

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

[Document Identifier: CMS–10466 and 10714]

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 13, 2020.**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 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–10466 Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions

CMS–10714 Electronic Medical Documentation Interoperability (EMDI) Pre and Post Pilot Measures 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

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; *Use:* The data collection and reporting requirements in "Patient

Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions" (78 FR 39494—July 1, 2013)), address federal requirements that states must meet with regard to the Exchange minimum function of performing eligibility determinations and issuing certificates of exemption from the shared responsibility payment. In the final regulation, CMS addresses standards related to eligibility, including the verification and eligibility determination process, eligibility redeterminations, options for states to rely on HHS to make eligibility determinations for certificates of exemption, and reporting. *Form Number:* CMS–10466 (OMB control number: 0938–1190); *Frequency:* Occasionally; *Affected Public:* Private Sector (Businesses or other for-profits); *Number of Respondents:* 45,060; *Total Annual Responses:* 45,060; *Total Annual Hours:* 12,150. For policy questions regarding this collection contact Katherine Bentley at 301–492–5209.

2. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Electronic Medical Documentation Interoperability (EMDI) Pre and Post Pilot Measures Survey; *Use:* The EMDI program assists the Centers for Medicare & Medicaid Services (CMS) Health Information Technology (health IT) standards and interoperability (S&I) initiative, which is to: (1) Facilitate and expand the secure transport of interoperable electronic documentation, (2) utilize and fill in the gaps in the current standards to achieve increased level of interoperability among systems and organizations, and (3) demonstrate the utility of these standards by establishing pilot programs with existing Health Information Handlers, Health Information Service Providers (HISP), and health care providers.

The EMDI Initiative, associated documentation, and pilots are for the purposes of evaluating the performance of CMS policies that involve interoperability and the collection of data/information only. The collected data/information will help CMS, and the EMDI team in determining the overall effectiveness of piloting the EMDI program, as well as assessing each provider's current ability to send, and receive electronic data. *Form Number:* CMS–10714 (OMB control number: 0938–New); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profit, not-for-profit institutions); *Number of Respondents:* 240; *Total Annual Responses:* 240; *Total Annual*

Hours: 120. For policy questions regarding this collection contact Christopher Lofts at 410-786-4076.

Dated: November 8, 2019.

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-4900]

Patient-Focused Drug Development Guidance: Incorporating Clinical Outcome Assessments Into Endpoints for Regulatory Decision Making; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public workshop to convene a discussion on incorporating clinical outcome assessments (COAs) into endpoints for regulatory decision making. This workshop will inform development of patient-focused drug development guidance as required by the 21st Century Cures Act (Cures Act) and as part of commitments made by FDA under the sixth authorization of the Prescription Drug User Fee Amendments (PDUFA VI). The Agency will publish a discussion document approximately 1 month before the workshop date. FDA is interested in seeking information and comments on the approaches proposed in the discussion document, as well as input on examples that could be illustrated in the forthcoming draft guidance, where approaches proposed in the discussion document have been successfully applied.

DATES: The public workshop will be held on December 6, 2019, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by February 4, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is

through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 4, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 4, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and

identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-N-4900 for "Patient-Focused Drug Development Guidance: Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision Making; Public Workshop; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Meghana Chalasani, Center for Drug Evaluation and Research, Food and