

providing clinical services (currently 7, previously 8) related to Healthy People 2020 and;

(7) removal of the outdated project specific Health Improvement Special Project measure (1 measure removed).

In total, the proposed changes reflect the addition of 43 measures and the removal of 5 measures for an increase in measures by a total of 38 measures. Of these measures, 17 are required and 26 are optional. All additional measures proposed are project specific (only applicable to anticipated total ranging from 15–16 out of 61 awardees). All

measures will not be applicable to all 61 respondents. Project specific measures will remain applicable only to Outreach Awardees focusing on the respective project specific topic.

**Likely Respondents:** The respondents would be award recipients of the Rural Health Care Services Outreach Program.

**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; 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; train personnel and to be able to respond to a collection of information; to search data sources; complete and review the collection of information; and 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
Rural Health Care Services Outreach PIMS .....	61	1	61	3.5	213.5
	61	.....	61	.....	213.5

HRSA specifically requests comments on the: (1) Necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: The Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment Surveys, OMB No. 0906–0014, Revision**

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the

Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than September 20, 2021.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto: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 more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

**Information Collection Request Title:** The Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment Surveys, OMB No. 0906–0014—Revision.

**Abstract:** The purpose of the Public Health System Assessment Surveys is to inform the Advisory Committee on Heritable Disorders in Newborns and Children (Committee) on states' ability to add newborn screening for particular conditions, 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, and Title XI § 1111 (42 U.S.C. 300b-10). 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:** The Committee's Evidence Review Group administers the surveys to collect data from state newborn screening programs in the United States.

The surveys have been developed to capture the following: (1) Readiness of state public health newborn screening programs to expand newborn screening to include the target condition, (2) specific requirements of screening for a condition that could hinder or facilitate implementation in each state, and (3) estimated timeframes needed for each state to complete major milestones toward full implementation of newborn screening for the condition.

The following is a summary of proposed changes to the Committee's Public Health System Assessment Surveys:

Proposed changes to the "INITIAL Survey of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment:"

- Survey title:
  - *Current title:* "INITIAL Survey of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment"
  - *Proposed change:* (strike "Secretary's") "INITIAL Survey of the Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment"
  - *Rationale:* Per the charter signed on November 10, 2020, the Advisory Committee on Heritable Disorders in Newborns and Children is the correct name for the Committee.
  - Introductory paragraph:
    - *Current introductory paragraph:* "The purpose of this survey is to inform the Secretary of Health and Human Services Advisory Committee on Heritable Disorders in Newborns and Children (Committee) about states' ability to add newborn screening (NBS) for [condition x] using information gathered from most of the state and territorial NBS programs in the U.S. . . ."
    - *Proposed change:* (strike "Secretary of Health and Human Services") "The purpose of this survey is to inform the

Advisory Committee on Heritable Disorders in Newborns and Children (Committee) about states' ability to add newborn screening (NBS) for [condition x] using information gathered from most of the state and territorial NBS programs in the U.S. . . ."

- *Rationale:* Per the charter signed November 10, 2020, the Advisory Committee on Heritable Disorders in Newborns and Children is the correct name of the Committee.
- Instructions for question 3 (grammatical edit):
  - *Current instructions:* ". . . The following question asks you to consider, in general, how much the following factors would be an issue in considering adding [condition x] to your NBS panel."
  - *Proposed change:* (strike "in" and replace with "when") ". . . The following question asks you to consider, in general, how much the following factors would be an issue when considering adding [condition x] to your NBS panel."
  - *Rationale:* Change made to correct a grammatical error.
- Proposed changes to the "FOLLOW-UP Survey of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment"
  - Survey title:
    - *Current title:* "INITIAL Survey of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment"
    - *Proposed change:* (strike "Secretary's") "INITIAL Survey of the Advisory Committee on Heritable Disorders in Newborns and Children's Pub.
    - *Rationale:* Per the charter signed November 10, 2020, the Advisory Committee on Heritable Disorders in Newborns and Children is the correct name of the Committee.
  - Question 9 (grammatical edits):
    - *Current question:* "Have you developed a follow up protocol and/or

educational materials for [condition x]? If so please describe the steps for short-term follow and how the plan was developed."

- *Proposed change:* (insert hyphen in "follow-up" and insert "-up" in the phrase "short-term follow") "Have you developed a follow-up protocol and/or educational materials for [condition x]? If so, please describe the steps for short-term follow-up and how the plan was developed.
- *Rationale:* Change made to correct grammatical errors.

The data gathered informs 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) gaps or limitations related to the feasibility or readiness of states to screen for a condition, and (4) 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 Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment .....	159	32	118	10.0	1,180
FOLLOW-UP Survey of the Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment .....	230	32	60	2.0	120
Total .....	89	.....	178	.....	1,300

\* It is anticipated that the proposed revisions will not impact the estimated annualized burden hours.

<sup>1</sup> The respondents to the survey will be state and territorial newborn screening programs.

<sup>2</sup> Up to 30 states and/or territories will be asked to complete a follow-up survey.

<sup>3</sup> Up to two conditions may be reviewed per year.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

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

**ACTION:** Notice.

**SUMMARY:** In accordance with the Public Health Service Act and the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) has scheduled a public meeting to be held on Thursday, August 12, 2021, and Friday, August 13, 2021. Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

**DATES:** Thursday, August 12, 2021, from 10:00 a.m. to 2:15 p.m. Eastern Time (ET) and Friday, August 13, 2021, from 10:00 a.m. to 2:00 p.m. ET.

**ADDRESSES:** This meeting will be held via webinar. While this meeting is open to the public, advance registration is required.

Please register online at <https://www.achdncmeetings.org/registration/> by the deadline of 12:00 p.m. ET on August 11, 2021. Instructions on how to access the meeting via webcast will be provided upon registration.

**FOR FURTHER INFORMATION CONTACT:** Alaina Harris, Maternal and Child Health Bureau, HRSA, 5600 Fishers

Lane, Rockville, Maryland 20857; 301-443-0721; or [ACHDNC@hrsa.gov](mailto:ACHDNC@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** ACHDNC provides advice and recommendations to the Secretary of HHS (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. The ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg-13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.*, policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the August 12-13, 2021, meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include the following:

(1) Overview of the Committee's review of its evidence-review processes and proposed updates,

(2) A presentation on phase one of the mucopolysaccharidosis type II evidence review,

(3) Guanidinoacetate methyltransferase (GAMT) deficiency nomination summary,

(4) Possible Committee vote on whether to move GAMT deficiency forward to a full evidence review,

(5) Committee discussion on emerging issues for newborn screening,

(6) A panel presentation on national registries followed by Committee discussion,

(7) A panel presentation on emerging issues facing the newborn screening

workforce followed by Committee discussion, and

(8) Public comments on any newborn screening related topic.

The public is also encouraged to provide public comment on the proposed updates to the Committee's evidence review processes. For reference, a summary of questions for public consideration is on the ACHDNC website. We request that public participants providing oral comments on the review of the Committee's evidence review process also submit a written version of their remarks.

The agenda for this meeting does not include any vote or decision to recommend a condition for inclusion in the Recommended Uniform Screening Panel. As noted in the agenda items, the Committee may hold a vote on whether or not to recommend a nominated condition (GAMT deficiency) to full evidence review, which may lead to such a recommendation at a future time. Agenda items are subject to change as priorities dictate. Information about the ACHDNC, including a roster of members and past meeting summaries, is available on the ACHDNC website listed above.

As previously noted, members of the public will have the opportunity to provide comments. Public participants providing general oral comments may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to provide a written statement or make oral comments to the ACHDNC must be submitted via the registration website by 10:00 a.m. ET on Monday, August 9, 2021.

Individuals who need special assistance or another reasonable accommodation should notify Alaina Harris at the address and phone number listed above at least 10 business days prior to the meeting.

**Maria G. Button,**

*Director, Executive Secretariat.*

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