The purpose of this analysis is to facilitate public comment on the proposed Consent agreement, and the Commission does not intend this analysis to constitute an official interpretation of the proposed Consent Agreement or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2018–05252 Filed 3–14–18; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2016–0094]

Final Revised Vaccine Information Materials for MMR (Measles, Mumps, and Rubella) and MMRV (Measles, Mumps, Rubella, and Varicella) Vaccines

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

ACTION: Notice.

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA), CDC must develop vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. On October 18, 2016, CDC published a notice in the **Federal Register** seeking public comments on proposed updated vaccine information materials for MMR vaccine and MMRV vaccine. Following review of comments submitted and consultation as required under the law, CDC has finalized the materials. Copies of the final vaccine information materials for MMR and MMRV vaccine are available to download from *http://www.cdc.gov/vaccines/hcp/vis/index.html* or *http://www.regulations.gov* (see Docket Number CDC–2016–0094).

DATES: Beginning no later than June 1, 2018, each health care provider who administers MMR or MMRV vaccine to any child or adult in the United States shall provide copies of the relevant vaccine information materials referenced in this notice, dated February 12, 2018, in conformance with the February 23, 2018 CDC Instructions for the Use of Vaccine Information Statements prior to providing such vaccinations.

FOR FURTHER INFORMATION CONTACT: Suzanne Johnson-DeLeon (*msj1@cdc.gov*), National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop A–19, 1600 Clifton Road NE, Atlanta, Georgia 30329.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660), as amended by section 708 of Public Law 103–183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa–26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers in the United States to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program (VICP).

Development and revision of the vaccine information materials, also known as Vaccine Information Statements (VIS), have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

(1) A concise description of the benefits of the vaccine,

(2) A concise description of the risks associated with the vaccine,

(3) A statement of the availability of the National Vaccine Injury Compensation Program, and

(4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella, and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Since then, the following vaccines have been added to the National Vaccine Injury Compensation Program, requiring use of vaccine information materials for them as well: Hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, rotavirus, hepatitis A, meningococcal, human papillomavirus (HPV), and seasonal influenza vaccines. Instructions for use of the vaccine information materials are found on the CDC website at: *http://www.cdc.gov/vaccines/hcp/vis/index.html.*

Revised Vaccine Information Materials

The vaccine information materials referenced in this notice were developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and healthcare provider organizations. Following consultation and review of comments submitted, the vaccine information materials covering MMR and MMRV vaccines have been finalized and are available to download from *http://www.cdc.gov/vaccines/hcp/vis/index.html* or *http://www.regulations.gov* (see Docket Number CDC–2016–0094). The Vaccine Information Statements (VISs) are ''MMR Vaccine (Measles, Mumps, and Rubella): What You Need to Know'' and ''MMRV Vaccine (Measles, Mumps, Rubella, and Varicella): What You Need to Know,'' publication date February 12, 2018.

With publication of this notice, by June 1, 2018, all health care providers must discontinue use of the previous editions and provide copies of these updated vaccine information materials prior to immunization in conformance with CDC's February 23, 2018 Instructions for the Use of Vaccine Information Statements.

Dated: March 12, 2018.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2018–05299 Filed 3–14–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–FY–1072; Docket No. CDC–2018–0020]

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 effort to reduce public

burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comments on the proposed revision of the information collection titled ''The Enhanced STD surveillance Network (SSuN),'' which is the only source for enhanced and sentinel sexually transmitted disease (STD) surveillance data in the United States that: (1) Serves to strengthen national and local surveillance capacity; (2) collects information on populations at risk for STDs attending healthcare facilities; and (3) provides more accurate estimates of the burden of disease, incidence of disease, trends and impact of STDs at the population level.

DATES: CDC must receive written comments on or before May 14, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0020 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.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. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments 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 Leroy A. Richardson, 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. 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 submissions of responses.

5. Assess information collection costs.

Proposed Project

The Enhanced STD surveillance Network (SSuN)—Revision—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 seeks to request a three-year revision approval of the information collection project entitled, *The Enhanced STD surveillance Network (SSuN).* Revisions to this submission include, removal of facility-based surveillance in family planning clinics, the addition of seven interview questions to the gonorrhea population component and eight new data elements to the facility component, and the addition of an enhanced surveillance activity to monitor adverse health outcomes of early syphilis cases with neurologic and/or ocular syphilis manifestations. The estimate of annualized burden hours will increase from 3,052 hours to 3,479 hours as a result of the revision.

The purpose of this project is to: (1) Provide supplemental information on case reports of notifiable STDs that enhances the ability of public health authorities to interpret trends in reported case incidence, assess inequalities in the burden of disease by population characteristics and to monitor STD treatment and selected adverse health outcomes of STDs; and (2) monitor STD screening, incidence, prevalence, epidemiologic and health care access trends in at-risk populations seeking STD services in specific clinical settings.

While routine STD surveillance activities are ongoing in all U.S. states and jurisdictions, through the *National Notifiable Disease Surveillance System,* these data are often missing critical patient demographics and are of limited scope with respect to risk behavior, provider and clinical information, treatment and partner characteristics needed to direct disease control activities. *Enhanced SSuN* is the only infrastructure providing information about diagnosed and reported STD cases with respect to patient and partner characteristics, clinical presentation, screening and uptake of HIV testing, treatment patterns or provider compliance with treatment recommendations for patients receiving STD-related care.

The precursor to *Enhanced SSuN* was the *STD Surveillance Network (SSuN),* established in 2005 as a network of collaborating state and local public health agencies to provide more comprehensive STD case-level and clinical facility information. In 2008, *SSuN* was expanded to 12 awardees to add important geographic diversity and to include visit-level data on a full census of patients being seen in categorical STD clinics. Activities of the previously funded *SSuN* were subsumed under the network's scope in establishing enhanced *SSuN* in 2013.

The current project comprises 10 US local/state health departments. These facilities include Baltimore City Health Department, California Department of Public Health, Florida Department of Health, Massachusetts Department of Public Health, Minnesota Department of Health, Multnomah County Health Department, New York City Department of Health & Mental Hygiene, Philadelphia Department of Public Health, San Francisco Department of Public Health, and Washington State Department of Health.

Since the initial OMB approval in 2015, *Enhanced SSuN* has provided ongoing data addressing CDC/Division of Sexually Transmitted Disease and Prevention priorities (DSTDP), including contributing to CDC's annual STD surveillance report, CDC's quarterly progress indicators, and informed policy discussions on expedited partner therapy, pre-exposure

prophylaxis to prevent HIV infection (PrEP), documentation of critical clinical services provided by categorical STD clinics, and on the proportion of cases treated with appropriate antimicrobial regimens, which is an essential indicator of compliance with CDC treatment recommendations.

The two major data collection components of the *Enhanced SSuN* project are grouped into two primary categories, reflecting sentinel and enhanced population-based surveillance activities. The first component includes sentinel surveillance in participating STD clinics, which monitors patient care, screening and diagnostic practices, treatment and STD-related services delivered. Participating local/state health departments have implemented common protocols to collect demographic, clinical, risk behaviors on patients presenting for care in selected facilities. Data for this activity is abstracted from existing electronic medical records at participating STD clinics, leveraging information routinely collected in the provision of clinical care. All records are fully de-identified by collaborating health departments and transmitted to CDC through secure file transport mechanisms six times annually (every 2 months). The estimated time for the clinic data managers to abstract data is 3 hours every 2 months.

The second population-focused component is comprised of two activities, including enhanced surveillance on a random sample of persons diagnosed with gonorrhea, and enhanced surveillance on person diagnosed and reported with early syphilis with ocular/neurologic manifestations. For the first activity a random sample of all gonorrhea cases diagnosed and reported to health departments among persons residing within the participating jurisdictions are selected for enhanced interview. The second population of interest are persons diagnosed with primary, secondary, and early latent syphilis. Cases determined to have neurologic/ocular manifestations will be selected for enhanced interview/investigation. In both these activities, jurisdictions follow consensus protocols to collect uniform data on demographic characteristics, behavioral risk factors, and health care seeking behaviors.

In 2016, there were 129,434 persons diagnosed and reported with gonorrhea across the 10 participating *Enhanced SSuN* jurisdictions. Approximately 10%, or 12,943 cases were randomly sampled for enhanced investigation. Many cases were lost to follow-up because of limited contact information. Hence, the response rate for gonorrhea patient interviews in the first three years of *Enhanced SSuN* data collection was 39.3%, with approximately 5,086 respondents interviewed.

In 2016, there were 25,253 early syphilis cases reported across the 10 participating *SSuN* jurisdictions. Studies estimate that 2% of all early syphilis cases will report neurologic and/or ocular manifestations, corresponding to 507 cases requiring additional investigation. CDC expects to interview 80% of 507 patients or 406 respondents. The 5,492 patient interviews for both the gonorrhea and early syphilis are estimated to take 10 minutes to complete for an estimated annualized burden hours of 934.

CDC will conduct an early syphilis case follow-up evaluation with diagnosing or reporting providers to ascertain additional information about physical exam findings, laboratory tests results, including cerebrospinal fluid (CSF) results, and prescribed (type and duration) treatment not present in the original case or laboratory report. CDC will collect clinical information from the diagnosing healthcare facilities for those diagnosed with early syphilis who reported neurologic/ocular symptoms (406 early syphilis cases). These evaluations can be either by direct contact with providers (phone) or through other methods such as secure fax-back, mail or other means as long as privacy of patient information can be strictly maintained.

Collection of this information is estimated to take approximately 10 minutes to complete, for 69 burden hours.

For the syphilis cases with neurologic and/or ocular manifestations only, there will be a three-month follow up interview to document resolution of symptoms. Data collection for this three-month follow-up is expected to take about five minutes per person and will be conducted through either telephone-administered or in-person interviews. With an estimated 50% follow-up success rate, the total burden hours is estimated at 16 hours.

Data managers at each of the 10 local/state health departments will be responsible for transmitting validated datasets to CDC every month, alternating between the facility and population-based activities in *Enhanced SSuN.* This reflects 2,280 burden hours for data management (10 respondents × 12 data transmissions × 19 hours).

The total estimated annual burden hours are 3,479 for *Enhanced SSuN.* Respondents from local/state health departments receive federal funds to participate in this project. Participation of patients and of facility staff are voluntary. There are no additional costs to 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 (in hours)	Total burden (in hours)
Data manager at Sentinel STD clinics	Record Abstraction	10	6	3	180
General Public—Adults (persons diagnosed with gonorrhea or early syphilis.	Interview	5,492	1	10/60	934
Diagnosing Provider	Data for early syphilis cases	406	1	10/60	69
General Public—Adults (persons with early syphilis who have neurologic/ocular manifestations.	Follow up Interview	203	1	5/60	16
Data Managers: 10 local/state health department.	Data cleaning/validation	10	12	19	2,280
Total					3,479

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. 2018–05243 Filed 3–14–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From the De Soto Avenue Facility in Los Angeles County, California, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: NIOSH gives notice of a decision to evaluate a petition to designate a class of employees from the De Soto Avenue Facility in Los Angeles County, California, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 1090 Tusculum Avenue, MS C–46, Cincinnati, OH 45226–1938, Telephone 877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

SUPPLEMENTARY INFORMATION:

Authority: 42 CFR 83.9–83.12.

Pursuant to 42 CFR 83.12, the initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: De Soto Avenue Facility.

Location: Los Angeles County, California.

Job Titles and/or Job Duties: All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the De Soto Avenue Facility.

Period of Employment: January 1, 1965 through December 31, 1995.

Frank Hearl,

Chief of Staff, National Institute for Occupational Safety and Health.

[FR Doc. 2018–05277 Filed 3–14–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–18–18PR; Docket No. CDC–2018–0021]

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 effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled *The World Trade Center Health Program (WTCHP): Impact Assessment and Strategic Planning for Translational Research—Focus Group Protocol.* This project includes a series of focus groups with different stakeholder groups to explore their perspectives on the decisions that each of them makes in the context of the WTCHP.

DATES: CDC must receive written comments on or before May 14, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0021 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.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. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments 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 Leroy A. Richardson, 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. 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 submissions of responses.

5. Assess information collection costs.

Proposed Project

The World Trade Center Health Program: Impact Assessment and Strategic Planning for Translational Research (Focus Group Protocol)—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The James Zadroga 9/11 Health and Compensation Act of 2010, Public Law 111–347 (hereafter referred to as ''the Zadroga Act''), established the World Trade Center Health Program (WTCHP). Under subtitle C, the Zadroga Act requires the establishment of a research program on health conditions resulting