Explanations and justifications for proposed revisions to OMB 0920-0666

Forty-four previously approved data collection tools under OMB No. 0920-0666 have been revised in this revision request. More specifically, forms are being revised to improve data collection. NHSN has experienced growth and an increase and decrease in some of its reporting facilities, and two forms are being added to this package. CDC is introducing a water management program related to Legionnaires' disease, which will add optional questions to four existing annual surveys. The new survey questions are added to allow facilities the opportunity to utilize NHSN as a resource for assessment and documentation of their specific policies and practices around water management. Proposed program changes are explained below.

1) Significant updates to annual facility surveys (57.103, 57.137, 57.150, 57.151, 57.404, 57.500, and 57.507)

Justification: Based on user feedback and internal reviews of the annual facility surveys, it was determined that questions and response options be amended, removed, or added to fit the evolving uses of the annual facility surveys. The surveys are being increasingly used to help intelligently interpret the other data elements reported into NHSN. Currently the surveys are used to appropriately risk-adjust the numerator and denominator data entered into NHSN while also guiding DHQP decisions on future division priorities for prevention.

2) Outpatient Procedure Component will be updating four data collection forms and adding two new forms to NHSN (57.400,57.401,57.402,57.403, and 57.404)

Justification: The addition of these forms will allow NHSN to collect data amid increasing interest in the public health impact of SSIs in Ambulatory Surgery Center (ASC) environment. The forms are adapted from those used in the Patient Safety – SSI Protocol and intended for use by ASCs as part of a standardized, evidence-based surveillance program for identifying and tracking incidence and outcomes of healthcare-associated infections in this unique patient care environment. Data collected by use of these forms may be used by ASCs to identify areas where prevention of SSIs may be improved. Additional changes were made to the form names to better align with the information being collected in the forms.

3) Fourteen adverse reaction forms were updated in the Hemovigilance Module (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: Medical History questions on all 14 forms are optional to report, and sub-questions for Transfusion History and Patient Treatment sections are now optional. Also, an 'Unknown' response option is added under the Patient Treatment Section of the Biovigilance Adverse Reaction Event on all 14 forms, which will eliminate recall bias for facilities. Based on user feedback, there was more time requested to acclimate to newly required fields. CDC opted to change the new fields from required to optional. This will allow for more robust data

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collection to identify emerging trends in transfusion-related adverse events among these facilities.

4) Seven forms were revised in the Patient Safety Component (57.108, 57.112, 57.113, 57.114, 57.116, 57.117, and 57.118)

Justification: Revisions were made to reflect the information that is conditionally required in denominator collection for Ventilator days when conducting PedVAE and Optional denominator collection for Patient days, Ventilator days, and Episodes of Mechanical Ventilation (EMV) for gestational age categories. In addition, more fields are being made optional to collect APRV denominator days within each form.

5) All other NHSN data collection form revisions.

Justification: A number of minor revisions, updates, and clarifications have been made to 38 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.