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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-0891]

[Docket No. CDC-2016-0099]

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 to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed revision to the "World Trade Center Health Program Enrollment, Treatment, Appeals & Reimbursement" information collection approved under OMB Control Number 0920-0891, which allows the collection of

information from Program members and affiliated medical providers for the purpose of determining eligibility and providing treatment services in accordance with the *James Zadroga 9/11 Health and Compensation Act of 2010*.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0099 by any of the following methods:

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

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: 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 OMB for approval. To comply

with this requirement, we are publishing this notice of proposed revisions to an existing data collection as described below.

Comments are invited on: (a) Whether the proposed revisions to an existing collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed revised collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. 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.

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 Publ. 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 (3) 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 (5) 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 1 hour. The burden estimate for certification denial appeals is 90 hours. Finally, 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 1 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 is expected 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 Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
FDNY Responder	World Trade Center Health Program FDNY Responder Eligibility Application	45	1	30/60	23
General Responder	World Trade Center Health	2,475	1	30/60	1,238

	Program Responder Eligibility Application (Other than FDNY)				
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	60	1	90/60	90

	Condition Certificatio n				
Responder (FDNY and General Responder)/ Survivor	Decertificat ion Letter and Appeal Notification	5	1	90/60	7.5
Responder (FDNY and General Responder)/S urvivor	Denial Letter and Appeal Notification -- Treatment Authorizatio n	26	1	90/60	39
Responder (FDNY and General Responder)/S urvivor	WTC Health Program Medical Travel Refund Request	10	1	10/60	2
Designated Rep Form	Form to designate a representati ve	10	1	15/60	3
HIPAA Release	Form to share member information	10	1	15/60	3
Pharmacy	Outpatient prescription pharmaceutic als	150	261	1/60	653
Program Medical Provider	Reimbursemen t Denial Letter and Appeal Notification	600	1	30/60	300
Responder/Su rvivor/Advoc ate (physician)	Petition for the addition of health conditions	60	1	60/60	60
Total					14,052

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Office of the Associate Director for Science
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