Explanations and justifications for proposed revisions to OMB 0920-0666

Twenty collection tools previously approved under OMB No. 0920-0666 have been revised to some extent in this revision request. In addition, six new forms are being submitted for approval. Proposed program changes are explained below.

1) Adding a Medicare ID number on all forms that collect patient level data.

Justification: The Centers for Medicare and Medicaid Services (CMS) have recently entered into a strong collaboration with the CDC and NHSN. CMS has chosen to designate NHSN as the reporting system into which facilities must enter data in order to fulfill the Inpatient Prospective Payment Systems (IPPS) requirements. The CMS rules have designated central line-associated bloodstream infections (CLABSIs) to be reported from acute care hospital intensive care units in 2011, and are expanding these reporting rules for 2012, and beyond. In order to assist CMS with appropriate patient and facility identification, they have requested the addition of a variable to collect the patient's Medicare Beneficiary number. Therefore, NHSN will be adding this number to all forms that collect patient identifier level data (thirteen in total). This variable will not be required, only optional, and so no additional burden adjustment is necessary.

2) Expand the scope of Long-Term Care Facility (LTCF) population coverage by adding a new LTCF NHSN Component, proposing three new forms (57.141 - 57.143).

Justification: A new Long-Term Care Facility (LTCF) Component will be used to more specifically and appropriately capture data from the residents of skilled nursing facilities. This component was to be launched in 2011, but the release has now been postponed until 2012. With the first version of this new component, users will be able to track and report urinary tract infections (UTIs), laboratory-identified (LabID) events for multidrug-resistant organisms and *C. difficile*, and/or hand hygiene and gown and gloves use, all at the facility-wide inpatient level. In order to facilitate this reporting, there are seven LTCF forms that have been created by using forms from the Patient Safety Component as a base, with modifications to specifically address the nuances of LTC residents. In the last OMB package submission from NHSN, four of the forms were included and approved. However, due to an unexpected oversight, three of the forms were not included in that package. Therefore, we are including those three remaining LTCF forms in this package submission for review and approval.

3) Expand the scope of data collection for dialysis-related event surveillance (57.109 & 57.119).

Justification: The scope of NHSN dialysis surveillance is being expanded to include all outpatient dialysis centers so that the existing Dialysis Annual Survey can be used to facilitate prevention objectives set forth in the Department of Health and Human Services (HHS) Healthcare Associated Infections Tier 2 Action Plan and to assess national practices in all Medicare-certified dialysis centers if the Centers for Medicare and Medicaid Services (CMS) reestablishes this survey method as expected. The scope was previously expanded for the Outpatient Dialysis Center Practices Survey (57.103) to 5,500 facilities. The expansion will now take place for the remaining dialysis forms (57.109 & 57.119)

4) Expand the scope of the Patient Safety Component to include an annual facility survey for Long-Term Acute Care Hospitals (57.150).

Justification: The CMS final rule for the FY 2012 IPPS includes a requirement for long-term acute care (LTAC) hospitals to report CAUTI and CLABSI data to NHSN by October 2012. As a result, all LTAC hospitals in the U.S. will be required to enroll in and report to NHSN. Since LTAC hospitals will be reporting as their own unique facility type, separate from acute care hospitals, there is a need for an LTAC-specific annual survey which will capture facility-level data specific and relevant to LTAC hospitals. The annual survey data are used for risk stratification and development of appropriate SIRs for reporting of data from LTAC hospitals.

5) Expand the scope of the Patient Safety Component to include an annual facility survey for Rehabilitation Hospitals (57.151).

Justification: The CMS final rule for the FY 2012 IPPS includes a requirement for inpatient rehabilitation facilities (IRF) hospitals to report CAUTI to NHSN by October 2012. As a result, all certified IRF hospitals in the U.S. will be required to enroll in and report to NHSN. Since IRF hospitals will be reporting as their own unique facility type, separate from acute care hospitals, there is a need for an IRF-specific annual survey which will capture facility-level data specific and relevant to IRF hospitals. The annual survey data are used for risk stratification and development of appropriate SIRs for reporting of data from IRF hospitals.

Add a proposed form (57.112) to more accurately assist in identifying ventilator-associated pneumonia cases.

Justification: A streamlined ventilator-associated pneumonia (SVAP) form is specifically introduced to provide a streamlined, objective definition via which NHSN users may detect and report cases of ventilator-associated pneumonia in adult patients only. The current NHSN pneumonia (PNEU) definitions are regarded as complex and subjective. The new SVAP definition provides an alternative means of detecting and reporting ventilator-associated pneumonia events, and may eventually replace PNEU.

7) 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.