Assessing the needs and capacity of state newborn screening programs and laboratories

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. The respondent universe for this data collection aligns with that of the OSC. Data will be collected from state public health newborn screening program personnel or their designees acting in their official capacities.

This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241).

Approximately 4,000,000 babies are born in the United States each year. Within days of birth, more than 98% in the United States have blood drawn for participation in state-based public health newborn screening programs. Blood is collected on specific newborn screening filter paper cards and is immediately transported to state public health newborn screening laboratories. Newborn screening laboratories test dried blood spots for life-threatening diseases requiring early intervention to promote optimal health outcomes and prevent death. Results from newborn screening laboratory tests are often available to clinicians within the first week of life. For a comprehensive review of current public health newborn screening practices in the United States, see the summary from the June 2012 *CDC Grand Rounds: Newborn Screening and Improved Outcomes* (**Attachment A—CDC Grand Rounds: Newborn Screening and Improved Outcomes MMWR**).

All 50 states have mandated public health newborn screening programs. Newborn screening practices vary significantly by state. Factors influencing newborn screening in states include number of babies screened, number of diseases screened, methods used to screen for specific diseases, policies for adding new conditions to the newborn screening panel, policies for retaining and using residual dried blood spots, and general infrastructure. Furthermore, 33 of the 50 states use a state-based public health newborn screening laboratory that only serves their state population. The remaining 17 states use 5 laboratories for their newborn screening activities--Wyoming uses the Colorado newborn screening laboratory; Mississippi uses the Nebraska newborn screening laboratory; North Dakota and South Dakota use the Iowa newborn screening laboratory; Alaska, Idaho, Nevada, and New Mexico use the Oregon newborn screening laboratory; New Hampshire, Rhode Island, Vermont, and Maine use the Massachusetts newborn screening laboratory. Thus, the 50 state newborn screening programs are served by 38 newborn screening laboratories.

Since 1978, CDC has supported the state newborn screening laboratories through the Newborn Screening Quality Assurance Program. The Newborn Screening Quality Assurance Program helps newborn screening laboratories ensure that testing accurately detects these disorders, does not delay diagnosis, minimizes false positive reports, and sustains high-quality performance. For over 30 years, the CDC's Newborn Screening Quality Assurance Program has performed this essential public health service, ensuring the quality and accuracy of screening tests for more than 4 million infants born each year in the United States and millions more worldwide. The Program has grown from 1 disorder in 1978 for 31 participants to more than 50 disorders for 459 participants in 2009. For additional information about the CDC Newborn Screening Quality Assurance Program, see the 2010 article: *Improving and Assuring Newborn Screening Laboratory Quality Worldwide: 30-year experience at the Centers for Disease Control and Prevention* **(Attachment B—30 Years Improving and Assuring NBS Quality at CDC)**.

The Newborn Screening Saves Lives Act of 2007 (**see Attachment C—Newborn Screening Saves Lives Act of 2007**) states that the Centers for Disease Control and Prevention (CDC) "shall provide for—1) quality assurance for laboratories involved in screening newborns and children for heritable disorders, including quality assurance for newborn screening tests, services, and technical assistance and technology transfer to newborn screening laboratories to ensure analytic validity and utility of screening tests; and 2) appropriate quality control and other performance test materials to assess new screening tools." The Act also creates a Secretary's Advisory Committee on Newborn Screening and Heritable Disorders in Newborns and Children (SACHDNC) (**see Attachment D—Secretary's Advisory Committee on Newborn Screening and Heritable Disorders Annual Report 2011**). This Committee is responsible for making systematic evidence-based recommendations and has developed a Recommended Uniform Screening Panel that includes 31 core disorders and 26 secondary conditions (**see Attachment E—Recommended Uniform Screening Panel**).

The CDC Newborn Screening and Molecular Biology Branch (CDC NSMBB) provides critical support to all state newborn screening laboratories. CDC NSMBB maintains in-house subject matter expertise to serve as a trusted resource for state newborn screening laboratories. CDC NSMBB routinely provides technical assistance, such as guidance on measuring specific newborn screening markers, promoting improved quality control within laboratories, and troubleshooting new tests, for state newborn screening laboratories and supports training and educational opportunities for the newborn screening laboratory workforce. Through its Newborn Screening Quality Assurance Program, CDC NSMBB delivers quality assurance materials—quality control and testing materials in the form of dried blood spots—to all newborn screening laboratories on a quarterly basis. CDC NSMBB provides formal feedback to newborn screening laboratories via quarterly and annual reports. CDC NSMBB endeavors to address current and emerging newborn screening laboratory needs.

Despite providing acknowledged support to state newborn screening programs since 1978, CDC NSMBB has never previously sought formal feedback from state newborn screening programs or laboratories regarding their needs, capacity to screen, or satisfaction with services provided by CDC NSMBB. CDC NSMBB does not provide grant funding to all newborn screening laboratories and has not had access to mechanisms that might promote type of information collection. Information about newborn screening markers used by state newborn screening is needed to inform and advance current efforts within CDC's Newborn Screening Quality Assurance Program and to deliver focused technical assistance to states. Information about the number of babies screened is readily available within state newborn screening programs and is necessary to appropriately demonstrate the capacity and impact of newborn screening laboratories on the health of newborns in the United States.

CDC NSMBB, located in the Division of Laboratory Sciences, National Center for Environmental Health, requests approval for a new data collection under the approved generic ICR that supports communications with public health officials to assess capacity and needs. This is the first time that CDC NSMBB has formally solicited input from state public health officials about the needs and capacity of their newborn screening programs and laboratories. These data will be used to identify state newborn screening laboratory needs, which will inform current and future CDC NSMBB activities. In addition, these data will demonstrate the capacity of state newborn screening programs to identify babies with life threatening conditions.

Privacy Impact Assessment

Overview of the Data Collection System – The data collection system consists of two web-based data collection instruments. Information about the capacity and impact of newborn screening programs within states, including information about the year when statewide screening began and the number of confirmed newborn screening cases of 31 disorders in each year, is maintained by the administrative section of state newborn screening offices or the newborn screening **PROGRAM**. Information about satisfaction with CDC technical laboratory assistance and measurement of specific newborn screening markers is located directly within the newborn screening **LABORATORY**. Some state newborn screening programs use a newborn screening laboratory that is located out of their physical state. Thus, two independent data collection instruments were created to capture information from newborn screening **PROGRAMS** and **LABORATORIES**.

The Newborn Screening **LABORATORY** Data Collection Instrument (**see Attachment F – Newborn Screening LABORATORY Data Collection Instrument: MS Word version and Attachment G – Newborn Screening Laboratory Data Collection Instrument: Survey Monkey Web version**) was designed to collect information from state newborn laboratory directors or their designees acting in their official capacities regarding newborn screening laboratory activities within their jurisdiction. All 37 United States newborn screening laboratory directors will be queried. The data collection instrument will be administered as a web-based data collection instrument. The data collection tool was pilot tested by 3

newborn screening laboratory directors. Feedback from this group was used to refine questions as needed, ensure accurate programming and skip patterns and establish the estimated time required to complete the survey.

The information requested from state newborn screening LABORATORIES—a 20 minute information request from state newborn screening laboratory directors to assess the needs of state newborn screening laboratories—will be used to assess strategies used by CDC NSMBB to promote state newborn screening laboratory activities. Somewhat detailed questions are asked about measurement of a specific marker in newborn screening laboratories because of guidance from HHS Secretary's Advisory Committee on Heritable Disorders in Newborns and Children and a lack of knowledge about best ways to improve laboratory processes within states. As a result CDC can tailor guidance and technical assistance to better meet the needs of state laboratories for screening newborns.

The Newborn Screening **PROGRAM** Data Collection Instrument (**see Attachment H – Newborn Screening PROGRAM Data Collection Instrument: MS Word version and Attachment I – Newborn Screening PROGRAM Data Collection Instrument: Survey Monkey Web version**) was designed to collect data from state newborn program directors or their designees acting in their official capacities regarding newborn screening program activities within their jurisdiction. All 50 United States newborn screening program directors will be queried. The data collection instrument will be administered as a web-based data collection instrument. The survey was pilot tested by 3 newborn screening program directors. Feedback from this group was used to refine questions as needed, ensure accurate programming and skip patterns and establish the estimated time required to complete the survey.

The information requested from state newborn screening PROGRAMS—information about the number of babies detected with newborn screening conditions—will be used to provide a point-in-time snapshot of newborn screening for the 2013 campaign. These data will be used to frame the overall impact of newborn screening at the national level and demonstrate the capacity of newborn screening programs. These data will not be used to measure the performance of the CDC newborn screening program nor the performance of state newborn screening laboratories.

Items of Information to be Collected –

The Newborn Screening **LABORATORY** Data Collection Instrument contains 6 sections with 20 or 21 total questions, depending on answers to one question. With the exception of the first section, all sections contain multiple choice questions and have a textbox available for additional comments. In the first section, the respondent will type the state(s) and/or

region(s) served by their newborn screening laboratory in a textbox. Respondents will then rate 5 current CDC NSMBB activities on a 5-point Likert scale. Next, respondents will rate 3 potential CDC NSMBB activities on a 5-point Likert scale. Section 4 will ask respondents to indicate whether or not (Yes/No) they have the capacity to measure a specific newborn screening marker in their newborn screening laboratory. An affirmative response to the question in Section 4 will lead to ten additional questions about reporting of these results to health care providers. If the laboratory does not currently measure this marker, 11 questions will determine the barriers to measuring and reporting this marker.

The Newborn Screening **PROGRAM** Data Collection Instrument requests information about each of the 31 newborn screening conditions currently on the Recommended Universal Screening Panel. Respondents are to indicate: 1) the year when screening began in their state, 2) the number of confirmed cases in 2009, 3) the number of confirmed cases in 2010, and 4) the number of confirmed cases in 2011. Respondents will use drop down menus to indicate the year screening started and the number of confirmed cases in each year. Respondents will be given the option to indicate the information is unknown or not applicable to their program.

The information requested from state newborn screening PROGRAMS—information about the number of babies detected with newborn screening conditions—will be used to provide a point-in-time snapshot of newborn screening for the 2013 campaign. These data will be used to frame the overall impact of newborn screening at the national level and demonstrate the capacity of newborn screening programs. These data will not be used to measure the performance of the CDC newborn screening program nor the performance of state newborn screening laboratories.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age – The data collection system involves using a web-based survey. Respondents will be sent an email invitation with a link directing them to the online survey only (i.e., not a website). No website content will be directed at children.

2. Purpose and Use of the Information Collection

The purposes of this information request are: 1) to determine the needs of state newborn screening laboratories for delivering focused technical assistance, and 2) to demonstrate the capacity and impact of state newborn screening program activities for the last 50 years.

The purpose of the Newborn Screening **LABORATORY** Data Collection Instrument is to assess the needs and capacity of state newborn screening laboratories to inform and prioritize future CDC NSMBB activities. Responses will be used to assess current and future CDC NSMBB activities and to recognize best ways to serve the needs of state newborn

screening laboratories. Responses will also be used to determine effective ways of supporting state newborn screening laboratories to adopt the use of the best newborn screening markers in their laboratories.

The purpose of the Newborn Screening **PROGRAM** Data Collection Instrument is to demonstrate the capacity of newborn screening laboratories and to measure the current national impact of newborn screening by ascertaining the number of affected babies identified in recent years. Furthermore, this instrument will determine the year when screening began for each newborn screening condition to show changes in state newborn screening programs over the past 50 years. This information will be used during the 2013 50 Years of Newborn Screening celebration to show the impact of this public health program.

Privacy Impact Assessment

No sensitive information is being collected. The proposed data collection will have no effect on respondent privacy because respondents will not be identified by name and are participating in their official capacity as staff in a state department of health. Cells with fewer than 5 responses will be suppressed.

3. Considerations Given to Information Technology

All responses will be collected via a web-based questionnaire (SurveyMonkey) allowing respondents to complete and submit their responses electronically. This method was chosen to reduce the overall burden on respondents. The survey was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to less than 50 survey questions per instrument).

4. Duplication of Information

After an extensive review of the scientific literature, viewing public health laboratory websites, and consulting public health professionals with extensive experience with newborn screening laboratories, we do not believe there is a substitute for the proposed information request. A publically available database containing the number of confirmed newborn screening cases by condition, state, and year does not exist. Major partners, including the Association of Public Health Laboratories, have indicated that this information is not currently available. A database containing the year states initiated newborn screening conditions does not exist.

Reducing the Burden on Small Entities

No small businesses will be involved in this data collection.

5. Consequences of Not Conducting Collection

This request is for a one time data collection. There are no legal obstacles to reduce the burden. If no data are collected, the Newborn Screening and Molecular Biology Branch will be unable to:

- Assess current CDC NSMBB activities, including the Newborn Screening Quality Assurance Program and the Molecular Assessment Program.
- Inform and prioritize funding opportunity announcements and cooperative agreements aimed to support state newborn screening laboratories.
- Accurately represent the impact of newborn screening as a national public health initiative during the 2013 "50 Years of Newborn Screening" awareness campaign.

6. Special Circumstances

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

7. Consultation with Persons Outside the Agency

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 22, 2010, Vol. 75, No. 204; pp. 65353-54. Two comments were received from the Association of State and Territorial Health Officials (ASTHO), and the National Association of County and City Health Officials (NACCHO).

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

8. Payment or Gift

CDC will not provide payments or gifts to respondents.

9. Confidentiality

The Privacy Act does not apply to this data collection. Employees of state and local public health agencies will be speaking from their official roles and will not be asked, nor will they provide individually identifiable information.

This data collection is not research involving human subjects.

10. Sensitive Nature

No information will be collected that are of personal or sensitive nature.

11. Burden of Information Collection

The estimate for burden hours is based on a pilot test for each data collection instrument by 3 public health newborn screening laboratory directors and 3 newborn screening program directors.

In the pilot tests for the **LABORATORY** Data Collection Instrument, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the survey, was approximately 15 minutes for the **LABORATORY** Data Collection Instrument. Based on these results, the estimated time range for actual respondents to complete this data collection is 5-20 minutes. For the purposes of estimating burden hours, the upper limit of this range (i.e., 20 minutes) is used.

In the pilot tests for the **PROGRAM** Data Collection Instrument, the average time to complete the surveys including time for reviewing instructions, gathering needed information and completing the survey, was approximately 35 minutes for the **PROGRAM** Data Collection Instrument. Based on these results, the estimated time range for actual respondents to complete the instrument is 20-38 minutes. For the purposes of estimating burden hours, the upper limit of this range (i.e., 38 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – medical and health services managers in state government (http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf). Based on DOL data, an average hourly wage of $57.11 is estimated for all 84 respondents who are medical and health services managers. Table A-12 shows estimated burden and cost information.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents – **LABORATORY** and **PROGRAM** Data Collection Instruments

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Newborn screening LABORATORY directors	38	1	20/60	13	57.11	716.30
Newborn screening PROGRAM directors	50	1	38/60	32	57.11	1799.00
TOTALS	**88**			**45**		**2515.30**

12. Costs to Respondents

There will be no direct costs to the respondents other than their time to participate in each survey.

13. Cost to Federal Government

There are no equipment or overhead costs. Contractors are not being used to support this data collection. The only cost to the federal government would be the salary of CDC staff supporting the data collection activities and associated tasks.

The staff for this project is a Health Scientist (GS-13). The staff will develop the survey, pilot test the survey, prepare the OMB application, collect the data, prepare the analysis plan, manage quality control, prepare the data for analysis, conduct quantitative data analysis, and prepare a summary report. An hourly rate of 40.97 is used to estimate staff cost.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Health Scientist (GS-13)—instrument development, pilot testing, OMB package preparation, data collection, data analysis, quality control, report preparation	200	40.97	8194.00
Estimated Total Cost of Information Collection			**8194.00**

14. Reason for Changes

This is a new data collection.

15. Tabulation of Results, Schedule, and Analysis Plan

We plan to analyze data using SAS using descriptive statistics to report state newborn screening activities. Once analyzed, we plan to share our data with other newborn screening stakeholders via the *CDC.gov/newbornscreening website*, a MMWR article describing the current state newborn screening activities, conference presentations associated with the 2013 50 Years of Newborn Screening campaign, and peer-reviewed journal articles.

Project Time Schedule

- ✓ Design survey questionnaire.....(COMPLETE)
- ✓ Develop survey protocol, instructions, and analysis plan.....(COMPLETE)
- ✓ Pilot test survey questionnaire.....(COMPLETE)
- ✓ Prepare OMB package.....(COMPLETE)
- ✓ Submit OMB package.....(COMPLETE)
- ❑ OMB approval.....(TBD)
- ❑ Conduct survey.....(Survey open 4 weeks)
- ❑ Collect, code, enter, quality control, and analyze data.....(4 weeks)
- ❑ Prepare report.....(4 weeks)
- ❑ Disseminate results/reports.....(4 weeks)

16. Display of OMB Approval Date

We are requesting no exemption.

17. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS – Section A

Note: Attachments are included as separate files as instructed.

A. **CDC Grand Rounds Newborn Screening MMWR**
B. **30 Years Improving and Assuring NBS Quality at CDC**
C. **Newborn Screening Saves Lives Act of 2007**
D. **Secretary's Advisory Committee on Heritable Disorders in Newborns and Children Annual Report 2011.**
E. **Recommended Uniform Screening Panel (RUSP)**
F. **Newborn Screening LABORATORY Data Collection Instrument: MS Word version**
G. **Newborn Screening LABORATORY Data Collection Instrument: Survey Monkey Web version**
H. **Newborn Screening PROGRAM Data Collection Instrument: MS Word version**
I. **Newborn Screening PROGRAM Data Collection Instrument: Survey Monkey Web version**