

Amy P. McNulty,

Acting Director, Division of the 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 Secretary's 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 must be received no later than August 6, 2018.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N-39, 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 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 Secretary's 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 Secretary's 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 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: The surveys are administered by the Committee's Evidence Review Group 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 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.

HRSA anticipates the following revisions will be made to the surveys: (1) Editing and adding response choices as needed, to provide more informative options; (2) revising language throughout the survey to ensure the survey can accommodate different types of conditions that may be nominated; (3) reorder current questions as needed; and (4) add new questions as needed.

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 ¹	59	1	59	10	590
FOLLOW-UP Survey of the Secretary's Discretionary Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment	² 30	1	30	2	60
Total	89	89	650

¹ The respondents to the survey will be State and territorial newborn screening programs.

² Up to 30 States and/or Territories will be asked to complete a follow-up survey.

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.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Tick-Borne Disease Working Group

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Office of HIV/AIDS and Infectious Disease Policy, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) announces the sixth meeting of the Tick-Borne Disease Working Group (Working Group) on June 21, 2018, from 9:30 a.m. to 6:00 p.m., Eastern Time. The sixth meeting will be an on-line meeting held via webcast. The Working Group will focus on subcommittee findings and will review and provide input on the content of the five chapters that will be submitted into the Working Group Congressional Report.

DATES: The on-line meeting will be held on June 21, 2018, from 9:30 a.m. to 6:00 p.m. Eastern Time.

ADDRESSES: This will be an on-line meeting that is held via webcast. Members of the public may attend the meeting via webcast. Instructions for attending this virtual meeting will be

posted prior to the meeting at: <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/index.html>.

FOR FURTHER INFORMATION CONTACT:

James Berger, Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services; via email at tickbornedisease@hhs.gov or by phone at 202-795-7697.

SUPPLEMENTARY INFORMATION: The Working Group invites public comment on issues related to the Working Group's charge. Comments may be provided over the phone during the meeting or in writing. Persons who wish to provide comments by phone should review directions at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/index.html> before submitting a request via email at tickbornedisease@hhs.gov on or before June 18, 2018.

Phone comments will be limited to three minutes each to accommodate as many speakers as possible. A total of 30 minutes will be allocated to public comments. If more requests are received than can be accommodated, speakers will be randomly selected. The nature of the comments will not be considered in making this selection. Public comments may also be provided in writing. Individuals who would like to provide written comment should review directions at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/index.html> before sending their comments to tickbornedisease@hhs.gov on or before June 18, 2018.

During the meeting, the Working Group will review and discuss the content of the five draft chapters that will be part of the Report to Congress. Persons who wish to receive the draft document should email the tickbornedisease@hhs.gov and request a copy. The document will be available prior to the meeting.

Background and Authority: The Tick-Borne Disease Working Group was established on August 10, 2017, in accordance with section 2062 of the 21st Century Cures Act, and the Federal

Advisory Committee Act, 5 U.S.C. App., as amended, to provide expertise and review all HHS, DoD and VA efforts related to tick-borne diseases to help ensure interagency coordination and minimize overlap, examine research priorities, and identify and address unmet needs. In addition, the Working Group is required to submit a report to the Secretary and Congress on their findings and any recommendations for improving the federal response to tick-borne disease prevention, treatment and research, and addressing gaps in those areas.

Dated: May 31, 2018.

James Berger,

Office of HIV/AIDS and Infectious Disease Policy, Designated Federal Officer, Tick-Borne Disease Working Group.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made on the part of Shiladitya Sen, former graduate student, Department of Chemistry and Biochemistry, The Ohio State University (OSU). Mr. Sen engaged in research misconduct in research supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant R01 GM083114. The administrative actions, including debarment for a period of three (3) years, were implemented beginning on May 16, 2018, and are detailed below.

FOR FURTHER INFORMATION CONTACT:

Wanda K. Jones, Dr.P.H., Interim Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8200.