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 |
|---|---|---|---|---|---|
| | BQASP Data Submission Form | 10 | 1 | 45/60 | 8 |
| IRATB Proficiency in Arsenic Speciation (PAsS) Program | | | | | |
| Public Health Labs | PAsS Enrollment Form | 28 | 1 | 10/60 | 5 |
| | PAsS Data Submission Form | 28 | 4 | 10/60 | 19 |
| IRATB Ensuring the Quality of Urinary Iodine Procedures (EQUIP) | | | | | |
| Public Health Labs | EQUIP Enrollment Form | 240 | 1 | 10/60 | 41 |
| | EQUIP Data Submission Form | 240 | 3 | 10/60 | 122 |
| IRATB Lead and Multielement Proficiency (LAMP) Testing Program | | | | | |
| Public Health Labs | LAMP Enrollment Form | 226 | 1 | 10/60 | 39 |
| | LAMP Data Submission Form | 226 | 4 | 10/60 | 154 |
| NSMBB Newborn Screening and Quality Assurance Program (NSQAP) | | | | | |
| Domestic NBS Labs | NSQAP Enrollment Form | 71 | 1 | 10/60 | 12 |
| | NSQAP Data Submission Portal Quality Control (QC). | 71 | 2 | 45/60 | 107 |
| | NSQAP Data Submission Portal Biochemical & Molecular Proficiency Tests (PT). | 71 | 3 | 45/60 | 160 |
| International NBS Labs | NSQAP Enrollment Form | 568 | 1 | 10/60 | 95 |
| | NSQAP Data Submission Portal QC | 568 | 2 | 45/60 | 129 |
| | NSQAP Data Submission Portal Biochemical & Molecular PT. | 568 | 3 | 45/60 | 1,278 |
| NBS Test Manufacturers | NSQAP Enrollment Form | 32 | 1 | 10/60 | 5 |
| | NSQAP Data Submission Portal QC | 32 | 2 | 45/60 | 48 |
| | NSQAP Data Submission Portal Biochemical & Molecular PT. | 32 | 3 | 45/60 | 72 |
| Total | | 1,720 | | | 4,293 |

**Jeffrey M. Zirger,**

*Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.*

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**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[30Day–22–1235]**

### 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 ''Assessments to Inform Program Refinement for HIV, other STD, and Pregnancy Prevention among Middle and High-School Aged Youth'' 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 2, 2021, to obtain comments from the public and affected agencies. CDC received two 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**

Assessments to Inform Program Refinement for HIV, other STD, and Pregnancy Prevention among Middle and High-School Aged Youth (OMB Control No. 0920–1235, Exp. 05/31/2022)—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The Centers for Disease Control and Prevention (CDC) requests three-year OMB approval for the extension of a Generic Information Collection Request (ICR) package (OMB Control No. 0920–1235, Exp. 05/31/2022) that supports collection of quantitative and qualitative information from adolescents (ages 11–19) and their parents/caregivers for the purpose of needs assessment and program refinement for programs and services to prevent HIV, other sexually transmitted diseases (STDs), and pregnancy among middle and high school aged adolescents.

NCHHSTP conducts behavioral and health service assessments and research projects as part of its response to the domestic HIV/AIDS epidemic, STD prevention, TB elimination and viral hepatitis control with national, state, and local partners. Adolescents are a population with specific developmental, health and social, and resource needs, and their health risk factors and access to health care are addressed as a primary mission by the Division of Adolescent and School Health (DASH). Adolescents are also a population of interest for several other NCHHSTP divisions. The assessment and research conducted by NCHHSTP is one pillar upon which recommendations and guidelines are revised and updated, and these recommendations and guidelines require a foundation of scientific evidence.

Assessment of programmatic practices for adolescents helps to assure effective and evidence-based sexual risk reduction practices and efficient use of resources. Such assessments also help to improve programs through better identification of strategies relevant to adolescents as a population, as well as specific sub-groups of adolescents at highest risk for HIV and other STDs so that programs can be better tailored for them.

The information collection requests under this generic package are intended to allow for data collection with two types of respondents:

- Adolescents (11–19 years old) of middle and high school age; and
- Parents and/or caregivers of adolescents of middle and high school age. For the purposes of this generic package, parents/caregivers include the adult primary caregiver(s) for a child's basic needs (*e.g.,* food, shelter, and safety). This includes biological parents; other biological relatives such as grandparents, aunts, uncles, or siblings; and non-biological parents such as adoptive, foster, or stepparents.

The types of information collection activities included in this generic package are:

(1) Quantitative data collection through electronic, telephone, or paper questionnaires to gather information about programmatic and service activities related to the prevention of HIV and other STDs among adolescents of middle- and high-school age.

(2) Qualitative data collection through electronic, telephone, or paper means to gather information about programmatic and service activities related to the prevention of HIV and other STDs among adolescents of middle- and high-school age. Qualitative data collection may involve focus groups and in-depth interviewing through group interviews, and cognitive interviewing.

For adolescents, data collection instruments will include questions on demographic characteristics; experiences with programs and services to reduce the risk of HIV and other STD transmission; and knowledge, attitudes, behaviors, and skills related to sexual risk and protective factors on the individual, interpersonal, and community levels. For parents and caregivers, data collection instruments will include questions on demographic characteristics as well as parents'/caregivers' (1) perceptions about programs and services provided to adolescents; (2) knowledge, attitudes, and perceptions about their adolescents' health risk and protective behaviors; and (3) parenting knowledge, attitudes, behaviors, and skills.

Any data collection request put forward under this generic clearance will identify the programs and/or services to be informed or refined, and will include a crosswalk of data elements to the aspects of the program the project team seeks to inform or refine. Because this request includes a wide range of possible data collection instruments, specific requests will include items of information to be collected and copies of data collection instruments. It is expected that all data collection instruments will be pilot tested, and will be culturally, developmentally, and age appropriate for the adolescent populations included.

Similarly, parent data collection instruments will be pilot-tested, and the data collection instruments will reflect the culture, developmental stage, and age of the parents' adolescent children. All data collection procedures will receive review and approval by an Institutional Review Board (IRB) for the Protection of Human Subjects and follow appropriate consent and assent procedures as outlined in the IRB approved protocols. These will be described in the individual information collection requests put forward under this Generic package.

The table below provides the estimated annualized response burden for up to 15 individual data collections per year under this generic clearance. CDC requests approval for an estimated 57,584 annual burden hours. Participation of respondents is voluntary. There is no cost to participants 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) |
|---|---|---|---|---|
| Middle and High School Age Adolescents | Youth Questionnaire | 20,000 | 1 | 50/60 |
| Middle and High School Age Adolescents | Pre/Post youth questionnaire | 10,000 | 2 | 50/60 |
| Middle and High School Age Adolescents | Youth interview/focus group guide | 3,000 | 2 | 90/60 |
| Parents/caregivers of adolescents | Parent/Caregiver questionnaire | 7,500 | 2 | 25/60 |
| Parents/caregivers of adolescents | Parent/Caregiver interview/focus group guide | 3,000 | 2 | 90/60 |

Jeffrey M. Zirger,
*Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.*

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**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[Docket No. CDC–2021–0001]**

### Final Revised Vaccine Information Materials

**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), the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) develops vaccine information materials that all healthcare providers are required to give to any patient (or to the patient's parent or legal representative in the case where the patient is a minor child) prior to administration of specific vaccines. On January 11, 2021, CDC published a notice in the **Federal Register** (86 FR 1977) seeking public comments on proposed updated vaccine information materials for vaccines covered by the National Vaccine Injury Compensation Program. Following review of comments submitted and consultation as required under the law, CDC has finalized the materials. By March 31, 2022, all healthcare providers must discontinue use of the previous editions and provide copies of these updated vaccine information materials prior to immunization.

**DATES:** No later than March 31, 2022, each healthcare provider who administers a vaccine covered by the National Vaccine Injury Compensation Program to any child or adult in the United States shall discontinue use of previous editions and provide copies of the updated vaccine information materials referenced in this notice, in conformance with the CDC Instructions for Use of Vaccine Information Statements dated October 15, 2021, prior to administering such vaccinations.

**FOR FURTHER INFORMATION CONTACT:** Suzanne Johnson-DeLeon, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop: H 24–6, 1600 Clifton Road NE, Atlanta, Georgia 30329. Telephone: (404) 639–8817.

**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 (the Secretary) to develop and disseminate vaccine information materials for distribution by all healthcare providers in the United States to any patient (or to the patient's parent or legal representative in the case where the patient is a minor child) receiving vaccines covered under the National Vaccine Injury Compensation Program.

Development and revision of the vaccine information materials, also known as Vaccine Information Statements, have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires 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 healthcare provider and parent organizations, and the Food and Drug Administration. Section 2126 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 healthcare 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: *https://www.cdc.gov/vaccines/hcp/vis/about/required-use-instructions.html.*

**Revised Vaccine Information Materials**

The revised 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 pertaining to vaccines covered under the National Vaccine Injury Compensation Program have been finalized and are available to download from *https://www.cdc.gov/vaccines/hcp/vis/index.html* or *http://www.regulations.gov* (see Docket Number CDC–2021–0001). The revised Vaccine Information Statements are the following:

''DTaP (Diphtheria, Tetanus, and Pertussis) Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Hepatitis A Vaccine: What You Need to Know,'' publication date October 15, 2021.

''Hepatitis B Vaccine: What You Need to Know,'' publication date October 15, 2021.

''*Haemophilus influenzae* type b (Hib) Vaccine: What You Need to Know,'' publication date August 6, 2021.

''HPV (Human Papillomavirus) Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Influenza (Flu) Vaccine (Live, Intranasal): What You Need to Know,'' publication date August 6, 2021.

''Influenza (Flu) Vaccine (Inactivated or Recombinant): What You Need to Know,'' publication date August 6, 2021.

''MMR Vaccine (Measles, Mumps, and Rubella): What You Need to Know,'' publication date August 6, 2021.

''MMRV Vaccine (Measles, Mumps, Rubella, and Varicella): What You Need to Know,'' publication date August 6, 2021.

''Meningococcal ACWY Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Meningococcal B Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Pneumococcal Conjugate Vaccine (PCV13): What You Need to Know,'' publication date August 6, 2021.

''Polio Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Rotavirus Vaccine: What You Need to Know,'' publication date October 15, 2021.

''Tdap (Tetanus, Diphtheria, and Pertussis) Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Td (Tetanus and Diphtheria) Vaccine: What You Need to Know,'' publication date August 6, 2021.