

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)
Medical/Clinical Laboratory Technologist	57.307 Hemovigilance Adverse Reaction—Acute Hemolytic Transfusion Reaction.	500	4	25/60
Medical/Clinical Laboratory Technologist	57.308 Hemovigilance Adverse Reaction—Allergic Transfusion Reaction.	500	4	25/60
Medical/Clinical Laboratory Technologist	57.309 Hemovigilance Adverse Reaction—Delayed Hemolytic Transfusion Reaction.	500	1	25/60
Medical/Clinical Laboratory Technologist	57.310 Hemovigilance Adverse Reaction—Delayed Serologic Transfusion Reaction.	500	2	25/60
Medical/Clinical Laboratory Technologist	57.311 Hemovigilance Adverse Reaction—Febrile Non-hemolytic Transfusion Reaction.	500	4	25/60
Medical/Clinical Laboratory Technologist	57.312 Hemovigilance Adverse Reaction—Hypotensive Transfusion Reaction.	500	1	25/60
Medical/Clinical Laboratory Technologist	57.313 Hemovigilance Adverse Reaction—Infection.	500	1	25/60
Medical/Clinical Laboratory Technologist	57.314 Hemovigilance Adverse Reaction—Post Transfusion Purpura.	500	1	25/60
Medical/Clinical Laboratory Technologist	57.315 Hemovigilance Adverse Reaction—Transfusion Associated Dyspnea.	500	1	25/60
Medical/Clinical Laboratory Technologist	57.316 Hemovigilance Adverse Reaction—Transfusion Associated Graft vs. Host Disease.	500	1	25/60
Medical/Clinical Laboratory Technologist	57.317 Hemovigilance Adverse Reaction—Transfusion Related Acute Lung Injury.	500	1	25/60
Medical/Clinical Laboratory Technologist	57.318 Hemovigilance Adverse Reaction—Transfusion Associated Circulatory Overload.	500	2	25/60
Medical/Clinical Laboratory Technologist	57.319 Hemovigilance Adverse Reaction—Unknown Transfusion Reaction.	500	1	25/60
Medical/Clinical Laboratory Technologist	57.320 Hemovigilance Adverse Reaction—Other Transfusion Reaction.	500	1	25/60
Medical/Clinical Laboratory Technologist	57.400 Patient Safety Component—Annual Facility Survey for Ambulatory Surgery Center (ASC).	5,000	1	5/60
Staff RN	57.401 Outpatient Procedure Component—Monthly Reporting Plan.	5,000	12	15/60
Staff RN	57.402 Outpatient Procedure Component Event.	5,000	25	40/60
Staff RN	57.403 Outpatient Procedure Component—Monthly Denominators and Summary.	5,000	12	40/60
Staff RN	57.500 Outpatient Dialysis Center Practices Survey.	6,500	1	2.0
Registered Nurse (Infection Preventionist)	57.501 Dialysis Monthly Reporting Plan	6,500	12	5/60
Staff RN	57.502 Dialysis Event	6,500	60	25/60
Staff RN	57.503 Denominator for Outpatient Dialysis ..	6,500	12	10/60
Staff RN	57.504 Prevention Process Measures Monthly Monitoring for Dialysis.	1,500	12	1.25
Staff RN	57.505 Dialysis Patient Influenza Vaccination	325	75	10/60
Staff RN	57.506 Dialysis Patient Influenza Vaccination Denominator.	325	5	10/60
Staff RN	57.507 Home Dialysis Center Practices Survey.	600	1	25/60

Jeffrey M. Zirger,

Health Scientist, Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-0010]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request

to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the

proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS) (formerly titled The National Birth Defects Prevention Study (NBDPS)), (OMB 0920-0010, Expiration 01/31/2017)—Revision—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC has been monitoring the occurrence of serious birth defects and genetic diseases in Atlanta since 1967 through the Metropolitan Atlanta Congenital Defects Program (MACDP).

The MACDP is a population-based surveillance system for birth defects currently covering three counties in Metropolitan Atlanta.

Since 1997, CDC has funded case-control studies of major birth defects that utilize existing birth defect surveillance registries (including MACDP) to identify cases and study birth defects causes in participating states/municipalities across the United States.

The current study, BD-STEPS, is a case-control study that is similar to the previous CDC-funded birth defects case-control study, NBDPS, which stopped interviewing participants in 2013. As with NBDPS, BD-STEPS control infants are randomly selected from birth certificates or birth hospital records; mothers of case and control infants are interviewed using a computer-assisted telephone interview.

The results from NBDPS have improved understanding of the causes of birth defects. Over 200 articles have been written in professional journals using the data from NBDPS, and BD-STEPS data will soon be added to NBDPS data for analysis. The current BD-STEPS revision is an addition to the study population for two BD-STEPS Centers. Specifically, in these two Centers mothers of stillbirths without major birth defects will be added to the study population for BD-STEPS and mothers of all stillbirths (with and without birth defects) and all controls in these two Centers will be asked to participate in a supplemental telephone interview.

The BD-STEPS interview takes approximately forty-five minutes to complete (burden estimate includes both the introductory telephone script/consent and questionnaire). For five Centers, a maximum of 275 interviews are planned per year per center, 200 cases and 75 controls; for the two Centers participating in additional stillbirth interviews, 495 interviews are planned per center, 200 cases with birth

defects, 75 controls, and 220 stillbirths without birth defects. With seven centers planned, the maximum interview burden for all centers combined would be approximately 1,774 hours. Mothers in five of the seven BD-STEPS Centers will also be asked to provide consent for the study to access previously collected infant bloodspots. It takes approximately 15 minutes to read, sign and return the informed consent for retrieval of bloodspots. For approximately one fifth of participants, some medical records review will be conducted. The medical records release form takes participants approximately 15 minutes to read, sign and return. In addition, it takes approximately 30 minutes for each medical record reviewer to conduct the review and send the medical record. The online questionnaire will be offered to approximately one third of participants who report certain occupations during the telephone interview; these participants will be asked to complete additional occupational questions via a Web site which will take approximately 20 minutes to answer. In addition, in two Centers, mothers of stillbirths with and without birth defects and controls will be asked to participate in a supplemental telephone interview that will take approximately 25 minutes to complete.

Information gathered from both the interviews and the Deoxyribonucleic acid specimens has been and will continue to be used to study independent genetic and environmental factors as well as gene-environment interactions for a broad range of carefully classified birth defects.

This request is submitted to revise the previously estimated burden details and to request OMB clearance for three additional years. The total estimated annual burden hours are 3,034. There are no costs to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Activity	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Mothers (interview)	Telephone consent and BD-STEPS questionnaire.	2,365	1	45/60
Mothers (consent for bloodspot retrieval)	Written consent for bloodspot retrieval	1,375	1	15/60
Mothers (online occupational questionnaire) ..	Online Occupational Questionnaire	790	1	20/60
Mothers (consent for medical records review)	Written release for medical records review ...	475	1	15/60
Records reviewers (medical records review)	Pulling and sending records	475	1	30/60
Mothers of all AR/MA stillbirths and controls (supplemental telephone interview).	Telephone consent and supplemental questionnaire.	710	1	25/60

Jeffrey M. Zirger,

Health Scientist, Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living, Administration on Aging

Agency Information Collection Activities; Proposed Collection; Comment Request; State Annual Long-Term Care Ombudsman Report Revised Data Collection to the National Ombudsman Reporting System

AGENCY: Administration for Community Living, Administration on Aging, HHS.

ACTION: Notice.

SUMMARY: The Administration on Community Living, Administration on Aging (ACL/AoA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to the National Ombudsman Reporting System per 45 CFR part 1324.21 and Older Americans Act Title VII.

DATES: Submit written or electronic comments on the collection of information by October 7, 2016.

ADDRESSES: Submit electronic comments on the collection of information to: louise.ryan@acl.hhs.gov.

Submit written comments on the collection of information to: U.S. Department of Health and Human Services: Administration for Community Living 701 Fifth Avenue, Suite 1600 M/S RX-33, Seattle, WA 98104, Attention: Louise Ryan.

FOR FURTHER INFORMATION CONTACT: Louise Ryan by telephone: (206) 615-2514 or by email: louise.ryan@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with PRA (44 U.S.C. 3501-3520), the Administration for Community Living (ACL, formerly the Administration for Aging) has submitted

the following proposed collection of information to the Office of Management and Budget (OMB) for review and clearance. The Administration for Community Living/ Administration on Aging (ACL/AoA) is requesting approval from the Office of Management and Budget (OMB) for data collection associated with the National Ombudsman Reporting System (NORS).

The report form and instructions have been in continuous use, with minor modifications, since they were first approved by OMB for the FY 1995 reporting period. This request is for approval to revise the data collection tool to enhance ACL's ability to understand and report on: LTCO program operations, experience of long-term care facility residents and to update to reflect changes in: LTC Ombudsman program operations and long-term supports and services policies, research, and practices. States will continue to provide the following data and narrative information in the report:

1. Numbers and descriptions of cases filed and complaints made on behalf of long-term care facility residents to the statewide ombudsman program;
 2. Major issues identified impacting on the quality of care and life of long-term care facility residents;
 3. Statewide program operations; and
 4. Ombudsman activities in addition to complaint investigation.
5. Organizational conflict of interest reporting as required by 45 CFR part 1324.21.

With respect to the following collection of information, ACL/AoA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL/AoA's functions, including whether the information will have practical utility; (2) the accuracy of ACL/AoA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The proposed data collection tools may be found on the ACL/AoA Web site at: http://www.aoa.acl.gov/AoA_Programs/Elder_Rights/Ombudsman/index.aspx.

AoA estimates the burden of this additional collection of information as follows: Approximately 7780 hours,

with 52 state Ombudsman programs responding annually.

Dated: August 2, 2016.

Edwin L. Walker,

Acting Assistant Secretary for Aging.

[FR Doc. 2016-18736 Filed 8-5-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities: Submission for OMB Review; Comment Request; the National Maltreatment Reporting System

AGENCY: Administration for Community Living, HHS

ACTION: Notice

SUMMARY: The Administration for Community Living (formerly the Administration on Aging (AoA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. The purpose of this notice is to allow for an additional 30 days of public comment on the information collection requirements relating to the National Adult Maltreatment Reporting System (NAMRS). The proposed collection of information tools may be found in the NAMRS section of the ACL Web site.

DATES: Submit written comments on the collection of information by September 7, 2016.

ADDRESSES: Submit written comments on the collection of information to the Office of Management and Budget, Office for Information and Regulatory Affairs, Attention: Desk Officer for ACL by email: OIRA_submission@omb.eop.gov or fax: 202.395.6974.

FOR FURTHER INFORMATION CONTACT: Stephanie Whittier Eliason, Administration for Community Living, 330 C St. SW., Washington, DC 20201; email: stephanie.whittiereliason@acl.hhs.gov; telephone: 202.795.7467.

Copies of available documents submitted to OMB may be obtained by contacting Stephanie Whittier Eliason.

SUPPLEMENTARY INFORMATION: In compliance with PRA (44 U.S.C. 3501-3520), the Administration for Community Living (ACL, formerly the Administration for Aging) has submitted the following proposed collection of information to the Office of Management and Budget (OMB) for