National Healthcare Safety Network (NHSN) Patient Impact Module for Coronavirus (COVID-19) Surveillance in Healthcare Facilities

Request for OMB approval of a New Information Collection

March 25, 2020

Supporting Statement A

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Table of Contents

- **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 hospitals 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. Patient-level data will not be collected.
- **How data will be analyzed:** Daily counts of COVID-19 patients 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 a 180-day emergency approval for a new information collection, "National Healthcare Safety Network (NHSN) Modules for 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 plans to introduce new COVID-19 Modules in the Patient Safety Component and the Long Term Care Component that will enable hospitals and long-term care facilities (LTCFs) 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 for hospitals in their jurisdiction. While additional data collection poses new burden on NHSN users in hospitals and LTCFs, the new Modules are 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 Module's 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]

NHSN's role as a shared platform for healthcare-associated infection surveillance provides a valuable foundation for COVID-19 surveillance. NHSN estimates that over 95% of all acute care hospitals, long term acute care hospitals, and inpatient rehabilitation facilities in the U.S. participate in NHSN, largely because of local, state, and federal reporting requirements. From one third to one half of all critical access hospitals also participate. Infection preventionists (IPs) in those hospitals have extensive experience submitting data to NHSN, adhering to the system's surveillance protocols, and using their own data and national benchmarks provided by NHSN for prevention and control purposes. The COVID-19 Modules will involve no patient-level data collection. The data may be submitted using manual entry or by uploading a comma separated values (CSV) file.

In further response to the COVID-19 pandemic—and more acutely to the particular challenges facing nursing homes during this crisis—CDC is developing 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.

[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 hospitals and LTCFs in their jurisdiction. A significant gap currently exists for healthcare facility-level data on COVID-19 case reporting from U.S. hospitals and 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 Patient Impact 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 IPs who are already familiar with the NHSN interface and reporting procedures (Attachments 4a and 4b). 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. Metrics collected in NHSN will include:

- Number of and proportion of all currently hospitalized patients in inpatient care locations with suspected or confirmed COVID-19
- Number of and proportion of all currently hospitalized patients in inpatient care locations with suspected or confirmed COVID-19 that are on mechanical ventilators

- Number of patients with suspected or confirmed COVID-19 who are currently in the emergency department (ED) or any overflow locations awaiting an inpatient bed
- Number of and proportion of inpatient COVID-19 patients with suspected or confirmed COVID-19 with onset 14 or more days after initial hospitalization due to a condition other than COVID-19 (most likely healthcare-associated)
- Proportion of inpatient beds occupied by those who are suspected or confirmed with COVID-19 (or proportion of inpatients who are suspected or confirmed with COVID-19)

In the metrics listed above, "suspected COVID-19" is defined as a patient without a laboratory confirmed COVID-19 diagnosis who has signs and symptoms compatible with COVID-19 (most patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness, such as cough, difficulty breathing). "Confirmed COVID-19" is defined as a patient with a laboratory confirmed COVID-19 diagnosis.

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 April 19, 2020, CMS announced new regulatory requirements that will require nursing homes to report cases of COVID-19 directly to CDC via NHSN (see announcement linked here). CMS' memo also reiterates nursing homes' longstanding requirements to report cases of infectious disease to their State and local health departments. Finally, CMS will also require 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), CMS warns in its guidance, 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 is introducing 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.

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, NHSN is the only existing surveillance system positioned to quickly receive and transmit such data directly from healthcare facilities. 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 Module is designed to standardize the data elements collected across the country regarding the impact of the COVID-19 emergency on acute-care 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 in the US and can provide a secure, sturdy infrastructure.

Beginning April 10th, NHSN will be able accept data submitted as a bulk upload from multiple hospitals at one time. This approach to data submission eases the burden on hospitals by enabling health systems, state health departments, hospital associations, and vendors with NHSN experience to upload data for multiple hospitals at once. We are able to work directly with vendors (examples include Cerner, Premier, 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 one vendor who is particular to this emergency incident management space (Juvare, EMResource), we are establishing a technical solution for them to submit on behalf of hospitals and states as well. Since they are not current NHSN users, we are establishing a secure pathway for them.

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. Daily 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 daily could place patients 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 is a request for an emergency clearance, CDC asks that the 60-day public comment period be waived. However, a 60-day *Federal Register* notice will be submitted to make the public aware of this investigation (Attachment 2).

B. DHQP has been 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.

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 April 7, 2020, 6,234 inpatient care facilities are enrolled in NHSN. We estimate that half of these facilities will participate in voluntarily reporting of COVID-19 case data via the NHSN Patient Impact and Healthcare Personnel Impact Modules. This estimate is based on previous response rates for voluntary data collections within NHSN completed by NHSN enrolled facilities. The bulk upload function added to NHSN on April 9, 2020, will enable 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. Due to this technical feature being a completely new function in NHSN, we do not have any baseline data for estimating burden to bulk upload. We are estimating that one-third of all eligible hospitals and LTCFs will 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 hospitals and LTCFs by uploading data on their behalf.

We have estimated that the Patient Impact Module form will take an average of 25 minutes to complete daily, knowing that the reporting burden includes surveillance and data entry. We further estimate that IPs will report this data on a daily basis. Even if reporting to NHSN is not completed on Saturdays and Sundays, data from those days will likely be entered into NHSN on Monday. The calendar-based data entry for this module allows retrospective data collected from previous dates to be entered. Because OMB PRA approval is requested for 180 days, the total number of responses per respondent is 180.

As of April 14, 2020, there are approximately 15,446 long term care facilities listed in the CMS Nursing Home Compare database. Since CMS will require these facilities to participate in data collection and reporting, we estimate that 95% of these facilities will report COVID-19 case data. This estimate is

based on previous response rates for data collections within NHSN completed by NHSN enrolled facilities.

We have estimated that the COVID-19 LTCF forms will take an average of 55 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 180 days, the total number of responses per respondent is 26.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Microbiologist (IP)	COVID-19 Patient Impact Module Form	2079	180	25/60	155,925
Business and financial operations occupations	COVID-19 Patient Impact Module Form	519	180	25/60	38,925
State and local health department occupations	COVID-19 Patient Impact Module Form	519	180	25/60	38,925
Microbiologist (IP)	COVID-19 Healthcare Worker Form	2079	180	25/60	155,925
Business and financial operations occupations	COVID-19 Healthcare Worker Form	519	180	25/60	38,925
State and local health department occupations	COVID-19 Healthcare Worker Form	519	180	25/60	38,925
Microbiologist (IP)	COVID-19 Supplies Form	2079	180	25/60	155,925
Business and financial operations occupations	COVID-19 Supplies Form	519	180	25/60	38,925
State and local health department occupations	COVID-19 Supplies Form	519	180	25/60	38,925
Microbiologist (IP)	COVID-19 Module, Long	9,782	26	15/60	63,583

	Term Care Facility: Staff and Personnel Impact form				
Business and financial operations occupations	COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form	2,446	26	15/60	15,899
State and local health department occupations	COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form	2,446	26	15/60	15,899
Microbiologist (IP)	COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form	9,782	26	20/60	84,777
Business and financial operations occupations	COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form	2,446	26	20/60	21,199
State and local health department occupations	COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form	2,446	26	20/60	21,199
Microbiologist (IP)	COVID-19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form	9,782	26	5/60	21,194
Business and	COVID-19	2,446	26	5/60	5,300

financial operations occupations	Module, Long Term Care Facility: Ventilator Capacity & Supplies form				
State and local health department occupations	COVID-19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form	2,446	26	5/60	5,300
Microbiologist (IP)	COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form	9,782	26	15/60	63,583
Business and financial operations occupations	COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form	2,446	26	15/60	15,899
State and local health department occupations	COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form	2,446	26	15/60	15,899
Total					1,051,056

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 at a senior (75th percentile average wage) level. We have

estimated that the bulk upload of data on behalf of hospitals and 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
Microbiologist infection preventionist (IP)	COVID-19 Patient Impact Module Form	155,925	$50.91	$7,938,141.75
Business and financial operations occupations	COVID-19 Patient Impact Module Form	25,950	$37.56	$974,682
State and local health department occupations	COVID-19 Patient Impact Module Form	25,950	$40.21	$1,043,449.50
Microbiologist (IP)	COVID-19 Healthcare Worker Form	155,925	$50.91	$7,938,141.75
Business and financial operations occupations	COVID-19 Healthcare Worker Form	25,950	$37.56	$974,682
State and local health department occupations	COVID-19 Healthcare Worker Form	25,950	$40.21	$1,043,449.50
Microbiologist (IP)	COVID-19 Supplies Form	155,925	$50.91	$7,938,141.75
Business and financial operations occupations	COVID-19 Supplies Form	25,950	$37.56	$974,682
State and local health department occupations	COVID-19 Supplies Form	25,950	$40.21	$1,043,449.50
LTCF personnel	COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form	63,583	$50.91	$3,237,011
Business and	COVID-19	15,899	$37.56	$597,166

financial operations occupations	Module, Long Term Care Facility: Staff and Personnel Impact form			
State and local health department occupations	COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form	15,899	$40.21	$639,299
LTCF personnel	COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form	84,777	$50.91	$4,315,997
Business and financial operations occupations	COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form	21,199	$37.56	$796,234
State and local health department occupations	COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form	21,199	$40.21	$852,412
LTCF personnel	COVID-19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form	21,194	$50.91	$1,078,987
Business and financial operations occupations	COVID-19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form	5,300	$37.56	$199,068
State and local health	COVID-19 Module, Long	5,300	$40.21	$213,113

department occupations	Term Care Facility: Ventilator Capacity & Supplies form			
LTCF personnel	COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form	63,583	$50.91	$3,237,011
Business and financial operations occupations	COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form	15,899	$37.56	$597,166
State and local health department occupations	COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form	15,899	$40.21	$639,299
Total				$46,271,582

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 daily burden for reporting COVID-19 counts to NHSN is significant. We emphasize that this is a voluntary collection, and during intense pressure on hospitals, the focus should remain on lifesaving work.

Further, CMS has suspended HAI reporting requirements and will not count data through June 30, 2020, which enables NHSN FTEs and contractors who would otherwise provide support to NHSN users for HAI data submissions to shift to support for COVD-19 reporting. NHSN's contractual obligations are additionally shifting to COVID-19 development and user support and away from support for HAI modules. NHSN's infection preventionists (IPs), data analysts, and user support staff are unlikely to

have the usual volume of HAI help requests in the coming months. Additionally, 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 180-day 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 4a – COVID-19 Patient Impact Module Form

Attachment 4b – Instructions for COVID-19 Patient Impact Module Form

Attachment 4c – 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 – NHSN COVID-19 Module Healthcare Worker Staffing form

Attachment 8 – NHSN COVID-19 Supplies form

Attachment 9 – COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form

Attachment 10 – COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form

Attachment 11 – COVID-19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form

Attachment 12 – COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form