Explanations and justifications for proposed revisions to OMB 0920-0666

The proposed ICR is comprised of 34 data collection tools under OMB No. 0920-0666 that will be updated in this revision request. Details related to changes in each NHSN component are provided below:

- 1. Ten form updates were made to the Patient Safety Component (PSC) (57.103,57.106, 57.108, 57.113, 57.114, 57.116, 57.117, 57.122, 57.123, 57.124). **Justification:** Ten forms within the NHSN Patient Safety Component are changing with this ICR. The number of reporting facilities using the patient safety forms 57.103,57.117, 57.123, and 57.124 have increased to reflect the actual number of facilities reporting data into NHSN for a more accurate burden estimate. Last year NHSN updated its reporting facilities using internal data for facilities that have reported data into NHSN. NHSN has added optional fields to form 57.108 to detect risk factors that can be associated with a blood-stream infection (BSI) but can potentially be excluded from CLABSI surveillance. Collection of this data will help with analysis of BSIs not associated with central line use. For form 57.106, an addition was made to the response options under the Device Associated Module of the form to accommodate the new NHSN Pediatric Ventilator Associated Event (PedVAE) surveillance module scheduled to be released in 2019. For form 57.113, the PedVAC was removed due to the scientific algorithm being single tiered and there only being one specific event for PedVAE. For 57.114, response options were updated to include "Suprapubic tenderness" to align the form with NHSN protocols. There is now a ventilator associated event available for NICU locations requiring related denominator reporting, in which CDC has provided an option to accommodate facilities that are reporting requested data by updating form 57.116, 57.117, and 57.121. NHSN has updated the Antimicrobial Use and Resistance (AUR) Data collection tools to monitor additional organisms and their antimicrobial susceptibility profiles, which will aid hospitals in clinical decision-making and assist with prioritizing transmission prevention efforts. The new optional survey form (57.122), has been added to the Patient Safety Component that is designed to be completed by state and local health departments that participate in HAI surveillance and prevention activities. This new form will provide data on legal and regulatory requirements that are pertinent to HAI reporting. CDC plans to include data from the health department survey in its annual National and State Healthcare-Associated Infection Progress Report. The report helps identify the progress in HAI surveillance and prevention at the state and national levels. Data about the extent to which state health departments have validated HAI data that healthcare facilities in their jurisdiction report to NHSN and the extent of state and local health department HAI reporting requirements are important data for users of CDC's HAI Progress Report to consider when they are reviewing and interpreting data in the report.
- 2. Three form updates to the Long-term Care Facility (LTCF) Component (57.139, 57.140,57.142).

Justification: Three LTCF forms will be updated, two of which (57.139, 57.142), will include an update for facilities to document the "CDI treatment start" variable. Early CDI reporting data from nursing homes has shown exceptionally low event rates for many

reporting facilities (e.g., zero events for six or more months). Since current CDI event detection is based on presence of a positive laboratory specimen, variability in the use of diagnostic testing as part of CDI management will have direct impact on the estimate of CDI burden in a facility (e.g., empiric treatment for CDI without confirmatory testing may result in the appearance of low disease burden). To determine whether low CDI event rates might be due to empiric CDI treatment practices, a new process measure is incorporated into the monthly summary data on CDI for LTCFs. This measure, called "CDI treatment starts", will allow providers to capture the number of residents started on antibiotic treatment for CDI that month based on clinical decisions (i.e., even those without a positive CDI test). This process measure should provide data on clinically treated CDI to inform our understanding of CDI management practices and serve as a proxy for CDI burden in nursing homes. CDC's alliance with CMS on a voluntary National Nursing Home Quality Collaborative, which focuses on the recruitment and retention of nursing homes collecting and reporting data into the NHSN in efforts to track and prevent Clostridioides difficile infections has contributed to these form revisions (57.140). Recruitment and NHSN enrollment began in May 2016 and continued through July 2019.

3. Three form updates to the Dialysis Component (57.500, 57.501, and 57.504).

Justification: (57.500) CDC added a new question and revised multiple response options to have a more accurate count of the facilities which are accredited by an organization outside of CMS and to better reflect the information captured using this data collection tool. (57.504)There is a decrease in the number of reporting facilities from 2,000 to 1,000 due to a decline in usage. (57.501) The 'Injection Safety' field on the Prevention Process Measures (PPM) summary form was split into two fields: 'Injection Safety- Medication Preparation' and 'Injection Safety – Medication Administration'. CDC is modifying the 'Injection Safety' field on the MRP to align with the PPM summary form to allow a user to indicate which injection safety practice(s) they are observing in-plan.

4. Fifteen forms updates in the Hemovigilance Module (57.300, 57.307, 57.308, 57.309, 57.310, 57.311, 57.312, 57.313, 57.314, 57.315, 57.316, 57.317, 57.318, 57.319, 57.320).

Justification: The Hemovigilance module survey (57.300) and 14 Adverse Reaction forms within the Biovigilance Component were modified (57.307-57.320) with this ICR. (57.300) Data collected on facility demographics has been made electronic and will now auto-populate data into the form that is pulled from the NHSN application, which will decrease the overall burden for the annual survey. (57.307-57.320) Response options for blood type and treatment were revised on each form to capture more detailed patient-specific treatment data, which will not affect the overall burden for these forms.

5. Removal of NHSN Healthcare Personnel Safety Monthly Reporting Plan form (57.203)

Justification: The removal of form (57.203) to meet the statutory waiver requirements for immunization-related work. The form is no longer included under this ICR.

6. Three form updates to the annual surveys for Patient Safety Component (57.103,57.150, and 57.151).

Justification: Three annual facility surveys for the Patient Safety Component for Hospitals (57.103), Long-Term Acute Care Facilities (57.150) and Inpatient Rehabilitation Facilities (57.151) in this ICR. Five questions on all three (3) surveys to add further clarity to the reporting requirements for the data collected on fungal testing, facility locations, and laboratory testing locations. Additionally, corresponding response options for these questions are revised to include updated testing methods used by facilities to capture current HAI specific data specification requirements for reporting to NHSN. Four (4) new required questions to all the surveys. The new questions will capture information related to existing protocols, policies, and standards organized by reporting facilities to ensure that when an event is detected the facility has the appropriate mechanism to conduct complete reporting. The hospital annual survey (57.103) added six required questions to capture information about neo-natal antimicrobial stewardship practices that differ from current practices conducted in adult and pediatric locations of facilities previously captured on the survey. Ten questions were removed and replaced on all three surveys to align better with the Core Elements of Hospital Antibiotic Stewardship guidelines from CDC to better describe the current stewardship programs. These guidelines are part of the larger CDC action plan of combating Antibiotic-resistant Bacteria. The new questions will add granularity to provide a better depiction of hospitals current stewardship programs. Finally, ten new optional question about hospitals antibiotic stewardship practices were added to all three surveys to add supplemental details related to the required questions.