National Healthcare Safety Network (NHSN)

OMB Control No. 0920-0666

83-C Change Request for OMB Review and Approval

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OMB No. 0920-0666

National Healthcare Safety Network (NHSN)

SUPPORTING STATEMENT

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 5,140,345 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. CDC is requesting approval to add 32,200 burden hours for this information collection, for a total of 5,172,545 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 Division of Healthcare Quality Promotion (DHQP), National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), Centers for Disease Control and Prevention (CDC) collects data from healthcare facilities as part of the National Healthcare Safety Network (NHSN) under OMB Control Number 0920-0666. CDC is requesting OMB approval to add a Hemovigilance module to the NHSN.

Based on the 2007 National Blood Collection and Utilization Survey Report (Attachment 1), 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 2) 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 3). 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 are found in Attachment 4.

2. Purpose and Use of Information Collection

The data collected under this OMB Control Number are used to determine the magnitude of various healthcare-associated adverse events and trends in the rates of these events among patients and healthcare personnel with similar risks or exposures. The NHSN provides facilities with risk-adjusted data that can be used for inter-facility comparisons and local quality improvement activities. CDC also assists facilities in developing surveillance and analysis methods that permit timely recognition of patient and healthcare personnel safety problems and prompt intervention with appropriate measures. Finally, facilities can conduct collaborative research with NHSN member facilities. For example, facilities can describe the epidemiology of emerging HAIs and pathogens, assess the importance of potential risk factors, further characterize HAI pathogens and their mechanism of resistance, and evaluate alternative surveillance and prevention strategies.

3. Use of Improved Information Technology and Burden Reduction

As stated in the 2007 submission to OMB, 100% of the data for the NHSN is collected electronically. Institutions that participate in NHSN are required to have a computer and Internet Service Provider (ISP), and they must provide the salaries of the data collectors and data entry personnel. These expenses would not exceed what is normally expended for a typical healthcare facility infection surveillance program. While the forms are provided for data collection, facilities are not required to use them for entry of data into NHSN. Direct data entry of information from the source document to NHSN through the web browser is possible and may

reduce the data reporting burden. Only the minimum amount of information necessary for the data collection is being requested.

4. Efforts to Identify Duplication and Use of Similar Information

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

There are other organizations within the Department of Health and Human Services (HHS) (e.g., Patient Safety Task Force, the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services) that work to improve patient safety and healthcare outcomes. These agencies use the information generated from the NHSN to support their mission, and currently, the data collections do not overlap.

5. Impact on Small Businesses or Other Small Entities

There are several vendors (some of which would be considered small businesses) that sell data management tools with similar capabilities as NHSN. However, since NSHN is a voluntary system, facilities are free to choose a vendor product over the NHSN. The exception is in those states that have mandated the use of NHSN for meeting their public reporting laws (see Section A.1). In order to minimize any negative impact on vendors (i.e., loss of potential market share), CDC has actively been working with vendors for the past two years to create a data transfer mechanism that would allow for a facility using a vendor product to still report to a state via NHSN. A pilot test of this mechanism is currently underway.

6. Consequences of Collecting the Information Less Frequently

Many adverse events associated with healthcare, such as hospital-associated infections, occur in both endemic and epidemic patterns. It is in the best interest of the healthcare institution to conduct routine prospective surveillance in an ongoing manner to identify trends and outbreaks and to report data that may indicate a problem. An important purpose of conducting routine prospective surveillance is to quickly identify potential problems that need to be investigated and to institute appropriate measures early to minimize the number of affected patients or healthcare personnel. Collecting the data sporadically or less often than required by NHSN could potentially place patients at risk.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Reporting data more frequently than quarterly. The healthcare institutions participating in NHSN are required to collect data in an ongoing manner and report them monthly to CDC. Such a schedule will not cause undue burden in most facilities, since data are usually collected daily or at least several times per week, and denominator data are tallied monthly. The data are usually entered into the computer at least monthly for their own analysis. Given these practices, it is advantageous to CDC to maintain a monthly reporting frequency. In NHSN, once the data are entered into the web forms, they are transmitted electronically to CDC via the Internet with no additional data preparation.

Generalizability of results. Although member institutions are not a probability sample of all such institutions in the United States, they are expected to be similar to mainstream institutions of that type. For example, in a 1999 survey of NNIS (National Nosocomial Infections Surveillance System [OMB Control No. 0920-0012], a surveillance system that was incorporated

into NHSN) hospitals, 86% of the 228 hospitals that responded were general medical-surgical hospitals, 6% were children's hospitals, and 8% were Veteran's Administration (VA) or military hospitals[3]. The mean average daily census was 239 patients. The geographic distribution of NNIS hospitals was remarkably similar to U.S. hospitals, although there was a slight overrepresentation of hospitals located in the northeast. Approximately 58% of the NNIS hospitals had a major teaching affiliation with a medical school. In comparison to all U.S. hospitals, NNIS hospitals were larger and more likely to be affiliated with a medical school and be located in the northeast region. As with the NNIS system, aggregated data from NHSN will be stratified by important hospital and patient characteristics and the rates will be adjusted by exposure to procedures and therapies known to be of primary importance in increasing risk to adverse outcomes. Further, because NHSN membership is now open to any healthcare facility, we expect that over time the results will be more representative of all healthcare facilities and may be generalizable.

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

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

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

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

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

Sincerely,
Curt Lindberg
President and CEO
Plexus Institute

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

The use of this data for purposes to include monitoring other 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) 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.

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

- **Interfaces with hospital systems.** The ability to gather information directly from electronic databases of healthcare facilities is made possible by the maturing of commercial products and the increasing standardization of interfaces. Initially, NHSN is developing interfaces to receive information from the laboratory, pharmacy, and admission/discharge/transfer (ADT) systems to support the automated collection and reporting of data for the Medication-associated Module, Patient Data and Healthcare Personnel Demographic Data forms. Detection and reporting of adverse events using all available electronic data sources are planned.

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

Comment #2:

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

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

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

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

Thank you for your assistance.

Best regards,

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

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

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

B. The Healthcare Infection Control Practices Advisory Committee (HICPAC) provides advice and guidance to the CDC Director, and the Director of NCPDCID , regarding strategies for surveillance, prevention and control of adverse events associated with healthcare in the United States. Committee members represent experts in the field of infection control. They are kept abreast of NHSN methodologies and results, and proposed studies related to the NHSN. The committee has the authority to make recommendations on the conduct of the surveillance systems and studies by DHQP.

Further, participants in the NHSN are invited to make suggestions on how NHSN can help them more effectively use their own and national surveillance data. Many of the surveillance personnel in participating institutions are experts in the field of preventing adverse events, especially, hospital-associated infections, and have had extensive experience. CDC personnel are available on a priority basis by telephone and e-mail to NHSN surveillance and occupational health personnel, and participating outpatient dialysis centers. Meetings for NHSN personnel are held each year in conjunction with annual professional meetings such as the International Conference of the Association for Professionals in Infection Control and Epidemiology (APIC).

9. Explanation of Any Payment or Gift to Respondents

No monetary incentive is provided to NHSN participants.

10. Assurance of Confidentiality Provided to Respondents

An Assurance of Confidentiality has been granted for all data collected under NHSN. Accordingly, "the information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306, and 308(d) of the Public Health Services Act (42 USC 242b, 242k, and 242m(d))". Published data will not identify individual facilities without permission from the institution. Collaborators at the participating institutions may publish data collected from their institutions and may identify themselves as NHSN participants. Further, the Office of the General Counsel

(OGC) believes that NHSN, as it is currently being utilized by CDC, is not a Privacy Act system of records and provides case law to support this determination (Henke v. U.S. Department of Commerce and Fisher v. NIH). Specifically, the OGC stated that "The CDC NHSN system is similar to the computerized information in both the Henke and Fisher cases. While CDC has the capability to retrieve data by personal identifier, CDC does not, as a matter of practice or policy, retrieve data in this way. Specifically, the primary practice and policy of CDC regarding NHSN data is to retrieve data by the name of the hospital or other non-personal identifier, not an individual patient, for surveillance and public health purposes. Furthermore, patient identifiers are not necessary for NHSN to operate, and CDC does not regularly or even frequently use patient names to obtain information about these individuals."

While the Privacy Act is not applicable, in accordance with the stringent safeguarding that must be in place for 308(d) assurance of confidentiality protected projects, all the safeguarding measures described in previous Section A.10 are still in effect. These include: requiring the use of a digital certificate via CDC's Secure Data Network for access to the application; data encryption using Secure Socket Layer technology; and lastly, storage of data in password protected files on secure computers in locked, authorized-access-only rooms.

This data collection effort is consistent with the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA), which expressly permits disclosures without individual authorization to public health authorities authorized by law to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to public health surveillance, investigation, and intervention.

For the participating healthcare institutions, data are collected in this system for the purposes of local surveillance and program evaluation. DHQP aggregates the data for national surveillance and public health practice evaluation purposes. No primary research will be conducted as part of this data collection effort and no patient consent forms will be used. Although this is not a research project, this Protocol was submitted for ethical review to the CDC Institutional Review Board (IRB) and was approved (Protocol #4062, exp. 05/18/05.) The most recent request for amendment and continuation was approved on 08/29/06 and expired on 05/18/07. Subsequently, in consultation with NCPDCID Senior Staff, the program has been advised that the activities of the NHSN are surveillance and evaluation of public health practice and that IRB review is no longer required, therefore the protocol has been closed.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

The tables below 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 Number and Title	No. of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
57.300 Hemovigilance Module Annual Facility Survey	500	1	2	1,000
57.301 Hemovigilance Module Monthly Reporting plan	500	12	2/60	200
57.302 Hemovigilance Module Blood Produce Incident Reporting – Summary Data	500	12	2	12,000
57.303 Hemovigilance Module Monthly Reporting Denominators	500	12	30/60	3,000
57.304 Hemovigilance Incident	500	72	10/60	6,000
57.305 Hemovigilance Adverse Reaction	500	120	10/60	10,000
TOTAL	500			32,200

B. Estimates of Annualized Cost

The average salary of the professional discipline that is expected to perform surveillance has been used in the calculations of burden and is based on data from the Department of Labor, Bureau of Labor & Statistics, 2007. Those most likely to complete this surveillance will be Medical Technologists in Hospital Transfusion Services at a mid or senior level. Salary is based on the 75th percentile of the salary range for medical technologists due to their specialized position.

Form Number and Title	Number of Respondents	Frequency of Response	Hourly Wage Rate	Respondent Cost
57.300 Hemovigilance Module Annual Facility Survey	500	1	$29.40	$29,400
57.301 Hemovigilance Module Monthly Reporting plan	500	12	$29.40	$5,880
57.302 Hemovigilance Module Blood Produce Incident Reporting – Summary Data	500	12	$29.40	$352,800
57.303 Hemovigilance Module Monthly Reporting Denominators	500	12	$29.40	$88,200
57.304 Hemovigilance Incident	500	72	$29.40	$176,400
57.305 Hemovigilance Adverse Reaction	500	120	$29.40	$294,000
TOTAL				$946,680

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

There is no change in the estimates of annual cost burden to respondents. Capital and start-up cost component: Healthcare institutions participating in the NHSN are responsible for choosing the specific computer brand and model to purchase. Recommended system requirements are as follows: 3 GHz processor – Intel Pentium IV or AMD K6/Athlon/Duron family, or compatible processor, 512 MB of RAM, sound card, speakers or headphones, CD-ROM or DVD drive, hard disk minimum 40 GB; Microsoft Internet Explorer 6 or higher, 17" Super VGA (800 X 600) or higher resolution video adaptor and monitor, Windows XP or Windows 2000 Operating system, laser printer, and high-speed Internet access >200 Kbs (e.g., T1, cable, DSL or ADSL); e-mail account. It is expected that most institutions will have met these requirements for other business purposes but if purchasing equipment for the first time, they will incur a one-time start up cost of approximately $1200. With anticipated enrollment of 4,500 additional facilities in the next year we estimate that approximately 3% (135 facilities) will need to purchase equipment. Therefore, we estimate an annualized cost of $162,000.

Recurring costs: Healthcare facilities participating in NHSN must have access to high-speed Internet, which most have for other business purposes. No other recurring costs are anticipated.

14. Annualized Cost to the Government

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

Table 14A. Estimated Annualized Cost to the Government

Expense Item	Description	Estimated Annual Cost
Personnel	A total of 12.3 FTE/contractor personnel are actively involved in the enhancement and maintenance of the NHSN. The personnel categories and their FTE contributions are as follows: 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

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 5,140,345 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. CDC is requesting approval to add 32,200 burden hours for this information collection, for a total of 5,172,545 burden hours. There are no additional respondents for this request as they are already part of the respondent population.

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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Attachments

Attachment 1: 2007 National Blood Collection and Utilization Survey Report

Attachment 2: Current Members of the Advisory Committee on Blood Safety and Availability

Attachment 3: Members of the Inter-organizational Task Force on Biovigilance

Attachment 4: Data Collection Forms

- **4a. Form 57.300: Hemovigilance Module Annual Facility Survey**
- **4b. Form 57.301: Hemovigilance Module Monthly Reporting Plan**
- **4c. Form 57.302: Hemovigilance Module Blood Product Incident Reporting – Summary Data**
- **4d. Form 57.303: Hemovigilance Module Monthly Reporting Denominators**
- **4e. Form 57.304: Hemovigilance Incident**
- **4f. Form 57.305: Hemovigilance Adverse Reaction**