ESTIMATED ANNUALIZED BURDEN HOURS

Type of Respondents	Form Name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Adult Household Member	Household Roster	36,000	1	4/60
Sample Adult	Adult Questionnaire	33,000	1	50/60
Adult Family Member	Child Questionnaire	10,000	1	22/60
Adult Family Member	Methodological Projects	15,000	1	20/60
Sample Child	NHIS-Teen	667	1	15/60
Adult Family Member	Reinterview Survey	5,500	1	5/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–25084 Filed 11–13–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–24–22FZ]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Provider Training and Adherence Assistance in Two High Priority Settings'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on August 21, 2023, to obtain comments from the public and affected agencies. CDC received three comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Provider Training and Adherence Assistance in Two High Priority Settings—New—National Center for HIV, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC is requesting approval for three years for a data collection titled mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Provider Training and Adherence Assistance in Two High Priority Settings. The purpose of the information collection is to implement and evaluate the effectiveness of mChoice, a clinic-based intervention designed to improve HIV preexposure prophylaxis (PrEP) adherence and persistence among young men who have sex with men (YMSM). The intervention targets both health providers and PrEP patients by providing evidence-based training for health providers to improve clinical knowledge and enhance provider communications with patients, and CleverCap, an electronic medication monitoring device and mobile phone application that provides health information and medication and appointment reminders for patients undergoing PrEP treatment.

Data collected through this study will be used to evaluate the mChoice intervention for YMSM. The information collected in this study will be used to: (1) describe real-world PrEP use including factors influencing selection and change of PrEP regimens; (2) understand and describe barriers and facilitators impacting the implementation of new PrEP modalities in clinical practice; (3) evaluate the feasibility and acceptability of the CleverCap mobile app among YMSM on PrEP; and (4) evaluate the feasibility and acceptability of implementing provider PrEP training.

The study will be carried out in four clinics in two locations, New York City, NY (2), and Birmingham, AL (2). For the cohort, convenience and referral-based sampling techniques will be used to identify and recruit participants. Participants will be young men between the ages of 18 and 39 who have sex with men; are using or initiating PrEP; and live in the New York City or Birmingham, AL area. Recruitment controls will ensure enrollment of at least 50% Black or African American or Hispanic or Latino men. Cohort participants will be recruited using a combination of approaches including print media posted in clinic waiting rooms, social media, referral, and in-person outreach.

For the provider training, convenience and referral-based sampling techniques will be used to identify and recruit a total of 20 healthcare providers from the four participating clinics. Providers will include, but are not limited to, medical doctors, nurse practitioners, physician associates, nurses, adherence counselors, pharmacists, and social workers. A provider can include any employee who discusses PrEP treatment with patients. Providers will be recruited using email invitations and flyers posted at the clinic sites.

To evaluate the effectiveness of the mChoice clinic intervention to increase PrEP adherence and persistence among YMSM, we will conduct a hybrid type II trial. Participants will be asked to complete computer assisted surveys at baseline and quarterly in-person visits. The surveys will assess participant attitudes, knowledge, behavior, and experiences related to PrEP, and risk factors for HIV acquisition. Participants will be given a CleverCap device to track medication dispensed from their prescription PrEP bottle. Participants will also be asked to download the companion CleverCap smartphone application. The application is designed to support PrEP adherence by providing health information, appointment reminders, medication reminders and other supportive information. Data collected from the app will include prescription adherence data from CleverCap and paradata to describe overall app use and use of app components. Data will also be collected from urine specimens and from electronic health records to describe the PrEP prescription regimen and any changes in PrEP regimen, evaluate PrEP adherence, and assess sexual risk through HIV and STI test results. To further examine the participant experience and intervention satisfaction, a subset of the cohort will be invited to participate in in-depth interviews. During the in-person interviews, participants will be asked to elaborate on intervention satisfaction; communications with providers; PrEP choices, switching and decision making; CleverCap and app use and acceptability; and PrEP knowledge.

CDC will also conduct a PrEP training for 20 healthcare providers from the four participating clinic sites. The provider training will include education on available PrEP modalities and will be aligned with the most recent CDC PrEP guidelines. To evaluate the training, providers will complete computer assisted self-administered pre- and post-training assessments to identify the potential impact of the training module on PrEP knowledge, attitudes, and practice. Six-months after completing the training, providers will be asked to complete a post-implementation interview to assess the impact of the intervention on the provider's work and interactions with their patients. Information to be collected from the interviews will include training satisfaction and opinions about the effect of the training on clinic operations, staff procedures, and client/patient responses; barriers to PrEP care; and attitudes and perceptions about PrEP. Healthcare providers will have the option to complete their interview in-person or using a web-based HIPAA-compliant platform. In addition to the training and provider-level assessments, at six-month intervals, clinic staff at each of the four participating clinic sites will complete a computer assisted clinic assessment to describe PrEP services implementation at the facility level. Information collected from the assessments will include facility hours and scheduling; patient services; PrEP services; PrEP prescribing information; and available PrEP options.

For the patient trial, we will enroll a total of 400 YMSM; over the three-year data collection period the estimated annual enrollment will be 134. It is expected that 50% of YMSM screened will meet study eligibility criteria and agree to join the study; therefore, we expect to screen 267 YMSM annually. The collection of initial screening information will take approximately 10 minutes to complete. Once enrolled, the collection of locator information will take an additional 10 minutes to complete. Participants will complete a baseline assessment which will take approximately 45 minutes to complete Participants will also complete follow-up assessments at 3-, 6-, 9-, 12- and 18-month time points. The follow-up assessments will take approximately 45 minutes to complete. Participants will receive their CleverCap and be asked to install the CleverCap app on their mobile phones. We estimate the CleverCap onboarding process will take approximately 10 minutes to complete. Use of the app after the initial install will be optional. A subset (30 total) of the YMSM participants will be invited to participate in an in-depth interview. The interview will take approximately 90 minutes to complete.

For the healthcare provider training, we will enroll a total of 20 healthcare providers. Over the 3-year data collection period, the estimated annual enrollment will be seven providers. It is expected that 50% of healthcare providers screened will meet study eligibility criteria and agree to join the study. Thus, we expect to screen 14 providers annually. The collection of initial screening information from the 14 providers will take approximately 10 minutes to complete. The collection of locator information from enrolled participants will take an additional 10 minutes to complete. Provider participants will be asked to complete an assessment before and after the PrEP training. Each assessment will take approximately 30 minutes to complete. Providers will also be asked to take part in a 60-minute interview.

To evaluate the impact of the intervention at the facility level, every six months during the 36-month data collection period, each of the four participating clinic sites will complete the clinic assessment tool to describe PrEP services implementation at the facility level. The clinic assessment will be completed by a single member of the clinic staff at each clinic (four respondents total). Clinic-level assessments at baseline and study end are estimated to take 120 minutes to complete. Clinic-level assessments conducted at six-month intervals between the baseline and study end points are expected to take 90 minutes to complete.

CDC is requesting OMB approval for 2,210 total burden hours across three years of data collection. Participation of respondents is voluntary. There are no costs to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response
General Public—Adults	Patient Screener	267	1	10/60
General Public—Adults	Patient Locator Form	134	1	10/60
General Public—Adults	Patient Baseline Assessment	134	1	45/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response
General Public—Adults	Patient Quarterly Assessment	134	3	45/60
General Public—Adults	CleverCap App Setup	134	1	10/60
General Public—Adults	Patient Interview Guide	10	1	90/60
Health Practitioners	Provider Screener	14	1	10/90
Health Practitioners	Provider Locator Form	7	1	10/90
Health Practitioners	Provider Pre-Training Assessment	7	1	30/60
Health Practitioners	Provider Post-Training Assessment	7	1	30/60
Health Practitioners	Provider Interview Guide	7	1	60/60
Health Practitioners	Clinic Assessment Baseline and Final	4	1	120/60
Health Practitioners	Clinic Assessment Every Six Months	4	2	90/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–25081 Filed 11–13–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–24–0109]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Respiratory Protective Devices—42 CFR part 84'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on November 28, 2022 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Respiratory Protective Devices—42 CFR part 84 (OMB Control No. 0920–0109, Exp. 03/31/2024)—Revision—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The regulatory authority for the National Institute for Occupational Safety and Health (NIOSH) certification program for respiratory protective devices is found in the Mine Safety and Health Amendments Act of 1977 (30 U.S.C. 577a, 651 *et seq.,* and 657(g)) and the Occupational Safety and Health Act of 1970 (30 U.S.C. 3, 5, 7, 811, 842(h), 844). These regulations have, as their basis, the performance tests and criteria for approval of respirators used by millions of American construction workers, miners, painters, asbestos removal workers, fabric mill workers, and fire fighters.

Regulations of the Environmental Protection Agency (EPA) and the Nuclear Regulatory Commission (NRC) also require the use of NIOSH Approved respirators. These regulations also establish methods for respirator manufacturers to submit respirators for testing under the regulation and have them certified as NIOSH Approved if they meet the criteria given in the above regulation. This data collection was formerly named Respiratory Protective Devices 30 CFR part 11 but in 1995, the respirator standard was moved to 42 CFR part 84.

NIOSH, in accordance with 42 CFR part 84: (1) issues certificates of approval for respirators which have met specified construction, performance, and protection requirements; (2) establishes procedures and requirements to be met in filing applications for approval; (3) specifies minimum requirements and methods to be employed by NIOSH and by applicants in conducting inspections, examinations, and tests to determine effectiveness of respirators; (4) establishes a schedule of fees to be charged for testing and certification; and (5) establishes approval labeling requirements. Information is collected from those who request services under 42 CFR part 84 in order to properly establish the scope and intent of request.

Information collected from requests for respirator approval functions includes contact information and information about factors likely to affect respirator performance and use. Such