

Research Exception under the Genetic Information Nondiscrimination Act; *Use:* Under the Genetic Information Nondiscrimination Act of 2008 (GINA), a plan or issuer may request (but not require) a genetic test in connection with certain research activities so long as such activities comply with specific requirements, including: (i) The research complies with 45 CFR part 46 or equivalent federal regulations and applicable State or local law or regulations for the protection of human subjects in research; (ii) the request for the participant or beneficiary (or in the case of a minor child, the legal guardian of such beneficiary) is made in writing and clearly indicates that compliance with the request is voluntary and that non-compliance will have no effect on eligibility for benefits or premium or contribution amounts; and (iii) no genetic information collected or acquired will be used for underwriting purposes. The Secretary of Labor or the Secretary of Health and Human Services is required to be notified if a group health plan or health insurance issuer intends to claim the research exception permitted under Title I of GINA. Nonfederal governmental group health plans and issuers solely in the individual health insurance market or Medigap market will be required to file with the Centers for Medicare & Medicaid Services (CMS). The Notice of Research Exception under the Genetic Information Nondiscrimination Act is a model notice that can be completed by group health plans and health insurance issuers and filed with either the Department of Labor or CMS to comply with the notification requirement. *Form Number:* CMS-10286 (OMB Control Number 0938-1077); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 2; *Total Annual Responses:* 2; *Total Annual Hours:* 1. (For policy questions regarding this collection contact Russell Tipps at 301-492-4371).

2. *Type of Information Collection Request:* Revision; *Title of Information Collection:* Consumer Experience Survey Data Collection; *Use:* Section 1311(c)(4) of the Affordable Care Act requires the Department of Health and Human Services (HHS) to develop an enrollee satisfaction survey system that assesses consumer experience with qualified health plans (QHPs) offered through an Exchange. It also requires public display of enrollee satisfaction information by the Exchange to allow individuals to easily compare enrollee satisfaction levels between comparable plans. HHS established the QHP

Enrollee Experience Survey (QHP Enrollee Survey) to assess consumer experience with the QHPs offered through the Marketplaces. The survey includes topics to assess consumer experience with the health care system such as communication skills of providers and ease of access to health care services. CMS developed the survey using the Consumer Assessment of Health Providers and Systems (CAHPS®) principles (<http://www.cahps.ahrq.gov/about.htm>) and established an application and approval process for survey vendors who want to participate in collecting QHP enrollee experience data.

The QHP Enrollee Survey, which is based on the CAHPS® Health Plan Survey, will (1) help consumers choose among competing health plans, (2) provide actionable information that the QHPs can use to improve performance, (3) provide information that regulatory and accreditation organizations can use to regulate and accredit plans, and (4) provide a longitudinal database for consumer research. CMS completed two rounds of developmental testing including 2014 psychometric testing and 2015 beta testing of the QHP Enrollee Survey. The psychometric testing helped determine psychometric properties and provided an initial measure of performance for Marketplaces and QHPs to use for quality improvement. Based on psychometric test results, CMS further refined the questionnaire and sampling design to conduct the 2015 beta test of the QHP Enrollee Survey. CMS obtained clearance for the national implementation of the QHP Enrollee Survey which is currently being conducted in 2016. At this time, CMS is requesting approval of adding six disability status items required by section 4302 of the Affordable Care Act and that were tested during the 2014 psychometric testing of the QHP Enrollee Survey. With the addition of these six questions, the revised total estimated annual burden hours of national implementation of the QHP Enrollee Survey is 37,823 hours with 105,015 responses. The revised total annualized burden over three years for this requested information collection is 113,469 hours and the total average annualized number of responses is 315,045 responses. *Form Number:* CMS-10488 (OMB control number 0938-1221). *Frequency:* Annually; *Affected Public:* Public Sector (Individuals and Household), Private Sector (business or other for-profit and not-for-profit institutions); *Number of Respondents:* 105,015; *Total Annual*

*Responses:* 105,015; *Total Annual Hours:* 37,823. (For policy questions regarding this collection contact Nidhi Singh Shah at 301-492-5110.)

Dated: July 7, 2016.

**William N. Parham, III,**  
*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2016-16445 Filed 7-11-16; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the National Preparedness and Response Science Board

**AGENCY:** Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Preparedness and Response Science Board (NPRSB) will be holding a public teleconference.

**DATES:** The NPRSB will hold a public meeting on July 29, 2016, from 4:00 p.m. to 5:00 p.m. EST. The agenda is subject to change as priorities dictate.

**ADDRESSES:** Individuals who wish to participate should send an email to [NPRSB@HHS.GOV](mailto:NPRSB@HHS.GOV) with "NPRSB Registration" in the subject line. The meeting will occur by teleconference. To attend via teleconference and for further instructions, please visit the NPRSB Web site at [HTTP://WWW.PHE.GOV/NPRSB](http://WWW.PHE.GOV/NPRSB).

**FOR FURTHER INFORMATION CONTACT:** Please submit an inquiry via the NPRSB Contact Form located at: <http://www.phe.gov/Preparedness/legal/boards/nprsb/Pages/RFNBSBComments.aspx>.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 319M of the Public Health Service Act (42 U.S.C. 247d-7f) and section 222 of the Public Health Service Act (42 U.S.C. 217a), HHS established the NPRSB. The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to HHS regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The NPRSB may also provide advice and guidance to the Secretary and/or the Assistant Secretary for Preparedness and Response on other matters related to

public health emergency preparedness and response.

*Background:* This public meeting via teleconference will be dedicated to the NPRSB's deliberation and vote on the Public Health Emergency Medical Countermeasures Enterprise Medical Countermeasures Preparedness Assessment report. Subsequent agenda topics will be added as priorities dictate. Any additional agenda topics will be available on the NPRSB July 29, 2016, meeting Web page, available at [HTTP://WWW.PHE.GOV/NPRSB](http://www.phe.gov/nprsb).

*Availability of Materials:* The meeting agenda and materials will be posted prior to the meeting on the July 29th meeting Web page at [HTTP://WWW.PHE.GOV/NPRSB](http://www.phe.gov/nprsb).

*Procedures for Providing Public Input:* Members of the public are invited to attend by teleconference via a toll-free call-in phone number which is available on the NPRSB Web site at [HTTP://WWW.PHE.GOV/NPRSB](http://www.phe.gov/nprsb). All members of the public are encouraged to provide written comment to the NPRSB. All written comments must be received prior to July 29, 2016, and should be sent by email to [NPRSB@HHS.GOV](mailto:NPRSB@HHS.GOV) with "NPRSB Public Comment" as the subject line. Public comments received by close of business one week prior to each teleconference will be distributed to the NPRSB in advance.

Dated: July 5, 2016.

**Nicole Lurie,**

*Assistant Secretary for Preparedness and Response.*

[FR Doc. 2016-16409 Filed 7-11-16; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; 60-Day Comment Request; Palliative Care: Conversations Matter® Phase Two Evaluation**

**SUMMARY:** In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Nursing Research (NINR), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*To Submit Comments and for Further Information:* To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact\*: Ms. Diana Finegold, Office of Communications and Public Liaison, NINR, NIH, Building 31, Suite 5B03, 31 Center Drive, Bethesda, MD

20892, or call non-toll-free number (301) 496-0209, or Email your request, including your address to: [Diana.Finegold@nih.gov](mailto:Diana.Finegold@nih.gov). Formal requests for additional plans and instruments must be requested in writing.

*Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

*Proposed Collection: Palliative Care: Conversations Matter® Phase Two Evaluation, 0925-NEW, National Institute of Nursing Research (NINR), National Institutes of Health (NIH).*

*Need and Use of Information Collection:* The NINR *Palliative Care: Conversations Matter®* initiative, which launched in FY 2014, is now in its second phase. The first phase was focused on providing materials and tools to assist health care providers in having sometimes difficult conversations with children and families about palliative care. The second phase of the campaign, launched in FY 2015, focuses on children, parents, and families. The *Palliative Care: Conversations Matter®* Phase Two evaluation will assess the information and materials being disseminated to children, parents, and families. Survey findings will help (1) determine if the campaign is effective, relevant, and useful to the families and caregivers of children living with serious illnesses; (2) to better understand the information needs of families and caregivers to inform future campaign efforts; and (3) examine how effective the campaign materials are in providing families and caregivers with information on palliative care.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 400 hours.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Screener .....	Parents and Caregivers .....	10,000	1	2/60	333
Main Survey .....	Parents and Caregivers of Children with Serious Illnesses—Completes.	150	1	15/60	38
Main Survey .....	Parents and Caregivers of Children with Serious Illnesses—Non-Completes.	350	1	5/60	29
Total .....	.....	10,500	10,500	.....	400