research activities in the health field. Historically, data have been used extensively in the development and monitoring of goals for the Year 2000, 2010, and 2020 Healthy People Objectives.

There is no cost to respondents other than their time to participate. The total annualized burden is 7,080 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)
Hospital Director of Health Information Management (DHIM) or Director of Health Information Technology (DHIT).	Initial Hospital Intake Questionnaire	150	1	1	150
Hospital Chief Executive Officer (CEO)/Chief Financial Officer (CFO).	Recruitment Survey Presentation	150	1	1	150
Hospital DHIM or DHIT	Prepare and transmit UB–04 or State File for Inpatient and Ambulatory.	399	12	1	4,788
Hospital DHIM or DHIT	Prepare and transmit EHR for Inpatient and Ambulatory.	199	4	1	796
Hospital CEO/CFO	Annual Hospital Interview	598	1	2	1,196
Total	.....	.....	.....	.....	7,080

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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

[30Day–18–0666]

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 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 May 11, 2018 to obtain comments from the public and affected agencies. CDC received one comment 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 (0920–0666, Expiration Date 1/31/2021)—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. Specifically, resulting data estimates the magnitude of Healthcare Associated Infections (HAI), monitor HAI trends, and facilitate inter-facility and intra-facility comparisons with risk-adjusted data used for local quality improvement activities. 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 six components: Patient Safety, Healthcare Personnel Safety, Biovigilance, Long-Term Care Facility (LTCF), Outpatient Procedure Component, and Dialysis.

Changes were made to 34 data collection facility surveys with this revision 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 34 forms within the package to clarify and/or update surveillance definitions, increase or decrease the number of reporting facilities, and add new forms.

Finally, NHSN has achieved significant burden reduction with this ICR due to a decrease in the number of respondents for the Specialty Care Area (SCA) and Oncology (ONC) facilities reporting to NHSN. NHSN re-evaluated these reporting facilities and determined that approximately 2,000 SCA and ONC facilities are reporting to NHSN compared to the estimated 6,000 that was estimated last year. Additionally, NHSN streamlined many response options, which also attributed to a reduction in the overall burden.

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)
Healthcare facility	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	6,000	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)	6,000	44	33/60
	57.111 Pneumonia (PNEU)	1,800	72	30/60
	57.112 Ventilator-Associated Event	6,000	144	28/60
	57.113 Pediatric Ventilator-Associated Event (PedVAE)	100	120	30/60
	57.114 Urinary Tract Infection (UTI)	6,000	40	20/60
	57.115 Custom Event	600	91	35/60
	57.116 Denominators for Neonatal Intensive Care Unit (NICU).	6,000	12	4

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
	57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC).	2,000	9	302/60
	57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA).	6,000	60	302/60
	57.120 Surgical Site Infection (SSI)	6,000	36	35/60
	57.121 Denominator for Procedure	6,000	540	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.	1,000	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.	100	100	25/60
	57.126 MDRO or CDI Infection Form	6,000	72	30/60
	57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring.	6,000	24	15/60
	57.128 Laboratory-identified MDRO or CDI Event	6,000	240	20/60
	57.129 Adult Sepsis	50	250	25/60
	57.137 Long-Term Care Facility Component—Annual Facility Survey.	2,600	1	2
	57.138 Laboratory-identified MDRO or CDI Event for LTCF	2,600	12	20/60
	57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF.	2,600	12	20/60
	57.140 Urinary Tract Infection (UTI) for LTCF	2,600	14	35/60
	57.141 Monthly Reporting Plan for LTCF	2,600	12	5/60
	57.142 Denominators for LTCF Locations	2,600	12	250/60
	57.143 Prevention Process Measures Monthly Monitoring for LTCF.	2,600	12	5/60
	57.150 LTAC Annual Survey	400	1	70/60
	57.151 Rehab Annual Survey	1,000	1	70/60
	57.200 Healthcare Personnel Safety Component Annual Facility Survey.	50	1	8
	57.203 Healthcare Personnel Safety Monthly Reporting Plan	19,500	1	5/60
	57.204 Healthcare Worker Demographic Data	50	200	20/60
	57.205 Exposure to Blood/Body Fluids	50	50	1
	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
	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.	200	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 Adverse Reaction—Transfusion Associated Dyspnea.	500	1	20/60
	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

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
	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.	5,000	1	10/60
	57.401 Outpatient Procedure Component—Monthly Reporting Plan.	5,000	12	20/60
	57.402 Outpatient Procedure Component Same Day Outcome Measures.	1,200	25	40/60
	57.403 Outpatient Procedure Component—Monthly Denominators for Same Day Outcome Measures.	1,200	12	40/60
	57.404 Outpatient Procedure Component—SSI Denominator.	5,000	540	10/60
	57.405 Outpatient Procedure Component—Surgical Site (SSI) Event.	5,000	36	35/60
	57.500 Outpatient Dialysis Center Practices Survey	7,000	1	127/60
	57.501 Dialysis Monthly Reporting Plan	7,000	12	5/60
	57.502 Dialysis Event	7,000	60	25/60
	57.503 Denominator for Outpatient Dialysis	7,000	12	10/60
	57.504 Prevention Process Measures Monthly Monitoring for Dialysis.	2,000	12	85/60
	57.505 Dialysis Patient Influenza Vaccination	325	75	10/60
	57.506 Dialysis Patient Influenza Vaccination Denominator	325	5	10/60
	57.507 Home Dialysis Center Practices Survey	350	1	30/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0294]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Contact Substance Notification Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with the Food Contact Substance Notification Program.

DATES: Submit either electronic or written comments on the collection of information by November 13, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 13, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 13, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2012–N–0294 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food