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

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I. Privacy Impact Assessment

- Since 2005, the National Healthcare Safety Network (NHSN) provides healthcare facilities, states, regions, and the nation with the data desired to identify healthcare-associated infection (HAI) problem areas, measure the progress of prevention efforts, and ultimately eliminate HAIs in conjunction with driving the achievement of the overall mission of the Department of Health and Human Services (DHHS). Enrollment in NHSN has continuously increased, with over 25,000 enrolled healthcare facilities and 21,700 actively reporting healthcare facilities across the U.S. Of these, there are over 5,000 acute care facilities; 7,800 dialysis facilities; 600 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 the new; Neonatal Component, NHSN Facility Administrator Change Request Form, and Long-term Care Facility Form. (4) To update and revise existing survey questions within NHSN's components by implementing elements of user feedback that has been further analyzed for 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 the CDC and posted on the NHSN website at https://www.cdc.gov/nhsn. The report is published in various scientific journals, to increase the scope of data that is made available by NHSN. Other types of in-depth analysis from NHSN is published in peer-reviewed journals and presented at scientific and professional meetings and conferences annually.

OMB No. 0920-0666
National Healthcare Safety Network (NHSN)
Revision Request, Updated April 2019

The Centers for Disease Control and Prevention is requesting a 3-year approval for revision for OMB Control No. 0920-0666, "National Healthcare Safety Network." The collection was approved for 11,515,655 responses; 5,397,438 burden hours and $191, 260, 525 in annual cost, due to expire on November 30, 2021. The proposed changes in this ICR include revisions to 40 out of a total of 76 data collection tools apart of this ICR (Attachment D-2). The reporting burden decreased by 2,389,147 hours for a total estimated burden of 3,114,323 hours. The annual cost of reporting will decrease by $83,788,496 for a total cost burden of $113,694,223 (Attachment D-2). NHSN has achieved significant burden reduction with this ICR due to a decrease in the number of respondents for the Patient Safety, Long-term care, and Dialysis components. Also, the application of the 2018 annual labor wages will result in changes to the burden for forms submitted with this ICR (Attachment D-4).

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

The Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC) collects data from healthcare facilities in the National Healthcare Safety Network (NHSN) under OMB Control Number 0920-0666. During the early stages of its development, NHSN began as a voluntary surveillance system in 2005 managed by DHQP. NHSN provides facilities, states, regions, and the nation with data necessary to identify problem areas, measure the progress of prevention efforts, and ultimately eliminate healthcare-associated infections (HAIs) nationwide. NHSN allows healthcare facilities to track blood safety errors and various healthcare-associated infection prevention practice methods such as healthcare personnel influenza vaccine status and corresponding infection control adherence rates.

NHSN currently has six components: Patient Safety (PS), Healthcare Personnel Safety (HPS), Biovigilance (BV), Long-Term Care Facility (LTCF), Outpatient Procedure (OPC), and the Dialysis Component. NHSN's new Neonatal Component is expected to launch during the summer of 2020. This component will focus on premature neonates and the healthcare-associated events that occur as a result of their prematurity. This component will be released with one module, which includes Late Onset-Sepsis and Meningitis. Late-onset sepsis (LOS) and Meningitis are common complications of extreme prematurity. Studies have indicated that 36% of extremely low gestational age (22-28 weeks) infants develop LOS and that 21% of very low birth weight infants surviving beyond 3 days of life will develop LOS.[1] Meningitis occurs in 23% of bacteremic infants, but 38% of infants with a pathogen isolated from the cerebrospinal fluid may not have an organism isolated from blood. These infections are usually serious, causing a prolongation of hospital stay, increased cost, and risk of morbidity and mortality.

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

Data reported under the Patient Safety Component are used to determine the magnitude of the healthcare-associated adverse events and trends in the rates of the events, in the distribution of pathogens, and in the adherence to prevention practices. Data will help detect changes in the epidemiology of adverse events resulting from new medical therapies and changing patient risks. Additionally, reported data is being used to describe the epidemiology of antimicrobial use and resistance and to better understand the relationship of antimicrobial therapy to this rising problem. Under the Healthcare Personnel Safety Component, protocols and data on events—both positive and adverse—are used to determine (1) the magnitude of adverse events in healthcare personnel, and (2) compliance with immunization and sharps injuries safety guidelines. Under the Biovigilance Component, data on adverse reactions and incidents associated with blood transfusions are reported and analyzed to provide national estimates of adverse reactions and incidents. Under the Long-Term Care Facility Component, data is captured from skilled nursing facilities. Reporting methods under the LTCF component have been created by using forms from the PS Component as a model with modifications to specifically address the specific characteristics of LTCF residents and the unique data needs of these facilities reporting into NHSN. The Dialysis Component offers a simplified user interface for dialysis users to streamline their data entry and analyses processes as well as provide options for expanding in the future to include dialysis surveillance in settings other than outpatient facilities. The Outpatient Procedure Component (OPC) gathers data on the impact of infections and outcomes related to operative procedures performed in Ambulatory Surgery Centers (ASCs). The OPC is used to monitor two event types: Same Day Outcome Measures and Surgical Site Infections (SSIs).

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

NHSN's data is used to aid in the tracking of HAIs and guide infection prevention activities/practices that protect patients. The Centers for Medicare and Medicaid Services (CMS) and other payers use these data to determine incentives for performance at healthcare facilities across the US and surrounding territories, and members of the public may use some

protected data to inform their selection among available providers. Each of these parties is dependent on the completeness and accuracy of the data. CDC and CMS work closely and are fully committed to ensuring complete and accurate reporting, which are critical for protecting patients and guiding national, state, and local prevention priorities.

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

NHSN's data collection updates continue to support the incentive programs managed by CMS. For example, survey questions support requirements for CMS' quality reporting programs. Additionally, CDC has collaborated with CMS on a voluntary National Nursing Home Quality Collaborative, which focuses on recruiting nursing homes to report HAI data to NHSN and to retain their continued participation. This project has resulted in a significant increase in long-term care facilities reporting to NHSN. The collection of information is authorized by the Public Health Service Act (42 USC 242b, 242k, and 242m (d)).(Attachment A). The ICR previously approved in November of 2018 included revisions to 34 data collection forms and the addition of one new Patient Safety form for a total of 73 proposed data collection forms. The current revision request includes revisions to 40 data collection forms which include: (1) 12 data collection forms in the patient safety component (2) updates to two data collection forms in the long-term care facility component and the addition of one new LTCF Respiratory Tract Infection form,and (3) updates to data collection forms within the dialysis component. (4) NHSN has implemented the new NHSN Facility Administrator Change Request Form. Other revisions include application of the annual labor and statistic wages for 2018, which have been applied across all components within NHSN, and changes to the response burden of 21 other data collection forms for a total of 76 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 40 changes to previously approved data collection tools. The following program changes with the appropriate burden modification per individual hospital/facility per year is reflected below.

1. Ten forms within the NHSN Patient Safety Component are changing with this ICR. Updates were made to the pathogens and susceptibility section for forms due to a program-wide name change for the organism from 'Enterobacter' to 'Klebsiella.' The name change is going into effect in January 2020. Updates were made to the facility water management program section for forms (57.103, 57.150, and 57.151) to include additional response options to gather information on the type of personnel that comprises a facility water management team. These

additional options were derived from previous survey responses that were reported in a free-text option choice. An update to question 30 on form 57.103 was made to help identify if antimicrobial administration was routine or rarely conducted in specific neonatal locations within the facility. NHSN will be implementing the new optional NHSN Facility Administrator Change Request Form (57.104), which is designed to streamline changes to the designated NHSN Facility Administrator. This form will be made electronically available in January 2020 in the NHSN application. Finally, the number of respondents using the patient safety forms has increased to reflect the actual number of facilities reporting data into NHSN for a more accurate burden estimate.

- 57.103 - Patient Safety Component-Annual Hospital Survey; the annual number of respondents will increase by 175, which will increase the overall annual time burden by 219 hours.
- 57.104 - NHSN Facility Administrator Change Request Form; Annual response burden will increase by 800 responses, increasing the overall annual time burden by 67 hours
- 57.108 - Primary Bloodstream Infection (BSI): Time burden for this form will increase by 5 minutes per facility. Participating facilities will decrease by approximately 225 facilities, and annual response burden will decrease by 39 responses, decreasing the overall annual time burden by 126,913 hours.
- 57.111- Pneumonia (PNEU): Annual response burden will decrease by 42 responses, decreasing the overall annual time burden by 37,800 hours.
- 57.112 - Ventilator-Associated Event: The number of respondents will decrease by 115 respondents annually, and the annual response burden will decrease by 39 responses, which will decrease the overall annual time burden by 364,495 hours.
- 57.113 - Pediatric Ventilator-Associated Event (PedVAE): Annual number of respondents will increase by 234 respondents, which will increase the overall annual time burden by 14,040 hours.
- 57.114 - Urinary Tract Infection (UTI): The number of respondents will decrease by 500 respondents annually, annual response burden will decrease by 139 responses, which will decrease the overall annual time burden by 70,833 hours.
- 57.115 - Custom Event: no change to the annual burden.
- 57.120- Surgical Site Infection (SSI): Annual number of respondents will decrease by 1,500; annual response burden will decrease by 25 responses per respondent annually, which will decrease the overall annual time burden by 97,125 hours.
- 57.127- MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring: Annual number of respondents will increase by 570, annual response burden will increase by 5 responses per respondent annually, which will increase the overall annual time burden by 10,295 hours.

2. The number of participating reporting facilities and their responses per respondent have either increased or decreased for 21 data collection tools with this ICR. Healthcare facility use of NHSN continues to change annually. This year the Patient Safety, Long-term Care Facility, Outpatient Procedure and Dialysis Components of NHSN have seen a change in their estimated number of respondents. Therefore, the CDC has changed the estimated number of facilities that will report data during the calendar year 2020. Many of the changes will result in a decrease in the annual burden and cost estimates.

- 57.108 - Primary Bloodstream Infection (BSI): Time burden for this form will increase by 5 minutes per facility, participating facilities will decrease by approximately 225 facilities, and annual response burden will decrease by 39 responses, decreasing the overall annual time burden by 126,913 hours.
- 57.111 - Pneumonia (PNEU): Annual response burden will decrease by 42 responses, decreasing the overall annual time burden by 37,800 hours.
- 57.112 - Ventilator-Associated Event: The number of respondents will decrease by 115 respondents annually, and the annual response burden will decrease by 39 responses, which will decrease the overall annual time burden by 364,495 hours.
- 57.113 - Pediatric Ventilator-Associated Event (PedVAE): Annual number of respondents will increase by 234 respondents, which will increase the overall annual time burden by 14,040 hours.
- 57.114 - Urinary Tract Infection (UTI): The number of respondents will decrease by 500 respondents annually, and annual response burden will decrease by 139 responses, which will decrease the overall annual time burden by 70,833 hours.
- 57.116 - Denominators for Neonatal Intensive Care Unit (NICU): Annual number of respondents will decrease by 500, annual response burden will increase by 3 responses per respondent annually, and the time burden to complete reporting increased by 9 minutes annually, which will decrease the overall annual time burden by 205,044 hours.
- 57.117 - Denominators for Specialty Care Area (SCA)/Oncology (ONC): Annual number of respondents will decrease by 1,835 responses, and annual response burden will increase by 3 responses per respondent annually, which will decrease the overall annual time burden by 80,634 hours.
- 57.118 - Denominators for Intensive Care Unit (ICU)/other locations (not NICU or SCA): Annual number of respondents will decrease by 500, and annual response burden will increase by 3 responses per respondent annually, which will decrease the overall annual time burden by 151,000 hours.
- 57.120 - Surgical Site Infection (SSI): Annual number of respondents will decrease by 1,500, annual response burden will decrease by 25 responses per respondent annually, which will decrease the overall annual burden cost by 97,125 hours.
- 57.121 - Denominator for Procedure: Annual number of respondents will decrease by 1,500; and annual response burden will increase by 140 responses per respondent annually, which will decrease the overall annual time burden by 30,000 hours.
- 57.123 - Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables: Annual number of respondents will increase by 500, increasing the overall annual time burden by 500 hours.
- 57.124 - Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables: Annual number of respondents will increase by approximately 1,200. This change will not impact the annual burden hours for this form, however, the annual cost will increase with labor wage increases for 2018.
- 57.125 - Central Line Insertion Practices Adherence Monitoring: Annual number of respondents will increase by 400, and the annual response burden will increase by 113 responses per respondent annually, which will increase the overall annual time burden by 40,208 hours.

- 57.126 - MDRO or CDI Infection Form: Annual number of respondents will decrease by 5,280; and annual response burden will decrease by 60 responses per respondent annually, which will decrease the overall annual time burden by 211,680 hours.
- 57.127 - MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring: Annual number of respondents will increase by 570, and annual response burden will increase by 5 responses per respondent annually, which will increase the overall annual time burden by 10,295 hours.
- 57.128 - Laboratory-identified (LabID) MDRO or CDI Event: Annual number of respondents will decrease by 410, and annual response burden will decrease by 153 responses per respondent annually, which will decrease the overall annual time burden by 255,200 hours.
- 57.400 - Outpatient Procedure Component—Annual Facility Survey: Annual number of respondents will decrease by 4,300; which will decrease the overall annual burden.
- 57.401- Outpatient Procedure Component - Monthly Reporting Plan: Annual number of respondents will decrease by 4,300; the time burden to complete reporting decreased by 5 minutes annually, which will decrease the overall annual time burden by 717 hours.
- 57.402- Outpatient Procedure Component Same Day Outcome Measures & Prophylactic Intravenous (IV) Antibiotic Timing Event: Annual number of respondents will decrease by 1,000; and annual response burden will decrease by 24 responses per respondent annually, which will decrease the overall annual time burden by 19,876 hours.
- 57.403 - Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures & Prophylactic Intravenous (IV) Antibiotic Timing Event: Annual number of respondents will increase by 4,300; and annual response burden will increase by 382 responses per respondent annually, which will increase the overall annual time burden by 43,733 hours.
- 57.404 - Outpatient Procedure Component – SSI Denominators: Annual number of respondents will decrease by 4,300; and annual response burden will decrease by 440 responses per respondent annually, which will decrease the overall annual time burden by 403,333 hours.
- 57.405 - Outpatient Procedure Component - Surgical Site (SSI) Event: Annual number of respondents will decrease by 4,300; and annual response burden will decrease by 31 responses per respondent annually, which will decrease the overall annual time burden by 102,667 hours.

3. Eight LTCF forms will be updated, two of which (57.138, 57.140), will include an update that will streamline how the facilities document the “Social Security Number” and “Resident type” variables. The resident social security number is being removed from all event forms as this information is not required to identify the resident. Additionally, the resident type will be auto-populated by the NHSN application, thereby decreasing the overall burden of these forms. Additionally, the LTCF Component of NHSN will be introducing the new Respiratory Tract Infection Infection form. For 2020, prior to introducing the new module and form to NHSN users, the CDC’s Epidemiology Research & Innovations (ERIB) team will use the form to perform field testing of the form variables to explore the utilization, applicability, and data collection burden associated with these variables. This process

will inform areas of improvement prior to incorporating the new module, including protocol, forms, and instructions into NHSN.

- 57.136- Long-Term Care Facility Component – Respiratory Tract Infection: Annual number of respondents will increase by 400 responses**,** which will increase the overall annual burden by 2,400 hours.
- 57.137 - Long-Term Care Facility Component – Annual Facility Survey: Annual number of respondents will decrease by 400, which will decrease the overall annual burden by 760 hours.
- 57.138 - Laboratory-identified MDRO or CDI Event for LTCF: Annual number of respondents will decrease by 450, and annual response burden will increase by 12 responses per respondent annually, which will increase the overall annual time burden by 5,100 hours.
- 57.139 - MDRO and CDI LabID Event Reporting Monthly Summary Data for LTCF: Annual number of respondents will decrease by 400, which will decrease the overall annual time burden by 1,600 hours.
- 57.140 - Urinary Tract Infection (UTI) for LTCF: Annual number of respondents will decrease by 2,200; and annual response burden will decrease by 2 responses per respondent annually, which will decrease the overall annual time burden by 15,800 hours.
- 57.141 - Monthly Reporting Plan for LTCF: Annual number of respondents will decrease by 400, which will decrease the overall annual time burden by 380 hours.
- 57.142 - Denominators for LTCF Locations: Annual Facility Survey: Annual number of respondents will decrease by 400, which will decrease the overall annual time burden by 19,000 hours.
- 57.143 - Prevention Process Measures Monthly Monitoring for LTCF: Annual number of respondents will decrease by 2,225; which will decrease the overall annual time burden for this form by 2,225 hours.

4. Three Dialysis component tools will be updated with this ICR. CDC added and revised multiple questions/options on the surveys to better understand possible risk factors for healthcare-associated infections (HAIs), as well as the patient population they serve for surveillance and prevention purposes. These changes will help inform future policies/guidelines to reduce bloodstream infections (57.500 and 57.507). Similar to the patient safety component, "Klebsiella aerogenes" was added to the dialysis event form (57.502) as an option to the antibiogram/drug susceptibility results. The purpose of this addition is to align the pathogen section of the dialysis event form to the rest of NHSN. Additionally, three new event-specific event dates were added to the dialysis event form (57.502) to gather more accurate information on dialysis events. There is an increase in the number of reporting facilities due to an increase in their use.

- 57.500 - Outpatient Dialysis Center Practices Survey: Annual number of respondents will increase by 100, which will increase the overall annual time burden by 212 hours.
- 57.501 - Dialysis Monthly Reporting Plan: Annual number of respondents will increase by 100, which will increase the overall annual time burden by 100 hours.

- 57.502 - Dialysis Event: Annual number of respondents will increase by 100, and the annual response burden will decrease by 30 responses per respondent annually, which will decrease the overall annual time burden by 86,250 hours.
- 57.503 - Denominator for Outpatient Dialysis: Annual number of respondents will increase by 100, which will increase the overall annual time burden by 200 hours.
- 57.504 - Prevention Process Measures Monthly Monitoring for Dialysis: Annual number of respondents will decrease by 240, and the time burden to complete reporting decreased by 10 minutes annually, which will decrease the overall annual time burden by 7,600 hours.
- 57.505 - Dialysis Patient Influenza Vaccination: Annual number of respondents will increase by 505, which will increase the overall annual time burden by 4,538 hours.
- 57.506 - Dialysis Patient Influenza Vaccination Denominator: Annual number of respondents will decrease by 505, the annual response burden will decrease by 4 responses per respondent annually, which will decrease the overall annual time burden by 199 hours.
- 57.507 - Home Dialysis Center Practices Survey: Annual number of respondents will increase by 80, which will increase the overall annual time burden by 40 hours.

2. Purpose and Use of Information Collection

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

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

- Provide to state and local agencies, at their request, facility-specific, NHSN patient safety component and healthcare personnel safety component adverse event and prevention practice adherence data for surveillance, prevention, and/or mandatory public reporting.

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

NHSN is also increasingly used to satisfy HAI reporting included in state legislation and local mandates. Compared to previous submissions, there has been an increase in the uptake of HAI Surveillance in approximately Thirty-six states, the District of Columbia, and the city of Philadelphia, Pennsylvania who have implemented HAI reporting using NHSN as the primary reporting mechanism, and more jurisdictions are expected in the coming years. In addition, CMS collects HAI data and healthcare personnel influenza vaccination summary data on a voluntary basis as part of its Fee-for-Service Medicare quality reporting programs. Facilities that fail to successfully report quality measure data are potentially subject to partial payment reduction in the applicable Medicare Fee-for-Service payment system. Facilities report HAI data and healthcare personnel influenza vaccination summary data to CMS via NHSN as part of CMS quality reporting programs to receive full payment.

Further, CDC DHQP is actively engaged with the CMS Center for Clinical Standards and Quality (CCSQ) in working to reduce healthcare-associated infections and improve the quality of care within U.S. healthcare facilities. Suggested revisions and enhancements for NHSN definitions and surveillance criteria were received from external partners such as CMS CCSQ, the Healthcare Infection Control Practices Advisory Committee (HICPAC), and the Infectious Diseases Society of America (IDSA). The revisions, which are proposed to NHSN by external partners, are further evaluated, developed, and vetted by internal CDC NHSN subject matter experts. Prior to CMS CCSQ adopting a new NHSN measure for requirement in a CMS Quality Reporting Program (QRP), they require the proposed measure is endorsed by the National Quality Forum (NQF), thus, resulting in updates and improvements to NHSN forms as CDC strives to obtain the highest standard for measuring infection surveillance and process improvement. Further, changes to the number of respondents and responses per respondent for NHSN forms are directly related to the expansion of CMS QRPs. The CMS QRP final rules and list of the NHSN forms used for the CMS QRPs and state-mandated reporting can be found in Attachment E.

3. Use of Improved Information Technology and Burden Reduction

As stated in previous submissions to OMB, 100% of the data for NHSN are collected via a secure internet application. Only the minimum amount of information necessary for data collection is requested. Institutions that participate in NHSN are required to have a computer and Internet Service Provider (ISP), and they must provide the salaries of the data collectors and data entry personnel. These expenses would not exceed what is normally expended for a typical healthcare facility infection surveillance program. While the paper forms are provided for data collection, facilities are not required to use them for entry of data into NHSN. There is no manual entry available to users for the new neonatal component. Both numerator and denominator data will be imported into the Clinical Document Architecture (CDA) via electronic data transfer. This will allow users to obtain data submitted via CDA and focus on prevention activities within their respective hospitals or facilities.

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

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

4. Efforts to Identify Duplication and Use of Similar Information

NHSN is the only modern national system that collects surveillance data on healthcare-associated infections, infection prevention process measure data, data on healthcare personnel safety measures such as blood and body fluid exposures and vaccination practices, and adverse events related to the transfusion of blood and blood products.

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

5. Impact on Small Businesses or Other Small Entities

There are several vendors, some of which may be considered small businesses, which sell data management tools with similar capabilities as NHSN. However, since NHSN is a voluntary system, facilities are free to choose a vendor product over NHSN. Exceptions are within those states that have mandated the use of NHSN. Mandates are required to help participants meet their public reporting laws in facilities that participate in the following programs listed below.

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

However, in order to minimize any negative impact on vendors (i.e., loss of potential market share); CDC actively assists all vendors with facility data submission into NHSN.

6. Consequences of Collecting the Information Less Frequently

Many adverse events associated with healthcare, such as HAIs, occur in both endemic and epidemic patterns. It is in the best interest of the healthcare institution to conduct routine prospective surveillance in an ongoing manner to identify trends in endemic rates as well as outbreaks so that potential problems may be identified in a timely manner and appropriate measures instituted to minimize the number of affected patients or healthcare personnel. Collecting the data sporadically or less often than required by NHSN could potentially place patients at risk. In addition, CMS and state mandates require monthly reporting of HAI data via NHSN.

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

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

As of April 2019, there are over 25,000 healthcare facilities enrolled in NHSN. Of these, there are over 5,000 acute care facilities; 7,100 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) Clostridium difficile infection (CDI) laboratory-identified (LabID) event data, and healthcare personnel (HCP) Influenza vaccination data. As very few acute care facilities opt out of these additional CMS reporting requirements, NHSN data are considered to be generalizable to all U.S. acute care facilities.

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

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

Further, because NHSN membership is now open to any healthcare facility and is increasingly being used to satisfy mandated reporting requirements at both the federal and state levels, we expect that over time the results will be more representative of all healthcare facility and infection types.

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

A. A 60-Day Federal Register Notice was published in the Federal Register on June 5, 2019, Vol. 84, No. 108, pp. 26110-26113 (Attachment 2). Two non-substantive public comments were received (Attachment 2a and 2b)

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

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

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

9. Explanation of Any Payment or Gift to Respondents

No monetary incentive is provided to NHSN participants.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by NCEZID who determined that the Privacy Act does not apply. The CDC Office of General Counsel (OGC) has also determined that the Privacy Act does not apply to this data collection. The CDC OGC believes that NHSN, as it is currently being utilized by CDC, is not a Privacy Act system of records and provides case law to support this determination (Henke v. U.S. Department of Commerce and Fisher v. NIH). Specifically, the OGC stated that "The CDC NHSN system is similar to the computerized information in both

the Henke and Fisher cases. While CDC can retrieve data by personal identifier, CDC does not, as a matter of practice or policy, retrieve data in this way. Specifically, the primary practice and policy of CDC regarding NHSN data are to retrieve data by the name of the hospital or another non-personal identifier, not an individual patient, for surveillance and public health purposes. Furthermore, patient identifiers are not necessary for NHSN to operate, and the CDC does not regularly or even frequently use patient names to obtain information about these individuals."

An Assurance of Confidentiality is granted for all data collected under NHSN. NHSN's Assurance of Confidentiality, states the following;

> "*the voluntarily provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).*"

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

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

While the Privacy Act is not applicable, in accordance with the stringent safeguarding that must be in place for 308(d) assurance of confidentiality protected projects, all the safeguarding measures described in previous Section A.10 are still in effect. These include the use of a password issued via CDC's Secure Access Management System for access to the application; data encryption using Secure Socket Layer technology; and lastly, storage of data in password protected files on secure computers in locked, authorized-access-only rooms.

This data collection effort is consistent with the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA), which expressly permits disclosures without individual authorization to public health authorities authorized by law to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to public health surveillance, investigation, and intervention.

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 the CDC, and CDC aggregates the data for national surveillance and public health practice evaluation purposes.

While the Privacy Act is not applicable, in accordance with the stringent safeguarding that must be in place for 308(d) assurance of confidentiality protected projects, all the safeguarding measures described in previous Section A.10 are still in effect. These include the use of a password issued via CDC's Secure Access Management System for access to the application; data encryption using Secure Socket Layer technology; and lastly, storage of data in password protected files on secure computers in locked, authorized-access-only rooms.

This data collection effort is consistent with the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA), which expressly permits disclosures without individual authorization to public health authorities authorized by law to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to public health surveillance, investigation, and intervention.

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

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

IRB Approval

For the participating healthcare institutions, data are collected in this system for the purposes of local surveillance and program evaluation. DHQP aggregates the data for national surveillance and public health practice evaluation purposes. No primary research will be conducted as part of this data collection effort, and no patient consent forms will be used. Although this is not a research project, this Protocol was submitted for ethical review to the CDC Institutional Review Board (IRB) and was approved (Protocol #4062, exp. 05/18/05.) The most recent request for amendment and continuation was approved on 08/29/06 and expired on 05/18/07. Subsequently, in consultation with NCEZID senior staff, the program was advised that the activities of the NHSN are surveillance and evaluation of public health practice and that IRB review is no longer required, therefore the protocol has been closed (Attachment F).

The justification for Sensitive Questions

The reporting of adverse events associated with healthcare can be sensitive unless the institution is assured that the data aggregating organization will provide security for the data and maintain the institution's confidentiality. As discussed in item A.10 above, NHSN is authorized to assure confidentiality to its participating individuals and institutions for voluntarily submitted data.

12. Estimates of Annualized Burden Hours and Costs

The tables below provide the burden hours and cost estimates for the proposed NHSN data collection tools. Detailed revisions of the previous burden tables are available in Attachments D-3 and D-4.

A. Estimates of Annualized Burden Hours

The tables below provide the burden hours and cost estimates for the proposed NHSN data collection tools. Completion of the NHSN data collection tools are required for participation in NHSN, participation in a CMS reporting program, or to fulfill state or local reporting mandates. To estimate annualized burden hours and costs, the number of respondents is first determined by the number of facilities that report to NHSN by component and includes projected growth or reductions in facilities reporting during the ICR period. For forms that are required for participation in NHSN or a CMS reporting program, CDC calculates burden based on a 100 percent response rate, whereas an estimated response rate less than 100 percent is calculated for those forms that are voluntary or optional. CDC then considers the burden associated with surveillance, data entry, analysis, and validation to determine the amount of time required for each form to be considered complete. Annual labor rates reported by the U.S. Department of Labor are used to calculate the annual burden costs based on the hourly rate of pay for health professionals most qualified to complete NHSN data submission. Incorporating all proposed revisions, the estimated burden for reporting reflects a decrease in hours by 2,389,147 hours for a total annual burden of 3,114,323 hours. Subsequently, the estimated cost burden reflects a decrease of $83,788,496 for a total annual cost of $113,694,223compared to the most recently approved ICR in November 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 (Min./Hour)	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	5,175	1	**1.25**	6,469	1,469	Yes; IQR, LTCHQR, PCHQR		Increase
57.104 NHSN Facility Administrator Change Request Form (NEW FORM)	800	1	5/60	67	0	No	NHSN requires this form to be completed when an NHSN facility administrator or NHSN component contact information will need to be updated by NHSN staff	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		Decrease
57.108 Primary Bloodstream Infection (BSI)	5,775	5	38/60	18,288	126,913	Yes; IQR, LTCHQR, PCHQR		Decrease
57.111 Pneumonia (PNEU)	1,800	30	30/60	27,000	37,800	No	This form must be completed for Pneumonia events reported to NHSN. The city of Pittsburgh in Pennsylvania has required reporting on this measure through NHSN by participating facilities in the state.	Decrease
57.112 Ventilator-Associated Event	5,615	5	28/60	12,833	364,495	No		Decrease

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	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)
57.113 Pediatric Ventilator-Associated Event (PedVAE)	334	120	30/60	20,040	14,040	No	This form is not required, it is in the developmental stages and will be active in 2019.	Increase
57.114 Urinary Tract Infection (UTI)	5,500	5	20/60	9,167	70,833	Yes; IQR PCHQR IRFQR LTCHQR		Decrease
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)	220	12	4.40	11,616	204,384	Yes; IQR		Decrease
57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	165	12	5.25	10,395	260,685	Yes; IQR		Decrease
57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	5,500	60	5.25	1,732,500	74,700	Yes; IQR		Decrease
57.120 Surgical Site Infection (SSI)	4,500	11	35/60	28,875	97,125	Yes; IQR, PCHQR		Decrease
57.121 Denominator for Procedure	4,500	680	10/60	510,000	30,000	Yes; IQR, PCHQR		Decrease

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	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)
57.122 HAI Progress Report State Health Department Survey	55	1	45/60	41	0	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.	
57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	1,500	12	5/60	1,500	500	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
57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	2,000	12	5/60	2,000	0	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 the 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.	
57.125 Central Line Insertion Practices Adherence Monitoring	500	213	25/60	44,375	40,208	No		Increase

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	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)
57.126 MDRO or CDI Infection Form	720	12	30/60	4,320	211,680	Yes; IQR, PCHQR		Decrease
57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	5,500	29	15/60	39,875	3,875	Yes; IQR, PCHQR		Increase
57.128 Laboratory-identified MDRO or CDI Event	4,800	87	20/60	139,200	255,200	Yes; IQR, PCHQR		Decrease
57.129 Adult Sepsis	50	250	25/60	5,208	0	No	This form is not required by NHSN; this module is in a developmental phase and is expected to be active by 2020	
57.136 Long-Term Care Facility Component – Respiratory Tract Infection (NEW FORM)	400	12	30/60	2,400	2,400	No	This form is optional for LTCF facilities that voluntarily report data into NHSN's National Nursing Home Quality Collaborative with CMS	**Increase**
57.137 Long-Term Care Facility Component – Annual Facility Survey	2,220	1	120/60	4,440	760	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.	Decrease

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	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)
57.138 Laboratory-identified MDRO or CDI Event for LTCF	2,150	24	15/60	12,900	5,100	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
57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	2,200	12	20/60	8,800	1,600	No	This form is required by NHSN for Health Departments to access the voluntarily reported data into NHSN's National Nursing Home Quality Collaborative with CMS to track and prevent Clostridioides difficile infections.	Decrease
57.140 Urinary Tract Infection (UTI) for LTCF	400	12	30/60	2,400	15,800	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.	Decrease
57.141 Monthly Reporting Plan for LTCF	2,220	12	5/60	2,220	380	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.	Decrease

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	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)
57.142 Denominators for LTCF Locations	2,220	12	4.40	117,216	12,784	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.	Decrease
57.143 Prevention Process Measures Monthly Monitoring for LTCF	375	12	5/60	375	2,225	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.	Decrease
57.150 LTAC Annual Survey	500	1	1.25	625	42	Yes; LTCHQR		Increase
57.151 Rehab Annual Survey	1,200	1	1.25	1,500	100	Yes; IRFQR		Increase
57.200 Healthcare Personnel Safety Component Annual Facility Survey	50	1	8	400	0	No	The form is required by NHSN but is not subject to PRA approval due to the statutory waiver for immunization-related work	
57.203 Healthcare Personnel Safety Monthly Reporting Plan	-0	1	5/60	-	0	No	The form is required by NHSN but is not subject to PRA approval due to the statutory waiver for immunization-related work	
57.204 Healthcare Worker Demographic Data	50	200	20/60	3,333	0	No		
57.205 Exposure to Blood/Body Fluids	50	50	60/60	2,500	0	No		
57.206 Healthcare Worker Prophylaxis/Treatment	50	30	15/60	375	0	No		

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	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)
57.207 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	2	708	0	No	This form is optional but only required by NHSN when a facility is reporting on its Biovigilance Component (BV) events.	
57.301 Hemovigilance Module Monthly Reporting Plan	500	12	1	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	1.25	7,500	500	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.	Increase
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.	
57.306 Hemovigilance Module Annual Survey - Non-acute care facility	500	1	35/60	292	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 (Min./Hour)	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)
57.307 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.	
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.	
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.	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	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)
57.313 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.	
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.	
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.	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	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)
57.319 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.	
57.400 Outpatient Procedure Component—Annual Facility Survey	700	1	10/60	117	717	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.	Decrease
57.401 Outpatient Procedure Component - Monthly Reporting Plan	700	12	15/60	2,100	17,900	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.	Decrease
57.402 Outpatient Procedure Component Same Day Outcome Measures	200	1	40/60	133	19,867	No	This form is optional for reporting into NHSN	Decrease
57.403 Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures	200	400	40/60	53,333	43,733	No	This form is optional for reporting into NHSN	Increase

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	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)
57.404 Outpatient Procedure Component – SSI Denominator	700	100	40/60	46,667	403,333	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.	Decrease
57.405 Outpatient Procedure Component - Surgical Site (SSI) Event	700	5	40/60	2,333	102,667	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.	Decrease
57.500 Outpatient Dialysis Center Practices Survey	7,100	1	2.25	15,975	1,625	Yes; ESRD QIP		Increase
57.501 Dialysis Monthly Reporting Plan	7,100	12	5/60	7,100	100	Yes; ESRD QIP		Increase
57.502 Dialysis Event	7,100	30	25/60	88,750	86,250	Yes; ESRD QIP		Decrease
57.503 Denominator for Outpatient Dialysis	7,100	12	10/60	14,200	200	Yes; ESRD QIP		Increase
57.504 Prevention Process Measures Monthly Monitoring for Dialysis	1,760	12	1.25	26,400	7,600	No		Decrease
57.505 Dialysis Patient Influenza Vaccination	860	60	10/60	8,600	4,538	No	This form is required by NHSN only when a dialysis facility reports flu data into NHSN	Increase
57.506 Dialysis Patient Influenza Vaccination Denominator	860	1	5/60	72	199	No	This form is required by NHSN only when a dialysis facility reports flu data into NHSN	Decrease
57.507 Home Dialysis Center Practices Survey	430	1	30	215	40	Yes; ESRD QIP		Increase
TOTAL(s)	**125,689**	**2,854**	**3,615**	**3,114,323**	**2,389,147**			

[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.

2018 Department Of Labor Salary Estimates		
Professional Labor Category	**Percentile**	**Hourly Wage**
Microbiologist (IP)	75th	$49.05
Clinical Laboratory Technologists and Technicians	75th	$31.54
Occupational Therapists (RN)	50th	$34.51
Pharmacist	50th	$59.70
Registered Nurse (RN)	50th	$33.65
Epidemiologists	50th	$33.49
Health Technologists and Technicians	50th	$24.89

https://data.bls.gov/oes/#/indOcc/Multiple%20occupations%20for%20one%20industry
Accessed: 3/23/2019

Estimated annualized burden cost[a]

Type of Respondents	Form Number & Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
Microbiologist	57.100 NHSN Registration Form	167	$49.05	$8,175
Microbiologist	57.101 Facility Contact Information	333	$49.05	$16,350
Microbiologist	57.103 Patient Safety Component--Annual Hospital Survey	6,469	$49.05	$317,292
Microbiologist	57.104 NHSN Facility Administrator Change Request Form	67	$49.05	$3,270
Epidemiologists	57.105 Group Contact Information	83	$33.49	$2,791
Microbiologist	57.106 Patient Safety Monthly Reporting Plan	18,000	$49.05	$882,900
Microbiologist	57.108 Primary Bloodstream Infection (BSI)	18,288	$49.05	$897,002
Microbiologist	57.111 Pneumonia (PNEU)	27,000	$49.05	$1,324,350
Microbiologist	57.112 Ventilator-Associated Event	12,833	$49.05	$629,475
Microbiologist	57.113 Pediatric Ventilator-Associated Event (PedVAE)	20,040	$49.05	$982,962
Microbiologist	57.114 Urinary Tract Infection (UTI)	9,167	$49.05	$449,625
Microbiologist	57.115 Custom Event	31,850	$49.05	$1,562,243
Microbiologist	57.116 Denominators for Neonatal Intensive Care Unit (NICU)	11,616	$33.56	$390,878
Microbiologist	57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	10,395	$33.56	$349,792
Registered Nurse	57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	1,732,500	$33.56	$58,298,625
Microbiologist	57.120 Surgical Site Infection (SSI)	28,875	$49.05	$1,416,319
Registered Nurse	57.121 Denominator for Procedure	510,000	$33.56	$17,161,500
Epidemiologists	57.122 HAI Progress Report State Health Department Survey	41	$49.05	$2,023
Registered Nurse	57.123 Antimicrobial Use and Resistance	1,500	$31.54	$47,310

Type of Respondents	Form Number & Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
	(AUR)-Microbiology Data Electronic Upload Specification Tables			
Registered Nurse	57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	2,000	$49.05	$98,100
Registered Nurse	57.125 Central Line Insertion Practices Adherence Monitoring	44,375	$49.05	$2,176,594
Microbiologist	57.126 MDRO or CDI Infection Form	4,320	$49.05	$211,896
Microbiologist	57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	39,875	$49.05	$1,955,896
Microbiologist	57.128 Laboratory-identified MDRO or CDI Event	139,200	$49.05	$6,827,760
Microbiologist	57.129 Adult Sepsis	5,208	$49.05	$255,469
Microbiologist	57.136 Long-Term Care Facility Component - Respiratory Tract Infection	2,400	$49.05	$117,720
Microbiologist	57.137 Long-Term Care Facility Component – Annual Facility Survey	4,440	$49.05	$217,782
Microbiologist	57.138 Laboratory-identified MDRO or CDI Event for LTCF	12,900	$49.05	$632,745
Microbiologist	57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	8,800	$49.05	$431,640
Microbiologist	57.140 Urinary Tract Infection (UTI) for LTCF	2,400	$49.05	$117,720
Microbiologist	57.141 Monthly Reporting Plan for LTCF	2,200	$49.05	$108,891
Microbiologist	57.142 Denominators for LTCF Locations	117,216	$49.05	$5,749,445
Microbiologist	57.143 Prevention Process Measures Monthly Monitoring for LTCF	375	$49.05	$18,394
Microbiologist	57.150 LTAC Annual Survey	625	$49.05	$30,656
Microbiologist	57.151 Rehab Annual Survey	1,500	$49.05	$73,575
Occupational Health RN/Specialist	57.200 Healthcare Personnel Safety Component Annual Facility Survey	400	$34.51	$13,804
Occupational Health RN/Specialist	57.203 Healthcare Personnel Safety Monthly Reporting Plan	0	$34.51	$0
Occupational Health RN/Specialist	57.204 Healthcare Worker Demographic Data	3,333	$34.51	$115,033
Occupational Health RN/Specialist	57.205 Exposure to Blood/Body Fluids	2,500	$34.51	$86,275
Occupational Health RN/Specialist	57.206 Healthcare Worker Prophylaxis/Treatment	375	$34.51	$12,941
Occupational Health RN/Specialist	57.207 Follow-Up Laboratory Testing	625	$31.54	$19,713
Occupational Health RN/Specialist	57.210 Healthcare Worker Prophylaxis/Treatment-Influenza	417	$34.51	$14,379
Medical/Clinical Laboratory Technologist	57.300 Hemovigilance Module Annual Survey	708	$31.54	$22,341
Medical/Clinical Laboratory Technologist	57.301 Hemovigilance Module Monthly Reporting Plan	100	$31.54	$3,154
Medical/Clinical Laboratory Technologist	57.303 Hemovigilance Module Monthly Reporting Denominators	7,500	$31.54	$236,550
Medical/Clinical Laboratory Technologist	57.305 Hemovigilance Incident	833	$31.54	$26,283
Medical/Clinical Laboratory Technologist	57.306 Hemovigilance Module Annual Survey - Non-acute care facility	292	$31.54	$9,199

Type of Respondents	Form Number & Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
Medical/Clinical Laboratory Technologist	57.307 Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction	667	$31.54	$21,027
Medical/Clinical Laboratory Technologist	57.308 Hemovigilance Adverse Reaction - Allergic Transfusion Reaction	667	$31.54	$21,027
Medical/Clinical Laboratory Technologist	57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction	167	$31.54	$5,257
Medical/Clinical Laboratory Technologist	57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction	333	$31.54	$10,513
Medical/Clinical Laboratory Technologist	57.311 Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction	667	$31.54	$21,027
Medical/Clinical Laboratory Technologist	57.312 Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction	167	$31.54	$5,257
Medical/Clinical Laboratory Technologist	57.313 Hemovigilance Adverse Reaction – Infection	167	$31.54	$5,275
Medical/Clinical Laboratory Technologist	57.314 Hemovigilance Adverse Reaction - Post Transfusion Purpura	167	$31.54	$5,275
Medical/Clinical Laboratory Technologist	57.315 Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea	167	$31.54	$5,275
Medical/Clinical Laboratory Technologist	57.316 Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease	167	$31.54	$5,275
Medical/Clinical Laboratory Technologist	57.317 Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury	167	$31.54	$5,275
Medical/Clinical Laboratory Technologist	57.318 Hemovigilance Adverse Reaction - Transfusion Associated Circulatory Overload	333	$31.54	$10,513
Medical/Clinical Laboratory Technologist	57.319 Hemovigilance Adverse Reaction - Unknown Transfusion Reaction	167	$31.54	$5,275
Medical/Clinical Laboratory Technologist	57.320 Hemovigilance Adverse Reaction - Other Transfusion Reaction	167	$31.54	$5,275
Registered Nurse	57.400 Outpatient Procedure Component—Annual Facility Survey	117	$33.65	$3,926
Registered Nurse	57.401 Outpatient Procedure Component - Monthly Reporting Plan	2,100	$33.65	$70,665
Registered Nurse	57.402 Outpatient Procedure Component Same Day Outcome Measures	133	$33.65	$4,487
Registered Nurse	57.403 Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures	53,333	$33.65	$1,794,667
Registered Nurse	57.404 Outpatient Procedure Component - SSI Denominator	46,667	$33.65	$1,570,333
Microbiologist	57.405 Outpatient Procedure Component - Surgical Site (SSI) Event	2,333	$49.05	$114,450
Microbiologist	57.500 Outpatient Dialysis Center Practices Survey	15,975	$49.05	$783,574
Registered Nurse	57.501 Dialysis Monthly Reporting Plan	7,100	$33.65	$238,915
Registered Nurse	57.502 Dialysis Event	88,750	$33.65	$2,986,438
Registered Nurse	57.503 Denominator for Outpatient Dialysis	14,200	$33.65	$447,830
Registered Nurse	57.504 Prevention Process Measures Monthly Monitoring for Dialysis	26,400	$49.05	$888,360
Registered Nurse	57.505 Dialysis Patient Influenza Vaccination	8,600	$33.65	$289,390
Registered Nurse	57.506 Dialysis Patient Influenza Vaccination Denominator	72	$33.65	$2,412

Type of Respondents	Form Number & Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
Microbiologist	57.507 Home Dialysis Center Practices Survey	215	$49.05	$10,546
		Total Estimated Cost		**$113,694,223**

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

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

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

14. Annualized Cost to the Government

A total of 127 FTE/contractor personnel are actively involved in the enhancement and maintenance of NHSN. The estimated cost to the government of this OMB revision of NHSN is based on expenses incurred in the following categories: personnel and programming contracts. The items and their costs relevant to the proposed modifications to NHSN are shown in the table below. The total cost to the government in 2020 is estimated to be **$18,045,604**.

NHSN Estimated Annual Cost to the Government

Expense Item	Description		Estimated Annual Cost
Personnel	The personnel categories and their FTE contributions are as follows:		FTE annual compensation in FY 2020 will be $4,365,598
	Supervisory Medical Officer	1	
	IT Specialist	2	
	Medical Epidemiologist	5	
	Statistician	3	
	Epidemiologist	6	
	Health Scientist	2	
	Nurse Consultant	1	
	Public Health Analyst	3	
	Computer Scientist	2	
Programming contracts	Design, develop, and deploy enhancements to NHSN		$13,680,006

Expense Item	Description	Estimated Annual Cost
Total		**$18,045,604**

15. The explanation for Program Changes or Adjustments

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

The proposed ICR is comprised of 40 data collection tools under OMB No. 0920-0666 that will be updated in this revision request. Details related to changes in each NHSN component are provided below:

1. There are 10 data collection tools within the patient safety component (PSC) of NHSN being revised within this ICR. (57.103, 57.108, 57.111, 57.112, 57.113, 57.114, 57.115, 57.120, 57.126, 57.127, 57.150, and 57.151)

Justification: Ten forms within the NHSN Patient Safety Component are changing with this ICR. Updates were made to the pathogens and susceptibility section for forms (57.111, 57.112, 57.113, 57.114, 57. 115, and 57.120) due to a program-wide name change for the organism from 'Enterobacter' to 'Klebsiella.' The name change is going into effect in January 2020. Updates were made to the facility water management program section for forms (57.103, 57.150, and 57.151) to include additional response options to gather information on the type of personnel that comprises a facility water management team. These additional options were derived from previous survey responses that were reported in a free-text option choice. An update to question 30 on form 57.103 was made to help identify if antimicrobial administration was routine or rarely conducted in specific neonatal locations within the facility. NHSN will be implementing the new optional NHSN Facility Administrator Change Request Form (57.104), which is designed to streamline changes to the contacts at the facility level responsible for being the primary contact. This form will be made electronically available in January 2020 in the NHSN application. Finally, the number of respondents using the patient safety forms has increased to reflect the actual number of facilities reporting data into NHSN for a more accurate burden estimate.

2. Eight LTCF forms will be updated, two of which (57.138, 57.140), will include an update that will streamline how the facilities document the "Social Security Number" and "Resident type" variables.

Justification: The resident social security number is currently an optional data field on all LTCF event forms. NHSN is not using the data in the analysis, nor to identify individual residents, therefore, a decision was made to remove social security number as an option on the event form. Additionally, the resident type will be auto-populated by the NHSN application based on internal business rules, thereby, decreasing the overall burden of these forms. The LTCF Component of NHSN will be introducing the new Respiratory Tract Infection form (57.136). For 2020, prior to introducing the new module and form to NHSN users, the CDC's Epidemiology Research & Innovations (ERIB) team will use the form to perform field testing of the form variables to explore the utilization, applicability, and data collection burden associated

with these variables. This process will inform areas of improvement prior to incorporating the new module, including protocol, forms, and instructions into NHSN.

3. Three form updates to the Dialysis Component (57.500, 57.502, and 57.507).

Justification: Three Dialysis component tools will be updated with this ICR. CDC added and revised multiple questions/options on the surveys to better understand possible risk factors for healthcare-associated infections (HAIs), as well as the patient population they serve for surveillance and prevention purposes. These changes will help inform future policies/guidelines to reduce bloodstream infections (57.500 and 57.507). Similar to the patient safety component, "Klebsiella aerogenes" was added to the dialysis event form (57.502) as an option to the antibiogram/drug susceptibility results. The purpose of this addition is to align the pathogen section of the dialysis event form to the rest of NHSN. Additionally, three new event-specific event dates were added to the dialysis event form (57.502) to gather more accurate information on dialysis events. There is an increase in the number of reporting facilities due to an increase in their use (57.500, 57.501, 57.502, 57.503, 57.504, 57.505, 57.506, and 57.507).

4. All other form changes include the application of the 2018 annual labor wages to all NHSN components. Additionally, NHSN has re-evaluated the reports used to determine responses per respondent and respondents annually, which accounts for major reductions to the annual burden and assist the program in achieving ultimate burden reduction.

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.