



Billing Code 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The Secretary's Discretionary Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment Surveys OMB No. 0906-0014 – Revised

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Secretary's Discretionary Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment Surveys OMB No. 0906-0014 – Revised

Abstract: The purpose of the public health system assessment surveys is to inform the Secretary's Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (Committee) on the ability to add newborn screening for particular conditions within a state, including the feasibility, readiness and overall capacity to screen for a new condition.

The Committee was established under Section 1111 of the Public Health Service Act, 42 U.S.C. 300b-10, as amended in the Newborn Screening Saves Lives Reauthorization Act of 2014. The Committee is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees. 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 newborn screening for conditions that have the potential to change the health outcomes for newborns.

The Committee tasks an external workgroup to conduct systematic evidence-based reviews for conditions being considered for addition to the Recommended Uniform Screening Panel, and

their corresponding newborn screening test(s), confirmatory test(s), and treatment(s). Reviews also include an analysis of the benefits and harms of newborn screening for a selected condition at a population level and an assessment of state public health newborn screening programs' ability to implement the screening of a new condition.

Need and Proposed Use of the Information: HRSA proposes that the data collection surveys be administered by the Committee's external Evidence Review Group to all state newborn screening programs in the United States up to twice a year for two conditions. The surveys were developed to capture the following: (1) the readiness of state public health newborn screening programs to expand newborn screening to include the target condition; (2) specific requirements of screening for the condition that could hinder or facilitate its implementation in each state; and (3) estimated timeframes needed for each state to complete major milestones toward full newborn screening of the condition.

HRSA published the 60-day notice on June 5, 2018 (FR Doc. 2018-12019). There were no comments received during the 60-day comment period. The survey tools have been revised to streamline responses to decrease the burden on the respondents, provide clarity with regard to what is being asked, ensure the survey can accommodate different types of conditions that may be nominated in the future, and offer additional response options. To accomplish this, questions were deleted, consolidated, reordered, and new questions were added to address gaps in information identified by those who have completed the survey and utilized the survey results.

The data gathered will inform the Committee on the following: (1) feasibility of implementing population-based screening for the target condition; (2) readiness of state newborn screening programs to adopt screening for the condition; (3) identify gaps in feasibility or readiness to screen for the condition; and (4) identify areas of technical assistance and resources needed to facilitate screening for conditions with low feasibility or readiness.

Likely Respondents: The respondents to the survey will be State and territorial newborn screening programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden - Hours

| Form Name | Number of Respondents | Number of Responses per Respondent | Total Responses | Average Burden per Response (in hours) | Total Burden Hours |
|---|-----------------------|------------------------------------|-----------------|--|--------------------|
| INITIAL Survey of the Secretary's Discretionary Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment | 59 | 2** | 118 | 10.0 | 1180 |
| FOLLOW-UP Survey of the Secretary's Discretionary Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment | 30* | 2** | 60 | 2.0 | 120 |
| Total | 89 | | 178 | | 1300 |

*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.

Amy P. McNulty,

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