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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-0666]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled National Healthcare Safety Network (NHSN) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on June 5, 2019 to obtain comments from the public and affected agencies. CDC received two comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Healthcare Safety Network (NHSN) – Revision – National Center for Emerging and Zoonotic Infection Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC) collects data from healthcare facilities in the National Healthcare Safety Network (NHSN) under OMB Control Number 0920-0666. During the early stages of its development, NHSN began as a voluntary surveillance system in 2005 managed by DHQP. NHSN provides facilities, states, regions, and the nation with data necessary to identify problem areas, measure the progress of prevention efforts, and ultimately eliminate healthcare-associated infections (HAIs) nationwide. NHSN allows healthcare facilities to track blood safety errors and various healthcare-associated infection prevention practice methods such as healthcare personnel influenza vaccine status and corresponding infection control adherence rates.

NHSN currently has six components: Patient Safety (PS), Healthcare Personnel Safety (HPS), Biovigilance (BV), Long-Term Care Facility (LTCF), Outpatient Procedure (OPC), and the Dialysis Component. NHSN's new Neonatal Component is expected to

launch during the summer of 2020. This component will focus on premature neonates and the healthcare-associated events that occur as a result of their prematurity. This component will be released with one module, which includes Late Onset-Sepsis and Meningitis. Late-onset sepsis (LOS) and Meningitis are common complications of extreme prematurity. Studies have indicated that 36% of extremely low gestational age (22-28 weeks) infants develop LOS and that 21% of very low birth weight infants surviving beyond three days of life will develop LOS. Meningitis occurs in 23% of bacteremic infants, but 38% of infants with a pathogen isolated from the cerebrospinal fluid may not have an organism isolated from blood. These infections are usually serious, causing a prolongation of hospital stay, increased cost, and risk of morbidity and mortality.

Some cases of LOS can be prevented through proper central line insertion and maintenance practices. These are addressed in the CDC's Healthcare Infection Control Practices Advisory Committee (CDC/HICPAC) *Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011*. However, almost one-third of LOS events in a quality-improvement study were not related to central-lines. Prevention strategies for the non-central line –related infection events have yet to be fully defined, but include adherence to hand-hygiene, parent and visitor education, and optimum nursery design features. Other

areas that likely influence the development of LOS include early enteral nutritional support and skin care practices. The data for this module will be electronically submitted, and manual data entry will not be available. This will allow more hospital personnel to be available to care for patients and will reduce annual burden across healthcare facilities. Additionally, LOS data will be utilized for prevention initiatives.

Data reported under the Patient Safety Component are used to determine the magnitude of the healthcare-associated adverse events and trends in the rates of the events, in the distribution of pathogens, and in the adherence to prevention practices. Data will help detect changes in the epidemiology of adverse events resulting from new medical therapies and changing patient risks. Additionally, reported data is being used to describe the epidemiology of antimicrobial use and resistance and to better understand the relationship of antimicrobial therapy to this rising problem. Under the Healthcare Personnel Safety Component, protocols and data on events—both positive and adverse—are used to determine (1) the magnitude of adverse events in healthcare personnel, and (2) compliance with immunization and sharps injuries safety guidelines. Under the Biovigilance Component, data on adverse reactions and incidents associated with blood transfusions are reported and analyzed to provide national estimates of adverse reactions and incidents.

Under the Long-Term Care Facility Component, data is captured from skilled nursing facilities. Reporting methods under the LTCF component have been created by using forms from the PS Component as a model with modifications to specifically address the specific characteristics of LTCF residents and the unique data needs of these facilities reporting into NHSN. The Dialysis Component offers a simplified user interface for dialysis users to streamline their data entry and analyses processes as well as provide options for expanding in the future to include dialysis surveillance in settings other than outpatient facilities. The Outpatient Procedure Component (OPC) gathers data on the impact of infections and outcomes related to operative procedures performed in Ambulatory Surgery Centers (ASCs). The OPC is used to monitor two event types: Same Day Outcome Measures and Surgical Site Infections (SSIs).

NHSN has increasingly served as the operating system for HAI reporting compliance through legislation established by the states. As of March 2019, 36 states, the District of Columbia and the City of Philadelphia, Pennsylvania have opted to use NHSN as their primary system for mandated reporting. Reporting compliance is completed by healthcare facilities in their respective jurisdictions, with emphasis on those states and municipalities acquiring varying consequences for failure to use NHSN. Additionally, healthcare facilities in five U.S.

territories (Puerto Rico, American Samoa, the U.S. Virgin Islands, Guam, and the Northern Mariana Islands) are voluntarily reporting to NHSN. Additional territories are projected to follow with similar use of NHSN for reporting purposes.

NHSN's data is used to aid in the tracking of HAIs and guide infection prevention activities/practices that protect patients. The Centers for Medicare and Medicaid Services (CMS) and other payers use these data to determine incentives for performance at healthcare facilities across the US and surrounding territories, and members of the public may use some protected data to inform their selection among available providers. Each of these parties is dependent on the completeness and accuracy of the data. CDC and CMS work closely and are fully committed to ensuring complete and accurate reporting, which are critical for protecting patients and guiding national, state, and local prevention priorities.

CMS collects some HAI data and healthcare personnel influenza vaccination summary data, which is done on a voluntary basis as part of its Fee-for-Service Medicare quality reporting programs, while others may report data required by a federal mandate. Facilities that fail to report quality measure data are subject to partial payment reduction in the applicable Medicare Fee-for-Service payment system. CMS links their quality reporting to payment for Medicare-eligible acute care hospitals,

inpatient rehabilitation facilities, long-term acute care facilities, oncology hospitals, inpatient psychiatric facilities, dialysis facilities, and ambulatory surgery centers. Facilities report HAI data and healthcare personnel influenza vaccination summary data to CMS via NHSN as part of CMS's quality reporting programs to receive full payment. Still, many healthcare facilities, even in states without HAI reporting legislation, submit limited HAI data to NHSN voluntarily.

NHSN's data collection updates continue to support the incentive programs managed by CMS. For example, survey questions support requirements for CMS' quality reporting programs. Additionally, CDC has collaborated with CMS on a voluntary National Nursing Home Quality Collaborative, which focuses on recruiting nursing homes to report HAI data to NHSN and to retain their continued participation. This project has resulted in a significant increase in long-term care facilities reporting to NHSN. The collection of information is authorized by the Public Health Service Act (42 U.S.C. 242b, 242k, and 242m (d)).

The proposed changes in this new ICR include revisions made to 40 NHSN data collection tools for a total of 76 data collection tools included in this ICR. The reporting burden decreased by 2,363,508 hours for a total estimated burden of 3,033,930 hours.

Estimated Annualized Burden Hours

Respondent Type	Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)
Healthcare Practitioner	57.100 NHSN Registration Form	2,000	1	5/60
	57.101 Facility Contact Information	2,000	1	10/60
	57.103 Patient Safety Component--Annual Hospital Survey	5,175	1	75/60
	57.105 Group Contact Information	1,000	1	5/60
	57.106 Patient Safety Monthly Reporting Plan	6,000	12	15/60
	57.108 Primary Bloodstream Infection (BSI)	5,775	5	38/60
	57.111 Pneumonia (PNEU)	1,800	30	30/60
	57.112 Ventilator-Associated Event	5,500	5	28/60
	57.113 Pediatric Ventilator-Associated Event (PedVAE)	334	120	30/60
	57.114 Urinary Tract Infection (UTI)	5,500	5	20/60
	57.115 Custom Event	600	91	35/60
	57.116 Denominators for Neonatal Intensive Care Unit (NICU)	220	12	249/60
	57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	165	12	302/60
	57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	5,500	60	302/60
	57.120 Surgical Site		11	35/60

Respondent Type	Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)
	Infection (SSI)	4,500		
	57.121 Denominator for Procedure	4,500	680	10/60
	57.122 HAI Progress Report State Health Department Survey	55	1	45/60
	57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	1,500	12	5/60
	57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	2,000	12	5/60
	57.125 Central Line Insertion Practices Adherence Monitoring	500	213	25/60
	57.126 MDRO or CDI Infection Form	720	12	30/60
	57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	5,500	29	15/60
	57.128 Laboratory-identified MDRO or CDI Event	4,800	87	20/60
	57.129 Adult Sepsis	50	250	25/60
	57.137 Long-Term Care Facility Component – Annual Facility Survey	2,220	1	120/60
	57.138 Laboratory-identified MDRO or CDI Event for LTCF	2,150	24	15/60
	57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	2,200	12	20/60
	57.140 Urinary Tract		12	30/60

Respondent Type	Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)
	Infection (UTI) for LTCF	400		
	57.141 Monthly Reporting Plan for LTCF	2,220	12	5/60
	57.142 Denominators for LTCF Locations	2,220	12	250/60
	57.143 Prevention Process Measures Monthly Monitoring for LTCF	375	12	5/60
	57.150 LTAC Annual Survey	500	1	70/60
	57.151 Rehab Annual Survey	1,200	1	70/60
	57.200 Healthcare Personnel Safety Component Annual Facility Survey	50	1	480/60
	57.203 Healthcare Personnel Safety Monthly Reporting Plan	-	1	5/60
	57.204 Healthcare Worker Demographic Data	50	200	20/60
	57.205 Exposure to Blood/Body Fluids	50	50	60/60
	57.206 Healthcare Worker Prophylaxis/Treatment	50	30	15/60
	57.207 Follow-Up Laboratory Testing	50	50	15/60
	57.210 Healthcare Worker Prophylaxis/Treatment-Influenza	50	50	10/60
	57.300 Hemovigilance Module Annual Survey	500	1	85/60
	57.301 Hemovigilance Module Monthly Reporting Plan	500	12	1/60

Respondent Type	Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)
	57.303 Hemovigilance Module Monthly Reporting Denominators	500	12	70/60
	57.305 Hemovigilance Incident	500	10	10/60
	57.306 Hemovigilance Module Annual Survey - Non-acute care facility	500	1	35/60
	57.307 Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction	500	4	20/60
	57.308 Hemovigilance Adverse Reaction - Allergic Transfusion Reaction	500	4	20/60
	57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction	500	1	20/60
	57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction	500	2	20/60
	57.311 Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction	500	4	20/60
	57.312 Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction	500	1	20/60
	57.313 Hemovigilance Adverse Reaction - Infection	500	1	20/60
	57.314 Hemovigilance Adverse Reaction - Post Transfusion Purpura	500	1	20/60
	57.315 Hemovigilance		1	20/60

Respondent Type	Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)
	Adverse Reaction - Transfusion Associated Dyspnea	500		
	57.316 Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease	500	1	20/60
	57.317 Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury	500	1	20/60
	57.318 Hemovigilance Adverse Reaction - Transfusion Associated Circulatory Overload	500	2	20/60
	57.319 Hemovigilance Adverse Reaction - Unknown Transfusion Reaction	500	1	20/60
	57.320 Hemovigilance Adverse Reaction - Other Transfusion Reaction	500	1	20/60
	57.400 Outpatient Procedure Component— Annual Facility Survey	700	1	10/60
	57.401 Outpatient Procedure Component - Monthly Reporting Plan	700	12	15/60
	57.402 Outpatient Procedure Component Same Day Outcome Measures	200	1	40/60
	57.403 Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures	200	400	40/60
	57.404 Outpatient Procedure Component – SSI Denominator	700	100	40/60

Respondent Type	Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)
	57.405 Outpatient Procedure Component - Surgical Site (SSI) Event	700	5	40/60
	57.500 Outpatient Dialysis Center Practices Survey	7,100	1	127/60
	57.501 Dialysis Monthly Reporting Plan	7,100	12	5/60
	57.502 Dialysis Event	7,100	30	25/60
	57.503 Denominator for Outpatient Dialysis	7,100	12	10/60
	57.504 Prevention Process Measures Monthly Monitoring for Dialysis	1,760	12	75/60
	57.505 Dialysis Patient Influenza Vaccination	860	60	10/60
	57.506 Dialysis Patient Influenza Vaccination Denominator	860	1	5/60
	57.507 Home Dialysis Center Practices Survey	430	1	30/60

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