

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|---|--|-----------------------|------------------------------------|--|
| EDN data entry staff at state and local health departments. | The EDN Tuberculosis Follow-up Worksheet for Newly-Arrived Persons With Overseas Tuberculosis Classifications. | 550 | 48 | 30/60 |

Jeffrey Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-18-0666; Docket No. CDC-2018-0042]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National Healthcare Safety Network (NHSN). NHSN is a public health surveillance system that collects, analyzes, reports, and makes available data for monitoring, measuring, and responding to healthcare associated infections (HAIs), antimicrobial use and resistance, blood transfusion safety events, and the extent to which healthcare facilities adhere to infection prevention practices and antimicrobial stewardship.

DATES: CDC must receive written comments on or before July 10, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0042 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.

- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and

4. 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 submissions of responses.
5. Assess information collection costs.

Proposed Project

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

Background and Brief Description

NHSN is a public health surveillance system that collects, analyzes, reports, and makes available data for monitoring, measuring, and responding to healthcare associated infections (HAIs), antimicrobial use and resistance, blood transfusion safety events, and the extent to which healthcare facilities adhere to infection prevention practices and antimicrobial stewardship. The data collected will be used to inform and detect changes in the epidemiology of adverse events resulting from new and current medical therapies and changing risks. NHSN is comprised of six components: Patient Safety, Healthcare Personnel Safety, Biovigilance, Long-Term Care Facility, Outpatient Procedure, and Dialysis.

Changes were made to 33 data collection facility surveys with this new ICR. CDC revised three annual facility surveys for the Patient Safety component for Hospitals, Long-Term Acute Care Facilities, and Inpatient Rehabilitation Facilities. CDC's revisions clarify the reporting requirements for the data collected on fungal testing, facility locations, and laboratory testing locations. Additionally, corresponding response

options for these questions have been revised to include updated testing methods used by facilities to capture current HAI specific data specification requirements for NHSN. New required questions have been added to all Patient Safety component surveys. The new questions are designed to provide data on surveillance processes, policies, and standards that are used 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 added new required questions to provide data about neonatal antimicrobial stewardship practices because the focus of stewardship efforts in neonatology differ from the focus in adult and pediatric practice. Questions were removed and replaced on all three Patient Safety surveys to align better with the Core Elements of Hospital Antibiotic Stewardship Programs specified by CDC. The Core Elements defined by CDC are part of broad-based efforts by CDC and its healthcare and public health partners to combat the threat of antibiotic-resistant bacteria. The new Antibiotic Stewardship Program questions will provide additional data about operational features of the programs that hospitals have implemented, which in turn will enable CDC and its healthcare and public health partners to target their efforts to help invigorate and extend antibiotic stewardship.

CDC is introducing a new optional survey form 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 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.

NHSN now includes a ventilator-associated event available for NICU locations, which requires additional denominator reporting, in which CDC has provided an option to accommodate facilities that are reporting requested data by updating the corresponding surveys. The Pediatric Ventilator-Associated Event (PedVAE) was removed from the survey because a single algorithm is used to detect PedVAE events.

NHSN has made updates to the Antimicrobial Use and Resistance (AUR) data collection tools for the purposes of monitoring additional microorganisms and their antimicrobial susceptibility profiles. Use of these updates in AUR surveillance will provide important additional data for clinical and public health responses to mounting antibiotic resistance problems.

The Long-term Care Facility Component (LTCF) will be updating three forms, two of which 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). In order to determine whether low CDI event rates might be due to empiric CDI treatment practices, a new process measure will be 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 in order to inform our understanding of CDI management practices and serve as a proxy for CDI burden in nursing homes.

Overall, minor revisions have been made to a total of 33 forms within the package to clarify and/or update surveillance definitions, increase or decrease the number of reporting facilities, and add new forms.

The previously approved NHSN package included 72 individual collection forms; the current revision request includes a total of 73 forms. The reporting burden will decrease by 109,745 hours, for a total of 5,393,725 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---------------------------|---|-----------------------|------------------------------------|--|-------------------------|
| Healthcare facility | 57.100 NHSN Registration Form | 2,000 | 1 | 5/60 | 167 |
| | 57.101 Facility Contact Information | 2,000 | 1 | 10/60 | 333 |
| | 57.103 Patient Safety Component—Annual Hospital Survey. | 6,000 | 1 | 1.17 | 7,500 |
| | 57.105 Group Contact Information | 1,000 | 1 | 5/60 | 83 |
| | 57.106 Patient Safety Monthly Reporting Plan | 6,000 | 12 | 15/60 | 18,000 |
| | 57.108 Primary Bloodstream Infection (BSI) ... | 6,000 | 44 | 33/60 | 145,200 |
| | 57.111 Pneumonia (PNEU) | 1,800 | 72 | 30/60 | 64,800 |
| | 57.112 Ventilator-Associated Event | 6,000 | 144 | 28/60 | 403,200 |
| | 57.113 Pediatric Ventilator-Associated Event (PedVAE). | 100 | 120 | 30/60 | 6,000 |
| | 57.114 Urinary Tract Infection (UTI) | 6,000 | 40 | 20/60 | 80,000 |
| | 57.115 Custom Event | 600 | 91 | 35/60 | 31,850 |
| | 57.116 Denominators for Neonatal Intensive Care Unit (NICU). | 6,000 | 12 | 4 | 288,000 |
| | 57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC). | 2,000 | 9 | 5.03 | 90,600 |

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---------------------|---|-----------------------|------------------------------------|--|-------------------------|
| | 57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA). | 6,000 | 60 | 5.03 | 1,812,000 |
| | 57.120 Surgical Site Infection (SSI) | 6,000 | 36 | 35/60 | 126,000 |
| | 57.121 Denominator for Procedure | 6,000 | 540 | 10/60 | 540,000 |
| | 57.122 HAI Progress Report State Health Department Survey. | 55 | 1 | 45/60 | 41 |
| | 57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables. | 1,000 | 12 | 5/60 | 1,000 |
| | 57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables. | 2,000 | 12 | 5/60 | 2,000 |
| | 57.125 Central Line Insertion Practices Adherence Monitoring. | 100 | 100 | 25/60 | 4,167 |
| | 57.126 MDRO or CDI Infection Form | 6,000 | 72 | 30/60 | 216,000 |
| | 57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring. | 6,000 | 24 | 15/60 | 36,000 |
| | 57.128 Laboratory-identified MDRO or CDI Event. | 6,000 | 240 | 20/60 | 480,000 |
| | 57.129 Adult Sepsis | 50 | 250 | 25/60 | 5,208 |
| | 57.137 Long-Term Care Facility Component—Annual. | 2,600 | 1 | 2 | 5,200 |
| | Facility Survey: | | | | |
| | 57.138 Laboratory-identified MDRO or CDI Event for LTCF. | 2,600 | 12 | 20/60 | 10,400 |
| | 57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF. | 2,600 | 12 | 20/60 | 10,400 |
| | 57.140 Urinary Tract Infection (UTI) for LTCF. | 2,600 | 14 | 35/60 | 18,200 |
| | 57.141 Monthly Reporting Plan for LTCF | 2,600 | 12 | 5/60 | 2,600 |
| | 57.142 Denominators for LTCF Locations | 2,600 | 12 | 4.17 | 130,000 |
| | 57.143 Prevention Process Measures Monthly Monitoring for LTCF. | 2,600 | 12 | 5/60 | 2,600 |
| | 57.150 LTAC Annual Survey | 400 | 1 | 1.17 | 467 |
| | 57.151 Rehab Annual Survey | 1,000 | 1 | 1.17 | 1,167 |
| | 57.200 Healthcare Personnel Safety Component Annual Facility Survey. | 50 | 1 | 8 | 400 |
| | 57.203 Healthcare Personnel Safety Monthly Reporting Plan. | 19,500 | 1 | 5/60 | 1,625 |
| | 57.204 Healthcare Worker Demographic Data. | 50 | 200 | 20/60 | 3,333 |
| | 57.205 Exposure to Blood/Body Fluids | 50 | 50 | 1 | 2,500 |
| | 57.206 Healthcare Worker Prophylaxis/Treatment. | 50 | 30 | 15/60 | 375 |
| | 57.207 Follow-Up Laboratory Testing | 50 | 50 | 15/60 | 625 |
| | 57.210 Healthcare Worker Prophylaxis/Treatment-Influenza. | 50 | 50 | 10/60 | 417 |
| | 57.300 Hemovigilance Module Annual Survey. | 500 | 1 | 1.42 | 708 |
| | 57.301 Hemovigilance Module Monthly Reporting Plan. | 500 | 12 | 1/60 | 100 |
| | 57.303 Hemovigilance Module Monthly Reporting Denominators. | 500 | 12 | 1.17 | 7,000 |
| | 57.305 Hemovigilance Incident | 500 | 10 | 10/60 | 833 |
| | 57.306 Hemovigilance Module Annual Survey—Non-acute care facility. | 200 | 1 | 35/60 | 117 |
| | 57.307 Hemovigilance Adverse Reaction—Acute Hemolytic Transfusion Reaction. | 500 | 4 | 20/60 | 667 |
| | 57.308 Hemovigilance Adverse Reaction—Allergic Transfusion Reaction. | 500 | 4 | 20/60 | 667 |
| | 57.309 Hemovigilance Adverse Reaction—Delayed Hemolytic Transfusion Reaction. | 500 | 1 | 20/60 | 167 |
| | 57.310 Hemovigilance Adverse Reaction—Delayed Serologic Transfusion Reaction. | 500 | 2 | 20/60 | 333 |

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---------------------|---|-----------------------|------------------------------------|--|-------------------------|
| | 57.311 Hemovigilance Adverse Reaction—Febrile Non-hemolytic Transfusion Reaction. | 500 | 4 | 20/60 | 667 |
| | 57.312 Hemovigilance Adverse Reaction—Hypotensive Transfusion Reaction. | 500 | 1 | 20/60 | 167 |
| | 57.313 Hemovigilance Adverse Reaction—Infection. | 500 | 1 | 20/60 | 167 |
| | 57.314 Hemovigilance Adverse Reaction—Post Transfusion Purpura. | 500 | 1 | 20/60 | 167 |
| | 57.315 Hemovigilance Adverse Reaction—Transfusion Associated Dyspnea. | 500 | 1 | 20/60 | 167 |
| | 57.316 Hemovigilance Adverse Reaction—Transfusion Associated Graft vs. Host Disease. | 500 | 1 | 20/60 | 167 |
| | 57.317 Hemovigilance Adverse Reaction—Transfusion Related Acute Lung Injury. | 500 | 1 | 20/60 | 167 |
| | 57.318 Hemovigilance Adverse Reaction—Transfusion Associated Circulatory Overload. | 500 | 2 | 20/60 | 333 |
| | 57.319 Hemovigilance Adverse Reaction—Unknown Transfusion Reaction. | 500 | 1 | 20/60 | 167 |
| | 57.320 Hemovigilance Adverse Reaction—Other Transfusion Reaction. | 500 | 1 | 20/60 | 167 |
| | 57.400 Outpatient Procedure Component—Annual Facility Survey. | 5,000 | 1 | 10/60 | 417 |
| | 57.401 Outpatient Procedure Component—Monthly Reporting Plan. | 5,000 | 12 | 20/60 | 15,000 |
| | 57.402 Outpatient Procedure Component Same Day Outcome Measures. | 1,200 | 25 | 40/60 | 20,000 |
| | 57.403 Outpatient Procedure Component—Monthly Denominators for Same Day Outcome Measures. | 1,200 | 12 | 40/60 | 9,600 |
| | 57.404 Outpatient Procedure Component—SSI Denominator. | 5,000 | 540 | 10/60 | 450,000 |
| | 57.405 Outpatient Procedure Component—Surgical Site (SSI) Event. | 5,000 | 36 | 35/60 | 105,000 |
| | 57.500 Outpatient Dialysis Center Practices Survey. | 7,000 | 1 | 2.12 | 14,817 |
| | 57.501 Dialysis Monthly Reporting Plan ... | 7,000 | 12 | 5/60 | 7,000 |
| | 57.502 Dialysis Event | 7,000 | 60 | 25/60 | 175,000 |
| | 57.503 Denominator for Outpatient Dialysis. | 7,000 | 12 | 10/60 | 14,000 |
| | 57.504 Prevention Process Measures Monthly Monitoring for Dialysis. | 2,000 | 12 | 1.42 | 17,000 |
| | 57.505 Dialysis Patient Influenza Vaccination. | 325 | 75 | 10/60 | 4,063 |
| | 57.506 Dialysis Patient Influenza Vaccination Denominator. | 325 | 5 | 10/60 | 271 |
| | 57.507 Home Dialysis Center Practices Survey. | 350 | 1 | 30/60 | 175 |
| Total | | | | | 5,393,725 |

Jeffrey M. Zirger,

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