

## ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent   | Form name  | Number of respondents | Number of responses per respondent | Average burden per response (in hr) |
|----------------------|--|-----------------------|------------------------------------|-------------------------------------|
| Epidemiologist ..... | U.S. Collaborating center for Influenza—Influenza Virus Surveillance.                          | 47                    | 52                                 | 10/60                               |
| Epidemiologist ..... | U.S. Collaborating Laboratories Influenza Testing Methods Assessment.                          | 113                   | 1                                  | 10/60                               |
| Epidemiologist ..... | U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet) Workfolder 55.20E.        | 1,800                 | 52                                 | 10/60                               |
| Epidemiologist ..... | Influenza-Associated Pediatric Mortality—Case Report Form                                      | 57                    | 3                                  | 30/60                               |
| Epidemiologist ..... | Human Infection with Novel Influenza A Virus Case Report Form.                                 | 57                    | 2                                  | 30/60                               |
| Epidemiologist ..... | Human Infection with Novel Influenza A Virus Severe Outcomes.                                  | 57                    | 1                                  | 90/60                               |
| Epidemiologist ..... | Novel Influenza A Virus Case Screening Form .....  | 57                    | 1                                  | 15/60                               |
| Epidemiologist ..... | Antiviral Resistant Influenza Infection Case Report Form .....                                 | 57                    | 3                                  | 30/60                               |
| Epidemiologist ..... | National Respiratory & Enteric Virus Surveillance System (NREVSS) (55.83A, B, D) (electronic). | 550                   | 52                                 | 15/60                               |
| Epidemiologist ..... | National Enterovirus Surveillance Report: (CDC 55.9) (electronic).                             | 20                    | 12                                 | 15/60                               |
| Epidemiologist ..... | National Adenovirus Type Reporting System (NATRS) .....  | 13                    | 4                                  | 15/60                               |
| Epidemiologist ..... | Middle East Respiratory Syndrome (MERS) Patient Under Investigation (PUI) Short Form.          | 57                    | 3                                  | 25/60                               |
| Epidemiologist ..... | Viral Gastroenteritis Outbreak Submission Form .....   | 20                    | 5                                  | 5/60                                |
| Epidemiologist ..... | Influenza Virus (Electronic, Year Round), PHLIP_HL7 messaging Data Elements.                   | 64                    | 52                                 | 5/60                                |
| Epidemiologist ..... | Influenza virus (electronic, year round) (PHIN-MS) .....                                       | 3                     | 52                                 | 5/60                                |
| Epidemiologist ..... | Suspect Respiratory Virus Patient Form .....   | 10                    | 5                                  | 30/60                               |
| Epidemiologist ..... | Aggregate counts of persons exposed to Highly Pathogenic Avian Influenza (HPAI).               | 52                    | 52                                 | 10/60                               |
| Epidemiologist ..... | Pediatric Hepatitis of Unknown Etiology Medical Record Abstraction Short Form.                 | 52                    | 4                                  | 15/60                               |
| Epidemiologist ..... | Pediatric Hepatitis of Unknown Etiology Medical Record Abstraction Form (CRF).                 | 52                    | 2                                  | 45/60                               |
| Epidemiologist ..... | Arthropod (Vector)-Borne Diseases (Non-Human Data) .....                                       | 57                    | 52                                 | 60/60                               |

**Jeffrey M. Zirger,**

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Office of Public Health Ethics and  
Regulations, Office of Science, Centers for  
Disease Control and Prevention.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10110]

#### 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 May 7, 2026.

**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/](http://www.reginfo.gov/public/do/PRAMain)  
*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/](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing)  
*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:* Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals and Supporting Regulations in 42 CFR 414.800–806; *Use:* Section 1847A of the Social Security Act requires that the Medicare Part B payment amounts for covered drugs and biologicals not paid on a cost or prospective payment basis be based upon manufacturers' average sales price data submitted quarterly to CMS. The reporting requirements are specified in 42 CFR part 414, subpart J. This April 2026 iteration proposes to revise the Bona Fide Service Fee Certification form and revise our active burden estimates. Since some of the changes are substantive, this 30-day collection of information request is a continuation of the 60-day collection of information request that published in the **Federal Register** on December 30, 2025 (90 FR 61154). *Form Number:* CMS–10110 (OMB control number: 0938–0921); *Frequency:* Quarterly; *Affected Public:* Private Sector; *Number of Respondents:* 500; *Total Annual Responses:* 4,500; *Total Annual Hours:* 49,500. (For policy questions regarding this collection contact: Rebecca Ray at 667–414–0879 or Laura Kennedy at 410–786–3377.)

**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–2026–N–2431]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Administrative Practices and Procedures; Formal Hearings

**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 information collection associated with general FDA administrative practices and procedures, including requests for formal hearings.

**DATES:** Either electronic or written comments on the collection of information must be submitted by June 8, 2026.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 8, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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”).

#### 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–2026–N–2431 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Administrative Practices and Procedures; Formal Hearings.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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 in 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