DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–18–0891; Docket No. CDC–2018–0045]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled World Trade Center Health Program Enrollment, Treatment, Appeals & Reimbursement.

DATES: CDC must receive written comments on or before July 10, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0045 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all Federal comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate 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. Enhance 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 through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

World Trade Center Health Program Enrollment, Treatment, Appeals & Reimbursement (OMB Control No. 0920–0891, Expires 09/30/2018)—Revision—National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH seeks to request OMB approval to revise the currently approved information collection activities that support the World Trade Center (WTC) Health Program. The James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347, as amended by Pub. L. 114–113) created the WTC Health Program to provide medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001, or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

This request also seeks to incorporate the World Trade Center Health Program Petition for the addition of a New WTC-Related Health Condition for Coverage under the WTC Health Program package (0920–0929) into the existing approval, World Trade Center Health Program Enrollment, Appeals, Reimbursement, & Petitions (OMB Control No. 0920–0891). Upon approval, OMB Control number 0920–0929 will be discontinued.

Since its inception in 2011, the WTC Health Program has been approved to collect information from applicants and Program members (enrolled WTC responders and survivors) concerning eligibility and enrollment, appointment of a designated representative, medical care, travel reimbursement, and appeal of adverse Program decisions. The WTC Health Program is also currently approved to collect information from Program medical providers, including health condition certification requests and pharmaceutical claims. Currently approved total estimated burden is 13,594 hours annually (see OMB Control No. 0920–0891, exp. September 30, 2018).

The WTC Health Program has determined that some existing forms need to be updated, and new information collections related to a recent rulemaking should be added. Changes to WTC Health Program regulations in 42 CFR part 88 will require the extension of existing information collections. Specifically, 42 CFR 88.13 establishes procedures for the appeal of Program decisions to disenroll Program members and deny enrollment to applicants. Appeals of enrollment denial decisions, which include the submission of appeal request letters, are currently approved; the Program proposes to extend this information collection to account for the burden of requests for appeal of disenrollment decisions. Of the over 70,000 Program members, we expect that 0.014 percent (10) will be subsequently disenrolled from the Program. Of those, we expect that 30 percent (three) will appeal the disenrollment decisions. We estimate that the disenrollment appeal requests will take no more than 0.5 hours per respondent. The annual burden estimate is 1.5 hours.

Section 42 CFR 88.21 establishes procedures for the appeal of WTC

Health Program decisions to decertify a WTC-related health condition, deny certification, and deny treatment authorization. Appeals of health condition certification denials and treatment authorization denials, which include the submission of appeal request letters, are currently approved; the Program proposes to extend this information collection to account for the burden of requests for appeal of decertification decisions. The information collection would also be expanded to allow Program members to provide additional information and/or an oral statement. Of the estimated 51,472 Program members who have at least one health condition certification, we estimate that 0.02 percent (10) will be decertified, and 50 percent (five) of those will appeal a decertification. We estimate that the appeal request letter will take no more than 0.5 hours per respondent. Providing additional information and/or an oral statement will take no more than 1 hour per respondent. The annual burden estimate for decertification appeals is 7.5 hours.

We estimate that Program members request certification for 20,000 health conditions each year. Of those 20,000, we estimate that 1 percent (200) of certification requests are denied by the WTC Health Program. We further expect that 30 percent of denied certifications, or 60 individuals, will be appealed. We estimate that the appeals letter takes no more than 30 minutes and providing additional information and/or an oral statement will take no more than one hour. The burden estimate for certification denial appeals is 90 hours.

Of the projected 51,472 Program members who receive medical care, we estimate that 0.05 percent (26) will appeal a determination by the WTC Health Program that the treatment being sought is not medically necessary. We estimate that the appeals letter will take no more than 30 minutes and providing additional information and/or an oral statement will take no more than one hour. The burden estimate for treatment authorization denial appeals is 39 hours.

Finally, 42 CFR 88.23 establishes procedures for the appeal of a WTC Health Program decision to deny reimbursement to a Program medical provider for treatment determined not to be medically necessary. Accordingly, the Program proposes the addition of information collected in the appeal request. We estimate that of the nearly 52,000 Program providers, we estimate that 1.15 percent (600) annually will be denied reimbursement for treatment found to be not medically necessary or in accordance with treatment protocols, and will appeal the decision. We estimate that the appeal letter will take no more than 0.5 hours to compile. The burden estimate for treatment reimbursement denial appeals is 300 hours.

The Program also finds it necessary to add a new form to allow applicants and Program members to grant permission to share information with a third person about an individual's application or case. We estimate that 30 applicants and members will submit a Health Insurance Portability and Accountability Act (HIPAA) Release Form annually. The form will to take no longer than 0.25 hours to complete. The burden estimate for the HIPAA Release form is 7.5 hours.

In addition to describing those burden estimates revised by this action, the estimated annualized burden hours for those collection instruments not subject to revision in this action are included in the table below.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
FDNY Responder	World Trade Center Health Program FDNY Responder Eligibility Application.	45	1	30/60	23
General Responder	World Trade Center Health Program Responder Eligibility Application (Other than FDNY).	2,475	1	30/60	1,238
Pentagon/Shanksville Responder	World Trade Center Health Program Pentagon/Shanksville Responder.	630	1	30/60	315
WTC Survivor	World Trade Center Health Program Survivor Eligibility Application (all languages).	1,350	1	30/60	675
General responder	Postcard for new general responders in NY/NJ to select a clinic.	2,475	1	15/60	619
Program Medical Provider	Physician Request for Certification	20,000	1	30/60	10,000
Responder (FDNY and General Responder)/Survivor.	Denial Letter and Appeal Notification—Enrollment.	45	1	30/60	23
Responder (FDNY and General Responder)/Survivor.	Disenrollment Letter and Appeal Notification.	3	1	30/60	1.5
Responder (FDNY and General Responder)/Survivor.	Denial Letter and Appeal Notification—Health Condition Certification.	60	1	90/60	90
Responder (FDNY and General Responder)/Survivor.	Decertification Letter and Appeal Notification.	5	1	90/60	7.5
Responder (FDNY and General Responder)/Survivor.	Denial Letter and Appeal Notification—Treatment Authorization.	26	1	90/60	39
Responder (FDNY and General Responder)/Survivor.	WTC Health Program Medical Travel Refund Request.	10	1	10/60	2
Designated Rep Form	Form to designate a representative	30	1	15/60	7.5
HIPAA Release	Form to share member information	30	1	15/60	7.5
Pharmacy	Outpatient prescription pharmaceuticals.	150	261	1/60	653
Program Medical Provider	Reimbursement Denial Letter and Appeal Notification.	600	1	30/60	300

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Responder/Survivor/Advocate (physician).	Petition for the addition of health conditions.	60	1	60/60	60
Total					14,061

Jeffrey M. Zirger,

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.

[FR Doc. 2018–10067 Filed 5–10–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–18–0950; Docket No. CDC–2018–0040]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National Health and Nutrition Examination Survey (NHANES). NHANES programs produce descriptive statistics, which measure the health and nutrition status of the general population.

DATES: CDC must receive written comments on or before July 10, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0040 by any of the following methods:

- *Federal eRulemaking Portal: Regulation.gov.* Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: *Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.*

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;

2. Evaluate 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. Enhance 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 through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

The National Health and Nutrition Examination Survey (NHANES), (OMB Control Number 0920–0950, Expiration Date 12/31/2019)—Revision — National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability; environmental, social and other health hazards; and determinants of health of the population of the United States. The National Health and Nutrition Examination Surveys (NHANES) have been conducted periodically between 1970 and 1994, and continuously since 1999 by the National Center for Health Statistics, CDC.

NHANES programs produce descriptive statistics, which measure the health and nutrition status of the general population. With physical examinations, laboratory tests, and interviews, NHANES studies the relationship between diet, nutrition and health in a representative sample of the United States.

NHANES monitors the prevalence of chronic conditions and risk factors. NHANES data are used to produce national reference data on height, weight, and nutrient levels in the blood. Results from more recent NHANES can be compared to findings reported from previous surveys to monitor changes in