

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**

AGENCY: Health Resources and Services Administration, HHS

ACTION: Notice

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (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, including the Information Collection Request Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email 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-xxxx – New

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 the Public Health Service Act, 42 U.S.C. 217a: Advisory Councils or Committees. This Committee fulfills the functions previously undertaken by the former Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, established under section 1111 of the Public Health Service Act (PHS), 42 U.S.C. 300b-10, as amended in the Newborn Screening Saves Lives Act of 2008. 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 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. The reviews are of rare, genetic conditions 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 Condition Review Workgroup 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 would 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.

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 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	59	2**	118	10.0	1180

Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment					
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.

Jackie Painter,
 Director,
 Division of the Executive Secretariat.

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