ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Individuals in households	Day1 Dietary Instrument; MEC Dietary Recruitment Scheduling Instrument; Dietary Front-End Instrument; Dietary Incentives and Scheduling Instrument; MEC Dietary Reminder Call-in Instrument; & Flexible Consumer Behavior Survey (FCBS) Instrument.	5,882	1	1
Individuals in households	Day2 Dietary Instrument	5,882	1	36/60
Individuals in households	Developmental Projects & Special Studies	3,500	1	3

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–22473 Filed 9–30–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10593]

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 December 2, 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–10539 Medicare and Medicaid Programs: Home Health Facilities (HHAs) and Supporting Regulations

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:* Revision of a currently approved collection; *Title of Information Collection:* Medicare and Medicaid Programs: Home Health Facilities (HHAs) and Supporting Regulations*; Use:* Home health services 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.

[FR Doc. 2024–22536 Filed 9–30–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1382]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic User Fee Payment Request Forms

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by October 31, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0805. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic User Fee Payment Request Forms—Form FDA 3913 and Form FDA 3914

OMB Control Number 0910–0805—Extension

This information collection supports FDA user fee programs. Form FDA 3913, User Fee Payment Refund Request, is designed to provide the minimum necessary information for FDA to review and process a user fee payment refund. The information collected includes the organization, contact, and payment information. The information is used to determine the reason for the refund, the refund amount, and who to contact if there are any questions regarding the refund request. A submission of the User Fee Payment Refund Request form does not guarantee that a refund will be issued. FDA estimates an average of 0.40 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. The estimated hours are based on past FDA experience with the user fee payment refund request.

In fiscal year 2023, approximately 1,856 user fee refunds were processed for cover sheets and invoices including 2 for Animal Drug User Fees, 2 for Animal Generic Drug User Fees, 3 for Biosimilar Drug User Fees, 1 for Color Additive Certification Fees, 1 for Compounding Quality fees, 32 for Export Certificate Program Fees, 7 for Freedom of Information Act requests, 94 for Generic Drug User Fees, 730 for Medical Device User Fees, 219 for Medical Device Federal Unified Registration and Listing fees, 666 for Mammography inspection fees, 19 for Over-The-Counter Monograph Drug User Fees, 77 for Prescription Drug User Fees, and 3 for Tobacco product fees.

Form FDA 3914, User Fee Payment Transfer Request, is designed to provide the minimum necessary information for FDA to review and process a user fee payment transfer request. The information collected includes payment and organization information. The information is used to determine the reason for the transfer, how the transfer should be performed, and who to contact if there are any questions regarding the transfer request. A submission of the User Fee Payment Transfer Request form does not guarantee that a transfer will be performed. FDA estimates an average of 0.25 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. FDA estimated hours are based on past FDA experience with the user fee payment transfer requests.

In fiscal year 2023, approximately 86 user fee payment transfers were processed for cover sheets and invoices including 0 for Animal Drug User Fees, 0 for Animal Generic Drug User Fees, 1 for Biosimilar Drug User Fees, 2 for Compounding Quality fees, 4 for Export Certificate Program Fees, 20 for Generic Drug User Fees, 6 for Medical Device User Fees, 37 for Medical Device Federal Unified Registration and Listing fees, 8 for Mammography inspection fees, 8 for Over-The-Counter Monograph Drug User Fees, 0 for Prescription Drug User Fees, and 0 for Tobacco product fees.

Respondents for the electronic request forms include domestic and foreign firms (including pharmaceutical, biological, medical device firms, etc.). Specifically, refund request forms target respondents who submitted a duplicate payment or overpayment for a user fee cover sheet or invoice. Respondents may also include firms that withdrew an application or submission. Transfer request forms target respondents who submitted payment for a user fee cover sheet or invoice and need that payment