OMB No. 0920-0666 National Healthcare Safety Network (NHSN) Revision Request, April 2011

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. The respondent universe for NHSN is potentially all institutions in the United States that provide healthcare, including acute or long-term care facilities, outpatient dialysis centers, and ambulatory surgery centers. In the original application for OMB, the NHSN protocols 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. In 2006, the number of Medicare certified LTACHs was 394, ASCs 4,707 and LTCFs 15,025.

As of March 2011, NHSN facilities totaled 4468, of which 3819 are acute care facilities, 191 are specialty care facilities, 210 are long-term care facilities, 178 are outpatient dialysis centers, and 70 are ambulatory surgery centers.

2. Procedures for Collection of Information

NHSN data collection methods vary by component and event type under surveillance as chosen by the participating facility. For example, many facilities opt to do surveillance for central-line associated infections (CLABSI) in ICUs only, while facilities participating in transfusion safety surveillance, or hemovigilance, must monitor blood transfusions facility-wide. Denominator data (central line days, ventilator days, units of blood components transfused, etc.) are entered on a monthly basis. Event data (CLABSI, surgical site infections, transfusion-associated lung injury) are collected and entered on a per-event basis. Each event must meet the case definitions provided in the surveillance protocols. Collection of information methods are explained in detail in the surveillance protocols (Attachment G).

3. Methods to Maximize Response Rates and Deal with Non-response

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. Healthcare institutions must apply for membership in NHSN by completing a series of forms that include identifying and contact information and agree to collect and report data using the NHSN protocols. However, many stakeholders external to CDC encourage or require participation in NHSN for varying purposes. 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 has resulted in increasing numbers of participants. Three examples are provided below.

- As of March 2011, 23 states or territories require facilities in their jurisdictions to join NHSN to comply with legal requirements including but not limited to state or federal laws, regulations, or other requirements for mandatory reporting of healthcare facility-specific adverse event, prevention practice adherence, and other public health purposes.
- The U.S. Center for Medicare and Medicaid Services (CMS) has identified NHSN as the surveillance mechanism to enable healthcare facilities to report HAI and prevention practice adherence data in fulfillment of CMS's quality measurement reporting requirements for those data.
- Hospitals accredited by The Joint Commission (TJC) are required to conduct ongoing hospital infection surveillance but the surveillance methodology or patient groups to be included in the surveillance are not specified. The Joint Commission accepts participation in NHSN to satisfy their surveillance requirements.

Methods to deal with non-response do not apply to NHSN as it is a voluntary surveillance system that neither samples from a specified respondent universe nor attempts a census of a specified respondent universe. The data reported to NHSN are aggregated, summarized, and disseminated to participating facilities and the public through peer-review journal publications. Aggregate statistics (pooled means, median event rates, standardized infection ratios, etc.) are built into the NHSN application to allow participating facilities to compare the

facility's data with published aggregate statistics. Detailed analysis methods and results can be reviewed in the NHSN data summary reports published in the *American Journal of Infection Control*, which can be found on the NHSN website:

http://www.cdc.gov/nhsn/dataStat.html. Similar analyses of the Healthcare Personnel Safety Component and Biovigilance Component data are planned. CDC has limited ability to make population-based national estimates using these data.

NHSN is used for a variety of surveillance purposes, including a general indication of the magnitude of HAIs, monitoring HAI trends, facilitating interfacility and intrafacility comparisons with risk-adjusted data, and assisting healthcare facilities in their efforts to identify and respond to patient safety problems. These purposes, along with other NHSN purposes, are listed comprehensively in the section titled Purpose and Use of Data Collection of the Supporting Statement Part A. Historically and currently, the sample of hospitals participating in NHSN was not selected randomly, rather, hospitals enter the sample through a combination of self-selection, state requirements, and medicare incentives, as discussed above. Thus, the sample does not represent all acute care hospitals in the U.S. As a result, NHSN cannot be used for national estimates of the magnitude of HAIs or for national HAI trend analyses. Limitations of NHSN data for HAI magnitude estimates and trend analyses are acknowledged and discussed in individual reports published by CDC. These limitations do not prevent the system for HAI surveillance, including use of a single set of HAI definitions and methods by surveillance staff in hospitals throughout the U.S. and a rapidly increasing number of U.S. hospitals participating in the system. Largely because of state and federal reporting requirements, participation in NHSN has increased to approximately 4500 hospitals in spring 2011, a 15-fold rise since the system's inception in 2005 that includes an influx of smaller hospitals that were previously underrepresented. One consequence is that interfacility comparisons with risk-adjusted data now might be done with caution, acknowledging the limitations with respect to representativeness within each range of hospital sizes. Also, intrafacility comparisons with risk-adjusted data are strengthened as more data are available to improve the performance of risk models used to risk adjust outcomes in individual facilities.

4. Test of Procedures or Methods to be Undertaken

NHSN is a surveillance system that integrates legacy patient and healthcare personnel safety surveillance systems managed by the Division of Healthcare Quality Promotion (DHQP) at CDC, served as successful pilot tests of the NHSN surveillance methods. Those systems were the National Nosocomial Infection Surveillance (NNIS) system, the National Surveillance System for Healthcare Workers (NaSH), and the Dialysis Surveillance Network (DSN).

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

It is the responsibility of the CDC Division of Healthcare Quality Promotion, Surveillance Branch staff to manage and analyze data collected through NHSN. In additions, facilities and groups of facilities (quality improvement organizations, state health departments, prevention collaborative) are able to analyze their data for their own purposes.