Record of Commission's Vote

On October 29, 2026, Commissioners Ferguson and Meador were recorded as voting in the affirmative to close this meeting for non-adjudicative matters. By this vote, the Commission approved withholding from this meeting notice such information as is exempt from disclosure under 5 U.S.C. 552b(c).

Commission's Explanation of Closing

The Commission has determined that the meeting will be closed to the public pursuant to 5 U.S.C. 552b(c)(3), (4), (7)(A), and (10), and 552b(d)(4) and that the public interest does not require the meeting to be open to the public.

General Counsel Certification

The General Counsel has certified that the meeting may properly be closed for the above agenda matters, citing the following relevant exemptive provisions: 5 U.S.C. 552b(c)(3), (4), (7)(A), and (10).

Expected Attendees

Commission employees and consultants and the stenographer or court reporter preparing any necessary verbatim transcript may attend the closed meeting to the extent permitted under Rule 4.15(c)(1) of the Commission's Rules of Practice.

By direction of the Commission.

Joel Christie,

Acting Secretary.

[FR Doc. 2026–22379 Filed 10–30–26; 11:15 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–304/–304a and CMS–368/–R–144]

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 January 4, 2027.

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**).

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:* Extension of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice (ROSI) and Prior Quarter Adjustment Statement (PQAS); *Use:* Form CMS–304 (ROSI) is used by manufacturers to respond to the state's rebate invoice for current quarter utilization. Form CMS–304a (PQAS) is required only in those instances where a change to the original rebate data submittal is necessary. *Form Number:* CMS–304 and –304a (OMB control number: 0938–0676); *Frequency:* Quarterly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 851; *Total Annual Responses:* 5,788; *Total Annual Hours:* 262,192. (For policy questions regarding this collection contact Robert Giles at 667–290–8626.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate Program State Reporting Forms; *Use:* Form CMS 368 is a report of contact for the State to name the individuals involved in the Medicaid Drug Rebate Program (MDRP) and is required only in those instances where a change to the originally submitted data is necessary. The ability to require the reporting of any changes to these data is necessary to the efficient operation of these programs. Form CMS–R–144 is required from States quarterly to report utilization for any drugs paid for during that quarter. *Form Number:* CMS–368 and –R–144 (OMB control number: 0938–0582); *Frequency:* Quarterly and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 234; *Total Annual Hours:* 12,325. (For policy

questions regarding this collection contact Robert Giles at 667–290–8626.)

William N. Parham III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–22370 Filed 11–2–26; 8:45 am]

BILLING CODE 4169–69–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–5942]

Recommendations for Reducing the Risk of Transfusion-Transmitted Hepatitis B Virus; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance titled ''Recommendations for Reducing the Risk of Transfusion-Transmitted Hepatitis B Virus.'' The guidance document provides blood establishments that collect blood and blood components, including Source Plasma, with FDA's recommendations for testing blood and blood components for hepatitis B virus (HBV) to reduce the risk of transfusion-transmitted HBV. The recommendations contained in the guidance apply to the collection of Whole Blood and blood components, including Source Plasma. The guidance announced in this notice finalizes the draft guidance titled ''Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen'' (July 2025 Draft Guidance). The guidance also supersedes the documents titled ''Recommendations for the Management of Donors and Units that are Initially Reactive for Hepatitis B Surface Antigen (HBsAg)'' (December 1987 Memorandum), ''FDA Recommendations Concerning Testing for Antibody to Hepatitis B Core Antigen (Anti-HBc)'' (September 1991 Memorandum), ''Adequate and Appropriate Donor Screening Tests for Hepatitis B; Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Donors of Whole Blood and Blood Components, Including Source Plasma and Source Leukocytes'' (November 2007 Final Guidance), ''Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc)'' (May 2010 Final Guidance), ''Requalification Method for Reentry of Donors Who Test Hepatitis B Surface Antigen (HBsAg) Positive Following a Recent Vaccination against Hepatitis B Virus Infection'' (November 2011 Final Guidance), and ''Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, Including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus'' (October 2012 Final Guidance). The guidance supersedes the recommendations specific to HBV in ''Recommendations for the Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human T-Lymphotropic Virus Type I (HTLV–I)'' (July 1996 Memorandum).

DATES: The announcement of the guidance is published in the **Federal Register** on November 3, 2026.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–D–5942 for ''Recommendations for Reducing the Risk of Transfusion-Transmitted Hepatitis B Virus.'' Received comments 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.'' 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 available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this 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.