

Knowledge Management database and places email subscription information into a database maintained by a third-party vendor that serves multiple Federal agencies and the White House. Customers can change, add, or delete

their information from either system at any time.

The respondents are behavioral health professionals, researchers, parents, caregivers, and the general public.

There are no changes to the burden or the forms.

SAMHSA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Website Registration	38,605	1	38,605	.033 (2 min.)	1,286
Email Update Subscription	21,138	1	21,138	.017 (1 min.)	359
Total	59,743	59,743	1,645

Send comments to Summer King, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57-B, Rockville, Maryland 20857, OR email a copy to summer.king@samhsa.hhs.gov. Written comments should be received by August 22, 2016.

Summer King,
Statistician.

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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: 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 section 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
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
Subtotal	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
Subtotal	1,900	33,719	2,507.70
Total	1,954	35,126	2,902.40

Written comments and recommendations concerning the proposed information collection should be sent by July 21, 2016 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 email to: OIRA_Submission@omb.eop.gov. Although commenters are encouraged to send their comments via email, 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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Project: Monitoring of the National Suicide Prevention Lifeline (OMB No. 0930-0274) Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Mental Health Services (CMHS) is requesting approval for the revision of data collection associated with the previously-approved Monitoring of the National Suicide Prevention Lifeline (OMB No. 0930-0274; Expiration, July 31, 2016). The current request will continue previously-cleared efforts to evaluate process and impacts of follow-up

services provided to suicidal individuals through the National Suicide Prevention Lifeline Crisis Center Follow-Up (NSPL Follow-Up) program.

The NSPL, or Lifeline, is SAMHSA's 24-hour crisis hotline (1-800-273-TALK [8255]) that serves as a central switchboard, seamlessly connecting callers from anywhere in the U.S. to the closest of its 165 crisis centers within the Lifeline network. Since its inception, the Lifeline has helped more than 6 million people. In 2008, SAMHSA launched the NSPL Follow-up program and began awarding cooperative agreements to crisis centers in the Lifeline network to reconnect with suicidal callers to offer emotional support and ensure they followed up with referrals to treatment. In 2013, the program was expanded to include crisis center follow-up with any suicidal individual referred from a partnering emergency department (ED) or inpatient hospital.

While previous evaluations of the NSPL demonstrated that suicidal callers experienced a reduction in hopelessness and suicidal intent after contacting the Lifeline, 43% of suicidal callers participating in follow-up assessments reported some recurrence of suicidality (e.g., ideation, plan, or attempt) since their crisis call (Gould et al., 2007). Even so, only about 35% of suicidal callers set up an appointment and even fewer had been seen by the behavioral health care system to which they were referred (Gould et al., 2007; Kalafat et al., 2007). Similarly, while several randomized, controlled trials have demonstrated that following up by telephone or letter with patients discharged from inpatient or ED settings can reduce rates of repeat suicide attempts (Vaiva et al., 2006), as well as completions (Fleischman et al., 2008; Motto & Bostrom, 2001), suicidal individuals discharged from EDs rarely link to ongoing care. As many as 70% of suicide attempters either never attend their first appointment or drop out of treatment after a few sessions (Knesper et al., 2010). Thus, it is imperative that EDs and inpatient settings link these individuals to follow-up care.

SAMHSA is addressing this need through the NSPL Follow-Up program. The Monitoring of the NSPL will continue to assess whether the NSPL Follow-Up program achieves its intended goals. This revision of the Monitoring of the NSPL represents

SAMHSA's desire to expand this process and impacts evaluation to assess follow-up with clients referred to the Lifeline from partnering inpatient hospitals and EDs and continue to improve the methods and standards of service delivery to suicidal individuals receiving crisis center services. This effort will build on information collected through previous and ongoing NSPL evaluations; expand our understanding of the outcomes associated with the NSPL Follow-Up program; and continue to contribute to the evidence base.

This revision requests approval for the removal of one previously-approved instrument and the continuation and renaming of five previously-approved activities. Six crisis centers funded through the NSPL Follow-Up program in FY 2016 will participate in this effort.

Instrument Removal

Due to the completion of the motivational interviewing/safety planning (MI/SP) training and the fulfillment of data collection goals, the currently-approved MI/SP Counselor Attitudes Questionnaire and its associated burden will be removed.

Instrument and Consent Revisions

Each of the five instruments and consents associated with the Monitoring of the NSPL was previously approved by OMB (No. 0930-0274; Expiration, July 31, 2016). Revisions include the following: (1) The term "caller" will be replaced with "client" to reflect the change in respondent type to clients referred from partnering EDs and inpatient hospitals rather than callers, and (2) MI/SP will be removed from the titles of all instruments and consents. No other changes are being made.

- The MI/SP Caller Follow-up Interview will be renamed "Client Follow-up Interview."
- The MI/SP Caller Initial Script will be renamed "Client Initial Script."
- The MI/SP Caller Follow-up Consent Script will be renamed "Client Follow-up Consent Script."
- The MI/SP Counselor Follow-up Questionnaire will be renamed "Counselor Follow-up Questionnaire."
- The MI/SP Counselor Consent will be renamed "Counselor Consent."

The estimated response burden to collect this information associated with the Monitoring of the NSPL annualized over the requested 3-year approval period is presented below: