Supporting Statement A

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

OMB Control No. 0906-0014 (Revision)

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 revised 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 inform the evidence-based review of a condition that has been nominated for inclusion on the Recommended Uniform Screening Panel, which falls under one of the legislative charges of the Committee. This is a continuation of an activity previously implemented, with revisions.

The 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. 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 of that condition that examines the accuracy of screening test, the population-level health outcomes of implementing screening for the condition, 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 add the condition under consideration to their state NBS programs. This evaluation allows the Committee to assess the resources and/or systems needed by states to implement screening for the condition 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 negatively as opposed to a screening test that can be added to an existing methodology. In addition to direct laboratory costs, NBS programs need to have systems in place to follow up on 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 and the variability among state NBS programs, 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 the necessary information to make a final decision as to what is added to the RUSP.

Since the implementation of these surveys in 2014, the Committee conducted evidence-based reviews, including an assessment of the public health system impact, for three conditions. The information gathered using the OMB-approved PHSI surveys has been used by the Committee to help them make decisions about whether or not to recommend to the Secretary

a condition be added to the RUSP. There is a continued need for these surveys and as such, HRSA has opted to request a continuation of approval for revised versions of the survey tools.

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 addition to 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 continue to 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 Task Force.

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.

Conditions that are included on the RUSP have been determined to be among the preventive services for which certain insurance companies are required to provide coverage without cost sharing under section 2713 of the PHS Act, 42 U.S.C. 300gg-13. It is therefore critical the Secretary has all of the available information and data before deciding which conditions are added to the RUSP. Administering the PHSI surveys is a key component in gathering the necessary data.

This package contains revisions to both survey tools and is intended to improve the overall quality and utility of data collected. In order to revise the survey tools, HRSA considered feedback from previous respondents, the contractor responsible for implementing the surveys and analyzing the data, and Committee members. Several questions were deleted or consolidated to eliminate redundancy. A few new questions were added across both survey tools. Language for several questions and responses were edited to provide more clarity and additional options. The questions were also edited to ensure the survey can accommodate different types of conditions that may be nominated in the future. Some of the questions were reordered to streamline responses and decrease the burden on respondents. This information collection request package (ICR) contains tracked changed and clean versions of both surveys.

3. Use of Improved Information Technology and Burden Reduction

The initial survey will be administered using an online platform. All questions and skip patterns will be programmed into Qualtrics and 100% of the responses will be collected electronically. The follow-up survey contains open ended questions with probe questions. The follow-up survey will primarily be conducted as an interview by phone, to make it easier on the states to respond. Respondents will also have the option to respond electronically via email if they prefer.

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. Additionally, revisions were made to the survey tools to reduce duplication of information that is already available.

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 1-2 times 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 June 5, 2018, vol. 83, No. 108; pp. 26064-26065. 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.

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.

As stated above, in order to revise the survey tools, HRSA considered feedback from previous respondents, the contractor responsible for implementing the surveys and analyzing the data, and Committee members. The revised surveys were pilot tested by five state NBS programs. Their names and contact information is listed in the chart below.

Name	Contact Information
Kelly Holland Director, Division of Newborn Screening and Genetics at Pennsylvania Dept. of Heath	kholland@pa.gov
Michele Caggana, Sc.D., FACMG Deputy Director of the Division of Genetics Director of the Newborn Screening Program New York State Department of Health	michele.caggana@health.ny.gov
John D. Thompson, PhD , MPH, MPA Director, Newborn Screening. Washington State Department of Health	John.Thompson@doh.wa.gov
Stanton L. Berberich, PhD Program Manager Medical Screening State Hygienic Laboratory at The University of Iowa Kimberly Noble Piper State Genetics Coordinator, Iowa Department of Public Health Carol K Johnson Follow-up Coordinator, Iowa Newborn Screening, University of Iowa Department of Pediatrics	stanton-berberich@uiowa.edu kimberly.piper@idph.iowa.gov carol-johnson@uiowa.edu
Cindy Ingham, RN Coordinator, Newborn Screening Program Vermont Department of Health	Cindy.Ingham@vermont.gov

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.

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 five 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 could be asked to complete the follow-up survey.
**Up to two conditions may be reviewed per year. Therefore, there could be up to two initial surveys and two follow-up surveys administered 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 2017, the national mean wage estimate for Medical and Health Services Managers in organizations that include public health agencies is $53.69. To account for the cost of fringe benefits and overhead, the hourly wage is multiplied by a factor of two, resulting in a final hourly wage estimate of $107.38. (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	$107.38	$139,594
Total	1,300		$139,594

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

In order to oversee the contractor, the Contracting Officer's Representative spends 5% time, at a cost of $6,303 (GS 13 Step 10 on OPM's Salary Table 2018-DCB, https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/DCB.pdf). 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 surveys are administered as part of a larger evidence-based review. The contractor uses a portion of the budget to subcontract for the implementation of the survey instruments, including data collection and analysis. The total annual cost to the Federal Government each time these surveys are administered is approximately $76,303.10. Total annual cost is $82,606.

15. Explanation for Program Changes or Adjustments

The current burden inventory in ROCIS for this ICR is 1,300 hours. This request is for the same number of hours.

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, which 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. A screen shot of the template for the Initial Survey, using the example condition spinal muscular atrophy (SMA), is provided in Attachment E.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments:

A. Legislation
B. Decision Matrix
C. 60 Day Federal Register Notice
D. April 2014 Expert Meeting – Participant Roster
E. Screen Shot of template for Initial Survey Tool