Explanations and justifications for proposed revisions to OMB 0920-0666

All data collection tools previously approved under OMB No. 0920-0666 have been revised to some extent in this revision request. In addition, five new forms are being submitted for approval, and four forms plus two flow charts are being removed from the package. Proposed program changes are explained below.

1. The NHSN Assurance of Confidentiality has been amended, necessitating an update of the Assurance of Confidentiality language that appears at the bottom of all forms, existing and proposed.

Justification: The National Healthcare Safety Network (NHSN) is a surveillance system used to gather national data on healthcare-associated adverse events, associated risk and preventive factors, and antimicrobial use and resistance. NHSN began as a voluntary surveillance system in 2005 and is managed by the Division of Healthcare Quality Promotion (DHQP) in the National Center for Emerging and Zoonotic Infectious Diseases (formerly the National Center for Infectious Diseases and the National Center for Preparedness, Detection, and Control of Infectious Diseases). However, since its launch that year, NHSN increasingly has served as the operational system for compliance with mandatory healthcare-associated infection (HAI) reporting requirements established by states. By 2010, 21 states had opted to use NHSN as the operational system for mandatory reporting by healthcare facilities in their jurisdictions, and additional states are expected to follow with similar use of NHSN for mandatory reporting purposes. In addition, the Center for Medicare and Medicaid (CMS) will require Medicare-eligible acute care hospitals to report HAI data to CMS via NHSN beginning with hospital discharges occurring January 1, 2011 as part of the Hospital Inpatient Quality Reporting Program. Further, federal legislative proposals could establish mandatory reporting of HAI data on the federal level. Still, many healthcare facilities, even in states with mandatory reporting requirements, submit at least some HAI data to NHSN voluntarily. As a result, the HAI data reported to NHSN are a mix of data reported voluntarily and mandatorily. The amended NHSN Assurance of Confidentiality is intended to cover those data that are voluntarily provided by healthcare facilities to DHQP through the NHSN and not data that are either (1) mandated by state or federal laws, regulations, or other requirements, or (2) requested by state agencies for surveillance or prevention purposes. The language that appears at the bottom of every data collection form in the NHSN OMB package has been updated to reflect the amended Assurance of Confidentiality.

2. Expanding the scope of selected Patient Safety Component surveillance forms to include the Long Term Care Facility (LTCF) population,

proposing four new forms (57.137-57.140).

Justification: This revision request includes four forms that have been adapted from current NHSN reporting forms for use by long-term care facilities (LTCFs). These forms will be developed within the current Patient Safety Component, and would be used by facilities that self-identify as a LTCF (i.e., nursing home or skilled nursing facility). These forms have been adapted to be more applicable for LTCFs compared to the current forms used by acute care facilities. The forms include a LTCF Annual Facility Survey, LTC-specific forms for Urinary Tract Infection (UTI) and Laboratory-identified MDRO/CDI events, and an MDRO/CDI Prevention Process Measures form.

In 2008, over 3 million individuals received care in nearly 16,000 long-term care facilities in the United States. Among the 1.6 to 4 million healthcare-associated infections (HAIs) estimated to occur in LTCFs annually, the majority are endemic, with UTIs often cited as the most common cause of infection. Recent studies have shown the burden of C. difficile infections and other multidrug-resistant organisms disproportionately affect residents in LTCFs both in morbidity and mortality. Infections are the leading reason for hospitalization in LTCF residents, and the resulting costs are high ($673 million to $2 billion each year).

LTCFs are highly regulated at the federal level by the Centers for Medicare and Medicaid Services (CMS). CMS released a revised version of the “Interpretive Guidance for Infection Control in Nursing Homes – F441” in September 2009 which sets an expectation for LTCFs to perform HAI surveillance as part of their infection control program activity. However, no current standardized methodology for defining and reporting HAIs exists in this setting. The use of the NHSN system in acute care hospitals for setting national benchmarks and supporting facility-level quality improvement activity serves as a model for addressing the same HAI reporting needs in LTCFs. Adapting the current HAI reporting forms to suit LTCFs required only small changes and will provide setting-specific data to provide an accurate comparison of facility-level rates, based on characteristics of the facility and resident population. Additionally, the inclusion of LTCFs in NHSN will provide the infrastructure necessary to support the expansion of the Department of Health and Human Services (HHS) HAI Prevention Action Plan into non-hospital settings.

CDC is requesting initial approval of these forms for use in a maximum of 250 facilities annually, for a total of 2,317 burden hours. If voluntary participation by LTCFs approaches that limit, we will request a burden revision in the future.

3. Expanding the scope of the Healthcare Personnel Safety Component

Annual Facility Survey and adding a new data collection form to the Healthcare Personnel Safety Component (57.200 and 57.213).

Justification: The Healthcare Personnel Safety component within the NHSN is currently comprised of the Blood and Body Fluids Exposure and Management module and the Influenza Vaccination and Exposure Management module. This component was launched in late August 2009, and is currently collecting data using a voluntary agreement among new and existing NHSN facilities. A new data collection instrument intended as an addition to the currently available Influenza Vaccination and Exposure Management module is proposed. The new instrument would collect aggregated monthly data on seasonal and non-seasonal influenza vaccination coverage among healthcare personnel. The tool would include numbers of healthcare personnel vaccinated by month, those who declined vaccine, and those who received vaccine elsewhere. These data would provide summary statistics on the uptake of influenza vaccine in healthcare facilities, and with the current facility surveys already required each year by the NHSN, measures of vaccine coverage may be stratified by healthcare facility size or type.

Piloting work for this tool is ongoing among key stakeholders, including collaborations with the National Center for Immunization and Respiratory Diseases, and with the Centers for Medicare and Medicaid Services (CMS). It is anticipated that CMS will include this aggregated measure of influenza vaccination coverage as a future reporting requirement for hospitals' annual reimbursement. For that reason, we request approval of this form for 6,000 respondents, which would include all acute care facilities in the United States. The new data collection form may also provide a platform for current and proposed mandated state and local reporting of aggregate measures of influenza vaccination.

Currently, the data collection tool for this module focuses on individual-level vaccination and declination data. It is projected that enrollment in this module will likely increase the number of participating facilities if reporting can be submitted in summary form. As a result, the Annual Facility Surveys for this component would increase proportionally to reflect the rise in healthcare facility enrollments. For this reason, CDC proposes expanding the scope of form 57.200 from 600 respondents to 6,000.

4. Expanding the scope of and revising data collection for dialysis-related event surveillance (57.104, 57.109, 57.110, 57.119).

Justification: Expansion of the Outpatient Dialysis Center Practices Survey (57.104) from 225 respondents to 5,500 annual respondents to include all outpatient dialysis facilities in the US will facilitate the prevention objectives

presented in the HHS healthcare-associated infection (HAI) tier 2 action plan and provide measures for Healthy People (HP) 2020 goals. The ability to assess national practices, rates of vaccination and infection prevalence in dialysis centers has been deemed a priority by HHS. This survey is currently the only mechanism for measuring vaccination rates to permit assessment of progress toward HP 2020 objectives, which requires national data. CMS has also expressed interest in re-establishing the national scope of this survey to permit assessment of practices in all Medicare-certified dialysis centers for quality improvement purposes. By expanding the scope of the Dialysis Survey, we are poised for immediate implementation should CMS make such a decision. The scope of Dialysis Event and Dialysis Denominator (57.109 and 57.119) reporting is being increased from 225 to 500 annual respondents to accommodate state-mandated reporting to NHSN, CMS prevention initiatives, and CMS requirements that dialysis facilities conduct infection surveillance. In addition, the Dialysis Event (57.109) surveillance has been simplified and will result in fewer responses per respondent, which produces a net decrease in response burden for that form. Itemized changes and justifications for these forms are available in Attachment D-2.

5. Elimination of manual data entry for the Antimicrobial Use and Resistance-Microbiology Laboratory and Pharmacy Data forms (57.123 and 57.124).

Justification: As indicated in previous OMB submissions, NHSN will greatly reduce burden for reporting pharmacy and microbiology data when electronic data capture capabilities are implemented for these two forms. Clinical Document Architecture (CDA) is in development and is scheduled to be implemented in 2011. The protocol has been revised to only accommodate submission of pharmacy and microbiology data by electronic means. Thus, we have discontinued manual entry of these data, which greatly reduces the estimated response burden for these data. Rather than individual responses per respondent, users will upload these data monthly via CDA. Monthly imports of all data are estimated to take no more than five minutes each. The burden reduction is significant: we are decreasing the estimated annual burden from 810,000 hours to 6,000 hours for Microbiology Laboratory Data (57.123) and decreasing the estimated annual burden from 432,000 hours to 6,000 hours for Pharmacy Data (57.124).

6. Removing the “NHSN Agreement to Participate and Consent" form (57.102) from package as it does not collect data or information and therefore does not constitute a “data collection form.”

Justification: It was determined that the NHSN Agreement to Participate and Consent was included in previously packages erroneously. The facility demographic data that appears on the form is populated by data collected

on the Facility Contact Information form (57.101). The “NHSN Agreement to Participate and Consent” must only be printed, signed, and delivered to NHSN. The required signatures are not considered “information” for OMB purposes and therefore the consent does not require OMB approval.

7. Consolidating and simplifying Patient Vaccination surveillance (57.130-57.133).

Justification: The 2010/2011 flu vaccination is a trivalent vaccine containing H1N1 and this vaccine is recommended for all persons >= 6 months of age. Therefore, the concept of “high risk” is no longer appropriate. The Patient Vaccination surveillance forms (previously High-Risk Inpatient Influenza Vaccination) have been renamed and simplified as it is no longer necessary to capture risk criteria. After removing all risk criteria questions from 57.132, only a small number of relevant questions remain. The remaining questions were moved to form 57.133, and 57.132 is being removed from the package. Since there is a possibility that monovalent H1N1 could be recommended for certain age groups and hence it would be considered a seasonal vaccination, we need to move it into that category on the forms/screens. Itemized changes and justifications to these forms are available in Attachment D-2.

8. Updating pathogens, antimicrobials, and terminology on specific HAI event forms.

Justification: The drugs required per specific organisms were expanded on all seven of the forms that collect healthcare-associated infection (HAI) data. This was done so that the NHSN pathogen and susceptibility data match the current Clinical Laboratory Standards Institute (CLSI) testing panels and the information that is reported by clinical microbiology laboratories to physicians who treat HAIs. Without this update and expansion, the data collected within NHSN would not be accurate or useful for tracking trends and changes for the growing antimicrobial resistance among the most common pathogens that cause HAIs.

The terminology “*Clostridium difficile*-Associated Disease (CDAD)” is being changed throughout the Multidrug-Resistant Organism (MDRO) and *Clostridium difficile*-Associated Disease (CDAD) Module of NHSN to “*Clostridium difficile* Infection (CDI)”. All references to CDAD anywhere in the module and the guidance materials are being updated to CDI. This revision is occurring to keep the module and NHSN current and consistent with the correct reference terminology that is being used by the scientific community of *C. difficile* experts. The use of CDAD is outdated and no longer holds the correct meaning when referring to disease caused by the *C. difficile* pathogen. This comprehensive change will bring the now MDRO and CDI

Module up to date with the most accurate use of the scientific terminology for the illness being reported and tracked within this NHSN module.

9. All other NHSN data collection form revisions.

Justification: A number of minor revisions, updates, and clarifications have been made to the NHSN data collection forms. See Attachment D-2 for itemized NHSN data collection forms revisions and justifications. Resulting burden revisions are itemized in Attachments D-3 and D-4.

10. Removing obsolete forms from the NHSN OMB package.

57.102 Agreement to Participate and Consent.
As stated in #6 above, this “form” is not used to collect data or information and is being removed from the OMB Package.

57.132 High-Risk Inpatient Influenza Vaccination Method B Form Part 1
As stated in #7 above, data collected on this form was either omitted or added to form 57.133.

57.112 Pneumonia Flow Diagram-Any Patient
This was a decision flow chart that was never used to collect data and is no longer in use.

57.113 Pneumonia Flow Diagram-Infant and Child
This was a decision flow chart that was never used to collect data and is no longer in use.

57.135 List of Blood Isolates
This form was never implemented and will not be used in the future.

57.136 Manual Categorization of Positive Blood Cultures
This form was never implemented and will not be used in the future.