# National Healthcare Safety Network (NHSN)

# OMB Control No. 0920-0666

# 83-C Change Request for OMB Review and Approval

**December, 2008**

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**OMB No. 0920-0666**

# National Healthcare Safety Network (NHSN)

## SUPPORTING STATEMENT

CDC is requesting OMB approval for an adjustment in the number of respondents to OMB Control No. 0920-0666: National Healthcare Safety Network (NHSN). This information collection request is currently approved for 1,500 respondents and 1,278,315 burden hours. Due to reporting requirements mandated by state legislatures, CDC is requesting approval to add 4,500 respondents, for a total of 6,000 respondents. The increase in respondents will result in an increase of 3,862,030 burden hours for this information collection, for a total of 5,140,345 burden hours.

## A. Justification

### 1. Circumstances Making the Collection of Information Necessary

The Division of Healthcare Quality Promotion (DHQP), National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), Centers for Disease Control and Prevention (CDC) collects data from healthcare facilities as part of the National Healthcare Safety Network (NHSN) under OMB Control Number 0920-0666.

OMB most recently approved this information collection request on March 25, 2008 for 1,500 respondents and 2,211,855 burden hours. At that time, CDC considered the number of respondents to be reasonable for the next three years. However, since that time, an increased number of state legislatures have passed legislation requiring healthcare institutions to use the NHSN to report healthcare-associated infection surveillance data. When CDC submitted its request in 2007, seven states were participating in the NHSN: Colorado, Connecticut, New York, Pennsylvania, South Carolina, Tennessee, and Vermont. In 2008, additional states (California, Delaware, Massachusetts, Maryland, Oklahoma, Virginia, and Washington) began to required the use for NHSN for reporting healthcare-associated infections (HAIs), including those due to multi-drug resistant organisms (MDROs). New Jersey has mandated the use of NHSN beginning in January, 2009 and West Virginia has mandated NHSN use beginning in July, 2009. The pace of state legislation requiring reporting of HAIs has accelerated such that CDC is close to exceeding its previous estimate of the number of respondents. Therefore, CDC is requesting OMB approval to increase the number of respondents (and number of burden hours) to include every acute care hospital in the United States.

The respondent universe for this information collection request includes long-term acute care hospitals, behavioral health hospitals, rehabilitation hospitals, surgical hospitals, long-term care facilities and ambulatory surgery centers. Increasingly, state mandated reporting of certain types of HAIs also applies to these facilities. Recognizing that different facilities choose different options within NHSN (i.e., every facility will not use every form, every module or every component) and will not necessarily report those every month, CDC is comfortable with an estimate of 6,000 respondents despite the potential reporting of non-acute care facilities.

With the larger number of facilities enrolled, we have also revised our estimates of healthcare personnel safety respondents to 10% of the total facilities enrolled for patient safety. This is the same percentage used in our 2007 submission to OMB and is based on the assumption

that once facilities have enrolled in NHSN for patient safety, some facilities may also express interest in monitoring healthcare worker exposures, influenza vaccination history and other events or use the healthcare personnel safety features. Numbers of dialysis center respondents have been revised to represent 5% of all dialysis centers in the U.S. since it is expected that some infections due to MDROs may be observed in those settings and thus, may require reporting.

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

The data collected under this OMB Control Number 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.

**3. Use of Improved Information Technology and Burden Reduction**

As stated in the 2007 submission to OMB, 100% of the data for the NHSN is collected electronically. 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 forms are provided for data collection, facilities are not required to use them for entry of data into NHSN. Direct data entry of information from the source document to NHSN through the web browser is possible and may reduce the data reporting burden. Only the minimum amount of information necessary for the data collection is being requested.

**4. Efforts to Identify Duplication and Use of Similar Information**

As stated in the 2007 submission to OMB, NHSN is the only current national system that collects surveillance data on healthcare-associated infections, infection prevention process measure data, and data on healthcare personnel safety measures.

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. 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 would be considered small businesses) that sell data management tools with similar capabilities as NHSN. However, since NSHN 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 (see Section A.1). In order to minimize any negative impact on vendors (i.e., loss of potential market

share), CDC has actively been working with vendors for the past two years to create a data transfer mechanism that would allow for a facility using a vendor product to still report to a state via NHSN. A pilot test of this mechanism is currently underway.

**6. Consequences of Collecting the Information Less Frequently**

Many adverse events associated with healthcare, such as hospital-associated infections, 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 and outbreaks and to report data that may indicate a problem. An important purpose of conducting routine prospective surveillance is to quickly identify potential problems that need to be investigated and to institute appropriate measures early 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.

**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 their own analysis. Given these practices, it is advantageous to CDC to maintain a monthly reporting frequency. In NHSN, once the data are entered into the web forms, they are transmitted electronically to CDC via the Internet 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 (National Nosocomial Infections Surveillance System [OMB Control No. 0920-0012], a surveillance system that was incorporated into NHSN) hospitals, 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[3]. 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, we expect that over time the results will be more representative of all healthcare facilities and may be generalizable.

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

A. The 60-Day Federal Register Notice was published July 26, 2007 (Vol. 72, page 41077). Two comments were received to the 60 day FRN. Those comments and CDC's response (in italics) follow:

Comment #1: I am writing to provide a comment regarding the proposed data collections submitted for public comment and recommendations for the National Healthcare Safety Network (NHSN) (OMB control No. 0920-0666)-revision- that was published in the federal register July 26, 2007. I believe these suggestions will both enhance the quality of the data collected and reduce the burden of data collection on hospitals.

The current OMB approval for NHSN includes the capture of existing data stored in electronic hospital information systems as an alternative means of data collection (including clinical microbiology results, pharmacy data, and admission/discharge/transfer data fields). As I understand it, the approval specifies that these data elements will be used for automated monitoring of antimicrobial use and resistance, and for identifying adverse events such as bloodstream infections. We believe that the current OMB renewal should be modified such that these electronic data can be used by CDC not only for the currently stated purpose of collection (automated monitoring of antimicrobial use and resistance), but also automated monitoring of any other adverse health event that can be appropriately identified by applying scientifically valid detection algorithms to the these data elements whenever this becomes feasible to do (e.g. bloodstream infections, the laboratory-identified MDRO Events, and potentially other adverse events reported to NHSN).

From our experience of working with a network of hospitals around the country on MRSA prevention, we believe that broadening the approved use of these data elements in this way would allow CDC to further reduce the burden of data collection included in this renewal while at the same time enhance the value of the information it collects through the NHSN.

Sincerely,
Curt Lindberg
President and CEO
Plexus Institute

CDC Response: *In this current OMB supporting statement electronic laboratory and pharmacy data are limited to the monitoring of antimicrobial use and resistance and bloodstream infection adverse events but expanding use of this data to fulfill other surveillance needs in the area of patient safety is desired.*

*The use of this data for purposes to include monitoring <u>other</u> adverse events (e.g., laboratory-identified multidrug-resistant organism events) that may be detected through scientific algorithms using the existing databases expands the purpose of the monitoring of antimicrobial use and resistance to include specific events associated with antimicrobial use and is within the scope of the purpose of NHSN. Therefore, we revised the wording of Section A3. (bullet 2)* ***Electronic Health Level 7 (HL7) message processing*** to read as follows:

- **Electronic Health Level 7 (HL7) <u>message and</u> document processing.** PHIN accepts, routes and processes electronic HL7 messages <u>and documents</u> containing laboratory and clinical content. Using the established HL7 format enables standardization of information exchange across the public health sector. NHSN will use this standard format initially in the development of its laboratory and pharmacy messages <u>and for capturing these data elements necessary for electronic detecting of events such as infections and reporting.</u>

*We have revised bullet 8* ***Interfaces with hospital systems*** *to read:*

- **Interfaces with hospital systems.** The ability to gather information directly from electronic databases of healthcare facilities is made possible by the maturing of commercial products and the increasing standardization of interfaces. Initially, NHSN is developing interfaces to receive information from the laboratory, pharmacy, and admission/discharge/transfer (ADT) systems to support the automated collection and reporting of data for the Medication-

associated Module, Patient Data and Healthcare Personnel Demographic Data forms. Detection and reporting of adverse events using all available electronic data sources are planned.

*We believe that revising the above paragraphs is sufficient to allow for expanded (but closely related) use of already collected information.*

Comment #2:

Ref: 7/26/07 Federal Register - Pages 41077 - 41079
National Healthcare Safety Network

This regards the proposed CDC project to revise NHSN data collection by adding four new forms for collecting healthcare worker influenza vaccination and antiviral administration information as posted in the above notice.

1) Please send me additional information and a copy of data collection plans and instruments.

2) Please especially clarify how the proposed data collection process will ensure that healthcare employers participating in this project or similar data collection efforts shall protect the confidentiality of their employees' and other workers' personal medical information by prohibiting its disclosure to other parties or to employer agents other than to the employer's approved employee/occupational health providers.

Thank you for your assistance.

Best regards,

Bernice Jackson, MD, MPH
Occupational Health / Employee Health Liaison County of Los Angeles Department of Public Health CDCP
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CDC Response: *Draft forms and associated instruction tables have been included in a ZIP attachment. (HCW_forms_instructions.zip).*

*CDC can protect only the confidentiality of the information it collects and maintains. NSHN data are collected under a 308(D) confidentiality protection that does not allow CDC to identify NHSN participants without their permission, nor to provide site-specific data without express permission of the site (See Section A10 of the supporting statement.) However, the data collected by NHSN facilities may be released to others by an individual facility as long as such release is consistent with federal, state, or local requirements (e.g., HIPAA). CDC has no control over release of occupational health data by its NHSN participants. Healthcare facilities have for years maintained occupational health information on their employees and it is hoped that local policies are in place for protection of the confidentiality of this information.*

The 30 day Federal Register Notice was published on November 21, 2007 (Vol. 72, No. 224, pp. 65578-65580. No comments were received to this notice.

B. The Healthcare Infection Control Practices Advisory Committee (HICPAC) provides advice and guidance to the CDC Director, and the Director of NCPDCID , 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, participants in the NHSN 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, especially, hospital-associated infections, and have had extensive experience. CDC personnel are available on a priority basis by telephone and e-mail to NHSN surveillance and occupational health personnel, and participating outpatient dialysis centers. Meetings for NHSN personnel 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).

**9. Explanation of Any Payment or Gift to Respondents**

No monetary incentive is provided to NHSN participants.

**10. Assurance of Confidentiality Provided to Respondents**

An Assurance of Confidentiality has been granted for all data collected under NHSN. Accordingly, "the 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 Services Act (42 USC 242b, 242k, and 242m(d))". Published data will not identify individual facilities without permission from the institution. Collaborators at the participating institutions may publish data collected from their institutions and may identify themselves as NHSN participants. Further, 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."

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 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.

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 NCPDCID Senior Staff, the program has been 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.

**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.

**12. Estimates of Annualized Burden Hours and Costs**

The detailed tables below provide the revised burden hour and cost estimates for this data collection. Estimates are based on a total of 6,000 participating facilities (respondents). Please note that CDC is not requesting to change the number of respondents for the Laboratory-Identified MDRO Summary Form at this time. CDC has found very limited usage of this form by its respondents, so the current approval for 1,500 respondents is adequate.

A. Estimates of Annualized Burden

| Form Letter and Name | No. of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Total Burden (in hours) |
|---|---|---|---|---|
| A. Patient Safety Monthly Reporting Plan | 6,000 | 9 | 35/60 | 31,500 |
| B. Healthcare Personnel Safety Reporting Plan | 600 | 9 | 10/60 | 900 |
| D. Primary Bloodstream Infection (BSI) ** | 6,000 | 36 | 30/60 | 108,000 |
| E. Dialysis Event | 225 | 200 | 15/60 | 11,250 |
| G. Pneumonia (PNEU) (includes decision algorithms: Ga. Any Patient – Pneumonia Flow Diagram Gb. Infant and Children – Pneumonia Flow Diagram | 6,000 | 72 | 30/60 | 216,000 |
| H. Urinary Tract Infection (UTI) | 6,000 | 27 | 30/60 | 81,000 |

| Form Letter and Name | No. of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Total Burden (in hours) |
|---|---|---|---|---|
| J. Denominators for Neonatal Intensive Care Units (NICU) | 6,000 | 9 | 4 | 216,000 |
| K. Denominators for Specialty Care Areas (SCA) | 6,000 | 9 | 5 | 270,000 |
| L. Denominators for Intensive Care Units (ICU)/Other locations (not NICU or SCA) | 6,000 | 18 | 5 | 540,000 |
| M. Denominator for Outpatient Dialysis | 225 | 9 | 5/60 | 169 |
| N. Surgical Site Infection (SSI) | 6,000 | 27 | 30/60 | 81,000 |
| O. Denominator for Procedure | 6,000 | 540 | 8/60 | 432,000 |
| P. Antimicrobial Use and Resistance (AUR) – Microbiology Laboratory Data ** | 6,000 | 45 | 3 | 810,000 |
| Q. Antimicrobial Use and Resistance (AUR) – Pharmacy Data** | 6,000 | 36 | 2 | 432,000 |
| R. Facility Contact Information | 6,000 | 1 | 10/60 | 1,000 |
| S. Patient Safety Component Annual Facility Survey | 6,000 | 1 | 30/60 | 3,000 |
| T. Agreement to Participate and Consent | 6,000 | 1 | 15/60 | 1,500 |
| U. Group Contact Information | 6,000 | 1 | 5/60 | 500 |
| V. Exposure to Blood/Body Fluids | 600 | 50 | 1 | 30,000 |
| W. Healthcare Worker Post-exposure Prophylaxis | 600 | 10 | 15/60 | 1,500 |
| X. Healthcare Worker Demographic Data | 600 | 200 | 20/60 | 40,000 |
| Y. Healthcare Worker Vaccination History | 600 | 300 | 10/60 | 30,000 |
| Z. Implementation of Engineering (Safety Device) Controls for Sharps Injury Prevention | 600 | 1 | 30/60 | 300 |
| Za. Healthcare Personnel Safety Component Facility Survey | 600 | 1 | 8 | 4,800 |
| AA. Healthcare Worker Survey | 600 | 100 | 10/60 | 10,000 |
| BB. Dialysis Survey | 225 | 1 | 1 | 225 |
| CC. List of Blood Isolates | 6,000 | 1 | 1 | 6,000 |
| DD. Manual Categorization of Positive Blood Cultures[+] | 6,000 | 1 | 1 | 6,000 |
| FF. Healthcare Worker Influenza Vaccination | 600 | 500 | 10/60 | 50,000 |

| Form Letter and Name | No. of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Total Burden (in hours) |
|---|---|---|---|---|
| GG. Healthcare Worker Influenza Antiviral Medication Administration | 600 | 50 | 10/60 | 5,000 |
| HH. Preseason Survey on Influenza Vaccination Programs for Healthcare Personnel | 600 | 1 | 10/60 | 100 |
| II. Postseason Survey on Influenza Vaccination Programs for Healthcare Personnel | 600 | 1 | 10/60 | 100 |
| JJ. Central Line Insertion Practices Adherence Monitoring Form | 6,000 | 100 | 10/60 | 100,000 |
| KK. Laboratory Testing | 600 | 100 | 15/60 | 15,000 |
| LL. Multi-drug Resistance Organism (MDRO) Prevention Process and Outcome Measures Monthly Monitoring Form | 6,000 | 24 | 10/60 | 24,000 |
| MM. MDRO or CDAD Infection Form | 6,000 | 72 | 30/60 | 216,000 |
| NN. Laboratory-identified MDRO or CDAD Event | 6,000 | 240 | 30/60 | 720,000 |
| OO. NHSN Registration Form | 6,000 | 1 | 5/60 | 500 |
| PP. High Risk Inpatient Influenza Vaccination Numerator Data Form – Method A | 6,000 | 5 | 16 | 480,000 |
| QQ. High Risk Inpatient Influenza Vaccination Numerator Data Form – Method B | 2,000 | 250 | 10/60 | 83,334 |
| RR. High Risk Inpatient Influenza Vaccination Monthly Monitoring Form – Method B | 2,000 | 5 | 4 | 40,000 |
| SS. High Risk Inpatient Influenza Vaccination Denominator Data Form – Method B | 2,000 | 250 | 5/60 | 41,667 |
| TOTAL | 6,000 | | | 5,140,345 |

[+] Burden during validation phase only, then eliminated.

** Burden will be eliminated for reporting these data when an NHSN institution implements electronic data capture.

B. Estimates of Annualized Cost

The average salaries of the professional disciplines most frequently involved in performing surveillance have been used in the calculations and they are base don data from the Department

of Labor, Bureau of Labor Statistics. All costs related to salary are the hourly salary in 2005 by occupation adjusted 4% annually for inflation. The disciplines most currently involved in hospital-associated infection s surveillance along with their average hourly salary in 2005 are: Infection Control/Occupational Health Professional, $34.65; Staff Registered Nurse, $29.58; Laboratory Technician, $17.25; and Pharmacy Technician, $13.18. The estimate of Infection Control/Occupational Health Professional's salary is based on the 75th percentile of Registered Nurse salary because of their specialized position.

| Form Letter and Name | No. of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Average Hourly Salary of Respondent | Total Cost |
|---|---|---|---|---|---|
| A. Patient Safety Monthly Reporting Plan | 6,000 | 9 | 35/60 | $34.65 | $1,091,475 |
| B. Healthcare Personnel Safety Reporting Plan | 600 | 9 | 10/60 | $34.65 | $31,185 |
| D. Primary Bloodstream Infection (BSI) ** | 6,000 | 36 | 30/60 | $34.65 | $3,742,200 |
| E. Dialysis Event | 225 | 200 | 15/60 | $29.58 | $332,775 |
| G. Pneumonia (PNEU) (includes decision algorithms: Ga. Any Patient – Pneumonia Flow Diagram Gb. Infant and Children – Pneumonia Flow Diagram | 6,000 | 72 | 30/60 | $34.65 | $7,484,400 |
| H. Urinary Tract Infection (UTI) | 6,000 | 27 | 30/60 | $34.65 | $2,806,650 |
| J. Denominators for Neonatal Intensive Care Units (NICU) | 6,000 | 9 | 4 | $29.58 | $6,389,280 |
| K. Denominators for Specialty Care Areas (SCA) | 6,000 | 9 | 5 | $29.58 | $7,986,600 |
| L. Denominators for Intensive Care Units (ICU)/Other locations (not NICU or SCA) | 6,000 | 18 | 5 | $29.58 | $15,973,200 |
| M. Denominator for | 225 | 9 | 5/60 | $29.58 | $4,999 |

| Form Letter and Name | No. of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Average Hourly Salary of Respondent | Total Cost |
|---|---|---|---|---|---|
| Outpatient Dialysis | | | | | |
| N. Surgical Site Infection (SSI) | 6,000 | 27 | 30/60 | $34.65 | $2,806,650 |
| O. Denominator for Procedure | 6,000 | 540 | 8/60 | $29.58 | $12,778,560 |
| P. Antimicrobial Use and Resistance (AUR) – Microbiology Laboratory Data ** | 6,000 | 45 | 3 | $17.25 | $13,972,500 |
| Q. Antimicrobial Use and Resistance (AUR) – Pharmacy Data** | 6,000 | 36 | 2 | $13.18 | $5,693,760 |
| R. Facility Contact Information | 6,000 | 1 | 10/60 | $34.65 | $34,650 |
| S. Patient Safety Component Annual Facility Survey | 6,000 | 1 | 30/60 | $34.65 | $103,950 |
| T. Agreement to Participate and Consent | 6,000 | 1 | 15/60 | $34.65 | $51,975 |
| U. Group Contact Information | 6,000 | 1 | 5/60 | $34.65 | $17,325 |
| V. Exposure to Blood/Body Fluids | 600 | 50 | 1 | $34.65 | $1,039,500 |
| W. Healthcare Worker Post-exposure Prophylaxis | 600 | 10 | 15/60 | $34.65 | $51,975 |
| X. Healthcare Worker Demographic Data | 600 | 200 | 20/60 | $34.65 | $1,386,000 |
| Y. Healthcare Worker Vaccination History | 600 | 300 | 10/60 | $34.65 | $1,039,500 |
| Z. Implementation of Engineering (Safety Device) Controls for Sharps Injury Prevention | 600 | 1 | 30/60 | $29.58 | $8,874 |
| Za. Healthcare Personnel Safety Component Facility Survey | 600 | 1 | 8 | $34.65 | $166,320 |

| Form Letter and Name | No. of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Average Hourly Salary of Respondent | Total Cost |
|---|---|---|---|---|---|
| AA. Healthcare Worker Survey | 600 | 100 | 10/60 | $34.65 | $346,500 |
| BB. Dialysis Survey | 225 | 1 | 1 | $34.65 | $7,796 |
| CC. List of Blood Isolates | 6,000 | 1 | 1 | $34.65 | $207,900 |
| DD. Manual Categorization of Positive Blood Cultures[+] | 6,000 | 1 | 1 | $34.65 | $207,900 |
| FF. Healthcare Worker Influenza Vaccination | 600 | 500 | 10/60 | $34.65 | $1,732,500 |
| GG. Healthcare Worker Influenza Antiviral Medication Administration | 600 | 50 | 10/60 | $34.65 | $173,250 |
| HH. Preseason Survey on Influenza Vaccination Programs for Healthcare Personnel | 600 | 1 | 10/60 | $34.65 | $3,465 |
| II. Postseason Survey on Influenza Vaccination Programs for Healthcare Personnel | 600 | 1 | 10/60 | $34.65 | $3,465 |
| JJ. Central Line Insertion Practices Adherence Monitoring Form | 6,000 | 100 | 5/60 | $34.65 | $1,732,500 |
| KK. Laboratory Testing | 600 | 100 | 15/60 | $17.25 | $25,875 |
| LL. Multi-drug Resistance Organism (MSRO) Prevention Process and Outcome Measures Monthly Monitoring Form | 6,000 | 24 | 10/60 | $34.65 | $831,600 |
| MM. MDRO or CDAD Infection Form | 6,000 | 72 | 30/60 | $34.65 | $7,484,400 |
| NN. Laboratory- | 6,000 | 240 | 30/60 | $34.65 | $24,948,000 |

| Form Letter and Name | No. of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Average Hourly Salary of Respondent | Total Cost |
|---|---|---|---|---|---|
| identified MDRO or CDAD Event | | | | | |
| OO. NHSN Registration Form | 6,000 | 1 | 5/60 | $34.65 | $17,325 |
| PP. High Risk Inpatient Influenza Vaccination Numerator Data Form – Method A | 6,000 | 5 | 16 | $34.65 | $16,632,000 |
| QQ. High Risk Inpatient Influenza Vaccination Numerator Data Form – Method B | 600 | 250 | 10/60 | $34.65 | $866,250 |
| RR. High Risk Inpatient Influenza Vaccination Monthly Monitoring Form – Method B | 2,000 | 5 | 4 | $34.65 | $1,386,000 |
| SS. High Risk Inpatient Influenza Vaccination Denominator Data Form – Method B | 2,000 | 250 | 5/60 | $34.65 | $1,443,762 |
| TOTAL | 6,000 | | | | $143,026,791 |

**13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers**

There is no change in the estimates of annual cost burden to respondents. Capital and start-up cost component: Healthcare institutions participating in the NHSN are responsible for choosing the specific computer brand and model to purchase. Recommended 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 these requirements for other business purposes but if purchasing equipment for the first time, they will incur a one-time start up cost of approximately $1200. With anticipated enrollment of 4,500 additional facilities in the next year we estimate that approximately 3% (135 facilities) will need to purchase equipment. Therefore, we estimate an annualized cost of $162,000.

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**

There are no changes in annualized cost to the government. The estimated cost of this renewal of NHSN to the government is based on expenses incurred in the following categories: personnel, programming contracts, and computer resources. The items included in each category and their costs relevant to the proposed modifications to NHSN are shown in the table below. The total cost to the government in 2007 is estimated to be $2,093,612.

Table 14A. Estimated Annualized Cost to the Government

| Expense Item | Description | Estimated Annual Cost |
|---|---|---|
| Personnel | A total of 12.3 FTE/contractor personnel are actively involved in the enhancement and maintenance of the NHSN. The personnel categories and their FTE contributions are as follows:<br>Medical Epidemiologist – 1.5<br>Statistician – 0.50<br>Epidemiologist – 1.0<br>Project Manager – 0.8<br>User Support – 2.0<br>Public Health Analyst – 2.0<br>Computer Programmer – 2.0<br>Database Analyst – 1.0<br>Business Analyst – 0.5<br>Tester – 1.0<br>Work-study Student – 0.5 | Their annual compensation in 2008 will be $1,253,612 |
| Programming contracts | Design, develop, and deploy enhancements to NHSN | $840,000 |
| | | |
| Total | | $2,093,612 |

**15. Explanation for Program Changes or Adjustments**

CDC is requesting OMB approval for an adjustment in the number of respondents to OMB Control No. 0920-0666: National Healthcare Safety Network (NHSN). This information collection request is currently approved for 1,500 respondents and 1,278,315 burden hours. Due to reporting requirements mandated by state legislatures, CDC is requesting approval to add 4,500 respondents, for a total of 6,000 respondents. The increase in respondents will result in an increase of 3,862,030 burden hours for this information collection, for a total of 5,140,345 burden hours. The increase is outlined in Table A12A.

**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. Reports containing aggregated data will be produced annually and posted on the NHSN website, which is http://www.cdc.gov/ncidod/dhqp/nhsn.html. The report is also published annually in a scientific journal to make NHSN data widely available[4]. Other in-depth analysis of data from the NHSN will be published in peer-reviewed journals[5], 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.

## B. Collections of Information Employing Statistical Methods

**1. Respondent Universe and Sampling Methods**

NHSN is an ongoing surveillance system that does not employ probability sampling methods for selecting participating hospitals. Participation in NHSN is voluntary and is open to all healthcare institutions with patient population groups that are addressed by the NHSN modules. Participating institutions have complete autonomy on choice of modules to use and modules are reported each year. This is unchanged from the original application for OMB approval of NHSN. Hospitals that previously participated in NNIS were the first participants in NHSN. Healthcare institutions must apply for membership in the NHSN by completing a series of forms that include identifying and contact information and agree to collect and report data using the NHSN protocols. The Chief Executive Officer or other designated facility official signs the agreement for participation in the NHSN.

The respondent universe for NHSN is potentially all institutions in the United States that provide healthcare. In the original application for OMB, the NHSN protocol addressed infections associated with acute care hospitals and outpatient dialysis centers of which there are approximately 5,800 and 4,500, respectively [6,7]. Recognizing that these infections also occur in long term acute care hospitals (LTACHs), long term care facilities (LTCFs) and ambulatory surgery centers (ASCs), NHSN enrollment has been extended to include them. In 2006, the number of Medicare certified LTACHs was 394, ASCs 4,707 and LTCFs 15,025[7].

Hospitals accredited by The Joint Commission are required to conduct ongoing hospital infection surveillance but the surveillance methodology or patient groups to be included in the surveillance are not specified. Since most acute care hospitals in the United States are accredited

by The Joint Commission, routine surveillance is a common and accepted practice. The flexibility of NHSN that permits healthcare institutions to choose from a wide array of options while participating in a national surveillance system that will permit them to comply with accreditation requirements and provide confidentiality to them and their patients, is expected to result in increasing numbers of participants.

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