National Healthcare Safety Network (NHSN)
OMB Control No. 0920-0666
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Revision Request
Supporting Statement Part A

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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 8,810,700 responses and 4,104,776 burden hours. This revision request includes removing three forms, adding one form, and revisions to 31 previously approved forms. The reporting burden will increase by 172,943 hours, for a total estimated burden of 4,277,716 hours; annual cost of reporting would increase by $8,230,580.

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.

Since its launch, NHSN increasingly has served as the operational system for compliance with mandatory HAI reporting requirements established by states. As of June, 2014, 32 states and the District of Columbia have opted to use NHSN as the operational system for mandatory reporting by healthcare facilities in their jurisdictions, and additional states are expected to follow with similar use of NHSN for mandatory reporting purposes. In addition, CMS requires Medicare-eligible acute care hospitals, inpatient rehabilitation facilities, long-term acute care facilities, dialysis facilities, oncology hospitals and ambulatory surgery centers to report HAI data and healthcare personnel influenza vaccination summary data to CMS via NHSN as part of CMS quality improvement and reporting programs. Still, many healthcare facilities, even in states with mandatory reporting requirements, submit at least some HAI data to NHSN voluntarily.

OMB most recently approved this request on 10/30/2013 for 4,104,776 burden hours. Approval of this revision request would result in a net increase of 172,943 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 October 2013 included 56 individual data collection forms; the current revision request includes revision of 31 of the previously approved forms, the addition of one new form, and the removal of three data collection forms,

for a total of 54 proposed data collection forms (Attachment C). A detailed explanation of the proposed program changes are provided in 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:

1) There are multiple updates and clarifications made to 31 of the approved data collection tools resulting in both increases and decreases to burden estimates.

2) A new component will be launched within NHSN that will specifically examine antimicrobial use (AU) and antimicrobial resistance (AR) within healthcare facilities: Antimicrobial Use and Resistance (AUR) Component. The goal of the AUR Component is to provide a mechanism for facilities to report and analyze antimicrobial use and/or resistance as part of local or regional efforts to reduce antimicrobial resistant infections through antimicrobial stewardship efforts or interruption of transmission of resistant pathogens at their facility. AU and AR functionalities currently exist within NHSN but participation is limited to inpatient healthcare facilities. Moving the AU and AR Modules to a separate NHSN Component will allow all healthcare facility types, such as outpatient dialysis facilities and long-term care facilities, to take advantage of these tools for antimicrobial stewardship.

With this new component, one new form will be added to the NHSN package: 57.154 Antimicrobial Use & Resistance Component - Monthly Reporting Plan.

3) Significant changes were made to four facility surveys. After an internal review of the annual facility surveys it was determined by DHQP Division Leadership that the surveys should be revised and updated to accommodate the evolving needs of obtaining information from healthcare facilities throughout the US. For the Facility Microbiology Laboratory Practices section of the survey it was determined that some questions were no longer needed as the majority of laboratories are following similar practices to adhere to industry guidelines. Response options were also added to be inclusive of all laboratory types used by healthcare facilities. A few questions were added to obtain information regarding activities to prevent furthering of antimicrobial resistance within the individual healthcare facility.

Two new sections were added to the surveys. Questions about infection control practices are being added to the survey for the purpose of gaining a better understanding of current practices and to identify areas to target prevention efforts among facilities that have reported a multidrug-resistant organism. The information collected will inform future efforts to improve facility implementation of recommended prevention measures to control spread of multidrug-resistant organisms. Questions about antibiotic stewardship are being added to the survey for the purpose of gaining a better understanding of current efforts to improve antibiotic use in hospitals and to assess the quality of hospital antibiotic stewardship programs. The information collected will inform efforts to improve

facility implementation of best practices to improve antibiotic stewardship programs and antibiotic use in hospitals.

4) Revision of susceptibility options for Cefepime (an antibiotic). Recently the Clinical and Laboratory Standards Institute (CLSI) has updated the susceptibility options for Cefepime to replace Intermediate (I) with Susceptible-dose dependent (S-DD) for three organisms: Escherichia coli, Enterobacter, and Klebsiella. However, because not all laboratories will implement this change at the same time, the susceptibility options for Cefepime for those three organisms will include both I and S-DD on all NHSN event forms.

5) A total of three forms will be removed from the PRA package as patient vaccination monitoring will be removed from NHSN because of low use. The removed forms are: 57.130 Vaccination Monthly Monitoring Form–Summary Method, 57.131 Vaccination Monthly Monitoring Form–Patient-Level Method, and 57.133 Patient Vaccination.

1.1 Privacy Impact Assessment

Overview of Data Collection System

The NHSN currently consists of five components: Patient Safety, Healthcare Personnel Safety, Biovigilance, Long-Term Care Facility, and Dialysis. Two new components will be added to NHSN within the next one to two years: Antimicrobial Use and Resistance Component & 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 new Antimicrobial Use and Resistance (AUR) Component was developed in order to separate reporting of antimicrobial use and resistance from the Patient Safety Component. This will allow all facility types to track and report antimicrobial use and resistance. The new Outpatient Procedure Component was 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 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 23.6% of facilities submit data electronically directly from a vendor system using Clinical Document Architecture (CDA).

Description of Information to be Collected

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.

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.

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 state-mandated HAI reporting requirements. Thirty-two states and the District of Columbia have implemented HAI reporting requirements using NHSN as the reporting mechanism and more are expected in the coming years. In addition, the Centers for Medicare and Medicaid Services (CMS) now requires Medicare-eligible acute care hospitals, inpatient rehabilitation facilities, long-term acute care hospitals, dialysis facilities, oncology hospitals, and ambulatory surgical centers to report HAI and healthcare personnel influenza vaccination data to CMS via NHSN. Therefore, the following purposes were added in 2010 to meet those needs:

- 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 requirements for 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.

2.1 Privacy Impact Assessment Information

Data are used to determine the magnitude of the adverse healthcare-associated events and trends in the rates of these events among patients and healthcare personnel with similar risks or exposures.

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 23.6% of 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.

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)

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 on central line-associated bloodstream infections (CLABSI), surgical site infections (SSI), catheter-associated urinary tract infections (CAUTI), central line insertion practices (CLIP), laboratory-identified (LabID) events, dialysis events and the pharmacy side of the antimicrobial use (AU) and resistance (AUR) module via CDA. NHSN is able to accept summary/denominator data for surgical procedures, Intensive Care Units (ICU)/Other Locations (not NICU and SCA), Neonatal Intensive Care Units (NICU), Specialty Care Areas (SCA), dialysis, and LabID.

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 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

Reporting data more frequently than quarterly

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.

Generalizability of results

As of June 2014, there are over 12,800 healthcare facilities enrolled in NHSN. Of these, there are over 4,800 acute care facilities, 6,400 dialysis facilities, 560 long-term acute care facilities, 290 inpatient rehabilitation facilities, 230 long-term care facilities, and 370 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. Therefore, while not all US acute care facilities have intensive care units, the NHSN data for central line-associated blood stream infections (CLABSI) and catheter-associated urinary tract infections (CAUTI) from intensive care units are considered to be generalizable to 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, these 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 is 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 06/19/2014, Vol. 79, No.118, pg. 35166 (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. Assurance of Confidentiality Provided to 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."

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. However, since its launch that year, NHSN increasingly has served as the operational system for compliance with mandatory healthcare-associated infection (HAI) reporting requirements established by states. As of June, 2014, 32 states and the District of Columbia have opted to use NHSN as the operational system for mandatory reporting by healthcare facilities in their jurisdictions, and additional states are expected to follow with similar use of NHSN for mandatory reporting purposes. In addition, CMS requires Medicare-eligible acute care hospitals, inpatient rehabilitation facilities, long-term acute care facilities, dialysis facilities, oncology hospitals and ambulatory surgery centers to report HAI data and healthcare personnel influenza vaccination summary data to CMS via NHSN as part of CMS quality improvement and reporting programs. Still, many healthcare facilities, even in states with mandatory reporting requirements, submit at least some HAI data to NHSN voluntarily. As a result, the HAI data reported to NHSN are a mix of data reported voluntarily and mandatorily. The previously amended NHSN Assurance of Confidentiality is intended to cover those data that are voluntarily provided by healthcare facilities to DHQP through the NHSN and not data that are either (1) mandated by state or federal laws, regulations, or other requirements, or (2) requested by state agencies for surveillance or prevention purposes (Attachment H). Collaborators at the participating institutions may publish data collected from their institutions and may identify themselves as NHSN participants.

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).

10.1 Privacy Impact Assessment Information

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. The CDC Office of General Counsel has determined that the Privacy Act does not apply to this data collection.

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: requiring the use of a digital certificate via CDC's Secure Data Network or use of a password issued via CDC's Secure Access Management System for access to the application; data

encryption using Secure Socket Layer technology; and lastly, storage of data in password protected files on secure computers in locked, authorized-access-only rooms.

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

The Office of the General Counsel (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."

11. 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 172,943 hours and $8,230,580 from the most recently-approved ICR in October, 2013. 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	Form 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	6,000	1	50/60	5,000
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
Infection Preventionist	57.114	Urinary Tract Infection (UTI)	6,000	40	30/60	120,000
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	54	5	1,620,000
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	5/60	270,000
Laboratory Technician	57.123	Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	6,000	12	5/60	6,000
Pharmacy Technician	57.124	Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	6,000	12	5/60	6,000
Registered Nurse (Infection Preventionist)	57.125	Central Line Insertion Practices Adherence Monitoring	1,000	100	5/60	8,333
Registered Nurse (Infection Preventionist)	57.126	MDRO or CDI Infection Form	6,000	72	30/60	216,000

Type of Respondent	Form Number	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)
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	15/60	360,000
Registered Nurse (Infection Preventionist)	57.137	Long-Term Care Facility Component – Annual Facility Survey	250	1	1	250
Registered Nurse (Infection Preventionist)	57.138	Laboratory-identified MDRO or CDI Event for LTCF	250	8	15/60	500
Registered Nurse (Infection Preventionist)	57.139	MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	250	12	5/60	250
Registered Nurse (Infection Preventionist)	57.140	Urinary Tract Infection (UTI) for LTCF	250	9	30/60	1,125
Registered Nurse (Infection Preventionist)	57.141	Monthly Reporting Plan for LTCF	250	12	5/60	250
Registered Nurse (Infection Preventionist)	57.142	Denominators for LTCF Locations	250	12	3.25	9,750
Registered Nurse (Infection Preventionist)	57.143	Prevention Process Measures Monthly Monitoring for LTCF	250	12	5/60	250
Registered Nurse (Infection Preventionist)	57.150	LTAC Annual Survey	400	1	50/60	333
Registered Nurse (Infection Preventionist)	57.151	Rehab Annual Survey	1,000	1	50/60	833
Registered Nurse (Infection Preventionist)	57.154	Antimicrobial Use & Resistance Component - Monthly Reporting Plan	100	12	5/60	100
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	11,000	1	5/60	917
Occupational Health RN/Specialist	57.204	Healthcare Worker Demographic Data	50	200	20/60	3,333
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

Type of Respondent	Form Number	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)
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	6,000
Medical/Clinical Laboratory Technologist	57.304	Hemovigilance Adverse Reaction	500	48	15/60	6,000
Medical/Clinical Laboratory Technologist	57.305	Hemovigilance Incident	500	10	10/60	833
Staff RN	57.400	Outpatient Procedure Component - Annual Facility Survey	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
Registered Nurse (Infection Preventionist)	57.500	Outpatient Dialysis Center Practices Survey	6,500	1	1.75	11,375
Staff RN	57.501	Dialysis Monthly Reporting Plan	6,500	12	5/60	6,500
Staff RN	57.502	Dialysis Event	6,500	60	20/60	130,000
Staff RN	57.503	Denominator for Outpatient Dialysis	6,500	12	6/60	7,800
Staff RN	57.504	Prevention Process Measures Monthly Monitoring for Dialysis	1,500	12	30/60	9,000
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
Epidemiologist	57.600	State Health Department Validation Record	152	50	15/60	1,900
			Total Estimated Annual Burden (Hours)			**4,277,716**

[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, 2013. 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.

2013 Department Of Labor Salary Estimates		
Professional Labor Category	**Percentile**	**Hourly Wage**
Infection Preventionist RN	75th	$38.55
Medical/Clinical Laboratory Technologist	75th	$33.61
Epidemiologist	75th	$41.29
Occupational Health Nurse (Occ Health RN)	50th	$32.15
Pharmacy Technician	50th	$14.25
Staff RN	50th	$31.84
Laboratory Technician	50th	$18.26

http://www.bls.gov/bls/blswage.htm#National
Accessed: 5/7/2014

Estimated annualized burden cost[a]

Type of Respondents	Form Number	Form Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
Registered Nurse (Infection Preventionist)	57.100	NHSN Registration Form	167	$38.55	$6,425
Registered Nurse (Infection Preventionist)	57.101	Facility Contact Information	333	$38.55	$12,850
Registered Nurse (Infection Preventionist)	57.103	Patient Safety Component--Annual Hospital Survey	5,000	$38.55	$192,750
Registered Nurse (Infection Preventionist)	57.105	Group Contact Information	83	$38.55	$3,213
Registered Nurse (Infection Preventionist)	57.106	Patient Safety Monthly Reporting Plan	18,000	$38.55	$693,900
Registered Nurse (Infection Preventionist)	57.108	Primary Bloodstream Infection (BSI)	132,000	$38.55	$5,088,600
Registered Nurse (Infection Preventionist)	57.111	Pneumonia (PNEU)	216,000	$38.55	$8,326,800
Registered Nurse (Infection Preventionist)	57.112	Ventilator-Associated Event	360,000	$38.55	$13,878,000
Infection Preventionist	57.114	Urinary Tract Infection (UTI)	120,000	$38.55	$4,626,000
Staff RN	57.116	Denominators for Neonatal Intensive Care Unit (NICU)	162,000	$31.84	$5,158,080
Staff RN	57.117	Denominators for Specialty Care Area (SCA)/Oncology (ONC)	270,000	$31.84	$8,596,800
Staff RN	57.118	Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	1,620,000	$31.84	$51,580,800
Registered Nurse (Infection Preventionist)	57.120	Surgical Site Infection (SSI)	126,000	$38.55	$4,857,300
Staff RN	57.121	Denominator for Procedure	270,000	$31.84	$8,596,800
Laboratory Technician	57.123	Antimicrobial Use and Resistance (AUR)-	6,000	$18.26	$109,560

Type of Respondents	Form Number	Form Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
		Microbiology Data Electronic Upload Specification Tables			
Pharmacy Technician	57.124	Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	6,000	$14.25	$85,500
Registered Nurse (Infection Preventionist)	57.125	Central Line Insertion Practices Adherence Monitoring	8,333	$38.55	$321,250
Registered Nurse (Infection Preventionist)	57.126	MDRO or CDI Infection Form	216,000	$38.55	$8,326,800
Registered Nurse (Infection Preventionist)	57.127	MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	36,000	$38.55	$1,387,800
Registered Nurse (Infection Preventionist)	57.128	Laboratory-identified MDRO or CDI Event	360,000	$38.55	$13,878,000
Registered Nurse (Infection Preventionist)	57.137	Long-Term Care Facility Component – Annual Facility Survey	250	$38.55	$9,638
Registered Nurse (Infection Preventionist)	57.138	Laboratory-identified MDRO or CDI Event for LTCF	500	$38.55	$19,275
Registered Nurse (Infection Preventionist)	57.139	MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	250	$38.55	$9,638
Registered Nurse (Infection Preventionist)	57.140	Urinary Tract Infection (UTI) for LTCF	1,125	$38.55	$43,369
Registered Nurse (Infection Preventionist)	57.141	Monthly Reporting Plan for LTCF	250	$38.55	$9,638
Registered Nurse (Infection Preventionist)	57.142	Denominators for LTCF Locations	9,750	$38.55	$375,863
Registered Nurse (Infection Preventionist)	57.143	Prevention Process Measures Monthly Monitoring for LTCF	250	$38.55	$9,638
Registered Nurse (Infection Preventionist)	57.150	LTAC Annual Survey	333	$38.55	$12,850
Registered Nurse (Infection Preventionist)	57.151	Rehab Annual Survey	833	$38.55	$32,125
Registered Nurse (Infection Preventionist)	57.154	Antimicrobial Use & Resistance Component - Monthly Reporting Plan	100	$38.55	$3,855
Occupational Health RN/Specialist	57.200	Healthcare Personnel Safety Component Annual Facility Survey	400	$32.15	$12,860
Occupational Health RN/Specialist	57.203	Healthcare Personnel Safety Monthly Reporting Plan	917	$32.15	$29,471
Occupational Health RN/Specialist	57.204	Healthcare Worker Demographic Data	3,333	$32.15	$107,167
Occupational Health RN/Specialist	57.205	Exposure to Blood/Body Fluids	2,500	$32.15	$80,375
Occupational Health RN/Specialist	57.206	Healthcare Worker Prophylaxis/Treatment	375	$32.15	$12,056
Laboratory Technician	57.207	Follow-Up Laboratory Testing	625	$18.26	$11,413
Occupational Health RN/Specialist	57.210	Healthcare Worker Prophylaxis/Treatment-Influenza	417	$32.15	$13,396
Medical/Clinical Laboratory Technologist	57.300	Hemovigilance Module Annual Survey	1,000	$33.61	$33,610
Medical/Clinical Laboratory Technologist	57.301	Hemovigilance Module Monthly Reporting Plan	100	$33.61	$3,361
Medical/Clinical Laboratory Technologist	57.303	Hemovigilance Module Monthly Reporting Denominators	6,000	$33.61	$201,660

Type of Respondents	Form Number	Form Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
Medical/Clinical Laboratory Technologist	57.304	Hemovigilance Adverse Reaction	6,000	$33.61	$201,660
Medical/Clinical Laboratory Technologist	57.305	Hemovigilance Incident	833	$33.61	$28,008
Staff RN	57.400	Outpatient Procedure Component - Annual Facility Survey	417	$31.84	$13,267
Staff RN	57.401	Outpatient Procedure Component - Monthly Reporting Plan	15,000	$31.84	$477,600
Staff RN	57.402	Outpatient Procedure Component Event	83,333	$31.84	$2,653,333
Staff RN	57.403	Outpatient Procedure Component - Monthly Denominators and Summary	40,000	$31.84	$1,273,600
Registered Nurse (Infection Preventionist)	57.500	Outpatient Dialysis Center Practices Survey	11,375	$38.55	$438,506
Staff RN	57.501	Dialysis Monthly Reporting Plan	6,500	$31.84	$206,960
Staff RN	57.502	Dialysis Event	130,000	$31.84	$4,139,200
Staff RN	57.503	Denominator for Outpatient Dialysis	7,800	$31.84	$248,352
Staff RN	57.504	Prevention Process Measures Monthly Monitoring for Dialysis	9,000	$31.84	$286,560
Staff RN	57.505	Dialysis Patient Influenza Vaccination	4,063	$31.84	$129,350
Staff RN	57.506	Dialysis Patient Influenza Vaccination Denominator	271	$31.84	$8,623
Epidemiologist	57.600	State Health Department Validation Record	1,900	$41.29	$78,451
			Total Estimated Cost		**$146,941,956**

[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, CD-ROM or DVD drive, 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 62 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 2015 is estimated to be $10,790,074.

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 2015 will be $2,489,136.
	Supervisory. Medical Officer Medical Epidemiologist Statistician Epidemiologist Nurse Epidemiologist Systems Analyst Public Health Analyst Computer Scientist	1 2.5 2 3.75 1 2 1 2.25	
Programming contracts	Design, develop, and deploy enhancements to NHSN		$8,300,938
Total			**$10,790,074**

15. Explanation for Program Changes or Adjustments

Thirty-one data collection tools previously approved under OMB No. 0920-0666 have been revised in this revision request. In addition, one form is being added and three forms are being removed from this package. A brief summary of the proposed program changes is provided below. An extensive explanation of the proposed program changes are provided in Attachment D-1. An itemized list of changes proposed to each data collection form and their justifications are provided in Attachment D-2. For additional information, surveillance protocols and completion instructions for each data collection tool can be found in Attachment G.

In summary, the proposed revisions to the information collection tools in NHSN include the following program changes:

1) There are multiple updates and clarifications made to 31 of the approved data collection tools resulting in both increases and decreases to burden estimates.

2) A new component will be launched within NHSN that will specifically examine antimicrobial use (AU) and antimicrobial resistance (AR) within healthcare facilities: Antimicrobial Use and Resistance (AUR) Component. The goal of the AUR Component is to provide a mechanism for facilities to report and analyze antimicrobial use and/or resistance as part of local or regional efforts to reduce antimicrobial resistant infections through antimicrobial stewardship efforts or interruption of transmission of resistant pathogens at their facility. AU and AR functionalities currently exist within NHSN but participation is limited to inpatient healthcare facilities. Moving the AU and AR Modules to a separate NHSN Component will allow all healthcare facility types, such as outpatient dialysis facilities and long-term care facilities, to take advantage of these tools for antimicrobial stewardship.

With this new component, one new form will be added to the NHSN package: 57.154 Antimicrobial Use & Resistance Component - Monthly Reporting Plan.

3) Significant changes were made to four facility surveys. After an internal review of the annual facility surveys it was determined by DHQP Division Leadership that the surveys should be revised and updated to accommodate the evolving needs of obtaining information from healthcare facilities throughout the US. For the Facility Microbiology Laboratory Practices section of the survey it was determined that some questions were no longer needed as the majority of laboratories are following similar practices to adhere to industry guidelines. Response options were also added to be inclusive of all laboratory types used by healthcare facilities. A few questions were added to obtain information regarding activities to prevent furthering of antimicrobial resistance within the individual healthcare facility.

Two new sections were added to the surveys. Questions about infection control practices are being added to the survey for the purpose of gaining a better understanding of current practices and to identify areas to target prevention efforts among facilities that have reported a multidrug-resistant organism. The information collected will inform future efforts to improve facility implementation of recommended prevention measures to control spread of multidrug-resistant organisms. Questions about antibiotic stewardship are being added to the survey for the purpose of gaining a better understanding of current efforts to improve antibiotic use in hospitals and to assess the quality of hospital antibiotic stewardship programs. The information collected will inform efforts to improve facility implementation of best practices to improve antibiotic stewardship programs and antibiotic use in hospitals.

4) Revision of susceptibility options for Cefepime. Recently the Clinical and Laboratory Standards Institute (CLSI) has updated the susceptibility options for Cefepime to replace Intermediate (I) with Susceptible-dose dependent (S-DD) for three organisms: Escherichia coli, Enterobacter, and Klebsiella. However, because not all laboratories will implement this change at the same time, the susceptibility options for Cefepime for those three organisms will include both I and S-DD on all NHSN event forms.

5) A total of three forms will be removed from NHSN as patient vaccination monitoring will be removed from NHSN. The removed forms are: 57.130 Vaccination Monthly Monitoring Form–Summary Method, 57.131 Vaccination Monthly Monitoring Form–Patient-Level Method, and 57.133 Patient Vaccination.

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.