DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–20–20LW]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled National Healthcare Safety Network (NHSN) Coronavirus (COVID–19) Surveillance in Healthcare Facilities, to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on April 16, 2020 to obtain comments from the public and affected agencies. CDC has received six comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(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. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Healthcare Safety Network (NHSN) Coronavirus (COVID–19) Surveillance in Healthcare Facilities—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC) collects data from healthcare facilities in the National Healthcare Safety Network (NHSN) under OMB Control Number 0920–0666. NHSN is a public health surveillance system that collects, analyzes, reports, and makes available data for monitoring, measuring, and responding to healthcare associated infections (HAIs), antimicrobial use and resistance, blood transfusion safety events, and the extent to which healthcare facilities adhere to infection prevention practices and antimicrobial stewardship.

On March 11, 2020, the World Health Organization declared COVID–19 a pandemic, and the President of the United States (U.S.) proclaimed the outbreak a national emergency on March 13, 2020. As rates of infection continue to rise across the U.S., healthcare facilities and public health departments are facing significant strain on patient care and infection prevention efforts.

In response to the COVID–19 pandemic, NHSN has planned and introduced new COVID–19 modules in the Patient Safety Component, Long-term Care and Dialysis Components that enable hospitals, long-term care facilities and ambulatory hemodialysis facilities to report daily COVID–19 patient counts to NHSN, and NHSN in turn will enable state and local health departments to gain immediate access to the COVID–19 data reported by healthcare facilities in their jurisdictions via existing NHSN groups. NHSN's role as a shared platform for HAI surveillance provides a valuable foundation for COVID–19 surveillance. This information is used to inform the overall real-time COVID–19 response efforts and possible resource allocation, including an understanding of cases that are community-acquired versus healthcare-associated. CDC and health departments alike will use this surveillance data to prioritize the allocation of resources and response efforts.

The COVID–19 Module in the Patient Safety Component was used for daily reporting by approximately 60% of the nation's hospitals from late March until July 15th, 2020. The July 13, 2020 HHS Guidance for Hospital Reporting and FAQ removed NHSN as a reporting option for hospitals to continue fulfilling the HHS and White House requested COVID–19 data reporting.

NHSN released the COVID–19 Module in the existing NHSN Long Term Care (LTC) Component on April 27, 2020, to collect data from long term care facilities (LTCFs) on confirmed and suspected resident COVID–19 cases and deaths, number of beds and access to testing, staff and personnel shortages and cases of COVID–19 and deaths, personal protective equipment availability, and ventilator availability. As with the initial data collection tool approved under Emergency OMB Control No. 0920–1290, facility-level data collected through NHSN as part of the COVID–19 modules are being made available to a broader set of federal, state, and local agency data users than data typically collected by NHSN. Specifically, COVID–19 data at the state, county, territory, and facility level submitted to NHSN will continue to be used for public health emergency response activities by CDC's emergency COVID–19 response, by the U.S. Department of Health and Human Services' (HHS) COVID–19 tracking system maintained in the Office of the Assistant Secretary of Preparedness and Response as part of the National Response Coordination Center at the Federal Emergency Management Agency (FEMA), and by the White House Coronavirus Task Force.

COVID–19 poses an unprecedented threat to older populations living in long-term care facilities, as well as healthcare and non-healthcare workers taking care of these residents and their homes. Examples of LTCFs include nursing homes, chronic care facilities for the developmentally disabled, skilled nursing facilities, and assisted living facilities. As rates of infection and resulting mortality across LTCFs continue to rise across the nation, LTCFs are facing significant barriers in facility capacity, staffing, and supplies, such as personal protective equipment.

These barriers pose significant risk of COVID–19 transmission and infections. Understanding the facilitators and barriers that impact these vulnerable populations is critical to the effective pandemic response across LTCFs.

The objectives of the data collection are to: (1) Determine the impact of COVID–19 among residents and facility workers, including morbidity and mortality (2) determine the nursing home capacity for housing suspected and confirmed cases, including in-house testing abilities; (3) identify staffing shortages among care givers and other facility personnel; (4) identify personal protective availability in the facility; and (5) to identify the availability and use of mechanical ventilators in LTCF with ventilator dependent units.

In support of filling the gaps in COVID–19 data from nursing homes, the Centers for Medicare and Medicaid Services (CMS) and CDC are partnering in an unprecedented data coordination effort with U.S. nursing homes to help fight COVID–19. On May 8, 2020, CMS published an Interim Final Rule with Comment Period that requires nursing homes to report cases of COVID–19 directly to CDC via NHSN. CMS also requires nursing homes to fully cooperate with CDC surveillance efforts around COVID–19 spread and will make the data publicly available. Failure to report a case of COVID–19 or persons under investigation (PUI), may result in an enforcement action. CMS is now requiring LTCFs report at a minimum the following data to NHSN no less than weekly:

(1) Facility name, address and CMS Certification Number;

(2) Number of beds in the facility;

(3) Current census of the facility;

(4) Number of current residents who are confirmed cases;

(5) Number of current residents who are suspected cases; and

(6) Number of deaths among residents who are either confirmed COVID–19 cases or suspected COVID–19 cases.

(7) Number of staff with suspected and confirmed COVID–19.

(8) Staffing shortages.

(9) PPE shortages.

CMS introduced this reporting requirement for national surveillance of COVID–19 in nursing homes. Long-term care facilities are primarily responsible for ensuring, in real time, they have adequate staffing and are taking measures to mitigate any infectious disease occurrences among residents or staff. CMS' role is to hold facilities accountable for the care they provide to their residents. CMS is also providing technical assistance to nursing homes through a variety of mechanisms based on needs identified via this data collection. Finally, the associated enforcement is focused on ensuring facilities report their data to NHSN in order inform CDC, FEMA, the White House Coronavirus Task Force, and public health departments at all levels of the magnitude of the pandemic, as well as resource allocation and medical capacity in nursing homes.

In Fall 2020, NHSN plans to release a COVID–19 Dialysis Module in the existing NHSN Dialysis Component. This Module will be used to collect voluntarily-reported data from ambulatory hemodialysis facilities on confirmed and suspected patient COVID–19 cases and deaths, staff and personnel shortages and cases of COVID–19 and deaths, personal protective equipment availability, and access to diagnostic testing. As with the LTC Module, facility-level data collected through NHSN as part of the COVID–19 Modules are being made available to a broader set of federal, state, and local agency data users than data typically collected by NHSN. Specifically, COVID–19 data at the state, county, territory, and facility level submitted to NHSN will continue to be used for public health emergency response activities by CDC's emergency COVID–19 response, by the U.S. Department of Health and Human Services' (HHS) COVID–19 tracking system maintained in the Office of the Assistant Secretary of Preparedness and Response as part of the National Response Coordination Center at the Federal Emergency Management Agency (FEMA), and by the White House Coronavirus Task Force. There will be no cost to respondents other than their time to complete the COVID–19 Module data fields on a weekly basis.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
LTCF personnel	NHSN and Secure Access Management Services (SAMS) enrollment.	11,500	1	60/60
LTCF personnel	COVID–19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form (57.144).	11,621	52	40/60
Business and financial operations occupations.	COVID–19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form (57.144).	1,870	52	40/60
State and local health department occupations.	COVID–19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form (57.144).	1,870	52	40/60
LTCF personnel	COVID–19 Module, Long Term Care Facility Resident Impact and Facility Capacity form (57.144) (retrospective data entry).	5,811	1	40/60
Business and financial operations occupations.	COVID–19 Module, Long Term Care Facility Resident Impact and Facility Capacity form (57.144) (retrospective data entry).	935	1	40/60
State and local health department occupations.	COVID–19 Module, Long Term Care Facility Resident Impact and Facility Capacity form (57.144) (retrospective data entry).	935	1	40/60
LTCF personnel	COVID–19 Module, Long Term Care Facility: Staff and Personnel Impact form (57.145).	11,621	52	15/60
Business and financial operations occupations.	COVID–19 Module, Long Term Care Facility: Staff and Personnel Impact form (57.145).	1,870	52	15/60
State and local health department occupations.	COVID–19 Module, Long Term Care Facility: Staff and Personnel Impact form (57.145).	1,870	52	15/60
LTCF personnel	COVID–19 Module, Long Term Care Facility Staff and Personnel Impact form (57.145) (retrospective data entry).	5,811	1	15/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Business and financial operations occupations.	COVID–19 Module, Long Term Care Facility Staff and Personnel Impact form (57.145) (retrospective data entry).	935	1	15/60
State and local health department occupations.	COVID–19 Module, Long Term Care Facility Staff and Personnel Impact form (57.145) (retrospective data entry).	935	1	15/60
LTCF personnel	COVID–19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form (57.146).	11,621	52	15/60
Business and financial operations occupations.	COVID–19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form (57.146).	1,870	52	15/60
State and local health department occupations.	COVID–19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form (57.146).	1,870	52	15/60
LTCF personnel	COVID–19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form (57.147).	11,621	52	5/60
Business and financial operations occupations.	COVID–19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form (57.147).	1,870	52	5/60
State and local health department occupations.	COVID–19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form (57.147).	1,870	52	5/60
Microbiologist (IP)	COVID–19 Dialysis Component Form	4,900	104	20/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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[30Day–20–0138]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Pulmonary Function Testing Course Approval Program to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on June 2, 2020 to obtain comments from the public and affected agencies. CDC received one non-substantial comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(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. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Pulmonary Function Testing Course Approval Program. (OMB Control No. 0920–0138, Exp. 11/30/2020)—Revision—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH has the responsibility under the Occupational Safety and Health Administration's Cotton Dust Standard, 29 CFR 1920.1043, for approving courses to train technicians to perform pulmonary function testing in the cotton industry. Successful completion of a NIOSH-approved course is mandatory under this Standard. In addition, regulations at 42 CFR 37.95(a) specify that persons administering spirometry tests for the national Coal Workers 'Health Surveillance Program must successfully complete a NIOSH-approved spirometry training course and maintain a valid certificate by periodically completing NIOSH-approved spirometry refresher training courses. Also, 29 CFR 1910.1053(i)(2)(iv), 29 CFR 1910.1053(i)(3), 29 CFR 1926.1153(h)(2)(iv) and 29 CFR 1926.1153(h)(3) specify that pulmonary function tests for initial and periodic examinations in general industry and construction performed under the respirable crystalline silica standard should be administered by a spirometry technician with a current certificate from a NIOSH-approved spirometry course. NIOSH is requesting a three-year approval.

To carry out its responsibility, NIOSH maintains a Pulmonary Function