



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-16-0666; Docket No. CDC-2017-0047]

**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 PUBLICATION DATE IN THE FEDERAL

REGISTER] .

ADDRESSES: You may submit comments, identified by Docket No. CDC-2017-0047 by any of the following methods:

- Federal eRulemaking Portal: Regulations.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 Leroy Richardson, 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) (OMB Control Number 0920-0666, Expires - Revision - National Center for Emerging and Zoonotic Infection Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) is requesting a three-year approval of the *National*

Healthcare Safety Network information collection project.

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 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. 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 2018. The development of this component has been previously delayed to obtain additional user feedback and support from outside partners.

Changes were made to four facility surveys. 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. Also, 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, two new forms were added to expand NHSN surveillance to enhance data collection by Ambulatory Surgical Centers to identify areas where prevention of SSIs may be improved. An additional 14 forms were modified within the Hemovigilance module to streamline data collection/entry for adverse reaction events.

Overall, minor revisions have been made to a total of 38 forms within the package to clarify and/or update surveillance definitions, increase or decrease the number of reporting facilities, and adding new forms. The previously approved NHSN package included 70 individual collection forms; the current revision request includes a total of 72 forms. The reporting burden will decrease by 811,985 hours, for a total of 5,922,953 hours.

This collection of information is authorized by the Public Health Service Act (42 U.S.C. 242b, 242k, and 242m (d)). There is no cost to respondents other than the time to participate.

Estimated Annualized Burden Hours

Type of Respondent	Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)
Registered Nurse (Infection Preventionist)	57.100 NHSN Registration Form	2,000	1	5/60	167
Registered Nurse (Infection Preventionist)	57.101 Facility Contact Information	2,000	1	10/60	333
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	57.112	6,000	144	25/60	360,000

Nurse (Infection Preventionist)	Ventilator - Associated Event				
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 Denominato rs for Neonatal Intensive Care Unit (NICU)	6,000	12	4	288,000
Staff RN	57.117 Denominato rs for Specialty Care Area (SCA)/Onco logy (ONC)	6,000	9	5	270,000
Staff RN	57.118 Denominato rs for Intensive Care Unit (ICU)/Othe r locations (not NICU or SCA)	6,000	60	5	1,800,000
Registered Nurse (Infection	57.120 Surgical Site	6,000	36	35/60	126,000

Preventionist)	Infection (SSI)				
Staff RN	57.121 Denominator for Procedure	6,000	540	10/60	540,000
Laboratory Technician	57.123 Antimicrobial Use and Resistance (AUR) - Microbiology Data Electronic Upload Specification Tables	6,000	12	5/60	6,000
Pharmacist	57.124 Antimicrobial Use and Resistance (AUR) - Pharmacy Data Electronic Upload Specification Tables	6,000	12	5/60	6,000
Registered Nurse (Infection Preventionist)	57.125 Central Line Insertion Practices Adherence Monitoring	100	100	25/60	4,167
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	6,000	24	15/60	36,000

	and Outcome Measures Monthly Monitoring				
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	2,600	1	2	5,200
Registered Nurse (Infection Preventionist)	57.138 Laboratory - identified MDRO or CDI Event for LTCF	2,600	12	15/60	7,800
Registered Nurse (Infection Preventionist)	57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	2,600	12	10/60	5,200
Registered Nurse (Infection Preventionist)	57.140 Urinary Tract Infection (UTI) for LTCF	2,600	14	30/60	18,200
Registered Nurse	57.141 Monthly	2,600	12	5/60	2,600

(Infection Preventionist)	Reporting Plan for LTCF				
Registered Nurse (Infection Preventionist)	57.142 Denominators for LTCF Locations	2,600	12	4	124,800
Registered Nurse (Infection Preventionist)	57.143 Prevention Process Measures Monthly Monitoring for LTCF	2,600	12	5/60	600
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	50	50	1	2,500

	Fluids				
Occupational Health RN/Specialist	57.206 Healthcare Worker Prophylaxis/Treatment	50	30	15/60	375
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	200	1	35/60	117

	facility				
Medical/Clinical Laboratory Technologist	57.307 Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction	500	4	20/60	667
Medical/Clinical Laboratory Technologist	57.308 Hemovigilance Adverse Reaction - Allergic Transfusion Reaction	500	4	20/60	667
Medical/Clinical Laboratory Technologist	57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction	500	1	20/60	167
Medical/Clinical Laboratory Technologist	57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction	500	2	20/60	333
Medical/Clinical Laboratory Technologist	57.311 Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction	500	4	20/60	667
Medical/Clinic	57.312	500	1	20/60	167

al Laboratory Technologist	Hemovigila nce Adverse Reaction - Hypotensiv e Transfusio n Reaction				
Medical/Clinic al Laboratory Technologist	57.313 Hemovigila nce Adverse Reaction - Infection	500	1	20/60	167
Medical/Clinic al Laboratory Technologist	57.314 Hemovigila nce Adverse Reaction - Post Transfusio n Purpura	500	1	20/60	167
Medical/Clinic al Laboratory Technologist	57.315 Hemovigila nce Adverse Reaction - Transfusio n Associated Dyspnea	500	1	20/60	167
Medical/Clinic al Laboratory Technologist	57.316 Hemovigila nce Adverse Reaction - Transfusio n Associated Graft vs. Host Disease	500	1	20/60	167
Medical/Clinic al Laboratory Technologist	57.317 Hemovigila nce Adverse Reaction -	500	1	20/60	167

	Transfusio n Related Acute Lung Injury				
Medical/Clinic al Laboratory Technologist	57.318 Hemovigila nce Adverse Reaction - Transfusio n Associated Circulator y Overload	500	2	20/60	333
Medical/Clinic al Laboratory Technologist	57.319 Hemovigila nce Adverse Reaction - Unknown Transfusio n Reaction	500	1	20/60	167
Medical/Clinic al Laboratory Technologist	57.320 Hemovigila nce Adverse Reaction - Other Transfusio n Reaction	500	1	20/60	167
Medical/Clinic al Laboratory Technologist	57.400 Outpatient Procedure Component- Annual Facility Survey	5,000	1	5/60	417
Staff RN	57.401 Outpatient Procedure Component - Monthly Reporting Plan	5,000	12	15/60	15,000
Staff RN	57.402- Outpatient Procedure	5,000	25	40/60	83,333

	Component Same Day Outcome Measures & Prophylactic Intravenous (IV) Antibiotic Timing Event				
Staff RN	57.403- Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures & Prophylactic Intravenous (IV) Antibiotic Timing Event	5,000	12	40/60	40,000
Staff RN	57.404 Outpatient Procedure Component - Annual Facility Survey	5,000	540	10/60	450,00
Registered Nurse (Infection Preventionist)	57.405 Outpatient Procedure Component - Surgical Site (SSI) Event	5,000	36	35/60	105,00
Staff RN	57.500 Outpatient Dialysis Center Practices	7,000	1	2.0	14,000

	Survey				
Registered Nurse (Infection Preventionist)	57.501 Dialysis Monthly Reporting Plan	7,000	12	5/60	7,000
Staff RN	57.502 Dialysis Event	7,000	60	25/60	175,000
Staff RN	57.503 Denominator for Outpatient Dialysis	7,000	12	10/60	14,000
Staff RN	57.504 Prevention Process Measures Monthly Monitoring for Dialysis	2,000	12	1.25	30,000
Staff RN	57.505 Dialysis Patient Influenza Vaccination	325	75	10/60	4,063
Staff RN	57.506 Dialysis Patient Influenza Vaccination Denominator	325	5	10/60	271
Staff RN	57.507 Home Dialysis Center Practices Survey	350	1	30/60	175
Total					5922,953

Leroy A. Richardson,
Chief,
Information Collection Review Office,
Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director,
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