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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-16-0666; Docket No. CDC-2016-0046]**

**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 efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the National Healthcare Safety Network (NHSN). NHSN is a system designed to accumulate, exchange, and integrate relevant information and resources among private and public stakeholders to support local and national

efforts to protect patients and promote healthcare safety.

**DATES:** Written comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2016-0046 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted 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 the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: 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 OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy

of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

**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 National Healthcare Safety Network (NHSN) is a system designed to accumulate, exchange, and integrate relevant information and resources among private and public stakeholders to support local and national efforts to protect patients and promote healthcare safety. Specifically, the data is used to determine the magnitude of various healthcare-associated adverse events and trends in the rates of these events among patients and healthcare workers with similar risks. The data will be used to detect changes in the epidemiology of adverse events resulting from new and current medical therapies and changing risks. The NHSN currently consists of five components: Patient Safety, Healthcare Personnel Safety, Biovigilance, Long-Term Care Facility (LTCF), and Dialysis. The Outpatient Procedure Component is on track to be released in NHSN in 2017/2018. The development of this component has been previously delayed to obtain additional user feedback and support from outside partners.

Changes were made to six facility surveys and two new facility surveys were added. 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 decisions on future division priorities for prevention.

Further, three new forms were added to expand NHSN surveillance to pediatric ventilator-associated events, adult sepsis, and custom HAI event surveillance. An additional 14 forms were added to the Hemovigilance Component to streamline data collection/entry for adverse reaction events.

Additionally, minor revisions have been made to 22 forms within the package to clarify and/or update surveillance definitions. The previously approved NHSN package included 52 individual collection forms; the current revision request adds nineteen forms and removes one form for a total of 70 forms. The reporting burden will increase by 489,174 hours, for a total of 5,110,716 hours.

Estimated Annualized Burden Hours

| Type of Respondents                        | Form Name                     | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in hrs.) | Total Burden (in hrs.) |
|--|-------------------------------|--------------------|---------------------------------|------------------------------------|------------------------|
| Registered Nurse (Infection Preventionist) | 57.100 NHSN Registration Form | 2,000              | 1                               | 5/60                               | 167                    |
| Registered Nurse                           | 57.101 Facility               | 2,000              | 1                               | 10/60                              | 333                    |

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|--|--|-------|-----|-------|---------|
| (Infection Preventionist)                  | Contact Information                                      |       |     |       |         |
| Registered Nurse (Infection Preventionist) | 57.103 Patient Safety Component-- Annual Hospital Survey | 5,000 | 1   | 55/60 | 4,583   |
| Registered Nurse (Infection Preventionist) | 57.105 Group Contact Information                         | 1,000 | 1   | 5/60  | 83      |
| Registered Nurse (Infection Preventionist) | 57.106 Patient Safety Monthly Reporting Plan             | 6,000 | 12  | 15/60 | 18,000  |
| Registered Nurse (Infection Preventionist) | 57.108 Primary Bloodstream Infection (BSI)               | 6,000 | 44  | 30/60 | 132,000 |
| Registered Nurse (Infection Preventionist) | 57.111 Pneumonia (PNEU)                                  | 6,000 | 72  | 30/60 | 216,000 |
| Registered Nurse (Infection Preventionist) | 57.112 Ventilator-Associated Event                       | 6,000 | 144 | 25/60 | 360,000 |
| Registered Nurse (Infection Preventionist) | 57.113 Pediatric Ventilator-Associated Event (PedVAE)    | 2,000 | 120 | 25/60 | 100,000 |
| Registered Nurse (Infection Preventionist) | 57.114 Urinary Tract Infection (UTI)                     | 6,000 | 40  | 20/60 | 80,000  |
| Registered Nurse (Infection Preventionist) | 57.115 Custom Event                                      | 2,000 | 91  | 35/60 | 106,167 |
| Staff RN                                   | 57.116 Denominators for Neonatal Intensive               | 6,000 | 9   | 3     | 162,000 |

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|--|---|-------|-----|-------|-----------|
|  | Care Unit (NICU)  |       |     |       |           |
| Staff RN                                   | 57.117<br>Denominators for Specialty Care Area (SCA)/Oncology (ONC)   | 6,000 | 9   | 5     | 270,000   |
| Staff RN                                   | 57.118<br>Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)                      | 6,000 | 60  | 5     | 1,800,000 |
| Registered Nurse (Infection Preventionist) | 57.120<br>Surgical Site Infection (SSI)   | 6,000 | 36  | 35/60 | 126,000   |
| Staff RN                                   | 57.121<br>Denominator for Procedure   | 6,000 | 540 | 10/60 | 540,000   |
| Laboratory Technician                      | 57.123<br>Antimicrobial Use and Resistance (AUR) - Microbiology Data Electronic Upload Specification Tables | 6,000 | 12  | 5/60  | 6,000     |
| Pharmacist                                 | 57.124<br>Antimicrobial Use and Resistance (AUR) - Pharmacy Data Electronic Upload Specification Tables     | 6,000 | 12  | 5/60  | 6,000     |
| Registered Nurse                           | 57.125<br>Central Line  | 1,000 | 100 | 25/60 | 41,667    |

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| (Infection Preventionist)                  | Insertion Practices Adherence Monitoring                                       |       |     |       |         |
| Registered Nurse (Infection Preventionist) | 57.126 MDRO or CDI Infection Form  | 6,000 | 72  | 30/60 | 216,000 |
| Registered Nurse (Infection Preventionist) | 57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring | 6,000 | 24  | 15/60 | 36,000  |
| Registered Nurse (Infection Preventionist) | 57.128 Laboratory-identified MDRO or CDI Event                                 | 6,000 | 240 | 20/60 | 480,000 |
| Registered Nurse (Infection Preventionist) | 57.129 Adult Sepsis  | 50    | 250 | 25/60 | 5,208   |
| Registered Nurse (Infection Preventionist) | 57.137 Long-Term Care Facility Component - Annual Facility Survey              | 350   | 1   | 1.08  | 378     |
| Registered Nurse (Infection Preventionist) | 57.138 Laboratory-identified MDRO or CDI Event for LTCF                        | 350   | 12  | 15/60 | 1,050   |
| Registered Nurse (Infection Preventionist) | 57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF    | 350   | 12  | 10/60 | 700     |
| Registered Nurse (Infection Preventionist) | 57.140 Urinary Tract Infection (UTI) for                                       | 350   | 14  | 30/60 | 2,450   |

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|--|---|--------|-----|-------|--------|
|  | LTCF  |        |     |       |        |
| Registered Nurse (Infection Preventionist) | 57.141 Monthly Reporting Plan for LTCF                              | 350    | 12  | 5/60  | 350    |
| Registered Nurse (Infection Preventionist) | 57.142 Denominators for LTCF Locations                              | 350    | 12  | 3.35  | 14,070 |
| Registered Nurse (Infection Preventionist) | 57.143 Prevention Process Measures Monthly Monitoring for LTCF      | 300    | 12  | 5/60  | 300    |
| Registered Nurse (Infection Preventionist) | 57.150 LTAC Annual Survey   | 400    | 1   | 55/60 | 367    |
| Registered Nurse (Infection Preventionist) | 57.151 Rehab Annual Survey  | 1,000  | 1   | 55/60 | 917    |
| Occupational Health RN/Specialist          | 57.200 Healthcare Personnel Safety Component Annual Facility Survey | 50     | 1   | 8     | 400    |
| Occupational Health RN/Specialist          | 57.203 Healthcare Personnel Safety Monthly Reporting Plan           | 17,000 | 1   | 5/60  | 1,417  |
| Occupational Health RN/Specialist          | 57.204 Healthcare Worker Demographic Data                           | 50     | 200 | 20/60 | 3,333  |
| Occupational Health RN/Specialist          | 57.205 Exposure to Blood/Body Fluids                                | 50     | 50  | 1     | 2,500  |
| Occupational Health                        | 57.206 Healthcare   | 50     | 30  | 15/60 | 375    |

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| RN/Specialist                            | Worker Prophylaxis/Treatment   |     |    |       |       |
| Laboratory Technician                    | 57.207 Follow-Up Laboratory Testing  | 50  | 50 | 15/60 | 625   |
| Occupational Health RN/Specialist        | 57.210 Healthcare Worker Prophylaxis/Treatment-Influenza                     | 50  | 50 | 10/60 | 417   |
| Medical/Clinical Laboratory Technologist | 57.300 Hemovigilance Module Annual Survey                                    | 500 | 1  | 2     | 1,000 |
| Medical/Clinical Laboratory Technologist | 57.301 Hemovigilance Module Monthly Reporting Plan                           | 500 | 12 | 1/60  | 100   |
| Medical/Clinical Laboratory Technologist | 57.303 Hemovigilance Module Monthly Reporting Denominators                   | 500 | 12 | 1.17  | 7,020 |
| Medical/Clinical Laboratory Technologist | 57.305 Hemovigilance Incident  | 500 | 10 | 10/60 | 833   |
| Medical/Clinical Laboratory Technologist | 57.306 Hemovigilance Module Annual Survey - Non-acute care facility          | 200 | 1  | 35/60 | 117   |
| Medical/Clinical Laboratory Technologist | 57.307 Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction | 500 | 4  | 25/60 | 833   |
| Medical/Clinical Laboratory Technologist | 57.308 Hemovigilance   | 500 | 4  | 25/60 | 833   |

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| Technologist                             | e Adverse Reaction - Allergic Transfusion Reaction                                 |     |   |       |     |
| Medical/Clinical Laboratory Technologist | 57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction     | 500 | 1 | 25/60 | 208 |
| Medical/Clinical Laboratory Technologist | 57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction     | 500 | 2 | 25/60 | 417 |
| Medical/Clinical Laboratory Technologist | 57.311 Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction | 500 | 4 | 25/60 | 833 |
| Medical/Clinical Laboratory Technologist | 57.312 Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction           | 500 | 1 | 25/60 | 208 |
| Medical/Clinical Laboratory Technologist | 57.313 Hemovigilance Adverse Reaction - Infection                                  | 500 | 1 | 25/60 | 208 |
| Medical/Clinical Laboratory Technologist | 57.314 Hemovigilance Adverse Reaction - Post Transfusion Purpura                   | 500 | 1 | 25/60 | 208 |
| Medical/Clinical Laboratory Technologist | 57.315 Hemovigilance Adverse   | 500 | 1 | 25/60 | 208 |

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|  | Reaction -<br>Transfusion<br>Associated<br>Dyspnea   |       |   |       |     |
| Medical/Clinical Laboratory Technologist | 57.316<br>Hemovigilance Adverse Reaction -<br>Transfusion Associated Graft vs.<br>Host Disease | 500   | 1 | 25/60 | 208 |
| Medical/Clinical Laboratory Technologist | 57.317<br>Hemovigilance Adverse Reaction -<br>Transfusion Related Acute Lung Injury            | 500   | 1 | 25/60 | 208 |
| Medical/Clinical Laboratory Technologist | 57.318<br>Hemovigilance Adverse Reaction -<br>Transfusion Associated Circulatory Overload      | 500   | 2 | 25/60 | 417 |
| Medical/Clinical Laboratory Technologist | 57.319<br>Hemovigilance Adverse Reaction -<br>Unknown Transfusion Reaction                     | 500   | 1 | 25/60 | 208 |
| Medical/Clinical Laboratory Technologist | 57.320<br>Hemovigilance Adverse Reaction -<br>Other Transfusion Reaction                       | 500   | 1 | 25/60 | 208 |
| Medical/Clinical Laboratory Technologist | 57.400<br>Patient Safety Component-<br>Annual Facility Survey for Ambulatory Surgery           | 5,000 | 1 | 5/60  | 417 |

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|---|--|-------|----|-------|---------|
|   | Center (ASC)   |       |    |       |         |
| Staff RN  | 57.401<br>Outpatient<br>Procedure<br>Component -<br>Monthly<br>Reporting<br>Plan           | 5,000 | 12 | 15/60 | 15,000  |
| Staff RN  | 57.402<br>Outpatient<br>Procedure<br>Component<br>Event                                    | 5,000 | 25 | 40/60 | 83,333  |
| Staff RN  | 57.403<br>Outpatient<br>Procedure<br>Component -<br>Monthly<br>Denominators<br>and Summary | 5,000 | 12 | 40/60 | 40,000  |
| Staff RN  | 57.500<br>Outpatient<br>Dialysis<br>Center<br>Practices<br>Survey                          | 6,500 | 1  | 2.0   | 13,000  |
| Registered<br>Nurse<br>(Infection<br>Preventionist) | 57.501<br>Dialysis<br>Monthly<br>Reporting<br>Plan   | 6,500 | 12 | 5/60  | 6,500   |
| Staff RN  | 57.502<br>Dialysis<br>Event  | 6,500 | 60 | 25/60 | 162,500 |
| Staff RN  | 57.503<br>Denominator<br>for<br>Outpatient<br>Dialysis                                     | 6,500 | 12 | 10/60 | 13,000  |
| Staff RN  | 57.504<br>Prevention<br>Process<br>Measures<br>Monthly<br>Monitoring<br>for Dialysis       | 1,500 | 12 | 1.25  | 22,500  |
| Staff RN  | 57.505<br>Dialysis<br>Patient<br>Influenza<br>Vaccination                                  | 325   | 75 | 10/60 | 4,063   |

|          |  |     |   |       |           |
|----------|--|-----|---|-------|-----------|
| Staff RN | 57.506<br>Dialysis<br>Patient<br>Influenza<br>Vaccination<br>Denominator | 325 | 5 | 10/60 | 271       |
| Staff RN | 57.507 Home<br>Dialysis<br>Center<br>Practices<br>Survey                 | 600 | 1 | 25/60 | 250       |
| Total    |  |     |   |       | 5,110,716 |

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