# National Healthcare Safety Network (NHSN)
# OMB Control No. 0920-0666
# Expiration 12/31/2022
# Revision Request
## Supporting Statement Part A

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**OMB No. 0920-0666**
**National Healthcare Safety Network (NHSN)**
**Revision Request, May 2020**

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F. Notice of IRB Closure
1. Closure of NHSN IRB Protocol
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G. Surveillance Methods Supporting Materials
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H. NHSN Assurance of Confidentiality Documentation
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I. Privacy Impact Assessment

- **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.

The Centers for Disease Control and Prevention is requesting a 3-year approval for revisions made to OMB Control No. 0920-0666 for the National Healthcare Safety Network. The collection was approved for 5,352,360 responses; 3,113,631 burden hours and $101,009,102 in annual cost, due to expire on December 31, 2022. The proposed changes in this new ICR include revisions made to fourteen NHSN data collection tools and the addition of two new forms for a total of **86** data collection tools included in this ICR (Attachment D-2). The reporting burden decreased by 1,744,182 hours for a total estimated burden of **1,369,449** hours. The annual cost of reporting will increase by $ 8,547,747 for a total cost burden of $**109,556,849** (Attachment D-2). NHSN has achieved significant reduction in burden hours(Attachment D-2). Also, the application of the 2019 annual labor wages will result in changes to the burden for forms submitted with this ICR (Attachment D-4).

## A. Justification

### 1. Circumstances Making the Collection of Information Necessary

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 healthcare-associated infection prevention practice methods such as healthcare personnel influenza vaccine status and corresponding infection control adherence rates.

Enrollment in NHSN has continuously increased, with over 30,000 enrolled healthcare facilities and 22,303 actively reporting healthcare facilities across the U.S. Of these, there are over 5,000 acute care facilities; 8,100 dialysis facilities; 600 long-term acute care facilities; 1,100 inpatient rehabilitation facilities; 800 inpatient psychiatric facilities; 9,700 long-term care facilities; and 6,000 ambulatory surgery facilities. NHSN currently has six components: Patient Safety (PS), Healthcare Personnel Safety (HPS), Biovigilance (BV), Long-Term Care Facility (LTCF), Outpatient Procedure (OPC), and the Dialysis Component. NHSN's new Neonatal Component is expected to launch during the winter of 2020/2021. This component will focus on premature neonates and the healthcare-associated events that occur as a result of their prematurity. This component will be released with one module, which includes Late Onset-Sepsis and Meningitis. Late-onset sepsis (LOS) and Meningitis are common complications of extreme prematurity. Studies have indicated that 36% of extremely low gestational age (22-28 weeks) infants develop LOS and that 21% of very low birth weight infants surviving beyond 3 days of life will develop LOS.[1] Meningitis occurs in 23% of bacteremic infants, but 38% of infants with a pathogen isolated from the cerebrospinal fluid may not have an organism isolated from blood. These infections are usually serious, causing a prolongation of hospital stay, increased cost, and risk of morbidity and mortality.

Some cases of LOS can be prevented through proper central line insertion and maintenance practices. These are addressed in the CDC's Healthcare Infection Control Practices Advisory Committee (CDC/HICPAC) *Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011*. However, almost one-third of LOS events in a quality-improvement study was not related to central-lines. Prevention strategies for the non-central line –related infection events have yet to be fully defined, but include adherence to hand-hygiene, parent and visitor education, and optimum nursery design features. Other areas that likely influence the development of LOS include early enteral nutritional support and skin care practices. The data for this module will be electronically submitted, and manual data entry will not be available. This will allow more hospital personnel to be available to care for patients and will reduce the annual burden across healthcare facilities. Additionally, LOS data will be utilized for prevention initiatives.

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, 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 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 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).

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' 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 collection of information is authorized by the Public Health Service Act (42 USC 242b, 242k, and 242m (d)),*(Attachment A).*

The current revision request includes:

- revisions to fourteen data collection forms (57.123, 57.124, 57.140, 57.500, 57.501, 57.502, 57.507, 57.108, 57.111, 57.112, 57.113, 57.114, 57.115, and 57.120)
- the addition of two new forms:
  - Patient Safety Component: LOS Denominator (57.135) and LOS Event Form
- Burden modifications based on changes to the number of respondents
- Other revisions include application of the annual labor and statistic wages for 2019, which have been applied across all components within NHSN.

The proposed revisions to fourteen information collection tools in NHSN are detailed below:

- Forms 57.108, 57.111, 57.112, 57.113, 57.114, 57.115, and 57.120:
  *Justification for Change*: The antimicrobial susceptibility data collection for reported pathogens is requested for the following events: PNEU, VAE, PedVAE, UTI, SSI, MDRO/CDI, and Custom event. The update includes removal of some antimicrobial agents that are no longer in use, addition of some new agents and updates to the result value options (S,I,R,N, S-DD) for a few existing agents.
- 57.123: Clarified required pathogens. Removed variables that are populated by the NHSN application and not submitted in the CDA file itself. Added a new variable to allow vendors to report no AR events. Increased the number of facilities submitting from 1,500 to 2,500 based on the number of submissions in 2019. The time to complete this form was not changed because all changes above are handled on the vendor side, thus not causing any additional time or burden on the responding facilities' part.
  *Justification for change:* provides more clarification for respondents.
- 57.124: Antimicrobial Use and Resistance (AUR): Pharmacy Data Monthly Electronic Upload Specification Tables-Added and removed drugs. Four drugs were added and three drugs were removed. Added new variables required to be included in the CDA file by the vendor software that produced the files. Removed variables that are populated by the NHSN application and not submitted in the CDA file itself. Increased the number of facilities submitting data from 2,000 to 2,500. The time to complete this form was not changed because all changes above are handled on the vendor side, thus not causing any additional time or burden on the responding facilities' part. All changes are made by the vendor once a year.
  *Justification for change:* provides more clarification for respondents and updated selections.
- 57.140: Urinary Tract Infection (UTI) for LTCF: Change the definition of leukocytosis from > 14,000 cells/$mm^3$ to > 10,000 cells/$mm^3$.
  *Justification for change*: This change is being made to improve sensitivity of UTI detection when using leukocytosis as a criterion. Changes to UTI pathogen susceptibility data collection form. Specifically, require susceptibility response for Proteus mirabilis and add Nitrofurantoin as a drug option for select pathogens.
  *Justification for change:* This change is being made to align with organism and susceptibility requirements reported by long-term care facilities in the LTCF 2018 Prevalence Survey. This change is being made to align with most recent CLSI guidelines.
- Four Dialysis component tools will be updated with this ICR (57.500, 57.501, 57.507, and 57.502).

*Justification for change*: CDC added and revised multiple questions/options on the surveys to better understand possible risk factors for healthcare-associated infections (HAIs), as well as the patient population they serve for surveillance and prevention purposes. The antimicrobial susceptibility data collection for reported pathogens is now requested for bloodstream infections (BSI). Additionally, the change and updates to the forms are to gather information on the practices that occur in the dialysis settings (outpatient, home, etc). We need to know the current practices, which informs our infection control guidelines and ultimately polices for clinics to follow. The goal is to reduce bloodstream infections but we need to know what are the risk factors, current practices, etc and we can only do so by identifying such factors. These changes will help inform future policies/guidelines to reduce BSIs. Additionally, new event-specific event dates were added to the dialysis event form (57.502) to gather more accurate information on dialysis events.

The following 2 data collection forms are proposed additions to NHSN:

- Patient Safety Component:
  - Late-onset Sepsis (LOS) Denominator Form (57.135)
  - LOS Event Form (57.136)

The number of participating reporting facilities and their responses per respondent have changed for ten data collection tools with this ICR due to more accurate methods for estimating the number of respondents. Healthcare facility use of NHSN continues to change annually. This year the Patient Safety, Long-term Care Facility, Outpatient Procedure and Dialysis Components of NHSN have seen a change in their estimated number of respondents. Therefore, the CDC has changed the estimated number of facilities that will report data during the calendar year 2020. Many of the changes will result in a decrease in the annual burden and cost estimates.

- 57.103 - Patient Safety Component-Annual Hospital Survey; the annual number of respondents will increase by 1590, which will increase the overall annual time burden by 268 hours.
- 57.104 - NHSN Facility Administrator Change Request Form; Annual response burden will increase by 800 responses, increasing the overall annual time burden by 67 hours.
- 57.111- Pneumonia (PNEU): Annual response burden will decrease by 28 responses, decreasing the overall annual time burden by 26,100 hours.
- 57.112 - Ventilator-Associated Event: The number of respondents will have no overall change in respondents annually, but the annual response burden will decrease by 37 responses, which will decrease the overall annual time burden by 5,271 hours.
- 57.114 - Urinary Tract Infection (UTI): The number of respondents will decrease by 500 respondents annually, which will decrease the overall annual time burden by 53,025 hours.
- 57.120- Surgical Site Infection (SSI): annual response burden will decrease by 2 responses per respondent annually, which will increase the overall annual time burden by 5,250 hours. Annual number of responses increased by 4,500.
- 57.505 - Dialysis Patient Influenza Vaccination: Annual number of respondents will decrease by 10, which will decrease the overall annual time burden by 3,475 hours.Annual number of responses decreased by 20,850. Annual time burden hours decreased by 3,475.
- 57.506 - Dialysis Patient Influenza Vaccination Denominator: Annual number of responses will increase by 4.

## 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.

NHSN is also increasingly used to satisfy HAI reporting included in state legislation and local mandates. Compared to previous submissions, there has been an increase in the uptake of HAI Surveillance in approximately Thirty-six states, the District of Columbia, and the city of Philadelphia,

Pennsylvania who have implemented HAI reporting using NHSN as the primary reporting mechanism, and more jurisdictions are expected in the coming years. In addition, CMS collects HAI data and healthcare personnel influenza vaccination summary data on a voluntary basis as part of its Fee-for-Service Medicare quality reporting programs. Facilities that fail to successfully report quality measure data are potentially subject to partial payment reduction in the applicable Medicare Fee-for-Service payment system. Facilities report HAI data and healthcare personnel influenza vaccination summary data to CMS via NHSN as part of CMS quality reporting programs to receive full payment.

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 the proposed measure is endorsed by the National Quality Forum (NQF), thus, resulting in updates and improvements to NHSN forms as CDC strives to obtain the highest standard for measuring infection surveillance and process improvement. 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

**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.

**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.

- 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)

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.

**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 06/15/2020, vol. 85, No.115, pp. 36208 (Attachment 2). CDC received two public comments related to this notice, and both comments were unrelated to the content of this notice.

**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)).*"

The document is in (Attachment H). The current NHSN Assurance of Confidentiality expires on December 31, 2020.

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 I).

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

*IRB Approval*

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 and that IRB review is no longer required, therefore the protocol has been closed (Attachment F).

*The 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. Detailed revisions of the previous burden tables are available in Attachments D-3 and D-4.

**A. Estimates of 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 are 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 include revisions made to fourteen NHSN data collection tools for a total of **86** data collection tools included in this ICR (Attachment D-2). The reporting burden decreased by 1,796,341 hours for a total estimated burden of **1,321,991** hours. The annual cost of reporting will increase by $705,618 for a total cost burden of $ **101,704,078** (Attachment D-2). NHSN has achieved significant reduction in burden hours (Attachment D-2). Also, the application of the 2019 annual labor wages will result in changes to the burden for forms submitted with this ICR (Attachment D-4).

## Estimated annual burden

| Form Number & Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (Min./Hour) | Total Burden (Hours) |
|---|---|---|---|---|
| 57.100 NHSN Registration Form | 2,000 | 1 | 5/60 | 167 |
| 57.101 Facility Contact Information | 2,000 | 1 | 10/60 | 333 |
| 57.103 Patient Safety Component--Annual Hospital Survey | 6765 | 1 | 55/60 | 6,201 |
| 57.104 Facility Administrator Change Request Form | 800 | 1 | 5/60 | 67 |
| 57.105 Group Contact Information | 1,000 | 1 | 5/60 | 83 |
| 57.106 Patient Safety Monthly Reporting Plan | 7,821 | 12 | 15/60 | 23,463 |
| 57.108 Primary Bloodstream Infection (BSI) | 5,775 | 5 | 38/60 | 18,288 |
| 57.111 Pneumonia (PNEU) | 1,800 | 2 | 30/60 | 1800 |
| 57.112 Ventilator-Associated Event | 5,463 | 8 | 28/60 | 20,395 |
| 57.113 Pediatric Ventilator-Associated Event (PedVAE) | 334 | 1 | 30/60 | 167 |
| 57.114 Urinary Tract Infection (UTI) | 6,000 | 5 | 20/60 | 10,000 |
| 57.115 Custom Event | 600 | 91 | 35/60 | 31,850 |
| 57.116 Denominators for Neonatal Intensive Care Unit (NICU) | 1,100 | 12 | 4/60 | 880 |
| 57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC) | 500 | 12 | 5/60 | 500 |
| 57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA) | 5,500 | 60 | 5/60 | 27,500 |
| 57.120 Surgical Site Infection (SSI) | 6,000 | 9 | 35/60 | 31,500 |
| 57.121 Denominator for Procedure | 6,000 | 602 | 10/60 | 602,000 |
| 57.122 HAI Progress Report State Health Department Survey | 55 | 1 | 28/60 | 26 |
| 57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data | 2,500 | 12 | 5/60 | 2500 |

| Form Number & Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (Min./Hour) | Total Burden (Hours) |
|---|---|---|---|---|
| Electronic Upload Specification Tables | | | | |
| 57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables | 2,500 | 12 | 5/60 | 2,500 |
| 57.125 Central Line Insertion Practices Adherence Monitoring | 500 | 213 | 25/60 | 44,375 |
| 57.126 MDRO or CDI Infection Form | 720 | 11 | 30/60 | 3,960 |
| 57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring | 5,500 | 29 | 15/60 | 39,875 |
| 57.128 Laboratory-identified MDRO or CDI Event | 4,800 | 79 | 20/60 | 126,400 |
| 57.129 Adult Sepsis | 50 | 250 | 25/60 | 5,208 |
| 57.135 Late Onset Sepsis/ Meningitis Denominator Form: Data Table for monthly electronic upload | 300 | 6 | 5/60 | 150 |
| 57.136 Late Onset Sepsis/ Meningitis Event Form: Data Table for Monthly Electronic Upload | 300 | 6 | 5/60 | 150 |
| 57.137 Long-Term Care Facility Component – Annual Facility Survey | 17,700 | 1 | 120/60 | 35,400 |
| 57.138 Laboratory-identified MDRO or CDI Event for LTCF | 1998 | 24 | 20/60 | 15,984 |
| 57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF | 1998 | 12 | 20/60 | 7,992 |
| 57.140 Urinary Tract Infection (UTI) for LTCF | 339 | 36 | 35/60 | 7,119 |
| 57.141 Monthly Reporting Plan for LTCF | 2011 | 12 | 5/60 | 2,011 |
| 57.142 Denominators for LTCF Locations | 339 | 12 | 35/60 | 2,373 |
| 57.143 Prevention Process Measures Monthly Monitoring for LTCF | 130 | 12 | 5/60 | 130 |
| 57.150 LTAC Annual Survey | 620 | 1 | 10/60 | 103 |
| 57.151 Rehab Annual Survey | 1,340 | 1 | 10/60 | 223 |

| Form Number & Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (Min./Hour) | Total Burden (Hours) |
|---|---|---|---|---|
| | | | | |
| 57.200 Healthcare Personnel Safety Component Annual Facility Survey | 50 | 1 | 480/60 | 400 |
| 57.204 Healthcare Worker Demographic Data | 50 | 200 | 20/60 | 3,333 |
| 57.205 Exposure to Blood/Body Fluids | 50 | 50 | 60/60 | 2,500 |
| 57.206 Healthcare Worker Prophylaxis/Treatment | 50 | 30 | 15/60 | 375 |
| 57.207 Follow-Up Laboratory Testing | 50 | 50 | 15/60 | 625 |
| 57.210 Healthcare Worker Prophylaxis/Treatment-Influenza | 50 | 50 | 10/60 | 417 |
| 57.300 Hemovigilance Module Annual Survey | 500 | 1 | 85/60 | 708 |
| 57.301 Hemovigilance Module Monthly Reporting Plan | 500 | 12 | 60/60 | 6,000 |
| 57.303 Hemovigilance Module Monthly Reporting Denominators | 500 | 12 | 70/60 | 7,000 |
| 57.305 Hemovigilance Incident | 500 | 10 | 10/60 | 833 |
| 57.306 Hemovigilance Module Annual Survey - Non-acute care facility | 500 | 1 | 35/60 | 292 |
| 57.307 Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction | 500 | 4 | 20/60 | 667 |
| 57.308 Hemovigilance Adverse Reaction - Allergic Transfusion Reaction | 500 | 4 | 20/60 | 667 |
| 57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction | 500 | 1 | 20/60 | 167 |
| 57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction | 500 | 2 | 20/60 | 333 |
| 57.311 Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction | 500 | 4 | 20/60 | 667 |
| 57.312 Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction | 500 | 1 | 20/60 | 167 |
| 57.313 Hemovigilance Adverse Reaction - Infection | 500 | 1 | 20/60 | 167 |
| 57.314 Hemovigilance Adverse Reaction - Post Transfusion Purpura | 500 | 1 | 20/60 | 167 |
| 57.315 Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea | 500 | 1 | 20/60 | 167 |
| 57.316 Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease | 500 | 1 | 20/60 | 167 |
| 57.317 Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury | 500 | 1 | 20/60 | 167 |
| 57.318 Hemovigilance Adverse Reaction - Transfusion Associated Circulatory Overload | 500 | 2 | 20/60 | 333 |
| 57.319 Hemovigilance Adverse Reaction - Unknown Transfusion Reaction | 500 | 1 | 20/60 | 167 |

| Form Number & Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (Min./Hour) | Total Burden (Hours) |
|---|---|---|---|---|
| 57.320 Hemovigilance Adverse Reaction - Other Transfusion Reaction | 500 | 1 | 20/60 | 167 |
| 57.400 Outpatient Procedure Component—Annual Facility Survey | 700 | 1 | 10/60 | 117 |
| 57.401 Outpatient Procedure Component - Monthly Reporting Plan | 700 | 12 | 15/60 | 2,100 |
| 57.402 Outpatient Procedure Component Same Day Outcome Measures | 200 | 1 | 40/60 | 133 |
| 57.403 Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures | 200 | 400 | 40/60 | 53,333 |
| 57.404 Outpatient Procedure Component – SSI Denominator | 700 | 100 | 40/60 | 46,667 |
| 57.405 Outpatient Procedure Component - Surgical Site (SSI) Event | 700 | 5 | 40/60 | 2,333 |
| 57.500 Outpatient Dialysis Center Practices Survey | 7,200 | 1 | 12/60 | 1,440 |
| 57.501 Dialysis Monthly Reporting Plan | 7,200 | 12 | 5/60 | 7,200 |
| 57.502 Dialysis Event | 7,200 | 30 | 25/60 | 90,000 |
| 57.503 Denominator for Outpatient Dialysis | 7,200 | 30 | 10/60 | 36000 |
| 57.504 Prevention Process Measures Monthly Monitoring for Dialysis | 1,730 | 12 | 75/60 | 25,950 |
| 57.505 Dialysis Patient Influenza Vaccination | 615 | 50 | 10/60 | 5,125 |
| 57.506 Dialysis Patient Influenza Vaccination Denominator | 615 | 5 | 10/60 | 513 |
| 57.507 Home Dialysis Center Practices Survey | 430 | 1 | 30/60 | 215 |
| | Total Estimated Annual Burden (Hours) | | | **1,321,199** |

Red text signifies changes or corrections to burden
[a] Columns may not total due to rounding.

**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

## B. Estimates of Annualized Costs

The average salary of the professional discipline that is expected to perform surveillance has been used in the calculations of burden and is based on data from the Department of Labor, Bureau of Labor & Statistics, 2019. 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.

| **2018 Department Of Labor Salary Estimates** | | |
|---|---|---|
| **Professional Labor Category** | **Percentile** | **Hourly Wage** |
| Microbiologist (IP) | 75th | $52.11 |
| Clinical Laboratory Technologists and Technicians | 75th | $32.74 |
| Occupational Therapists (RN) | 50th | $40.84 |
| Pharmacist | 50th | $61.58 |
| Registered Nurse (RN) | 50th | $35.24 |
| Epidemiologists | 50th | $34.13 |
| Health Technologists and Technicians | 50th | $24.89 |

https://data.bls.gov/oes/#/indOcc/Multiple%20occupations%20for%20one%20industry
Accessed: 4/28/2020

**Estimated annualized burden cost[a]**

| **Type of Respondents** | **Form Number & Name** | **Total Burden (Hours)** | **Hourly Wage Rate** | **Total Respondent Costs** |
|---|---|---|---|---|
| Microbiologist | 57.100 NHSN Registration Form | 167 | $52.11 | $8,702.37 |
| Microbiologist | 57.101 Facility Contact Information | 333 | $52.11 | $17,352.63 |
| Microbiologist | 57.103 Patient Safety Component--Annual Hospital Survey | 6,201 | $52.11 | $323,134.11 |
| Microbiologist | 57.104 NHSN Facility Administrator Change Request Form | 67 | $52.11 | $3,491.37 |
| Epidemiologists | 57.105 Group Contact Information | 83 | $34.13 | $2,832.79 |
| Microbiologist | 57.106 Patient Safety Monthly Reporting Plan | 23,463 | $52.11 | $1,222,656.93 |
| Microbiologist | 57.108 Primary Bloodstream Infection (BSI) | 18,288 | $52.11 | $952,987.68 |
| Microbiologist | 57.111 Pneumonia (PNEU) | 1,800 | $52.11 | $93,798.00 |
| Microbiologist | 57.112 Ventilator-Associated Event | 20,395 | $52.11 | $1,062,783.45 |
| Microbiologist | 57.113 Pediatric Ventilator-Associated Event (PedVAE) | 167 | $52.11 | $8,702.37 |
| Microbiologist | 57.114 Urinary Tract Infection (UTI) | 10,000 | $52.11 | $521,100.00 |
| Microbiologist | 57.115 Custom Event | 31,850 | $52.11 | $1,659,703.50 |
| Microbiologist | 57.116 Denominators for Neonatal Intensive Care Unit (NICU) | 880 | $36.37 | $32,005.60 |
| Microbiologist | 57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC) | 500 | $36.37 | $18,185.00 |
| Registered Nurse | 57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA) | 27,500 | $35.24 | $969,100.00 |
| Microbiologist | 57.120 Surgical Site Infection (SSI) | 31,500 | $52.11 | $1,641,465.00 |
| Registered Nurse | 57.121 Denominator for Procedure | 602,000 | $35.24 | $21,214,480.00 |
| Epidemiologists | 57.122 HAI Progress Report State Health Department Survey | 26 | $52.11 | $1,354.86 |
| Registered Nurse | 57.123 Antimicrobial Use and Resistance | 2500 | $32.74 | $81,850.00 |

| Type of Respondents | Form Number & Name | Total Burden (Hours) | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|---|
| | (AUR)-Microbiology Data Electronic Upload Specification Tables | | | |
| Registered Nurse | 57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables | 2500 | $52.11 | $130,275.00 |
| Registered Nurse | 57.125 Central Line Insertion Practices Adherence Monitoring | 44,375 | $52.11 | $2,312,381.25 |
| Microbiologist | 57.126 MDRO or CDI Infection Form | 3960 | $52.11 | $206,355.60 |
| Microbiologist | 57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring | 39,875 | $52.11 | $2,077,886.25 |
| Microbiologist | 57.128 Laboratory-identified MDRO or CDI Event | 126,400 | $52.11 | $6,586,704.00 |
| Microbiologist | 57.129 Adult Sepsis | 5,208 | $52.11 | $271,388.88 |
| Microbiologist | 57.130 | 233,755 | $52.11 | $12,180,973.05 |
| Microbiologist | 57.131 | 233,755 | $52.11 | $12,180,973.05 |
| Microbiologist | 57.132 | 233,755 | $52.11 | $12,180,973.05 |
| Microbiologist | 57.135 Late Onset Sepsis/ Meningitis Denominator Form | 150 | $52.11 | $7,816.50 |
| Microbiologist | 57.136 Late Onset Sepsis/ Meningitis Event Form | 150 | $52.11 | $7,816.50 |
| Microbiologist | 57.137 Long-Term Care Facility Component – Annual Facility Survey | 6,158 | $52.11 | $320,893.38 |
| Microbiologist | 57.138 Laboratory-identified MDRO or CDI Event for LTCF | 15,984 | $52.11 | $832,926.24 |
| Microbiologist | 57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF | 7,992 | $52.11 | $416,463.12 |
| Microbiologist | 57.140 Urinary Tract Infection (UTI) for LTCF | 7,119 | $52.11 | $370,971.09 |
| Microbiologist | 57.141 Monthly Reporting Plan for LTCF | 2,011 | $52.11 | $104,793.21 |
| Microbiologist | 57.142 Denominators for LTCF Locations | 2,373 | $52.11 | $123,657.03 |
| Microbiologist | 57.143 Prevention Process Measures Monthly Monitoring for LTCF | 130 | $52.11 | $6,774.30 |
| Microbiologist | 57.144 | 127,175 | $52.11 | $6,627,089.25 |
| Microbiologist | 57.145 | 95,381 | $52.11 | $4,970,303.91 |
| Microbiologist | 57.146 | 31,794 | $52.11 | $1,656,785.34 |
| Microbiologist | 57.147 | 31,794 | $52.11 | $1,656,785.34 |
| Microbiologist | 57.150 LTAC Annual Survey | 583 | $52.11 | $30,380.13 |
| Microbiologist | 57.151 Rehab Annual Survey | 1,400 | $42.11 | $58,954.00 |
| Occupational Health RN/Specialist | 57.200 Healthcare Personnel Safety Component Annual Facility Survey | 400 | $40.84 | $16,336.00 |
| Occupational Health RN/Specialist | 57.204 Healthcare Worker Demographic Data | 333 | $40.84 | $13,599.72 |
| Occupational Health RN/Specialist | 57.205 Exposure to Blood/Body Fluids | 2,500 | $40.84 | $102,100.00 |
| Occupational Health RN/Specialist | 57.206 Healthcare Worker Prophylaxis/Treatment | 375 | $40.84 | $15,315.00 |
| Occupational Health RN/Specialist | 57.207 Follow-Up Laboratory Testing | 625 | $40.84 | $25,525.00 |
| Occupational Health RN/Specialist | 57.210 Healthcare Worker Prophylaxis/Treatment-Influenza | 417 | $40.84 | $17,030.28 |
| Medical/Clinical Laboratory Technologist | 57.300 Hemovigilance Module Annual Survey | 708 | $40.84 | $28,914.72 |
| Medical/Clinical | 57.301 Hemovigilance Module Monthly | 6,000 | $40.84 | $245,040.00 |

| Type of Respondents | Form Number & Name | Total Burden (Hours) | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|---|
| Laboratory Technologist | Reporting Plan | | | |
| Medical/Clinical Laboratory Technologist | 57.303 Hemovigilance Module Monthly Reporting Denominators | 7,000 | $40.84 | $285,880.00 |
| Medical/Clinical Laboratory Technologist | 57.305 Hemovigilance Incident | 833 | $40.84 | $34,019.72 |
| Medical/Clinical Laboratory Technologist | 57.306 Hemovigilance Module Annual Survey - Non-acute care facility | 292 | $40.84 | $11,925.28 |
| Medical/Clinical Laboratory Technologist | 57.307 Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction | 667 | $40.84 | $27,240.28 |
| Medical/Clinical Laboratory Technologist | 57.308 Hemovigilance Adverse Reaction - Allergic Transfusion Reaction | 667 | $40.84 | $27,240.28 |
| Medical/Clinical Laboratory Technologist | 57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction | 167 | $40.84 | $6,820.28 |
| Medical/Clinical Laboratory Technologist | 57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction | 333 | $40.84 | $13,599.72 |
| Medical/Clinical Laboratory Technologist | 57.311 Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction | 667 | $40.84 | $27,240.28 |
| Medical/Clinical Laboratory Technologist | 57.312 Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction | 167 | $40.84 | $6,820.28 |
| Medical/Clinical Laboratory Technologist | 57.313 Hemovigilance Adverse Reaction – Infection | 167 | $40.84 | $6,820.28 |
| Medical/Clinical Laboratory Technologist | 57.314 Hemovigilance Adverse Reaction - Post Transfusion Purpura | 167 | $40.84 | $6,820.28 |
| Medical/Clinical Laboratory Technologist | 57.315 Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea | 167 | $40.84 | $6,820.28 |
| Medical/Clinical Laboratory Technologist | 57.316 Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease | 167 | $40.84 | $6,820.28 |
| Medical/Clinical Laboratory Technologist | 57.317 Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury | 167 | $40.84 | $6,820.28 |
| Medical/Clinical Laboratory Technologist | 57.318 Hemovigilance Adverse Reaction - Transfusion Associated Circulatory Overload | 333 | $40.84 | $13,599.72 |
| Medical/Clinical Laboratory Technologist | 57.319 Hemovigilance Adverse Reaction - Unknown Transfusion Reaction | 167 | $40.84 | $6,820.28 |
| Medical/Clinical Laboratory Technologist | 57.320 Hemovigilance Adverse Reaction - Other Transfusion Reaction | 167 | $40.84 | $6,820.28 |
| Registered Nurse | 57.400 Outpatient Procedure Component—Annual Facility Survey | 117 | $35.24 | $4,123.08 |
| Registered Nurse | 57.401 Outpatient Procedure Component - Monthly Reporting Plan | 2,100 | $35.24 | $74,004.00 |
| Registered Nurse | 57.402 Outpatient Procedure Component Same Day Outcome Measures | 133 | $35.24 | $4,686.92 |
| Registered Nurse | 57.403 Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures | 53,333 | $35.24 | $1,879,454.92 |
| Registered Nurse | 57.404 Outpatient Procedure Component - SSI Denominator | 46,667 | $35.24 | $1,644,545.08 |
| Microbiologist | 57.405 Outpatient Procedure Component - Surgical Site (SSI) Event | 68,792 | $52.11 | $3,584,751.12 |
| Microbiologist | 57.500 Outpatient Dialysis Center Practices Survey | 15,240 | $52.11 | $794,156.40 |
| Registered Nurse | 57.501 Dialysis Monthly Reporting Plan | 7,200 | $35.24 | $253,728.00 |
| Registered Nurse | 57.502 Dialysis Event | 90,000 | $35.24 | $3,171,600.00 |

| Type of Respondents | Form Number & Name | Total Burden (Hours) | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|---|
| Registered Nurse | 57.503 Denominator for Outpatient Dialysis | 14,400 | $35.24 | $507,456.00 |
| Registered Nurse | 57.504 Prevention Process Measures Monthly Monitoring for Dialysis | 25,950 | $52.11 | $1,352,254.50 |
| Registered Nurse | 57.505 Dialysis Patient Influenza Vaccination | 5,125 | $35.24 | $180,605.00 |
| Registered Nurse | 57.506 Dialysis Patient Influenza Vaccination Denominator | 513 | $35.24 | $18,078.12 |
| Microbiologist | 57.507 Home Dialysis Center Practices Survey | 215 | $52.11 | $11,203.65 |
| | | Total Estimated Cost | | **$101,704,078** |

[a] Columns and rows may not total due to rounding.

**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 2020 is estimated to be **$18,045,604**

**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 FY 2020 will be $4,365,598 |
| | Supervisory Medical Officer | 1 | |
| | IT Specialist | 2 | |
| | Medical Epidemiologist | 5 | |
| | Statistician | 3 | |
| | Epidemiologist | 6 | |
| | Health Scientist | 2 | |

| Expense Item | Description | | Estimated Annual Cost |
|---|---|---|---|
| | Nurse Consultant<br>Public Health Analyst<br>Computer Scientist | 1<br>3<br>2 | |
| Programming contracts | Design, develop, and deploy enhancements to NHSN | | $13,680,006 |
| **Total** | | | **$18,045,604** |

**15. The explanation for Program Changes or Adjustments**

The proposed revisions to fourteen information collection tools in NHSN are detailed below:

- Forms 57.108, 57.111, 57.112, 57.113, 57.114, 57.115, and 57.120:
  *Justification for Change*: The antimicrobial susceptibility data collection for reported pathogens is requested for the following events: PNEU, VAE, PedVAE, UTI, SSI, MDRO/CDI, and Custom event. The update includes removal of some antimicrobial agents that are no longer in use, addition of some new agents and updates to the result value options (S,I,R,N, S-DD) for a few existing agents.
- 57.123: Clarified required pathogens. Removed variables that are populated by the NHSN application and not submitted in the CDA file itself. Added a new variable to allow vendors to report no AR events. Increased the number of facilities submitting from 1,500 to 2,500 based on the number of submissions in 2019. The time to complete this form was not changed because all changes above are handled on the vendor side, thus not causing any additional time or burden on the responding facilities' part.
  *Justification for change:* provides more clarification for respondents.
- 57.124: Antimicrobial Use and Resistance (AUR): Pharmacy Data Monthly Electronic Upload Specification Tables-Added and removed drugs. Four drugs were added and three drugs were removed. Added new variables required to be included in the CDA file by the vendor software that produced the files. Removed variables that are populated by the NHSN application and not submitted in the CDA file itself. Increased the number of facilities submitting data from 2,000 to 2,500. The time to complete this form was not changed because all changes above are handled on the vendor side, thus not causing any additional time or burden on the responding facilities' part. All changes are made by the vendor once a year.
  *Justification for change:* provides more clarification for respondents and updated selections.
- 57.140: Urinary Tract Infection (UTI) for LTCF: Change the definition of leukocytosis from > 14,000 cells/$mm^3$ to > 10,000 cells/$mm^3$.
  *Justification for change*: This change is being made to improve sensitivity of UTI detection when using leukocytosis as a criterion. Changes to UTI pathogen susceptibility data collection form. Specifically, require susceptibility response for Proteus mirabilis and add Nitrofurantoin as a drug option for select pathogens.

*Justification for change:* This change is being made to align with organism and susceptibility requirements reported by long-term care facilities in the LTCF 2018 Prevalence Survey. This change is being made to align with most recent CLSI guidelines.

- Four Dialysis component tools will be updated with this ICR (57.500, 57.501, 57.507, and 57.502).
  *Justification for change*: CDC added and revised multiple questions/options on the surveys to better understand possible risk factors for healthcare-associated infections (HAIs), as well as the patient population they serve for surveillance and prevention purposes. The antimicrobial susceptibility data collection for reported pathogens is now requested for bloodstream infections (BSI). These changes will help inform future policies/guidelines to reduce BSIs. Additionally, the change and updates to the forms are to gather information on the practices that occur in the dialysis settings (outpatient, home, etc). We need to know the current practices, which informs our infection control guidelines and ultimately polices for clinics to follow. The goal is to reduce bloodstream infections but we need to know what are the risk factors, current practices, etc and we can only do so by identifying such factors. New event-specific event dates were also added to the dialysis event form (57.502) to gather more accurate information on dialysis events.

**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.