National Healthcare Safety Network (NHSN)

OMB Control No. 0920-0666

Revision Request for OMB Review and Approval

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SUPPORTING STATEMENT

The Centers for Disease Control and Prevention (CDC) is requesting OMB approval to add a Hemovigilance module to OMB Control No. 0920-0666: National Healthcare Safety Network (NHSN). This information collection request is currently approved for 6,000 respondents and 5,144,844 burden hours. This module is a response to a recommendation from HHS' Advisory Committee on Blood Safety and Availability (ACBSA) to develop a national system for outcome surveillance that includes recipients of blood and blood products. In this revision request, CDC is also requesting approval to delete two forms currently approved under OMB Control No. 0920-0666 because they are no longer used within the NHSN. This revision request will net an increase of 27,400 burden hours for this information collection, for a new total of 5,172,244 burden hours. There are no additional respondents for this request as they are already part of the respondent population.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The vision of National Healthcare Safety Network (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 is used to determine the magnitude of various healthcare-associated adverse events and trends in the rates of these events among patients and healthcare personnel with similar risks or exposures.

The NHSN was first approved by OMB in 2005 and a revision request was approved by OMB in 2008. The 2008 revision request included modifications to approved forms, new modules, and an increase in the number of respondents. Later in 2008, CDC requested and received OMB approval to increase the number of respondents for the NHSN to 6,000 healthcare facilities. This change was a result of an increasing number of State legislatures requiring reporting of healthcare-acquired infections by healthcare facilities using the NHSN.

Although 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.

This revision request includes a new module, the Hemovigilance Module, which is a response to a recommendation from HHS' Advisory Committee on Blood Safety and

Availability (ACBSA) to develop a national system for outcome surveillance that includes recipients of blood and blood products.

Based on the 2007 National Blood Collection and Utilization Survey Report (Attachment 3), the total supply of whole blood and red blood cells collected in the U.S. in 2007 was approximately 16.2 million units which were processed into 30 million blood products. Recipients received on average, 3.0 units each, resulting in a national estimate of 5.4 million patients transfused.

While the risk of infectious disease as a result of transfusion can often be estimated (for example, the risk of HIV is approximately 1 in 2 million), estimates of transfusion related non-infectious adverse reactions and medical errors (incidents) associated with transfusion are not collected in the U.S. using a routine reporting system with standard definitions. Therefore, actual numbers or percentages of events are unknown. In the 2007 survey of 2006 data, 1,707 medical facilities reported 72,000 transfusion-related reactions that required diagnostic or therapeutic intervention. While any transfusion associated adverse reaction is considered rare, the general consensus in the U.S. is that there could be considerable underreporting based on surveillance reports of similar events from national surveillance programs in the United Kingdom and Canada.

In addition, the risk of error associated with administration of a particular blood product to a particular patient is a growing concern. In 1999, the Institute of Medicine report, To Err is Human, estimated that between 44,000 and 98,000 Americans die each year as a result of medical errors. In terms of blood safety, mistransfusion of blood (failure to give the right product to the right patient) is the error of greatest concern.

In 2006, the Department of Health and Human Services' (HHS) Advisory Committee on Blood Safety and Availability (ACBSA) (Attachment 4) convened to identify ways to improve patient safety related to transfusion and transplantation. One of the recommendations identified the need to development a national system for outcome surveillance that would include recipients of blood and blood products. Subsequently, the AABB (formerly, American Association of Blood Banks) formed an Inter-organizational Task Force on Biovigilance (Attachment 5). The committee defined Biovigilance as, "a comprehensive and integrated national patient safety program to collect, analyze and report on the outcomes of collection and transfusion and/or transplantation of blood components and derivatives, cells, tissues and organs. The program should be outcome driven with the objectives of providing early warning systems of safety issues, exchanging of safety information, and promoting education and the application of evidence for practice improvement."

An active surveillance system that is used for reporting common, well-defined events (that may also include untoward events) and outcomes using selected methodology can help to identify problems at a facility and aggregate and/or national level that may require process changes within a facility or nationally that ultimately impact patient safety. After a review of the different systems that can be used to collect transfusion safety data, the AABB Biovigilance Task Force recommended a multi-organizational collaboration using NHSN as the surveillance system that could most closely meet the data requirements for a national surveillance system for blood transfusion adverse event tracking.

While Biovigilance also includes organ and tissue transplant safety, the first module to be developed and piloted in the NHSN will be a Hemovigilance module. The Hemovigilance module is intended to demonstrate the feasibility of collecting blood transfusion safety data using a voluntary system to collect, analyze and report information on blood transfusion-related

adverse events and will include two sections: adverse reactions and incident reporting. The data collection instruments for this module are found in Attachment 7. The module consists of 6 additional forms: 1) the Hemovigilance Module Annual Survey (1,000 annualized burden hours); 2) the Hemovigilance Module Monthly Reporting Plan (200 annualized burden hours); 3) Hemovigilance Module Blood Produce Incident Reporting – Summary Data (12,000 annualized burden hours); 4) Hemovigilance Module Monthly Reporting Denominators (3,000 annualized burden hours); 5) Hemovigilance Incident form (6,000 annualized burden hours); and 6) Hemovigilance Adverse Reaction form (10,000 annualized burden hours). The Hemovigilance Module totals an estimated 32,200 annualized burden hours.

This submission also includes a request to delete two forms that are no longer being used by the NHSN: Implementation of Engineering Controls (currently approved for 300 burden hours) and the Laboratory Identified Multi-drug Resistant Organism (MDRO) Event Summary Form (currently approved for 4,500 burden hours). These forms are no longer being utilized by NHSN participants. These deletions total 4,800 burden hours.

There are no additional respondents for this request as they are already part of the respondent population. The currently approved NHSN forms are found in Attachment 6.

CDC is requesting an expedited review of this information collection request by OMB. .The AABB, a key member of ACBSA is holding its annual meeting in October 2009 and plans to use the annual meeting to roll out the Hemovigilance module to its membership.

This collection of information is authorized by the Public Health Service Act (Attachment 1) and the Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41) (Attachment 2).

Privacy Impact Assessment

Overview of the Data Collection System

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.

Items of Information to be Collected

Items of information to be collected include surveillance data related to various healthcare-associated adverse events and trends. Examples of these items are medical information and notes, medical records numbers, and biological specimens. Results are reported to CDC and CDC aggregates the data for national surveillance and public health practice evaluation purposes.

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

Respondents directly enter data from the source document to NHSN through the web browser. Respondents are required to obtain a digital certificate via CDC's Secure Data

Network. Data may be retrieved by the name of the hospital or other non-personal identifier, not an individual patient. The website is not directed at children under 13 years of age.

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.

Privacy Impact Assessment Information

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

The surveillance data are typically obtained by designated and trained staff, primarily registered nurses in infection control or occupational health, 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.

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))."

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 some 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. In a conference call with CDC on June 24, 2009, OMB agreed to waive the 60 day FRN requirement because of the urgent need to approve this request and implement the module.

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))"(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 submissions 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. CDC 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.

Privacy Impact Assessment Information

A. , The CDC 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). 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 submissions are still in effect.

B. All the safeguarding measures described in previous submissions 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. 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))."

C. 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. No primary research is conducted as part of this data collection effort and no patient consent forms are used. 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.

D.. The use of the NHSN is both voluntary and mandated. State legislatures have mandated the use of the NHSN for public reporting of healthcare-acquired infections by healthcare facilities in their state. The CDC Office of General Counsel has determined that the Privacy Act does not apply to this data collection.

11. Justification for Sensitive Questions

The reporting of adverse events associated with healthcare can be sensitive unless the institution is assured that the data aggregating organization will provide security for the data and maintain the institution's confidentiality. As discussed in item A.10 above, NHSN is authorized to assure confidentiality to its participating individuals and institutions.

12. Estimates of Annualized Burden Hours and Costs

The tables below reflect the 2008 change request (increasing respondents to 6000) and provide the burden hour and cost estimates for the Hemovigilance module. CDC estimates that 500 of the respondents for the NHSN will participate in this module. There will be no new respondents for this data collection.

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	600	9	10/60	900

Form Letter and Name	No. of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Reporting Plan				
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
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
Za. Healthcare Personnel Safety	600	1	8	4,800

Form Letter and Name	No. of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Component Facility Survey				
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
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 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
Hemovigilance Module Annual	500	1	2	1,000

Form Letter and Name	No. of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Survey				
Hemovigilance Module Monthly Reporting Plan	500	12	2/60	200
Hemovigilance Module Blood Produce Incident Reporting – Summary Data	500	12	2	12,000
Hemovigilance Module Monthly Reporting Denominators	500	12	30/60	3,000
Hemovigilance Incident form	500	72	10/60	6,000
Hemovigilance Adverse Reaction	500	120	10/60	10,000
TOTAL	6,000			5,172,244

[+] 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

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
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 Outpatient Dialysis	225	9	5/60	$29.58	$4,999
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	6,000	1	30/60	$34.65	$103,950

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
Facility Survey					
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
Za. Healthcare Personnel Safety Component Facility Survey	600	1	8	$34.65	$166,320
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	600	1	10/60	$34.65	$3,465

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 Programs for Healthcare Personnel					
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-identified MDRO Event	6,000	240	30/60	$34.65	$24,948,000
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	2,000	250	5/60	$34.65	$1,443,762

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
Form – Method B					
Hemovigilance Module Annual Survey	500	1	2	$34.65	$34,650
Hemovigilance Module Monthly Reporting Plan	500	12	2/60	$34.65	$6,930
Hemovigilance Module Blood Product Incident Reporting – Summary Data	500	12	2	$34.65	$415,800
Hemovigilance Module Monthly Reporting Denominators	500	12	30/60	$34.65	$103,950
Hemovigilance Incident	500	72	10/60	$34.65	$207,900
Hemovigilance Adverse Reaction	500	120	10/60	$34.65	$346,500
TOTAL	6,000				$144,151,737

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

There is no change in the estimates of annual cost burden to respondents. Capital and start-up cost 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 to the 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 was 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: 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

This submission includes a request to add the Hemovigilance Module to the list of approved data collection instruments for the NHSN. The module consists of 6 additional forms: 1) the Hemovigilance Module Annual Survey (1,000 annualized burden hours); 2) the Hemovigilance Module Monthly Reporting Plan (200 annualized burden hours); 3) Hemovigilance Module Blood Produce Incident Reporting – Summary Data (12,000 annualized burden hours); 4) Hemovigilance Module Monthly Reporting Denominators (3,000 annualized burden hours); 5) Hemovigilance Incident form (6,000 annualized burden hours); and 6) Hemovigilance Adverse Reaction form (10,000 annualized burden hours). The Hemovigilance Module totals an estimated 32,200 annualized burden hours.

This submission also includes a request to delete two forms that are no longer being used by the NHSN: Implementation of Engineering Controls (currently approved for 300 burden hours) and the Laboratory Identified Multi-drug Resistant Organism (MDRO) Event Summary Form (currently approved for 4,500 burden hours). These forms are no longer being utilized by NHSN participants. These deletions total 4,800 burden hours.

Thus, revision submission is for a net increase of 27,400 burden hours for this information collection, for a new total of 5,172,244 burden hours.

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 are 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. Other in-depth analysis of data from the NHSN are published in peer-reviewed journals, and presented at scientific and professional meetings. The proposed modifications to NHSN will not alter the plans for tabulation, publication, nor the time schedule.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Expiration date display exemption does not apply to the NHSN.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

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

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. 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.

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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LIST OF ATTACHMENTS

1. Public Health Service Act (42 USC 241)
2. Patient Safety and Quality Improvement Act of 2005 (PL 109-41)
3. 2007 National Blood Collection and Utilization Survey Report
4. HHS Advisory Committee on Blood Safety and Availability
5. Inter-organizational Task Force on Biovigilance
6. Currently approved NHSN forms
7. Hemovigilance Module forms