Dated: October 27, 2016.

Lorin S. Curit,

Director, Federal Acquisition Policy Division, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2016–26396 Filed 11–1–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10632]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

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 any of the following subjects: 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 3, 2017.

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' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

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: Reports Clearance Office 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–10632 Evaluating Coverage to Care (C2C)

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:* New collection (Request for a new OMB control number); *Title of Information Collection:* Evaluating Coverage to Care (C2C); *Use:* CMS OMH has contracted with the RAND Corporation to evaluate From Coverage to Care (C2C). From the beginning of the Affordable Care Act's implementation, the Centers for Medicare & Medicaid Services, Office of Minority Health (CMS OMH) recognized that achieving better health and reduced health care costs would require individuals to take an active role in their health care and regularly use primary and preventive care services. To address this need, CMS OMH launched From Coverage to Care (C2C) in June 2014. C2C was designed to help consumers understand what it means to have health insurance coverage, how to find a provider, when and where to seek appropriate health services, and why prevention and partnering with a provider is important for achieving optimal health. It was also designed to equip health care providers and stakeholders in the community who support consumers' connection to care with the tools needed to promote consumer engagement and to promote changes in the health care system that improve access to care. As part of C2C, CMS produced a range of consumer-oriented materials, both web-based and in print. The most in-depth of the print materials is an eight-step booklet titled ''A Roadmap to Better Care and a Healthier You.'' Based on the need for the information to be communicated in smaller, more digestible packets, booklets were developed to correspond to each of the eight steps. Four of the most popular pages of the Roadmap have been made available as single-page handouts for easier distribution. These materials are currently available in eight languages, including English, Spanish, Arabic, Chinese, Haitian Creole, Korean, Russian, and Vietnamese.

Since the national launch in 2014, CMS has disseminated C2C through speaking engagements, webinars, and meetings sponsored by CMS regional offices. CMS fills product orders and recently completed a redesign of the C2C Web site. C2C has grown to address emerging needs of consumers, as well as stakeholders or organizations that work with and support consumers, across the full continuum of health insurance and care: Plan selection, enrollment, finding a provider, and engaging in care over time.

RAND spent the past year designing and preparing for this evaluation to assess C2C's impact on consumer health insurance literacy and care utilization. This evaluation will also help CMS understand how C2C is spread within a community and disseminated to consumers, and in turn how best to

maximize C2C's impact. The next three years will be dedicated to implementing the evaluation described in this submission. We are proposing four data collection activities: (1) A cross-sectional survey of organizations that have ordered and used the materials with consumers; (2) A cross-sectional survey of consumers, drawn from the Knowledge Networks panel, to measure the association between C2C and consumer knowledge and behavior; (3) semi-structured interviews with staff from a limited set of community organizations as part of a case study; and (4) focus groups of consumers as part of a case study. The case study will be conducted in a community where English is not the preferred language, and where C2C materials in another language (*e.g.,* Spanish, Arabic, Chinese, Haitian Creole, Korean, Russian, and Vietnamese) were used with consumers. *Form Number:* CMS–10632 (OMB control number: 0938-New); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 3,460; *Total Annual Responses:* 3,460; *Total Annual Hours:* 1,176. (For policy questions regarding this collection contact Ashley Peddicord-Austin at 410–786–0757).

Dated: October 28, 2016.

William N. Parham, III,

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

[FR Doc. 2016–26493 Filed 11–1–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0117]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by December 2, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0670. Also include the FDA docket number found in brackets in the heading of this document.

Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims; OMB Control Number 0910–0670—Extension

This guidance is intended to assist applicants in developing labeling for outcome claims for drugs that are indicated to treat hypertension. With few exceptions, current labeling for antihypertensive drugs includes only the information that these drugs are indicated to reduce blood pressure; the labeling does not include information on the clinical benefits related to cardiovascular outcomes expected from such blood pressure reduction. However, blood pressure control is well established as beneficial in preventing serious cardiovascular events, and inadequate treatment of hypertension is acknowledged as a significant public health problem. FDA believes that the appropriate use of these drugs can be encouraged by making the connection between lower blood pressure and improved cardiovascular outcomes more explicit in labeling. The intent of the guidance is to provide common labeling for antihypertensive drugs except where differences are clearly supported by clinical data. The guidance encourages applicants to submit labeling supplements containing the new language.

The guidance contains two provisions that are subject to OMB review and approval under the PRA and one provision that would be exempt from OMB review:

1. Section IV.C of the guidance requests that the CLINICAL STUDIES section of the Full Prescribing Information of the labeling should include a summary of placebo or active-controlled trials showing evidence of the specific drug's effectiveness in lowering blood pressure. If trials demonstrating cardiovascular outcome benefits exist, those trials also should be summarized in this section. Table 1 in Section V of the guidance contains the specific drugs for which FDA has concluded that such trials exist. If there are no cardiovascular outcome data to cite, one of the following two paragraphs should appear:

''There are no trials of [DRUGNAME] or members of the [name of pharmacologic class] pharmacologic class demonstrating reductions in cardiovascular risk in patients with hypertension,'' or ''There are no trials of [DRUGNAME] demonstrating reductions in cardiovascular risk in patients with hypertension, but at least one pharmacologically similar drug has demonstrated such benefits.''

In the latter case, the applicant's submission generally should refer to table 1 in section V of the guidance. If the applicant believes that table 1 is incomplete, it should submit the clinical evidence for the additional information to Docket No. FDA–2008–D–0150. The labeling submission should reference the submission to the docket. FDA estimates that no more than one submission to the docket will be made annually from one company, and that each submission will take approximately 10 hours to prepare and submit. Concerning the recommendations for the CLINICAL STUDIES section of the Full Prescribing Information of the labeling, FDA regulations at §§ 201.56 and 201.57 (21 CFR 201.56 and 201.57) require such labeling, and the information collection associated with these regulations is approved by OMB under OMB control number 0910–0572.

2. Section VI.B of the guidance requests that the format of cardiovascular outcome claim prior approval supplements submitted to FDA under the guidance should include the following information:

- A statement that the submission is a cardiovascular outcome claim supplement, with reference to the guidance and related Docket No. FDA–2008–D–0150.
- Applicable FDA forms (*e.g.,* 356h, 3397).
- Detailed table of contents.
- Revised labeling to:
  - Include draft revised labeling conforming to the requirements in §§ 201.56 and 201.57 and
  - include marked-up copy of the latest approved labeling, showing all additions and deletions, with annotations of where supporting data (if applicable) are located in the submission.

FDA estimates that approximately 1 cardiovascular outcome claim supplement will be submitted annually from approximately 1 different companies, and that each supplement will take approximately 20 hours to