

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****[Document Identifier: CMS–10599]****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 October 20, 2025.

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. 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:* Extension of a currently approved collection; *Title of Information Collection:* Review Choice Demonstration for Home Health Services; *Use:* Section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1(a)(1)(J)) authorizes the Secretary to "develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act (the Act)." Pursuant to this authority, the CMS seeks to develop and implement a Medicare demonstration project, which CMS believes will help assist in developing improved procedures for the identification, investigation, and prosecution of Medicare fraud occurring among Home Health Agencies (HHA) providing services to Medicare beneficiaries.

This revised demonstration helps assist in developing improved procedures for the identification, investigation, and prosecution of potential Medicare fraud. The demonstration helps make sure that payments for home health services are appropriate through either pre-claim or post payment review, thereby working towards the prevention and identification of potential fraud, waste, and abuse; the protection of Medicare Trust Funds from improper payments; and the reduction of Medicare appeals. CMS has implemented the demonstration in Illinois, Ohio, North

Carolina, Florida, and Texas with the option to expand to other states in the Palmetto/JM jurisdiction. Under this demonstration, CMS offers choices for providers to demonstrate their compliance with CMS' home health policies. Providers in the demonstration states may participate in either 100 percent pre-claim review or 100 percent post payment review. These providers will continue to be subject to a review method until the HHA reaches the target affirmation or claim approval rate. Once an HHA reaches the target pre-claim review affirmation or post-payment review claim approval rate, it may choose to be relieved from claim reviews, except for a spot check of their claims to ensure continued compliance. Providers who do not wish to participate in either 100 percent pre-claim or post payment reviews have the option to furnish home health services and submit the associated claim for payment without undergoing such reviews; however, they will receive a 25 percent payment reduction on all claims submitted for home health services and may be eligible for review by the Recovery Audit Contractors.

The information required under this collection is required by Medicare contractors to determine proper payment or if there is a suspicion of fraud. Under the pre-claim review option, the HHA sends the pre-claim review request along with all required documentation to the Medicare contractor for review prior to submitting the final claim for payment. If a claim is submitted without a pre-claim review decision on one file, the Medicare contractor will request the information from the HHA to determine if payment is appropriate. For the post payment review option, the Medicare contractor will also request the information from the HHA provider who submitted the claim for payment from the Medicare program to determine if payment was appropriate. *Form Number:* CMS–10599 (OMB control number: 0938–1311); *Frequency:* Frequently, until the HHA reaches the target affirmation or claim approval threshold and then occasionally; *Affected Public:* Private Sector (Business or other for-profits and Not-for-profits); *Number of Respondents:* 4,700; *Number of Responses:* 3,173,016; *Total Annual Hours:* 1,600,608. (For questions

regarding this collection contact Jennifer McMullen (410) 786–7635.)

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–2025–N–3657]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Southern Hemisphere Influenza Virus Vaccines; Center for Biologics Evaluation and Research (CBER) Allergen Standardization Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on October 9, 2025, from 8:30 a.m. to 6:00 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

The online web conference meeting will be available at the following link on the day of the meeting at: <https://youtube.com/live/UpPFM1bGOog?feature=share>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2025–N–3657. The docket will close on October 8, 2025. 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 October 8, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before September 30, 2025, will be provided to the Committee. Comments received after that date and on October 8, 2025, will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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–

2025–N–3657 for “Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Topic I: Southern Hemisphere Influenza Virus Vaccines; Topic II: Center for Biologics Evaluation and Research (CBER) Allergen Standardization Program”. 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 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.” FDA 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 the 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.

FOR FURTHER INFORMATION CONTACT: Cicely Reese or Valerie Marshall; Center for Biologics Evaluation and Research,