

are covered for the elderly and disabled under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program and are described in section 1861(m) of the Social Security Act (the Act) (42 U.S.C. 1395x). These services must be furnished by, or under arrangement with, an HHA that participates in the Medicare program, and be provided on a visiting basis in the beneficiary's home. They may include the following:

- Part-time or intermittent skilled nursing care furnished by or under the supervision of a registered nurse.
- Physical therapy, speech-language pathology, or occupational therapy.
- Medical social services under the direction of a physician.
- Part-time or intermittent home health aide services.
- Medical supplies (other than drugs and biologicals) and durable medical equipment.
- Services of interns and residents if the HHA is owned by or affiliated with a hospital that has an approved medical education program.
- Services at hospitals, Skilled Nursing Facilities (SNFs), or rehabilitation centers when they involve equipment too cumbersome to bring to the home.

Under the authority of sections 1861(o), 1871 and 1891 of the Act, the Secretary has established in regulations the requirements that an HHA must meet to participate in the Medicare program. These requirements are set forth in 42 CFR part 484 as Conditions of Participation for Home Health Agencies. The CoPs apply to an HHA as an entity as well as the services furnished to each individual under the care of the HHA, unless a condition is specifically limited to Medicare beneficiaries. Under section 1891(b) of the Act, the Secretary is responsible for assuring that the CoPs, and their enforcement, are adequate to protect the health and safety of individuals under the care of an HHA and to promote the effective and efficient use of Medicare funds. To implement this requirement, State survey agencies generally conduct surveys of HHAs to determine whether they are complying with the CoPs. *Form Number:* CMS-10539 (OMB Control Number: 0938-1299); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other for-profit, and not-for-profit institutions); *Number of Respondents:* 20,765; *Number of Responses:* 12,300,588 *Total Annual Hours:* 870,000. (For policy questions regarding this collection contact Claudia

Molinar at claudia.molinar@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

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10464]

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 September 19, 2025.

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-10464 Agent/Broker Data Collection in Federally-Facilitated Health Insurance Exchanges

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 Collections

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Agent/Broker Data Collection in Federally-Facilitated Health Insurance Exchanges; *Use:* The Patient Protection and Affordable Care Act, Public Law 111-148, enacted on

March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111–152, enacted on March 30, 2010 (collectively, “Affordable Care Act”), expands access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), also called Marketplaces, including the Small Business Health Options Program (SHOP).

Section 1312(e) of the Affordable Care Act and 45 CFR 155.220(a)(1) expands the role of agents/brokers by permitting them to enroll qualified individuals or small employers/employees in qualified health plans (QHPs) through the Exchanges and assist individuals in applying for Advance Premium Tax Credits (APTCs) and Cost Sharing Reductions (CSRs). To participate as facilitators to enrollment, agents/brokers must register with the FFE, complete a training course covering eligibility and enrollment criteria for assisting in QHP enrollment, and sign agreements that formalize their understanding and commitment to adhere to the rules of the program. This requirement is specific to the FFE and does not automatically apply to State-based Exchanges (SBEs). *Form Number:* CMS–10464 (OMB control number: 0938–1204); *Frequency:* Annually; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 100,000; *Number of Responses:* 100,000; *Total Annual Hours:* 12,000. (For questions regarding this collection, contact Madeline Pellish at 301–492–4390).

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–2018–D–1922]

Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Biosimilar User Fee Act Products; Guidance for Industry; 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 for industry entitled “Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products.” This guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of proposed biosimilar, including interchangeable biosimilar, products regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). This guidance finalizes the draft guidance of the same title issued on August 11, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on July 21, 2025.

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–2018–D–1922 for “Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Biosimilar User Fee Act Products.” 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)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug