

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

2. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* ICF/IID Survey Report Form and Supporting Regulations; *Use:* The information collected with forms 3070G-I is used to determine the level of compliance with Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) CoPs necessary to participate in the Medicare/Medicaid program. Information needed to monitor the State's performance as well as the ICF/IID program in general, is available to CMS only through the use of information abstracted from the survey report form. The form serves as a coding worksheet designed to facilitate data entry and retrieval into the Automated Survey Processing Environment Suite (ASPEN) in the State and at the CMS regional offices. *Form Number:* CMS-3070G-I (OMB control number: 0938-0062); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 6,100; *Total Annual Responses:* 6,100; *Total Annual Hours:* 18,300. (For policy questions regarding this collection contact Melissa Rice at 410-786-3270.)

2. *Type of Information Collection Request:* Reinstatement with change of a

previously approved collection; *Title of Information Collection:* Initial and Renewal Model of Care Submissions Off-cycle Submission of Summaries of Model of Care; *Use:* Section 3205(e) of the Affordable Care Act requires that all skilled nursing facilities (SNPs) be approved by NCQA. This approval is based on NCQA's evaluation of SNPs' MOC narratives using MOC scoring guidelines. The Bipartisan Budget Act (BBA) of 2018 Section 50311 modified the MOC requirements for C-SNPs in section 1859 (b)(6)(B)(iii) of the Act. Specifically, section (B)(iv) requires that beginning in 2020 and subsequent years, C-SNPs will submit MOCs annually for evaluation and approval.

SNPs are a specific type of Medicare Advantage coordinated care plan that provide targeted care to individuals with unique special need. SNPs are required to submit Models of Care (MOC) as a component of the Medicare Advantage application process through the Health Plan Management System (HPMS). NCQA and CMS will use information collected in the SNP Application HPMS module to review and approve MOC narratives in order for a Medicare Advantage Organization (MAO) to operate as a new SNP in the upcoming calendar year(s). This information is used by CMS as part of the Medicare Advantage SNP application process. NCQA and CMS will use information collected in the Renewal Submission section of the HPMS MOC module to review and approve the MOC narrative in order for the SNP to receive a new approval period and operate in the upcoming calendar year(s). NCQA and CMS will use information in the Off-Cycle Submission section of the HPMS MOC module to review changes made to an approved MOCs by SNPs. It is the responsibility of SNPs to notify CMS of significant changes to their MOC in HPMS. NCQA will conduct a review for CMS to determine if the changes made to a MOC are consistent with the overall approved MOC before SNPs may implement the changes. *Form Number:* CMS-10565 (OMB control number 0938-1296); *Frequency:* Occasionally; *Affected Public:* State, Local, and Tribal Governments; *Number of Respondents:* 323; *Total Annual Responses:* 323; *Total Annual Hours:* 1856. (For policy questions regarding this collection contact Donna B. Williamson at 410-786-4647.)

Dated: March 25, 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

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10305]

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 May 28, 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 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-10305 Medicare Part C and Part D Data Validation (42 CFR 422.516g and 423.514g)

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 with change of a currently approved collection; *Title of Information Collection:* Medicare Part C and Part D Data Validation (42 CFR 422.516g and 423.514g); *Use:* The

Centers for Medicare and Medicaid Services (CMS) established reporting requirements for Medicare Part C and Part D sponsoring organizations (Medicare Advantage Organizations [MAOs], Cost Plans, and Medicare Part D sponsors) under the authority described in 42 CFR 422.516(a) and 423.514(a), respectively. Under these reporting requirements, each sponsoring organization must submit Medicare Part C, Medicare Part D, or Medicare Part C and Part D data. In order for the reported data to be useful for monitoring and performance measurement, the data must be reliable, valid, complete, and comparable among sponsoring organizations. To maintain the independence of the validation process, sponsoring organizations do not use their own staff to conduct the data validation. Sponsoring organizations are responsible for hiring external, independent data validation contractors (DVCs) who meet a minimum set of qualifications and credentials, which CMS outlines in the "Standards for Selecting Data Validation Contractors" document. For the retrospective review in 2020, the DVCs will review data submitted by sponsoring organizations for CY2019. *Form Number:* CMS-10305 (OMB control number: 0938-1115); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 553; *Total Annual Responses:* 553; *Total Annual Hours:* 15,332. (For policy questions regarding this collection contact Maria Sotirelis at 410-786-0552.)

Dated: March 25, 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-1131]

Annual Public Meeting; Reagan-Udall Foundation for the Food and Drug Administration

AGENCY: Reagan-Udall Foundation, FDA, HHS.

ACTION: Notice of annual meeting.

SUMMARY: The Reagan-Udall Foundation (the Foundation) for the Food and Drug Administration (FDA), which was created by Title VI of the Food and Drug Administration Amendments Act of 2007, is announcing its annual public

meeting. The Foundation will discuss its activities and how they support FDA.

DATES: The public meeting will be held on May 2, 2019, from 10 a.m. until 12 noon. Registration to attend the meeting must be received by April 30, 2019, at 5 p.m. Eastern Time. Requests for oral presentation must be received before April 30, 2019, at 5 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information. The public is also invited to submit written comments by sending them via email to Kelly Catterton (see **FOR FURTHER INFORMATION CONTACT**) before April 30, 2019, at 5 p.m. Eastern Time.

ADDRESSES: The public meeting will be held at the PEW Charitable Trusts, 901 E St. NW, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Kelly Catterton, Executive Assistant to the Executive Director, Reagan-Udall Foundation for FDA, 202-849-2255, kcatterton@reaganudall.org.

SUPPLEMENTARY INFORMATION:

I. Background

The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) not-for-profit, organization created by Congress to advance the mission of FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development; accelerate innovation, and enhance product safety. With the ultimate goal of improving public health, the Foundation provides a unique opportunity for different sectors (FDA, patient groups, academia, other government entities, and industry) to work together in a transparent way to create exciting new research and engagement projects to advance regulatory science.

The Foundation acts as a neutral third party to establish novel, scientific collaborations. Much like any other independently developed information, FDA evaluates the scientific information from these collaborations to determine how the Foundation projects can help the Agency to fulfill its mission.

Foundation projects currently include: Innovation in Medical Evidence Development and Surveillance, a public-private partnership that allows researchers to study drug safety concerns of interest to public health; an Expanded Access Navigator that offers instructional material and resources for physicians, patients, and their caregivers on how to access investigational drugs outside of clinical trials; and a new joint Foundation and FDA regulatory science fellowship program.