

National Healthcare Safety Network (NHSN)
OMB Control No. 0920-0666
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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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Supporting Statement Part A – Table of Contents

A. Justification

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of the Information Collection
3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Businesses or Other Small Entities
6. Consequences of Collecting the Information Less Frequently
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
9. Explanation of Any Payment or Gift to Respondents
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
11. Institutional Review Board (IRB) and Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs
13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
14. Annualized Cost to the Federal Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act Submission

Attachments

A. Public Health Service Act

1. 42 USC 242b
2. 42 USC 242k
3. 42 USC 242m

B. 60 Day Federal Register Notice

C. NHSN Forms Submitted for Approval

D. ICR Revision Supporting Documentation

1. Explanations and justifications for proposed revisions to OMB 0920-0666
2. Itemized IC Revisions and Justifications
3. Revision of Estimated Annual Burden Hours
4. Revision of Estimated Annual Cost Burden

E. CMS Reporting Requirements

1. NHSN Forms used for CMS QRPs and State Mandated Reporting
2. Acute Care Facilities, Long-term Acute Care Facilities, and Oncology Hospitals – CLABSI, CAUTI, SSI, MRSA LabID, CDI LabID, VAE, Flu, AU

3. Inpatient Rehabilitation Facilities – CAUTI, MRSA LabID, CDI LabID, Flu
4. Dialysis Facilities – Dialysis Event, Flu
5. Ambulatory Surgery Centers and Outpatient Acute Care Facility Departments – Flu
6. Inpatient Psychiatric Facilities – Flu

F. Notice of IRB Closure

1. Closure of NHSN IRB Protocol
2. NHSN - Report of End of Human Research Review 0.1253

G. Surveillance Methods Supporting Materials

1. Crosswalk for Supporting Documentation in Attachment G and Corresponding Data Collection Forms in Attachment C
2. Antimicrobial Use and Resistance
3. Biovigilance Component
4. Catheter-Associated Urinary Tract Infection
5. Central Line-Associated Blood Stream Infection
6. Central Line Insertion Practices Adherence
7. Custom Event Surveillance
8. Denominators for Patient Safety Component
9. Dialysis Event
10. Dialysis Patient Influenza Vaccination
11. Dialysis Prevention Process Measures
12. Healthcare Personnel Exposure
13. LTCF MDRO CDI
14. LTCF Prevention Process Measures
15. LTCF Urinary Tract Infection
16. MDRO & CDI
17. Outpatient Procedure Component
18. Pediatric Ventilator-Associated Event
19. Sepsis
20. Surgical Site Infection
21. Surveys – Hospital, LTAC, IRF, and Dialysis
22. Ventilator-Associated Event
23. Ventilator-Associated Pneumonia

H. NHSN Assurance of Confidentiality Documentation

1. NHSN 308d Approval 2015
2. NHSN 308d Request for Extension and Amendment

- This system, which has been ongoing since 2005 provides facilities, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate healthcare-associated infections. The revisions being sought in this ICR are designed to add surveillance and reporting opportunities for specific types of facilities (i.e., home hemodialysis centers, non-acute care facilities) and event types (i.e., pediatric ventilator-associated events, adult sepsis, and adverse blood transfusion reactions). In addition, clarifications were made on many existing forms to assist in understanding and completion of the questions..
- The intended uses of the resulting data are: estimate the magnitude of healthcare-associated infections (HAIs), monitor HAI trends; facilitate interfacility and intrafacility comparisons with risk-adjusted data that can be used for local quality improvement activities; enable healthcare facilities to report HAI and prevention practice adherence data via NHSN to the U.S. Centers for Medicare and Medicaid Services (CMS) in fulfillment of CMS’s quality measurement programs (is the word “requirement” correct – is it an optional source of reporting?) for those data; and provide to 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 are collected via a secure Internet application.
- NHSN participation is open all US healthcare facilities.
- Reporting institutions will be able to access their own 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, which is <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 the NHSN will be published in peer-reviewed journals, and presented at scientific and professional meetings.

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The Centers for Disease Control and Prevention (CDC) is requesting 3-year approval of revisions to OMB Control No. 0920-0666: National Healthcare Safety Network. This collection is currently approved for 9,007,950 responses and 4,621,542 burden hours. This revision request includes adding 19 forms, removing 1 form and revisions to 22 previously approved forms. The revisions being sought in this ICR are designed to add surveillance and reporting opportunities for specific types of facilities (i.e., home hemodialysis centers, non-acute care facilities) and event types (i.e., pediatric ventilator-associated events, adult sepsis, and adverse blood transfusion reactions). In addition, clarifications were made on many existing forms to assist in understanding and completion of the questions. The reporting burden will increase by 489,424 hours, for a total estimated burden of 5,110,966 hours; annual cost of reporting would increase by \$20,092,219.

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. NHSN began as a voluntary surveillance system in 2005 and is managed by the Division of Healthcare Quality Promotion (DHQP) in the National Center for Emerging and Zoonotic Infectious Diseases. NHSN provides facilities, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate healthcare-associated infections (HAIs). In addition, NHSN allows healthcare facilities to track blood safety errors and important healthcare process measures such as healthcare personnel influenza vaccine status and infection control adherence rates.

The NHSN currently consists of five components: Patient Safety, Healthcare Personnel Safety, Biovigilance, Long-Term Care Facility, and Dialysis. One new component will be added to NHSN within the next one to two years: Outpatient Procedure Component. In general, the data reported under the Patient Safety Component protocols are used to (1) determine the magnitude of the healthcare-associated adverse events under study, trends in the rates of the events, in the distribution of pathogens, and in the adherence to prevention practices, and (2) to detect changes in the epidemiology of adverse events resulting from new medical therapies and changing patient risks. Additionally, reported data will be used to describe the epidemiology of antimicrobial use and resistance and to understand the relationship of antimicrobial therapy to this growing problem. Under the Healthcare Personnel Safety Component protocols, 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 used to provide national estimates of adverse reactions and incidents. The Long-Term Care Facility (LTCF) Component more specifically and appropriately captures data from the residents of skilled nursing facilities. Reporting methods have been created by using forms

from the Patient Safety Component as a base, with modifications to specifically address the nuances of LTCF residents. 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 the in the future to include dialysis surveillance in settings other than outpatient facilities.

The Outpatient Procedure Component will be developed to gather data on the impact of infections and other outcomes related to outpatient procedures that are performed in settings such as Ambulatory Surgery Centers (ASCs), Hospital Outpatient Departments (HOPDs), and physicians' offices. Three event types will be monitored in this new component: Same Day Outcome Measures, Prophylactic Intravenous (IV) Antibiotic Timing, and Surgical Site Infections (SSI). The development of this component has been previously delayed to obtain additional user feedback and support from outside partners. This component is on track to be released in NHSN in 2017/2018.

Since its launch, NHSN increasingly has served as the operational system for compliance with HAI reporting legislation established by states. As of January, 2016, 33 states and the District of Columbia have opted to use NHSN as the operational system for mandated reporting by healthcare facilities in their jurisdictions with states having varied consequences for failing to use NHSN. Additional states are expected to follow with similar use of NHSN for reporting purposes. 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. CMS links 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 quality reporting programs to receive full payment. Still, many healthcare facilities, even in states with HAI reporting legislation, submit at least some HAI data to NHSN voluntarily.

OMB most recently approved this request on 12/28/2015 for 4,621,542 burden hours. Approval of this revision request would result in a net increase of 489,424 burden hours. This collection of information is authorized by the Public Health Service Act (42 USC 242b, 242k, and 242m(d)) (Attachment A).

The previously-approved NHSN OMB revision in December 2015 included 52 individual data collection forms; the current revision request includes revision of 22 of the previously approved forms, the addition of 19 forms and the removal of one data collection forms, for a total of 70 proposed data collection forms (Attachment C). A detailed explanation of the proposed program changes are provided in A15 of this document and Attachment D-1. An itemized list of changes proposed to each data collection form and their justifications are provided in Attachment D-2.

In summary, the proposed revisions to the information collection tools in NHSN include the following program changes with the associated change in time burden per individual hospital/facility per year:

- 1) There are multiple updates and clarifications made to 22 of the requested updates to the previously approved data collection tools, resulting in both increases and decreases to burden estimates. Questions and response options have been further clarified to assist in

user interpretation and correct completion of the form(s). Questions have been added to support the CDC priority of prevention and surveillance of HAIs and healthcare process measures. Questions have been removed if they no longer meet the needs of CDC. Those forms not detailed in 2-6 below are listed here:

- 57.100 – NHSN Registration Form: No change in burden per facility
- 57.121 – Denominator for Procedure: Increase of 45 hours per facility per year
- 57.127 – MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring: No change in burden per facility
- 57.138 – Laboratory-identified MDRO or CDI Event for LTCF: Increase of 1 hour per facility per year
- 57.139 – MDRO and CDI LabID Event Reporting Monthly Summary Data for LTCF: Increase of 1 hour per facility per year
- 57.140 – Urinary Tract Infection (UTI) for LTCF: Increase of 2.5 hours per facility per year
- 57.142 – Denominators for LTCF Locations: Increase of 1.2 hours per facility per year
- 57.303 – Hemovigilance Module Monthly Reporting Denominators: Increase of 2.04 hours per facility per year
- 57.502 – Dialysis Event: No change in burden per facility
- 57.503 – Denominator for Outpatient Dialysis: No change in burden per facility

- 2) Changes were made to six existing facility surveys and two brand new facility surveys were added. Based on user feedback and internal reviews of the annual facility surveys it was determined that questions and response options be amended, removed, or added to fit the evolving uses of the annual facility surveys such as informing DHQP of nationwide infection control and antimicrobial stewardship practices within healthcare. In addition, the surveys are being increasingly used to help intelligently interpret the other data elements reported into NHSN. Currently the surveys are used to appropriately risk adjust the numerator and denominator data entered into NHSN while also guiding DHQP decisions on future division priorities for prevention. The addition of two new annual facility surveys (57.306 & 57.507) will expand the universe of facility types able to complete the NHSN facility surveys. Specifically this allows non-acute care facilities to complete a survey for the Hemovigilance Module and home hemodialysis centers to complete a survey for the Dialysis Component.

- 57.103 – Patient Safety Component – Annual Hospital Survey: Increase of 5 minutes per hospital per year
- 57.137 – Long-Term Care Facility Component – Annual Facility Survey: Increase of 5 minutes per facility per year
- 57.150 – Patient Safety Component – Annual Facility Survey for LTAC: Increase of 5 minutes per hospital per year
- 57.151 – Patient Safety Component – Annual Facility Survey for IRF: Increase of 5 minutes per hospital per year

57.300 – Hemovigilance Module Annual Survey – Acute Care Facility: No change in burden per facility
57.306 – Hemovigilance Module Annual Survey – Non-acute care facility: (New form) Increase of 35 minutes per facility per year
57.500 – Outpatient Dialysis Center Practices Survey: No change in burden per facility
57.507 – Home Dialysis Center Practices Survey: (New form) Increase of 25 minutes per facility

- 3)** Six forms within the NHSN Patient Safety Component were revised to reflect the newer non-culture diagnostic tests that may be used to identify the presence of organisms.

57.108 – Primary Bloodstream Infection (BSI): No change in burden per hospital
57.111 – Pneumonia (PNEU): No change in burden per hospital
57.112 – Ventilator-Associated Event: No change in burden per hospital
57.114 – Urinary Tract Infection (UTI): No change in burden per hospital
57.120 – Surgical Site Infection (SSI): No change in burden per hospital
57.126 – MDRO or CDI Infection: No change in burden per hospital

- 4)** Three new forms were added within the NHSN Patient Safety Component: 57.113 - Pediatric Ventilator-Associated Event (PedVAE), 57.115 - Custom Event, and 57.129 - Adult Sepsis. The addition of these forms will allow NHSN to collect data on additional healthcare-associated infections such as ventilator-associated events in the pediatric patient population and sepsis in the adult patient population. Further, the Custom Event form will be used by healthcare facilities as part of a standardized, evidence-based surveillance method for identifying and tracking incidence and outcomes of healthcare-associated infections in US healthcare facilities beyond CLABSI, CAUTI, VAP, VAE, and SSI events.

57.113 – Pediatric Ventilator-Associated Event: (New form) Increase of 50 hours per hospital per year
57.115 – Custom Event: (New form) Increase of 53 hours per hospital per year
57.129 – Adult Sepsis: (New form) Increase of 104 hours per hospital per year

- 5)** The Adverse Reaction form within the Hemovigilance Component was removed (57.304) and instead split into 14 reaction-specific forms (57.307-57.320). The forms include general questions and reaction-specific questions. Instead of the detailed questions pertaining to all 14 specific reactions being listed in one form, the specific reactions were split into 14 separate form to reduce the length of a specific reaction form. Splitting the form prevents facilities from reading through questions that do not pertain to the transfusion reaction they are submitting. If these forms weren't separated, the single form would be over 47 pages long due to the reaction-specific questions that were added.

57.307 – Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction: (New form) Increase of 1.67 hours per hospital per year

57.308 – Hemovigilance Adverse Reaction - Allergic Transfusion Reaction: (New form) Increase of 1.67 hours per hospital per year

57.309 – Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction: (New form) Increase of 25 minutes per hospital per year

57.310 – Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction: (New form) Increase of 50 minutes per hospital per year

57.311 – Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction: (New form) Increase of 1.67 hours per hospital per year

57.312 – Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction: (New form) – Increase of 25 minutes per hospital per year

57.313 – Hemovigilance Adverse Reaction – Infection: (New form) Increase of 25 minutes per hospital per year

57.314 – Hemovigilance Adverse Reaction - Post Transfusion Purpura: (New form) Increase of 25 minutes per hospital per year

57.315 – Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea: (New form) Increase of 25 minutes per hospital per year

57.316 – Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease: (New form) Increase of 25 minutes per hospital per year

57.317 – Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury: (New form) Increase of 25 minutes per hospital per year

57.318 – Hemovigilance Adverse Reaction - Transfusion Associated Circulatory Overload: (New form) Increase of 50 minutes per hospital per year

57.319 – Hemovigilance Adverse Reaction - Unknown Transfusion Reaction: (New form) Increase of 25 minutes per hospital per year

57.320 – Hemovigilance Adverse Reaction - Other Transfusion Reaction: (New form) Increase of 25 minutes per hospital per year

2. **Purpose and Use of Information Collection**

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

- Estimation of the magnitude of healthcare-associated infections (HAIs)
- Monitoring of HAI trends
- Facilitation of interfacility and intrafacility 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 initially as internal benchmarks for healthcare facilities to measure their own performance and eventually—as a result of 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 U.S. Centers for Medicare and Medicaid Services (CMS) in fulfillment of CMS's quality measurement reporting programs including those data.
- Provide state departments of health with information that identifies the healthcare facilities in their state that participate in NHSN.
- Provide to 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 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 in an ongoing manner and report them monthly, seasonally, or yearly to CDC based on the specific data element being reported. The 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 yearly to estimate and characterize the national burden of healthcare-associated infections. These publications can be accessed here: <http://www.cdc.gov/nhsn/dataStat.html>.

NHSN is also increasingly being used to satisfy HAI reporting included in state legislation. Thirty-three states and the District of Columbia have implemented HAI reporting using NHSN as the reporting mechanism and more 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 CMS Center for Clinical Standards and Quality (CCSQ) in working to reduce healthcare associated infections and improve the quality of care within US healthcare facilities. Suggested revisions and enhancements for NHSN definitions and surveillance criteria are received from and vetted with NHSN users, as well as with external partners such as CMS CCSQ, the Healthcare Infection Control Practices Advisory Committee (HICPAC), and the Infectious Diseases Society of America (IDSA), as they are evaluated and developed by the 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 often require that the measure be endorsed by the National Quality Forum (NQF) therefore resulting in updates and improvements to the 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 the NHSN forms are directly related to

the expansion of CMS QRPs. The CMS QRP finalized rules and a 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 the NHSN are collected via a secure Internet application. Only the minimum amount of information necessary for the data collection is being 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 which provides a framework for formats of electronic documents. Currently, NHSN is able to 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 current 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, 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 the NHSN. The exception is in those states that have mandated the use of NHSN for meeting their public reporting laws and in facilities that participate in the CMS Hospital Inpatient Quality Reporting Program, the 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), the CMS PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program, and the 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 2016, there are over 18,100 healthcare facilities enrolled in NHSN. Of these, there are over 5,000 acute care facilities, 6,600 dialysis facilities, 530 long-term acute care facilities, 320 inpatient rehabilitation facilities, 540 inpatient psychiatric facilities, 310 long-term care facilities, and 4,600 ambulatory surgery facilities. The majority of these facilities are participating in CMS reporting programs for specific infection types. In 2011, the CMS Hospital Inpatient Quality Reporting Program began for all acute care facilities with intensive care units. Further, in 2013, the CMS Hospital Inpatient Quality Reporting Program 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 US 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 05/31/2016, Vol. 81, No.104, pg. 34337 (Attachment B). No public comments were received.

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 the 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.

In addition, DHQP actively interfaces with CMS and AHRQ as well as state 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 has the capability to 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 is to retrieve data by the name of the hospital or other 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. Accordingly, "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))." (Attachment H) The NHSN Assurance of Confidentiality expires December 31, 2020.

The use of the NHSN is both voluntary and mandated. State legislatures have mandated the use of the NHSN for public reporting of healthcare-acquired infections by healthcare facilities in their state.

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: 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 are 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 hard-copy data collection forms and later entered into the NHSN web interface. However, roughly 4,220 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) and 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: 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.

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).

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 hour and cost estimates for the proposed NHSN data collection tools. Incorporating all proposed revisions, the estimated burden for reporting reflects an increase of 489,424 hours and \$20,092,219 from the most recently-approved ICR in December, 2015. Detailed revisions of the previous burden tables are available in Attachments D-3 and D-4.

A. Estimates of Annualized Burden Hours

Burden estimates were derived using the estimated number of facilities participating in NHSN for each facility type and form. State and Federal HAI reporting mandates were taken into account when estimating the number of facilities (respondents) and the annual number of responses per facility. Subject matter expert and user feedback was used to determine the time

burden of completing each data collection form. NHSN has integrated legacy OMB-approved patient and healthcare personnel safety surveillance systems, National Nosocomial Infection Surveillance (NNIS) system, the National Surveillance System for Healthcare Workers (NaSH), and the Dialysis Surveillance Network (DSN), which served as successful pilot tests of the NHSN surveillance methods.

Estimated annual burden^a

Type of Respondent	Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)
Registered Nurse (Infection Preventionist)	57.100 NHSN Registration Form	2,000	1	5/60	167
Registered Nurse (Infection Preventionist)	57.101 Facility Contact Information	2,000	1	10/60	333
Registered Nurse (Infection Preventionist)	57.103 Patient Safety Component--Annual Hospital Survey	5,000	1	55/60	4,583
Registered Nurse (Infection Preventionist)	57.105 Group Contact Information	1,000	1	5/60	83
Registered Nurse (Infection Preventionist)	57.106 Patient Safety Monthly Reporting Plan	6,000	12	15/60	18,000
Registered Nurse (Infection Preventionist)	57.108 Primary Bloodstream Infection (BSI)	6,000	44	30/60	132,000
Registered Nurse (Infection Preventionist)	57.111 Pneumonia (PNEU)	6,000	72	30/60	216,000
Registered Nurse (Infection Preventionist)	57.112 Ventilator-Associated Event	6,000	144	25/60	360,000
Registered Nurse (Infection Preventionist)	57.113 Pediatric Ventilator-Associated Event (PedVAE)	2,000	120	25/60	100,000
Registered Nurse (Infection Preventionist)	57.114 Urinary Tract Infection (UTI)	6,000	40	20/60	80,000
Registered Nurse (Infection Preventionist)	57.115 Custom Event	2,000	91	35/60	106,167
Staff RN	57.116 Denominators for Neonatal Intensive Care Unit (NICU)	6,000	9	3	162,000
Staff RN	57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	6,000	9	5	270,000
Staff RN	57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	6,000	60	5	1,800,000
Registered Nurse (Infection Preventionist)	57.120 Surgical Site Infection (SSI)	6,000	36	35/60	126,000
Staff RN	57.121 Denominator for Procedure	6,000	540	10/60	540,000
Laboratory Technician	57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	6,000	12	5/60	6,000
Pharmacist	57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data	6,000	12	5/60	6,000

Type of Respondent	Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)
	Electronic Upload Specification Tables				
Registered Nurse (Infection Preventionist)	57.125 Central Line Insertion Practices Adherence Monitoring	1,000	100	25/60	41,667
Registered Nurse (Infection Preventionist)	57.126 MDRO or CDI Infection Form	6,000	72	30/60	216,000
Registered Nurse (Infection Preventionist)	57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	6,000	24	15/60	36,000
Registered Nurse (Infection Preventionist)	57.128 Laboratory-identified MDRO or CDI Event	6,000	240	20/60	480,000
Registered Nurse (Infection Preventionist)	57.129 Adult Sepsis	50	250	25/60	5,208
Registered Nurse (Infection Preventionist)	57.137 Long-Term Care Facility Component – Annual Facility Survey	350	1	1.08	378
Registered Nurse (Infection Preventionist)	57.138 Laboratory-identified MDRO or CDI Event for LTCF	350	12	15/60	1,050
Registered Nurse (Infection Preventionist)	57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	350	12	10/60	700
Registered Nurse (Infection Preventionist)	57.140 Urinary Tract Infection (UTI) for LTCF	350	14	30/60	2,450
Registered Nurse (Infection Preventionist)	57.141 Monthly Reporting Plan for LTCF	350	12	5/60	350
Registered Nurse (Infection Preventionist)	57.142 Denominators for LTCF Locations	350	12	3.35	14,070
Registered Nurse (Infection Preventionist)	57.143 Prevention Process Measures Monthly Monitoring for LTCF	300	12	5/60	300
Registered Nurse (Infection Preventionist)	57.150 LTAC Annual Survey	400	1	55/60	367
Registered Nurse (Infection Preventionist)	57.151 Rehab Annual Survey	1,000	1	55/60	917
Occupational Health RN/Specialist	57.200 Healthcare Personnel Safety Component Annual Facility Survey	50	1	8	400
Occupational Health RN/Specialist	57.203 Healthcare Personnel Safety Monthly Reporting Plan	17,000	1	5/60	1,417
Occupational Health RN/Specialist	57.204 Healthcare Worker Demographic Data	50	200	20/60	3,333

Type of Respondent	Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)
Occupational Health RN/Specialist	57.205 Exposure to Blood/Body Fluids	50	50	1	2,500
Occupational Health RN/Specialist	57.206 Healthcare Worker Prophylaxis/Treatment	50	30	15/60	375
Laboratory Technician	57.207 Follow-Up Laboratory Testing	50	50	15/60	625
Occupational Health RN/Specialist	57.210 Healthcare Worker Prophylaxis/Treatment-Influenza	50	50	10/60	417
Medical/Clinical Laboratory Technologist	57.300 Hemovigilance Module Annual Survey	500	1	2	1,000
Medical/Clinical Laboratory Technologist	57.301 Hemovigilance Module Monthly Reporting Plan	500	12	1/60	100
Medical/Clinical Laboratory Technologist	57.303 Hemovigilance Module Monthly Reporting Denominators	500	12	1.17	7,020
Medical/Clinical Laboratory Technologist	57.305 Hemovigilance Incident	500	10	10/60	833
Medical/Clinical Laboratory Technologist	57.306 Hemovigilance Module Annual Survey - Non-acute care facility	200	1	35/60	117
Medical/Clinical Laboratory Technologist	57.307 Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction	500	4	25/60	833
Medical/Clinical Laboratory Technologist	57.308 Hemovigilance Adverse Reaction - Allergic Transfusion Reaction	500	4	25/60	833
Medical/Clinical Laboratory Technologist	57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction	500	1	25/60	208
Medical/Clinical Laboratory Technologist	57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction	500	2	25/60	417
Medical/Clinical Laboratory Technologist	57.311 Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction	500	4	25/60	833
Medical/Clinical Laboratory Technologist	57.312 Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction	500	1	25/60	208
Medical/Clinical Laboratory Technologist	57.313 Hemovigilance Adverse Reaction - Infection	500	1	25/60	208
Medical/Clinical Laboratory Technologist	57.314 Hemovigilance Adverse Reaction - Post Transfusion Purpura	500	1	25/60	208
Medical/Clinical Laboratory Technologist	57.315 Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea	500	1	25/60	208

Type of Respondent	Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)
Medical/Clinical Laboratory Technologist	57.316 Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease	500	1	25/60	208
Medical/Clinical Laboratory Technologist	57.317 Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury	500	1	25/60	208
Medical/Clinical Laboratory Technologist	57.318 Hemovigilance Adverse Reaction - Transfusion Associated Circulatory Overload	500	2	25/60	417
Medical/Clinical Laboratory Technologist	57.319 Hemovigilance Adverse Reaction - Unknown Transfusion Reaction	500	1	25/60	208
Medical/Clinical Laboratory Technologist	57.320 Hemovigilance Adverse Reaction - Other Transfusion Reaction	500	1	25/60	208
Medical/Clinical Laboratory Technologist	57.400 Patient Safety Component—Annual Facility Survey for Ambulatory Surgery Center (ASC)	5,000	1	5/60	417
Staff RN	57.401 Outpatient Procedure Component - Monthly Reporting Plan	5,000	12	15/60	15,000
Staff RN	57.402 Outpatient Procedure Component Event	5,000	25	40/60	83,333
Staff RN	57.403 Outpatient Procedure Component - Monthly Denominators and Summary	5,000	12	40/60	40,000
Staff RN	57.500 Outpatient Dialysis Center Practices Survey	6,500	1	2.0	13,000
Registered Nurse (Infection Preventionist)	57.501 Dialysis Monthly Reporting Plan	6,500	12	5/60	6,500
Staff RN	57.502 Dialysis Event	6,500	60	25/60	162,500
Staff RN	57.503 Denominator for Outpatient Dialysis	6,500	12	10/60	13,000
Staff RN	57.504 Prevention Process Measures Monthly Monitoring for Dialysis	1,500	12	1.25	22,500
Staff RN	57.505 Dialysis Patient Influenza Vaccination	325	75	10/60	4,063
Staff RN	57.506 Dialysis Patient Influenza Vaccination Denominator	325	5	10/60	271
Staff RN	57.507 Home Dialysis Center Practices Survey	600	1	25/60	250
Total Estimated Annual Burden (Hours)					5,110,966

^a Columns may not total due to rounding.

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, 2015. Those most likely to complete this surveillance are health practitioners at a mid (50th percentile average wage) or senior (75th percentile average wage) level. Those 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

<http://www.bls.gov/bls/blswage.htm#National>
 Accessed: 4/25/2016

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	4,583	\$39.66	\$181,775
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)	132,000	\$39.66	\$5,235,120
Registered Nurse (Infection Preventionist)	57.111 Pneumonia (PNEU)	216,000	\$39.66	\$8,566,560
Registered Nurse (Infection Preventionist)	57.112 Ventilator-Associated Event	360,000	\$39.66	\$14,277,600
Registered Nurse (Infection Preventionist)	57.113 Pediatric Ventilator-Associated Event (PedVAE)	100,000	\$39.66	\$3,966,000
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	106,167	\$39.66	\$4,210,570
Staff RN	57.116 Denominators for Neonatal Intensive Care Unit (NICU)	162,000	\$32.45	\$5,256,900
Staff RN	57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	270,000	\$32.45	\$8,761,500
Staff RN	57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	1,800,000	\$32.45	\$58,410,000

Type of Respondents	Form Number & Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
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
Laboratory Technician	57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	6,000	\$18.73	\$112,380
Pharmacist	57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	6,000	\$58.41	\$350,460
Registered Nurse (Infection Preventionist)	57.125 Central Line Insertion Practices Adherence Monitoring	41,667	\$39.66	\$1,652,500
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	36,000	\$39.66	\$1,427,760
Registered Nurse (Infection Preventionist)	57.128 Laboratory-identified MDRO or CDI Event	480,000	\$39.66	\$19,036,800
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	378	\$39.66	\$14,991
Registered Nurse (Infection Preventionist)	57.138 Laboratory-identified MDRO or CDI Event for LTCF	1,050	\$39.66	\$41,643
Registered Nurse (Infection Preventionist)	57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	700	\$39.66	\$27,762
Registered Nurse (Infection Preventionist)	57.140 Urinary Tract Infection (UTI) for LTCF	2,450	\$39.66	\$97,167
Registered Nurse (Infection Preventionist)	57.141 Monthly Reporting Plan for LTCF	350	\$39.66	\$13,881
Registered Nurse (Infection Preventionist)	57.142 Denominators for LTCF Locations	14,070	\$39.66	\$558,016
Registered Nurse (Infection Preventionist)	57.143 Prevention Process Measures Monthly Monitoring for LTCF	300	\$39.66	\$11,898
Registered Nurse (Infection Preventionist)	57.150 LTAC Annual Survey	367	\$39.66	\$14,542
Registered Nurse (Infection Preventionist)	57.151 Rehab Annual Survey	917	\$39.66	\$36,355
Occupational Health RN/Specialist	57.200 Healthcare Personnel Safety Component Annual Facility Survey	400	\$33.75	\$13,500
Occupational Health RN/Specialist	57.203 Healthcare Personnel Safety Monthly Reporting Plan	1,417	\$33.75	\$47,813
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	1,000	\$34.99	\$34,990

Type of Respondents	Form Number & Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
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	7,020	\$34.99	\$245,630
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	833	\$34.99	\$29,158
Medical/Clinical Laboratory Technologist	57.308 Hemovigilance Adverse Reaction - Allergic Transfusion Reaction	833	\$34.99	\$29,158
Medical/Clinical Laboratory Technologist	57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction	208	\$34.99	\$7,290
Medical/Clinical Laboratory Technologist	57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction	417	\$34.99	\$14,579
Medical/Clinical Laboratory Technologist	57.311 Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction	833	\$34.99	\$29,158
Medical/Clinical Laboratory Technologist	57.312 Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction	208	\$34.99	\$7,290
Medical/Clinical Laboratory Technologist	57.313 Hemovigilance Adverse Reaction - Infection	208	\$34.99	\$7,290
Medical/Clinical Laboratory Technologist	57.314 Hemovigilance Adverse Reaction - Post Transfusion Purpura	208	\$34.99	\$7,290
Medical/Clinical Laboratory Technologist	57.315 Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea	208	\$34.99	\$7,290
Medical/Clinical Laboratory Technologist	57.316 Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease	208	\$34.99	\$7,290
Medical/Clinical Laboratory Technologist	57.317 Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury	208	\$34.99	\$7,290
Medical/Clinical Laboratory Technologist	57.318 Hemovigilance Adverse Reaction - Transfusion Associated Circulatory Overload	417	\$34.99	\$14,579
Medical/Clinical Laboratory Technologist	57.319 Hemovigilance Adverse Reaction - Unknown Transfusion Reaction	208	\$34.99	\$7,290
Medical/Clinical Laboratory Technologist	57.320 Hemovigilance Adverse Reaction - Other Transfusion Reaction	208	\$34.99	\$7,290
Medical/Clinical Laboratory Technologist	57.400 Patient Safety Component—Annual Facility Survey for Ambulatory Surgery Center (ASC)	417	\$32.45	\$13,521
Staff RN	57.401 Outpatient Procedure Component - Monthly Reporting Plan	15,000	\$32.45	\$486,750
Staff RN	57.402 Outpatient Procedure Component Event	83,333	\$32.45	\$2,704,167
Staff RN	57.403 Outpatient Procedure Component - Monthly Denominators and Summary	40,000	\$32.45	\$1,298,000
Staff RN	57.500 Outpatient Dialysis Center Practices Survey	13,000	\$39.66	\$515,580
Registered Nurse (Infection Preventionist)	57.501 Dialysis Monthly Reporting Plan	6,500	\$32.45	\$210,925
Staff RN	57.502 Dialysis Event	162,500	\$32.45	\$5,273,125
Staff RN	57.503 Denominator for Outpatient Dialysis	13,000	\$32.45	\$421,850
Staff RN	57.504 Prevention Process Measures Monthly Monitoring for Dialysis	22,500	\$32.45	\$730,125

Type of Respondents	Form Number & Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
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	250	\$39.66	\$9,915
Total Estimated Cost				\$180,066,067

^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 annual cost burden to respondents. Capital and start-up cost: Healthcare institutions participating in the 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, and high-speed Internet access >200 Kbs (e.g., T1, cable, DSL or ADSL); 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 144 FTE/contractor personnel are actively involved in the enhancement and maintenance of the 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 2017 is estimated to be \$13,786,099.

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 2017 will be \$3,118,012
	Supervisory. Medical Officer	1
	Medical Epidemiologist	2
	Statistician	2
	Epidemiologist	8
	Nurse Epidemiologist	2
	Systems Analyst	3
	Public Health Analyst	2
	Computer Scientist	3
Programming contracts	Design, develop, and deploy enhancements to NHSN	\$10,668,087
Total		\$13,786,099

15. Explanation for Program Changes or Adjustments

Twenty-two data collection tools previously approved under OMB No. 0920-0666 have been revised in this revision request. In addition, nineteen forms are being added and one form is being removed from this package. Proposed program changes are explained below.

- 1) Significant updates to annual facility surveys (57.103, 57.137, 57.150, 57.151, 57.300, and 57.500)

Justification: Based on user feedback and internal reviews of the annual facility surveys it was determined that questions and response options be amended, removed, or added to fit the evolving uses of the annual facility surveys. The surveys are being increasingly used to help intelligently interpret the other data elements reported into NHSN. Currently the surveys are used to appropriately risk adjust the numerator and denominator data entered into NHSN while also guiding DHQP decisions on future division priorities for prevention.

- 2) Pediatric Ventilator-Associated Event (PedVAE) surveillance will be added to NHSN (57.113)

Justification: The NHSN PedVAE Form was developed amid increasing interest in the public health impact of conditions and complications in mechanically-ventilated neonates and children in acute care hospitals, long term acute care hospitals, and inpatient rehabilitation facilities. PedVAE surveillance will extend NHSN's current VAE surveillance to pediatric populations (currently, VAE surveillance is only conducted in adult locations). PedVAE surveillance will provide a standardized, evidence-based surveillance method for identifying and tracking incidence and outcomes of ventilator-associated conditions in children in US healthcare facilities. These data may be used by facilities to identify areas where prevention and patient safety efforts may be improved.

- 3) Custom Event surveillance will be added to NHSN (57.115)

Justification: The NHSN Custom Event Form for reporting of healthcare-associated infections other than CLABSI, CAUTI, VAP, VAE, and SSI was developed amid increasing interest in the public health impact of infections in acute care hospitals, long term acute care hospitals, and inpatient rehabilitation facilities. The Custom Event Form is used by healthcare facilities as part of a standardized, evidence-based surveillance method for identifying and tracking incidence and outcomes of healthcare-associated infections in US healthcare facilities. These data may be used by facilities to identify areas where prevention of healthcare-associated infections may be improved.

- 4) Adult Sepsis surveillance will be added to NHSN (57.129)

Justification: The NHSN Adult Sepsis Module was developed amid increasing interest in the public health impact of sepsis. The Adult Sepsis module provides a standardized, evidence-based surveillance method for identifying and tracking incidence and outcomes of sepsis among adults in US healthcare facilities. These data may be used by facilities to identify areas where sepsis management may be improved. Data may also be used by public health authorities to identify regions and facilities with poor sepsis outcomes and target interventions accordingly.

- 5) One new survey was added to the Hemovigilance Component (57.306)

Justification: Non-acute care facilities can now report to the NHSN Hemovigilance Module. All participating facilities complete an Annual Facility Survey. This new form contains questions specific to non-acute care facilities. The inclusion of non-acute care facilities will broaden the scope of facilities reporting to the Hemovigilance Module. This will allow for more robust data collection to identify emerging trends in transfusion related adverse events among these facilities.

- 6) One existing form was removed (57.304) and fourteen new specific adverse reaction forms were added to the Hemovigilance Component (57.306, 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 Adverse Reaction form within the Hemovigilance Component was removed (57.304) and instead split into 14 reaction-specific forms to reduce the length of form. The forms include general questions and reaction-specific questions. Splitting the form prevents facilities from reading through questions that do not pertain to the transfusion reaction they are submitting.

- 7) One new survey was added to the Dialysis Component (57.507)

Justification: Dialysis centers that provide training and support for patients who undergo hemodialysis and/or peritoneal dialysis in their own homes have different practices than centers that provide in-center hemodialysis. The existing “Outpatient Dialysis Center Practices Survey” was tailored to in-center hemodialysis practices and could not be completed correctly by facilities that do not offer that type of care. Therefore a new survey has been created to collect information specific to facilities that support home dialysis patients. Practice information being collected includes:

- Information about the center’s affiliation, medical records systems, and isolation practices
- Patient and staff census
- Vaccination practices
- Hepatitis screening practices
- Practices related to cannulation and cleaning of vascular accesses as well as peritoneal catheters

- 8) All other NHSN data collection form revisions.

Justification: A number of minor revisions, updates, and clarifications have been made to 22 NHSN data collection forms. See Attachment D-2 for itemized NHSN data collection forms revisions and justifications. Resulting burden revisions are itemized in Attachments D-3 and D-4.

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 also by non-participating healthcare institutions that collect their data using NHSN methodology.

The reporting institutions will be able to access their own 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, which is <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 the 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 time 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.