instructions)
D. Long-term cognitive impairment (Change in cognition after delirium that has a long-term duration or is possibly permanent)
E. Institutionalization (living in an assisted living facility or nursing home)
F. Caregiver burden/strain
G. Falls
H. Memory of patient distress
III. Resource utilization
A. Re-admissions to hospital or ICU
B. Length of stay in ICU
C. Length of stay in hospital
D. Length of stay in skilled nursing facility
E. Sitter use
F. Hospice enrollment
IV. Adverse effects of intervention(s)
A. Sedation
B. Weight gain
C. Changes in appetite
D. Cardiac effects
E. Neurologic effects
F. Paradoxical reactions
G. Hypersensitivity reactions
H. Inappropriate continuation of antipsychotic medication
I. Swallowing difficulties
J. Aspiration pneumonia
III. Timing
A. Any duration of follow-up
IV. Settings
A. Hospital setting
B. Post-acute care setting
C. Palliative care setting

Francis D. Chesley, Jr.,

Deputy Director.

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BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2018–0093; NIOSH–320]

Self-Contained Breathing Apparatus Compressed Breathing Gas Containers; Request for Information

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Request for information.

SUMMARY: In October 2017, the Department of Transportation (DOT) issued a special permit to the Digital Wave Corporation, allowing the company to extend the service life of certain carbon-fiber reinforced aluminum-lined cylinders. Some stakeholders, including respirator and cylinder manufacturers, have expressed concern to the National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention, about the safety of cylinders extended beyond the manufacturers' stated service life. NIOSH is seeking information about the potential effect of the special permit, as it may relate to the safety of self-contained breathing apparatus respirators approved by NIOSH for use in U.S. workplaces.

DATES: Comments must be received by November 30, 2018.

ADDRESSES:

Written comments: You may submit comments by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments to the docket.
- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 1090 Tusculum Avenue, Cincinnati, OH 45226.

Instructions: All submissions received must include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC–2018–0093; NIOSH–320) for this action. All relevant comments, including any personal information provided, will be posted without change to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Peterson, NIOSH National Personal Protective Technology Laboratory, 626 Cochrans Mill Road, Pittsburgh, PA 15236; 1–888–654–2294 (this is a toll-free number); *PPEconcerns@cdc.gov.*

SUPPLEMENTARY INFORMATION: The Department of Transportation approves certain carbon-fiber reinforced aluminum-lined cylinders (hereinafter ''DOT–CFFC''), which are commonly used to provide breathing air in the self-contained breathing apparatus (SCBA) respirators typically carried by firefighters and other industrial workers to protect them in atmospheres immediately dangerous to life and health. Currently, all DOT–CFFC approved cylinders that are a sub-component of NIOSH-approved SCBA have a service life of 15 years; DOT regulations require ''requalification'' every 5 years to ensure that each cylinder can hold its rated pressure for the duration of the 15-year service life.

In October 2017, the DOT Pipeline and Hazardous Materials Safety Administration issued special permit, DOT–SP 16320 (Third Revision), to Digital Wave Corporation of Centennial, CO.[1] Digital Wave Corporation manufactures ultrasonic examination cylinder testing equipment, modal acoustic emission testing equipment, and provides associated inspection services, including the requalification of carbon-fiber reinforced aluminum-lined cylinders. Pursuant to DOT–SP 16320, modal acoustic emission requalification testing allows DOT–CFFC cylinders to be authorized for use for 5 years after the original 15-year service life; cylinders could be requalified three times beyond the original 15-year service life, for a total service life of 30 years.

Modal acoustic emission testing is an advanced, non-destructive evaluation of carbon-fiber reinforced aluminum-lined cylinders that detects structural damage which can compromise burst pressure strength in a composite overwrapped pressure vessel. The modal acoustic emission waveforms can be used to identify damage such as fiber breakage and delamination. Some stakeholders have expressed concerns regarding potential cylinder failure when the service life is extended past the service life identified on the original special permit. Since DOT–SP 16320 was issued, more than 3,500 carbon-fiber reinforced aluminum-lined cylinders have been requalified beyond their original 15-year service life using the modal acoustic emission method.

NIOSH has published guidance advising SCBA users who may be concerned about using modal acoustic emission-requalified cylinders as part of their NIOSH-approved SCBA configuration to review the user instructions, supplemental informational inserts, safety precautions, and SCBA warranty information provided by the NIOSH approval holder.[2] The guidance further encourages approval holders to provide respiratory protection program administrators and SCBA users with current recommendations regarding the DOT–SP 16320 requalification method with regard to service life limitations or other relevant matters.

NIOSH seeks to better understand the use of modal acoustic emission testing to requalify DOT–CFFC cylinders beyond the original 15-year service life, as permitted by DOT–SP 16320, as well as the safety and health concerns of users in industrial settings, including the fire service and first responders.

[1] DOT Pipeline and Hazardous Materials Safety Administration, DOT–SP 16320, *https://www.phmsa.dot.gov/approvals-and-permits/hazmat/file-serve/offer/SP16320.pdf/offerserver/SP16320.*

[2] *https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/respprotect/CA-2018-1006.html.*

Accordingly, NIOSH is seeking data and information from all interested stakeholders in response to the following questions:

1. Are users of DOT–CFFC cylinders that have been requalified for service life beyond 15 years, pursuant to the provisions of DOT–SP 16320, exposed to any elevated safety or health risk as a result of either the modal acoustic emission requalification testing itself or the service life extension? If so, identify the concern or concerns and provide substantive data, studies, references, and information to further characterize and/or quantify the concern.

2. Does the service-life extension offered by DOT–SP 16320 or the modal acoustic emission testing itself provide a benefit to either end users or institutional users (*e.g.,* fire departments)? If so, please provide any relevant data, studies, references, or other corroborating information.

3. What factors do respiratory protection program managers consider in determining whether to replace an expiring cylinder with a new replacement cylinder or requalify the expiring cylinder using modal acoustic emission testing?

4. In which industries and operations are modal acoustic emission-requalified cylinders currently being used?

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10142, CMS–R–262, and CMS–179]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid 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 November 30, 2018.

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 the following:

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

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–1326.

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–10142 Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP)

CMS–R–262 Contract Year 2020 Plan Benefit Package (PBP) Software and Formulary Submission

CMS–179 Medicaid State Plan Base Plan Pages

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:* Revision of a currently approved collection; *Title of Information Collection:* Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* The competitive bidding process defined by the ''The Medicare Prescription Drug, Improvement, and Modernization Act'' (MMA) applies to both the MA and Part D programs. It was first used for Contract Year 2006. It is an annual process that encompasses the release of the MA rate book in April, the bid's that plans submit to CMS in June, and the release of the Part D and RPPO benchmarks, which typically occurs in August.

CMS requires that Medicare Advantage Organizations (MAOs) and Prescription Drug Plans (PDPs) complete the BPT as part of the annual bidding process. During this process, organizations prepare their proposed actuarial bid pricing for the upcoming contract year and submit them to CMS for review and approval. The purpose of the BPT is to collect the actuarial pricing information for each plan. It is an Excel workbook with multiple worksheets and special functions through which bidders present to CMS their plan pricing information. Bidders enter information, such as plan experience, projected enrollment, and risk profile, and the BPT calculates the plan premiums and other values that