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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA OH-23-004, NIOSH Miner Safety and Health Program—Western Mining States Review, and RFA OH-23-005, NIOSH Robotic Mining Review; Amended Notice of Closed Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA OH-23-004, NIOSH Miner Safety and Health Program—Western Mining States Review, and RFA OH-23-005, NIOSH Robotic Mining Review; May 25, 2023, 1 p.m.–5 p.m., EDT, teleconference, in the original **Federal Register** notice. The meeting was published in the **Federal Register** on February 22, 2023, Volume 88, Number 35, page 10905.

The meeting is being amended to change the Notice of Funding Opportunity (NOFO) titles and should read as follows:

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA—OH-23-004, Miner Safety and Health Training Program—Western United States, and RFA—OH-23-005, NIOSH Robotics and Intelligent Mining Technology and Workplace Safety Research (U60).

The meeting is closed to the public.

FOR FURTHER INFORMATION CONTACT:

Michael Goldcamp, Ph.D., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1905 Willowdale Road, Morgantown, West Virginia, 26506. Telephone: (304) 285-5951; Email: MGoldcamp@cdc.gov.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit,
Office of the Chief Operating Officer, Centers
for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-23-0666]

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 (NHSN)” 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 August 26, 2022 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. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. 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 (NHSN) (OMB Control No. 0920-0666, Exp. 7/31/2023)—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) under 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 seven components:

Patient Safety (PS), Healthcare Personnel Safety (HPS), Biovigilance (BV), Long-Term Care Facility (LTCF), Outpatient Procedure (OPC), Dialysis Component, and the Neonatal Component. 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 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 US 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.

In January 2023, CDC obtained emergency OMB approval for a number of changes, effective immediately (Exp.

7/31/2023). These changes included the addition of a new Monthly Survey on Patient Days & Nurse Staffing, as well as minor changes to 14 information collection forms. The changes primarily supported clarifications to use of CIDTs, HAI forms with susceptibility reporting requirements, vendor information, testing options for UTI events, and all y-types of hepatitis B vaccines administered to patients and staff members at outpatient dialysis centers. The changes increased total annualized burden for NHSB from 1,584,651 hours to 1,616,151 hours.

In this Revision, CDC requests OMB approval to continue those changes for three years. In addition, CDC requests OMB approval to begin phased implementation of two new questions on Sex at Birth and Gender Identity, which will replace the current Gender question. The new questions will be voluntary for the remainder of 2023 and required in 2024. The proposed change will be used to help assess the true impact of sex at birth and gender identify on HAIs, individually and in combination with other risk factors, and to inform public health programs. The new questions will add one minute of burden to 31 forms that are currently in use, a total of 77,064 annualized burden hours. The total estimated annualized burden hours for NHSN will increase to 1,693,215 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Form number/name	Number of respondents	Number of responses per respondent	Average burden per response (min/hour)
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	6,765	1	90/60
57.104 Facility Administrator Change Request Form	800	1	5/60
57.105 Group Contact Information	1,000	1	5/60
57.106 Patient Safety Monthly Reporting Plan	7,821	12	15/60
57.108 Primary Bloodstream Infection (BSI)	5,775	5	39/60
57.111 Pneumonia (PNEU)	1,800	2	31/60
57.112 Ventilator-Associated Event	5,463	8	29/60
57.113 Pediatric Ventilator-Associated Event (PedVAE)	334	1	31/60
57.114 Urinary Tract Infection (UTI)	6,000	5	21/60
57.115 Custom Event	600	91	36/60
57.116 Denominators for Neonatal Intensive Care Unit (NICU)	1,100	12	4/60
57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	500	12	5/60
57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	5,500	60	5/60
57.120 Surgical Site Infection (SSI)	6,000	9	36/60
57.121 Denominator for Procedure	6,000	602	11/60
57.122 HAI Progress Report State Health Department Survey	55	1	28/60
57.123 Antimicrobial Use and Resistance (AUR)—Microbiology Data Electronic Upload Specification Tables	2,500	12	5/60
57.124 Antimicrobial Use and Resistance (AUR)—Pharmacy Data Electronic Upload Specification Tables	4,000	12	5/60
57.125 Central Line Insertion Practices Adherence Monitoring	500	213	26/60
57.126 MDRO or CDI Infection Form	720	11	31/60
57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	5,500	29	15/60
57.128 Laboratory-identified MDRO or CDI Event	4,800	79	21/60
57.129 Adult Sepsis	50	250	25/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form number/name	Number of respondents	Number of responses per respondent	Average burden per response (min/hour)
57.135 Late Onset Sepsis/Meningitis Denominator Form: Data Table for monthly electronic upload	300	6	5/60
57.136 Late Onset Sepsis/Meningitis Event Form: Data Table for Monthly Electronic Upload	300	6	5/60
57.137 Long-Term Care Facility Component—Annual Facility Survey	17,700	1	120/60
57.138 Laboratory-identified MDRO or CDI Event for LTCF	1,998	24	20/60
57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	1,998	12	20/60
57.140 Urinary Tract Infection (UTI) for LTCF	339	36	35/60
57.141 Monthly Reporting Plan for LTCF	2,011	12	5/60
57.142 Denominators for LTCF Locations	339	12	35/60
57.143 Prevention Process Measures Monthly Monitoring for LTCF	130	12	5/60
57.150 LTAC Annual Survey	620	1	82/60
57.151 Rehab Annual Survey	1,340	1	82/60
57.200 Healthcare Personnel Safety Component Annual Facility Survey	50	1	480/60
57.204 Healthcare Worker Demographic Data	50	200	20/60
57.205 Exposure to Blood/Body Fluids	50	50	60/60
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	86/60
57.301 Hemovigilance Module Monthly Reporting Plan	500	12	60/60
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	500	1	36/60
57.307 Hemovigilance Adverse Reaction—Acute Hemolytic Transfusion Reaction	500	4	21/60
57.308 Hemovigilance Adverse Reaction—Allergic Transfusion Reaction	500	4	21/60
57.309 Hemovigilance Adverse Reaction—Delayed Hemolytic Transfusion Reaction	500	1	21/60
57.310 Hemovigilance Adverse Reaction—Delayed Serologic Transfusion Reaction	500	2	21/60
57.311 Hemovigilance Adverse Reaction—Febrile Non-hemolytic Transfusion Reaction	500	4	21/60
57.312 Hemovigilance Adverse Reaction—Hypotensive Transfusion Reaction	500	1	21/60
57.313 Hemovigilance Adverse Reaction—Infection	500	1	21/60
57.314 Hemovigilance Adverse Reaction—Post Transfusion Purpura	500	1	21/60
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	21/60
57.317 Hemovigilance Adverse Reaction—Transfusion Related Acute Lung Injury	500	1	21/60
57.318 Hemovigilance Adverse Reaction—Transfusion Associated Circulatory Overload	500	2	21/60
57.319 Hemovigilance Adverse Reaction—Unknown Transfusion Reaction	500	1	21/60
57.320 Hemovigilance Adverse Reaction—Other Transfusion Reaction	500	1	21/60
57.400 Outpatient Procedure Component—Annual Facility Survey	700	1	10/60
57.401 Outpatient Procedure Component—Monthly Reporting Plan	700	12	15/60
57.402 Outpatient Procedure Component Same Day Outcome Measures	200	1	41/60
57.403 Outpatient Procedure Component—Monthly Denominators for Same Day Outcome Measures	200	400	40/60
57.404 Outpatient Procedure Component—SSI Denominator	700	100	41/60
57.405 Outpatient Procedure Component—Surgical Site (SSI) Event	700	5	41/60
57.500 Outpatient Dialysis Center Practices Survey	7,200	1	12/60
57.501 Dialysis Monthly Reporting Plan	7,200	12	5/60
57.502 Dialysis Event	7,200	30	26/60
57.503 Denominator for Outpatient Dialysis	7,200	30	10/60
57.504 Prevention Process Measures Monthly Monitoring for Dialysis	1,730	12	75/60
57.505 Dialysis Patient Influenza Vaccination	615	50	10/60
57.506 Dialysis Patient Influenza Vaccination Denominator	615	5	10/60
57.507 Home Dialysis Center Practices Survey	430	1	30/60
Weekly Healthcare Personnel Influenza Vaccination Cumulative Summary for Non-Long-Term Care Facilities	125	52	60/60
Weekly Healthcare Personnel Influenza Vaccination Cumulative Summary for Long-Term Care Facilities	1,200	52	60/60
Weekly Resident Influenza Vaccination Cumulative Summary for Long-Term Care Facilities ..	2,500	52	60/60
Annual Healthcare Personnel Influenza Vaccination Summary	5,000	1	120/60
Monthly Survey Patient Days & Nurse Staffing	2,500	12	60/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10844]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. 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 or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by May 24, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA

website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

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. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Small Biotech Exception; *Use:* Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (Pub. L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (the Act). In accordance with section 1192(d)(2) of the Act, the term "negotiation-eligible drug" excludes, with respect to the initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets the requirements for the exception for small biotech drugs (the "Small Biotech Exception").

This information is required in order for CMS to accurately identify whether a given drug meets the criteria for the Small Biotech Exception in accordance with section 1192(d)(2) of the Act. To ensure that only covered Part D drugs that meet the requirements for the Small Biotech Exception are excluded from the term "negotiation-eligible drug," a manufacturer that seeks the Small Biotech Exception for its covered Part D drug ("Submitting Manufacturer") must submit information to CMS about the

company and its products in order for the drug to be considered for the exception. If the Submitting Manufacturer seeks the Small Biotech Exception for a covered Part D drug it acquired after December 31, 2021, the Submitting Manufacturer must also submit information related to the separate entity that had the Medicare Coverage Gap Discount Program agreement for the drug on December 31, 2021. The Information Collection Request Form for the Small Biotech Exception must be submitted to CMS before CMS establishes the selected drug list for initial price applicability year 2026. *Form Number:* CMS-10844 (OMB control number: 0938-New); *Frequency:* Once; *Affected Public:* Private sector, Business or other for-profit; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 68.5. (For policy questions regarding this collection contact Corey Rosenberg at 410-786-9763.)

Dated: April 19, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023-08600 Filed 4-21-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Intent To Award a Single-Source Supplement To Provide the National Aging Network With Timely, Relevant, High-Quality Opportunities To Further Enhance Knowledge, Awareness and Models Related to Falls Prevention

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award a single-source supplement to the current cooperative agreement held by the National Council on Aging (NCOA) for the National Falls Prevention Resource Center. The purpose of this program is to advance the development and expansion of technical assistance, education, and resources to increase public awareness about the risk of falls and how to prevent them; increase the number of older adults and adults with disabilities who participate in evidence-based community falls prevention programs; and support the integration and sustainability of evidence-based falls prevention programs within community integrated health networks.