instructions to reflect the changes to the financial disclosure regulation. Specifically, OGE proposes to: Revise the reporting period for termination reports to include the entire preceding calendar year if a required annual report has not been filed; revise the income disclosure requirement to include only received income; revise the ''widely diversified'' criterion for purposes of determining whether a fund qualifies as an ''excepted investment fund;'' add a new feature (checkbox) for purposes of managing early termination report filing on the *Integrity* version of the Form 278e; clarify the Definition section of Part 2; clarify when a source of compensation need not be disclosed and the method for disclosing the existence of such sources; and eliminate the disclosure of transactions that occurred before the reporting individual became subject to the public financial disclosure requirements.

OGE is also proposing to update the Privacy Act statement in accordance with changes to the applicable system of records and to make certain minor formatting changes and corrections to the instructions and one of the data entry fields.

OGE published a first round notice of its intent to request paperwork clearance for a modified OGE Form 278e Executive Branch Personnel Public Financial Disclosure Report. *See* 83 FR 32122 (July 11, 2018). OGE received three responses to that notice. The first response was unrelated to the notice and did not address the information collection.

The second comment suggested eliminating the requirement to report diversified mutual funds. The financial disclosure requirements are dictated by the Ethics in Government Act (EIGA), 5 U.S.C. app. sec. 102, as amended. The commenter's suggested change could not be made without revisions to the EIGA. Accordingly, OGE declines to adopt this suggestion as a modification of the OGE Form 278e.

The third comment was from an individual identifying himself as a former nominee to a Presidentially-appointed, Senate-confirmed position. The commenter made several suggestions about how the government should address potential conflicts of interest identified through the financial disclosure review and certification process, as well as ways that the government could make that process more efficient. These matters are beyond the scope of the information collection and cannot be addressed through the modification of the OGE Form 278e. The commenter also made suggestions regarding the detail with which filers are required to report certain assets, suggesting that the form requires excessive reporting of ''low value'' data. As discussed above, the financial disclosure requirements are dictated by the EIGA. Therefore, OGE cannot make substantive changes to the financial disclosure reporting requirements through a modification of the OGE Form 278e.

Finally, the third commenter also stated that the government's estimate of the reporting burden vastly understates the actual burden for candidates with extensive or complicated financial holdings. In addressing this issue, the commenter noted that completing the form required ''at least 40 hours of work'' by him and his family. He also noted that the government's cumulative response time during the review and certification process was 114 days. As an initial matter, OGE notes that its estimate of the average reporting burden for the 278e is currently ten hours, not three as stated by the commenter. Moreover, the estimated burden properly does not include the time spent by the government in reviewing and responding to the filers' completed forms. OGE's estimated time per response is an average based on the estimated burden on *all* types of filers—those with complicated financial holdings and those with simpler financial holdings. While OGE recognizes that the burden for a filer with extensive or complicated financial holdings may be significantly more than ten hours, the estimated burden for the majority of filers is fewer than five hours. Accordingly, OGE declines to revise its estimated burden at this time.

Request for Comments: Agency and public comment is again invited specifically on the need for and practical utility of this information collection, the accuracy of OGE's burden estimate, the enhancement of quality, utility, and clarity of the information collected, and the minimization of burden (including the use of information technology). Comments received in response to this notice may be included with the OGE request for approval of the modified information collection. The comments will also become a matter of public record.

Approved: September 26, 2018.

Diana Veilleux,

Chief, Legal, External Affairs and Performance Branch, Office of Government Ethics.

[FR Doc. 2018–21270 Filed 9–28–18; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Antipsychotics for the Prevention and Treatment of Delirium: A Systematic Review

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of *Antipsychotics for the Prevention and Treatment of Delirium: A Systematic Review,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before October 31, 2018.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Antipsychotics for the Prevention and Treatment of Delirium: A Systematic Review.* AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the

literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Antipsychotics for the Prevention and Treatment of Delirium: A Systematic Review,* including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: *https://effectivehealthcare.ahrq.gov/topics/antipsychotics/research-protocol.*

This is to notify the public that the EPC Program would find the following information on *Antipsychotics for the Prevention and Treatment of Delirium: A Systematic Review* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

The Key Questions

I. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to prevent delirium?

A. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to prevent delirium in persons aged 65 years or older?

B. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to prevent delirium in persons with dementia?

C. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to prevent delirium in patients in an intensive care unit?

D. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to prevent delirium in patients in a post-acute care facility?

E. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to prevent delirium in patients in palliative or hospice care?

F. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to prevent delirium in patients in post-operative care?

II. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to treat delirium?

A. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to treat delirium in persons aged 65 years or older?

B. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to treat delirium in persons with dementia?

C. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to treat delirium in patients in an intensive care unit?

D. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to treat delirium in patients in a post-acute care facility?

E. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to treat delirium in patients in palliative or hospice care?

F. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to treat delirium in patients in post-operative care?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

Population(s):

I. KQ 1: Hospitalized adults, adults in post-acute care, adults in palliative or hospice care, or adults in post-operative care

II. KQ 2: Hospitalized adults, adults in post-acute care, adults in palliative or hospice care, or adults in post-operative care who have been diagnosed with delirium using a validated instrument

Interventions:

I. Antipsychotic drugs, including
- A. Any first-generation agent (chlorpromazine, droperidol, fluphenazine, haloperidol, loxapine, molindone, perphenazine, pimozide, prochlorperazine, thiothixene, thioridazine, trifluoperazine)
- B. Any second-generation agent (aripiprazole, asenapine, brexpiprazole, cariprazine, clozapine, iloperidone, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, ziprasidone)

II. We will only include studies where the effects of the antipsychotic drugs can be isolated.

Comparators

I. KQ 1: Non-drug approaches to preventing delirium, placebo, active control, usual care

II. KQ 2: Non-drug approaches to treating delirium, placebo, active control, usual care

Outcomes:

I. Intermediate outcomes
- A. Short-term delirium symptoms
- B. Delirium severity
- C. Delirium-free, coma-free days alive
- D. Duration of delirium
- E. Patient distress
- F. Use of rescue therapy
- G. Use of physical restraint

II. Final health or patient-centered outcomes
- A. Mortality
- B. Quality of life
- C. Cognitive and emotional functioning (includes functioning related to memory, communication, concentration, and understanding

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.*