Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Cigarette smoking is the leading preventable cause of premature death and disability in our nation. Each year more than 480,000 deaths occur as the result of cigarette smoking-related diseases. The CDC's Office on Smoking and Health (OSH) is the lead federal agency for comprehensive tobacco prevention and control. Since 1986, as required by the Comprehensive Smoking Education Act (CSEA) of 1984, which amended the Federal Cigarette Labeling and Advertising Act (FCLAA), 15 U.S.C. 1335a, CDC has collected information about the ingredients used in cigarette products. HHS has delegated responsibility for implementing the required information collection to CDC's OSH. Respondents are commercial cigarette manufacturers, packagers, or importers (or their representatives), who are required by FCLAA to submit ingredient reports to HHS on an annual basis.

Respondents are not required to submit specific forms; however, they are required to submit a list of all ingredients used in their products. CDC requires the ingredient report to be submitted by chemical name and Chemical Abstract Service (CAS) Registration Number, consistent with accepted reporting practices for other companies currently required to report ingredients added to other consumer products. The information collected is subject to strict confidentiality provisions.

Ingredient reports are due annually on March 31. Information is submitted to CDC by mailing or faxing a written report on the respondent's letterhead. All faxed lists should be followed up with a mailed original. Electronic mail submissions are not accepted. Mail Annual Ingredient Submissions to Attention: FCLAA Program Manager, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS S107–7, Atlanta, GA 30341–3717.

Upon receipt and verification of the annual ingredient report, CDC issues a Certificate of Compliance to the respondent. As deemed appropriate by the Secretary of HHS, HHS is authorized to use the information to report to Congress the health effects of ingredients, research activities related to the health effects of ingredients, and other information that the Secretary determines to be of public interest.

There are no costs to respondents other than their time. The total estimated annualized burden hours are 358. OMB approval is requested for three years.

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)
Business Entities	N/A	55	1	6.5	358
Total					358

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–20844 Filed 9–24–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–21–0666; Docket No. CDC–2021–0100]

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 the nation's most widely used healthcare-associated infection tracking system, providing facilities, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate healthcare-associated infections.

DATES: CDC must receive written comments on or before November 26, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0100 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, Mailstop H21–8, 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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–8, 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;

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; and

5. Assess information collection costs.

Proposed Project

National Healthcare Safety Network (NHSN) (OMB Control No. 0920–0666, Exp. 12/31/2023)—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) (OMB Control Number 0920–0666). 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 planned Neonatal Component is expected to launch during the winter of 2021, and 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 (LOS) and Meningitis. LOS and Meningitis are common complications of extreme prematurity. These infections result in a prolongation of hospital stay, increased cost, and risk of morbidity and mortality. The data for this module will be electronically submitted, allowing more hospital personnel to be available to care for patients and reducing 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 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 (HPS), 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.

The Biovigilance (BV) Component collects data on adverse reactions and incidents associated with blood transfusions. Data is reported and analyzed to provide national estimates of adverse reactions and incidents.

Under the Long-Term Care Facility (LTCF) 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 Respiratory Tract Infection Form (RTI), titled ''Denominators for Healthcare Associated Infections (HAIs): Respiratory Tract Infections,'' will not to be used by NHSN users, but rather as part of an EIP project with 4 EIP sites. The purpose of this form is to allow testing prior to introducing a new module and forms to NHSN users. The CDC's Epidemiology Research & Innovations Branch (ERIB) team will use the form to perform field testing of variables to explore the utilization, applicability, and data collection burden associated with these variables. This process will inform areas of improvement prior to incorporating the new module, including protocol, forms, and instructions 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 April 2020, 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 U.S. 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.

NHSN was previously approved in December 2020 for 1,321,991 burden hours. The proposed changes in this new ICR include revisions to 10 data collection forms and no new forms for a total of 86 proposed data collection forms. In this Revision, CDC requests OMB approval for an estimated 1,718,591 annual burden hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Form number & name	Number of respondents	Number of responses per respondent	Avg. burden per response (hours)	Total burden (hours)
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	6,765	1	90/60	10,148
57.104 Facility Administrator Change Request Form	800	1	5/60	67
57.105 Group Contact Information	1,000	1	5/60	83
57.106 Patient Safety Monthly Reporting Plan	7,821	12	15/60	23,463
57.108 Primary Bloodstream Infection (BSI)	5,775	5	38/60	18,288
57.111 Pneumonia (PNEU)	1,800	2	30/60	1,800
57.112 Ventilator-Associated Event	5,463	8	28/60	20,395
57.113 Pediatric Ventilator-Associated Event (PedVAE)	334	1	30/60	167
57.114 Urinary Tract Infection (UTI)	6,000	5	20/60	10,000
57.115 Custom Event	600	91	35/60	31,850
57.116 Denominators for Neonatal Intensive Care Unit (NICU)	1,100	12	4/60	880
57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	500	12	5/60	500
57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	5,500	60	5/60	27,500
57.120 Surgical Site Infection (SSI)	6,000	9	35/60	31,500
57.121 Denominator for Procedure	6,000	602	10/60	602,000
57.122 HAI Progress Report State Health Department Survey	55	1	28/60	26
57.123 Antimicrobial Use and Resistance (AUR)—Microbiology Data Electronic Upload Specification Tables	2,500	12	5/60	2,500
57.124 Antimicrobial Use and Resistance (AUR)—Pharmacy Data Electronic Upload Specification Tables	2,500	12	5/60	2,500
57.125 Central Line Insertion Practices Adherence Monitoring	500	213	25/60	44,375
57.126 MDRO or CDI Infection Form	720	11	30/60	3,960
57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	5,500	29	15/60	39,875
57.128 Laboratory-identified MDRO or CDI Event	4,800	79	20/60	126,400
57.129 Adult Sepsis	50	250	25/60	5,208
57.135 Late Onset Sepsis/Meningitis Denominator Form: Data Table for monthly electronic upload	300	6	5/60	150
57.136 Late Onset Sepsis/Meningitis Event Form: Data Table for Monthly Electronic Upload	300	6	5/60	150
57.137 Long-Term Care Facility Component—Annual Facility Survey	17,700	1	120/60	35,400
57.138 Laboratory-identified MDRO or CDI Event for LTCF	1,998	24	20/60	15,984
57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	1,998	12	20/60	7,992
57.140 Urinary Tract Infection (UTI) for LTCF	339	36	35/60	7,119
57.141 Monthly Reporting Plan for LTCF	2011	12	5/60	2,011
57.142 Denominators for LTCF Locations	339	12	35/60	2,373
57.143 Prevention Process Measures Monthly Monitoring for LTCF	130	12	5/60	130
57.150 LTAC Annual Survey	620	1	82/60	847
57.151 Rehab Annual Survey	1,340	1	82/60	1,831
57.200 Healthcare Personnel Safety Component Annual Facility Survey	50	1	480/60	400
57.204 Healthcare Worker Demographic Data	50	200	20/60	3,333
57.205 Exposure to Blood/Body Fluids	50	50	60/60	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	85/60	708
57.301 Hemovigilance Module Monthly Reporting Plan	500	12	60/60	6,000
57.303 Hemovigilance Module Monthly Reporting Denominators	500	12	70/60	7,000
57.305 Hemovigilance Incident	500	10	10/60	833

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form number & name	Number of respondents	Number of responses per respondent	Avg. burden per response (hours)	Total burden (hours)
57.306 Hemovigilance Module Annual Survey—Non-acute care facility	500	1	35/60	292
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
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	700	1	10/60	117
57.401 Outpatient Procedure Component—Monthly Reporting Plan	700	12	15/60	2,100
57.402 Outpatient Procedure Component Same Day Outcome Measures	200	1	40/60	133
57.403 Outpatient Procedure Component—Monthly Denominators for Same Day Outcome Measures	200	400	40/60	53,333
57.404 Outpatient Procedure Component—SSI Denominator	700	100	40/60	46,667
57.405 Outpatient Procedure Component—Surgical Site (SSI) Event	700	5	40/60	2,333
57.500 Outpatient Dialysis Center Practices Survey	7,200	1	12/60	1,440
57.501 Dialysis Monthly Reporting Plan	7,200	12	5/60	7,200
57.502 Dialysis Event	7,200	30	25/60	90,000
57.503 Denominator for Outpatient Dialysis	7,200	30	10/60	36000
57.504 Prevention Process Measures Monthly Monitoring for Dialysis	1,730	12	75/60	25,950
57.505 Dialysis Patient Influenza Vaccination	615	50	10/60	5,125
57.506 Dialysis Patient Influenza Vaccination Denominator	615	5	10/60	513
57.507 Home Dialysis Center Practices Survey	430	1	30/60	215
Weekly Healthcare Personnel Influenza Vaccination Cumulative Summary for Non-Long-Term Care Facilities	125	52	60/60	6,500
Weekly Healthcare Personnel Influenza Vaccination Cumulative Summary for Long-Term Care Facilities	1,200	52	60/60	62,400
Weekly Resident Influenza Vaccination Cumulative Summary for Long-Term Care Facilities	2,500	52	60/60	130,000
Annual Healthcare Personnel Influenza Vaccination Summary	5,000	1	120/60	10,000
Total	.....	.....	.....	1,718,591

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–20846 Filed 9–24–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the Clinical Laboratory Improvement Advisory Committee (CLIAC)

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is seeking nominations for membership on the CLIAC. The CLIAC consists of 20 experts including the Chair, represents a diverse membership across laboratory specialties, professional roles (laboratory management, technical specialists, physicians, nurses) and practice settings (academic, clinical, public health), and includes a consumer representative.

DATES: Nominations for membership on CLIAC must be received no later than March 1, 2022. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nominations should be mailed to Nancy Anderson, MMSc, MT(ASCP), CLIAC Secretary, Senior Advisor for Clinical Laboratories, Division of Laboratory Systems, Center