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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10688]

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 January 14, 2019.

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 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) 786-4669.

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-10688 Home Health (HH) National Provider Survey

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

Type of Information Collection Request: New collection (Request for a new OMB control number); *Title of Information Collection:* Home Health (HH) National Provider Survey; *Use:* Section 1890A(a)(6) of the Social

Security Act (the Act) requires the Secretary of HHS every three years to assess the quality and efficiency effects of the use of endorsed measures in specific Medicare quality reporting and incentive programs. This request is for review and approval of a survey and qualitative interview guide for the home health setting, which CMS proposes to use to address critical needs regarding the impact of use of quality and efficiency measures in the home health setting, including the burden they impose on home health agencies.

CMS plans to use the findings from surveys and qualitative interviews for multiple purposes. The qualitative interviews and standardized survey will inform CMS about the impact of measures used to assess care in HHAs. The surveys will help CMS understand whether the use of performance measures has been associated with changes in HHA behavior—namely, what quality improvements (QI) investments HHAs are making and whether adoption of QI changes is associated with higher performance on the measures. The survey will help CMS identify characteristics associated with high performance, which, if understood, could be used to leverage improvements in care among lower-performing HHAs. The survey and interviews, assuming approval by August 2019, would be fielded from fall 2019 through spring 2020. *Form Number:* CMS-10688 (OMB control number: 0938-NEW); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 1,040; *Total Annual Responses:* 1,040; *Total Annual Hours:* 1,040. (For policy questions regarding this collection contact Noni Bodkin at 410-786-7837.)

Dated: November 9, 2018.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018-24951 Filed 11-14-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3692]

Evaluating the Pressor Effects of Drugs; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public workshop entitled “Evaluating the Pressor Effects of Drugs.” This public workshop is convened by the Duke-Robert J. Margolis, MD, Center for Health Policy at Duke University and supported by a cooperative agreement with FDA. The purpose of this public workshop is to bring the stakeholder community together to discuss the premarketing assessment of a drug’s effect on blood pressure. Elevated blood pressure is known to increase the risk of stroke, heart attack, and death. The effect of a drug on blood pressure may therefore be an important consideration in benefit-risk assessment. Agency staff will present findings related to the use of ambulatory blood pressure monitoring to assess treatment effects.

DATES: The public workshop will be held on Monday, February 4, 2019 from 8:30 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at 1777 F Street NW, Washington, DC 20006. For additional travel and hotel information, please refer to the following website: <https://healthpolicy.duke.edu/events/evaluating-pressor-effects-drugs-ambulatory-blood-pressure-monitoring-studies>.

FOR FURTHER INFORMATION CONTACT: Norman Stockbridge, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4166, Silver Spring, MD 20903, 301-796-2240, email: Norman.Stockbridge@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop regarding FDA’s assessment of the pressor effects of drugs. Elevated blood pressure is known to increase the risk of stroke, heart attack, and death. The effect of a drug on blood pressure may therefore be an important consideration in benefit-risk assessment. Following FDA’s announcement in the **Federal Register** of the availability of a draft guidance for industry entitled “Assessment of Pressor Effects of Drugs” (May 31, 2018, 83 FR 25013), FDA is convening this public meeting in collaboration with the Duke-Margolis Center for Health Policy to discuss the Agency’s current thinking with expert stakeholders and to consider public comments.

II. Topics for Discussion at the Public Workshop

Topics for discussion during this meeting include:

- Risk associated with blood pressure change
- Aspects and FDA analyses related to ambulatory blood pressure monitoring
- Evaluating a drug’s effect on blood pressure and understanding the optimal regulatory approach to assigning risk

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: <https://healthpolicy.duke.edu/events/evaluating-pressor-effects-drugs-ambulatory-blood-pressure-monitoring-studies>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by Thursday, January 31, 2019, midnight Eastern Time. There will be no onsite registration. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. Duke-Margolis will post on its website if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Sarah Supsiri at the Duke-Margolis Center for Health Policy (202-791-9561, email: sarah.supsiri@duke.edu) no later than November 29, 2018.

Streaming webcast of the public workshop: This public workshop will be webcast live. Persons interested in viewing the live webcast may register ahead of the event by visiting <https://healthpolicy.duke.edu/events/evaluating-pressor-effects-drugs-ambulatory-blood-pressure-monitoring-studies>. The live webcast will also be available at the website above on the day of the event without preregistration. Archived video footage will be available at the Duke-Margolis website following the workshop.

All event materials will be provided to registered attendees via email prior to the workshop and will be publicly available at the Duke-Margolis Center for Health Policy website <https://healthpolicy.duke.edu/events/>

evaluating-pressor-effects-drugs-ambulatory-blood-pressure-monitoring-studies.

Dated: November 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-24961 Filed 11-14-18; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

[Docket No.: DHS-2018-0063]

First Responders Community of Practice (FRCoP)

AGENCY: Science and Technology Directorate, Department of Homeland Security.

ACTION: 30-Day Notice of Information Collection; request for comment. (Reinstatement of a Currently Approved Collection, 1640-0016).

SUMMARY: The Department of Homeland Security (DHS), Science and Technology (S&T) is proposing to reinstate OMB 1640-0016, an information collection, by inviting the public to comment on the collection: First Responders Community of Practice (FRCoP) User Registration Page (DHS Form 10059 (9/09)). The FRCoP web based tool collects profile information from first responders and select authorized non-first responder users to facilitate networking and formation of online communities. All users are required to authenticate prior to entering the site. In addition, the tool provides members the capability to create wikis, discussion threads, blogs, documents, etc., allowing them to enter and upload content in accordance with the site’s Rules of Behavior. Members are able to participate in threaded discussions and comment on other members’ content. The FRCoP program is responsible for providing a collaborative environment for the first responder community to share information, best practices, and lessons learned. The Homeland Security Act of 2002 established this requirement. Interested persons may receive a copy of the collection by contacting the DHS S&T Paperwork Reduction Act (PRA) Coordinator.

DATES: Comments are encouraged and accepted until December 17, 2018.

ADDRESSES: You may submit comments, identified by docket number DHS-2018-0063, at:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Please follow the instructions for submitting comments.

- *Mail and hand delivery or commercial delivery:* Science and