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

Request for OMB approval of a Revision to 0920-1317

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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 hospitals, 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. hospitals.
  - **How data will be analyzed:** COVID-19 data on patients, healthcare facility capacity, and supplies will be calculated and summarized.

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 three-year approval for a revision to the "National Healthcare Safety Network (NHSN) Modules for Coronavirus (COVID-19) Surveillance in Healthcare Facilities."

1. Circumstances Making the Collection of Information Necessary

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. NHSN 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. 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.

Before July 10, 2020, HHS permitted the use of submission of data via the NHSN COVID-19 module, Teletracking, or other mechanisms, including the use of EHRs for direct submission. The data fields requested were agnostic of submission vehicle.

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 purpose of this inherently duplicative approach was to ensure hospitals began collecting this critical data expeditiously, consciously leveraging hospitals' long-standing familiarity and use of NHSN. However, as our experience grew throughout the pandemic, it became clear that this duplication was not effective and was an additional burden on the respondents and on the Department to maintain and update as the response and the associated data needs changed. Thus, on July 10, 2020 HHS discontinued collection using National Healthcare Safety Network, which was collecting similar information. This single collection (along with collections intermediated through state health departments) represent the source for hospitalization information related to COVID-19 feeding the HHS Protect platform. To reduce duplication of effort across the broader system, HHS makes available this data to state health departments through HHS Protect and to the broader public through HealthData.gov (in various forms of aggregation to protect individual persons/entities). This collection is transitioning back to CDC's NHSN beginning mid-December 2022 because the Teletracking contract ends December 31, 2022.

NHSN's COVID-19 reporting modules are currently approved under OMB Control No. 0920-1317, expiration 12/31/2023. 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 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.

NHSN accepts 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 established a technical solution for them to submit on behalf of hospitals and states as well. Since they are not current NHSN users, we have established 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 60-day Federal Register Notice was published in the Federal Register on September 12th, 2022 vol. 87, No. 175, pp. 55815 (Attachment 2). CDC received 2 public comments related to this notice. See responses in Attachment 4a and 4b.

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, 2025.

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

There are no start-up costs, beyond customary and usual business practices that a hospital incurs to maintain inventories of beds, maintain inventories of supplies, and manage basic metrics associated with hospital utilization. Hospitals may choose, at their discretion, to provide this information collection through automated means (direct File Transfer Protocol Secure (FTPS), etc.). In this case, there are various configuration costs that may be incurred to automate the response to this collection. For example, a hospital could create reports in their business intelligence systems to support ease of information collection. Due to the variability of complex, multi-hospital systems vs. small acute care facilities (who may be manually counting),

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
LTCF personnel	NHSN and Secure Access Management Services (SAMS) enrollment	11,500	1	60/60	11,500

LTCF personnel, Business and financial operations occupations, State and local health department occupations	COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form (57.144)	16,512	52	60/60	858,624
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	151,073

Business and financial operations occupations	COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form (57.145)	1,870	52	15/60	24,310
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	24,310
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 Facility Staff and Personnel Impact form (57.145) (retrospective data	935	1	15/60	234

	entry)				
LTCF personnel	COVID-19 Module, Long-Term Care Facility: Resident Therapeutics (57.158)	11,621	52	10/60	100,715
Business and financial operations occupations	COVID-19 Module, Long-Term Care Facility: Resident Therapeutics (57.158)	1,870	52	10/60	16,207
State and local health department occupations	COVID-19 Module, Long-Term Care Facility: Resident Therapeutics (57.158)	1,870	52	10/60	16,207
LTCF personnel	LTCF VA Resident COVID-19 Event Form	188	36	35/60	3,948
LTCF personnel	LTCF VA Staff and Personnel COVID-19 Event Form	188	36	20/60	2,256
Facility personnel	Weekly Healthcare Personnel COVID-19 Vaccination Cumulative Summary	12,600	52	90/60	982,800
LTCF personnel	Weekly Resident COVID-19 Vaccination Cumulative Summary for Long-Term Care Facilities	16,864	52	75/60	1,096,160
Microbiologist (IP)	Weekly Patient COVID-19	7,700	52	75/60	500,500

	Vaccination Cumulative Summary for Dialysis Facilities				
LTCF personnel	Monthly Reporting Plan form for Long-term Care Facilities	16,864	9	5/60	12,648
Microbiologist (IP)	Healthcare Personnel Safety Monthly Reporting Plan - completed by Dialysis Facilities	7,700	9	5/60	5,775
Microbiologist (IP)	Healthcare Personnel Safety Monthly Reporting Plan - completed by Inpatient Psychiatric Facilities	394	12	5/60	394
Microbiologist (IP)	COVID-19 Dialysis Component Form	7,700	104	25/60	333,667
Hospitals	NHSN COVID-19 Hospital Module	6000	365	90/60	3,285,000
Infusion Centers and Outpatient Clinics reporting Inventory & use of	NHSN COVID-19 Hospital Module	400	52	15/60	5,200

therapeutics (MABs)					
Total					7,438,335

Estimated Annualized Respondent 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 Capacity form	402,861	50.91	$20,509,654
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	3,874	50.91	$197,225

	Facility Capacity form			
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
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	151,073	50.91	$7,691,126

	Protective Equipment form			
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 occupations	COVID-19 LTC: Ventilator Capacity & Supplies form	8,103	37.56	$304,349
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
Hospital Staff – Registered Nurses and Other Administrative Staff Persons		3,285,000	$70.48	$231,526,800
Infusion Center Staff – Registered Nurses and Other Administrative Staff Persons		5,200	$70.48	$366,496
Total				$289,373,113

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.

15. Explanation for Program Changes or Adjustments

This is a revision to an existing collection NHSN COVID-19 (0920-1317).

Beginning July 2020, at the request of the White House Coronavirus Task Force, this collection was sent to HHS/ASPR and housed in the TeleTracking portal. The National Healthcare Safety Network (NHSN) will assume responsibility for collection of COVID-19 hospital data mid-December 2022. This revision will cause an increase in burden hours in the amount of 3,662,498. There will also be a revision in burden cost in the amount of $231,893,296

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.

Attachments

1. Authorizing Legislation
2. 60-Day FRN
3. Information Collection instrument
4. Additional attachments (IRB, scripts, consent forms, etc.)
5. (a-c) Authorizing Legislation
6. Published 60-day FRN
7. Privacy Act Documentation
8. 60-day comment period:
    a. Public comment and response 1
    b. Public comment and response 2
9. Human Research Review
10. IRB Closure
11. Information Collection instrument