

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: September 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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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: National Survey of Substance Abuse Treatment Services (N-SSATS) (OMB No. 0930-0106)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting a revision of the National Survey of Substance Abuse Treatment (N-SSATS) data collection (OMB No. 0930-0106), which expires on December 31, 2018. N-SSATS provides both national and state-level data on the numbers and types of patients treated and the characteristics of facilities providing substance abuse treatment services. It is conducted under the authority of Section 505 of the Public Health Service Act (42 U.S.C. 290aa-4) to meet the specific mandates for annual information about public and private substance abuse treatment providers and the clients they serve.

This request includes:

- Collection of N-SSATS, which is an annual survey of substance abuse treatment facilities; and
- Updating of the Inventory of Behavioral Health Services (I-BHS) which is the facility universe for the N-SSATS as well as the annual survey of mental health treatment facilities, the National Mental Health Services Survey (N-MHSS). The I-BHS includes all

substance abuse treatment and mental health treatment facilities known to SAMHSA. (The N-MHSS data collection is covered under OMB No. 0930-0119.)

The information in I-BHS and N-SSATS is needed to assess the nature and extent of these resources, to identify gaps in services, and to provide a database for treatment referrals. Both I-BHS and N-SSATS are components of the Behavioral Health Services Information System (BHSIS).

The request for OMB approval will include a request to update the I-BHS facility listing on a continuous basis and to conduct the N-SSATS and the between cycle N-SSATS (N-SSATS BC) in 2019, 2020, and 2021. The N-SSATS BC is a procedure for collecting services data from newly identified facilities between main cycles of the survey and will be used to improve the listing of treatment facilities in the online Behavioral Health Treatment Services Locator.

Planned Changes

I-BHS: Only minor form changes corresponding with updated technology are planned.

N-SSATS: The N-SSATS with client counts will continue to be conducted in alternate years, as in the past, and the Treatment Locator will be updated monthly.

Version A (2019 and 2021)

The following items have been added compared to the 2017 N-SSATS: Add questions about: Where clients obtain their medications for opioid use disorder if they originate elsewhere; how facilities treat alcohol use disorder; where clients obtain their medications for alcohol use disorder if they originate elsewhere; whether the facility only treats alcohol use disorder; detoxification from opioids of abuse with lofexidine or clonidine; the percent of clients on MAT for opioid use disorder that receive maintenance services, detoxification, and relapse prevention; testing for metabolic syndrome; drug and alcohol oral fluid testing; professional interventionist/educational consultant; recovery coach; vocational training or educational support; Naloxone and overdose education; “Outcome follow-up after discharge” which was moved from another question; medications for HIV treatment; medications for Hepatitis C treatment; the medications lofexidine and clonidine; Hepatitis A and B vaccinations; Buprenorphine (*extended-release, injectable, for example, Sublocade®*); clients with co-occurring pain and substance use; Federally

Qualified Health Centers (FQHC); Disulfiram, Naltrexone, or Acamprostate for alcohol use disorder for outpatient, inpatient, and residential. Also, response categories were added to select that services are not provided, and for medication services provided, an “other” category was added.

The following items have been deleted compared to the 2017 N-SSATS: Questions about religious affiliation, standard operating procedures, outpatient capacity, how (paper/electronic/both) a facility performs selected activities, and the item asking about Access To Recovery (ATR) client payments have been deleted.

The following additional changes have been made compared to the 2017 N-SSATS: Removed the asterisk from the question about primary focus of facilities, which means the information will no longer be published on the N-SSATS treatment locator; reorganized the question about services offered; moved the question on types of counseling to the question about services offered; changed the wording from Screening for Hepatitis B and C to Testing for Hepatitis B and C; changed “Screening for mental health disorders” to “Screening for mental disorders”; changed the question about clinical/therapeutic approaches to a “mark all that apply” format; changed the wording from “Computerized substance abuse treatment/telemedicine” to “Telemedicine/telehealth”; changed the question wording about the number of outpatient clients so it states, “As of March 29, 2019, how many active clients were receiving each of the following outpatient substance abuse services at this facility?” and changed the instructions to state “An active client is a client who received treatment in March and is still enrolled in treatment on March 29, 2019.”; and changed the question about halfway houses so it states, “Does this facility operate transitional housing, a halfway house, or a sober home for substance abuse clients at this location, that is, the location listed on the front cover?”

For the question about how facilities treat opioid use disorder, information was added about the question that states, “For this question, MAT refers to any or all of these medications unless specified.” Also, category 5 was reworded to say “This facility administers naltrexone to treat opioid use disorder. Naltrexone use is authorized through any medical staff who have prescribing privileges.” In addition, a category was added, “This facility prescribes buprenorphine to treat opioid use disorder.”

Buprenorphine use is authorized through a DATA 2000 waived physician, physician assistant, or nurse practitioner.” Finally, for the last option, the wording was changed to “This facility is a *federally-certified* Opioid Treatment Program (OTP). (Most OTPs administer/dispense methadone; some only use buprenorphine.)”

Version B (2020)

All changes to the 2019 N–SSATS were made for the 2020 N–SSATS except: Add the question asking if a facility is part of an organization with multiple facilities or sites, and if applicable, the question asking information about the parent site; remove the question about the percent

of clients on MAT for opioid use disorder that receive maintenance services, detoxification, and relapse prevention; All of Section B (Reporting Client Counts) has been deleted which includes: How the facility will complete client counts; number of facilities in client counts; names and addresses of additional facilities reported for; number of hospital inpatient client counts by category, by number under age 18, number receiving methadone, buprenorphine, or naltrexone, and number of dedicated beds; number of residential client counts by category, by number under age 18, and number receiving methadone, buprenorphine, or naltrexone, and number of dedicated beds; number of outpatient client counts

by category, by number under age 18, and number receiving methadone, buprenorphine, or naltrexone; type of substance abuse problem, percent of co-occurring clients; and 12-month admissions; remove questions about how many hospital inpatients, residential clients, and outpatient clients received Disulfiram, Naltrexone, and Acamprosate for alcohol use disorder; and add several new electronic health record questions.

N–SSATS (Between Cycles—BC)

The same changes to the 2020 N–SSATS (Version B) are requested for the N–SSATS BC except the electronic health record questions will not be added.

ESTIMATED ANNUAL BURDEN FOR THE BHSIS ACTIVITIES IS SHOWN BELOW

Type of respondent and activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
States:					
I–BHS Online ¹	56	75	4,200	0.08	336
State Subtotal	56	4,200	336
Facilities:					
I–BHS application ²	800	1	800	0.08	64
Augmentation screener	1,300	1	1,300	0.08	104
N–SSATS questionnaire	17,000	1	17,000	0.66	11,333
N–SSATS BC	1,000	1	1,000	0.58	580
Facility Subtotal	20,100	20,100	12,081
Total	20,156	24,300	12,417

¹ States use the I–BHS Online system to submit information on newly licensed/approved facilities and on changes in facility name, address, status, etc.

² New facilities complete and submit the online I–BHS application form in order to get listed on the Inventory.

Written comments and recommendations concerning the proposed information collection should be sent by October 31, 2018 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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Project: Testing of Electronic Health Records Questions for the National Survey of Substance Abuse Treatment Services (N–SSATS) and the National Mental Health Services Survey (N–MHSS)—NEW

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Behavioral Health Statistics and Quality (CBHSQ), is requesting approval for conducting cognitive testing on the use of electronic health records (EHRs) by substance abuse and mental health treatment facilities in the United States. The final goal of this cognitive testing is to incorporate questions on electronic health records to SAMHSA’s National Survey of Substance Abuse Treatment Services (N–SSATS) and the National Mental Health Services Survey (N–MHSS).

Currently, there is a lack of national level data that exists on behavioral health care providers’ progress toward interoperability. The National Council