National Healthcare Safety Network (NHSN)

OMB No. 0920-0666

Revision Request for OMB Approval

Supporting Statement A

April 2011

Contact:
Paulette Ford-Knights
Office of Policy and Planning
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., MS D-76
Atlanta, Georgia 30333
Phone: (404) 639-4895
Fax: (404) 639-4146
Email: pbf7@cdc.gov

OMB No. 0920-0666
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The Centers for Disease Control and Prevention (CDC) is requesting 3-year approval of revisions to OMB Control No. 0920-0666: National Healthcare Safety Network. This collection is currently approved for 9,620,950 responses and 5,172,244 burden hours. The revision request includes the addition of 5 new forms, the removal of 4 approved forms, and substantial revision of all remaining forms in the package. If all proposed revisions are approved, the reporting burden will decrease by 1,258,119 hours, for a total estimated burden of 3,914,125 hours; annual cost for reporting would decreased by $12,843,886.

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 8/19/2009 for 5,172,244 burden hours. Approval of this revision request would result in a net decrease of 1,258,119 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. 75, No. 197) on October 13, 2010 (Attachment B).

The previously-approved NHSN OMB revision in 2009 included 47 individual data collection forms; the current revision request includes the removal of four previously-approved forms from the package, revision of the 43 remaining forms, and the addition of five newly-proposed data collection forms, for a total of 48 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. Revisions to all data collection tools include updated Assurance of Confidentiality language necessitated by a recently-approved request for extension and amendment of the confidentiality protections provided by CDC to NHSN participants (Attachment E).

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 all of the approved data collection tools, including updated Assurance of Confidentiality language on every form.

2) The Patient Safety (PS) Component is being expanded to include long term care facilities to facilitate healthcare-associated infections (HAI) surveillance in this setting, for which no standardized reporting methodology or mechanism currently exists. Four new forms are proposed for this purpose.

3) A new Healthcare Personnel Safety (HPS) Component form is proposed to facilitate summary reporting of influenza vaccination in healthcare workers, which is anticipated to be required by CMS in the near future. In addition to this new form, the scope of the HPS Annual Facility Survey is being expanded to include all acute care facilities that would enroll if CMS does implement this requirement.

4) 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.

5) The NHSN Antimicrobial Use and Resistance module is transitioning from manual web entry to electronic data upload only, which results in a significant decrease to the reporting burden for two forms in this package.

6) Four forms and two flow charts that are no longer in use are being removed from this information collection request.

Privacy Impact Assessment

Overview of the Collection System

The NHSN consists of four components: Patient Safety, Healthcare Personnel Safety, Biovigilance, 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.

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

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.

Identification of Websites and Website Content Directed at Children Under 13 Years of Age

Respondents access training and support resources from the NHSN web pages on CDC's public website and enter data from source documents to NHSN through their web browser. Respondents are required to obtain a digital certificate via CDC's Secure Data Network to access the NHSN reporting application. The website is not directed at children under 13 years of age.

2. Purpose and Use of Information Collection

The data collected under OMB Control No. 0920-0666 are 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-two states are 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) will require Medicare-eligible acute care hospitals to report HAI data to CMS via NHSN beginning 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.

Privacy Impact Assessment Information

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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 2007 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) and their denominators (central line days) as well as surgical site infections (SSI) and their denominators (operative procedures) via CDA. CDA capabilities for urinary tract infections (UTI), central line insertion practices (CLIP), and laboratory-identified events are expected to deploy in October 2010. CDA capabilities for the collection of Biovigilance Component data are in production; the targeted time period for pilot testing is Fall 2011.

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, that 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.4.), 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 January 2011, more than 4100 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 October 13, 2010, Vol. 75, No. 197, pg. 62832 (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 (formerly the National Center for Infectious Diseases and the National Center for Preparedness, Detection, and Control of 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 2010, 22 states 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) will require Medicare-eligible acute care hospitals to report HAI data to CMS via NHSN beginning with hospital discharges occurring 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 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. The language that appears at the bottom of every data collection form in the NHSN OMB package has been updated to reflect the amended Assurance of Confidentiality:

> “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)).”

Collaborators at the participating institutions may publish data collected from their institutions and may identify themselves as NHSN participants.

Privacy Impact Assessment Information

A. 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."

B. 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.

C. 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).

D. 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.

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 a decrease of 1,258,119 hours and $12,843,886 from the most recently-approved ICR in 2009. 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.

Form Number	Form Name	Number of Respondents (Annual)	Responses per Respondent (Annual)	Burden per Response (Hours)	Total Annual Burden (Hours)
57.100	NHSN Registration Form	6,000	1	5/60	500
57.101	Facility Contact Information	6,000	1	10/60	1,000
57.103	Patient Safety Component--Annual Facility Survey	6,000	1	40/60	4,000
57.104	Patient Safety Component--Outpatient Dialysis Center Practices Survey	5,500	1	1	5,500
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	32/60	115,200
57.109	Dialysis Event	500	75	15/60	9,375
57.111	Pneumonia (PNEU)	6,000	72	32/60	230,400
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	4	216,000
57.117	Denominators for Specialty Care Area (SCA)	6,000	9	5	270,000
57.118	Denominators for Intensive Care Unit (ICU)/Other	6,000	18	5	540,000

Form Number	Form Name	Number of Respondents (Annual)	Responses per Respondent (Annual)	Burden per Response (Hours)	Total Annual Burden (Hours)
	locations (not NICU or SCA)				
57.119	Denominator for Outpatient Dialysis	500	12	5/60	500
57.120	Surgical Site Infection (SSI)	6,000	27	32/60	86,400
57.121	Denominator for Procedure	6,000	540	10/60	540,000
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	6,000	100	5/60	50,000
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	25/60	600,000
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	30/60	1,000
57.139	MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	250	3	7/60	88
57.140	Urinary Tract Infection (UTI) for LTCF	250	9	30/60	1,125
57.200	Healthcare Personnel Safety Component Annual Facility Survey	6,000	1	8	48,000
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

Form Number	Form Name	Number of Respondents (Annual)	Responses per Respondent (Annual)	Burden per Response (Hours)	Total Annual Burden (Hours)
		Total Estimated Annual Burden (Hours)			**3,914,125**

B. Estimates of Annual Cost

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, 2009. 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	$37.84
Infection Preventionist RN	75th	$37.49
Clinical Laboratory Technologist	75th	$31.27
Pharmacy Technician	50th	$13.49
Staff RN	50th	$30.65
Laboratory Technician	50th	$17.32

http://www.bls.gov/bls/blswage.htm#National
Accessed: 9/15/2010

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

Form Number	Form Name	Respondents	Total Estimated Burden (Hours)	Estimated Hourly Wage of Respondent	Total Estimated Annual Cost Burden
57.100	NHSN Registration Form	Infection Preventionist	500	$37.49	$18,745
57.101	Facility Contact Information	Infection Preventionist	1,000	$37.49	$37,490
57.103	Patient Safety Component--Annual Facility Survey	Infection Preventionist	4,000	$37.49	$149,960
57.104	Patient Safety Component--Outpatient Dialysis Center Practices Survey	Infection Preventionist	5,500	$37.49	$206,195
57.105	Group Contact Information	Infection Preventionist	500	$37.49	$18,745
57.106	Patient Safety Monthly Reporting Plan	Infection Preventionist	31,500	$37.49	$1,180,935
57.108	Primary Bloodstream Infection (BSI)	Infection Preventionist	115,200	$37.49	$4,318,848
57.109	Dialysis Event	Staff RN	9,375	$30.65	$287,344
57.111	Pneumonia (PNEU)	Infection Preventionist	230,400	$37.49	$8,637,696
57.114	Urinary Tract Infection (UTI)	Infection Preventionist	86,400	$37.49	$3,239,136
57.116	Denominators for Neonatal Intensive Care Unit (NICU)	Staff RN	216,000	$30.65	$6,620,400
57.117	Denominators for Specialty Care Area (SCA)	Staff RN	270,000	$30.65	$8,275,500
57.118	Denominators for Intensive Care	Staff RN	540,000	$30.65	$16,551,00

Form Number	Form Name	Respondents	Total Estimated Burden (Hours)	Estimated Hourly Wage of Respondent	Total Estimated Annual Cost Burden
	Unit (ICU)/Other locations (not NICU or SCA)				0
57.119	Denominator for Outpatient Dialysis	Staff RN	500	$30.65	$15,325
57.120	Surgical Site Infection (SSI)	Infection Preventionist	86,400	$37.49	$3,239,136
57.121	Denominator for Procedure	Staff RN	540,000	$30.65	$16,551,000
57.123	Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	Laboratory Technician	6,000	$17.32	$103,920
57.124	Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	Pharmacy Technician	6,000	$13.49	$80,940
57.125	Central Line Insertion Practices Adherence Monitoring	Infection Preventionist	50,000	$37.49	$1,874,500
57.126	MDRO or CDI Infection Form	Infection Preventionist	230,400	$37.49	$8,637,696
57.127	MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	Infection Preventionist	24,000	$37.49	$899,760
57.128	Laboratory-identified MDRO or CDI Event	Infection Preventionist	600,000	$37.49	$22,494,000
57.130	Vaccination Monthly Monitoring Form–Summary Method	Infection Preventionist	420,000	$37.49	$15,745,800
57.131	Vaccination Monthly Monitoring Form–Patient-Level Method	Infection Preventionist	20,000	$37.49	$749,800
57.133	Patient Vaccination	Infection Preventionist	83,333	$37.49	$3,124,167
57.137	Patient Safety Component--Annual Facility Survey for LTCF	Infection Preventionist	104	$37.49	$3,905
57.138	Laboratory-identified MDRO or CDI Event for LTCF	Infection Preventionist	1,000	$37.49	$37,490
57.139	MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	Infection Preventionist	88	$37.49	$3,280
57.140	Urinary Tract Infection (UTI) for LTCF	Infection Preventionist	1,125	$37.49	$42,176
57.200	Healthcare Personnel Safety Component Annual Facility Survey	Occ Health RN	48,000	$37.84	$1,816,320
57.202	Healthcare Worker Survey	Occ Health RN	10,000	$37.84	$378,400
57.203	Healthcare Personnel Safety Monthly Reporting Plan	Occ Health RN	900	$37.84	$34,056
57.204	Healthcare Worker Demographic Data	Occ Health RN	40,000	$37.84	$1,513,600
57.205	Exposure to Blood/Body Fluids	Occ Health RN	30,000	$37.84	$1,135,200
57.206	Healthcare Worker Prophylaxis/Treatment	Occ Health RN	1,500	$37.84	$56,760
57.207	Follow-Up Laboratory Testing	Laboratory Technician	15,000	$17.32	$259,800
57.208	Healthcare Worker Vaccination History	Occ Health RN	30,000	$37.84	$1,135,200
57.209	Healthcare Worker Influenza Vaccination	Occ Health RN	50,000	$37.84	$1,892,000
57.210	Healthcare Worker Prophylaxis/Treatment-Influenza	Occ Health RN	5,000	$37.84	$189,200
57.211	Pre-season Survey on Influenza Vaccination Programs for Healthcare Personnel	Occ Health RN	100	$37.84	$3,784
57.212	Post-season Survey on Influenza Vaccination Programs for	Occ Health RN	100	$37.84	$3,784

Form Number	Form Name	Respondents	Total Estimated Burden (Hours)	Estimated Hourly Wage of Respondent	Total Estimated Annual Cost Burden
	Healthcare Personnel				
57.213	Healthcare Personnel Influenza Vaccination Monthly Summary	Occ Health RN	72,000	$37.84	$2,724,480
57.300	Hemovigilance Module Annual Survey	Clinical Laboratory Technologist	1,000	$31.27	$31,270
57.301	Hemovigilance Module Monthly Reporting Plan	Clinical Laboratory Technologist	200	$31.27	$6,254
57.302	Hemovigilance Module Monthly Incident Summary	Clinical Laboratory Technologist	12,000	$31.27	$375,240
57.303	Hemovigilance Module Monthly Reporting Denominators	Clinical Laboratory Technologist	3,000	$31.27	$93,810
57.304	Hemovigilance Adverse Reaction	Clinical Laboratory Technologist	10,000	$31.27	$312,700
57.305	Hemovigilance Incident	Clinical Laboratory Technologist	6,000	$31.27	$187,620
		Total Estimated Annual Cost Burden			$135,294,367

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

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 **$7,451,954**.

NHSN Estimated Annual Cost to the Government

Expense Item	Description		Estimated Annual Cost
Personnel	A total of 39.5 FTE/contractor personnel are actively involved in the enhancement and maintenance of the NHSN. The personnel categories and their FTE contributions are as follows:		Their annual compensation in 2010 will be **$5,196,557.**
	Supervisory. Medical Officer	2	
	Medical Epidemiologist	2.5	
	Statistician	3	
	Epidemiologist	9	
	Nurse Epidemiologist	3	
	User Support	5	
	Systems Analyst	4	
	Business Analyst	1	
	Public Health Analyst	3	
	Database Specialist	2	
	Project Manager	3	
	Computer Scientist	1	
	Program Specialist	1	

Expense Item	Description	Estimated Annual Cost
Programming contracts	Design, develop, and deploy enhancements to NHSN	**$2,255,397**
Total		**$7,451,954**

15. Explanation for Program Changes or Adjustments

All data collection tools previously approved under OMB No. 0920-0666 have been revised to some extent in this revision request. In addition, five new forms are being submitted for approval, and four forms are being removed. 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 various changes, updates, and/or clarifications proposed for all of the data collection tools, including an update of the Assurance of Confidentiality language on every data collection form.
2) The Patient Safety (PS) Component is being expanded to include long term care facilities to facilitate healthcare-associated infections (HAI) surveillance in this setting, for which no standardized reporting methodology or mechanism currently exists. Four new forms are proposed for this purpose.
3) A new Healthcare Personnel Safety (HPS) Component form is proposed to facilitate summary reporting of influenza vaccination in healthcare workers, which is anticipated to be required by CMS in the near future. In addition to this new form, the scope of the HPS Annual Facility Survey is being expanded to include all acute care facilities that would enroll if CMS does implement this requirement.
4) 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. This change results in an increase in reporting burden for dialysis surveillance.
5) The NHSN Antimicrobial Use and Resistance module is transitioning from manual web entry to electronic data upload only, which results in a significant decrease to the reporting burden for two data collection tools in this package.

6) Four forms and two flow charts that are no longer in use are being removed from this information data collection package.

16. Plans for Tabulation and Publication and 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 the sponsoring agency 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.

NSHN Contact:

Daniel A. Pollock. MD
Surveillance Branch Chief
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
Atlanta, Georgia 30333
Phone: (404) 639-4237
Fax: (404) 639-4043
Email: dap1@cdc.gov

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

57.100 NHSN Registration Form
57.101 Facility Contact Information
57.103 Patient Safety Component--Annual Facility Survey
57.104 Patient Safety Component--Outpatient Dialysis Center Practices Survey
57.105 Group Contact Information
57.106 Patient Safety Monthly Reporting Plan
57.108 Primary Bloodstream Infection (BSI)
57.109 Dialysis Event
57.111 Pneumonia (PNEU)
57.114 Urinary Tract Infection (UTI)
57.116 Denominators for Neonatal Intensive Care Unit (NICU)
57.117 Denominators for Specialty Care Area (SCA)
57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)
57.119 Denominator for Outpatient Dialysis
57.120 Surgical Site Infection (SSI)
57.121 Denominator for Procedure
57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data
Electronic Upload Specification Tables
57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data
Electronic Upload Specification Tables
57.125 Central Line Insertion Practices Adherence Monitoring
57.126 MDRO or CDI Infection Form
57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring

57.128 Laboratory-identified MDRO or CDI Event
57.130 Vaccination Monthly Monitoring Form–Summary Method
57.131 Vaccination Monthly Monitoring Form–Patient-Level Method
57.133 Patient Vaccination
57.137 Patient Safety Component--Annual Facility Survey for LTCF
57.138 Laboratory-identified MDRO or CDI Event for LTCF
57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF
57.140 Urinary Tract Infection (UTI) for LTCF
57.200 Healthcare Personnel Safety Component Annual Facility Survey
57.202 Healthcare Worker Survey
57.203 Healthcare Personnel Safety Monthly Reporting Plan
57.204 Healthcare Worker Demographic Data
57.205 Exposure to Blood/Body Fluids
57.206 Healthcare Worker Prophylaxis/Treatment
57.207 Follow-Up Laboratory Testing
57.208 Healthcare Worker Vaccination History
57.209 Healthcare Worker Influenza Vaccination
57.210 Healthcare Worker Prophylaxis/Treatment-Influenza
57.211 Pre-season Survey on Influenza Vaccination Programs for Healthcare Personnel
57.212 Post-season Survey on Influenza Vaccination Programs for Healthcare Personnel
57.213 Healthcare Personnel Influenza Vaccination Monthly Summary
57.300 Hemovigilance Module Annual Survey
57.301 Hemovigilance Module Monthly Reporting Plan
57.302 Hemovigilance Module Monthly Incident Summary
57.303 Hemovigilance Module Monthly Reporting Denominators
57.304 Hemovigilance Adverse Reaction
57.305 Hemovigilance Incident

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. NHSN Assurance of Confidentiality Documentation
   1. NHSN 308d approval 2010
   2. NHSN 308d approval memo 2010
   3. NHSN 308d Request for Extension and Amendment

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

G. Surveillance Methods Supporting Materials
   1. Patient Safety Component Protocol
   2. Healthcare Personnel Safety Component Protocol
   3. Biovigilance Component Protocol
   4. Forms Instructions-All Components