National Healthcare Safety Network (NHSN)
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Revision Request
Supporting Statement Part A

Daniel A. Pollock. MD
Surveillance Branch Chief
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
Atlanta, Georgia 30329-4018
Phone: (404) 639-4237
Fax: (404) 639-4043
Email: dap1@cdc.gov

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I. Privacy Impact Assessment

- Since 2005, the National Healthcare Safety Network (NHSN) provides facilities, states, regions, and the nation with the data needed to identify problem areas, measure the progress of prevention efforts, and ultimately eliminate healthcare-associated infections (HAIs) in conjunction with driving the achievement of the overall mission of the Department of Health and Human Services (DHHS). Participation in NHSN has continuously increased, with over 23,000 actively reporting healthcare facilities across the U.S. Of these, there are over 5,000 acute care facilities, 6,700 dialysis facilities, 500 long-term acute care facilities, 1,100 inpatient rehabilitation facilities, 800 inpatient psychiatric facilities, 3,100 long-term care facilities, and 6,000 ambulatory surgery facilities. The top priorities for the DHHS involve reducing and preventing HAI prevalence and improving patient safety and the value of federally funded health care coverage. In pursuit of these Departmental goals, CDC works alongside the Centers for Medicare and Medicaid Services (CMS), to enable the use of NHSN data in CDC's surveillance and prevention programs and CMS's quality improvement, public reporting, and payment programs. CDC reports NHSN data to CMS on behalf of thousands of healthcare facilities that report HAI data to NHSN and participate in CMS's quality programs. In effect, NHSN serves as a multi-purpose platform that consolidates HAI-related reporting and analysis functions into one system, with a single set of data definitions, reporting specifications, and summary statistics. NHSN is an extensible platform that enables coverage to be expanded, both by enrolling additional types of healthcare facilities, such as long-term care facilities (LTCFs), and by adding or further specifying reportable event types, such as surgical site infections (SSIs) following operative procedures in ambulatory surgical centers (ASCs) and adverse reactions during or following administration of blood products. 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; (2) To enhance NHSN surveillance and data quality practices exercised by NHSN users and facilities alike; (3) To introduce a new Patient Safety component survey targeted to capture data form states about their mandated HAI reporting and have access to NHSN through a Data Use Agreement between CDC and State or Local Health Departments; (4) To update and revise existing survey questions within NHSN's Patient Safety, Long term care facility, Dialysis, and Hemovigilance components, by further analyzing user feedback provided to NHSN and its partnering organizations, intended to advance NHSN data reporting quality for HAI events, dialysis events, and hemovigilance adverse reaction protocols. 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.
- 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.
- The data for NHSN is collected via a secure internet application.

- NHSN participation is open to all U.S. healthcare facilities.
- Reporting institutions can access their own data at any time and analyze it through the internet interface. Reports containing aggregated data is published annually by 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 in-depth analysis of data from NHSN is published in peer-reviewed journals and presented at scientific and professional meetings.

OMB No. 0920-0666
National Healthcare Safety Network (NHSN)
Revision Request, Updated November 14, 2018

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 11,537,900 responses; 5,503,470 burden hours and $197,482,719 in annual cost, due to expire on January 31, 2021. The proposed changes in this new ICR include revisions made to 34 NHSN data collection tools and the addition of one new data collection form **(57.122)** within the Patient Safety Component **(Attachment D-2).** The reporting burden will decrease by **228,912** hours for a total estimated burden of **5,274,558 hours**. The annual cost of reporting will decrease by **$13,972,858** for a total cost burden of **$$183,509,861 (Attachment D-2).** NHSN has achieved significant burden reduction with this CR due to a decrease in the number of respondent for the Specialty Care Area (SCA) and Oncology (ONC) facilities reporting to NHSN. **Form (57.203) has been removed from this ICR because it is not subject to PRA approval due to the statutory waiver for immunization-related work.** Reporting facilities were re-evaluated by NHSN and it has been determined after conducting some additional analysis that the data collection tool is only being used by approximately 2,000 facilities compared to what was estimated last year. Additionally, NHSN has streamlined many of the response options for its data collection tools, which attributes to a reduction in the overall burden.

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.

NHSN currently has six components: Patient Safety (PS), Healthcare Personnel Safety (HPS), Biovigilance (BV), Long-Term Care Facility (LTCF), Outpatient Procedure (OPC), and Dialysis. **NHSN's new Outpatient Procedure Component will launch during the summer of 2018, which is intended to capture SSI data among Ambulatory Surgical Centers that reported data to NHSN.** Generally, 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. The Long-Term Care Facility Component captures data from skilled nursing facilities. Reporting methods under this component have been created by using forms from the PS Component as a base with modifications to specifically address the characteristics of LTCF residents and the specific data needs of facilities. 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 (SSI).

NHSN has increasingly served as the operating system for HAI reporting compliance through legislation established by the states. As of March 2018, 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 that protect patients. The Centers for Medicare and Medicaid Services (CMS) and other payers use these data to determine incentives for performance, and members of the public may use the data to select among available providers. Each of these parties relies on the completeness and accuracy of the data. CDC and CMS 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)), which is in (Attachment A).

The ICR previously approved in January of 2018 included 72 individual data collection forms; the current revision request includes revisions to 34 data collection forms and the addition of one new Patient Safety form for a total of 73 proposed data collection forms (Attachment C). A detailed explanation of the proposed program changes is included in section A-15 of this document and Attachment D-1. An itemized list of proposed changes to each data collection form and their justifications are located in Attachment D-2.

In summary, the proposed revisions to the information collection tools in NHSN include 34 changes to previously approved data collection tools and the addition of one new form. The following program changes with the appropriate burden modification per individual hospital/facility per year reflected below;

1. Three annual facility surveys for the Patient Safety component for Hospitals (57.103), Long-Term Acute Care Facilities (57.150) and Inpatient Rehabilitation Facilities (57.151) underwent multiple revisions for this ICR. On all three surveys, five questions were revised to add further clarity to the reporting requirements of data collected related to fungal testing, facility locations, and laboratory testing locations. Additionally, corresponding response options for these questions have been revised to include updated testing methods used by facilities to capture current HAI specific data requirements for reporting to NHSN. Four new required questions have been added to all the surveys. The new questions will capture information related to existing protocols, policies, and standards organized by reporting facilities to ensure that when an event is detected the facility has the appropriate mechanism to conduct complete reporting. The hospital annual survey (57.103) added six required questions to capture information about neo-natal antimicrobial stewardship practices that differ from current practices conducted in adult and pediatric locations of facilities previously captured on the survey. Ten questions were removed from all three surveys to better align with the Core Elements of Hospital Antibiotic Stewardship specified by CDC. In addition, changes will improve descriptions of the current stewardship programs listed in NHSN protocols. The Core Elements are part of a broad-based effort by CDC and its healthcare and public health partners to combat antibiotic-resistant bacteria. The new questions will provide additional data about operational features of the Antibiotic Stewardship Programs that hospitals have implente4d, which in turn will help CDC and healthcare and public health partners target their efforts to invigorate and extend stewardship programs. Finally, 10 new optional questions regarding a hospitals' antibiotic stewardship practices were added to all three surveys, which provide supplemental details related to the required questions.
    - 57.103 - Patient Safety Component Annual Hospital Survey: Time burden for this form will increase by 15 minutes per facility, participating facilities will increase by approximately 1,000 facilities, increasing the overall annual cost burden.

- **57.150 - Patient Safety Component Annual Facility Survey for LTAC: Reporting facilities updated to 500 from 400. The time burden for this form will increase by 10 minutes per facility, increasing the overall annual cost burden.**
- **57.151 - Patient Safety Component Annual Facility Survey for IRF: Reporting facilities updated to 1200 from 1000. Time burden for this form will increase by 10 minutes per facility, increasing the overall annual cost burden.**

2. The number of participating facilities has increased for five data collection tools. Additional healthcare facilities continue to enroll in the Patient Safety, Healthcare Personnel Safety and Dialysis Components of NHSN; therefore, CDC has increased the estimated number of facilities that will report data during the calendar year 2019. Many of the changes will result in an increase in burden and cost estimates.

- 57.103 - Patient Safety Component Annual Hospital Survey: Time burden for this form will increase by 10 minutes per facility, participating facilities will increase by approximately 1,000 facilities, increasing the overall annual cost burden
- 57.123 - Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables: Participating facilities will increase by approximately 650 facilities, increasing the overall annual cost burden
- 57.124 - Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables: Participating facilities will increase by approximately 1,200 facilities, increasing the overall annual cost burden
- **57.203 - Healthcare Personnel Safety Monthly Reporting Plan: Participating facilities will decrease by approximately 17,000 facilities, decreasing the overall annual cost burden**
- 57.504 - Prevention Process Measures Monthly Monitoring for Dialysis: Participating facilities will decrease by approximately 1,000 facilities, decreasing the overall annual cost burden

3. Ten HAI forms within the NHSN Patient Safety Component are changing with this ICR. The number of reporting facilities using the Patient Safety forms (57.103, 57.117, 57.123), and (57.124) have increased to reflect the actual number of facilities reporting data to NHSN for a more accurate burden estimate. More specifically, NHSN has added optional fields to form (57.108) to detect risk factors that can be associated with a Bloodstream Infection (BSI) but have great potential to be excluded from Central Line-Associated Bloodstream Infection (CLABSI) surveillance. Collection of this data will help with analysis of BSIs not associated with central line use. For form (57.106), an addition was made to the response options under the Device Associated Module of the form to accommodate the new NHSN Pediatric Ventilator Associated Event (PedVAE) surveillance module scheduled to be released in 2019. For form (57.113), the Pediatric Ventilator-associated Event PedVAE was removed due to the scientific algorithm being single tiered and there only being one specific event for PedVAE. For the UTI form (57.114), response options were updated to include “Suprapubic tenderness” to align the form with NHSN protocols. NHSN receives data reported on ventilator-associated events available for NICU locations. NICU facility locations will now be required to report data to NHSN for denominator event reporting, in which CDC has provided an option to accommodate facilities that are reporting requested data by updating forms (57.116, 57.117), and (57.121). Finally, NHSN has updated the Antimicrobial Use and Resistance (AUR) data collection tools for the purposes of monitoring additional

microorganisms and their antimicrobial susceptibility profiles, which will provide additional data for healthcare and public health responses to mounting antibiotic resistance problems.

- 57.103 - Patient Safety Component Annual Hospital Survey: Time burden for this form will increase by 10 minutes per facility, participating facilities will increase by approximately 1,000 facilities, increasing the overall annual cost burden
- 57.106- Patient Safety Monthly reporting Plan: No change in annual burden per hospital
- 57.108 Primary Bloodstream Infection (BSI): No change in burden per hospital
- 57.113 - Pediatric Ventilator-Associated Event: No change in burden per hospital
- 57.114 - Urinary Tract Infection (UTI): No change in burden per hospital
- 57.116 - Denominators for Neonatal Intensive Care Unit (NICU): No change in burden per hospital
- 57.117 - Denominators for Specialty Care Area (SCA)/Oncology (ONC): Participating facilities will decrease by approximately 4,000 facilities, decreasing the overall annual burden by 180,480 hours
- 57.123 - Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables; Participating facilities will increase by approximately 650 facilities, increasing the overall annual burden by 650 hours
- 57.124 - Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables; Participating facilities will increase by approximately 1,200 facilities, increasing the overall annual burden by 1,200 hours

4. A new optional survey form (57.122), has been added to the Patient Safety Component that is designed to be completed by state and local health departments that participate in HAI surveillance and prevention activities. This new form will provide data on legal and regulatory requirements that are pertinent to HAI reporting. CDC plans to include data the health department survey in its annual National and State Healthcare-Associated Infection Progress Report. The report helps identify the progress in HAI surveillance and prevention at the state and national levels. Data about the extent to which state health departments have validated HAI data that healthcare facilities in their jurisdiction report to NHSN and the extent of state and local health department HAI reporting requirements are important data for users of CDC's HAI Progress Report to consider when they are reviewing and interpreting data in the report.
   - 57.122 - HAI Progress Report State Health Department Survey: departments completing this form will see a burden increase of 41 hours annually per facility

5. The Hemovigilance module survey (57.300) and 14 Adverse Reaction forms within the Biovigilance Component were modified (57.30757.320) with this ICR. Data collected on facility demographics has been made electronic and will now auto-populate data into the form that collected from the NHSN application, which will decrease the overall burden for the annual survey. Additionally, response options for blood type and treatment were revised on each form to capture more detailed patient-specific treatment data, which will not impact the overall burden for these forms.

   - 57.300 - Hemovigilance Module Annual Survey: Time burden for this form will decrease by 35 minutes per facility, the annual burden will decrease by 292 hours per facility

- 57.307 – Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction: No burden change per hospital per year
- 57.308 – Hemovigilance Adverse Reaction - Allergic Transfusion Reaction: No burden change per hospital per year
- 57.309 – Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction: No burden change per hospital per year
- 57.310 – Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction: No burden change per hospital per year
- 57.311 – Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction: No burden change per hospital per year
- 57.312 – Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction: No burden change per hospital per year
- 57.313 – Hemovigilance Adverse Reaction – Infection: No burden change per hospital per year
- 57.314 – Hemovigilance Adverse Reaction - Post Transfusion Purpura: No burden change per hospital per year
- 57.315 – Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea: No burden change per hospital per year
- 57.316 – Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease: No burden change per hospital per year
- 57.317 – Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury: No burden change per hospital per year
- 57.318 – Hemovigilance Adverse Reaction - Transfusion Associated Circulatory Overload: No burden change per hospital per year
- 57.319 – Hemovigilance Adverse Reaction - Unknown Transfusion Reaction: No burden change per hospital per year
- 57.320 – Hemovigilance Adverse Reaction - Other Transfusion Reaction: No burden change per hospital per year

6. Three LTCF forms will be updated, two of which (57.139, 57.142), will include an update for facilities to document the "CDI treatment start" variable. Early CDI reporting data from nursing homes has shown exceptionally low event rates for many reporting facilities (e.g., zero events for six or more months). Since current CDI event detection is based on the presence of a positive laboratory specimen, variability in the use of diagnostic testing as part of CDI management will have direct impact on the estimate of CDI burden in a facility (e.g., empiric treatment for CDI without confirmatory testing may result in the appearance of low disease burden). To better determine whether low CDI event rates are due to empiric CDI treatment practices, a new process measure will incorporate the monthly summary data on CDI for LTCFs. This measure, called "CDI treatment starts," will allow providers to capture the number of residents started on antibiotic treatment for CDI that month based on clinical decisions (i.e., even those without a positive CDI test). This process measure should provide data on clinically-treated CDI to inform our understanding of CDI management practices and serve as a proxy for CDI burden in nursing homes. Additionally, CDC's work with CMS on a voluntary National Nursing Home Quality Collaborative, which focuses on the recruitment and retention of nursing homes collecting and reporting data into the NHSN in efforts to track and prevent *Clostridioides difficile* infections, has contributed to the revision of these

form (57.140). Recruitment and NHSN enrollment began in May 2016 and continued through July 2019.

- 57.139 - MDRO and CDI LabID Event Reporting Monthly Summary Data for LTCF: Time burden for this form will increase by 10 minutes per facility, the annual burden will increase by 5,200 hours per facility, increasing the annual cost burden
- 47.140 - Urinary Tract Infection (UTI) for LTCF: No burden change per hospital per year
- 47.142 - Denominators for LTCF Locations: Annual Facility Survey: Time burden for this form will increase by 10 minutes per facility, the annual burden will increase by 5,200 hours per facility, increasing the annual cost burden

7. Three Dialysis component tools will be updated with this ICR. CDC added a new question and revised multiple response options to have a more accurate count of the facilities which are accredited by an organization outside of CMS and to better reflect the information captured using this data collection tool (57.500). There is a decrease in the number of reporting facilities from 2,000 to 1,000 due to a decline in use (57.504). The 'Injection Safety' field of the Prevention Process Measures (PPM) summary form was divided into two fields: 'Injection Safety- Medication Preparation' and 'Injection Safety – Medication Administration.' CDC is modifying the 'Injection Safety' field on the Monthly Reporting Plan MRP to align with the PPM summary form to allow a user to indicate which injection safety practice(s) they are observing in-plan (57.501).
   - 57.500- Outpatient Dialysis Center Practices Survey: Time burden for this form will increase by 2 minutes per facility, the annual burden will increase by 13,883 hours per facility, increasing the annual cost burden
   - 57.501- Dialysis Monthly Reporting Plan: No burden change per hospital per year
   - 57.504-Prevention Process Measures Monthly Monitoring for Dialysis: Participating facilities will increase by approximately 1,000 facilities, the annual burden will increase by 13,000 hours per facility, increasing the annual cost burden

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 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.

Clinical Document Architecture (CDA) is a Health Level 7 (HL7) standard that provides technical specifications for electronic formatting documents for inter-operable 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

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 (IQRP)
- CMS Prospective Payment System (PPS)
- End-stage Renal Disease (ESRD)
- Quality Incentive Program
- CMS Inpatient Rehabilitation Facility Quality Reporting Program
- CMS Inpatient Psychiatric Facility Quality Reporting Program
- CMS Long-Term Care Hospital Quality Reporting Program (LTCHQR)
- CMS PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program
- CMS Ambulatory Surgical Center Quality Reporting (ASCQR) Program

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 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.

As of April 2018, there are over 23,000 healthcare facilities enrolled in NHSN. Of these, there are over 5,000 acute care facilities; 6,700 dialysis facilities; 500 long-term acute care facilities; 1,100 inpatient rehabilitation facilities; 800 inpatient psychiatric facilities; 3,100 long-term care facilities; and 6,000 ambulatory surgery facilities. The majority of these facilities are participating in CMS reporting programs for specific infection types. In 2011, the CMS IQRP began for all acute care facilities with intensive care units. Further, in 2013, the CMS IQRP

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) Clostridioides 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.

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 is published in the *Federal Register* on 05/11/2018, Vol. 83, No. 92, pg. 22074-22076 (Attachment B). One non-substantive public comment was received (Attachment B2).

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 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.

10.1 Privacy Impact Assessment Information

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 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. Incorporating all proposed revisions, the estimated burden for reporting reflects a decrease in hours by **228,912** hours while annual cost decrease by **$ 13,972,858 for a total annual cost of $ $183,509,861** compared to the most recently approved ICR in January 2018. Detailed revisions of the previous burden tables are available in Attachments D-3 and D-4.

Estimated annual burden

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.100 NHSN Registration Form	2,000	1	5/60	167	0	Yes	This form must be completed during NHSN enrollment, which is required for CMS reporting	
57.101 Facility Contact Information	2,000	1	10/60	333	0	Yes	This form must be completed during NHSN enrollment, which is required for CMS reporting	
57.103 Patient Safety Component--Annual Hospital Survey	6,000	1	1.17	7,500	2,500	Yes; IQR, LTCHQR, PCHQR		**Increase**
57.105 Group Contact Information	1,000	1	5/60	83	0	No	NHSN requires this form to be completed for NHSN group user registration	
57.106 Patient Safety Monthly Reporting Plan	6,000	12	15/60	18,000	0	Yes; IQR, LTCHQR, PCHQR		

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.108 Primary Bloodstream Infection (BSI)	6,000	44	33/60	145,200	0	Yes; IQR, LTCHQR, PCHQR		
57.111 Pneumonia (PNEU)	1,800	72	30/60	64,800	0	No	This form must be completed for Pneumonia events reported to NHSN. The city of Pittsburg in Pennsylvania has required reporting on this measure through NHSN by participating facilities in the state.	
57.112 Ventilator-Associated Event	**5,615**	**144**	**28/60**	**377,328**	**25,872**	**No**		**Decrease**
57.113 Pediatric Ventilator-Associated Event (PedVAE)	100	120	30/60	6,000	0	No	This form is not required, it is in the developmental stages and will be active in 2019.	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.114 Urinary Tract Infection (UTI)	6,000	40	20/60	80,000	0	Yes; IQR PCHQR IRFQR LTCHQR		
57.115 Custom Event	600	91	35/60	31,850	0	No	This form is required by NHSN only when a facility customizes data for their event. This data is optional and for facility-level analysis only.	
57.116 Denominators for Neonatal Intensive Care Unit (NICU)	6,000	12	4	288,000	0	Yes; IQR		
57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	2,000	9	5.03	90,600	180,480	Yes; IQR		**Decrease**
57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	6,000	60	5.03	1,812,000	0	Yes; IQR		

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.120 Surgical Site Infection (SSI)	6,000	36	35/60	126,000	0	Yes; IQR, PCHQR		
57.121 Denominator for Procedure	6,000	540	10/60	540,000	0	Yes; IQR, PCHQR		
57.122 HAI Progress Report State Health Department Survey	55	1	45/60	41	41	No	**This is an optional data collection form and is completed by participating healthcare facilities only if a state or local health department is using NHSN data to conduct/manage their HAI surveillance activities. Data captured will aid in the development of the annual HAI progress report. See Attachment D-2 for detailed justification.**	**Increase**

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	1,000	12	5/60	1,000	650	Yes; MU3	**This form is required by NHSN for facilities that report data through electronic health records and as a part of the Meaningful Use Stage 3 incentive. The antimicrobials that are required to be reported for susceptibility testing were reviewed and updated per the most recent Clinical and Laboratory Standards Institute (CLSI) standards. Attachment D-2 for detailed justification.**	**Increase**

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	2,000	12	5/60	2,000	1,200	Yes; MU3	**This form is required by NHSN for facilities that report data through electronic health records and as a part of MU3. Two new antimicrobials were recently approved by FDA and will be used by hospitals for treating infections. By capturing the use of these two new drugs, hospitals will be able to better track use and implement stewardship interventions if needed.**	**Increase**
57.125 Central Line Insertion Practices Adherence Monitoring	100	100	25/60	4,167	0	No		
57.126 MDRO or CDI Infection Form	6,000	72	30/60	216,000	0	Yes; IQR, PCHQR		

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	4930	24	15/60	29,580	**6,420**	Yes; IQR, PCHQR	The form is not required by NHSN, and is no longer subject to PRA approval due to the statutory waiver for immunization-related work.	**Decrease**
57.128 Laboratory-identified MDRO or CDI Event	4930	240	20/60	394,400	85,600	Yes; IQR, PCHQR		**Decrease**
57.129 Adult Sepsis	50	250	25/60	5,208		No	This form is not required by NHSN; this module is in a developmental phase and is expected to be active by 2020	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.137 Long-Term Care Facility Component – Annual Facility Survey	2,600	1	2	5,200	0	No	This form is required by NHSN for facilities that voluntarily report data into NHSN's National Nursing Home Quality Collaborative with CMS to track and prevent Clostridioides difficile infections. The state of Nevada has mandated that all Skilled Nursing Facilities report data to NHSN.	
57.138 Laboratory-identified MDRO or CDI Event for LTCF	2,600	12	20/60	10,400	0	No	This form is required by NHSN for facilities that voluntarily report data into NHSN's National Nursing Home Quality Collaborative with CMS to track and prevent Clostridioides difficile infections. The state of Nevada has mandated that all Skilled Nursing Facilities report data to NHSN.	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	2,600	12	20/60	10,400	**5,200**	No	**This form is required by NHSN for Health Departments to acess the voluntarily reported data into NHSN's National Nursing Home Quality Collaborative with CMS to track and prevent Clostridioides difficile infections.**	**increase**
57.140 Urinary Tract Infection (UTI) for LTCF	2,600	14	35/60	18,200	0	No	This form is required by NHSN for facilities that voluntarily report data into NHSN's National Nursing Home Quality Collaborative with CMS to track and prevent Clostridioides difficile infections. The state of Nevada has mandated that all Skilled Nursing Facilities report data to NHSN.	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.141 Monthly Reporting Plan for LTCF	2,600	12	5/60	2,600	0	No	This form is required by NHSN for facilities that voluntarily report data into NHSN's National Nursing Home Quality Collaborative with CMS to track and prevent Clostridioides difficile infections. The state of Nevada has mandated that all Skilled Nursing Facilities report data to NHSN.	
57.142 Denominators for LTCF Locations	2,600	12	4.17	130,000	**5,200**	No	**This form is required by NHSN for facilities that voluntarily report data into NHSN's National Nursing Home Quality Collaborative with CMS to track and prevent Clostridioides difficile infections. The state of Nevada has mandated that all Skilled Nursing Facilities report data to NHSN.**	**Increase**

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.143 Prevention Process Measures Monthly Monitoring for LTCF	2,600	12	5/60	2,600	0	No	This form is required by NHSN for facilities that voluntarily report data into NHSN's National Nursing Home Quality Collaborative with CMS to track and prevent Clostridioides difficile infections. The state of Nevada has mandated that all Skilled Nursing Facilities report data to NHSN.	
57.150 LTAC Annual Survey	500	1	1.17	583	183	Yes; LTCHQR		**Increase**
57.151 Rehab Annual Survey	1,200	1	1.17	1,400	400	Yes; IRFQR		**Increase**
57.200 Healthcare Personnel Safety Component Annual Facility Survey	50	1	8	400	0	No	This form is required by NHSN and optional for facilities to report various HPS events	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.203 Healthcare Personnel Safety Monthly Reporting Plan	0	1	5/60	0	1,417	No	**The form is required by NHSN: and removed from this ICR to meet the statutory waiver requirements for immunization-related work.**	**Decrease**
57.204 Healthcare Worker Demographic Data	50	200	20/60	3,333	0	No		
57.205 Exposure to Blood/Body Fluids	50	50	1	2,500	0	No		
57.206 Healthcare Worker Prophylaxis/Treatment	50	30	15/60	375	0	No		
57.207 Follow-Up Laboratory Testing	50	50	15/60	625	0	No		
57.210 Healthcare Worker Prophylaxis/Treatment-Influenza	50	50	10/60	417	0	No		
57.300 Hemovigilance Module Annual Survey	500	1	1.42	708	**292**	No	**This form is optional but only required by NHSN when a facility is reporting on their Biovigilance Component (BV) events.**	**Decrease**

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.301 Hemovigilance Module Monthly Reporting Plan	500	12	1/60	100	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	
57.303 Hemovigilance Module Monthly Reporting Denominators	500	12	1.17	7,000	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	
57.305 Hemovigilance Incident	500	10	10/60	833	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.306 Hemovigilance Module Annual Survey - Non-acute care facility	200	1	35/60	117	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	
57.307 Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction	500	4	20/60	667	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	
57.308 Hemovigilance Adverse Reaction - Allergic Transfusion Reaction	500	4	20/60	667	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction	500	1	20/60	167	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	
57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction	500	2	20/60	333	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	
57.311 Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction	500	4	20/60	667	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.312 Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction	500	1	20/60	167	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	
57.313 Hemovigilance Adverse Reaction - Infection	500	1	20/60	167	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	
57.314 Hemovigilance Adverse Reaction - Post Transfusion Purpura	500	1	20/60	167	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.315 Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea	500	1	20/60	167	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	
57.316 Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease	500	1	20/60	167	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	
57.317 Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury	500	1	20/60	167	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.318 Hemovigilance Adverse Reaction - Transfusion Associated Circulatory Overload	500	2	20/60	333	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	
57.319 Hemovigilance Adverse Reaction - Unknown Transfusion Reaction	500	1	20/60	167	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	
57.320 Hemovigilance Adverse Reaction - Other Transfusion Reaction	500	1	20/60	167	0	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.400 Outpatient Procedure Component—Annual Facility Survey	5,000	1	10/60	417	0	No	This form is required for Ambulatory Surgery Centers (ASC) that have state-based surgical site infection (SSI) surveillance reporting mandates. There are 36 states that have SSI reporting mandates.	
57.401 Outpatient Procedure Component - Monthly Reporting Plan	5,000	12	20/60	15,000	0	No	This form is required for Ambulatory Surgery Centers (ASC) that have state-based surgical site infection (SSI) surveillance reporting mandates. There are 36 states that have SSI reporting mandates.	
57.402 Outpatient Procedure Component Same Day Outcome Measures	1,200	25	40/60	20,000	0	No	This form is optional for reporting into NHSN	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.403 Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures	1,200	12	40/60	9,600	0	No	This form is optional for reporting into NHSN	
57.404 Outpatient Procedure Component – SSI Denominator	5,000	540	10/60	450,000	0	No	This form is required for Ambulatory Surgery Centers (ASC) that have state-based surgical site infection (SSI) surveillance reporting mandates. There are 36 states that have SSI reporting mandates.	
57.405 Outpatient Procedure Component - Surgical Site (SSI) Event	5,000	36	35/60	105,000	0	No	This form is required for Ambulatory Surgery Centers (ASC) that have state-based surgical site infection (SSI) surveillance reporting mandates. There are 36 states that have SSI reporting mandates.	
57.500 Outpatient Dialysis Center Practices Survey	7,000	1	2.12	14,817	467	Yes; ESRD QIP		**Increase**

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.501 Dialysis Monthly Reporting Plan	7,000	12	5/60	7,000	0	Yes; ESRD QIP		**These changes will not have an impact on the overall annual burden for this form.**
57.502 Dialysis Event	7,000	60	25/60	175,000	0	Yes; ESRD QIP		
57.503 Denominator for Outpatient Dialysis	7,000	12	10/60	14,000	0	Yes; ESRD QIP		
57.504 Prevention Process Measures Monthly Monitoring for Dialysis	2,000	12	1.42	17,000	**13,000**	No		
57.505 Dialysis Patient Influenza Vaccination	325	75	10/60	4,063	0	No	This form is required by NHSN only when a dialysis facility reports flu data into NHSN	
57.506 Dialysis Patient Influenza Vaccination Denominator	325	5	10/60	271	0	No	This form is required by NHSN only when a dialysis facility reports flu data into NHSN	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Total burden change from previous Year	Required by a CMS Reporting program	The requirement for NHSN participation or state reporting	Burden change (Hours Increase or Decrease)
57.507 Home Dialysis Center Practices Survey	350	1	30/60	175	0	Yes; ESRD QIP		
	Total Estimated Annual Burden (Hours)			**5,274,558**	**228,912**			

[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, 2017. 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.

2015 Department Of Labor Salary Estimates		
Professional Labor Category	**Percentile**	**Hourly Wage**
Infection Preventionist RN	75th	$39.66
Medical/Clinical Laboratory Technologist	75th	$34.99
Occupational Health Nurse	50th	$33.75
Pharmacist	50th	$58.41
Staff RN	50th	$32.45
Laboratory Technician	50th	$18.73

https://www.bls.gov/bls/blswage.htm#National
Accessed: 4/2/2018

Estimated annualized burden cost[a]

Type of Respondents	Form Number & Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
Registered Nurse (Infection Preventionist)	57.100 NHSN Registration Form	167	$39.66	$6,610
Registered Nurse (Infection Preventionist)	57.101 Facility Contact Information	333	$39.66	$13,220
Registered Nurse (Infection Preventionist)	57.103 Patient Safety Component--Annual Hospital Survey	7,500	$39.66	$297,450
Registered Nurse (Infection Preventionist)	57.105 Group Contact Information	83	$39.66	$3,305
Registered Nurse (Infection Preventionist)	57.106 Patient Safety Monthly Reporting Plan	18,000	$39.66	$713,880
Registered Nurse (Infection Preventionist)	57.108 Primary Bloodstream Infection (BSI)	145,200	$39.66	$5,758,632
Registered Nurse (Infection Preventionist)	57.111 Pneumonia (PNEU)	64,800	$39.66	$2,569,968
Registered Nurse (Infection Preventionist)	57.112 Ventilator-Associated Event	395,808	$39.66	$15,697,745
Registered Nurse (Infection Preventionist)	57.113 Pediatric Ventilator-Associated Event (PedVAE)	6,000	$39.66	$237,960
Registered Nurse (Infection Preventionist)	57.114 Urinary Tract Infection (UTI)	80,000	$39.66	$3,172,800
Registered Nurse (Infection Preventionist)	57.115 Custom Event	31,850	$39.66	$1,263,171
Staff RN	57.116 Denominators for Neonatal Intensive Care Unit (NICU)	288,000	$32.45	$9,345,600

Type of Respondents	Form Number & Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
Staff RN	57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	90,600	$32.45	$2,939,970
Staff RN	57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	1,812,000	$32.45	$58,799,400
Registered Nurse (Infection Preventionist)	57.120 Surgical Site Infection (SSI)	126,000	$39.66	$4,997,160
Staff RN	57.121 Denominator for Procedure	540,000	$32.45	$17,523,000
Registered Nurse (Infection Preventionist)	57.122 HAI Progress Report State Health Department Survey	41	$39.66	$1,636
Laboratory Technician	57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	1,000	$18.73	$18,730
Pharmacist	57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	2,000	$58.41	$116,820
Registered Nurse (Infection Preventionist)	57.125 Central Line Insertion Practices Adherence Monitoring	4,167	$39.66	$165,250
Registered Nurse (Infection Preventionist)	57.126 MDRO or CDI Infection Form	216,000	$39.66	$8,566,560
Registered Nurse (Infection Preventionist)	57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	29,580	$39.66	$1,173,143
Registered Nurse (Infection Preventionist)	57.128 Laboratory-identified MDRO or CDI Event	394,400	$39.66	$15,641,904
Registered Nurse (Infection Preventionist)	57.129 Adult Sepsis	5,208	$39.66	$206,563
Registered Nurse (Infection Preventionist)	57.137 Long-Term Care Facility Component – Annual Facility Survey	5,200	$39.66	$206,232
Registered Nurse (Infection Preventionist)	57.138 Laboratory-identified MDRO or CDI Event for LTCF	10,400	$39.66	$412,464
Registered Nurse (Infection Preventionist)	57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	10,400	$39.66	$412,464
Registered Nurse (Infection Preventionist)	57.140 Urinary Tract Infection (UTI) for LTCF	18,200	$39.66	$721,812
Registered Nurse (Infection Preventionist)	57.141 Monthly Reporting Plan for LTCF	2,600	$39.66	$103,116
Registered Nurse (Infection Preventionist)	57.142 Denominators for LTCF Locations	130,000	$39.66	$5,155,800
Registered Nurse (Infection Preventionist)	57.143 Prevention Process Measures Monthly Monitoring for LTCF	2,600	$39.66	$103,116
Registered Nurse (Infection Preventionist)	57.150 LTAC Annual Survey	583	$39.66	$23,135
Registered Nurse (Infection Preventionist)	57.151 Rehab Annual Survey	1,400	$39.66	$55,524
Occupational Health RN/Specialist	57.200 Healthcare Personnel Safety Component Annual Facility Survey	400	$33.75	$13,500

Type of Respondents	Form Number & Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
Occupational Health RN/Specialist	57.203 Healthcare Personnel Safety Monthly Reporting Plan	1,625	$33.75	$54,844
Occupational Health RN/Specialist	57.204 Healthcare Worker Demographic Data	3,333	$33.75	$112,500
Occupational Health RN/Specialist	57.205 Exposure to Blood/Body Fluids	2,500	$33.75	$84,375
Occupational Health RN/Specialist	57.206 Healthcare Worker Prophylaxis/Treatment	375	$33.75	$12,656
Laboratory Technician	57.207 Follow-Up Laboratory Testing	625	$18.73	$11,706
Occupational Health RN/Specialist	57.210 Healthcare Worker Prophylaxis/Treatment-Influenza	417	$33.75	$14,063
Medical/Clinical Laboratory Technologist	57.300 Hemovigilance Module Annual Survey	708	$34.99	$24,785
Medical/Clinical Laboratory Technologist	57.301 Hemovigilance Module Monthly Reporting Plan	100	$34.99	$3,499
Medical/Clinical Laboratory Technologist	57.303 Hemovigilance Module Monthly Reporting Denominators	7,000	$34.99	$244,930
Medical/Clinical Laboratory Technologist	57.305 Hemovigilance Incident	833	$34.99	$29,158
Medical/Clinical Laboratory Technologist	57.306 Hemovigilance Module Annual Survey - Non-acute care facility	117	$34.99	$4,082
Medical/Clinical Laboratory Technologist	57.307 Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction	667	$34.99	$23,327
Medical/Clinical Laboratory Technologist	57.308 Hemovigilance Adverse Reaction - Allergic Transfusion Reaction	667	$34.99	$23,327
Medical/Clinical Laboratory Technologist	57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction	333	$34.99	$11,663
Medical/Clinical Laboratory Technologist	57.311 Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction	667	$34.99	$23,327
Medical/Clinical Laboratory Technologist	57.312 Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.313 Hemovigilance Adverse Reaction – Infection	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.314 Hemovigilance Adverse Reaction - Post Transfusion Purpura	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.315 Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.316 Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.317 Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.318 Hemovigilance Adverse Reaction - Transfusion Associated Circulatory Overload	333	$34.99	$11,663

Type of Respondents	Form Number & Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
Medical/Clinical Laboratory Technologist	57.319 Hemovigilance Adverse Reaction - Unknown Transfusion Reaction	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.320 Hemovigilance Adverse Reaction - Other Transfusion Reaction	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.400 Outpatient Procedure Component—Annual Facility Survey	417	$32.45	$13,532
Staff RN	57.401 Outpatient Procedure Component - Monthly Reporting Plan	15,000	$32.45	$486,750
Staff RN	57.402 Outpatient Procedure Component Same Day Outcome Measures	20,000	$32.45	$649,000
Staff RN	57.403 Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures	9,600	$32.45	$311,520
Staff RN	57.404 Outpatient Procedure Component - SSI Denominator	450,000	$39.66	$14,602,500
Registered Nurse (Infection Preventionist)	57.405 Outpatient Procedure Component - Surgical Site (SSI) Event	105,000	$32.45	$3,407,250
Staff RN	57.500 Outpatient Dialysis Center Practices Survey	14,817	$39.66	$587,629
Registered Nurse (Infection Preventionist)	57.501 Dialysis Monthly Reporting Plan	7,000	$32.45	$227,150
Staff RN	57.502 Dialysis Event	175,000	$32.45	$5,678,750
Staff RN	57.503 Denominator for Outpatient Dialysis	14,000	$32.45	$454,300
Staff RN	57.504 Prevention Process Measures Monthly Monitoring for Dialysis	17,000	$32.45	$551,650
Staff RN	57.505 Dialysis Patient Influenza Vaccination	4,063	$32.45	$131,828
Staff RN	57.506 Dialysis Patient Influenza Vaccination Denominator	271	$32.45	$8,789
Staff RN	57.507 Home Dialysis Center Practices Survey	175	$39.66	$6,941
		Total Estimated Cost		**$183,509,861**

[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 additional 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 147 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 2019 is estimated to be $18,132,059.

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 2019 will be $4,452,052
	Supervisory. Medical Officer	1	
		2	
	Medical Epidemiologist	2	
	Statistician	9	
	Epidemiologist	2	
	Nurse Epidemiologist	3	
	Systems Analyst	2	
	Public Health Analyst	3	
	Computer Scientist		
Programming contracts	Design, develop, and deploy enhancements to NHSN		$13,680,007
Total			**$18,132,059**

15. The explanation for Program Changes or Adjustments

Thirty-three data collection tools under OMB No. 0920-0666 have been revised in this revision request.

1. Nine form updates to the Patient Safety Component (PSC) (57.103, 57.016, 57.108, 57.113, 57.114, 57.116, 57.117, 57.122, 57.123, 57.124).

8. **Justification:** Ten forms within the NHSN Patient Safety Component are changing with this ICR. The number of reporting facilities using the patient safety forms 57.103, 57.117, 57.123, and 57.124 has increased to reflect the actual number of facilities reporting data into NHSN for a more accurate burden estimate. Last year NHSN updated its reporting facilities using internal data for facilities that have reported data into NHSN. NHSN has added optional fields to form 57.108 to detect risk factors that can be associated with a Bloodstream Infection (BSI) but can potentially be excluded from CLABSI surveillance. Collection of this data will help with analysis of BSIs not associated with central line use. For form (57.106),

an addition was made to the response options under the Device Associated Module of the form to accommodate the new NHSN Pediatric Ventilator Associated Event (PedVAE) surveillance module scheduled to be released in 2019. For form 57.113, the PedVAC was removed due to the scientific algorithm being single tiered and there only being one specific event for PedVAE. For the UTI form 57.114, response options were updated to include "Suprapubic tenderness" to align the form with NHSN protocols. NHSN receives data reported on ventilator-associated events available for NICU locations. NICU facility locations will now be required to report data to NHSN for denominator event reporting, in which CDC has provided an option to accommodate facilities that are reporting requested data by updating forms (57.116, 57.117), and (57.121). NHSN has updated the Antimicrobial Use and Resistance (AUR) Data collection tools to monitor additional organisms and their antimicrobial susceptibility profiles, which will aid healthcare and public health responses to mounting antibiotic resistance problems. The new optional survey form(57.122), has been added to the Patient Safety Component, which is designed to be completed by state and local health departments that participate in HAI surveillance and prevention activities. This new form will provide data on legal and regulatory requirements that are pertinent to HAI reporting. CDC plans to include data from the health department survey in its annual National and State Healthcare-Associated Infection Progress Report. The report helps identify the progress in HAI surveillance and prevention at the state and national levels. Data about the extent to which state health departments have validated HAI data that healthcare facilities in their jurisdiction report to NHSN and the extent of state and local health department HAI reporting requirements are important data for users of CDC's HAI Progress Report to consider when they are reviewing and interpreting data in the report.

2. Three form updates to the Long-term Care Facility (LTCF) Component (57.139, 57.140, 57.142).

   Justification: Three LTCF forms will be updated, two of which (57.139, 57.142), will include an update for facilities to document the "CDI treatment start" variable. Early CDI reporting data from nursing homes has shown exceptionally low event rates for many reporting facilities (e.g., zero events for six or more months). Since current CDI event detection is based on presence of a positive laboratory specimen, variability in the use of diagnostic testing as part of CDI management will have direct impact on the estimate of CDI burden in a facility (e.g., empiric treatment for CDI without confirmatory testing may result in the appearance of low disease burden). To determine whether low CDI event rates are due to empiric CDI treatment practices, a new process measure is incorporated into the monthly summary data on CDI for LTCFs. This measure, called "CDI treatment starts," will allow providers to capture the number of residents started on antibiotic treatment for CDI that month based on clinical decisions (i.e., even those without a positive CDI test). This process measure should provide data on clinically treated CDI to inform our understanding of CDI management practices and serve as a proxy for CDI burden in nursing homes. CDC's alliance with CMS on a voluntary National Nursing Home Quality Collaborative, which focuses on the recruitment and retention of nursing homes collecting and reporting data into the NHSN in efforts to track and prevent Clostridioides difficile infections, has contributed to the revision of these

forms (57.140). Recruitment and NHSN enrollment began in May 2016 and continued through July 2019.

3. Three form updates to the Dialysis Component (57.500, 57.501, and 57.504).

   Justification: CDC added a new question and revised multiple response options to have a more accurate count of the facilities which are accredited by an organization outside of CMS and to better reflect the information captured using this data collection tool (57.500). There is a decrease in the number of reporting facilities from 2,000 to 1,000 due to a decline in use (57.504). The 'Injection Safety' field of the Prevention Process Measures (PPM) summary form was divided into two fields: 'Injection Safety-Medication Preparation' and 'Injection Safety – Medication Administration.' CDC is modifying the 'Injection Safety' field on the MRP to align with the PPM summary form to allow a user to indicate which injection safety practice(s) they are observing in-plan (57.501).

4. Fifteen forms updates in the Hemovigilance Module (57.300, 57.307, 57.308, 57.309, 57.310, 57.311, 57.312, 57.313, 57.314, 57.315, 57.316, 57.317, 57.318, 57.319, 57.320).

   Justification: The Hemovigilance module survey (57.300) and fourteen Adverse Reaction forms within the Biovigilance Component were modified (57.307-57.320) with this ICR. (57.300) Data collected on facility demographics has been made electronic and will now auto-populate data into the form that is pulled from the NHSN application, which will decrease the overall burden for the annual survey. (57.307-57.320) Response options for blood type and treatment were revised on each form to capture more detailed patient-specific treatment data, which will not impact the overall burden for these forms.

5. Three form updates to the annual surveys for Patient Safety Component (57.103, 57.150, and 57.151).

   Justification: Three annual facility surveys for the Patient Safety component for Hospitals (57.103), Long-Term Acute Care Facilities (57.150) and Inpatient Rehabilitation Facilities (57.151) will be revised with this ICR. Five questions on all three surveys will be revised to add further clarity to the reporting requirements for the data collected on fungal testing, facility locations, and laboratory testing locations. Additionally, corresponding response options for these questions have been revised to include updated testing methods that are being used by facilities to capture current HAI specific data specification requirements for reporting to NHSN. Four new required questions have been added to all the surveys. The new questions will capture information related to existing protocols, policies, and standards that are organized by reporting facilities to ensure that when an event is detected the facility has the appropriate mechanism to conduct complete reporting. The hospital annual survey (57.103) added six required questions to capture information about neo-natal antimicrobial stewardship practices that differ from current practices conducted in adult and pediatric locations of facilities previously captured on the survey. Ten questions were removed and replaced on all three surveys to align better with the Core Elements of Hospital Antibiotic

Stewardship guidelines from CDC to better describe current stewardship programs. These guidelines are part of the larger CDC action plan of combating antibiotic-resistant bacteria. The new questions will add granularity to provide a better depiction of hospitals current stewardship programs. Finally, ten new optional question about hospitals antibiotic stewardship practices were added to all three surveys to add supplemental details related to the required questions.

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.