



BILLING CODE 4162-20-P

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) 276-1112.

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: 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 825 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	826	1	826	0.83	686
Follow-Up Clinical Certifications	70	1	70	0.83	58
Total	896		896		744

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

Send comments to Janet Heekin, SAMHSA Reports Clearance Officer, Room 15E21B, 5600

Fishers Lane, Rockville, MD 20857 **OR** email a copy at **janet.heekin@samhsa.hhs.gov**.

Written comments should be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Dated: June 6, 2019.

Carlos Castillo,
Committee Management Officer.

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