National Healthcare Safety Network (NHSN) Coronavirus (COVID-19) Surveillance in Healthcare Facilities

Request for OMB approval of a New Information Collection

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Supporting Statement A

Contact:
Lauren Wattenmaker
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333
Phone: (404) 718-5842
Email: nlh3@cdc.gov

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- **Goal of the study:** The goal of this information collection is to 1) capture the daily, aggregate impact of COVID-19 on healthcare facilities, and 2) monitor medical capacity to respond at local, state, and national levels.
- **Intended use of the resulting data:** This information will be used to inform the overall real-time COVID-19 response efforts and possible resource allocation and enable state and local health departments to gain immediate access to the COVID-19 data for healthcare facilities within their jurisdiction.
- **Methods to be used to collect:** The data for National Healthcare Safety Network (NHSN) reporting is collected via a secure internet application (e.g., prospective cohort design; randomized trial; etc.)
- **The subpopulation to be studied:** The respondent universe for this information collection request is U.S. healthcare facilities.
- **How data will be analyzed:** COVID-19 data on patients, healthcare facility capacity, and supplies will be calculated and summarized.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP) requests approval for a new information collection, “National Healthcare Safety Network (NHSN) Coronavirus (COVID-19) Surveillance in Healthcare Facilities.”

On March 11, 2020, the World Health Organization declared COVID-19 a pandemic, and President Trump 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. Forthcoming waves of COVID-19 infections, predicted from historical pandemic experience and anticipated in models of COVID-19 activity, coupled with regional variations in disease burden, already evident across the nation, place a premium on standing up and supporting a surveillance module that can provide standardized data that are timely, easy to interpret, and readily accessible for multiple end users at all geographic levels. NHSN introduced new COVID-19 Modules in the Patient Safety Component and the Long Term Care Component that enable hospitals and long-term care facilities (LTCFs) to report daily COVID-19 patient counts to NHSN, and NHSN in turn enables state and local health departments to gain immediate access to the COVID-19 data for healthcare facilities in their jurisdiction. While additional data collection poses new burden on NHSN users in hospitals and LTCFs, the new Module is tightly targeted in terms of data collection requirements and designed to enable the COVID-19 data to be immediately available for pandemic responses by state and local health departments, and multiple federal intra- and inter-agency entities, including end users in the Veterans Health Administration and Department of

Defense. To the fullest extent, input from these end users has been sought actively and included in the new Modules' design. Further, reporting to a single system, NHSN, and enabling COVID-19 data sharing with organizations and agencies that have integral roles in pandemic response will obviate or substantially reduce requirements that would otherwise call for NHSN users to submit patient impact data to multiple systems. Leveraging the existing platform that the vast majority of U.S. hospitals currently use for reporting healthcare-associated infection (HAI) and antimicrobial resistance data, CDC is augmenting NHSN to assist hospitals and LTCFs with COVID-19 case reporting by streamlining data sharing with local, state, and national partners. Facility-level data collected through NSHN 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.[1]

In further response to the COVID-19 pandemic—and more acutely to the particular challenges facing nursing homes during this crisis—CDC developed a COVID-19 Module in the existing NHSN Long Term Care (LTC) Component that will be used 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. The new forms are included as attachments 9-12.

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.

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[1] Members of the White House Coronavirus Task Force are listed here:
https://www.whitehouse.gov/briefings-statements/vice-president-pence-secretary-azar-add-key-administration-officials-coronavirus-task-force-2/
https://www.whitehouse.gov/briefings-statements/statement-press-secretary-regarding-presidents-coronavirus-task-force/

This information collection is authorized by Section 301 of the Public Health Service Act (42 USC 242b, 242k, and 242m (d)) (Attachments 1a-1c).

2. Purpose and Use of Information Collection

The data collected under this information collection request (ICR) will be used immediately by CDC's emergency COVID-19 response at the national level as well as to enable state and local health departments to gain immediate access to the COVID-19 data for healthcare facilities in their jurisdiction. A significant gap currently exists for healthcare facility-level data on COVID-19 case reporting from U.S. LTCFs. It is critically important to address this gap, as facility-level data will be able to inform federal, state, and local approaches as well as inform resource allocation. This facility-level data, which will be reported to NHSN daily, is necessary to inform CDC and public health departments at all levels of the magnitude of the outbreak, as well as medical capacity in healthcare facilities. Via direct data access in NHSN, CDC and health departments will have the ability to make comparisons among facilities and needs assessments based on analysis of reported data.

Most health departments do not have an existing, standardized mechanism for accessing this data from facilities in their jurisdictions. Often, they piece together surveillance reports from individual facilities, with data arriving at different times and from disparate systems and routes of communication, some formal and some informal. NHSN COVID-19 data, standardized and immediately available to public health agencies will enable multiple agencies and organizations to assess and act rapidly both within their traditional domain and in cross-domain collaborations. Resource allocation decisions can be guided by patient impact and hospital bed capacity data that will help identify hospitals and LTCFs and/or geographic areas that are disproportionately affected or overwhelmed by patients with COVID-19.

COVID-19 patient surveillance data will be reported to NHSN by infection preventionists (IPs) who are already familiar with the NHSN interface and reporting procedures (Attachment 4). State and local health departments will be able to gain immediate access to this data reported by facilities in their jurisdictions via the existing NHSN group function, a technical feature within the NHSN application that enables healthcare facilities to share some or all of their NHSN data with a NHSN group user, i.e., a third party (other than the facility and CDC) such as a corporate headquarters or a state or local health department. This information will be used to inform the overall real-time COVID-19 response efforts and possible resource allocation, including an improved understanding of confirmed and suspected cases that are community-acquired versus healthcare-associated, meaning onset of suspected or confirmed COVID-19 fourteen or more days after a patient was hospitalized. CDC and health departments alike will use this surveillance data to prioritize the allocation of resources and response efforts.

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 to 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.

HHS additionally announced on September 3, 2020 a Provider Relief Fund (PRF) performance-based incentive payment distribution to nursing homes that will utilize data from the NHSN LTCF COVID-19 module. Data from this module will be used to assess nursing home performance and determine incentive payments.

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.

NHSN is currently approved under OMB Control No. 0920-0666 (expiration date: 12/31/2022). Since 2005, NHSN has provided healthcare facilities, states, regions, and the nation with the data desired to identify healthcare-associated infection (HAI) and antimicrobial resistance problem areas, measure the progress of prevention efforts, and ultimately eliminate HAIs in conjunction with driving the achievement of the overall mission of the Department of Health and Human Services (DHHS). As of March 2020, enrollment in NHSN has continuously increased, with over 25,000 enrolled healthcare facilities and over 22,500 actively reporting healthcare facilities across the U.S. Of these, there are over 5,700 acute care facilities; 8,100 dialysis facilities; 600 long-term acute care facilities, 430 free-standing inpatient rehabilitation facilities; 800 inpatient psychiatric facilities; over 3,800 long-term care facilities; and 5,580 ambulatory surgery facilities.

All data for NHSN is collected via a secure internet application, and NHSN participation is open to all U.S. healthcare facilities. Reporting institutions can access their own data at any time and analyze it through the secure internet interface. As with HAI data, NHSN plans to use COVID-19 data aggregated from multiple hospitals to establish and update statistical benchmarks of disease burden at various geographic levels, including state and national, that can be shared with individual hospitals within the NHSN application and in online reports without compromising NHSN's commitment to preserving the confidentiality of each hospital's data.

In effect, NHSN serves as a multi-purpose platform that consolidates healthcare-associated infections (HAI) - related reporting and analysis functions into one system, with a single set of data definitions, reporting specifications, and summary statistics. NHSN is an extensible platform that enables coverage to be expanded, both by enrolling additional types of healthcare facilities, such as long-term care facilities (LTCFs), and by adding or further specifying reportable event types, such as surgical site infections (SSIs) following operative procedures in ambulatory surgical centers (ASCs) and adverse reactions during or following administration of blood products.

3. Use of Improved Information Technology and Burden Reduction

All data reported to NHSN are collected via a secure internet application. Only the minimum amount of information necessary for data collection is requested. Institutions that participate in

NHSN are required to have a computer and Internet Service Provider (ISP), and they must provide the salaries of the data collectors and data entry personnel. These expenses would not exceed what is normally expended for a typical healthcare facility infection surveillance program. While the paper forms are provided for data collection, facilities are not required to use them for entry of data into NHSN. Data reported in these new modules will be submitted by manually entering directly into the web-based application or by uploading a CSV file.

4. Efforts to Identify Duplication and Use of Similar Information

NHSN is the only national system that collects surveillance data on healthcare-associated infections, infection prevention process measures, healthcare personnel safety measures, such as blood and body fluid exposures and vaccination practices, and adverse events related to the transfusion of blood and blood products. While there are other organizations within DHHS and the Federal Government that are working to capture data on COVID-19 from hospitals, NHSN is the only existing surveillance system positioned to quickly receive and transmit such data directly from additional healthcare facilities such as LTCFs and dialysis centers. The existing platform allows facilities to share data immediately with local, state, and national partners for impact monitoring, decision-making, and surveillance activities.

The NHSN COVID-19 Modules are designed to standardize the data elements collected across the country regarding the impact of the COVID-19 emergency on healthcare facilities. Current efforts at data collection are individualized at each state and local region. In collecting standardized data, NHSN provides a vendor-neutral platform and a national lens into the burden hospitals are experiencing in a way that is designed to support the public health response. We are able to take on this task because NHSN is a platform that exists in nearly all acute-care hospitals, nursing homes, and dialysis facilities in the US and can provide a secure, sturdy infrastructure.

As a new development feature added to NHSN during the public health emergency, NHSN now accepts data submitted as a bulk upload from multiple facilities at one time. This approach to data submission eases the burden on facilities by enabling health systems, state health departments, hospital associations, and vendors with NHSN experience to upload data for multiple facilities at once. We are able to work directly with vendors (examples include Cerner, Premier, and BD who are all current NHSN users) because we have long-standing relationships with them; they submit data to us on a regular basis for our Patient Safety Surveillance programs. For vendors that are particular to this emergency incident management space (Juvare, EMResource), we have established a technical solution for them to submit on behalf of facilities and states as well.

We have developed a streamlined set of data elements in NHSN to provide a signal for a public health response without undue data collection.

5. Impact on Small Businesses or Other Small Entities

Some of the respondents may be considered small businesses. However, data collection variables are kept to an absolute minimum to minimize burden on these entities. Participation in the COVID-19 modules is completely voluntary. Many infection preventionists (IPs) are already responsible for COVID-19 case counting and/or tracking in their hospitals. To the fullest extent, the COVID-19 modules are designed to enable IPs to submit data they are collecting and reporting already. Impact or burden on rural hospitals and other small care entities is not expected to be more than their larger peers.

6. Consequences of Collecting the Information Less Frequently

As COVID-19 has been declared a pandemic and national emergency, healthcare facilities are already actively conducting routine surveillance and monitoring medical capacity in order to minimize exposure of the virus to patients and healthcare personnel. At least weekly collection of this information is imperative for the public health and safety of communities, and the nature of the situation changes rapidly on a day to day basis. Thus collecting the data less often than weekly could place patients, residents, and personnel at even greater risk.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. Because this was initially a request for an emergency clearance, CDC asked that the 60-day public comment period be waived. However, a 60-day Federal Register notice was submitted to make the public aware of this investigation (Attachment 2) and published 4/17/2020 (85 FR 21443). CDC received six public comments to the Federal Register Notice and has responded accordingly.

B. DHQP was contacted and urged by private industry representatives and DHHS emergency response leadership to develop a reporting mechanism in NHSN for COVID-19 patient counts in healthcare facilities. Comments in response to the 60-day *Federal Register* notice urged CDC to lessen the burden on hospitals for reporting COVID-19 information to NHSN. 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, thus hospitals no longer have a reporting burden for COVID-19 data to NHSN.

9. Explanation of Any Payment or Gift to Respondents

No monetary incentive is provided to NHSN participants.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by NCEZID who determined that the Privacy Act does not apply (Attachment 3). The CDC Office of General Counsel (OGC) has also determined that the Privacy Act does not apply to this data collection. The CDC OGC believes that NHSN, as it is currently being utilized by CDC, is not a Privacy Act system of records and provides case law to support this determination (Henke v. U.S. Department of Commerce and Fisher v. NIH). Specifically, the OGC stated that "The CDC NHSN system is similar to the computerized information in both the Henke and Fisher cases. While CDC can retrieve data by personal identifier, CDC does not, as a matter of practice or policy, retrieve data in this way. Specifically, the primary practice and policy of CDC regarding NHSN data are to retrieve data by the name of the hospital or another non-personal identifier, not an individual patient, for surveillance and public health purposes. Furthermore, patient identifiers are not necessary for NHSN to operate, and the CDC does not regularly or even frequently use patient names to obtain information about these individuals."

An Assurance of Confidentiality is granted for all data collected under NHSN. NHSN's Assurance of Confidentiality, states the following;

> "*the voluntarily provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).*"

The current NHSN Assurance of Confidentiality expires on December 31, 2020.

The use of NHSN for COVID-19 surveillance is voluntary. While the Privacy Act is not applicable, in accordance with the stringent safeguarding that must be in place for 308(d) assurance of confidentiality protected projects, all the safeguarding measures are still in effect. These include the use of a password issued via CDC's Secure Access Management System for access to the application; data encryption using Secure Socket Layer technology; and lastly, storage of data in password protected files on secure computers in locked, authorized-access-only rooms.

This data collection effort is consistent with the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA), which expressly permits disclosures without individual

authorization to public health authorities authorized by law to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to public health surveillance, investigation, and intervention.

As NHSN group users, health departments are custodians of the data to which they gain access via the NHSN group functionality, and they are responsible for establishing, using, and maintaining appropriate administrative, technical, and physical safeguards to prevent unauthorized access or use of the NHSN data to which they have gained access. The confidentiality protections that CDC commits to providing healthcare facilities that participate in NHSN cover CDC's custodianship and use of the NHSN data for the purposes listed in the NHSN Agreement to Participate and Consent Form. However, CDC's confidentiality protections do not extend to NHSN groups; NHSN group users are responsible for assuring the confidentiality of the data to which they gain access.

Health department group users assume data governance responsibilities for how analysts and researchers within their organizations or external to them gain access to and use the accessible NHSN data. These responsibilities include use of data non-disclosure agreements and, when appropriate, data use agreements (DUAs), such as DUAs with external analysts and researchers whose access to NHSN data has been enabled by the NHSN group user. A DUA for analytic work that goes beyond the purposes and plans that a NHSN group user previously communicated to the healthcare facilities participating in the group should be accompanied by an informed consent process, which can be accomplished via email communications, in which facilities have the opportunity to reject use of their NHSN data for the additional purpose(s).

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

For the participating healthcare institutions, data are collected in this system for the purposes of local surveillance and program evaluation. DHQP aggregates the data for national surveillance and public health practice evaluation purposes. No primary research will be conducted as part of this data collection effort, and no patient consent forms will be used. Although this is not a research project, a NHSN protocol was submitted for ethical review to the CDC Institutional Review Board (IRB) and was approved (Protocol #4062, exp. 05/18/05). The most recent request for amendment and continuation was approved on 08/29/06 and expired on 05/18/07. Subsequently, in consultation with NCEZID senior staff, the program was advised that the activities of the NHSN are surveillance and evaluation of public health practice and that IRB review is no longer required, therefore the protocol has been closed (Attachments 5 and 6).

Justification for Sensitive Questions

The reporting of adverse events associated with healthcare can be sensitive unless the institution is assured that the data aggregating organization will provide security for the data and maintain

the institution’s confidentiality. As discussed in item A.10 above, NHSN is authorized to assure confidentiality to its participating individuals and institutions for voluntarily submitted data.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

As of September 1, 2020, there are 15,361 unique CMS-certified skilled nursing facilities/ nursing facilities reporting to the NHSN LTC COVID-19 Module. The bulk upload function added to NHSN on April 9, 2020, enables external entities to report COVID-19 data on behalf of facilities in their NHSN groups. Such entities include state and local health departments, state hospital associations, corporate health systems, and IT vendors. Approximately 3,740 LTCFs report via the bulk upload feature. We have heard from many small and rural facilities that will be completing COVID-19 manually. Conversely, we have heard from many health systems representatives and other group users that seek to reduce burden on reporting LTCFs by uploading data on their behalf.

We have estimated that the COVID-19 LTCF forms will take an average of 75 minutes to complete weekly, knowing that the reporting burden includes surveillance and data entry. We further estimate that LTCF users will report these data on a weekly basis. The Module allows retrospective data collected from previous dates to be entered. Because OMB PRA approval is requested for 365 days, the total number of responses per respondent is 52.

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total burden (in hours)
LTCF personnel	NHSN and Secure Access Management Services (SAMS) enrollment	11,500	1	60/60	11,500
LTCF personnel	COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form (57.144)	11,621	52	40/60	40 2,861

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	4,827 6
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	4,827 6
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	3,874
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	623
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	623

LTCF personnel	COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form (57.145)	11,621	52	15/60	15 1,073
Business and financial operations occupations	COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form (57.145)	1,870	52	15/60	2 4,310
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	2 4,310
LTCF personnel	COVID-19 Module, Long Term Care Facility Staff and Personnel Impact form (57.145) (retrospective data entry)	5,811	1	15/60	1,453
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	234
state and local health department occupations	COVID-19 Module, Long Term Care	935	1	15/60	234

	Facility Staff and Personnel Impact form (57.145) (retrospective data entry)				
LTCF personnel	COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form (57.146)	11,621	52	15/60	15 1,073
Business and financial operations occupations	COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form (57.146)	1870	52	15/60	2 4,310
State and local health department occupations	COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form (57.146)	1870	52	15/60	2 4,310
LTCF personnel	COVID-19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form (57.147)	11,621	52	5/60	5 0,358
Business and financial operations occupations	COVID-19 Module, Long Term Care Facility: Ventilator Capacity &	1,870	52	5/60	8,103

	Supplies form (57.147)				
State and local health department occupations	COVID-19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form (57.147)	1,870	52	5/60	8,103
Microbiologist (IP)	COVID-19 Dialysis Component Form	4900	104	20/60	169,867
Total					1,186,873

B. Estimated Annualized Burden Costs

The average salary of the professional discipline that is expected to perform surveillance has been used in the calculations of burden and is based on data from the Department of Labor, Bureau of Labor & Statistics, May 2018 (https://www.bls.gov/oes/2018/may/oes191022.htm). Those most likely to complete this surveillance are Microbiologists/ LTCF personnel at a senior (75th percentile average wage) level. We have estimated that the bulk upload of data on behalf of long-term care facilities will be completed by a wide variety of professionals from the various group user categories listed above in 12. A. Therefore we are using an average hourly wage for business and financial operations occupations and for state and local health department occupations to estimate average burden costs.

Type of Respondent	**Form Name**	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
LTCF personnel	NHSN and Secure Access Management Services (SAMS) enrollment	11,500	$50.91	$585,465
LTCF personnel	COVID-19 Module, LTC: Resident Impact and Facility	402,861	50.91	$20,509,654

	Capacity form			
64,827 Business and financial operations occupations	COVID-19 Module, LTC: Resident Impact and Facility Capacity form	64,827	37.56	$2,434,902
State and local health department occupations	COVID-19 Module, LTC: Resident Impact and Facility Capacity form	64,827	40.21	$2,606,694
LTCF personnel (retrospective data entry)	COVID-19 Module, LTC: Resident Impact and Facility Capacity form	3,874	50.91	$197,225
Business and financial operations occupations (retrospective data entry)	COVID-19 Module, LTC: Resident Impact and Facility Capacity form	623	37.56	$23,400
State and local health department occupations (retrospective data entry)	COVID-19 Module, LTC: Resident Impact and Facility Capacity form	623	40.21	$25,051
LTCF personnel	COVID-19 Module, LTC: Staff and Personnel Impact form	151,073	50.91	$7,691,126
Business and financial operations occupations	COVID-19 Module, LTC: Staff and Personnel Impact form	24,310	37.56	$913,084
State and local health department occupations	COVID-19 Module, LTC: Staff and Personnel Impact form	24,310	40.21	$977,505

234 234 151,073 24,310 LTCF personnel (retrospective data entry)	COVID-19 Module, LTC: Staff and Personnel Impact form	1,453	50.91	$73,972
Business and financial operations occupations (retrospective data entry)	COVID-19 Module, LTC: Staff and Personnel Impact form	234	37.56	$8,789
State and local health department occupations (retrospective data entry)	COVID-19 Module, LTC: Staff and Personnel Impact form	234	40.21	$9,409
LTCF personnel	COVID-19 Module, LTC: Supplies & Personal Protective Equipment form	151,073	50.91	$7,691,126
Business and financial operations occupations	COVID-19 Module, LTC: Supplies & Personal Protective Equipment form	24,310	37.56	$913,084
State and local health department occupations	COVID-19 Module, LTC: Supplies & Personal Protective Equipment form	24,310	40.21	$977,505
LTCF personnel	COVID-19 LTC: Ventilator Capacity & Supplies form	50,358	50.91	$2,563,726
Business and financial operations	COVID-19 LTC:	8,103	37.56	$304,349

occupations	Ventilator Capacity & Supplies form			
State and local health department occupations	COVID-19 LTC: Ventilator Capacity & Supplies form	8,103	40.21	$325,822
Microbiologist (Infection Preventionist)	Dialysis COVID-19 form	169,867	50.91	$8,647,929
Total				$57,479,817

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents other than their time to participate.

14. Annualized Cost to the Government

We do not estimate that this new ICR will pose additional cost to the government beyond what is already approved for NHSN under OMB Control No. 0920-0666. Nonetheless, we recognize that weekly burden for reporting COVID-19 counts to NHSN is significant.

NHSN approved OMB Control No. 0920-0666 planned for a new Neonatal component in June/July, but we moved this project to December 2020. Doing so has made development and staffing resources available for the COVID-19 Modules, so that there will be no additional incurred costs associated with this data collection.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

NHSN is an ongoing data collection system and as such does not have an annual timeline. The data are reported on a continuous basis by participating institutions and aggregated by CDC into a national database that is analyzed for two main purposes: to describe the epidemiology of healthcare-associated adverse events, and to provide comparative data for populations with similar risks. Comparative data can be used by participating and by non-participating healthcare institutions that collect their data using NHSN methodology. The reporting institutions will be able to access their data at any time and analyze them through the internet interface.

Reports containing aggregated data will be produced annually and posted on the NHSN website, http://www.cdc.gov/nhsn. The report is also published annually in a scientific journal to make NHSN data widely available. Other in-depth analysis of data from NHSN will be published in peer-reviewed journals and presented at scientific and professional meetings. The proposed modifications to NHSN will not alter the plans for tabulation, publication, nor the schedule.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB Expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

Attachment 1a – 42 USC 242b

Attachment 1b – 42 USC 242k

Attachment 1c – 42 USC 242m

Attachment 2 – Draft 60-day FRN

Attachment 3 – PIA

Attachment 4 – How to Enter and Access COVID-19 Summary Data

Attachment 5 – Closure of CDC Protocol #4062

Attachment 6 – NHSN Report of End of Human Research Review

Attachment 7 – COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form

Attachment 8 – COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form

Attachment 9 – COVID-19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form

Attachment 10 – COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form

Attachment 11- COVID-19 Dialysis Component Form