National Healthcare Safety Network (NHSN) COVID-19
OMB Control No. 0920-1317

Expiration 3/31/2026

Revision ICR

Supporting Statement A

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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 and respiratory viruses 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 and respiratory virus response efforts and possible resource allocation and enable state and local health departments to gain immediate access to the COVID-19 and respiratory virus 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 and respiratory virus data on patients will be calculated and summarized. Reporting institutions can access their own data at any time and

1. Circumstances Making the Collection of Information Necessary

Overview

The Centers for Disease Control and Prevention (CDC) is requesting a 3-year approval for revisions made to OMB Control No. 0920-1317 for the National Healthcare Safety Network (NHSN) Modules for Coronavirus (COVID-19) Surveillance in Healthcare Facilities. Data collection is currently approved for 2,766,084 annual burden hours and is due to expire on March 31, 2026. CDC NHSN reviewed all data collection forms in this package. The proposed changes in this ICR includes revisions made to 10 approved NHSN data collection tools and 2 new forms, for a total of 12 forms in this package. CDC requests OMB approval for an estimated 1,752,540 annual burden hours. This Revision ICR provides complete discussion and justification of all information collection plans.

Background

The Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC) collects COVID-19 and respiratory virus data from healthcare facilities in the National Healthcare Safety Network (NHSN) under OMB Control Number 0920-1317. 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 and other respiratory viruses on healthcare facilities. 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.

This information collection is authorized by Section 301 of the Public Health Service Act (42 USC 242b, 242k, and 242m (d)) (Attachments A1-3).

2. Purpose and Use of Information Collection

The data collected under OMB Control No. 0920-1317 are used for the following purposes:

- Estimation of the magnitude of COVID-19 and respiratory virus infections
- Monitoring of COVID-19 and respiratory virus trends to identify problem areas and measure the progress of prevention efforts.
- Facilitation of inter-facility and intra-facility comparisons with risk-adjusted data that can be used for local quality improvement activities.
- Assistance to facilities in developing surveillance and analysis methods that permit timely recognition of patient safety problems and prompt intervention with appropriate measures.
- Development of clinical quality measures that can be used as a benchmark for healthcare facilities reporting data to NHSN to measure their own performance. One of the goals is to eventually—as a result, measure experience, and measure enhancements or other changes as needed—as summary statistics that can be publicly reported for multiple healthcare facilities and serve as metrics for externally evaluating their care and incentivizing quality and patient safety.
- Comply with legal requirements – including but not limited to state or federal laws, regulations, or other requirements – for mandatory reporting of healthcare facility-specific adverse event, prevention practice adherence, and other public health data.
- Enable healthcare facilities to report COVID-19 and respiratory virus data and prevention practice adherence data via NHSN to the Centers for Medicare and Medicaid Services (CMS) in fulfillment of CMS's quality measurement reporting programs including those data.
- Provide state and local health departments with information that identifies the healthcare facilities in their state that participate in NHSN.
- Provide to state and local agencies, at their request, facility specific, NHSN patient safety component and healthcare personnel safety component adverse event and prevention practice adherence data for surveillance, prevention, and/or mandatory public reporting.

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 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. 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. 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 can 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.

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. 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

Many adverse events associated with healthcare, occur in both endemic and epidemic patterns. It is in the best interest of healthcare institutions to conduct routine prospective surveillance of COVID-19 and other respiratory virus infections and prevention actives in an ongoing manner to identify trends in endemic rates as well as outbreaks, so that potential problems may be identified in a timely manner and appropriate measures instituted to minimize the number of affected patients or healthcare personnel. Collecting the data sporadically or less often than required by NHSN could potentially place patients at risk.

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

This request fully complies with the regulation 5 CFR 1320.5.

CDC/NHSN Justification for Sensitive Questions (Race, Ethnicity, and Gender Identity):

NHSN collects secondary source data from healthcare facilities rather than primary source data directly from patients/individuals. Therefore, NHSN is limited to collecting only what Race, Ethnicity, and Gender Identity data that exist in the electronic health record (EHR) and is dependent on national data exchange standards to drive updates to the way the data are collected and made available for reporting to NHSN.

Certified EHR systems are required to comply with federal interoperability standards for health information technology. To minimize data collection burden on healthcare facilities, NHSN collects data for Race, Ethnicity, and Gender Identity in alignment with base Health Level Seven (HL7) and The Office of the National Coordinator for Health Information Technology (ONC) United States Core Data for Interoperability (USCDI) standardized terminology that is implemented in EHRs.

NHSN worked with the Health Level Seven (HL7) Gender Harmony Project to utilize the standardized terminology that is implemented in EHRs to minimize data collection burden on facilities. The NHSN Gender Identity response options are adapted from current Gender Identity USCDI Core value set published in Value Set Authority Center (VSAC) and utilized by EHR vendors for Clinical Document Architecture (CDA) submission of data.

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for Interoperability (USCDI) standardized terminology that is implemented in EHRs. CDC NHSN is working to implement the new OMB guidance as soon as possible, but no later than the required date of March 28, 2029. NHSN is working with the Office of the National Coordinator (ONC) to update their standards to coincide with OMB's directives, but this takes time to work through the process. We are in the process of complying with the guidelines and data fields in the OMB packages with the first step being the addition of MENA as a Race choice on the data collection forms. Due to NHSN's heavy dependency on secondary source data (i.e., data collected within electronic health record [EHRs] vendors) we cannot collect data according to OMB guidance until EHR vendors comply with this directive. EHR vendors (e.g. Epic, Cerner) have until January 1, 2026, to meet Cures Act requirements, and implement the United States Core Data for Interoperability (USCDI) version 3, which includes CDC Race and Ethnicity Code Set Version 1.2 that complies with OMB guidance. NHSN will continue to collect Race and Ethnicity data separately until such time when EHR vendors are able to align with OMB guidance. NHSN's target is to update data collection forms to comply with the OMB directive by January 1, 2026.

USCDI Core represents a standardized set of health data elements defined by the Office of the National Coordinator (ONC) for interoperability. This is a set of essential health data elements that should be included when exchanging patient information electronically, ensuring a minimum level of data is always available across different systems. VSAC (Value Set Authority Center) is a repository for public value sets of standardized codes used to define clinical concepts. Provided by the National Library of Medicine, in collaboration with the Office of the National Coordinator for Health Information Technology (ONC) and Centers for Medicare & Medicaid Services (CMS), VSAC is a repository where sets of standardized clinical codes (from standard clinical terminologies like SNOMED CT, LOINC) are stored and curated, allowing for consistent interpretation of data elements, which supports effective and interoperable health information (data) exchange. CDA (Clinical Document Architecture) is a standardized format for structuring and exchanging clinical documents, like progress notes or discharge summaries, ensuring that the data elements (defined by USCDI and coded using VSAC) are presented in a consistent and organized manner when exchanged between healthcare providers. EHR vendors utilize CDA to electronically transmit data to the NHSN.

USCDI, VSAC, and CDA work together to ensure consistent and meaningful exchange of patient health information across different healthcare systems and public health entities; essentially, USCDI specifies the core data needed, VSAC provides the standardized codes to represent these data, and CDA provides the structure to package and transmit the data.

VSAC is a repository and authoring tool for public value sets created by external programs. Value sets are lists of codes and corresponding terms, from NLM-hosted standard clinical vocabularies (such as SNOMED CT®, RxNorm, LOINC® and others), that define clinical concepts to support effective and interoperable health information exchange. The VSAC provides downloadable access to all official versions of value sets specified by the Centers for Medicare & Medicaid Services (CMS) electronic Clinical Quality Measures (eCQMs). The VSAC does not create value set content and requires a license to obtain access to the value sets. For information on CMS eCQMs, visit the eCQI Resource Center. The

VSAC is provided by the National Library of Medicine (NLM), in collaboration with the Office of the National Coordinator for Health Information Technology (ONC) and CMS. https://vsac.nlm.nih.gov/.
Reference websites

HealthIT.gov Interoperability Standards Platform
https://www.healthit.gov/isp/uscdi-data-class/patient-demographicsinformation#uscdi-v2
https://www.healthit.gov/isp/representing-patient-gender-identity
Representing Patient Race and Ethnicity | Interoperability Standards Platform (ISP)

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 June 4th, 2024, vol. 89, No. 108, pp. 47962 (Attachment B). CDC received 4 public comments related to this notice. See comments in Attachments B1-B4 . Three of the commenters did not provide their contact information, so we are unable to respond. One commenter agreed with the collection of COVID-19 and other respiratory virus data; thus, the comment was deemed unsubstantial.

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 G). 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. See Attachments F1 and F2.

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 (Attachment E 1-3).

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

The tables below provide the burden hours and cost estimates for the proposed NHSN data collection tools. Completion of the NHSN data collection tools is required for participation in NHSN, participation in a CMS reporting program, or to fulfill state or local reporting mandates. To estimate annualized burden hours and costs, the number of respondents is first determined by the number of facilities that report to NHSN by component and includes projected growth or reductions in facilities reporting during the ICR period. For forms that are required for participation in NHSN or a CMS reporting program, CDC calculates burden based on a 100 percent response rate, whereas an estimated response rate less than 100 percent is calculated for those forms that are voluntary or optional. CDC then considers the burden associated with surveillance, data entry, analysis, and validation to determine the amount of time required for each form to be considered complete. Annual labor rates reported by the U.S. Department of Labor are used to calculate the annual burden costs based on the hourly rate of pay for health professionals most qualified to complete NHSN data submission.

The proposed changes in this new ICR includes revisions made to 10 approved NHSN data collection tools and 2 new forms, for a total of 12 proposed data collection forms, with a total estimated annual burden of 1,752,540 hours. There is no cost to respondents other than their time to participate. The total cost burden will be $102,185,301. The burden table below shows the effect of the additional changes requested by CDC.

B. Estimated Annualized Burden Costs

The average salary of the professional discipline expected to perform surveillance is used in the calculations of burden and is based on data from the Department of Labor, Bureau of Labor & Statistics, 2023 (latest available). Those most likely to complete this surveillance are health practitioners at a mid

(50th percentile average wage) or senior (75th percentile average wage) level. That personnel and their estimated hourly wages are shown below.

May 2023 Department of Labor Salary Estimates		
Professional Labor Category	**Percentile**	**Hourly Wage**
Microbiologist (IP)	75th	$58.60
Information Technologists	50th	$56.50

Occupational Employment and Wage Statistics (bls.gov). Accessed: 7/12/2024.

	Form No.	Form	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in minutes)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs	Type of Respondent
1	57.101	Hospital Respiratory Data Form (Weekly) (user entry)	1148	52	202	200977	$58.60	$11,777,225	Microbiologist
	57.101	Hospital Respiratory Data Form (Weekly) (.csv import)	3444	52	29	86559	$58.60	$5,072,369	Microbiologist
	57.101	Hospital Respiratory Data Form (Weekly) (API)	1786	52	15	23218	$56.50	$1,311,817	Information Technology
2	57.102	Hospital Respiratory Data Form (Daily) (user entry)	492	365	58	173594	$58.60	$10,172,608	Microbiologist
	57.102	Hospital Respiratory Data Form (Daily) (.csv import)	1476	365	29	260391	$58.60	$15,258,913	Microbiologist
	57.102	Hospital Respiratory Data Form (Daily) (API)	765	365	15	69806	$56.50	$3,944,053	Information Technology
3	57.140	National Healthcare Safety Network (NHSN) Registration Form	11500	1	5	958	$58.60	$56,158	Microbiologist
4	57.155	Point of Care Testing Results-Manual	3135	150	12	94050	$58.60	$5,511,330	Microbiologist
	57.155	Point of Care Testing Results-CSV	3135	150	12	94050	$58.60	$5,511,330	Microbiologist
5	57.216	Optional Person Level Reporting of Weekly COVID-19 Vaccination for Long-Term Care Residents (manual)	1669	52	62	89681	$58.60	$5,255,303	Microbiologist
	57.216	Optional Person Level Reporting of Weekly COVID-19 Vaccination for Long-Term Care Residents (.csv)	167	52	62	8973	$56.50	$507,001	Information Technology
6	57.217	Optional Person Level Reporting of	96	52	62	5158	$58.60	$302,282	Microbiologist

		Weekly COVID-19 Vaccination for Healthcare Personnel (manual)							
	57.217	Optional Person Level Reporting of Weekly COVID-19 Vaccination for Healthcare Personnel (.csv)	106	52	62	5696	$56.50	$321,809	Information Technology
7	57.218	Weekly Respiratory Pathogen and Vaccination Summary for Residents of Long-Term Care Facilities (manual)	10500	52	25	227500	$58.60	$13,331,500	Microbiologist
	57.218	Weekly Respiratory Pathogen and Vaccination Summary for Residents of Long-Term Care Facilities (csv)	6000	52	20	104000	$56.50	$5,876,000	Information Technology
8	57.219	Healthcare Personnel COVID-19 Vaccination Cumulative Summary (manual)	11360	12	45	102240	$58.60	$5,991,264	Microbiologist
	57.219	Healthcare Personnel COVID-19 Vaccination Cumulative Summary (.csv)	4107	12	40	32856	$56.50	$1,856,364	Information Technology
9	57.220	Weekly Person Level Respiratory Pathogen and Vaccination for Residents of Long-Term Care Facilities-Long-term Care Facility Component (Manual Entry)	1600	52	60	83200	$58.60	$4,875,520	Microbiologist
	57.220	Weekly Person Level Respiratory Pathogen and Vaccination for Residents of Long-Term Care Facilities-Long-term Care Facility Component (CSV Entry)	1600	52	40	55467	$58.60	$3,250,347	Microbiologist
10	57.221	Healthcare Personnel COVID-19 Person Level Vaccination-Long-Term Care Component (Manual)	73	52	60	3796	$58.60	$222,446	Microbiologist
	57.221	Healthcare Personnel COVID-19 Person Level Vaccination-Long-Term Care Component (CSV)	73	52	40	2531	$58.60	$148,297	Microbiologist
	57.221	Healthcare Personnel COVID-19 Person Level Vaccination-Healthcare Personnel	73	12	60	876	$58.60	$51,334	Microbiologist

		Safety Component (Manual)							
	57.221	Healthcare Personnel COVID-19 Person Level Vaccination-Healthcare Personnel Safety Component (CSV)	73	12	40	584	$58.60	$34,222	Microbiologist
11	57.509	Weekly Patient COVID-19 Vaccination Cumulative Summary for Dialysis Facilities-Manual	107	12	45	963	$58.60	$56,432	Microbiologist
	57.509	Weekly Patient COVID-19 Vaccination Cumulative Summary for Dialysis Facilities-.CSV	2802	12	40	22416	$58.60	$1,313,578	Microbiologist
12	57.510	COVID–19 Module Dialysis Outpatient Facility-manual	500	12	20	2000	$58.60	$117,200	Microbiologist
	57.510	COVID–19 Module Dialysis Outpatient Facility-.csv	500	12	10	1000	$58.60	$58,600	Microbiologist
						Total Burden - 1,752,540 **Total Respondent Cost -** $102,185,301			

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

There is no change in the estimates of the annual cost burden to respondents. Capital and start-up cost: Healthcare institutions participating in NHSN are responsible for choosing the specific computer brand and model to purchase. Minimum system requirements are as follows: 3 GHz processor – Intel Pentium IV or AMD K6/Athlon/Duron family or compatible processor; 512 MB of RAM; sound card; speakers or headphones; hard disk minimum 40 GB; Microsoft Internet Explorer 7 or higher; 17" Super VGA (800 X 600) or higher resolution video adaptor and monitor; Windows XP, Windows 2000, Windows Vista, or Windows 7 Operating system; laser printer; high-speed internet access >200 Kbs (e.g., T1, cable, DSL or ADSL); and e-mail account. It is expected that most institutions will have met or exceeded these recommendations for other business purposes. Recurring costs: Healthcare facilities participating in NHSN must have access to high-speed Internet, which most have for other business purposes. No other recurring costs are anticipated.

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, which is listed below.

A total of 127 FTE/contractor personnel are actively involved in the enhancement and maintenance of NHSN. The estimated cost to the government of this OMB revision of NHSN is based on expenses incurred in the following categories: personnel and programming contracts. The items and their costs

relevant to the proposed modifications to NHSN are shown in the table below. The total cost to the government in 2024 is estimated to be **$49,992,135.**

NHSN OMB Control No. 0920-0666 Estimated Annual Cost to the Government

Expense Item	Description		Estimated Annual Cost
Personnel	The personnel categories and their FTE contributions are as follows:		FTE annual compensation in FY2024 will be $6,595,430
	Supervisory Medical Officer	1	
	Business Support Specialist	1	
	IT Specialist	1	
	IT Project Manager	1	
	Medical Epidemiologist	1	
	Statistician	1	
	Epidemiologist	1	
	Health Scientist	11	
	Nurse Consultant	8	
	Public Health Analyst	2	
	Senior Service Fellow	3	
	Public Health Informatics Fellow	2	
Programming contracts	Design, develop, and deploy enhancements to NHSN		$43,396,705
Total			**$49,992,135**

15. Explanation for Program Changes or Adjustments

See Attachment D which includes a summary of the changes to the data collection forms.

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

A. Authorizing Legislation (The Public Health Service Act)
   1. 42 USC 242b
   2. 42 USC 242k
   3. 42 USC 242m

B. Published 60-day Federal Register
   1. Public Comment #1
   2. Public Comment #2
   3. Public Comment #3
   4. Public Comment #4

C. NHSN Forms Submitted for Approval

D. Explanation for Program Changes or Adjustments

E. Notice of IRB Closure
   1. Closure of NHSN IRB Protocol
   2. NHSN - Report of End of Human Research Review 0.1253
   3. Human Subjects Determination

F. NHSN Assurance of Confidentiality Documentation
   1. NHSN final version of 308(d) Amend/Extension
   2. NHSN memo requesting extension/amendment

G. Privacy Impact Assessment