

Explanations and justifications for proposed revisions to OMB 0920-0666

Thirty-two collection tools previously approved under OMB No. 0920-0666 have been revised to some extent in this revision request. In addition, one form is being removed from the package and nine forms are being added. Proposed program changes are explained below.

1) Addition of new NHSN Component: Dialysis Component

Justification: Over the past year, the number of outpatient dialysis facilities participating in NHSN has increased exponentially. As of May 13, 2013, there were approximately 5,700 outpatient dialysis facilities enrolled in NHSN, accounting for about 50% of all facilities in NHSN. Historically, dialysis surveillance has been a module within the Patient Safety Component along with modules for surveillance in inpatient healthcare settings. However, the outpatient dialysis setting is very different than inpatient healthcare settings, and the type of NHSN user representing outpatient dialysis facilities is different than most NHSN users representing inpatient healthcare settings. Two goals are achieved by moving dialysis to its own NHSN component:

- Tailor the NHSN user interface for dialysis users to simplify their data entry and analysis processes.
- Provide options for expanding the Dialysis Component in the future to include dialysis surveillance in settings other than outpatient facilities (e.g., home hemodialysis, peritoneal dialysis, etc.).

With the new component, four new forms were added to this ICR package:

- 57.501 – Dialysis Monthly Reporting Plan
- 57.504 – Prevention Process Measures Monthly Monitoring for Dialysis
- 57.505 – Dialysis Patient Influenza Vaccination
- 57.506 – Dialysis Patient Influenza Vaccination Denominator

Further, three previously approved forms have been renumbered to allow all forms for this new component to follow the same numbering system:

- 57.500 – Outpatient Dialysis Center Practices Survey (previously: 57.104 - Patient Safety Component-Outpatient Dialysis Center Practices Survey)
- 57.502 – Dialysis Event (previously: 57.109 – Dialysis Event)
- 57.503 – Denominator for Outpatient Dialysis (previously: 57.119 – Denominator for Outpatient Dialysis)

2) Addition of new NHSN Component: Outpatient Procedure Component

Justification: The National Healthcare Safety Network (NHSN) Outpatient Procedure Component (OPC) was developed amid increasing interest in the public health impact of infections and other outcomes related to outpatient procedures that are performed in settings such as Ambulatory Surgery Centers (ASCs), Hospital Outpatient Departments (HOPDs), and physicians' offices. Though outbreak investigations by state health departments and the Centers for Disease Control and Prevention (CDC) have shown that serious adverse outcomes of outpatient procedures do occur, there are no national estimates of the number of healthcare associated infections (HAIs) or other adverse outcomes originating in ASCs or HOPDs. As of 2010, there were more than 5,300 Medicare-certified ASCs in the U.S., which represents an approximate 50% increase since 2002. Also, a majority (89%) of acute care hospitals provided

outpatient surgery services in 2009 (<http://www.medpac.gov/chapters/Jun10DataBookSec8.pdf>, chart 8-8 and 8-15).

The OPC provides surveillance methods to identify and track process and outcomes measures of outpatient procedures that are performed in freestanding ASCs. It is anticipated that some or all event types of the OPC may also be available for future use in HOPDs. However, more work is needed to address how to implement the OPC without requiring duplicative or burdensome new reporting requirements in addition to the surgical site infection (SSI) and CMS, Hospital Outpatient Quality Reporting measures that are already being reported by HOPDs.

Three event types are included in the NHSN Outpatient Procedure Component (OPC) and planned for implementation beginning in 2014: Same Day Outcome Measures, Prophylactic Intravenous (IV) Antibiotic Timing, and Surgical Site Infection (SSI). Four forms have been added to this package with the implementation of this component:

- 57.400 - Outpatient Procedure Component - Annual Facility Survey
- 57.401 - Outpatient Procedure Component - Monthly Reporting Plan
- 57.402 - Outpatient Procedure Component Event
- 57.403 - Outpatient Procedure Component - Monthly Denominators and Summary

3) Revision of antibiogram requirements on all NHSN healthcare-associated event (HAI) forms

Justification: The breadth of organism susceptibility data required on all of the healthcare-associated infection (HAI) report forms (i.e., BSI, UTI, SSI, PNEU (VAP and VAE), DE, LTUTI, and MDRO Infection Surveillance) has been reduced for the purposes of streamlining, simplification, and removing undue burden where possible. Of those that are tracked and reported, the remaining required organisms and antimicrobials are among the most common to cause HAIs reported into NHSN. As these organisms cause the most serious resistant infections, it is important to infection prevention and control that these requirements remain. The specific reductions include: removal of “Intermediate” as a susceptibility result category for Colistin/Polymyxin B to match standardized test results; two less commonly reported pathogens were completely removed - *Serratia marcescens* and *Stenotrophomonas maltophilia*; seven antibiotics of lower concern were removed for Enterococcus reporting; antibiogram requirements for Enterococcus will be limited to the most common and serious species - *Enterococcus faecalis*, *Enterococcus faecium* and *Enterococcus* spp. not identified to the species level; two antibiotics of lower concern were removed for *Staphylococcus aureus*; one antibiotic of lower concern was removed for the Enterobacteriaceae organisms (*E.coli*, *Enterobacter*, *Klebsiella*); and the antibiogram requirements for *Klebsiella* will be limited to the most common and serious - *Klebsiella pneumoniae* and *Klebsiella oxytoca*.

4) Significant changes to Hemovigilance forms.

Justification: Significant changes were made to the NHSN Biovigilance Component as a result of a subject matter expert and stakeholder working groups conducted in Spring 2013. The changes made to the six Hemovigilance forms in this PRA package are aimed at decreasing the burden and increasing the participation for this component of NHSN. One form, 57.302-Hemovigilance Module Monthly Incident Summary, was removed from this package as it was

determined that this form should no longer be required per NHSN Biovigilance surveillance protocol. All five remaining Hemovigilance forms underwent significant revisions.

5) New form added to the package: 57.600-State Health Department Validation Record
Justification: This new form represents a collection of aggregate validation results that will be collected by state health departments when conducting facility-level validation of NHSN healthcare-associated infection (HAI) data within their jurisdictions using the CDC/NHSN Validation Guidance and Toolkits. Validation of NHSN data is important to state health departments as the data are used for facility reimbursement, policy making, and consumer information. The NHSN application will be built to accept these data entries and will maintain a dataset that will provide state health departments with calculations of sensitivity, specificity, and accuracy of the NHSN facility-reported HAI data. This form allows state health departments to collect validation data for any of the possible mandated HAIs and for any year of data that is validated. The purpose of state health departments entering these data into NHSN is to maintain high-level security of facility-specific validation results. The data collection form and the calculations and aggregations of entered data is being provided to the state health departments to maintain standardized, comparable, and reliable validation results. This also serves to ease the burden off of state health departments for the independent creation of data collection forms, a system database, and appropriate metric calculations.

6) 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.