**Supporting Statement**

**The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment Surveys**

**OMB Control No. 0906-XXXX**

## A. Justification

### 1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA) is requesting that the Office of Management and Budget (OMB) review and approve two data collection forms for the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (Committee). The purpose of the data collection strategy is to measure progress in meeting the legislative charge of the Committee. This is a new activity.

The Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (Committee) was established under the Public Health Service Act, Title XI, § 1111 (42 U.S.C. 300b-10), as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (P.L. 113-240). Please see Attachment A. The Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees. The Health Resources and Services Administration/Maternal and Child Health Bureau (HRSA/MCHB) provides coordination, management, and operational services to the Committee, with direction and guidance from the U.S. Department of Health and Human Services.

The purpose of the Committee is to provide the Secretary with recommendations, advice, and technical information regarding the most appropriate application of technologies, policies, guidelines, and standards for: (a) effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders; and (b) enhancing the ability of state and local health agencies to provide for newborn and child screening, counseling, and health care services for newborns and children having, or at risk for, heritable disorders. Specifically, the Committee makes systematic, evidence-based recommendations on screening all newborns for conditions that have the potential to significantly impact their health and evaluates the potential public health impact of expanding newborn screening (NBS).

To fulfill 42 U.S. Code § 300b–10, Sections (3) and (4), the Committee recommends conditions to the Secretary for inclusion on the Recommended Uniform Screening Panel (RUSP) based on 1) an assessment of the certainty and magnitude of the net benefit of screening and 2) the capability of States to implement NBS. The RUSP is a list of conditions that the Secretary of Health and Human Services recommends States include in their NBS

panels. Conditions are nominated for inclusion on the RUSP by the public and the Committee strongly recommends that nominations are proposed by multi-disciplinary teams of researchers, clinicians, and advocates.

To assess the certainly and magnitude of the net benefit of adding a condition to the RUSP, the Committee conducts a systematic, evidence-based review that examines the accuracy of screening, the population-level health outcomes of implementing screening, the effectiveness of early treatment, and the potential harms related to population-level screening, diagnosis, and treatment.

To assess the capability of States to add a new condition, the Committee requires a public health system impact (PHSI) assessment to evaluate the feasibility and readiness of state NBS programs to implement and expand comprehensive screening within their state NBS programs. This evaluation allows the Committee to identify the resources and/or systems needed by States to implement comprehensive screening and how long it would take NBS programs to expand their screening panels. The resources needed, impacts, and costs, including opportunity costs, can affect the ability of States to implement screening for new conditions. For example, upfront costs to a State to add a condition that requires expanding laboratory space, bringing in new technologies, training staff, or adding new staff can influence the rate of adoption. In addition to direct laboratory costs, NBS programs need to have systems in place to follow-up presumptive positive results and initiate confirmatory testing and treatment.

In the past, the Committee used surveys of a selected sample of representative NBS programs (less than 9) to better understand the PHSI of adding new conditions to the RUSP at the state level. However, due to the complexity of the newborn screening system, the Committee concluded that a more detailed assessment of the PHSI of expanding NBS is needed.

In April 2014, the Committee convened an expert meeting of key NBS stakeholders to develop a more comprehensive assessment of the PHSI of conditions being considered for addition to the RUSP. The meeting resulted in the identification of key factors for the Committee to consider when assessing the public health impact of expanding NBS. The only way to gather the information is through surveying all state NBS programs in the U.S. This information will result in better informed Committee recommendations to the Secretary of Health and Human Services and the Secretary will have all the information to make a final decision as to what is added to the RUSP.

## 2. Purpose and Use of Information Collection

The purpose of the public health system impact assessment is to inform the Committee about the feasibility and readiness of state NBS programs to add a condition under consideration for the RUSP. Due to the need for the Committee to understand the diverse issues facing NBS programs, information regarding implementation will be requested from each State. Based on the expert meeting held in 2014, key factors were identified to best assess the PHSI of expanding NBS. These factors include:

- NBS Program Organization and Authorization
- Screening Methods
- Short-Term Follow-up
- Long-Term Follow-Up
- Anticipated resources and costs
- Projected timeline for adoption

A direct way to gather the information on these factors is through surveying all state NBS programs. The information will be used to inform the Committee's decision making process. Specifically, the Committee developed a decision matrix (Attachment B) that is a methodological tool for categorizing and assigning value to nominated conditions to support the development of specific recommendations to the Secretary. Data collected on the PHSI will assist the Committee in determining which category the nominated condition falls under and depending on the category, whether or not the Committee recommends to the Secretary an addition to the RUSP. The Committee's decision matrix and the decision making process is similar to how other established evidence-based review entities conduct business, including the U.S. Preventative Services Taskforce.

The consequence of not having national level PHSI data is that the Committee and the Secretary of Health and Human Services will not be able to make an informed recommendation and decision that has implications for all States. Although each State has the final authority for deciding what tests are on their newborn screening panel, the RUSP is seen as a "gold standard" by States, researchers, advocates, and families and results in more uniform NBS practices across the United States.

The RUSP also has ACA implications. Section 2713 of the Public Health Service Act, as added by the Affordable Care Act (ACA), requires non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual coverage to provide benefits for certain preventive care and screening services without the imposition of cost-sharing. This includes preventive care and screenings for infants, children, and adolescents, as provided in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). One source of such HRSA-supported comprehensive guidelines is conditions added to the RUSP by the Secretary. It is critical that the Secretary has all of the available information and data before deciding which conditions are added to the RUSP.

## 3. Use of Improved Information Technology and Burden Reduction

The initial survey questions will be programmed into Qualtrics, an online survey platform. 100% of the responses will be collected electronically. For the follow-up survey, respondents will have the option to electronically submit via email their responses or be interviewed via phone. The follow-up survey will contain open ended questions so an option was added to conduct interviews over the phone as a way to help ease any burden States may face in reporting their information.

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

This collection tool is not duplicative of another collection source. Efforts to identify duplication included review of the literature, data base searches, and expert opinion from Advisory Committee meetings.

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

No small businesses will be involved in this study.

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

States only respond when a condition is undergoing evidence review. Typically this occurs twice a year. The consequence of not having national level PHSI data is that the Committee and the Secretary of Health and Human Services will not be able to make an informed recommendation and decision that has implications for all States.

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

The request fully complies with the regulation.

**8. Comments in Response to the Federal Register Notice/Outside Consultation**

**Section 8A:**
A 60-day Federal Register Notice was published in the *Federal Register* on October 20, 2014, vol. 79, No. 202; pp. 62636-62637. There were no public comments. In an effort to derive a realistic burden estimate for the reporting requirements, five State newborn screening programs were contacted. Their names and contact information are provided below.

| **Name** | **Contact Information** |
|---|---|
| Patrick Hopkins<br>Chief, Newborn Screening Unit<br>Missouri State Public Health Laboratory | (Telephone) 573-751-2662<br>(Email) Patrick.hopkins@health.mo.gov |

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| Joe Orsini, PhD<br>New York State Department of Health | (Telephone) 518-473-7552<br>(Email) Joseph.orsini@health.ny.gov |
| Mei Baker, MD<br>Newborn Screening Laboratory Director<br>Wisconsin State Laboratory of Hygiene | (Telephone) 608-262-6547<br>(Email) mei.baker@wisc.edu |
| Sylvia Mann, MS<br>State Genetics Coordinator<br>State of Hawaii, Department of Health<br>Hawaii Genetics Program | (Telephone) 808-733-9063<br>(Email) sylvia@hawaiigenetics.org |
| Susan Tanksley, PhD<br>Laboratory Operations Unit Manager<br>Texas Department of State Health Services | (Telephone) (512) 776-3106<br>(Email) susan.tanksley@dshs.state.tx.us |

**Section 8B:**

There was an extensive collaboration process in the development of the PHSI surveys. In April 2014, the Committee convened an expert meeting of key NBS stakeholders to develop a more comprehensive assessment of the PHSI of conditions being considered for addition to the RUSP. Participants included: state public health NBS programs; national and state-level public health laboratories; genetic counseling experts; patient and family advocacy groups; pediatric primary care providers; pediatric specialty care providers (i.e., heritable and metabolic disorder specialists); experts in community public health and implementation, research and evaluation; multi-criteria models of health intervention decision-making experts; public health ethicists; and experts in systematic evidence reviews in genetic testing, members of the Committee, and Federal Agency partners. In many cases, participants represented multiple stakeholder groups. Please see Attachment D. Through a collaborative, consensus driven process, participants identified key factors for the Committee to consider in assessing public health impact of expanding NBS, and survey methodology for obtaining the information. The Committee has ex-officio members who represent the Agency for Healthcare Research and Quality Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration and National Institutes of Health. All ex-officios took part in the public health systems impact discussions and what information should be collected but is not currently collected.

**9. Explanation of any Payment/Gift to Respondents**

Respondents will not receive any payments or gifts.

**10. Assurance of Confidentiality Provided to Respondents**

Data will be kept private to the extent allowed by law. Personal identifiers will not be collected.

**11. Justification for Sensitive Questions**

The proposed survey instruments will not be collecting sensitive information.

**12. Estimates of Annualized Hour and Cost Burden**

**12A. Estimated Annualized Burden Hours**

The basis for the estimates was taken from a sample of 5 state newborn screening programs and ranged from 30 minutes and above. The average was rounded up due to the size and high birth rates in several States.

| Type of Respondent | Form Name | Number of Respondents | Number of Responses per Respondent | Total Responses | Average Burden per Response (in hours) | Total Burden Hours |
|---|---|---|---|---|---|---|
| State newborn screening program | INITIAL Survey of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment | 59 | 2** | 118 | 10.0 | 1180 |
| State newborn screening program | FOLLOW-UP Survey of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment | 30* | 2** | 60 | 2.0 | 120 |
| | Total | 59 | | 178 | | 1,300 |

*Up to 30 States and/or Territories will be asked to complete a follow-up survey.
**Up to two conditions may be reviewed per year. Therefore, there will be two initial surveys and two follow-up surveys per year.

**12B. Estimated Annualized Burden Costs**

The salary of staff supported within a State newborn screening program varies significantly across States. Organizational capacity also varies, with the larger States typically utilizing more program staff than do smaller States. Each State newborn screening program has a unique organizational structure. Given its public health leadership role, the administration of newborn screening programs requires multiple partners and health department units (e.g., MCH Director and staff, Newborn Screening Director and staff, Laboratorians, Follow-up Coordinators, Genetic Counselors and other supportive staff in Vital Statistics and Laboratory Services.)

Based on the Bureau of Labor Statistics, Occupational Employment and Wages for May 2013, the national mean wage estimate for Medical and Health Services Managers in organizations that include public health agencies is $48.72.
(http://www.bls.gov/oes/current/oes119111.htm)

| **Type of Respondent** | **Average Total Annual Burden Hours** | **Hourly Wage Rate** | **Total Respondent Costs** |
|---|---|---|---|
| Health Services Manager | 1,300 | $48.72 | $63,336 |
| **Total** | 1,300 | $48.72 | $63,336 |

**13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs**

There is no capital, start-up costs, or operation and maintenance costs associated with this data collection.

**14. Annualized Cost to Federal Government**

A GS-14/Step 5 at 5% of time in the amount of $6,082 is needed to oversee the contractor. In order to collect and analyze the information from the requested survey tools, MCHB will award a contract for one base year plus four option years. The total cost of this five year contract is $442,583. The average annual cost is $88,517. The contractor estimated the cost and set up a subcontract to pay for the implementation of the survey instruments and the collection and analysis of the data. The total annual cost to the Federal Government is $94,599.

**15. Explanation for Program Changes or Adjustments**

This is a new information collection.

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

Data from the surveys will be presented in an aggregate manner and stratified when necessary. All information will be de-identified. No sampling, imputation, or other statistical estimation techniques will be used. A summary report will be given to state newborn screening programs that participated in the surveys and to the Committee. Due to the Federal Advisory Committee Act, the final report and presentation that will contain data from the surveys will be posted on the Committee's website for the public to view. Although statistical methods will not be used to select respondents, the intent of these surveys is to evaluate the impact of screening for additional conditions on state newborn screening programs. Therefore, a Supporting Statement B was completed.

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

The OMB number and Expiration date will be displayed on every page of every form/instrument.

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

There are no exceptions to the certification.

Attachments:

A. Legislation
B. SACHDNC's Decision Matrix
C. 60 Day Federal Register Notice
D. April 2014 Expert Meeting – Participant Roster