National Healthcare Safety Network (NHSN)

OMB Control No. 0920-0666

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Revision ICR Request

Supporting Statement A

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- **Goal of the study:** The proposed revisions included in this ICR are designed to (1) increase the overall attainment of CDC's NHSN HAI surveillance goals and event reporting coverage for all facility types that are active and reporting data to NHSN, and (2) to enhance NHSN surveillance and data quality practices exercised by NHSN users and facilities alike. Lastly, the proposed revisions will further improve the overall quality of existing data collection forms, which are intended to ensure complete data reporting into CDC's NHSN by all participating facilities.
- **Intended use of the resulting data:** Resulting data are intended to estimate the magnitude of (HAIs), monitor HAI trends, and facilitate inter-facility and intra-facility comparisons with risk-adjusted data that can be used for local quality improvement activities. Data reported to NHSN enables healthcare facilities to report HAI and prevention practice adherence data via NHSN to CMS in fulfillment of CMS's quality programs. In addition, to provide state 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, or mandated public reporting.
- **Methods to be used to collect:** The data for NHSN is collected via a secure internet application.
- **The subpopulation to be studied:** NHSN participation is open to all U.S. healthcare facilities.
- **How data will be analyzed:** Reporting institutions can access their own data at any time and analyze it through the internet interface. Reports containing aggregated data is published annually by the CDC and posted on the NHSN website at https://www.cdc.gov/nhsn. The report is published in various scientific journals, to increase the scope of data that is made available by NHSN. Other types of in-depth analysis from NHSN is published in peer-reviewed journals and presented at scientific and professional meetings and conferences annually.

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. 0920-0666 for the National Healthcare Safety Network (NHSN). Data collection was previously approved in June of 2023 for 1,693,215 annual burden hours and is due to expire on June 30, 2026. The proposed changes in this new ICR includes revisions made to 23 approved NHSN data collection tools and 9 new forms. CDC requests OMB approval for an estimated annual burden 2,434,196 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 data from healthcare facilities in the National Healthcare Safety Network (NHSN) under OMB Control Number 0920-0666. During the early stages of its development, NHSN began as a voluntary surveillance system in 2005 managed by DHQP. NHSN provides facilities, states, regions, and the nation with data

necessary to identify problem areas, measure the progress of prevention efforts, and ultimately eliminate healthcare-associated infections (HAIs) nationwide. NHSN allows healthcare facilities to track blood safety errors and various HAI prevention practice methods such as healthcare personnel influenza vaccine status and corresponding infection control adherence rates.

Enrollment in NHSN has continuously increased, with over 37,000 actively reporting healthcare facilities across the U.S. Of the total enrolled healthcare facilities, there are over 6,000 acute care facilities; 8,400 dialysis facilities; 600 long-term acute care facilities; 400 inpatient rehabilitation facilities; 800 inpatient psychiatric facilities; nearly 20,000 long-term care facilities; and 6,000 ambulatory surgery facilities. NHSN currently has eight components: Patient Safety (PS), Healthcare Personnel Safety (HPS), Biovigilance (BV), Long-Term Care Facility (LTCF), Outpatient Procedure (OPC), Dialysis Component, Neonatal Component, and Medication Safety Component.

Data reported under the Patient Safety Component are used to determine the magnitude of the healthcare-associated adverse events and trends in the rates of the events, in the distribution of pathogens, and in the adherence to prevention practices. Data will help detect changes in the epidemiology of adverse events resulting from new medical therapies and changing patient risks. Additionally, reported data is being used to describe the epidemiology of antimicrobial use and resistance and to better understand the relationship of antimicrobial therapy to this rising problem.

Under the Healthcare Personnel Safety Component, protocols and data on events—both positive and adverse—are used to determine (1) the magnitude of adverse events in healthcare personnel, and (2) compliance with immunization and sharps injuries safety guidelines.

Under the Biovigilance Component, data on adverse reactions and incidents associated with blood transfusions are reported and analyzed to provide national estimates of adverse reactions and incidents.

Under the Long-Term Care Facility Component (LTCF), data is captured from skilled nursing facilities. Reporting methods under the LTCF component have been created by using forms from the PS Component as a model with modifications to specifically address the specific characteristics of LTCF residents and the unique data needs of these facilities reporting into NHSN.

The Outpatient Procedure Component (OPC) gathers data on the impact of infections and outcomes related to operative procedures performed in Ambulatory Surgery Centers (ASCs). The OPC is used to monitor two event types: Same Day Outcome Measures and Surgical Site Infections (SSIs).

The Dialysis Component offers a simplified user interface for dialysis users to streamline their data entry and analyses processes as well as provide options for expanding in the future to include dialysis surveillance in settings other than outpatient facilities.

The Neonatal Component includes one module, Late-Onset Sepsis/ Meningitis (LOS/MEN). This module will track late-onset sepsis and meningitis events in very low birthweight neonates housed in Level II/III, Level III, and Level IV nursery locations.

The Medication Safety Component tracks medication safety and adverse drug events (ADEs) that are among the most common causes of iatrogenic harm in U.S. hospitals.

NHSN has increasingly served as the operating system for HAI reporting compliance through legislation established by the states. As of March 2019, 36 states, the District of Columbia and the City of Philadelphia, Pennsylvania have opted to use NHSN as their primary system for mandated reporting. Reporting compliance is completed by healthcare facilities in their respective jurisdictions, with emphasis on those states and municipalities acquiring varying consequences for failure to use NHSN. Additionally, healthcare facilities in five U.S. territories (Puerto Rico, American Samoa, the U.S. Virgin Islands, Guam, and the Northern Mariana Islands) are voluntarily reporting to NHSN. Additional territories are projected to follow with similar use of NHSN for reporting purposes.

NHSN's data is used to aid in the tracking of HAIs and guide infection prevention activities/practices that protect patients. The Centers for Medicare and Medicaid Services (CMS) and other payers use these data to determine incentives for performance at healthcare facilities across the US and surrounding territories, and members of the public may use some protected data to inform their selection among available providers. Each of these parties is dependent on the completeness and accuracy of the data. CDC and CMS work closely and are fully committed to ensuring complete and accurate reporting, which are critical for protecting patients and guiding national, state, and local prevention priorities.

CMS collects some HAI data and healthcare personnel influenza vaccination summary data, which is done on a voluntary basis as part of its Fee-for-Service Medicare quality reporting programs, while others may report data required by a federal mandate. Facilities that fail to report quality measure data are subject to partial payment reduction in the applicable Medicare Fee-for-Service payment system. CMS links their quality reporting to payment for Medicare-eligible acute care hospitals, inpatient rehabilitation facilities, long-term acute care facilities, oncology hospitals, inpatient psychiatric facilities, dialysis facilities, and ambulatory surgery centers. Facilities report HAI data and healthcare personnel influenza vaccination summary data to CMS via NHSN as part of CMS's quality reporting programs to receive full payment. Still, many healthcare facilities, even in states without HAI reporting legislation, submit limited HAI data to NHSN voluntarily.

NHSN's data collection updates continue to support the incentive programs managed by CMS. For example, survey questions support requirements for CMS's quality reporting programs. Additionally, CDC has collaborated with CMS on a voluntary National Nursing Home Quality Collaborative, which focuses on recruiting nursing homes to report HAI data to NHSN and to retain their continued participation. This project has resulted in a significant increase in long-term care facilities reporting to NHSN.

The NHSN is currently comprised of 89 information collection forms that may be updated over time to improve HAI surveillance and inform public health action. The collection of information is authorized by the Public Health Service Act (42 USC 242b, 242k, and 242m (d)), *(Attachment A1-A3).*

2. Purpose and Use of Information Collection

The data collected under OMB Control No. 0920-0666 are used for the following purposes:

- Estimation of the magnitude of healthcare-associated infections (HAIs)
- Monitoring of HAI 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 HAI 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.

NHSN is used to determine the magnitude of various healthcare-associated adverse events and trends in the rates of these events among patients and healthcare personnel with similar risks or exposures. The healthcare institutions participating in NHSN are required to collect data regularly and report them monthly, seasonally, or annually to CDC based on the specific data element being reported. NHSN provides facilities with risk-adjusted data that can be used for inter-facility comparisons and local quality improvement activities. CDC also assists facilities in developing surveillance and analysis methods that permit timely recognition of patient and healthcare personnel safety problems and prompt intervention with appropriate measures. Finally, facilities can conduct collaborative research with NHSN member facilities. For example, facilities can describe the epidemiology of emerging HAIs and pathogens, assess the importance of potential risk factors, further characterize HAI pathogens and their mechanism of resistance, and evaluate alternative surveillance and prevention strategies. In aggregate, CDC analyzes and publishes surveillance data annually to estimate and characterize the national burden of healthcare-associated infections. These publications can be accessed here: https://www.cdc.gov/nhsn/dataStat.html.

Further, CDC DHQP is actively engaged with the CMS Center for Clinical Standards and Quality (CCSQ) in working to reduce healthcare-associated infections and improve the quality of care within

U.S. healthcare facilities. Suggested revisions and enhancements for NHSN definitions and surveillance criteria were received from external partners such as CMS CCSQ, the Healthcare Infection Control Practices Advisory Committee (HICPAC), and the Infectious Diseases Society of America (IDSA). The revisions, which are proposed to NHSN by external partners, are further evaluated, developed, and vetted by internal CDC NHSN subject matter experts. Prior to CMS CCSQ adopting a new NHSN measure for requirement in a CMS Quality Reporting Program (QRP), they require that the proposed measure is endorsed by a CMS consensus-based entity (CBE); CBE endorsed measures are considered the gold standard for quality measurement. Further, changes to the number of respondents and responses per respondent for NHSN forms are directly related to the expansion of CMS QRPs. The CMS QRP final rules and list of the NHSN forms used for the CMS QRPs and state-mandated reporting can be found in Attachment E.

3. Use of Improved Information Technology and Burden Reduction

As stated in previous submissions to OMB, 100% of the data for 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. There is no manual entry available to users for the new neonatal component. Both numerator and denominator data will be imported into the Clinical Document Architecture (CDA) via electronic data transfer. This will allow users to obtain data submitted via CDA and focus on prevention activities within their respective hospitals or facilities.

Clinical Document Architecture (CDA) is a Health Level 7 (HL7) standard that provides technical specifications for electronic formatting documents for interoperable data exchange and re-use. Currently, NHSN can accept data for the following event types/summary data via CDA:

- Central line-associated bloodstream infections (CLABSI)
- Catheter-associated urinary tract infections (CAUTI)
- Central line insertion practices (CLIP)
- Surgical site infections (SSI)
- Laboratory-identified (LabID) events
- Summary data for Intensive Care Units (ICU)/Other Locations (not NICU and SCA)
- Summary data for Neonatal Intensive Care Units (NICU)
- Summary data for Specialty Care Areas (SCA)
- Surgical procedures
- MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring
- Antimicrobial use (AU)
- Antimicrobial resistance events (AR)
- Antimicrobial resistance (AR) summary data

- Dialysis events
- Dialysis summary data
- Late-onset sepsis/ Meningitis (LOS/MEN) data electronically via CDA

In alignment with CDC's Data Modernization Initiative, NHSN is developing a new approach to the collection of surveillance data for healthcare safety with the goal to minimize reporting burden of facilities and providers. To that end, NHSN is designing and developing new fully electronic definitions for healthcare-acquired events that adopt new healthcare data exchange standards **(**Fast Healthcare Interoperability Resources i.e. FHIR) that will be collected via new collection methods (NHSNLink). This new model is based on submission of FHIR bundles that contain up to 18 unique FHIR resources (such as Patient and Encounter) which contain specific FHIR data elements that can be used to calculate metrics and provide patient-level risk adjustment. With this single stream of data, metrics for multiple healthcare associated events can be calculated. Because of the shift to new healthcare data exchange standards (FHIR) and fully electronic definitions for metrics, FHIR measures will require very little human time to input answers to a traditional form. FHIR is not fully implemented and will be effective for the following measures Respiratory Pathogens Surveillance (57.130), Hospital-Onset Bacteremia & Fungemia (HOB) 57.132, Healthcare facility-onset, antibiotic-Treated Clostridiodes difficile Infection (HT-CDI) 57.132, Venous Thromboembolism (VTE) 57.133, Late Onset Sepsis Meningitis (LOSMEN) 57.600, and Hypoglycemia (Hypo) 57.700.

4. Efforts to Identify Duplication and Use of Similar Information

NHSN is the only modern national system that collects surveillance data on healthcare-associated infections, infection prevention process measure data, data on 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.

There are other organizations within the Department of Health and Human Services (HHS) (e.g., Patient Safety Task Force, the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, and the Centers for Medicare and Medicaid Services) that work to improve patient safety and healthcare outcomes. In many cases, these agencies use the information generated from the NHSN to support their mission, and currently, the data collections do not overlap.

For the new data collection of Billing Code Data: 837I Upload, data received from this collection will be similar to data collected by CMS (UB-04 CMS-1450 form approved under OMB Control No. 0938-0997)
, however, CDC NHSN will receive additional respondents as CMS data is only collected on Medicare patients and the CDC NHSN data will be collected for all patients.

5. Impact on Small Businesses or Other Small Entities

There are several vendors, some of which may be considered small businesses, which sell data management tools with similar capabilities as NHSN. However, since NHSN is a voluntary system, facilities are free to choose a vendor product over NHSN. Exceptions are within those states that have

mandated the use of NHSN. Mandates are required to help participants meet their public reporting laws in facilities that participate in the following programs listed below. However, in order to minimize any negative impact on vendors (i.e., loss of potential market share); CDC actively assists all vendors with facility data submission into NHSN.

- CMS Hospital Inpatient Quality Reporting Program (IQR)
- CMS Prospective Payment System (PPS)
- End-stage renal disease (ESRD) Quality Incentive Program (QIP)
- CMS Inpatient Rehabilitation Facility Quality Reporting Program (IRFQR)

6. Consequences of Collecting the Information Less Frequently

Many adverse events associated with healthcare, such as HAIs, occur in both endemic and epidemic patterns. It is in the best interest of the healthcare institution to conduct routine prospective surveillance 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. In addition, CMS and state mandates require monthly reporting of HAI data via NHSN.

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

The healthcare institutions participating in NHSN are required to collect data in an ongoing manner and report them monthly to the CDC. Such a schedule will not cause undue burden in most facilities, since data are usually collected daily or at least several times per week, and denominator data are tallied monthly. The data are usually entered into the computer at least monthly for a facility's analysis. Given these practices, it is advantageous to CDC to maintain a monthly reporting frequency. In NHSN, once the data are entered into the internet-based application, they are transmitted electronically to CDC with no additional data preparation.

The majority of facilities active in NHSN are participating in CMS reporting programs for specific infection types. In 2011, the CMS' Hospital Inpatient Quality Reporting (HIQR) began for all acute care facilities with intensive care units. Further, in 2013, the CMS HIQR expanded its requirements to include reporting of facility-wide inpatient (FacWideIN) Methicillin-Resistant Staphylococcus aureus (MRSA) blood specimen (Bacteremia) laboratory-identified (LabID) event data, facility-wide Inpatient (FacWideIN) Clostridium difficile infection (CDI) laboratory-identified (LabID) event data, and healthcare personnel (HCP) Influenza vaccination data. As very few acute care facilities opt out of these additional CMS reporting requirements, NHSN data are considered to be generalizable to all U.S. acute care facilities.

In 2012, CMS ESRD Quality Incentive Program was implemented for all dialysis facilities, therefore dialysis event data are considered to be generalizable to all outpatient dialysis facilities. Furthermore, CLABSI and CAUTI data from long-term acute care facilities, and CAUTI data from inpatient

rehabilitation facilities are considered generalizable to those facility and infection types as CMS reporting programs for those facility types went into effect in October 2012.

As part of the national COVID-19 response, CMS began requiring that all nursing homes report counts of COVID-19 cases and deaths among nursing home residents and personnel to NHSN. The data is used by CDC, the White House Coronavirus Task Force, and by CMS to respond to the pandemic. There are additionally plans for the data to be publicly displayed on a CMS website. (https://www.cms.gov/files/document/covid-medicare-and-medicaid-ifc2.pdf.) Further, because NHSN membership is now open to any healthcare facility and is increasingly being used to satisfy mandated reporting requirements at both the federal and state levels, we expect that over time the results will be more representative of all healthcare facility and infection types.

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

A. A 60-day Federal Register Notice was published in the *Federal Register* on August 21, 2023, Vol. 88, No. 160, pp. 56827-56830 - (Attachment B). CDC received one public comment related to this notice (Attachment B1). The commenter did not provide their contact information, so we are unable to respond.

B. The Healthcare Infection Control Practices Advisory Committee (HICPAC) provides advice and guidance to the CDC Director and the Director of NCEZID regarding strategies for surveillance, prevention, and control of adverse events associated with healthcare in the United States. Committee members represent experts in the field of infection control. They are kept abreast of NHSN methodologies and results, and proposed studies related to NHSN. The committee has the authority to make recommendations on the conduct of the surveillance systems and studies by DHQP.

Further, participating NHSN facilities are invited to make suggestions on how NHSN can help them more effectively use their own and national surveillance data. Many of the surveillance personnel in participating institutions are experts in the field of preventing adverse events such as hospital-associated infections and have extensive experience in the field. CDC personnel are available on a priority basis by e-mail to NHSN users. Member meetings for NHSN users are held each year in conjunction with annual professional meetings such as the International Conference of the Association for Professionals in Infection Control and Epidemiology (APIC) and the International Conference on Healthcare-Associated Infections.

Also, DHQP actively interfaces with CMS and Agency for Healthcare Research and Quality (AHRQ) as well as state and local health departments to ensure adequate but minimal data collection as well as effective data sharing mechanisms to meet the purposes and surveillance needs of each agency using NHSN to operationalize HAI reporting mandates.

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. 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))."*

See Attachment G1 and G2.

The use of NHSN is both voluntary and mandated. State legislatures and some local health departments have mandated the use of NHSN for public reporting of HAIs by healthcare facilities in their jurisdiction.

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 described in previous Section A.10 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.

The surveillance data is typically obtained by designated and trained staff, primarily registered nurses in infection control or occupational health or transfusion medicine laboratory personnel who routinely access administrative and clinical services reports and medical records, make observations during ward and patient rounds, and verbally discuss patients' conditions with direct caregivers. Persons with training in other healthcare disciplines such as medical technology and microbiology also perform surveillance. Information on antibiotic resistance of clinical isolates and antimicrobial use is reported from the clinical laboratory and pharmacy, respectively. In most institutions, the data are recorded on a hard-copy data collection forms and later entered into the NHSN via a web interface. However, approximately 7,500 NHSN facilities submit data electronically directly from a vendor system using Clinical Document Architecture (CDA).

Items of information to be collected include surveillance data related to various healthcare-associated adverse events and trends. Examples of these items are medical information and notes, medical records numbers, date of birth, gender, and biological specimen information. Personal identifying information is collected for one of two purposes. The information is used to either a) enumerate a specific event and minimize duplication (e.g., medical record number) or b) analyze risk factors related to the event data being collected (e.g., date of birth and gender). Data are reported to the CDC, and CDC aggregates the data for national surveillance and public health practice evaluation purposes.

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 described in previous Section A.10 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.

A signed Privacy Impact Assessment is included with this submission (Attachment H).

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, this 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 (Attachment F3), and that IRB review is no longer required, therefore the protocol has been closed (Attachment F1, F2).

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

The tables below provide the burden hours and cost estimates for the proposed NHSN data collection tools.

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 23 approved NHSN data collection tools and 9 new forms, for a total of 89 proposed data collection forms, with a total estimated annual burden of 2,434,196 hours. There is no cost to respondents other than their time to participate. The total cost burden will be $112,969,409. 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, 2022 (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.

2021 Department of Labor Salary Estimates		
Professional Labor Category	**Percentile**	**Hourly Wage**
Microbiologist (IP)	75th	$47.53
Clinical Laboratory Technologists and Technicians	75th	$37.62
Occupational Therapists	50th	$46.83
Pharmacist	50th	$66.08
Registered Nurse (RN)	50th	$39.54
Epidemiologists	50th	$45.79
Health Technologists and Technicians	50th	$22.70
Information Technologists	50th	$50.12

Occupational Employment and Wage Statistics (bls.gov). Accessed: 8/22/2023.

			Estimated Annualized Burden Hours and Cos	
Form Number & Name	**No. of Respondents**	**No. of Responses per Respondent**	**Avg. Burden per Response (Min./Hour 60)**	**T B (H**
57.100 NHSN Registration Form	2,000	1	5/60	
57.101 Facility Contact Information	2,000	1	10/60	
57.103 Patient Safety Component--Annual Hospital Survey	5,311	1	135/60	1
57.104 NHSN Facility Administrator Change Request Form	800	1	5/60	
57.105 Group Contact Information	1,000	1	5/60	
57.106 Patient Safety Monthly Reporting Plan	7,821	12	15/60	2
57.108 Primary Bloodstream Infection (BSI)	5,775	5	39/60	1
57.111 Pneumonia (PNEU)	1,800	2	31/60	1
57.112 Ventilator-Associated Event	5463	8	29/60	2
57.113 Pediatric Ventilator-Associated Event (PedVAE)	334	1	31/60	
57.114 Urinary Tract Infection (UTI)	6000	5	21/60	1
57.115 Custom Event	600	91	36/60	3
57.116 Denominators for Neonatal Intensive Care Unit (NICU)	1,100	12	4/60	

57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	500	12	5/60	
57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	5500	60	5/60	2
57.120 Surgical Site Infection (SSI)	3,800	12	36/60	2
57.121 Denominator for Procedure	3,800	12	10/60	
57.122 HAI Progress Report State Health Department Survey	55	1	28/60	
57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	5,500	12	5/60	
57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	5,500	12	5/60	
57.125 Central Line Insertion Practices Adherence Monitoring	500	213	26/60	4
57.126 MDRO or CDI Infection Form	720	11	31/60	
57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	5,500	29	15/60	3
57.128 Laboratory-identified MDRO or CDI Event	4800	79	21/60	1
57.129 Adult Sepsis	50	250	25/60	
57.135 Late Onset Sepsis/ Meningitis Denominator Form: Late Onset Sepsis/ Meningitis Denominator Form: Data Table for monthly electronic upload	300	6	5/60	
57.136 Late Onset Sepsis/ Meningitis Event Form: Data Table for Monthly Electronic Upload	300	6	5/60	
57.137 Long-Term Care Facility Component – Annual Facility Survey	17,700	1	120/60	3
57.138 Laboratory-identified MDRO or CDI Event for LTCF	1,086	24	20/60	
57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	1,019	12	20/60	
57.140 Urinary Tract Infection (UTI) for LTCF	339	36	35/60	
57.141 Monthly Reporting Plan for LTCF	1,099	12	15/60	
57.142 Denominators for LTCF Locations	714	12	35/60	
57.143 Prevention Process Measures Monthly Monitoring for LTCF	357	12	5/60	
57.149 Weekly Healthcare Personnel Influenza Vaccination Cumulative Summary for Long-Term Care Facilities	1200	52	60/60	6
57.150 LTAC Annual Survey	392	1	89/60	
57.151 Rehab Annual Survey	1,160	1	89/60	

57.200 Healthcare Personnel Safety Component Annual Facility Survey	50	1	480/60	
57.204 Healthcare Worker Demographic Data	50	200	20/60	
57.205 Exposure to Blood/Body Fluids	50	50	60/60	
57.206 Healthcare Worker Prophylaxis/Treatment	50	30	15/60	
57.207 Follow-Up Laboratory Testing	50	50	15/60	
57.210 Healthcare Worker Prophylaxis/Treatment-Influenza	50	50	10/60	
57.211 Weekly Healthcare Personnel Influenza Vaccination Cumulative Summary for Non-Long-Term Care Facilities	125	52	60/60	
57.214 Annual Healthcare Personnel Influenza Vaccination Summary	5,000	1	120/60	
57.218 Weekly Resident Influenza Vaccination Cumulative Summary for Long-Term Care Facilities	2,500	52	60/60	
57.300 Hemovigilance Module Annual Survey	500	1	86/60	
57.301 Hemovigilance Module Monthly Reporting Plan	500	12	60/60	
57.303 Hemovigilance Module Monthly Reporting Denominators	500	12	77/60	
57.305 Hemovigilance Incident	500	10	10/60	
57.306 Hemovigilance Module Annual Survey - Non-acute care facility	500	1	36/60	
57.307 Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction	500	4	21/60	
57.308 Hemovigilance Adverse Reaction - Allergic Transfusion Reaction	500	4	21/60	
57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction	500	1	21/60	
57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction	500	2	21/60	

57.311 Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction	500	4	21/60	
57.312 Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction	500	1	21/60	
57.313 Hemovigilance Adverse Reaction – Infection	500	1	21/60	
57.314 Hemovigilance Adverse Reaction - Post Transfusion Purpura	500	1	21/60	
57.315 Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea	500	1	20/60	
57.316 Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease	500	1	21/60	
57.317 Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury	500	1	21/60	
57.318 Hemovigilance Adverse Reaction - Transfusion Associated Circulatory Overload	500	2	21/60	
57.319 Hemovigilance Adverse Reaction - Unknown Transfusion Reaction	500	1	21/60	
57.320 Hemovigilance Adverse Reaction - Other Transfusion Reaction	500	1	21/60	
57.400 Outpatient Procedure Component—Annual Facility Survey	350	1	10/60	
57.401 Outpatient Procedure Component - Monthly Reporting Plan	350	12	15/60	1
57.402 Outpatient Procedure Component Same Day Outcome Measures	50	1	40/60	
57.403 Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures	50	400	40/60	1
57.404 Outpatient Procedure Component - SSI Denominator	300	100	10/60	5
57.405 Outpatient Procedure Component - Surgical Site (SSI) Event	300	36	35/60	6
57.408 Monthly Survey Patient Days & Nurse Staffing	2500	12	60/60	3
57.500 Outpatient Dialysis Center Practices Survey	7400	1	12/60	1
57.501 Dialysis Monthly Reporting Plan	7400	12	5/60	7

57.502 Dialysis Event	7400	12	15/60	2
57.503 Denominator for Outpatient Dialysis	7400	24	10/60	2
57.504 Prevention Process Measures Monthly Monitoring for Dialysis	1730	12	75/60	2
57.505 Dialysis Patient Influenza Vaccination	615	50	10/60	5
57.506 Dialysis Patient Influenza Vaccination Denominator	615	5	10/60	
57.507 Home Dialysis Center Practices Survey	450	1	36/60	
57.130 New Form - Patient Safety Component FHIR Measure Respiratory Pathogens Surveillance (RPS)-IT Initial Set up	5,500	1	1620/60	14
57.130 New Form - Patient Safety Component FHIR Measure Respiratory Pathogens Surveillance (RPS)-IT Yearly Maintenance	5,500	1	1200/60	11
57.130 New Form - Patient Safety Component FHIR Measure Respiratory Pathogens Surveillance (RPS)-Infection Preventionist	5,500	1	6/60	
57.130 New Form - Patient Safety Component CSV Data Collection-Infection Preventionist CSV Data Collection-Infection Preventionist	5500	365	2/60	6
57.132 New Form - Patient Safety Component FHIR Measures-HOB, HT-CDI Modules-IT Initial Set up	5500	1	1620/60	14
57.132 New Form - Patient Safety Component FHIR Measures-HOB, HT-CDI Modules-IT Yearly Maintenance	5500	1	1200/60	11
57.132 New Form - Patient Safety Component FHIR Measures-HOB, HT-CDI Modules-Infection Preventionist	5500	6	6/60	3
57.133 New Form - Patient Safety Component FHIR Measures-VTE Module-IT Initial Set up	5500	1	1620/60	14
57.133 New Form - Patient Safety Component FHIR Measures-VTE Module-IT Yearly Maintenance	5500	1	1200/60	11
57.133 New Form - Patient Safety Component FHIR Measures-VTE Module- Infection Preventionist	5500	6	6/60	3
57.600 New Form - Neonatal Component FHIR Measure-Late Onset Sepsis Meningitis (LOSMEN) Module-IT Initial Set up	5500	1	1620/60	14
57.600 New Form - Neonatal Component FHIR Measure-Late Onset Sepsis Meningitis (LOSMEN) Module-IT Yearly Maintenance	5500	1	1200/60	11

57.600 New Form - Neonatal Component FHIR Measure-Late Onset Sepsis Meningitis (LOSMEN) Module-Infection Preventionist	5500	6	6/60	3
57.600 New Form - Neonatal Component Late Onset Sepsis Meningitis (LOSMEN) Module CDA Data Collection-Infection Preventionist	5500	12	2/60	2
57.700 New Form - Medication Safety Component FHIR Measure-Glycemic Control Module Hypoglycemia-IT Initial Set up	5500	1	1620/60	1
57.700 New Form - Medication Safety Component FHIR Measure-Glycemic Control Module Hypoglycemia-IT Yearly Maintenance	5500	1	1200/60	1
57.700 New Form - Medication Safety Component FHIR Measure-Glycemic Control Module Hypoglycemia-Infection Preventionist	5500	6	6/60	3
57.701 New Form - Glycemic Control Module-HYPO Annual Survey	10	1	120/60	
57.144 New Form - Long Term Care Respiratory Tract Infections (RTI) Module	16,500	24	25/60	1
57.145 New Form - Long Term Care Antimicrobial Use (LTC-AU) Module CDA	16,500	12	5/60	1
New Form - Billing Code Data: 837I Upload	5500	4	5/60	

- ❖ Items highlighted in yellow denote updates from the last submission.

CMS Program Definitions:

End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) - ESRD QIP
Hospital Inpatient Quality Reporting Program - IQR
Hospital Outpatient Quality Reporting Program - OQR
Long-Term Care Hospital* Quality Reporting Program - LTCHQR
Meaningful Use Stage 3- MU3
Inpatient Rehabilitation Facility Quality Reporting Program - IRFQR
Ambulatory Surgery Centers Quality Reporting Program - ASCQR
PPS-Exempt Cancer Hospital Quality Reporting Program - PCHQR
Inpatient Psychiatric Facility Quality Reporting Program - IPFQR

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

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 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	

Expense Item	Description		Estimated Annual Cost
	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.

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

C. NHSN Forms Submitted for Approval

D. ICR Revision Supporting Documentation

E. CMS Reporting Requirements

F. 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

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

H. Privacy Impact Assessment