

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

[60Day-21-21DS; Docket No. CDC-2021-0026]

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 Lighting Interventions for Improving the Health, Safety, and Well-Being of Underground Mineworkers. The purpose of this information collection is to examine the effect of human centric lighting (HCL) interventions on circadian disruption (CD) and well-being in underground mineworkers via survey administration and biometric data collection.

DATES: Written comments must be received on or before May 18, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2021-0026 by any of the following methods:

- *Federal eRulemaking Portal:* Regulation.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, 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*.

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, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7118; 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; and
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.
5. Assess information collection costs.

Proposed Project

Pre-shift Lighting Interventions to Improve Miner Safety and Well-being—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Institute for Occupational Safety and Health seeks a two-year approval from the Office of Management and Budget (OMB) to collect information needed to develop strategies and guidance to improve the safety, health, and well-being of underground coal and metal shiftworkers in the U.S. mining industry. Light has both visual and non-visual impacts on the human body, enabling us to visually perceive the world, and non-visually experience circadian entrainment and acute effects that include alertness, concentration, and performance on cognitive tasks. Hence, light drives our fundamental physiological functioning.

It is not surprising that underground miners have significant reductions in exposure to daylight—especially those miners working shifts. This lacking exposure can lead to fatigue and circadian disruption (CD) that can result in sleep loss and reduced alertness. This increases the risk of accidents, and can lead to health problems that include obesity, diabetes, and cancer.

This study will evaluate the impacts of blue and red-light treatment at the beginning of the work shift on task performance, sleepiness and alertness, subjective well-being, sleep efficiency and circadian rhythms in underground mine workers. A 2x2 randomized crossover, mixed design will be used to test the efficacy and acceptability an HCL intervention using light-emitting eyewear delivered to shift workers over a two-year study period. A cross-over design has a significant advantage because the subjects serve as their own control, which serves to minimize variations caused by circadian phase differences and sleep patterns of the individual participants. The other advantages include greater sample size efficiency with randomization of treatment order, and all subjects will receive all the treatments. Participants will be divided between coal and metal miners, and will be those who regularly work the 1st, 2nd and 3rd shifts at one underground coal and one underground metal mine.

NIOSH researchers will visit one underground coal mine and one underground metal mine to obtain informed consent from volunteer mineworkers to conduct an intervention study and administer both electronic and paper and pencil surveys. Before beginning the study, the respondents will provide their informed consent to participate, be given an overview of the demographic information that will be collected and will be instructed how to

properly wear the lighted eyewear and how to use the actigraphy device. Next, participants will be asked to complete six short surveys: (1) Demographic information; (2) the Checklist of Individual Strengths; (3) the Karolinska Sleepiness Scale (KSS); (4) the Munich Chronotype Questionnaire; (5) the Pittsburgh Sleep Quality Index (PSQI); (6) a shiftwork disorder screening; (7) the Lighted Eyeglasses Intervention Acceptability Survey, and (8) the NASA Psychomotor Vigilance Test (PVT). They will also be asked to log caffeine intake and sleep.

Intervention lighting doses will be administered via commercially available lightweight, light-emitting glasses during the nonworking periods of pre-shift. Each participant will experience two lighting interventions: Treatment A is dim red light (10 lx, 3000 K, the placebo control), and treatment B is blue-enriched, polychromatic lighting, the treatment intervention. For each study group, half of the subjects will first experience the blue, and half will first experience the red-light exposure during a three-week experimental phase. After a two-week washout period

designed to minimize carryover or residual learning effects from the prior treatments, subjects will experience the lighting treatment condition they did not yet experience for another three-week period. While wearing lighted eyewear the participants will evaluate comfort, glare and acceptability of the eyewear, while the KSS, the PSQI, and the NASA PVT will be re-administered at various intervals throughout the course of the study.

The total number of responses for each data collection instrument are indicated in the estimated annualized burden hours table below. Survey data will be collected during pre-shift periods and at home on working days and at home on non-working days. Time for data collection at the beginning of the shift will be no more than 25 minutes. NIOSH researchers will collect data at participating sites in above ground facilities on working days. Participants will also complete brief caffeine and sleep logs and wear an actigraphy wristband that records activity and sleep patterns, and light/dark exposure while at home. At various intervals of the study for a total of 12

occasions, participants will swallow a remote temperature monitoring pill to assess circadian rhythms in core body temperature. It is estimated that at-home data collection time will be no more than five minutes per participant.

This data collection will occur within a two-year period beginning after OMB approval and is designed to gather information not previously available. This lighting intervention with these data collection instruments is not being used in any other research in the mining industry. Potential impacts of this project include improvement of the health, safety, and well-being of underground mineworkers by reducing fatigue and CD through new recommendations and HCL-interventions. This project will also answer several research questions that will help establish the efficacy of the new HCL interventions so that they could be commercialized by mine lighting companies and used by underground coal and metal mining companies. The total estimated annualized burden hours are 910. There are no costs to respondents other than their time.

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) |
|---|---|-----------------------|------------------------------------|--|-------------------------|
| Underground Coal and Metal Mineworkers. | Informed consent | 90 | 1 | 10/60 | 15 |
| Underground Coal and Metal Mineworkers. | Demographics | 90 | 1 | 1/60 | 2 |
| Underground Coal and Metal Mineworkers. | Checklist of Individual Strengths | 90 | 1 | 2/60 | 3 |
| Underground Coal and Metal Mineworkers. | Karolinska Sleepiness Scale | 90 | 36 | 1/60 | 54 |
| Underground Coal and Metal Mineworkers. | Lighted Eyewear | 90 | 2 | 2/60 | 6 |
| Underground Coal and Metal Mineworkers. | Lighted Eyeglasses Intervention Acceptability Survey. | 90 | 2 | 1/60 | 3 |
| Underground Coal and Metal Mineworkers. | Munich Chronotype Questionnaire .. | 90 | 1 | 5/60 | 8 |
| Underground Coal and Metal Mineworkers. | Pittsburgh Sleep Quality Index | 90 | 4 | 10/60 | 60 |
| Underground Coal and Metal Mineworkers. | Psychomotor Vigilance Test | 90 | 36 | 6/60 | 324 |
| Underground Coal and Metal Mineworkers. | Shiftwork Disorder Screening | 90 | 1 | 8/60 | 12 |
| Underground Coal and Metal Mineworkers. | Actigraphy don and remove | 90 | 49 | 3/60 | 221 |
| Underground Coal and Metal Mineworkers. | Caffeine log | 90 | 49 | 1/60 | 74 |
| Underground Coal and Metal Mineworkers. | Core body temperature pill—open package and swallow. | 180 | 12 | 3/60 | 54 |
| Underground Coal and Metal Mineworkers. | Sleep log | 180 | 49 | 1/60 | 74 |
| Total | | | | | 910 |

Jeffrey M. Zirger,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-29, CMS-437, CMS-10185 and CMS-10452]

Agency Information Collection Activities: Proposed Collection; 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by May 18, 2021.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

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

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-29 Verification of Clinic Data—Rural Health Clinic Form and Supporting Regulations
CMS-437 Psychiatric Unit Criteria Work Sheet
CMS-10185 Medicare Part D Reporting Requirements
CMS-10452 CMS Identity Management (IDM) System

Under the 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 requires federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of*

Information Collection: Verification of Clinic Data—Rural Health Clinic Form and Supporting Regulations; *Use:* The form is utilized as an application to be completed by suppliers of Rural Health Clinic (RHC) services requesting participation in the Medicare program. This form initiates the process of obtaining a decision as to whether the conditions for certification are met as a supplier of RHC services. It also promotes data reduction or introduction to and retrieval from the Automated Survey Process Environment (ASPEN) and related survey and certification databases by the CMS Regional Offices. Should any question arise regarding the structure of the organization, this information is readily available. *Form Number:* CMS-29 (OMB control number 0938-0074); *Frequency:* Occasionally (initially and then every six years); *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 1,887; *Total Annual Responses:* 5,661; *Total Annual Hours:* 1,269. (For policy questions regarding this collection contact Shonte Carter at 410-786-3532.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Psychiatric Unit Criteria Work Sheet; *Use:* Certain specialty hospitals and hospital specialty distinct-part units may be excluded from the Inpatient Medicare Prospective Payment System (IPPS) and be paid at a different rate. These specialty hospitals and distinct-part units of hospitals include Inpatient Rehabilitation Facilities (IRFs) units, Inpatient Rehabilitation Facilities (IRFs) hospitals and Inpatient Psychiatric Facilities (IPFs).

CMS regulations at 42 CFR 412.20 through 412.29 describe the criteria under which these specialty hospitals and specialty distinct-part hospital units are excluded from the IPPS. Form CMS-437 is used by Inpatient Psychiatric Facilities (IPFs) to attest to meeting the necessary requirements that make them exempt for receiving payment from Medicare under the IPPS. These IPFs must use CMS-437 to attest that they meet the requirements for IPPS exempt status prior to being placed into excluded status. The IPFs must re-attest to meeting the exclusion criteria annually. *Form Number:* CMS-437 (OMB control number: 0938-0358); *Frequency:* Annually; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 1,598; *Total Annual Responses:* 1,598; *Total Annual Hours:* 1,732. (For policy questions regarding this collection