

OMB No. 0920-0666
National Healthcare Safety Network (NHSN)
Revision Request, September 2011

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 8,809,350 responses and 3,914,125 burden hours. This revision request includes six new forms and small revisions to 20 previously approved forms. The reporting burden will increase by 64,050 hours, for a total estimated burden of 3,978,175 hours; annual cost of reporting would increase by \$4,781,769.

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. OMB most recently approved this request on 5/12/2011 for 3,914,125 burden hours. Approval of this revision request would result in a net increase of 64,050 burden hours. This collection of information is authorized by the Public Health Service Act (42 USC 242b, 242k, and 242m(d)) (Attachment A). Public notification of this information collection revision request was published in the *Federal Register* (Vol. 76, No. 177) on 09/13/2011 (Attachment B).

The previously-approved NHSN OMB revision in May 2011 included 48 individual data collection forms; the current revision request includes revision of 20 of the previously approved forms and the addition of six newly-proposed 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 20 of the approved data collection tools resulting in both increases and decreases to burden estimates.
- 2) User feedback has allowed us to recognize two forms on which the burden should be decreased. Estimated burden will be decreased by 15 minutes on both the Laboratory-identified Multidrug-resistant Organism (MDRO) or *Clostridium difficile* Infection (CDI) Event form and the Laboratory-identified MDRO or CDI Event for Long-Term Care Facility (LTCF) form.
- 3) The Centers for Medicare and Medicaid Services (CMS) have recently entered into a strong collaboration with the CDC and NHSN. CMS has chosen to designate NHSN as

the reporting system into which facilities must enter data in order to fulfill the Inpatient Prospective Payment Systems (IPPS) requirements. The CMS rules have designated central line-associated bloodstream infections (CLABSIs) to be reported from acute care hospital intensive care units in 2011, and are expanding these reporting rules for 2012, and beyond. In order to assist CMS with appropriate patient and facility identification, they have requested the addition of a variable to collect the patient's Medicare Beneficiary number. Therefore, NHSN will be adding this number to all forms that collect patient identifier level data (thirteen in total). This variable will not be required, only optional, and so no additional burden adjustment is necessary.

- 4) A new Long-Term Care Facility (LTCF) Component is under development within NHSN, in order to more specifically and appropriately capture data from the residents of skilled nursing facilities. This component was to be launched in 2011, but the release has now been postponed until 2012. With the first version of this new component, users will be able to track and report urinary tract infections (UTIs), laboratory-identified (LabID) events for multidrug-resistant organisms and *C. difficile*, and/or hand hygiene and gown and gloves use, all at the facility-wide inpatient level. In order to facilitate this reporting, there are 7 LTCF forms that have been created by using forms from the Patient Safety Component as a base, with modifications to specifically address the nuances of long-term care (LTC) residents. In the last OMB package submission from NHSN, 4 of the forms were included and approved. However, due to an unexpected oversight, 3 of the forms were not included in that package. Therefore, we are including those 3 remaining LTCF forms in this package submission for review and approval.
- 5) The scope of NHSN dialysis surveillance is being expanded to include all outpatient dialysis centers so that the existing Dialysis Annual Survey can be used to facilitate prevention objectives set forth in the Department of Health and Human Services (HHS) Healthcare Associated Infections Tier 2 Action Plan and to assess national practices in all Medicare-certified dialysis centers if the Centers for Medicare and Medicaid Services (CMS) re-establishes this survey method as expected.
- 6) The CMS final rule for the FY 2012 IPPS includes a requirement for long-term acute care (LTAC) hospitals to report catheter-associated urinary tract infection (CAUTI) and central line-associated blood stream infection (CLABSI) data to NHSN by October 2012. As a result, all LTAC hospitals in the U.S. will be required to enroll in and report to NHSN. Since LTAC hospitals will be reporting as their own unique facility type, separate from acute care hospitals, there is a need for an LTAC-specific annual survey which will capture facility-level data specific and relevant to LTAC hospitals. The annual survey data are used for risk stratification and development of appropriate standardized infection ratios (SIRs) for reporting of data from LTAC hospitals.
- 7) The CMS final rule for the FY 2012 IPPS includes a requirement for inpatient rehabilitation facilities (IRF) hospitals to report CAUTI to NHSN by October 2012. As a result, all certified IRF hospitals in the U.S. will be required to enroll in and report to NHSN. Since IRF hospitals will be reporting as their own unique facility type, separate from acute care hospitals, there is a need for an IRF-specific annual survey which will

capture facility-level data specific and relevant to IRF hospitals. The annual survey data are used for risk stratification and development of appropriate SIRs for reporting of data from IRF hospitals.

- 8) A streamlined ventilator-associated pneumonia (SVAP) form is specifically introduced to provide a streamlined, objective definition via which NHSN users may detect and report cases of ventilator-associated pneumonia in adult patients only. The current NHSN pneumonia (PNEU) definitions are regarded as complex and subjective. The new SVAP definition provides an alternative means of detecting and reporting ventilator-associated pneumonia events, and may eventually replace PNEU.

1.1 Privacy Impact Assessment

Overview of Data Collection System

The NHSN consists of five components: Patient Safety, Healthcare Personnel Safety, Biovigilance, Long Term Care Facility, and eSurveillance. 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. A new Long-Term Care Facility (LTCF) Component is under development within NHSN, in order to more specifically and appropriately capture data from the residents of skilled nursing facilities. In order to facilitate this reporting, there are 7 LTCF forms that have been created by using forms from the Patient Safety Component as a base, with modifications to specifically address the nuances of LTC residents.

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.

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 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 to estimate and characterize the national burden of healthcare-associated infections. These publications can be accessed here: <http://www.cdc.gov/nhsn/dataStat.html>.

The NHSN is also increasingly being used to satisfy state-mandated HAI reporting requirements. Twenty-six 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 (CMS) now requires Medicare-eligible acute care hospitals to report HAI data to CMS via NHSN as of January 1, 2011 as part of the Hospital Inpatient Quality Reporting Program. Therefore, the following purposes have been added to meet these 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. Center 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.

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))."

3. Use of Improved Information Technology and Burden Reduction

As stated in the May, 2011, submission 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, and the pharmacy side of the antimicrobial use and resistance (AUR) module via CDA. CDA capabilities for dialysis events and the resistance side of the AUR module are expected to deploy in 2012 with the Hemovigilance Component following after.

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.

In order to minimize any negative impact on vendors (i.e., loss of potential market share), CDC has actively been working with vendors to create a data transfer mechanism via CDA (described in A.3.), that would allow for a facility using a vendor product to still report to a state or CMS via 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, states that mandate HAI reporting via NHSN expect monthly reporting of HAI data.

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

Although member institutions are not a probability sample of all such institutions in the United States, they are expected to be similar to mainstream institutions of that type. For example, in a 1999 survey of NNIS hospitals (National Nosocomial Infections Surveillance System, a surveillance system that was incorporated into NHSN), 86% of the 228 hospitals that responded were general medical-surgical hospitals, 6% were children's hospitals, and 8% were Veteran's Administration (VA) or military hospitals. The mean average daily census was 239 patients. The geographic distribution of NNIS hospitals was remarkably similar to U.S. hospitals, although there was a slight overrepresentation of hospitals located in the northeast. Approximately 58% of the NNIS hospitals had a major teaching affiliation with a medical school. In comparison to all U.S. hospitals, NNIS hospitals were larger and more likely to be affiliated with a medical school and be located in the northeast region. As with the NNIS system, aggregated data from NHSN will be stratified by important hospital and patient characteristics and the rates will be adjusted by exposure to procedures and therapies known to be of primary importance in increasing risk to adverse outcomes.

Further, because NHSN membership is now open to any healthcare facility and is increasingly being used to satisfy mandated reporting requirements, we expect that over time the results will be more representative of all healthcare facilities and may be generalizable. As of August 2011, more than 4500 of the approximately 5600 acute care facilities in the United States are enrolled in NHSN. With the implementation of the CMS Hospital Inpatient Quality Reporting Program in 2011 as well as the continual increase in states that mandate some level of HAI reporting via NHSN, we expect enrollment to continue to grow.

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 09/13/2011, Vol. 76, No. 177, pg. 56458 (Attachment B). There were no public comments.

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

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. By August, 2011, 26 states and the District of Columbia had 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, the Center for Medicare and Medicaid (CMS) requires Medicare-eligible acute care hospitals to report HAI data to CMS via NHSN beginning with hospital discharges as of January 1, 2011 as part of the Hospital Inpatient Quality Reporting Program. Further, federal legislative proposals could establish mandatory reporting of HAI data on the federal level. 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. Collaborators at the participating institutions may publish data collected from their institutions and may identify themselves as NHSN participants.

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.

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 E).

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 64,050 hours and \$4,781,769 from the most recently-approved ICR in May, 2011. Detailed revisions of the previous burden tables are available in Attachments D-3 and D-4.

A. Estimates of Annualized Burden Hours

Estimated annual burden, in number of hours, by NHSN data collection form.^a

Form Number	Form Name	No. of Respondents	Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)
57.100	NHSN Registration Form	6,000	1	5/60	500
57.101	Facility Contact Information	6,000	1	10/60	1000
57.103	Patient Safety Component--Annual Facility Survey	6,000	1	30/60	3000
57.104	Patient Safety Component--Outpatient Dialysis Center Practices Survey	5,500	1	1	5500
57.105	Group Contact Information	6,000	1	5/60	500
57.106	Patient Safety Monthly Reporting Plan	6,000	9	35/60	31,500
57.108	Primary Bloodstream Infection (BSI)	6,000	36	33/60	118,800
57.109	Dialysis Event	5,500	75	16/60	110,000
57.111	Pneumonia (PNEU)	6,000	72	32/60	230,400
57.112	Streamlined Ventilator-Associated Pneumonia	6,000	144	25/60	360,000
57.114	Urinary Tract Infection (UTI)	6,000	27	32/60	86,400
57.116	Denominators for Neonatal Intensive Care Unit (NICU)	6,000	9	3	162,000
57.117	Denominators for Specialty Care Area (SCA)	6,000	9	5	270,000
57.118	Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	6,000	18	5	540,000
57.119	Denominator for Outpatient Dialysis	5,500	12	6/60	6,600
57.120	Surgical Site Infection (SSI)	6,000	36	32/60	115,200
57.121	Denominator for Procedure	6,000	540	8/60	432,000
57.123	Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	6,000	12	5/60	6,000
57.124	Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	6,000	12	5/60	6,000
57.125	Central Line Insertion Practices Adherence Monitoring	1,000	100	5/60	8,333
57.126	MDRO or CDI Infection Form	6,000	72	32/60	230,400
57.127	MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	6,000	24	10/60	24,000
57.128	Laboratory-identified MDRO or CDI Event	6,000	240	15/60	360,000
57.130	Vaccination Monthly Monitoring Form--Summary Method	6,000	5	14	420,000
57.131	Vaccination Monthly Monitoring Form--Patient-Level Method	2,000	5	2	20,000
57.133	Patient Vaccination	2,000	250	10/60	83,333
57.137	Patient Safety Component--Annual Facility Survey for LTCF	250	1	25/60	104
57.138	Laboratory-identified MDRO or CDI Event for LTCF	250	8	15/60	500
57.139	MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	250	3	5/60	63
57.140	Urinary Tract Infection (UTI) for LTCF	250	9	30/60	1,125
57.141	Monthly Reporting Plan for LTCF	250	12	5/60	250
57.142	Denominators for LTCF Locations	250	12	3	9,000
57.143	Prevention Process Measures Monthly Monitoring for LTCF	250	12	5/60	250
57.150	Patient Safety Component-Annual Facility Survey for LTAC	400	1	30/60	200
57.151	Patient Safety Component-Annual Facility Survey for IRF	1,000	1	25/60	417
57.200	Healthcare Personnel Safety Component Annual Facility Survey	6,000	1	8	48,000

Form Number	Form Name	No. of Respondents	Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)
57.202	Healthcare Worker Survey	600	100	10/60	10,000
57.203	Healthcare Personnel Safety Monthly Reporting Plan	600	9	10/60	900
57.204	Healthcare Worker Demographic Data	600	200	20/60	40,000
57.205	Exposure to Blood/Body Fluids	600	50	1	30,000
57.206	Healthcare Worker Prophylaxis/Treatment	600	10	15/60	1,500
57.207	Follow-Up Laboratory Testing	600	100	15/60	15,000
57.208	Healthcare Worker Vaccination History	600	300	10/60	30,000
57.209	Healthcare Worker Influenza Vaccination	600	500	10/60	50,000
57.210	Healthcare Worker Prophylaxis/Treatment-Influenza	600	50	10/60	5,000
57.211	Pre-season Survey on Influenza Vaccination Programs for Healthcare Personnel	600	1	10/60	100
57.212	Post-season Survey on Influenza Vaccination Programs for Healthcare Personnel	600	1	10/60	100
57.213	Healthcare Personnel Influenza Vaccination Monthly Summary	6,000	6	2	72,000
57.300	Hemovigilance Module Annual Survey	500	1	2	1,000
57.301	Hemovigilance Module Monthly Reporting Plan	500	12	2/60	200
57.302	Hemovigilance Module Monthly Incident Summary	500	12	2	12,000
57.303	Hemovigilance Module Monthly Reporting Denominators	500	12	30/60	3,000
57.304	Hemovigilance Adverse Reaction	500	120	10/60	10,000
57.305	Hemovigilance Incident	500	72	10/60	6,000
Total Estimated Annual Burden (Hours)					3,978,175

^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, 2011. Those most likely to complete this surveillance are health practitioners at a mid or senior level. Those personnel and their estimated hourly wages are shown below.

2009 Department Of Labor Salary Estimates		
Professional Labor Category	Percentile	Hourly Wage
Occupational Health Nurse (Occ Health RN)	75th	\$38.67
Infection Preventionist RN	75th	\$37.99
Clinical Laboratory Technologist	75th	\$31.91
Pharmacy Technician	50th	\$13.65
Staff RN	50th	\$31.10
Laboratory Technician	50th	\$17.44

<http://www.bls.gov/bls/blswage.htm#National>
 Accessed: 7/11/2011

Estimated national annual cost burden of data collection by NHSN data collection form.^a

Form Number	Form Name	Respondents	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
57.100	NHSN Registration Form	Registered Nurse (Infection Preventionist)	500	\$37.99	\$18,995
57.101	Facility Contact Information	Registered Nurse (Infection Preventionist)	1,000	\$37.99	\$37,990
57.103	Patient Safety Component--Annual Facility Survey	Registered Nurse (Infection Preventionist)	3,000	\$37.99	\$113,970
57.104	Patient Safety Component--Outpatient Dialysis Center Practices Survey	Registered Nurse (Infection Preventionist)	5,500	\$37.99	\$208,945
57.105	Group Contact Information	Registered Nurse (Infection Preventionist)	500	\$37.99	\$18,995
57.106	Patient Safety Monthly Reporting Plan	Registered Nurse (Infection Preventionist)	31,500	\$37.99	\$1,196,685
57.108	Primary Bloodstream Infection (BSI)	Registered Nurse (Infection Preventionist)	118,800	\$37.99	\$4,513,212
57.109	Dialysis Event	Staff RN	110,000	\$31.10	\$3,421,000
57.111	Pneumonia (PNEU)	Registered Nurse (Infection Preventionist)	230,400	\$37.99	\$8,752,896
57.112	Streamlined Ventilator-Associated Pneumonia	Registered Nurse (Infection Preventionist)	360,000	\$37.99	\$13,676,400
57.114	Urinary Tract Infection (UTI)	Registered Nurse (Infection Preventionist)	86,400	\$37.99	\$3,282,336
57.116	Denominators for Neonatal Intensive Care Unit (NICU)	Staff RN	162,000	\$31.10	\$5,038,200
57.117	Denominators for Specialty Care Area (SCA)	Staff RN	270,000	\$31.10	\$8,397,000
57.118	Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	Staff RN	540,000	\$31.10	\$16,794,000
57.119	Denominator for Outpatient Dialysis	Staff RN	6,600	\$31.10	\$205,260
57.120	Surgical Site Infection (SSI)	Registered Nurse (Infection Preventionist)	115,200	\$37.99	\$4,376,448
57.121	Denominator for Procedure	Staff RN	432,000	\$31.10	\$13,435,200
57.123	Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	Laboratory Technician	6,000	\$17.44	\$104,640
57.124	Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	Pharmacy Technician	6,000	\$13.65	\$81,900
57.125	Central Line Insertion Practices Adherence Monitoring	Registered Nurse (Infection Preventionist)	8,333	\$37.99	\$316,583
57.126	MDRO or CDI Infection Form	Registered Nurse (Infection Preventionist)	230,400	\$37.99	\$8,752,896
57.127	MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	Registered Nurse (Infection Preventionist)	24,000	\$37.99	\$911,760
57.128	Laboratory-identified MDRO or CDI Event	Registered Nurse (Infection Preventionist)	360,000	\$37.99	\$13,676,400
57.130	Vaccination Monthly Monitoring Form--Summary Method	Registered Nurse (Infection Preventionist)	420,000	\$37.99	\$15,955,800
57.131	Vaccination Monthly Monitoring Form--Patient-Level Method	Registered Nurse (Infection Preventionist)	20,000	\$37.99	\$759,800
57.133	Patient Vaccination	Registered Nurse (Infection Preventionist)	83,333	\$37.99	\$3,165,833
57.137	Patient Safety Component--Annual Facility	Registered Nurse	104	\$37.99	\$3,957

Form Number	Form Name	Respondents	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
	Survey for LTCF	(Infection Preventionist)			
57.138	Laboratory-identified MDRO or CDI Event for LTCF	Registered Nurse (Infection Preventionist)	500	\$37.99	\$18,995
57.139	MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	Registered Nurse (Infection Preventionist)	63	\$37.99	\$2,374
57.140	Urinary Tract Infection (UTI) for LTCF	Registered Nurse (Infection Preventionist)	1,125	\$37.99	\$42,739
57.141	Monthly Reporting Plan for LTCF	Registered Nurse (Infection Preventionist)	250	\$37.99	\$9,498
57.142	Denominators for LTCF Locations	Registered Nurse (Infection Preventionist)	9,000	\$37.99	\$341,910
57.143	Prevention Process Measures Monthly Monitoring for LTCF	Registered Nurse (Infection Preventionist)	250	\$37.99	\$9,498
57.150	Patient Safety Component-Annual Facility Survey for LTAC	Registered Nurse (Infection Preventionist)	200	\$37.99	\$7,598
57.151	Patient Safety Component-Annual Facility Survey for IRF	Registered Nurse (Infection Preventionist)	417	\$37.99	\$15,829
57.200	Healthcare Personnel Safety Component Annual Facility Survey	Occupational Health RN/Specialist	48,000	\$38.67	\$1,856,160
57.202	Healthcare Worker Survey	Occupational Health RN/Specialist	10,000	\$38.67	\$386,700
57.203	Healthcare Personnel Safety Monthly Reporting Plan	Occupational Health RN/Specialist	900	\$38.67	\$34,803
57.204	Healthcare Worker Demographic Data	Occupational Health RN/Specialist	40,000	\$38.67	\$1,546,800
57.205	Exposure to Blood/Body Fluids	Occupational Health RN/Specialist	30,000	\$38.67	\$1,160,100
57.206	Healthcare Worker Prophylaxis/Treatment	Occupational Health RN/Specialist	1,500	\$38.67	\$58,005
57.207	Follow-Up Laboratory Testing	Laboratory Technician	15,000	\$17.44	\$261,600
57.208	Healthcare Worker Vaccination History	Occupational Health RN/Specialist	30,000	\$38.67	\$1,160,100
57.209	Healthcare Worker Influenza Vaccination	Occupational Health RN/Specialist	50,000	\$38.67	\$1,933,500
57.210	Healthcare Worker Prophylaxis/Treatment-Influenza	Occupational Health RN/Specialist	5,000	\$38.67	\$193,350
57.211	Pre-season Survey on Influenza Vaccination Programs for Healthcare Personnel	Occupational Health RN/Specialist	100	\$38.67	\$3,867
57.212	Post-season Survey on Influenza Vaccination Programs for Healthcare Personnel	Occupational Health RN/Specialist	100	\$38.67	\$3,867
57.213	Healthcare Personnel Influenza Vaccination Monthly Summary	Occupational Health RN/Specialist	72,000	\$38.67	\$2,784,240
57.300	Hemovigilance Module Annual Survey	Medical/Clinical Laboratory Technologist	1,000	\$31.91	\$31,910
57.301	Hemovigilance Module Monthly Reporting Plan	Medical/Clinical Laboratory Technologist	200	\$31.91	\$6,382
57.302	Hemovigilance Module Monthly Incident Summary	Medical/Clinical Laboratory Technologist	12,000	\$31.91	\$382,920
57.303	Hemovigilance Module Monthly Reporting Denominators	Medical/Clinical Laboratory Technologist	3,000	\$31.91	\$95,730
57.304	Hemovigilance Adverse Reaction	Medical/Clinical	10000	\$31.91	\$319,100

Form Number	Form Name	Respondents	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
		Laboratory Technologist			
57.305	Hemovigilance Incident	Medical/Clinical Laboratory Technologist	6,000	\$31.91	\$191,460
Total Estimated Annual Burden Cost					\$140,076,136

^a Columns 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 6 or higher, 17” Super VGA (800 X 600) or higher resolution video adaptor and monitor, Windows XP or Windows 2000 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 but if purchasing equipment for the first time, they will incur a one-time start up cost of approximately \$1200. 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 65 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 2011 is estimated to be **\$8,673,111**.

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 2011 will be \$4,255,218 .
	Supervisory, Medical Officer	2
	Medical Epidemiologist	4.5
	Statistician	2
	Epidemiologist	6
	Nurse Epidemiologist	2
	Systems Analyst	2
	Public Health Analyst	1
	Project Manager	1
	Computer Scientist	1
Programming	Design, develop, and deploy enhancements to NHSN	\$4,417,893

Expense Item	Description	Estimated Annual Cost
contracts		
Total		\$8,673,111

15. Explanation for Program Changes and Adjustments

Twenty data collection tools previously approved under OMB No. 0920-0666 have been revised in this revision request. In addition, six new forms are being submitted for approval. 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 F.

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 20 of the approved data collection tools resulting in both increases and decreases to burden estimates.
- 2) User feedback has allowed us to recognize two forms on which the burden should be decreased. Estimated burden will be decreased by 15 minutes on both the Laboratory-identified MDRO or CDI Event form and the Laboratory-identified MDRO or CDI Event for LTCF form.
- 3) The Centers for Medicare and Medicaid Services (CMS) have recently entered into a strong collaboration with the CDC and NHSN. CMS has chosen to designate NHSN as the reporting system into which facilities must enter data in order to fulfill the Inpatient Prospective Payment Systems (IPPS) requirements. The CMS rules have designated central line-associated bloodstream infections (CLABSIs) to be reported from acute care hospital intensive care units in 2011, and are expanding these reporting rules for 2012, and beyond. In order to assist CMS with appropriate patient and facility identification, they have requested the addition of a variable to collect the patient's Medicare Beneficiary number. Therefore, NHSN will be adding this number to all forms that collect patient identifier level data (thirteen in total). This variable will not be required, only optional, and so no additional burden adjustment is necessary.
- 4) A new Long-Term Care Facility (LTCF) Component is under development within NHSN, in order to more specifically and appropriately capture data from the residents of skilled nursing facilities. This component was to be launched in 2011, but the release has now been postponed until 2012. With the first version of this new component, users will be able to track and report urinary tract infections (UTIs), laboratory-identified (LabID) events for multidrug-resistant organisms and *C. difficile*, and/or hand hygiene and gown and gloves use, all at the facility-wide inpatient level. In order to facilitate this reporting, there are 7 LTCF forms that have been created by using forms from the Patient Safety Component as a base, with modifications to specifically address the nuances of LTC residents. In the last OMB package submission from NHSN, 4 of the forms were

included and approved. However, due to an unexpected oversight, 3 of the forms were not included in that package. Therefore, we are including those 3 remaining LTCF forms in this package submission for review and approval.

- 5) The scope of NHSN dialysis surveillance is being expanded to include all outpatient dialysis centers so that the existing Dialysis Annual Survey can be used to facilitate prevention objectives set forth in the Department of Health and Human Services (HHS) Healthcare Associated Infections Tier 2 Action Plan and to assess national practices in all Medicare-certified dialysis centers if the Centers for Medicare and Medicaid Services (CMS) re-establishes this survey method as expected.
- 6) The CMS final rule for the FY 2012 IPPS includes a requirement for long-term acute care (LTAC) hospitals to report CAUTI and CLABSI data to NHSN by October 2012. As a result, all LTAC hospitals in the U.S. will be required to enroll in and report to NHSN. Since LTAC hospitals will be reporting as their own unique facility type, separate from acute care hospitals, there is a need for an LTAC-specific annual survey which will capture facility-level data specific and relevant to LTAC hospitals. The annual survey data are used for risk stratification and development of appropriate SIRs for reporting of data from LTAC hospitals.
- 7) The CMS final rule for the FY 2012 IPPS includes a requirement for inpatient rehabilitation facilities (IRF) hospitals to report CAUTI to NHSN by October 2012. As a result, all certified IRF hospitals in the U.S. will be required to enroll in and report to NHSN. Since IRF hospitals will be reporting as their own unique facility type, separate from acute care hospitals, there is a need for an IRF-specific annual survey which will capture facility-level data specific and relevant to IRF hospitals. The annual survey data are used for risk stratification and development of appropriate SIRs for reporting of data from IRF hospitals.
- 8) A streamlined ventilator-associated pneumonia (SVAP) form is specifically introduced to provide a streamlined, objective definition via which NHSN users may detect and report cases of ventilator-associated pneumonia in adult patients only. The current NHSN pneumonia (PNEU) definitions are regarded as complex and subjective. The new SVAP definition provides an alternative means of detecting and reporting ventilator-associated pneumonia events, and may eventually replace PNEU.

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

Expiration date display exemption does not apply to the NHSN.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

The collection of this information complies with all provisions of certification except the healthcare institutions participating in NHSN may not be a representative sample of all healthcare institutions in the United States because participation is voluntary and participants have wide flexibility in their choice of modules for collecting the data.

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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. Notice of IRB Closure

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

F. Surveillance Methods Supporting Materials

1. Patient Safety Component Protocol
2. Healthcare Personnel Safety Component Protocol
3. Biovigilance Component Protocol
4. Long Term Care Facility Component Protocol