

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](mailto: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

### 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, [PRAMain@fda.hhs.gov](mailto:PRAMain@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

to be re-applied to another cover sheet or invoice (transfer of funds).

The electronic user fee payment request forms streamline the refund and transfer processes, facilitate processing, and improve the tracking of refund or transfer requests. The burden for this collection of information is the same for all customers (small and large organizations). The information being

requested or required has been held to the absolute minimum required for the intended use of the data. Respondents are able to request a user fee payment refund or transfer online at <https://www.fda.gov/forindustry/userfees/default.htm>. This electronic submission is intended to reduce the burden for customers to submit a user fee payment refund and transfer request.

In the **Federal Register** of April 26, 2024 (89 FR 32445), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1 2</sup>

FDA form No.	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
User Fee Payment Refund Request—Form FDA 3913.	1,856	1	1,856	0.40 (24 minutes) .....	742
User Fee Payment Transfer Request—Form FDA 3914.	86	1	86	0.25 (15 minutes) .....	22
Total .....	.....	.....	.....	.....	764

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Numbers have been rounded.

Our estimated burden for the information collection reflects an overall increase of 525 hours and a corresponding increase of 1,274 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: September 25, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Announcement of Solicitation of Written Comments on Proposed Healthy People 2030 Objectives**

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary of Health, Office of Disease Prevention and Health Promotion.

**ACTION:** Notice.

**SUMMARY:** The U.S. Department of Health and Human Services (HHS) solicits written comments from the public on 12 new objectives proposed to be added to Healthy People 2030, and written comments from the public proposing additional new core, developmental, or research objectives or topics to be included in Healthy People 2030. Public comment informed the development of Healthy People 2030. HHS will provide opportunities for public input periodically throughout the decade to ensure Healthy People 2030

reflects current public health priorities and public input. The updated set of Healthy People 2030 objectives and topics will be incorporated on <https://health.gov/healthypeople>. This updated set will reflect further review and deliberation by federal Healthy People topic area workgroups, the Federal Interagency Workgroup on Healthy People 2030, and other federal subject matter experts.

**DATES:** Written comments will be accepted through 11:59 p.m. ET, October 31, 2024.

**ADDRESSES:** Written comments should be submitted by email to [HP2030Comment@hhs.gov](mailto:HP2030Comment@hhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Erik Orta, Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 420, Rockville, MD 20852; Phone: 240-268-0823; Email: [HP2030@hhs.gov](mailto:HP2030@hhs.gov).

**SUPPLEMENTARY INFORMATION:** Since 1980, Healthy People has provided a comprehensive set of national health promotion and disease prevention objectives with 10-year targets aimed at improving the health of all. Healthy People 2030 objectives present a picture of the nation's health at the beginning of the decade, establish national goals and targets to be achieved by the year 2030, and monitor progress over time. The U.S. Department of Health and Human Services (HHS) is soliciting the submission of written comments regarding 12 new objectives proposed to be added to the current set of Healthy People 2030 objectives. The public is also invited to submit proposals for

additional new core, developmental, or research objectives that meet the criteria outlined below.

Healthy People 2030 is the product of an extensive collaborative process that relies on input from a diverse array of individuals and organizations, both within and outside the federal government, with a common interest in improving the nation's health. Public comments were a cornerstone of Healthy People 2030's development. During the first phase of planning for Healthy People 2030, HHS asked for the public's comments on the initiative's vision, mission, and overarching goals. Those comments helped set the framework for Healthy People 2030. The public was also invited to submit comments on proposed Healthy People 2030 objectives, which helped shape the current set of Healthy People 2030 objectives.

The public now is invited to comment on 12 new objectives proposed to be added to Healthy People 2030. These new objectives were developed by Healthy People topic area workgroups led by various agencies within the Federal Government. They have been reviewed by the Federal Interagency Workgroup on Healthy People 2030 and are presented now for the public's review and comment. They are:

1. *CKD-NEW-11*: Increase the proportion of people with chronic kidney disease and diabetes who receive glucose-lowering medications based on the most recent guidelines. This objective is new to Healthy People 2030. Data source: National Health and Nutrition Examination Survey (NHANES).