

Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Kalwant Smagh,**

*Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifiers: CMS–10280]

**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 (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 August 26, 2024.

**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, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

**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–10280 Home Health Change of Care Notice

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; *Titles of*

*Information Collection:* Home Health Change of Care Notice; *Use:* The purpose of the Home Health Change of Care Notice (HHCCN) is to notify original Medicare beneficiaries receiving home health care benefits of plan of care changes. Consistent with the Medicare Conditions of Participation (COPs) for home health agencies (HHAs) and the decision of the US Court of Appeals 2nd Circuit decision in *Lutwin v. Thompson*, HHAs must provide the HHCCN to a beneficiary whenever they reduce or terminate that beneficiary's home health services due to physician/provider orders or limitation of the HHA in providing the specific service. Notification is required for covered and non-covered services listed in the plan of care (POC). Implementing regulations are found at 42 CFR 484.10(c). These requirements are fulfilled by the HHCCN.

Home health agencies (HHAs) are required to provide written notice to Original Medicare beneficiaries under various circumstances involving the reduction or termination of items and/or services consistent with Home Health Agencies Conditions of Participation (COPs). The beneficiary will use the information provided to decide whether or not to pursue alternative options to continue receiving the care noted on the HHCCN. *Form Numbers:* CMS–10280 (OMB control number: 0938–1196); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 11,353; *Total Annual Responses:* 19,004,850; *Total Annual Hours:* 1,265,723. (For policy questions regarding this collection contact, Jennifer McCormick at 410–786–2852.)

**William N. Parham, III,**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifiers: CMS–1694 and CMS–R–246]

**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 July 25, 2024.

**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](http://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, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

**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:* Revision of a currently approved collection; *Title of Information Collection:* Appointment of Representative and Supporting Regulations in 42 CFR 405.910; *Use:* The requirements for appointing representatives for claims and appeals processed under 42 CFR part 405 subpart I were codified into regulation at 42 CFR 405.910. In summary, section 405.910 states an individual or entity may appoint a representative to act on their behalf in exercising their rights relative to an initial claim determination or an appeal. The appointment of representation must be in writing and must include all the required elements specified in 405.910(c). The burden associated with this requirement is the time and effort of the individual or entity to prepare an appointment of representation containing all the required information of this section. To reduce some of the burden associated with this requirement, we developed a standardized form that the individual/entity may opt (but is not required) to use.

This form would be completed by Medicare beneficiaries, providers and suppliers (typically their billing clerk, or billing company), and any party who wish to appoint a representative to assist them with their initial Medicare claims determinations and filing appeals on Medicare claims. The information supplied on the form is reviewed by Medicare claims and appeals adjudicators. The adjudicators make determinations whether the form was completed accurately, and if the form is correct and accepted, the form is appended to the claim or appeal that it was filed with. *Form Number:* CMS-1696 (OMB control number: 0938-0950); *Frequency:* Occasionally; *Affected Public:* Individuals and Households and Private Sector; *Number of Respondents:* 213,208; *Total Annual Responses:* 213,208; *Total Annual Hours:* 53,302. (For policy questions regarding this collection contact Liz Hosna at 410-786-4993.

2. *Type of Information Collection Request:* Revision of a currently

approved collection; *Title of Information Collection:* Medicare Advantage, Medicare Part D, and Medicare Fee-For-Service Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey; *Use:* CMS is required to collect and report information on the quality of health care services and prescription drug coverage available to persons enrolled in a Medicare health or prescription drug plan under provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Specifically, the MMA under Sec. 1860D-4 (Information to Facilitate Enrollment) requires CMS to conduct consumer satisfaction surveys regarding Medicare prescription drug plans and Medicare Advantage plans and report this information to Medicare beneficiaries prior to the Medicare annual enrollment period. The Medicare CAHPS survey meets the requirement of collecting and publicly reporting consumer satisfaction information. The Balanced Budget Act of 1997 also requires the collection of information about fee-for-service plans. The CAHPS survey measures are incorporated into the Part C and D Star Ratings that are published on [www.medicare.gov](http://www.medicare.gov) each fall to help consumers choose a Medicare plan. A subset of the CAHPS measures is also included in the *Medicare & You Handbook*. CAHPS information from MA contracts also feeds into the calculation of MA Quality Bonus Payment Ratings that are required by statute and regulation.

The primary purpose of the Medicare CAHPS surveys is to provide information to Medicare beneficiaries to help them make more informed choices among health and prescription drug plans available to them. Survey results are reported by CMS in the *Medicare & You Handbook* published each fall and on the Medicare Plan Finder website. Beneficiaries can compare CAHPS scores for each health and drug plan as well as compare MA and FFS scores when making enrollment decisions. The Medicare CAHPS also provides data to help CMS and others monitor the quality and performance of Medicare health and prescription drug plans and identify areas to improve the quality of care and services provided to enrollees of these plans. CAHPS data are included in the Medicare Part C & D Star Ratings and used to calculate MA Quality Bonus Payments. *Form Number:* CMS-R-246 (OMB control number: 0938-0732); *Frequency:* Yearly; *Affected Public:* Individuals and Households *Number of Respondents:* 794,500; *Total Annual Responses:* 794,500; *Total Annual*

Hours: 192.265. (For policy questions regarding this collection contact Lauren Fuentes at 410-786-2290 or [lauren.fuentes@cms.hhs.gov](mailto:lauren.fuentes@cms.hhs.gov)).

**William N. Parham, III,**

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2023-N-2177]

#### Laboratory Developed Tests: Small Entity Compliance Guide; Guidance for Laboratory Manufacturers and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Laboratory Developed Tests: Small Entity Compliance Guide.” The laboratory developed tests (LDT) final rule amended FDA’s regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory. This small entity compliance guide (SECG) is intended to help small entities comply with applicable medical device regulations, consistent with the LDT final rule, including the phasing out of FDA’s general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs.

**DATES:** The announcement of the guidance is published in the **Federal Register** on June 25, 2024.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

#### 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-2023-N-2177 for “Laboratory Developed Tests: Small Entity Compliance Guide.” Received comments 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, 240-402-7500.

- **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.govinfo.gov/content/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, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Laboratory Developed Tests: Small Entity Compliance Guide” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Brittany Schuck, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5422, Silver Spring, MD 20993-0002, 301-796-5199, [LDTFinalRule@fda.hhs.gov](mailto:LDTFinalRule@fda.hhs.gov); or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of May 6, 2024 (89 FR 37286), FDA issued a final rule to amend its regulations to make explicit that IVDs are devices under the FD&C Act including when the