

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

[Document Identifier CMS–10589]

Agency Information Collection Activities: Submission for OMB Review; Comment Request**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human 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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by *February 8, 2021*.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

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 <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>

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:* Reinstatement without change of a currently approved collection; *Title of Information Collection:* QECF Annual Report Workbook Submission Requirement for Qualified Entities under ACA Section 10332; *Use:* This collection focuses on the expansion of qualified entities. This collection covers the requirement that a qualified entity must submit an annual report to CMS. In addition, this collection covers the requirement that a qualified entity must have a qualified entity data use agreement (QE DUA) or non-public analyses agreement in place with an authorized user prior to providing or selling data or analyses to that authorized user.

Section 10332 of the Patient Protection and Affordable Care Act (ACA) requires the Secretary to make standardized extracts of Medicare claims data under Parts A, B, and D available to "qualified entities" for the evaluation of the performance of providers of services and suppliers. The statute provides the Secretary with discretion to establish criteria to determine whether an entity is qualified to use claims data to evaluate the performance of providers of services and suppliers.

Section 105 of the Medicare Access and Reauthorization Act of 2015 (MACRA) expands how qualified entities will be allowed to use and disclose data under the qualified entity program consistent with other

applicable laws, including information, privacy, security, and disclosure laws.

The information from the collection will be used by CMS to determine whether a qualified entity continues to meet the qualified entity certification requirements under section 10332 of the Affordable Care Act and Section 105 of MACRA. In addition, it will ensure that certain privacy and security requirements are met when qualified entities provide or sell data or sell non-public analyses that contains individually identifiable beneficiary information to authorized users. *Form Number:* CMS–10589 (OMB control number: 0938–1309); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for profits, and Not for profits institutions; *Number of Respondents:* 15; *Total Annual Responses:* 15; *Total Annual Hours:* 3,450. (For policy questions regarding this collection contact Kari Gaare at 410–786–8612.)

Dated: January 4, 2021.

William N. Parham, III,

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

[FR Doc. 2021–00080 Filed 1–7–21; 8:45 am]

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

[Document Identifiers: CMS–10198]

Agency Information Collection Activities: Proposed Collection; Comment Request**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human 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 March 9, 2021.

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. 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-10198—Creditable Coverage

Disclosure to CMS On-Line Form and Instructions

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:* Creditable Coverage Disclosure to CMS On-Line Form and Instructions; *Use:* Most entities that currently provide prescription drug benefits to any Medicare Part D eligible individual must disclose whether their prescription drug benefit is creditable (expected to pay at least as much, on average, as the standard prescription drug plan under Medicare). The disclosure must be provided annually and upon any change that affects whether the coverage is creditable prescription drug coverage. *Form Number:* CMS-10198; *Frequency:* Annually; *Affected Public:* Individuals and Households, State, Local, or Tribal Governments, Federal Government; *Number of Respondents:* 110,217; *Number of Responses:* 110,217; *Total Annual Hours:* 9,185. (For questions regarding this collection, contact Tammie Hill at (410) 786-3317.)

Dated: January 4, 2021.

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-2018-N-3728]

Agency Information Collection Activities; Proposed Collection; Comment Request; Collection of Information for Participation in the Food and Drug Administration Non-Employee Fellowship and Traineeship Programs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on “Collection of Information for Participation in FDA Non-Employee Fellowship and Traineeship Programs.”

DATES: Submit either electronic or written comments on the collection of information by March 9, 2021.

ADDRESSES: 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 March 9, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 9, 2021. 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”).