | Hours/response | Total hours |
|--------------------|----------------------------------|-----------------------|----------------------|-----------------|----------------|-------------|
| 8.3(b)(1-11) | Initial approval (SMA-163) | 1 | 1 | 1 | 6.00 | 6.00 |

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR ACCREDITATION BODIES—Continued

| 42 CFR citation | Purpose | Number of respondents | Responses/ respondent | Total responses | Hours/ response | Total hours |
|-----------------------|---|-----------------------|-----------------------|-----------------|-----------------|-------------|
| 8.3(c) | Renewal of approval (SMA-163) | 2 | 1 | 2 | 1.00 | 2.00 |
| 8.3(e) | Relinquishment notification | 1 | 1 | 1 | 0.50 | 0.50 |
| 8.3(f)(2) | Non-renewal notification to accredited OTPs. | 1 | 90 | 90 | 0.10 | 9.00 |
| 8.4(b)(1)(ii) | Notification to SAMHSA for seriously noncompliant OTPs. | 2 | 2 | 4 | 1.00 | 4.00 |
| 8.4(b)(1)(iii) | Notification to OTP for serious non-compliance. | 2 | 10 | 20 | 1.00 | 20.00 |
| 8.4(d)(1) | General documents and information to SAMHSA upon request. | 6 | 5 | 30 | 0.50 | 15.00 |
| 8.4(d)(2) | Accreditation survey to SAMHSA upon request. | 6 | 75 | 450 | 0.02 | 9.00 |
| 8.4(d)(3) | List of surveys, surveyors to SAMHSA upon request. | 6 | 6 | 36 | 0.20 | 7.20 |
| 8.4(d)(4) | Report of less than full accreditation to SAMHSA. | 6 | 5 | 30 | 0.50 | 15.00 |
| 8.4(d)(5) | Summaries of Inspections | 6 | 50 | 300 | 0.50 | 150.00 |
| 8.4(e) | Notifications of Complaints | 12 | 6 | 72 | 0.50 | 36.00 |
| 8.6(a)(2) and (b)(3). | Revocation notification to Accredited OTPs. | 1 | 185 | 185 | 0.30 | 55.50 |
| 8.6(b) | Submission of 90-day corrective plan to SAMHSA. | 1 | 1 | 1 | 10.00 | 10.00 |
| 8.6(b)(1) | Notification to accredited OTPs of Probationary Status. | 1 | 185 | 185 | 0.30 | 55.50 |
| Sub Total | | 54 | | 1,407 | | 394.70 |

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS

| 42 CFR citation | Purpose | Number of respondents | Responses/ respondent | Total responses | Hours/ response | Total hours |
|------------------|---|-----------------------|-----------------------|-----------------|-----------------|-------------|
| 8.11(b) | Renewal of approval (SMA-162) | 386 | 1 | 386 | 0.15 | 57.90 |
| 8.11(b) | Relocation of Program (SMA-162) ... | 35 | 1 | 35 | 1.17 | 40.95 |
| 8.11(e)(1) | Application for provisional certification. | 42 | 1 | 42 | 1.00 | 42.00 |
| 8.11(e)(2) | Application for extension of provisional certification. | 30 | 1 | 30 | 0.25 | 7.50 |
| 8.11(f)(5) | Notification of sponsor or medical director change (SMA-162). | 60 | 1 | 60 | 0.10 | 6.00 |
| 8.11(g)(2) | Documentation to SAMHSA for interim maintenance. | 1 | 1 | 1 | 1.00 | 1.00 |
| 8.11(h) | Request to SAMHSA for Exemption from 8.11 and 8.12 (including SMA-168). | 1,325 | 25 | 33,125 | 0.07 | 2,318.75 |
| 8.11(i)(1) | Notification to SAMHSA Before Establishing Medication Units (SMA-162). | 10 | 1 | 10 | 0.25 | 2.50 |
| 8.12(j)(2) | Notification to State Health Officer When Patient Begins Interim Maintenance. | 1 | 20 | 20 | 0.33 | 6.60 |
| 8.24 | Contents of Appellant Request for Review of Suspension. | 2 | 1 | 2 | 0.25 | .50 |
| 8.25(a) | Informal Review Request | 2 | 1 | 2 | 1.00 | 2.00 |
| 8.26(a) | Appellant's Review File and Written Statement. | 2 | 1 | 2 | 5.00 | 10.00 |
| 8.28(a) | Appellant's Request for Expedited Review. | 2 | 1 | 2 | 1.00 | 2.00 |
| 8.28(c) | Appellant Review File and Written Statement. | 2 | 1 | 2 | 5.00 | 10.00 |
| Sub Total | | 1,900 | | 33,719 | | 2,507.70 |
| Total | | 1,954 | | 35,126 | | 2,902.40 |

Send comments to Summer King, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57B, Rockville, MD 20857 or email a copy at summer.king@samhsa.hhs.gov. Written comments should be received by June 20, 2016.

Summer King,
Statistician.

[FR Doc. 2016-09020 Filed 4-18-16; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2016-0104]

Navigation and Vessel Inspection Circular (NVIC) No. 02-16; Inspection Guidance for Sail Rigging and Masts on Inspected Sailing Vessels

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability.

SUMMARY: The Coast Guard announces the availability of NVIC 02-16. This Circular provides guidance to vessel owners, riggers, marine surveyors, other marine service providers, and Coast Guard marine inspectors regarding inspection of sail rigging, masts, and associated components for commercial sailing vessels and the use of preventative maintenance as a good marine practice. It provides guidance for the purpose of assisting vessel owners and operators, and U.S. Coast Guard personnel with the inspection and recommended documentation of maintenance for sail rigging and masts on inspected sailing vessels. It is intended to enhance consistency with the Coast Guard inspection process for the commercial sailing fleet.

DATES: NVIC 02-16 is available on April 13, 2016.

ADDRESSES: This NVIC is available at the following Coast Guard Web site: <http://www.uscg.mil/hq/cg5/nvic/>.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call LCDR James T. Fogle, Office of Commercial Vessel Compliance, Coast Guard, telephone 202-372-1216, email James.T.Fogle@uscg.mil.

Dated: April 13, 2016.

Paul F. Thomas,
USCG, Assistant Commandant for Prevention Policy.

[FR Doc. 2016-09022 Filed 4-18-16; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2016-0291]

Cooperative Research and Development Agreement: Troposcatter Communications Exploratory Development

AGENCY: Coast Guard, DHS.

ACTION: Notice of intent; request for comments.

SUMMARY: The Coast Guard announces its intent to enter into a Cooperative Research and Development Agreement (CRADA) with Comtech Systems, Inc., to investigate the potential operational use of troposcatter technology. The research includes employment of their Modular Transportable Transmission System (MTTS) in northern Alaska to establish beyond line of sight (BLOS) network links without using existing infrastructure or satellite communications. Specifically, the MTTS will provide a wireless IEEE 802.3 (Ethernet) data link between two locations separated by long distances and elevated terrain. The MTTS will be setup in locations with no shelter/protection from the Northern Alaskan environment. A Pilot Demonstration schedule has been proposed in which Comtech Systems will provide their MTTS to connect two points separated by 68 miles with a 3000 foot elevation in between. The Coast Guard Research and Development Center (R&D Center) will prepare a Pilot Demonstration Assessment Plan and Comtech Systems will operate the equipment for exploratory development over a one week period to collect information on suitability, reliability, maintenance requirements, and ease of use. While the Coast Guard is currently considering partnering with Comtech Systems, Inc., the agency is soliciting public comment on the possible nature of and participation of other parties in the proposed CRADA. In addition, the Coast Guard also invites other potential non-Federal participants to propose similar CRADAs.

DATES: Comments must be submitted to the online docket via <http://www.regulations.gov>, or reach the Docket Management Facility, on or before May 19, 2016.

Synopses of proposals regarding future CRADAs must reach the Coast Guard (see **FOR FURTHER INFORMATION CONTACT**) on or before May 19, 2016.

ADDRESSES: Submit comments online at <http://www.regulations.gov> in accordance with Web site instructions.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice or wish to submit proposals for future CRADAs, contact LCDR Samuel Nassar, Project Official, C4ISR Branch, U.S. Coast Guard Research and Development Center, 1 Chelsea Street, New London, CT 06320, telephone 860-271-2727, email samuel.r.nassar@uscg.mil.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We request public comments on this notice. Although we do not plan to respond to comments in the **Federal Register**, we will respond directly to commenters and may modify our proposal in light of comments.

Comments should be marked with docket number USCG-2016-0291 and should provide a reason for each suggestion or recommendation. You should provide personal contact information so that we can contact you if we have questions regarding your comments; but please note that all comments will be posted to the online docket without change and that any personal information you include can be searchable online (see the **Federal Register** Privacy Act notice regarding our public dockets, 73 FR 3316, Jan. 17, 2008). We also accept anonymous comments.

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the Coast Guard (see **FOR FURTHER INFORMATION CONTACT**). Documents mentioned in this notice and all public comments, are in our online docket at <http://www.regulations.gov> and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

Do not submit detailed proposals for future CRADAs to the Docket Management Facility. Instead, submit them directly to the Coast Guard (see **FOR FURTHER INFORMATION CONTACT**).

Discussion

CRADAs are authorized under 15 U.S.C. 3710(a).¹ A CRADA promotes the transfer of technology to the private sector for commercial use, as well as specified research or development

¹ The statute confers this authority on the head of each Federal agency. The Secretary of DHS's authority is delegated to the Coast Guard and other DHS organizational elements by DHS Delegation No. 0160.1, para. II.B.34.