National Healthcare Safety Network (NHSN)

OMB Control No. 0920-0666

Request for OMB Review and Approval

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SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Division of Healthcare Quality Promotion (DHQP), in the National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID) at CDC, requests renewal of the National Healthcare Safety Network (NHSN) under OMB Control Number 0920-0666. Included in this renewal request are revised and new data collection instruments that substantially change the paperwork burden estimates. The vision of NHSN is to create a knowledge system for accumulating, exchanging and integrating relevant information and resources among private and public stakeholders to support local and national efforts to protect patients and healthcare personnel by promoting healthcare safety. Specifically, the data will be 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.

CDC is requesting an expedited review of this information collection request by OMB. Several events have occurred recently that necessitate this request. On October 17, 2007, an article in the Journal of the American Medical Association reported that over 90,000 Americans become infected each year with MRSA. Just 2 days earlier, a high school football player in Virginia died of an MRSA infection. The resulting media interest from these two events also fueled interest by Congress in MRSA infections and reporting mechanisms for these infections. To date, CDC has provided briefings to staffers from three Congressional Committees and participated in two Congressional Town Hall meetings. In addition to increased Congressional interest, CDC has been given the lead responsibility at HHS to develop a strong HHS plan for fast action on eliminating MRSA infections in healthcare. CDC is working with the Centers for Medicare and Medicaid Services (CMS) and the Agency for Healthcare Research and Quality (AHRQ) to standard case definitions, measurement tools, and reporting systems. The revisions to the NHSN will allow CDC to provide leadership in this assignment.

NHSN was approved on February 3, 2005. While participating healthcare institutions are

expected to stringently follow the protocols in NHSN, they have wide flexibility in the adverse events and populations they choose to monitor, as well as the number of months of data they wish to collect and report. However, data for at least one module must be submitted for a minimum of six months of the calendar year to maintain active status. The surveillance data are typically obtained by designated and trained staff, primarily registered nurses in infection control or occupational health, who routinely access administrative and clinical services reports, patients' 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 on-line NHSN system.

The first component of NHSN to become functional was the Patient Safety Component. Its modules have focused on collection of outcome measures, namely rates of central line-associated bloodstream infections (CLABSIs), ventilator-associated pneumonia, catheter-associated urinary tract infections, dialysis events, and surgical site infections and post-procedure pneumonia.

Several developments have led to the modifications of NHSN that are proposed. Recently, the Healthcare Infection Control Practices Advisory Committee (HICPAC) published guidelines on public reporting of healthcare-associated outcome and process measures, partly in response to increasing consumer demand for healthcare information (Attachment A). The process measures included central-line insertion practices, surgical antimicrobial prophylaxis, and influenza vaccination coverage among patients and healthcare personnel. The outcome measures included rates of CLABSIs and surgical site infections following selected operations. HICPAC has also published guidance on the control of multidrug-resistant organisms (MDROs), which includes recommendations for active surveillance for asymptomatic colonization in certain high-risk settings (Attachment B). DHQP has been actively collaborating with several groups of US healthcare facilities that are working together to implement these recommendations in their facilities because there is currently no systematic method to collect information on central line insertion practices, MDRO prevention efforts, or influenza vaccination coverage of hospitalized individuals. Reasons for the low-level of influenza vaccination coverage among healthcare

personnel (HCP) are also not well-described and there is no systematic method to collect information either on adverse events related to the prevention and treatment of influenza with antiviral medications, or on declination of influenza vaccination by HCP.

The above mentioned facilities have expressed a desire to use NHSN to collect information on transmission of MDROs, colonization, and process measures including adherence to surveillance culture swabbing, hand hygiene, and contact precautions (i.e., the use of gowns and gloves). Therefore, we plan to provide these collaborators with an opportunity to submit these data using new modules and an additional process monitor within the NHSN.

Two new modules of the NHSN Patient Safety Component are proposed: MDRO, and Patient Influenza Vaccination. In addition, a new process monitor--Central Line Insertion Practices Adherence Monitoring—will be added to the Device-associated Module of the Patient Safety Component. To the NHSN Healthcare Personnel Safety Component, we propose adding an influenza vaccination module. Amendments to previously approved NHSN Healthcare Personnel Safety Component forms are also requested. These changes are necessitated by the introduction of the influenza module, as well as a need to revise several of the forms to better reflect current technology and best practices and ideally, to simplify data analysis. The addition of the proposed new forms will increase the burden of data collection, as reflected in the detailed tables of Attachment I. Form changes are detailed in Attachment C. All of the data collection forms are found in Attachment J.

Public reporting of healthcare performance measures has become mandatory in a number of states and is intended to enable consumers to make more informed choices about their own healthcare. Colorado, Delaware, Missouri, New York, Oklahoma, Pennsylvania, South Carolina, Tennessee, Virginia, and Vermont have proposed to have their hospitals use NHSN as an infection reporting system. While original NHSN burden estimates were based on 350 respondents, the transition of 270 facilities from NNIS and Dialysis Surveillance Network (DSN) to NHSN, the addition of 200 facilities due to state-mandated reporting in 2007, and 155 sites due to methicillin-resistant *Staphylococcus aureus* (MRSA) prevention initiatives has resulted in a current enrollment of 625 facilities. The increased interest in the use of NHSN for mandatory healthcare-associated infection and process measure reporting, in addition to the opening of enrollment to facilities nationwide in June 2007, prompted the revision of the estimated burden to include an anticipated total of 1500 respondents.

2. Purpose and Use of Information Collection

The proposed additional collections in the NHSN Patient Safety Component would enable participating facilities and CDC to monitor practices important for prevention of central line-associated bloodstream infections; MDRO infections; and influenza vaccination coverage in individual patient-care units and facilities and to provide aggregate adherence data and coverage estimates for all participating facilities. Use of these forms will facilitate quality improvement by identifying specific gaps in adherence to recommended prevention practices to which intervention strategies for reducing CLABSI and MDRO rates can be targeted, as well as strategies to increase influenza vaccination coverage among patients in healthcare facilities.

The proposed additional data collection in the NHSN Healthcare Personnel Safety Component would enable participating facilities and CDC to monitor influenza vaccination coverage among HCP at individual facilities and to provide aggregate coverage estimates for all participating facilities; monitor progress towards attaining the Healthy People 2010[1] goal of 60% vaccination coverage among HCP; monitor influenza vaccination coverage by ward/unit of the facility and occupational group so that areas or groups with low vaccination rates can be targeted for interventions; monitor adverse reactions related to receipt of the vaccine or receipt of antiviral medications; and assess the characteristics of influenza vaccination programs pre- and post-influenza season to identify practices associated with high vaccination rates.

3. Use of Improved Information Technology and Burden Reduction

One hundred percent (100%) of the data for the NHSN will be collected electronically. The Public Health Information Network (PHIN) provides the architectural foundation of the NHSN. PHIN is CDC's vision for advancing fully capable and interoperable information systems for the many public health partners. It is a national initiative to implement a multi-organizational business and technical architecture for public health information systems. PHIN promotes the goals of integration and standardization that are key to NHSN success. The enabling technologies of that architecture include:

- **Web browser based data entry and data management.** PHIN takes full advantage of the Internet as a system platform. Access to the NHSN is via web browser. This enables

the widest possible system deployment and access and, for NHSN's centralized architecture, it facilitates deployment.

- **Electronic Health Level 7 (HL7) message and document processing.** PHIN accepts, routes and processes electronic HL7 messages and documents 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 and for capturing these data elements necessary for electronic detecting of events such as infections and reporting.
- **Integrated data repository.** PHIN uses modern database systems and standards to implement a shared data repository. The data repository is patient-centered (where appropriate) and uses the Public Health Conceptual Data Model (PHCDM) to promote standardization and data exchange. It enables access by standards-based commercial products for reporting, statistical analysis, geographic mapping, and automatic outbreak detection.
- **Data translation and exchange.** PHIN relies on XML as the enabling technology for data translation and exchange. This includes dynamic bi-directional system messaging to facilitate integration with other organizations, and flexible construction of human interfaces that can be deployed to a variety of interface devices.
- **Data reporting and visualization.** PHIN takes advantage of current, commercial off-the-shelf products, statistical packages, and other visualization tools to enable display and mapping functions. The interface is implemented through industry standards for access to the data repository (such as open database connection and Java database connection)
- **Shareable directory for authorization.** PHIN uses, where appropriate, enterprise directory services in order to avoid redundant security architecture. It uses the standard lightweight directory application protocol infrastructure.
- **Security system and policies.** The sensitive nature of medical information makes it critical to implement security measures that are robust enough to be safe, yet simple enough to encourage compliance. PHIN specifies a flexible, three-dimensional model for authentication and authorization that is used by NHSN.

In addition to the technologies taken directly from PHIN architecture, the NHSN system is designed for eventual implementation of the following:

- **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.
- **Handheld computing technology.** Most healthcare institutions rely on paper forms for the collection of adverse event data with later bulk entry into NHSN. While handheld computing devices are convenient for instant messaging and scheduling, their use as data entry devices for a data intensive system such as NHSN are not deemed feasible at this time.

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 instruments 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. The following recent unsolicited (by CDC) comment from an NHSN user on the APIC (Association for Professionals in Infection Control and Epidemiology) listserve provides an excellent description of the burden for a single facility:

> "Our facility has been a participant in NNIS/NHSN since 1991. As with any surveillance process, there is work in the beginning setting up sources of data such as line days, surgical procedure information, etc. Once the processes are in place, utilization of the NHSN software takes very little time. We currently import our surgical denominator data from our surgical software. It takes about one hour to export from the surgical software, "clean up the data," and then import it into NHSN. We choose to import 6 months of data at a time. Entering the SSI infections takes about 1-2 minutes each. Generating the risk adjusted data takes about 5 minutes.

For bloodstream infection data, all you do is enter the monthly summary of denominator data (line days and patient days by unit) and then enter the infections. Generating the unit specific rates takes less than 5 minutes. We have found the front end investment of setting it all up to be well worth the time. The credibility of the data and benchmarks are well respected both inside and outside our facility.

Regarding your specific question about how labor intensive it is: When you join NHSN, you do not have to do all components at the same time. I would suggest that you select one component, such as BSI for one unit and get that component working smoothly, then expand. For surgical surveillance, select one procedure at first and then expand. It doesn't have to be overwhelming. We currently conduct BSI surveillance for approximately 120 ICU beds in 6 different units, VAP in 7 ICUs and up to 5 or 6 surgical procedures at a time utilizing a portion of 2.5 FTE's of our IC staff (those 2.5 FTEs have multiple other responsibilities). We expect to expand to VAP and BSI surveillance of all units (approx 160 beds in 10 units) in the next few months due to mandatory reporting requirements.

Many states, including Tennessee are requiring participation in NHSN and are using NHSN as the mechanism for mandatory reporting of infection rates. Those of us already participating in NHSN are well prepared for the mandatory reporting."

4. Efforts to Identify Duplication and Use of Similar Information

The Division of Healthcare Quality Promotion staff keeps abreast of the infection control and occupational health fields by reviewing literature, participating in scientific conferences, and serving on committees of professional organizations.

There are other organizations within the Department of Health and Human Services (HHS) 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.

The Patient Safety Task Force, which included CDC/NHSN staff as members, was an HHS effort to integrate research, data collection, and analysis of medical errors, through the creation of the Patient Safety and Quality Improvement Act of 2005 (Attachment D). This Act has not yet been implemented.

The Health Resources and Services Administration (HRSA) is the primary Federal agency for improving access to healthcare services for people who are uninsured, underserved or have special needs. While part of its mission is to support programs to improve health outcomes and the quality of healthcare, it does not maintain and support a healthcare-associated infection surveillance system.

The Agency for Healthcare Research and Quality (AHRQ) supports research and projects that translate research into practice to improve patient care in a variety of healthcare settings. Healthcare Cost and Utilization Project (HCUP) Quality Indicators were first released

in November 2001 and were predecessors to the Patient Safety Indicators (PSIs) that are currently in use. These are software programs that measure health care quality by identifying potential adverse events (including hospital-associated infections) through the use of inpatient administrative data (ICD-9-CM discharge codes). Their use is voluntary and the software programs are distributed at no charge to hospitals. In contrast, NHSN is an ongoing, prospective national surveillance system that relies on routine data collection by infection control professionals who follow established protocols to identify and define a case. While the PSIs can be used to identify potential problems and trends within a facility, they are not an accurate source for measuring true incidence of particular infections.[2] Therefore, these data collection efforts are not duplicative.

The Centers for Medicare and Medicaid Services (CMS) is also concerned with quality of healthcare and improved outcomes and, in conjunction with the Hospital Quality Alliance (HQA), has instituted a number of Quality Initiatives to assure quality of healthcare through accountability, public disclosure and pay-for-performance. A standardized set of hospital quality measures has been refined for use in voluntary public reporting.

- *Hospital Compare*, a web tool designed to publicly report these measures was implemented in April 2005 (www.hospitalcompare.hhs.gov). Using at least the 10 "starter set" quality measures, hospitals submit data to a data warehouse prior to its display on Hospital Compare. Hospitals paid by Medicare who want to receive their full annual Medicare payment will have payments reduced if they do not submit quality data that achieve an 80 percent or greater agreement rate across selected elements. Section 501 (b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 stipulated that a hospital that does not submit performance data for at least the 10 "starter measures" will receive a 0.4 percentage point reduction in its annual payment update from CMS for fiscal years 2005, 2006 and 2007. In addition, The Deficit Reduction Act of 2005 states, "the payment update for FY2007 will be reduced by 2.0 percentage points for any acute-care inpatient prospective payment system hospitals that do not submit quality data…." This is strong incentive for hospitals to institute quality measure reporting. Hospitals can also use this tool to submit data to The Joint Commission in order to meet requirements for accreditation. These "starter measures" do not overlap NHSN measures, however, three measures are proposed that would be useful to include

in NHSN (called the Surgical Infection Prevention measures). Rather than duplicate data collection efforts, CMS and CDC are discussing options for sharing these measure data without creating additional user burden.

- The End Stage Renal Disease (ESRD) Quality Initiative Component includes Dialysis Facility Compare (DFC), a website that allows consumers and patients to review and compare facilities. The ESRD Clinical Performance Measures (CPM) Project collects data annually for a standard set of measures on a random national sample of dialysis patients that include adequacy of hemodialysis and peritoneal dialysis, anemia management and vascular access management. Their *Fistula First Breakthrough Initiative* was developed to achieve 65% arterial venous fistula utilization by 2009. This is the preferred vascular access type for patients because it has a low complication rate. NHSN collects dialysis information through facility reporting that provides a denominator for comparison of changes instituted over time that are designed to improve patient safety and outcomes. These data collections do not overlap.
- The Medicare Quality Monitoring System (MQMS) processes, analyzes, interprets and disseminates health related data at the national or state level to monitor quality of care delivered to its fee-for-service beneficiaries and payment/coverage policies. While its data can be used to identify potential problems, it does not seek to explain causes or evaluate individual facility performance.

In summary, 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.

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 participation in the NHSN is voluntary and 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. (Attachment E)

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). A contact list of outside consultants is included in Attachment F.

C. CDC response (in italics) to comments received as a result of the 60-day Federal Register notice:

1. Comment: 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

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.

2. Comment:

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,

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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.

9. Explanation of Any Payment or Gift to Respondents

The renewal and proposed changes follow the same protocol as the previously approved data collection. No monetary incentive is provided to NHSN participants.

10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed for privacy act applicability and it has been determined that the Privacy Act does not apply. Rationale: Although personal information, including Social Security Numbers (SSN) maybe collected, data retrieval is not by name, SSN or any personal identifier, but rather by hospital or other non-personal identifier.

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))”(Attachment G). 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 (See Attachment H for the IRB closure notice).

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 in Attachment I provide the estimated burden hour and cost for the proposed new forms, as well as the burden hour and cost estimates for all currently approved forms, some which have had minor revisions. Estimates of national annual burden and cost are based on 9 months of active data collection, not 12 months. This is based on previous experience and current healthcare institution practice. The burden hours and annual cost burden estimates have increased significantly due to the addition of facilities in states where healthcare-associated infection reporting is now mandatory, as well as the opening of enrollment in NHSN to all facilities nationwide. To date, the following states require that their hospitals use NHSN for reporting healthcare-associated infections: Colorado, Delaware, New York, Oklahoma,

Pennsylvania, South Carolina, Tennessee, Vermont, and Virginia. We estimate this group alone will add over 700 hospitals.

Estimates are based on a total of 1,500 participating facilities (respondents).

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	1,500	9	35/60	7,875
AA. Healthcare Worker Survey	150	100	10/60	2,500
B. Healthcare Personnel Safety Reporting Plan	150	9	10/60	225
BB. Dialysis Survey	80	1	1	80
CC. List of Blood Isolates +	1,500	1	1	1,500
D. Primary Bloodstream Infection (BSI) **	1,500	36	30/60	27,000
DD. Manual Categorization of Positive Blood Cultures +	1,500	1	1	1,500
E. Dialysis Event	80	200	15/60	4,000
FF. Healthcare Worker Influenza Vaccination	150	500	10/60	12,500
G. Pneumonia (PNEU) (includes decision algorithms: Ga. Any Patient – Pneumonia Flow Diagram Gb. Infant and Children – Pneumonia Flow Diagram	1,500	72	30/60	54,000
GG. Healthcare Worker Influenza Antiviral Medication Administration	150	50	10/60	1,250
H. Urinary Tract Infection (UTI)	1,500	27	30/60	20,250
HH. Preseason Survey on Influenza Vaccination Programs for Healthcare Personnel	150	1	10/60	25
II. Postseason Survey on Influenza Vaccination Programs for Healthcare Personnel	150	1	10/60	25
J. Denominators for Neonatal Intensive Care Units (NICU)	1,500	9	4	54,000
JJ. Central Line Insertion Practices Adherence Monitoring Form	1,500	100	5/60	12,500
K. Denominators for Specialty Care Areas (SCA)	1,500	9	5	67,500

Form Letter and Name	No. of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
KK. Laboratory Testing	150	100	15/60	3,750
L. Denominators for Intensive Care Units (ICU)/Other locations (not NICU or SCA)	1,500	18	5	135,000
LL. Multi-drug Resistant Organism (MDRO) Prevention Process and Outcome Measures Monthly Monitoring Form	1,500	24	10/60	6,000
M. Denominator for Outpatient Dialysis	80	9	5/60	60
MM. MDRO Infection Form	1,500	72	30/60	54,000
N. Surgical Site Infection (SSI)	1,500	27	30/60	20,250
NN. Laboratory-identified MDRO Event	1,500	240	30/60	180,000
O. Denominator for Procedure	1,500	540	8/60	108,000
OO. NSHN Registration Form	1,500	1	5/60	125
P. Antimicrobial Use and Resistance (AUR) – Microbiology Laboratory Data **	1,500	45	3	202,500
PP. High Risk Inpatient Influenza Vaccination Monthly Monitoring Form – Method A	1,500	5	16	120,000
Q. Antimicrobial Use and Resistance (AUR) – Pharmacy Data**	1,500	36	2	108,000
QQ. High Risk Inpatient Influenza Vaccination Numerator Data Form – Method B	500	250	10/60	20,833
R. Facility Contact Information	1,500	1	10/60	250
RR. High Risk Inpatient Influenza Vaccination Monthly Monitoring Form – Method B	500	5	4	10,000
S. Patient Safety Component Annual Facility Survey	1,500	1	30/60	750
SS. High Risk Inpatient Influenza Vaccination Denominator Data Form – Method B	500	250	5/60	10,417
T. Agreement to Participate and Consent	1,500	1	15/60	375
TT. Laboratory-identified MDRO Event Summary Form	1,500	3	1	4,500
U. Group Contact Information	1,500	1	5/60	125

Form Letter and Name	No. of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
V. Exposure to Blood/Body Fluids	150	50	1	7,500
W. Healthcare Worker Post-exposure Prophylaxis	150	10	15/60	375
X. Healthcare Worker Demographic Data	150	200	20/60	10,000
Y. Healthcare Worker Vaccination History	150	300	10/60	7,500
Z. Implementation of Engineering (Safety Device) Controls for Sharps Injury Prevention	150	1	30/60	75
Za. Healthcare Personnel Safety Component Facility Survey	150	1	8	1,200
TOTAL	1,500			1,278,153

[+] 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	1,500	9	35/60	$34.65	$272,868.75
AA. Healthcare Worker Survey	150	100	10/60	$34.65	$86,625.00
B. Healthcare Personnel Safety Reporting Plan	150	9	10/60	$34.65	$7,796.25
BB. Dialysis Survey	80	1	1	$34.65	$2,772.00

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
CC. List of Blood Isolates +	1,500	1	1	$34.65	$51,975.00
D. Primary Bloodstream Infection (BSI) **	1,500	36	30/60	$34.65	$935,550.00
DD. Manual Categorization of Positive Blood Cultures +	1,500	1	1	$34.65	$51,975.00
E. Dialysis Event	80	200	15/60	$29.58	$118,320.00
FF. Healthcare Worker Influenza Vaccination	150	500	10/60	$34.65	$433,125.00
G. Pneumonia (PNEU) (includes decision algorithms: Ga. Any Patient – Pneumonia Flow Diagram Gb. Infant and Children – Pneumonia Flow Diagram	1,500	72	30/60	$34.65	$1,871,100.00
GG. Healthcare Worker Influenza Antiviral Medication Administration	150	50	10/60	$34.65	$43,312.50
H. Urinary Tract Infection (UTI)	1,500	27	30/60	$34.65	$701,662.50
HH. Preseason Survey on Influenza Vaccination Programs for Healthcare Personnel	150	1	10/60	$34.65	$866.25
II. Postseason Survey on Influenza Vaccination Programs for Healthcare Personnel	150	1	10/60	$34.65	$866.25
J. Denominators for Neonatal Intensive	1,500	9	4	$29.58	$1,597,320.00

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
Care Units (NICU)					
JJ. Central Line Insertion Practices Adherence Monitoring Form	1,500	100	5/60	$34.65	$433,125.00
K. Denominators for Specialty Care Areas (SCA)	1.500	9	5	$29.58	$1,996,650.00
KK. Laboratory Testing	150	100	15/60	$17.25	$64,687.50
L. Denominators for Intensive Care Units (ICU)/Other locations (not NICU or SCA)	1,500	18	5	$29.58	$3,993,300.00
LL. Multi-drug Resistant Organism (MDRO) Prevention Process and Outcome Measures Monthly Monitoring Form	1,500	24	10/60	$34.65	$207,900.00
M. Denominator for Outpatient Dialysis	80	9	5/60	$29.58	$1,774.80
MM. MDRO Infection Form	1,500	72	30/60	$34.65	$1,871,100.00
N. Surgical Site Infection (SSI)	1,500	27	30/60	$34.65	$701,662.50
NN. Laboratory-identified MDRO Event	1,500	240	30/60	$34.65	$6,237,000.00
O. Denominator for Procedure	1,500	540	8/60	$29.58	$3,194,640.00
OO. NSHN Registration Form	1,500	1	5/60	$34.65	$4,331.25
P. Antimicrobial Use and Resistance (AUR) – Microbiology Laboratory Data **	1,500	45	3	$17.25	$3,493,125.00
PP. High Risk Inpatient Influenza Vaccination Monthly Monitoring Form –	1,500	5	16	$34.65	$4,158,000.00

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
Method A					
Q. Antimicrobial Use and Resistance (AUR) – Pharmacy Data**	1,500	36	2	$13.18	$1,423,440.00
QQ. High Risk Inpatient Influenza Vaccination Numerator Data Form – Method B	500	250	10/60	$34.65	$721,863.45
R. Facility Contact Information	1,500	1	10/60	$34.65	$8,662.50
RR. High Risk Inpatient Influenza Vaccination Monthly Monitoring Form – Method B	500	5	4	$34.65	$346,500.00
S. Patient Safety Component Annual Facility Survey	1,500	1	30/60	$34.65	$25,987.50
SS. High Risk Inpatient Influenza Vaccination Denominator Data Form – Method B	500	250	5/60	$34.65	$360,949.05
T. Agreement to Participate and Consent	1,500	1	15/60	$34.65	$12,993.75
TT. Laboratory-identified MDRO Event Summary Form	1,500	3	1	$34.65	$155,925.00
U. Group Contact Information	1,500	1	5/60	$34.65	$4,331.25
V. Exposure to Blood/Body Fluids	150	50	1	$34.65	$259,875.00
W. Healthcare Worker Post-exposure Prophylaxis	150	10	15/60	$34.65	$12,993.75
X. Healthcare Worker Demographic Data	150	200	20/60	$34.65	$346,500.00
Y. Healthcare Worker	150	300	10/60	$34.65	$259,875.00

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
Vaccination History					
Z. Implementation of Engineering (Safety Device) Controls for Sharps Injury Prevention	150	1	30/60	$29.58	$2,218.50
Za. Healthcare Personnel Safety Component Facility Survey	150	1	8	$34.65	$41,580.00
TOTAL	1,500				$36,517,125.30

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

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 900 additional facilities in the next year we estimate that approximately 3% (27 facilities) will need to purchase equipment. Therefore, we estimate an annualized cost of $40,500.

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 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. In subsequent years there could be changes in programming contract costs as additional modules are added.

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: Medical Epidemiologist – 1.5 Statistician – 0.50 Epidemiologist – 1.0 Project Manager – 0.8 User Support – 2.0 Public Health Analyst – 2.0 Computer Programmer – 2.0 Database Analyst – 1.0 Business Analyst – 0.5 Tester – 1.0 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

The National Healthcare Safety Network is currently approved for 65,817 burden hours. This request is seeking approval for 1,278,315 hours, a net increase of 1,212,498 hours. The increase is due to the addition of new forms to this information collection request and an increased number of respondents. The data collections being added are:

1) Healthcare Worker Influenza Vaccination form;
2) Healthcare Worker Influenza Antiviral Medical Administration form;
3) Pre-season Survey on Influenza Vaccination Programs for Healthcare Personnel;

4) Post-season Survey on Influenza Vaccination Programs for Healthcare Personnel;
5) Central Line Insertion Practices Adherence Monitoring form;
6) Laboratory Testing form;
7) Multi-drug Resistant Organism (MDRO) Prevention Process and Outcome Measures Monthly Monitoring form;
8) MDRO Infection Event form;
9) Laboratory-identified MDRO Event form;
10) NHSN Registration form;
11) High Risk Inpatient Influenza Vaccination Monthly Monitoring Form – Method A;
12) High Risk Inpatient Influenza Vaccination Numerator Data Form – Method B;
13) High Risk Inpatient Influenza Vaccination Monthly Monitoring Form – Method B;
14) High Risk Inpatient Influenza Vaccination Denominator Data Form – Method B;
15) Laboratory-identified MDRO Even Summary Form; and
16) High Risk Inpatient Influenza Vaccination Standing Orders Form. This form is an optional form and is not required as part of the High Risk Inpatient Influenza Vaccination module.

Please see Attachment C for details of changes.

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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[3] Richards C, Emori TG, Edwards J, et al. Characteristics of hospitals and infection control professionals participating in the National Nosocomial Infections Surveillance System 1999. Am J Infect Control 2001; 29:400-3.

[4]Edwards JR, Peterson KD, Andrus ML, Tolson JS, Goulding JS, Dudeck MA, et al. National Healthcare Safety Network (NHSN) Report, data summary for 2006, Issued June 2007. Am J Infect Control 2007; 35:290-301.

[5]Klevens RM, Edwards JR, Andrus M, Peterson K, Dudeck MA, Horan TC and the NHSN Participants in Outpatient Dialysis Surveillance Report, National Healthcare Safety Network (NHSN), Data Summary for 2006. Seminars in Dialysis 2007 (publication planned)

[6]American Hospital Association, 2005 Survey

[7]MedPAC Data Book, June 2007 http://www.medpac.gov/

LIST OF ATTACHMENTS

A. Guidance on Public Reporting of Healthcare-Associated Infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee.
B. Management of Multidrug-Resistant Organisms in Healthcare Settings, 2006.
C. Explanation of changes to data collection forms
D. Patient Safety and Quality Improvement Act of 2005
E. 60 Day Federal Register Notice
F. List of outside consultants
G. Public Health Service Act (42 USC 241, 242b, 242k, and 242m(d))
H. Notification of IRB Closure
I. Estimates of Annualized Burden Hours and Cost
J. Data Collection Forms