



**BILLING CODE: 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-16-16KA; Docket No. CDC-2016-0011]**

**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 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 newly proposed information collection project entitled "Monitoring and Coordinating Personal Protective Equipment (PPE) in Healthcare to Enhance

Domestic Preparedness for Ebola Response". The development of an ongoing Personal Protective Technology (PPT) sentinel surveillance system in the hospital setting will document data used to evaluate and monitor use and effectiveness for PPE usage in healthcare workers including Ebola protection.

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-2016-0011 by any of the following methods:

Federal eRulemaking Portal: [Regulation.gov](http://www.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, 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](http://www.Regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](http://www.Regulations.gov).

Please note: All public comment should be submitted through the Federal eRulemaking portal ([Regulations.gov](https://www.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 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](mailto: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 a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed 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 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

Monitoring and Coordinating Personal Protective Equipment (PPE) in Healthcare to Enhance Domestic Preparedness for Ebola Response - New - National Center for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

## Background and Brief Description

The National Institute for Occupational Safety and Health (NIOSH) has the authority under the Occupational Safety and Health Act [29 CFR § 671] to "develop recommendations for health and safety standards", to "develop information on safe levels of exposure to toxic materials and harmful physical agents and substances", and to "conduct research on new safety and health problems". There is growing national concern for better understanding of the particular personal protective equipment (PPE) needs of healthcare workers to ensure the health and safety of this workforce during times of pandemic disease or bioterrorist threat. The use and effectiveness of the proper PPE are paramount to the management and mitigation of the effects of a disaster. NIOSH is requesting a three approval from OMB to develop an ongoing PPT sentinel surveillance system in the hospital setting that will document data used to evaluate and monitor use and effectiveness for PPE usage in healthcare

workers including Ebola protection.

NIOSH conducted a pilot study and partnered with four hospitals where respirator-related data were collected from a variety of stakeholders (less than 10 respondents) including Infection Control, Occupational Health, Emergency Preparedness, Environmental Health & Safety, and Purchasing. Surveillance metrics were established and shared with pilot participants on a regular basis throughout the pilot. Partners identified key performance indicators that this data might provide, such as the average number of respirators used per isolation order in the hospital, and identification of stakeholders and protocols impacting effective respirator use. Recommendations were made for monitoring schedules and survey improvement. The data collected during the pilot study provided experience and knowledge of respirator selection, availability, fit testing, usage patterns, outcomes, and confounders of respirator use and effectiveness at the four participating hospitals.

NIOSH now seeks approval to execute an approach for a minimum viable product (MVP) multi-hospital (15-20), real-time monitoring phase. The 15-20 facilities shall reflect the tiered approach recommended by CDC involving Frontline Healthcare Facilities, Ebola Assessment Hospitals and Ebola Treatment Centers. The effort shall be built upon the experience and knowledge obtained from the pilot projects, and shall be

structured as the next step in the establishment of a national system to monitor usage and training for PPE used to protect against the Ebola virus based on current CDC recommendations. With this effort, the contractor shall develop and deploy the system to include a contingent of the domestic acute healthcare facilities in this three tier approach. The system content shall include status information for all PPE categories identified for protection against the hazards of Ebola exposure. The system will use a general interface engine designed to accept, validate, and process data from multiple, disparate sources.

The system will be developed to identify PPE replenishment needs to facilitate local, state, and eventually regional resource sharing and local purchasing as needed. It will also be compatible with PPE previously used at these facilities to allow seamless continuity of patient care and worker protection. This capacity will offer a much-improved process for monitoring and maintaining appropriate PPE supplies through the constant, real-time monitoring of user demand, thus avoiding the misdirection of tens of millions of dollars' worth of respirators and other PPE to facilities that may not use distributed supplies due to a mismatch between products typically used and the supplies provided.

Respondents targeted for this study include hospital managers (also referred to in some cases as executives,

coordinators or supervisors). These individuals are responsible for the day-to-day administration and/or implementation of the MVP. It is estimated that a sample of up to 20 hospitals will agree to participate among a variety of Ebola and Frontline treatment facilities. Participation will require no more than 255 minutes of workers' time per quarter. The hospitals will complete a baseline form and will also send quarterly and annual response as explained in the table below.

The Emergency and Crisis surveys are administered to hospitals via text message. The emergency survey is designed for an event spanning multiple weeks (e.g., pandemic). There are 3 preset questions that are related to Ebola and PPT supply concerns. The crisis survey is designed for an unanticipated scenario in which we may need to push ad hoc questions on a daily basis to hospitals. They will only be administered in a non-routine situation. During the 3 year approval period, we will test/train hospitals on each survey. However, they will not be part of the regular data collection.

#### Estimated Annualized Burden Hours

The following is an explanation of the number of respondents for the annualized burden table. The baseline form is completed once by each hospital as they come onboard (20/3 = 7 rounded up). The annual form is completed by the hospitals in

each year following their onboarding. Example: year one, 5 hospitals onboarded; year two 6 new + 5 from previous year; year three 9 new + 11 from previous years. Thus, taking the sum of the previous year hospitals leads to 16 total ( $16/3 = 5$  rounded down). The quarterly form is completed by all onboarded hospitals four times a year. The emergency and crisis forms are completed on all onboarded hospitals as needed but at least once for training and use the annualized number in the baseline form.

| Type of Respondent | Form Name | Number of Respondents | Number of Responses per respondent | Average Burden per Response (in hours) | Total Burden per respondent (Hours) |
|--------------------|-----------|-----------------------|------------------------------------|--|-------------------------------------|
| Hospital           | Baseline  | 7                     | 1                                  | 8                                      | 56                                  |
| Hospital           | Annual    | 5                     | 1                                  | 3                                      | 15                                  |
| Hospital           | Quarterly | 12                    | 4                                  | 3                                      | 144                                 |
| Hospital           | Emergency | 7                     | 4                                  | 15/60                                  | 7                                   |
| Hospital           | Crisis    | 7                     | 7                                  | 10/60                                  | 8                                   |
| Total              |           |                       |                                    |  | 230 hours                           |

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Leroy A. Richardson,  
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Office of Scientific Integrity,  
Office of the Associate Director for Science,  
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