Register. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on March 3, 2020. This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's website.

II. Drug Products for Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Abiraterone acetate.
Amoxicillin.
Aprepitant.
Brexanolone.
Buprenorphine.
Desvenlafaxine.
Dolutegravir sodium; Lamivudine.
Efavirenz; Lamivudine; Tenofovir disoproxil fumarate.
Estradiol.
Fish oil triglycerides.
Fluorometholone.
Gilteritinib fumarate.
Glycopyrrolate; Indacaterol maleate.
Ivosidenib.
Latanoprost.
Metformin hydrochloride.
Methylphenidate hydrochloride (multiple reference listed drugs).
Metronidazole.
Prucalopride succinate.
Revefenacin.
Sodium zirconium cyclosilicate.
Tafenoquine succinate.
Talazoparib tosylate.
Tretinoin.
Triclabendazole.

III. Drug Products for Which Revised Draft Product-Specific Guidances are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Albendazole.
Azelastine hydrochloride; Fluticasone propionate.
Buprenorphine.
Carglumic acid.
Clindamycin phosphate (multiple referenced listed drugs).
Clindamycin phosphate; Tretinoin (multiple referenced listed drugs).
Dapagliflozin.
Dapagliflozin; Saxagliptin hydrochloride.
Desvenlafaxine.
Desvenlafaxine fumarate.
Desvenlafaxine succinate.
Dihydroergotamine mesylate.
Diltiazem hydrochloride (multiple referenced listed drugs).
Everolimus.
Ferric citrate.
Fluticasone furoate.
Fluticasone propionate.
Fluticasone propionate; Salmeterol xinafoate.
Methylphenidate hydrochloride (multiple referenced listed drugs).
Metoprolol tartrate.
Metronidazole.
Mometasone furoate.
Tretinoin (multiple referenced listed drugs).
Triamcinolone acetonide.

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidances at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: June 1, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–12100 Filed 6–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Substance Use Disorder Treatment and Recovery Loan Repayment Program, OMB No. 0906—xxxx—New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than August 3, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Substance Use Disorder Treatment and Recovery Loan Repayment Program, OMB No. 0906—xxxx—New.

Abstract: The Further Consolidated Appropriations Act, 2020 included no less than $12,000,000 for HRSA's Bureau of Health Workforce to establish the Loan Repayment Program for Substance Use Disorder (SUD) Treatment Workforce. This funding will allow HRSA to provide the repayment of education loans for individuals working in either a full-time SUD treatment job that involves direct patient care in a Health Professional Shortage Area (HPSA) designated for Mental Health or a county where the

average drug overdose death rate exceeds the national average.

The program expands the types of disciplines eligible to include but not limited to behavioral health paraprofessionals, occupational therapists and bachelor trained counselors. The program also expands the treatment facilities, to include but not limited to inpatient psychiatric facilities, recovery centers, detox facilities, emergency department and local community jails and detention centers. HHS agrees to repay the qualifying educational loans up to $250,000.00 in return for 6 years of service obligation. The forms utilized by the Substance Use Disorder Treatment and Recovery (STAR) Loan Repayment Program (LRP) include the following: The STAR LRP Application, the Authorization for Disclosure of Loan Information form, and the Privacy Act Release Authorization form, if applicable. The aforementioned forms collect information that is needed for selecting participants and repaying qualifying educational loans.

Eligible facilities for the STAR LRP are facilities that provide in-patient and outpatient, ambulatory, primary and mental/behavioral health care services to populations residing in mental health HPSA or a county where the average drug overdose death rate exceeds the national average. The facilities that may provide related in-patient services may include, but are not limited to CMS-approved Critical Access Hospitals, Indian Health Service facilities, inpatient rehabilitation centers and psychiatric facilities. HRSA will recruit facilities for approval. New facilities must submit an application for review and approval. The application requests will contain supporting information on the clinical service site, recruitment contact and services provided. Assistance in completing this application may be obtained through the appropriate HRSA personnel. HRSA will use the information collected on the applications to determine eligibility of the facility for the assignment of health professionals and to verify the need for clinicians. The STAR LRP service site approval will undergo a recertification after no more than 5 years to ensure SUD services are being rendered and the desired population is receiving care.

Despite the similarity in the titles, the STAR LRP is not the existing NHSC SUD LRP (OMB #0915–0127), which is authorized under Title III of the Public Health Service Act. The STAR LRP is a newly authorized Title VII program that has different service requirements, loan repayment protocols, and authorized employment facilities.

Need and Proposed Use of the Information: The need and purpose of this information collection is to obtain information that is used to assess an STAR LRP applicant's eligibility and qualifications for the program, and to obtain information for eligible site applicants. Clinicians interested in participating in the STAR LRP must submit an application to the program in order to participate, and health care facilities located in any HPSAs with high overdose rate and MHPSs must submit a Site Application to determine the eligibility of sites to participate in the STAR LRP. The STAR LRP application asks for personal, professional and financial information needed to determine the applicant's eligibility to participate in the STAR LRP. In addition, applicants must provide information regarding the loans for which repayment is being requested.

Likely Respondents: Licensed primary care medical, mental and behavioral health providers, and other paraprofessionals who are employed or seeking employment, and are interested in serving underserved populations; health care facilities interested in participating in the STAR LRP, and becoming an approved service site; STAR LRP sites providing behavioral health care services directly, or through a formal affiliation with a comprehensive community-based primary behavioral health setting, facility providing comprehensive behavioral health services, or various substance abuse treatment facility sub-types.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
STAR LRP Application	300	1	300	.50	150
Authorization for Disclosure of Loan Information Form	300	1	300	.50	150
Privacy Act Release Authorization Form	300	1	300	.50	150
Site Application	400	1	400	1	400
Total	1,600		1,600		1000

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–12040 Filed 6–3–20; 8:45 am]

BILLING CODE 4165–15–P

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) 276–0361.

Project: National Survey of Substance Abuse Treatment Services (N–SSATS) (OMB No. 0930–0106)—Extension

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting an extension of the National Survey of Substance Abuse Treatment (N–SSATS) data collection (OMB No. 0930–0106), which expires on September 30, 2020. 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. I–BHS is also the facility universe for the annual survey of mental health treatment facilities, the National Mental Health Services Survey (N–MHSS). 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 2021, 2022, and 2023. 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.

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	0.67	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.