ESTIMATED ANNUALIZED TOTAL BURDEN BY DATA COLLECTION INSTRUMENT/ACTIVITY

Instrument/activity	Number of respondents	Responses per respondent	Total number of responses	Hours per response [a]	Total burden hours
Sustainability Interviews	98	1	98	1	98
Implementation Interviews	124	1	124	1	124
Stakeholder Interviews	183	1	183	1	183
Provider Survey	74	1	74	1	74
Focus groups	288	1	288	1	288
Total	767		767		767

[a] Hours per response is an average annualized estimate.

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

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: Registration for Behavioral Health Web Site and Resources (OMB No. 0930–0313)—Extension

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting OMB approval for an extension to the Behavioral Health Web site and Resources data collection. SAMHSA is authorized under section 501(d)(16) of the Public Health Service Act (42 U.S.C. 290aa(d)(16)) to develop and distribute materials for the prevention, treatment, and recovery from substance abuse and mental health disorders. To improve customer service and lessen the burden on the public to locate and obtain these materials, SAMHSA has developed a Web site that includes more than 1,400 free publications from SAMHSA and its component Agencies: the Center for Substance Abuse Treatment, the Center for Substance Abuse Prevention, the Center for Mental Health Services, the Center for Behavioral Health Statistics and Quality, and other SAMHSA partners, such as the Office of National Drug Control Policy. These products are available to the public for ordering and download. When a member of the public chooses to order hard-copy publications, it is necessary for SAMHSA to collect certain customer information in order to fulfill the request. To further lessen the burden on the public and provide the level of customer service that the public has come to expect from product Web sites, SAMHSA has developed a voluntary registration process for its publication Web site that allows customers to create accounts. Through these accounts, SAMHSA customers are able to access their order histories and save their shipping addresses. This reduces the burden on customers of having to re-identify materials they ordered in the past and to re-enter their shipping information each time they place an order with SAMHSA. During the Web site registration process, SAMHSA also asks customers to provide optional demographic information that helps SAMHSA evaluate the use and distribution of its publications and improve services to the public.

SAMHSA is employing a web-based form for information collection to avoid duplication and unnecessary burden on customers who register both for an account on the product Web site and for email updates. The web technology allows SAMHSA to integrate the email update subscription process into the Web site account registration process. Customers who register for an account on the product Web site are given the option of being enrolled automatically to receive SAMHSA email updates. Any optional questions answered by the customer during the Web site registration process automatically are mapped to the profile generated for the email update system, thereby reducing the collection of duplicate information.

SAMHSA collects all customer information submitted for Web site registration and email update subscriptions electronically via a series of web forms on the samhsa.gov domain. Customers can submit the web forms at their leisure, or call SAMHSA's toll-free Call Center and an information specialist will submit the forms on their behalf. The electronic collection of information reduces the burden on the respondent and streamlines the data-capturing process. SAMHSA places Web site registration information into a

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