reportable conditions, which include infectious and non-infectious diseases, vary by jurisdiction depending upon each jurisdiction's health priorities and needs. Infectious disease agents and environmental hazards often cross geographical boundaries. Each year, the Council of State and Territorial Disease Epidemiologists (CSTE), supported by CDC, determines which reportable conditions should be designated nationally notifiable and voluntarily submitted to CDC so that information can be shared across jurisdictional boundaries and both surveillance and prevention and control activities can be coordinated at regional and national levels.

CDC requests a three-year approval for a revision the NNDSS information collection. This Revision includes requests for approval to receive: (1) Case notification data for Chikungunya, Dengue-like illness, Non-HPS Hantavirus, and Acute Flaccid Myelitis; (2) new laboratory and vaccine data elements for all conditions; and (3) new disease-specific data elements for Mumps, Pertussis, and Sexually Transmitted Diseases.

Although this Revision includes case notifications that were not part of the last NNDSS Revision, the estimate of the average burden per response based on the burden tables from all of the consolidated applications has not changed. The burden on the states and cities is estimated to be 10 hours per response and the burden on the territories is estimated to be 5 hours per response. The addition of new vaccine, laboratory, and disease-specific data elements do not add any additional burden because the states, territories, and cities already collect those data elements. There will be no increase in burden for the states, territories, and cities to send those data elements to CDC. The estimated annual burden is 28,340 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)	Total burden (in hrs.)
States	Weekly and Annual	50	52	10	26,000
Territories	Weekly and Annual	5	52	5	1,300
Cities	Weekly and Annual	2	52	10	1,040
Total					28,340

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–11514 Filed 5–12–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–15–15AGK; Docket No. CDC–2015–0032]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention, CDC, Department of Health and Human Services, HHS.

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a new information collection request entitled, ''Understanding Barriers and Facilitators to HIV prevention for Men Who Have Sex with Men (MSM)'' to conduct qualitative research with most at risk HIV-negative MSM. The research is intended to understand issues surrounding HIV risk for MSM, identify influences of high risk behaviors and to investigate risk management and resiliency among HIV-negative MSM.

DATES: Written comments must be received on or before July 13, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0032 by any of the following methods:

- *Federal eRulemaking Portal: Regulation.gov.* Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is 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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. 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.

Proposed Project

Understanding Barriers and Facilitators to HIV prevention for Men Who Have Sex with Men (MSM) (Pulse Study)—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)/Division of HIV/AIDS Prevention (DHAP) is requesting approval for one year of a data collection entitled, ''Understanding Barriers and Facilitators to HIV prevention for Men Who Have Sex with Men (MSM).'' The purpose of this study is to conduct primarily qualitative research with most at risk HIV-negative MSM. There are four goals to this study: (1) Understand issues surrounding HIV risk for MSM; (2) learn more about how gay community or peer norms, and community identification influence risk behaviors; (3) understand individual HIV risk management, such as having an HIV-positive partner with suppressed viral load, barriers and facilitators for use of biomedical interventions (*i.e.,* pre-exposure prophylaxis (PrEP), non-occupational post-exposure prophylaxis (nPEP); and (4) understand factors that promote resiliency among HIV-negative MSM.

The present research will be conducted in the top five Southern metropolitan areas in the United States with the highest HIV diagnoses for MSM—Atlanta, Georgia; Jackson, Mississippi; Miami, Florida; and New Orleans and Baton Rouge, Louisiana. These cities rank among those in the South with the highest prevalence and incidence of HIV and sexually transmitted infections (STIs) among black/African American and Hispanic/Latino MSM.

The study population will consist of black/African-American and Hispanic/Latino (1) male adolescents who are attracted to men and report they are HIV negative or have not been tested and (2) adult MSM who are recently tested and verified as HIV-negative.

All study participants will be 13 years of age or older. Participants will be recruited in the selected cities through referrals from Health Departments, clinics and other HIV testing centers. In addition, we will recruit via word-of-mouth referrals or flyers given out by community-based, advocacy, faith-based, and service-providing agencies.

Primarily, we will use a qualitative research design and will include a brief quantitative survey to reduce participant burden where possible (for example, when we do not need to know an in-depth answer for socio-demographics, HIV testing history, housing status, health insurance status). The first portion of the interview instrument consists of brief structured questions to characterize the respondents. The second portion of the instrument consists of open-ended in-depth qualitative questions. This research design was chosen based on the exploratory nature of our study purpose.

All data collection tools will be pre-tested and interviews conducted by trained personnel. The data collection will take place at a time and place that is convenient to the respondent. Locations will be private. Data collection may be audio-recorded and transcribed with the consent of the respondent.

We anticipate that consent forms and screener forms to take five minutes to complete each. We anticipate 50 percent of HIV-negative MSM screened will be eligible for the study. The brief structured survey (15 minutes) and in-depth interview (45 minutes) for HIV-negative MSM are expected to take a total of 60 minutes (1 hour) total. We will complete interviews for 105 black/African-American and 45 Hispanic/Latino HIV-negative MSM at greatest risk for HIV in high prevalence cities in the U.S. South. We anticipate screening 300 potential respondents. The total number of burden hours are 192.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
General Public—Adults	HIV-negative MSM Screener—English.	210	1	5/60	18
General Public—Adults	HIV-negative MSM Screener—Spanish.	90	1	5/60	8
General Public—Adults	HIV-negative MSM Contact Information Form—English.	105	1	1/60	2
General Public—Adults	HIV-negative MSM Contact Information Form—Spanish.	45	1	1/60	1
General Public—Adults	HIV-negative MSM Consent Form—English.	95	1	5/60	8
General Public—Adults	HIV-negative MSM Consent Form—Spanish.	35	1	5/60	3
General Public—Adults	HIV-negative MSM Assent for Minors Form—English.	10	1	3/60	1
General Public—Adults	HIV-negative MSM Assent for Minors Form—Spanish.	10	1	3/60	1

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
General Public—Adults	HIV-negative MSM In-Depth Interview Guide—English.	105	1	1	105
General Public—Adults	HIV-negative In-Depth Interview Guide—Spanish.	45	1	1	45
Total					192

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–11512 Filed 5–12–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0404]

Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order; Draft Guidance for Tobacco Retailers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for tobacco retailers entitled ''Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order.'' The draft guidance, when finalized, will represent FDA's current thinking with respect to imposing no-tobacco-sale orders (NTSOs) on retailers who have committed repeated violations of certain restrictions on the sale and distribution of tobacco products. This draft guidance discusses, among other things, the period of time covered by an NTSO and a retailer's compliance with an NTSO.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 29, 2015.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Colleen Maschal, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993, 1–877–287–1373, *colleen.maschal@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to give FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. Section 906(d) of the FD&C Act (21 U.S.C. 387f(d)) authorizes FDA to issue regulations that restrict the sale and distribution of tobacco products if FDA determines such regulations would be appropriate for the protection of the public health. Section 303(f)(8) of the FD&C Act (21 U.S.C. 333(f)(8)) authorizes FDA to impose an NTSO against a person found to have committed repeated violations, at a particular retail outlet, of restrictions on the sale and distribution of tobacco products issued under section 906(d) of the FD&C Act, such as FDA's ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents'' (21 CFR part 1140). The term ''no-tobacco-sale order'' refers to an order prohibiting the sale of tobacco products at a retail outlet indefinitely or for a specified period of time under section 303(f)(8) of the FD&C Act. A ''repeated violation'' means ''at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation . . .'' (section 103(q)(1)(A) of the Tobacco Control Act).

FDA conducts inspections of retail outlets to evaluate compliance with the requirements of the FD&C Act and implementing regulations. This draft guidance discusses the period of time to be covered by an NTSO where there is evidence of ''repeated violations'' at a particular retail outlet. It also discusses a retailer's compliance with an NTSO. This draft guidance is meant to supplement FDA's guidances entitled ''Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers'' and ''Civil Money Penalties for Tobacco Retailers and No-Tobacco-Sale Orders: Responses to Frequently Asked Questions.''

II. Significance of Draft Guidance

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking with respect to the period of time to be covered by NTSOs and retailers' compliance with NTSOs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.