**Early Hearing Detection and Intervention**

**Hearing Screening and Follow-up Survey**

 **Reinstatement with Change**

**OMB# 0920-0733**

**Expiration: 8/31/2016**

**Supporting Statement A**

Suhana Alam

Epidemiologist

 (404) 498-3031 (O)

(770) 488.0270 (F)

SAlam1@cdc.gov

National Center on Birth Defects
and Developmental Disabilities
Centers for Disease Control and Prevention

1600 Clifton Rd. MS E-88

Atlanta, GA 30333

**March 8, 2017**

|  |  |
| --- | --- |
| **Table of Contents** |  |
| A. Justification |  |
| A.1. Circumstances Making the Collection of Information Necessary | 2 |
| A.2. Purpose and Use of the Information  | 4 |
| A.3. Use of Improved Information Technology and Burden Reduction | 5 |
| A.4. Efforts to Identify Duplication and Use of Similar Information | 5 |
| A.5. Impact on Small Businesses or Other Small Entities | 6 |
| A.6. Consequences of Collecting the Information Less Frequently | 6 |
| A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5 | 6 |
| A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency | 6 |
| A.9. Explanation of Any Payment or Gift to Respondents | 8 |
| A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents | 8 |
| A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions | 9 |
| A.12. Estimates of Annualized Burden Hours and Costs | 9 |
| A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers | 10 |
| A.14. Annualized Costs to the Government | 10 |
| A.15. Explanations for Program Changes or Adjustments | 11 |
| A.16. Plans for Tabulation and Publication and Project Time Schedule | 11 |
| A.17. Reason(s) Display of OMB Expiration Date is Inappropriate | 16 |
| A.18. Exceptions to Certification for Paperwork Reduction Act Submissions | 16 |
| References | 16 |

**Attachments**

Attachment 1: Authorizing Legislation and Other Relevant Laws

Attachment 2: 60-Day Federal Register Notice

Attachment 3: National EHDI Goals

Attachment 4A: CDC EHDI Hearing Screening and Follow-up Survey (HSFS) Directions

Attachment 4B: CDC EHDI Hearing Screening and Follow-up Survey (HSFS)

Attachment 4C: Screenshot of CDC EHDI Hearing Screening and Follow-up Survey (HSFS) Directions

Attachment 4D: Screenshots of CDC EHDI Hearing Screening and Follow-up Survey (HSFS)

Attachment 5: DSHPSHWA Annual Survey

Attachment 6: Proposed Data Reports

Attachment 7: Unclear Response Email

Attachment 8: Invitation to Complete the Survey

Attachment 9: Survey Reminder Email

Attachment 10: Non-Response Email

* Goal of the Study: This purpose of this data collection is to obtain standardized annual jurisdictional data related to the number of children screened for hearing loss, referred for and receiving follow-up testing, such as diagnostic audiologic evaluation.
* Intended use of the resulting data: Data will be used to determine annual rates of hearing screening, referral for further diagnostic testing, loss of follow-up, incidence of hearing loss in infants, and enrollment in early intervention; to determine rates of loss to follow-up within different stages of the Early Hearing Detection and Intervention (EHDI) process; to determine rates of loss to follow-up with different stages of the EHDI process; to help in determining to what extent jurisdictional tracking and surveillance systems are capturing essential information related to follow-up services; and to aid in efforts to determine the prevalence of differing degrees of hearing loss among infants and children.
* Methods to be used to collect data: Data will be collected via an Excel template that can be completed manually.
* The subpopulation to be studied: The target population is state and territorial EHDI program directors.
* How data will be analyzed: Data will be analyzed by the CDC EHDI personnel. The generated statistics will be compared to data previously reported to CDC to assess jurisdictional, regional, and national performance at different stages in the EHDI process.

**A. Justification**

**A.1. Circumstances Making the Collection of Information Necessary**

This Information Collection Request is submitted under the classification “**reinstatement with change.”** The length of the data collection request for OMB-PRA approval is three years. The National Center on Birth Defects and Developmental Disabilities (NCBDDD) at the Centers for Disease Control and Prevention (CDC) is making this request as authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241; **Attachment 1**).

The previously approved revision for this study (OMB # 0920-0733) expired on 08/31/2016. This request is to reinstate this study with the proposed changed listed below.

**Survey Part 1 (Screening, Diagnosis, and Intervention)**

* **Hearing Screening Section**:
	+ Added a dropdown menu on the first page for respondents to select one of the three options for the screening protocol used by their specific jurisdiction. The respondent will be directed to the respective chosen tab: the one-stage, two-stage or blended screening protocol. This was done in response to feedback to better accommodate states who use one-stage, two-stage, or blended screening protocol.
	+ Added an optional field to report the total number of occurrent homebirths, in response to requests from several respondents to be able to provide this information.
	+ Deleted the fields to report the number of infants in the NICU for more than 30 days and the number of infants who did not pass inpatient screening and did not receive an outpatient screening. This was done because the information provided through these fields was found to often be incomplete and of limited use.
	+ Added fields to report no documented hearing screening due to infant adopted, parents contacted but unresponsive, or unable to contact, in response to feedback that these were also reasons some infants were not screened. Adding these fields also standardizes this section with the format of the reasons for no documentation in the Diagnostic and Intervention sections of the survey.
	+ Deleted fields to report pass or not pass after 1 month but before 3 months of age, after 3 months of age, and age unknown. This was done to improve data quality and better determine whether jurisdictions were meeting the nationwide benchmarks for hearing screening.
* **Diagnostic Section:**
	+ Deleted fields to report no hearing loss or hearing loss identified after 3 months but before 6 months of age, after 6 months of age, and age unknown. This was done to improve data quality and better determine whether jurisdictions were meeting the nationwide benchmarks for diagnostics.
	+ Added field to report no documented diagnosis due to infant adopted, in response to feedback that these were also reasons some infants were not diagnosed. Adding this field also standardizes this section with the format of the reasons for no documentation in the Screening and Intervention sections of the survey.
	+ Changed field to report no documented diagnosis due to “ENT did not refer infant for diagnostic testing” to “PCP/ENT did not refer infant for diagnostic testing,” in response to feedback that lack of referral from PCP and/or ENT were also reasons some infants were not diagnosed. ENT stands for Ear-Nose-Throat specialist and PCP stands for Primary Care Physician.
		- * **Intervention Section:**
	+ Changed the order of fields in the “Referrals to Part C Early Intervention (EI)” to include only categories related to referrals and not eligibility. This was done in response to feedback from respondents.
	+ The category “Referred to Part C EI before Six Months of Age” was changed from optional to a required field. Eligibility is reported at the end of this section as “Number Eligible for Part C EI.” These fields were added to improve data accuracy and relevance.
	+ Restructured the fields in the “Total Enrolled in Part C EI” section to only include data for signed Individual Family Services Plan (IFSP) before 6 months of age and signed IFSP after 6 months of age. The fields for enrollment after 6 months but before 12 months of age, after 12 months of age, and age unknown were deleted in order to simplify the survey and better determine whether jurisdictions were meeting the nationwide benchmark for intervention services.
	+ Added a “Receiving Part C EI Services” section with fields to report the total receiving Part C EI services before 6 months of age, after 6 months of age, and intervention services received after 6 months of age due to family initially declining services. This was done in response to feedback from respondents to distinguish between data about referral, enrollment, and actual receipt of services.
	+ Restructured the fields in the “Receiving Only Intervention Services from Non-Part C EI” section to only include services before 6 months of age and services after 6 months of age. The fields to report services after 6 months but before 12 months of age, services after 12 months of age, and age unknown were deleted in order to improve data quality and better determine whether jurisdictions were meeting the nationwide benchmarks for intervention services.
	+ Added fields to report no intervention services due to infant adopted and unable to receive EI due to medical reasons, in response to feedback that these were also the reasons some infants did not receive EI. These changes were also made to help increase standardization by matching the reasons listed for no documentation in the Screening and Diagnostics sections of the survey
		- * **Additional Cases Not Reported Section:**
	+ Deleted all age categories under the “Hearing loss cases not reported in ‘Permanent Identified (ID) Hearing Loss’” section and added fields to report the number of cases of non-permanent, transient hearing loss identified and number of permanent cases of hearing loss identified. This was done in response to feedback that these were reasons these cases were not included in the diagnostic data. The previous age-related fields were removed to improve standardization in data collection throughout the survey.
	+ Combined the two fields “Total Enrolled in Part C EI” and “Total Services from Non-Part C EI Services” under the section of “Cases of Hearing Loss Not Included in Early Intervention (EI)” to one field “Total Enrolled in EI (Part C or non-Part C).” This was done to improve data accuracy and improve standardization with the Intervention section of the survey.

**Survey Part 2 (Type and Severity)**

* The option to use the DSHPSHWA (**Attachment 5**) systems has been removed.

**Survey Part 3 (Demographics)**

* Several data fields from the table in Part 3 were removed in order to simplify the survey. These changes included removing the fields “Total pass before 1 month,” “Total not pass before 1 month,” “Normal hearing before 3 months,” “Hearing loss before 3 months,” “Total enrolled in Part C EI before 6 months,” “Total services Non-Part C EI,” and “Total Services Non-Part C EI before 6 months”.

Background

NCBDDD promotes the health of babies, children, and adults, with a focus on preventing birth defects and developmental disabilities and optimizing the health outcomes of those with disabilities. As part of these efforts the Center is actively involved in addressing the early identification of hearing loss among newborns and infants. Congenital hearing loss is a common birth defect that affects 1 to 3 per 1,000 live births, or approximately 12,000 children across the United States annually.1, 2 Studies have shown that children with a delayed diagnosis of hearing loss can experience preventable delays in speech, language, and cognitive development.3 - 5 To ensure children with hearing loss are identified as soon as possible, many states and United States (U.S.) territories have implemented Early Hearing Detection and Intervention (EHDI) programs and enacted laws related to infant hearing screening. The majority of these EHDI programs have adopted the “1-3-6” plan, which consists of three core goals: 1) screening all infants for hearing loss before 1 month of age, 2) ensuring diagnostic audiologic evaluation before 3 months of age for those who do not pass the screening, and 3) enrollment in early intervention services before 6 months of age for those identified with hearing loss.

Federal support for identifying children with hearing loss began with the Children’s Health Act of 2000,which authorized federal programs to support EHDI activities at the state level. Since then, funds have been distributed to states via cooperative agreements from the CDC and grants from the Health Resources and Services Administration (HRSA). States are using these federal monies to enhance EHDI programs and develop corresponding tracking and surveillance systems. These systems are intended to help EHDI programs ensure infants and children are receiving recommended hearing screening, follow-up, and intervention services.

The mission of the CDC EHDI team is for every state and U.S. territory to have a complete EHDI tracking and surveillance system that will help ensure infants and children with hearing loss achieve communication and social skills commensurate with their cognitive abilities. As part of this mission the CDC EHDI team, in collaboration with representatives of state and U.S. territorial EHDI programs, developed seven National EHDI Goals that reflect the “1-3-6 plan” and address integration with the medical home (coordinated care by a medical provider) and development of tracking and surveillance systems to minimize loss to follow-up and loss to documentation (**Attachment 3**). Many of the defined performance indicators for these goals involve obtaining data related to the number of children screened for hearing loss, referred for and receiving follow-up testing (e.g., diagnostic audiologic evaluation) and enrolled in early intervention services.

The Hearing Screening and Follow-up Survey (HSFS) has enabled the CDC to monitor progress toward the national EHDI benchmarks and other areas, such as the number of infants identified early and not receiving or not documented to have received recommended follow-up services. This is referred to as loss follow-up / loss to documentation and addressing this issue is a priority of the CDC EHDI team. The collection of this data via the HSFS has enabled the CDC EHDI team to consistently document clear progress towards the national EHDI goals. For example data for 2014 indicated screening rates had improved to over 97% and between 2005 and 2014 over 45,000 infants that are deaf or hard of hearing had been identified early. In addition, data from the HSFS has also been able to show that some infants have fallen through the cracks by not receiving recommended follow-up and becoming lost to EHDI tracking and surveillance systems. The annual data from the HSFS are also used to guide the provision of technical assistance by the CDC EHDI team to jurisdictions and help measure progress towards objectives within FOAs, including a new three year funding opportunity that has been released by the CDC.

The proposed revisions to the HSFS are designed to provide more complete and standardized information about the receipt of recommended EHDI services and the reasons about why some infants are loss to follow-up (**Attachment 4B**). Continued use of the HSFS, with the proposed revisions, will ensure that the CDC EHDI team is able to continue monitoring progress towards national EHDI goals, disseminate information to stakeholders, assess progress towards meeting Healthy People 2020 goals related to EHDI, measure progress towards Funding Opportunity Announcement (FOA) objectives, and guide the provision of technical assistance.

**A.2. Purpose and Use of the Information**

1. How this information will be used and for what purpose:

The CDC’s NCBDDD will fund this work toobtain standardized annual jurisdictional data related to the number of children screened for hearing loss, referred for and receiving follow-up testing (e.g., diagnostic audiologic evaluation). As with the original and reinstated information collection the overall purpose of this updated survey is to consistently gather the aggregate-level data required to assess progress toward the National EHDI Goals.

The collected data will continue to be used in four key ways. First, it will be used to determine annual rates of hearing screening, referral for further diagnostic testing, loss to follow-up, incidence of hearing loss in infants, and enrollment in early intervention. These data will assist in determining if infants and children are receiving recommended EHDI-related services in a timely fashion. The information is intended to be made available through presentations, articles related to EHDI programs and infant hearing loss, and online at: [www.cdc.gov/ncbddd/hearingloss/ehdi-data.html](http://www.cdc.gov/ncbddd/hearingloss/ehdi-data.html). Second, the data will be used to determine rates of loss to follow-up within different stages of the EHDI process. Aggregated information about maternal race, ethnicity, education, and age will be used to help determine whether rates of loss to follow-up are correlated with any of these demographic variables. As with the most recent reinstatement with change (2013), the updated survey will continue to use same set of demographic data items, which will make it possible to continue analyzing the association between factors such as maternal race and loss to follow-up, maintain comparability between previous and future data, and minimize burden on respondents by continuing to request the same data that programs are currently collecting and able to report. This information is anticipated to continue to be important in developing methods to help minimize loss to follow-up so all children receive recommended hearing-related services in a timely manner. Third, the data will be helpful in determining to what extent jurisdictional tracking and surveillance systems are capturing essential information related to follow-up services, identification, and enrollment in early intervention. It will also be used by CDC EHDI to identify areas in jurisdictional EHDI systems that may require additional modification. This is anticipated to be helpful in providing technical support to funded jurisdictions as well as for assessing the impact of federal initiatives related to hearing loss in infants and children. Fourth, the requested data will aid in efforts to determine the prevalence of differing degrees of hearing loss (e.g., mild, severe, profound, etc.) among infants and children.

Information provided by this updated survey also has the potential to be used for other purposes. These include quality improvement activities by jurisdictional EHDI programs (e.g., identifying areas within the EHDI processes that could benefit from further development) and providing requested data for Healthy People 2020, Objective ENT-VSL-1 on newborn hearing screening, evaluation, and intervention. In addition, the aggregate-level data will continue to be made available online to other state and federal agencies, organizations, and the general public.

1. Justification for data collection in terms of positive needs and the negative consequences of not having the information:

The accuracy of these data are regarded as suitable for the stated purpose and intended uses. Although some jurisdictions may not be able to answer every question on the survey, the information will nonetheless be important in determining overall progress toward the National EHDI Goals, including the development and status of EHDI tracking and surveillance systems.

If these data are not consistently available on an annual basis it will be difficult, if not impossible, to determine whether infants and children are receiving recommended services and how EHDI programs are progressing towards achievement of the National EHDI Goals. This situation is anticipated to severely limit the ability of CDC and other state, federal, and private agencies to assist jurisdictions and ensure infants and children with hearing loss are identified and enrolled in intervention services as early as possible.

**A.3. Use of Improved Information Technology and Burden Reduction**

In order to reduce the burden on respondents and improve data quality this survey will be made available for completion using an Excel template that needs to be completed manually by the respondents and returned by e-mail to a CDC EHDI mailbox. It includes built-in automatic checks to help minimize data errors and should continue to help ensure a minimal level of burden in reporting. Financial costs will continue to be minimized because no mailing fees will be associated with responding to this survey.

As with the original and reinstated information collection, data quality with the updated survey should remain high because it will continue to feature several built-in error checks that have to be satisfied before the survey can be finalized and submitted. As before there will also be no need to reenter the data into a separate database at CDC, which will decrease the potential for data entry errors. This system has and should continue to help ensure a complete data set that will provide the information needed to generate the statistics (e.g., annual rates of hearing screening) required to ensure infants and children are receiving recommended services, assess progress related to the National EHDI Goals and address questions from the public and other stakeholders.

**A.4. Efforts to Identify Duplication and Use of Similar Information**

No other federal agencies collect this type of information. In the past there have been other surveys conducted by non-governmental organizations attempting to collect some information from state EHDI programs; however, these surveys did not provide the standardized, high-quality data needed to measure progress towards National EHDI Goals, Healthy People (particularly Objective ENT-VSL), and NCBDDD and HHS performance measures. HRSA also continues to rely on the EHDI-related data collected by CDC to help assess progress of jurisdictions. In addition, the Directors of Speech and Hearing Programs in State Health and Welfare Agencies (DSHPSHWA) no longer surveys state EHDI programs and instead solely relies on the data collected by CDC.

**A.5. Impact on Small Businesses or Other Small Entities**

“This data collection will not involve small businesses.”

**A.6. Consequences of Collecting the Information Less Frequently**

As with other state health agencies reporting to Federal agencies (e.g., Department of Education/Special Education, Title V MCH Block Grant, immunizations, etc.), and the original information collection, jurisdictions will continue to be requested to complete this survey on an annual basis for several reasons. They report each year’s birth and death data (i.e., Vital Statistics) annually. By using these established intervals, we will continue to minimize the burden to the respondent by employing a clear reporting schedule that states and territories already use to report data. Collecting data annually has and will continue to enable more expeditious tracking and analysis of trends over time.

There are no legal obstacles to reduce the burden.

**A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

“This request fully complies with the regulation 5 CFR 1320.5.”

**A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency**

In addition to internal review, CDC EHDI solicited input on data collection efforts from outside reviewers in two ways: (A) public comment in response to a *Federal Register Notice* and (B) experts in early newborn hearing screening. These opportunities for feedback are discussed below.

1. A copy of the agency’s 60-day Federal Register Notice is attached (*60-day Federal Register Notice* **Attachment 2**). The notice, as required by 5 CFR 1320.8 (d), was published on October 6, 2016 (volume 81, number 194, pages 69530). No public comments were received in response to this notice.
2. Consultations with Individuals Outside of the Organization: Several efforts were made during the development of the original and subsequent updated versions of the information collection to consult with persons outside the agency to maximize the quality and utility of this collection and ensure that it provided essential information.
	1. Regarding development of the original information collection a meeting was held in June 2004 with representatives from other federal agencies (e.g., HRSA, the National Institutes of Health, and the Department of Education), DSHPSHWA and state EHDI programs to discuss data-related issues, including the need, availability, method, and frequency of collection. Participants agreed that aggregate-level data was required in order to determine progress towards the National EHDI Goals. HRSA, DSHPSHWA, and states again provided input related to the minor changes that are now being proposed for the revised survey.
	2. DSHPSHWA allowed the CDC EHDI team to use their retired 2004 survey as a model for the design of the original CDC EHDI information collection (**Attachment 5**) and provided significant input during the development of the original survey. DSHPSHWA also provided input for the minor changes that are being proposed for the revised survey.
	3. Representatives from multiple state EHDI programs and the EHDI Data Committee provided input about updates for this survey, reviewed draft versions of the updated survey that included the proposed changes, and provided comments.

Craig Mason, Ph.D

EHDI Consultant

University of Maine, Orono

5717 Corbet Hall, Room 3

Orono, Maine 04469

Phone: 207-581-9059

E-mail: craig.mason@maine.edu

Sharon Ringwalt

TA Specialist

The Early Childhood Technical Assistance Center

CB 8040

Chapel Hill, North Carolina 27599

Phone: 919.843.2275

E-mail: sharon.ringwalt@unc.edu

Erica McKiever, MA, LPC
Newborn Hearing Screening Coordinator
Colorado Department of Public Health & Environment
4300 Cherry Creek Drive South
Denver, CO 80246-1530
Phone: 303-692-2948
E-mail: erica.mckiever@state.co.us

Tammy O’Hollearn, LBSW

Iowa EHDI Director
Iowa Dept. of Public Health
Lucas State Office Bldg. 5th Floor
321 East 12th Street
Des Moines, IA 50319-0075
Phone: 515-242-5639
E-mail: tammy.ohollearn@idph.iowa.gov

Pam Tempson
Early Hearing Detection and Intervention Program Coordinator
Florida Newborn Screening Program
Department of Health
Children's Medical Services
4052 Bald Cypress Way, Bin A-06
Tallahassee, Florida 32399-1707
Phone: 850-245-4673

E-mail: pam.tempson@flhealth.gov

**A.9. Explanation of Any Payment or Gift to Respondents**

This collection of information does not involve any payment or gift to respondents.

**A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

The NCBDDD Privacy Officer reviewed the original information collection and determined that the Privacy Act was not applicable. Survey respondents will continue to provide information based on their roles as directors of jurisdictional EHDI programs. While the names of respondent in each jurisdiction will be known, these respondents will not provide personal information about themselves or any personally identifiable information about infants screened for hearing loss. Each survey respondent will provide aggregate-level data about the screening and follow-up status of infants born in the jurisdiction represented by the respondent. Participation in the survey will continue to be voluntary and respondents will be advised that CDC plans to post jurisdictional-specific aggregated data on the CDC EHDI website, which is accessible to the public, and in publications (for a representative publication, see the April 2015 MMWR article, Progress in Identifying Infants with Hearing Loss -- United States, 2006-2012).

**1.1** **t**

1. Overview of the Data Collection System

This data collection is intended to target only state and territorial EHDI program directors. CDC will utilize a revised survey (HSFS) (**Attachment 4B**) to obtain standardized annual state data related to the number of children screened for hearing loss, referred for and receiving follow-up testing (e.g., diagnostic audiologic evaluation). The survey will be administered via e-mail using an Excel template that can be returned via e-mail to a CDC EHDI mailbox. The invitational request to complete this survey (**Attachment 8**) is planned to be disseminated to a total of 59 respondents via an e-mail, which will include a summary of the request (**Attachment 4A**) and other relevant information.

1. Items of Information to be Collected

The survey will be administered to state and territorial EHDI program directors. While the names of respondents in each jurisdiction will be known, these respondents will not provide personal information about themselves or any information in identifiable form about infants screened for hearing loss. Each survey respondent will provide aggregate-level data about the screening and follow-up status of infants born in the jurisdiction represented by the respondent. Participation in the survey will continue to be voluntary and respondents will be advised that CDC plans to post jurisdictional-specific aggregated data on the CDC EHDI website, which is accessible to the public, and in publications (available at: www.cdc.gov/ncbddd/hearingloss/ehdi-data.html). As noted, survey responses will be evaluated in order to assess the states and territories’ overall progress in meeting the National EHDI Goals. The first component is the overall survey response rate and item-specific completion rates. The second component will involve the use of the data reported by states and territories. This will include standard indicators such as whether the information is made available to the public, referenced in presentations, and used in published EHDI-related articles. Additional indicators include determining through discussions within the CDC EHDI Team whether the reported data is being used effectively to identify systematic areas of loss to follow-up.

(iii) Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

No website content directed at children under 13 years of age is involved in this information collection request.

**A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

1. IRB approval is not required for this data collection. It was determined that this project is not considered to be research and that no further action is required by CDC for human subjects’ protection in accordance with federal regulation for the protection of human subjects in research.
2. As with the original information collection this updated version will request aggregate-level, non-identifiable data, including demographic information, which has already been collected by jurisdictions for other purposes. Key demographic variable, including maternal race, ethnicity, and age are needed to better describe and analyze the resulting data. As with the original, the updated information collected does not include any sensitive questions.

**A.12. Estimates of Annualized Burden Hours and Costs**

A total of 59 respondents will be sent the Invitation to Complete the Survey (**Attachment 8**) to complete the updated survey each year during the 3-year requested data collection approval timeframe. Based on findings from the previous information collection it is estimated that the burden for individuals to read through the survey and decide whether or not to complete it is 10 minutes per person (**see Attachment 4A**). The 10-minute calculation was based on feedback received in pre-tests with 5 individuals and confirmed by the experience with the survey since the original OMB-PRA approval.

A Non-Response Email (**Attachment 10**) will be sent out 5-7 days as a reminder for respondents’ receipt of the survey. Approximately 2-4 weeks later a Survey Reminder email (**Attachment 9**) will be sent out asking respondents to complete the survey if they have not. It is expected that 57 of the 59 potential respondents will complete the survey (**see Attachment 4B**) and therefore incur an additional burden of up to 4 hours per respondent (see table A.12-1). The more conservative time estimate of 4 hours per response from each of the 55 anticipated participants is shown in the Table below. This estimate is identical to the time estimate for the reinstated OMB-PRA approved estimate from 2010; the only change is the estimated number of respondents.

Total estimated burden hours are 238.

|  |  |
| --- | --- |
|  |   **A.12 – 1 Estimates of Annualized Burden Hours**  |
| Respondents | Form Name | Number of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Total Burden Hours |
| EHDI Program State Program Coordinators Contacted | Survey Directions | 59 | 1 | 10/60 | 10 |
| EHDI Program State Program Coordinators who return the survey | Survey | 57 | 1 | 4 | 228 |
| **Totals** |  |  |  |  |  238 |

Estimates of annualized cost to respondents for the burden hours for collections of information were based on the mean hourly wage from the U.S. Department of Labor’s “May 2014 National Occupational Employment and Wage Estimates.” (See <http://www.bls.gov/oes/current/oes_nat.htm>.)

**A.12. Annualized Cost to Respondents**

The hourly wage for respondents was estimated using budget information provided in the annual reports for those jurisdictions with funding from the CDC EHDI program. Based on this information the average annual salary for the director of a state EHDI program is estimated to be $65,000. This salary divided by 40 hours per week results in an estimated hourly wage of approximately $34.00 for an EHDI Program Director. The total estimated cost burden on all potential survey respondents is $8,092 (238 x $34.00). The average cost per respondent is estimated to be $137.15 ($8,092 / 59).

|  |
| --- |
|   **A.12 – 2 Annualized Cost To Respondents** |
| **Type of Respondents**  | **Total Burden Hours** | **Hourly Wage Rate** | **Respondent Cost** |
| Contacted (n = 59) | 10 | $34.00\* |  $340 |
| Complete (n = 57) | 228 | $34.00\* | $7,752 |
| **Total** | $8,092 |

 \*Based on an estimated yearly salary of $65,000

**A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers**

There are no capital or maintenance costs to survey respondents.

**A.14. Annualized Costs to the Government**

As with the original information collection costs associated with this data collection are the result of the CDC EHDI program personnel time involved in the design and distribution of the survey and the analysis of the collected data. The individuals responsible for these tasks are members of the CDC EHDI team. Below costs for staff time dedicated to this survey are based on an average compensation equivalent to the GS 12 level (i.e., approximately $80,000). These costs are summarized in Table 1 below. Based on the reinstated version of the information collection, the time required by the designated CDC EHDI team member to conduct this survey, which will consist of contacting jurisdictions primarily by e-mail, is estimated to be 10 hours. Based on an average annual salary or $42.00 per hour, the cost of conducting this survey will be $420 annually. The time required to prepare the data for analysis, again based on experience from conducting the reinstated information collection, will be approximately 15 hours, resulting in a cost of $630 annually based on the current average salary. Data analysis is estimated to require 160 hours resulting in annualized analysis costs of approximately $6,720.

The time spent revising the reinstated information collection required an estimated 50 hours and was conducted by members of the CDC EHDI team. The average annual salary of these individuals were equivalent to the GS 12 level (i.e., approximately $80,000). This resulted in an estimated development cost of $2,100. The costs associated with these updates are not anticipated to be incurred again during the requested three-year life of this annual data collection because no changes to the survey are planned during this period. Also, no additional developmental costs related to this survey are anticipated during the next three years. Approximately 30 hours were spent preparing the renewal application for OMB, which resulted in a cost of $1,260 based on an average annual salary.

Based on the calculations described above, the estimated annualized cost to the Government is $8,890.

**Table 1. Estimated Annual Cost to Conduct EHDI Surveys**

|  |  |
| --- | --- |
| **Task** | **Cost** |
| **Labor Costs** |  |
| Survey Development (one-time costs) |  $2,100  |
| OMB Application (one-time costs) |  $1,260 |
| Survey Administration ($420 per year X 3 years) |  $1,260  |
| Data Preparation ($630 per year X 3 years) |  $1,890  |
| Data Analysis ($6,720 per year X 3 years) |  $20,160  |
| **Total Costs for 3 Years** |  **$26,670**  |
| **Annual Estimated Costs** |  **$8,890**  |

\*Labor Costs include Fringe and Benefits

**A.15. Explanations for Program Changes or Adjustments**

Proposed changes for the updated survey have been made in response to feedback from respondents and requests for additional information from state and national partners. These updates are intended to further increase the standardization and completeness of the data collected and make the survey easier to complete. These changes include adding new fields to capture data about hearing screening conducted by using one-stage, two-stage, or blended (both one-stage and two-stage) screening protocol. In addition, fields were added to be able to report the number of occurrent homebirths and the number of infants not documented to have received recommended screening, diagnostic and/or intervention services, due to reasons such as the infant being adopted, no referral from the Primary Care Physician (PCP)/Ear-Nose-Throat (ENT) specialist and/or due to medical reasons. Several fields have been removed in order to improve data quality and better evaluate whether jurisdictions are meeting the nationwide benchmarks. The table for reporting type and severity of hearing loss data has been updated so that this data can be reported using only the classification system from the American Speech and Hearing Association (ASHA). The table for reporting demographics has also been updated to include fewer columns, in order to improve data quality and data standardization with the previous sections of the survey.

The Burden has not changed from the burden shown in the current inventory.

**A.16. Plans for Tabulation and Publication and Project Time Schedule**

The table below shows the anticipated project time schedule for Years 1, 2, and 3 of this revised survey.

|  |
| --- |
| **A.16-1 Project Time Schedule\*** |
| **Activity** | **Time Schedule** |
| Distribute surveys to respondents | 2 - 3 months after OMB approval |
| E-mail Reminders (to increase response rate) | 3 - 4 months after OMB approval |
| Provide phone support for survey completion | 3 – 4 months after OMB approval |
| Combine data from template into a file for data analysis  | 5 - 6 months after OMB approval |
| Data management and validation | 5 - 6 months after OMB approval |
| Initial Tabulation of Results | 5 - 6 months after OMB approval |
| Data validation with states (as needed) | 5 - 6 months after OMB approval |
| Final data analysis | 6 - 7 months after OMB approval |
| Dissemination of results | 6 – 7 months after OMB approval |
| REPEAT of all steps above for **Year Two** of Survey | 13 - 24 months after OMB approval |
| REPEAT of all steps above for **Year Three** of Survey | 25 - 36 months after OMB approval |

*\*Note: This time schedule is dependent on if and when the information collection is approved by OMB and the amount of time for all respondents to return the survey.*

*Analysis Plan:* As with the original survey all information reported for the updated survey will be at the aggregate level. Therefore, annual national and regional calculations will continue to be performed on the jurisdiction-based aggregate-level data to determine a number of relevant statistics, including overall rates of children screened for hearing loss, identified with hearing loss, enrolled in early intervention services, and loss to follow-up / loss to documentation. Prevalence rates of hearing loss per 1,000 infants screened and the frequency of differing types and severity of hearing loss will also be determined for all jurisdictions that provide the data. All statistics will be calculated by CDC EHDI personnel. A list of relevant statistics and an explanation of how they will be calculated is provided in the table below. Additional statistics may be generated as needed.

Generated statistics will be compared to data previously reported to CDC to assess jurisdictional, regional, and national performance at different stages in the EHDI process (e.g., percent screened for hearing loss). Aggregated statistics will also be compared across jurisdictions. The titles of potential reports to be produced from the aforementioned analyses are listed in **Attachment 6**. Although the primary intent of this information collection is to generate aggregated jurisdictional and national-level statistics on hearing screening, referral, receipt of follow-up testing, identification of hearing loss, and intervention, within-state subgroups, analyses will be performed as the data allow.

Data Management: To ensure the accuracy of the information submitted, the data will be inspected for outliers and compared to data reported in previous years. Respondents will be contacted via e-mail and/or phone in cases where any responses appear to be incomplete or do not correspond to other information reported. Please see **Attachment 7** for a copy of this e-mail request.

**A.17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The display of the OMB expiration date is not inappropriate.

**A.18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

**References**

1. Finitzo T, Albright K, O'Neal J. The newborn with hearing loss: detection in the nursery. Pediatrics. 1998 Dec; 102(6):1452-60.
2. Van Naarden K, Decoufle P, Caldwell K. Prevalence and characteristics of children with serious hearing impairment in metropolitan Atlanta, 1991–1993. Pediatrics. 1999 Mar; 103(3):570-5.
3. Yoshinaga-Itano C. Early intervention after universal neonatal hearing screening: impact on outcomes. Ment Retard Dev Disabil Res Rev. 2003; 9(4):252-66.
4. Yoshinaga-Itano C, Sedey AL, Coulter DK, Mehl AL. Language of early- and later-identified children with hearing loss. Pediatrics. 1998 Nov;102(5):1161-71.
5. Robinshaw HM. The pattern of development from non-communicative behavior to language by hearing impaired and hearing infants. Br J Audiol. 1996 Jun; 30(3):177-98.