ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS—Continued

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Total responses	Hours/ response	Total hours
8.11(e)(1)	Application for provisional certification	42	1	42	1	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	0.1	6.00
8.11(g)(2)	Documentation to SAMHSA for interim maintenance.	1	1	1	1	1.00
8.11(h)	Request to SAMHSA for Exemption from 8.11 and 8.12 (including SMA–168).	1,200	20	24,000	0.07	1,680
8.11(i)(1)	Notification to SAMHSA Before Establishing Medication Units (SMA–162).	10	1	10	0.25	2.5
8.12(j)(2)	Notification to State Health Officer When Patient Begins Interim Maintenance.	1	20	20	0.33	6.6
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		1,775		24,594		1,868.95
Total		1,829		26,001		2,263.15

Written comments and recommendations concerning the proposed information collection should be sent by September 12, 2019 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.

[FR Doc. 2019–17261 Filed 8–12–19; 8:45 am]

BILLING CODE 4162–20–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) 276–1112.

Project: 2020 National Survey on Drug Use and Health, Clinical Validation Study and Redesign Field Test (OMB No. 0930–0110)—Revision to 2019 NSDUH Collection

The National Survey on Drug Use and Health (NSDUH) is a survey of the U.S. civilian, non-institutionalized population aged 12 years old or older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, the Office of National Drug Control Policy (ONDCP), federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

2020 NSDUH Main Study

NSDUH must be updated periodically to reflect changing substance use and mental health issues and to continue producing current data. For the 2020 NSDUH main study the following changes from 2019 are planned: (1) The addition of lifetime and recency questions about vaping anything and vaping nicotine or tobacco; the addition of lifetime and recency questions on synthetic marijuana and synthetic stimulants; (2) the addition of questions in concordance with the Diagnostic and Statistical Manual of Mental Disorders (DSM), fifth edition criteria (*DSM–5*) to measure the occurrence of marijuana withdrawal symptoms, occurrence of prescription tranquilizer misuse withdrawal symptoms and occurrence of craving for all substances; (3) minor revisions to the marijuana marketplace module; and (4) other minor wording changes to improve the flow of the interview, increase respondent comprehension or to be consistent with text in other questions.

By including these new questions in NSDUH, estimates may be generated on the use of these substances among the general population and allow SAMHSA to provide national-level estimates among adults and adolescents on the

use of vaping, synthetic marijuana, and synthetic stimulants. In addition, because NSDUH collects demographic, socioeconomic, and health information about each respondent, the inclusion of these questions would permit a more detailed understanding of factors associated with their use.

The new questions on craving for all substances and withdrawal for marijuana/cannabis were added to the 2020 NSDUH main study to reflect the updated *DSM–5* diagnostic criteria for substance use disorders. Questions measuring withdrawal for tranquilizers have been added to ensure SUD for tranquilizers is accurately assessed as well.

The marijuana marketplace module (originally dropped in the 2015 redesign questionnaire) was reinserted in the NSDUH main study questionnaire starting in 2018 at the request of ONDCP but was unchanged from the version previously used in the 2014 NSDUH. (This module was not part of the NSDUH questionnaire from 2015–2017.) This module consists of a series of questions that seek to gather data such as the location, quantity, cost and type of marijuana being purchased across the nation. Revisions have been made to this module for 2020 to reflect the availability that marijuana can now be purchased from a retail store or dispensary.

As with all NSDUH/NHSDA surveys conducted since 1999, the sample size of the NSDUH main study for 2020 will be sufficient to permit prevalence estimates for each of the fifty states and the District of Columbia. (Prior to 2002, the NSDUH was referred to as the National Household Survey on Drug Abuse (NHSDA). The total annual burden estimate for the NSDUH main study is shown below in Table 1.

TABLE 1—ANNUALIZED ESTIMATED BURDEN FOR 2020 NSDUH

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
Household Screening	143,255	1	143,255	0.083	11,890
Interview	69,007	1	69,007	1.000	69,007
Screening Verification	4,348	1	4,348	0.067	291
Interview Verification	10,351	1	10,351	0.067	694
Total	143,255	.....	226,961	.....	81,882

Clinical Validation Study

In addition, a Clinical Validation Study (CVS) is planned to be embedded within the first six months of 2020 NSDUH main study data collection to assess revisions to the substance use disorders (SUD) module to be consistent with the *DSM–5.* The CVS will examine the validity of this revised NSDUH assessment of SUD by administering questions to adults and adolescents who will then be interviewed by clinical interviewers (who are blinded to the NSDUH main study responses) and classified as having or not having substance use disorders based on past year *DSM–5* disorders, as assessed by the Structured Clinical Interview for *DSM–5* (SCID–5)

During CVS data collection from January through June 2020, approximately 1,500 NSDUH main study interview respondents will be selected for a follow-up clinical interview at the end of the main study interview in order to produce a final sample size of approximately 826 CVS respondents. These follow-up clinical interviews will be conducted via telephone using the SCID–5 within two to four weeks following the NSDUH main study interview.

Many of the procedures and protocols planned for inclusion in this CVS are based upon those previously employed as part of the 2018 National Mental Health Study (approved under OMB No. 0930–0380) and the 2008–2012 NSDUH Mental Health Surveillance Study (approved as an add-on to NSDUH under OMB No. 0930–0110).

Also, to complete training prior to CVS data collection, each clinical interviewer candidate hired must successfully administer the follow-up clinical interview with a volunteer respondent. These 70 certification interviews will be administered in the same manner as CVS follow-up clinical interviews.

The total annual burden estimate for the CVS is shown below in Table 2.

TABLE 2—ANNUALIZED ESTIMATED BURDEN FOR 2020 NSDUH CVS

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
Follow-Up Clinical Interviews	800	1	800	0.83	664
Follow-Up Clinical Certifications	70	1	70	0.83	58
Total	870	.....	870	.....	722

Redesign Field Test

Also, as part of SAMHSA's ongoing effort to ensure NSDUH continues producing current and accurate data, a Redesign Field Test (FT) is planned from August through November 2020 to assess potential revisions to the NSDUH main study questionnaire. These revisions are designed to address changing policy and research data needs; in addition, modifications to associated survey materials and methods are designed to improve the quality of estimates and the efficiency of data collection. Planned FT modifications include changes to respondent incentives, respondent materials, the household screening questionnaire, the interview questionnaire, and other data collection methods.

The FT is essential for providing a thorough examination of these planned changes prior to their deployment on the NSDUH main study to determine potential impact across operational and

substantive domains, including effects on data quality (as measured by outcomes such as unit nonresponse, item nonresponse, and survey responses), questionnaire timing, data collection efficiency, and possible differences in reporting of substance use or mental health items.

During FT data collection from August through November 2020, conducted separately from ongoing 2020 NSDUH main study data collection at that time, screenings will be completed with approximately 8,110 English-speaking respondents in the contiguous United States. (Alaska and Hawaii are excluded from the FT to control study costs.) From those screenings, approximately 4,000 respondents, as representatives of the civilian, noninstitutional population aged 12 years old or older, are expected to complete a FT interview using the revised questionnaire and materials.

For the NSDUH FT screening, revisions may include: (1) A revised roster structure; (2) various wording edits to improve respondent comprehension and flow; (3) the use of revised materials, such as the lead letter, study description and question & answer brochure; (4) a conditional test of a $5 screening incentive to assess impact on response rates; and (5) the inclusion of two outcome questions on past month alcohol and past month cigarette use at the end of the screening to assess nonresponse bias from the screening incentive.

For the NSDUH FT interview, revisions may include: (1) A conditional test of a $50 interview incentive to assess impact on response rates; (2) revisions to the *DSM–5*-based SUD module as a result of prior testing in the CVS; (3) the inclusion of new modules on substance use treatment and mental health service utilization; (4) the addition of new and/or revised questions on a variety of items such as Electronic Nicotine Delivery Systems (ENDS), synthetic drugs, pain and sleep, vaping and needle use, and criminal justice; (5) the addition of measures of adolescent psychological distress and/or impairment; (6) the expansion of suicide items; and (7) other general questionnaire revisions such as clarifying wording and terminology, reordering for improved question flow, formatting changes, removal of questions with low prevalence rates, and other minor updates and revisions.

The total annual burden estimate for the FT is shown below in Table 3.

TABLE 3—ANNUALIZED ESTIMATED BURDEN FOR REDESIGN FIELD TEST

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
Household Screening	8,110	1	8,110	0.083	673
Interview	4,000	1	4,000	1.000	4,000
Screening Verification	246	1	246	0.067	17
Interview Verification	600	1	600	0.067	40
Total	8,110	.....	12,596	.....	4,730

Written comments and recommendations concerning the proposed information collection should be sent by September 12, 2019 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 HOMELAND SECURITY

U.S. Customs and Border Protection

Test Concerning Entry of Section 321 Low-Valued Shipments Through Automated Commercial Environment (ACE)

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces that U.S. Customs and Border Protection (CBP) is conducting a test of new functionalities related to the electronic entry filing for low-valued shipments through the Automated Commercial Environment (ACE). The Section 321 *de minimis* administrative exemption admits free from duty and tax, shipments of merchandise (other than bona-fide gifts and certain personal and household goods) imported by one person on one day having an aggregate fair retail value in the country of shipment of not more than $800. During this test, an owner, or purchaser of a Section 321 low-valued shipment or, when appropriately designated, a customs broker appointed by an owner, purchaser, or consignee, will be able to file a new type of informal entry in ACE for Section 321 low-valued shipments. Section 321 low-valued shipments subject to Partner Government Agency (PGA) requirements will also be able to be entered using this new Section 321 informal entry type. This notice provides a description of the test, the requirements for filing the new informal entry type, and the regulations that will be waived for test participants. CBP invites public comment concerning the test program. The test will be known as the ACE Entry Type 86 Test.

DATES: The test will commence no earlier than September 28, 2019 and will continue until concluded by an announcement published in the **Federal Register**. Comments will be accepted throughout the duration of the test.

ADDRESSES: Comments concerning this notice and any aspect of this test may be submitted at any time during the test via email to *OTENTRYSUMMARY@cbp.dhs.gov.* In the subject line of your email, please indicate, ''Comment on the ACE Entry Type 86 Test.''

FOR FURTHER INFORMATION CONTACT: Randy Mitchell, Director, Commercial Operations, Revenue and Entry Division, Office of Trade, U.S. Customs