System (HH PPS) Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin (IVIG) Items and Services Rate Update; and Other Medicare Policies (July 2, 2024/89 FR 55312). In this proposed rule, we revised the LTC requirements for COVID–19 reporting to establish a new requirement for respiratory illness reporting that includes COVID–19, RSV, and influenza. *Form Number:* CMS–10573 (OMB control number: 0938–1363); *Frequency:* Occasionally; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profits; *Number of Respondents:* 14,926; *Number of Responses:* 14,926; *Total Annual Hours:* 6,253,995. (For policy questions regarding this collection contact Diane Corning at 410–786–8486).

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Financial Statement of Debtor; *Use:* When a Medicare Administrative Contractor (MAC) overpays a physician or supplier, the overpayment is associated with a single claim, and the amount of the overpayment is moderate. In these cases, the physician/supplier usually refunds the overpaid amount in a lump sum. Alternatively, the MAC may recoup the overpaid amount against future payments. A recoupment is the recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness. The recoupment can be made only if the physician/supplier accepts assignment since the MAC makes payment to the physician/supplier only on assigned claims.

The physician/supplier may be unable to refund a large overpaid amount in a single payment. The MAC cannot recover the overpayment by recoupment if the physician/supplier does not accept assignment of future claims, or is not expected to file future claims because of going out of business, illness or death. In these unusual circumstances, the MAC has authority to approve or deny extended repayment schedules up to 12-months or may recommend to the Centers for Medicare and Medicaid Services (CMS) to approve up to 60 months. Before the MAC takes these actions, the MAC will require full documentation of the physician's/supplier's financial situation. Thus, the physician/supplier must complete the CMS–379, Financial Statement of Debtor.

Section 1893(f)(1)) of the Social Security Act and 42 CFR 401.607 provides the authority for collection of this information. Section 42 CFR 405.607 requires that, CMS recover amounts of claims due from debtors including interest where appropriate by direct collections in lump sums or in installments. *Form Number:* CMS–379 (OMB control number: 0938–0270); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 1,000 hours. (For policy questions regarding this collection contact Monica Thomas, at 410–786–4292.)

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 Identifier: CMS–R–240]

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 September 19, 2024.

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:* Reinstatement of a previously approved collection; *Title of Information Collection:* Prospective Payments for Hospital Outpatient Services and Supporting Regulations in 42 CFR 413.65; Use: Section 1833(t) of the Act, as added by section 4523 of the Balanced Budget Act of 1997 (the BBA) requires the Secretary to establish a prospective payment system (PPS) for hospital outpatient services. Successful implementation of an outpatient PPS

requires that CMS distinguish facilities or organizations that function as departments of hospitals from those that are freestanding, so that CMS can determine which services should be paid under the OPPS, the clinical laboratory fee schedule, or other payment provisions applicable to services furnished to hospital outpatients. Information from the reports required under sections 413.65(b)(3) and (c) is needed to make these determinations. In addition, section 1866(b)(2) of the Act authorizes hospitals and other providers to impose deductible and coinsurance charges for facility services but does not allow such charges by facilities or organizations which are not provider-based. Implementation of this provision requires that CMS have information from the required reports, so it can determine which facilities are provider-based. *Form Number:* CMS–R–240 (OMB control number: 0938–0798); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 2032; *Total Annual Responses:* 15,138,400; *Total Annual Hours:* 683,670. (For policy questions regarding this collection contact Emily Lipkin at 410–786–3633.)

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–3698]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA or we) 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 committee will discuss considerations related to the use of pertussis controlled human infection models (CHIMs) in pivotal studies to demonstrate efficacy of pertussis vaccines for the purpose of licensure and will hear an overview of the Laboratory of Mucosal Pathogens and Cellular Immunology (LMPCI) research program in the Center for Biologics Evaluation and Research (CBER). At least one portion of the meeting will be closed to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on September 20, 2024, from 8:30 a.m. to 5 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. The online web conference meeting will be available at the following link on the day of the meeting: *https://youtube.com/live/_IHObqjNpYc.*

Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2024–N–3698. The docket will close on September 19, 2024. 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 September 19, 2024. 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 12, 2024, will be provided to the committee. Comments received after that date 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–2024–N–3698 for ''Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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