

C. Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans

Section 1876(c)(5)(B) of the Act states that the annual adjustment to the AIC dollar amounts set forth in section 1869(b)(1)(E)(iii) of the Act applies to certain beneficiary appeals within the context of health maintenance organizations and competitive medical plans. The applicable implementing regulations for Medicare Part C appeals are set forth in 42 CFR part 422, subpart M and apply to these appeals in accordance with 42 CFR 417.600(b). The Medicare Part C appeals rules also apply to health care prepayment plan appeals in accordance with 42 CFR 417.840.

D. Medicare Part D (Prescription Drug Plan) Appeals

The annually adjusted AIC threshold amounts for ALJ hearings and judicial review that apply to Medicare Parts A, B, and C appeals also apply to Medicare Part D appeals. Section 1860D–4(h)(1) of the Act regarding Part D appeals requires a prescription drug plan sponsor to meet the requirements set forth in sections 1852(g)(4) and (g)(5) of the Act, in a similar manner as MA organizations. The implementing regulations for Medicare Part D appeals can be found at 42 CFR part 423,

subparts M and U. More specifically, § 423.2006 addresses the AIC threshold amounts for ALJ hearings and judicial review. Sections 423.2002 and 423.2006 grant a Part D enrollee who is dissatisfied with the independent review entity (IRE) reconsideration determination a right to an ALJ hearing if the amount remaining in controversy after the IRE reconsideration meets the threshold amount established annually by the Secretary, and other requirements set forth in § 423.2002. Sections 423.2006 and 423.2136 allow a Part D enrollee to request judicial review of an ALJ or Medicare Appeals Council decision if the AIC meets the threshold amount established annually by the Secretary, and other requirements are met as set forth in these provisions.

II. Provisions of the Notice—Annual AIC Adjustments

A. AIC Adjustment Formula and AIC Adjustments

Section 1869(b)(1)(E)(iii) of the Act requires that the AIC threshold amounts be adjusted annually, beginning in January 2005, by the percentage increase in the medical care component of the CPI for all urban consumers (U.S. city average) for July 2003 to July of the year preceding the year involved and rounded to the nearest multiple of \$10.

B. Calendar Year 2027

The AIC threshold amount for ALJ hearings will remain \$200 for calendar year (CY) 2027, and the AIC threshold amount for judicial review will increase from \$1,960 for CY 2026 to \$2,000 for CY 2027. These amounts are based on the 99.523 percent change in the medical care component of the CPI, which was at 297.600 in July 2003 and rose to 593.781 in July 2026. The AIC threshold amount for ALJ hearings changes to \$199.52 based on the 99.523 percent increase over the initial threshold amount of \$100 established in 2003. In accordance with section 1869(b)(1)(E)(iii) of the Act, the adjusted threshold amounts are rounded to the nearest multiple of \$10. Therefore, the CY 2027 AIC threshold amount for ALJ hearings is \$200.00. The AIC threshold amount for judicial review changes to \$2,000 based on the 99.523 percent increase over the initial threshold amount of \$1,000. This amount was rounded to the nearest multiple of \$10, resulting in the CY 2027 AIC threshold amount of \$2,000 for judicial review.

C. Summary Table of Adjustments in the AIC Threshold Amounts

In the following table we list the CYs 2023 through 2027 threshold amounts.

	CY 2023	CY 2024	CY 2025	CY 2026	CY 2027
ALJ Hearing	180	180	190	200	200
Judicial Review	1,850	1,840	1,900	1,960	2,000

III. Collection of Information Requirements

This document announces the annual adjustment in the AIC threshold amounts and does not impose any “collection of information” requirements as defined under 5 CFR 1320.3(c). Consequently, the notice is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Dr. Mehmet Oz having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2026–19016 Filed 9–15–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0027]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biological Products: Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Product Deviations in Manufacturing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 16, 2026.

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 0910–0458. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Stephen Chang, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–2287, PRASStaff@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.

Biological Products: Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Product Deviations in Manufacturing; Forms FDA 3486 and 3486A

OMB Control Number 0910–0458—Reinstatement

Under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), all biological products, including human blood and blood components, offered for sale in interstate commerce must be licensed and meet standards, including those prescribed in the FDA regulations, designed to ensure the continued safety, purity, and potency of such products. In addition, under section 361 of the PHS Act (42 U.S.C. 264), FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or possessions or from foreign countries into the States or possessions. Further, the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351) provides that drugs and devices (including human blood and blood components) are adulterated if they do not conform with current good manufacturing practice (CGMP) assuring that they meet the requirements of the FD&C Act. Establishments manufacturing biological products, including human blood and blood components, must comply with the applicable CGMP regulations (parts 211, 606, and 820 (21 CFR parts 211, 606, and 820)) and current good tissue practice (CGTP) regulations (part 1271 (21 CFR part 1271)) as appropriate. FDA regards biological product deviation (BPD) reporting and human cells, tissues, and cellular and tissue-based products (HCT/P) deviation reporting to be an essential tool in its directive to protect public health by establishing and maintaining surveillance programs that provide timely and useful information.

Section 600.14 (21 CFR 600.14), in brief, requires the manufacturer who holds the biological product license, for other than human blood and blood components, and who had control over

a distributed product when the deviation occurred, to report to the Center for Biologics Evaluation and Research (CBER) or to the Center for Drugs Evaluation and Research (CDER) as soon as possible but at a date not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. Section 606.171, in brief, requires licensed manufacturers of human blood and blood components, including Source Plasma, unlicensed registered blood establishments, and transfusion services, who had control over a distributed product when the deviation occurred, to report to CBER as soon as possible but at a date not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. Similarly, § 1271.350(b), in brief, requires HCT/P establishments that manufacture non-reproductive HCT/Ps described in § 1271.10 to investigate and report to CBER all HCT/P deviations relating to a distributed HCT/P that relates to the core CGTP requirements, if the deviation occurred in the establishment's facility or in a facility that performed a manufacturing step for the establishment under contract, agreement or other arrangement. Form FDA 3486 is used to submit BPD reports and HCT/P deviation reports.

Respondents to this collection of information are (1) licensed manufacturers of biological products other than human blood and blood components, (2) licensed manufacturers of blood and blood components including Source Plasma, (3) unlicensed registered blood establishments, (4) transfusion services, and (5) establishments that manufacture non-reproductive HCT/Ps regulated solely under section 361 of the PHS Act as described in § 1271.10. The number of respondents and total annual responses are based on the BPD reports and HCT/P deviation reports FDA received in fiscal year (FY) 2024. The number of licensed manufacturers and total annual responses under § 600.14 include the estimates for BPD reports submitted to both CBER and CDER. Based on the information from industry, the estimated average time to complete a deviation report is 2 hours, which includes a minimal one-time burden to create a user account for those reports submitted electronically. The availability of the standardized report

form, Form FDA 3486, and the ability to submit this report electronically to CBER (CDER does not currently accept electronic filings) further streamlines the report submission process.

CBER has developed a web-based addendum to Form FDA 3486 (Form FDA 3486A) to provide additional information when a BPD report has been reviewed by FDA and evaluated as a possible recall. The additional information requested includes information not contained in the Form FDA 3486 such as: (1) distribution pattern, (2) method of consignee notification, (3) consignee(s) of products for further manufacture, (4) additional product information, (5) updated product disposition, and (6) industry recall contacts. This information is requested by CBER through email notification to the submitter of the BPD report. This information is used by CBER for recall classification purposes. CBER estimates that 5 percent of the total BPD reports submitted to CBER would need additional information submitted in the addendum. CBER further estimates that it would take between 10 to 20 minutes to complete the addendum. For calculation purposes, CBER is using 15 minutes.

Activities such as investigating, changing standard operating procedures or processes, and follow up are currently required under parts 211, (approved under OMB control number 0910–0139), 606 (approved under OMB control number 0910–0116), 820 (approved under OMB control number 0910–0073) and 1271 (approved under OMB control number 0910–0543) and, therefore, are not included in the burden calculation for the separate requirement of submitting a deviation report to FDA.

In the **Federal Register** of February 25, 2026 (91 FR 9287), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment raised concerns about the long-term safety of amniotic membrane-based products and whether additional toxicological information, including long-term carcinogenicity, should be considered. While we appreciate the comment, the concerns raised did not suggest we alter our current burden estimates, and we have therefore made no changes.

We estimate the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
600.14 Reporting of product deviations by licensed manufacturers.	3486	70	7.186	503	2.0	1,006
606.171 Reporting of product deviations by licensed manufacturers, unlicensed registered blood establishments and transfusion services.	3486	2,455	6.630	16,277	2.0	32,554
1271.350(b) Reporting requirements (human cells tissues and cellular and tissue-based products).	3486	86	2.465	212	2.0	424
1271.350(b) CBER addendum report	3486A ²	127	6.50	826	0.25	207
Total				17,818		34,191

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

² Five percent of the number of respondents ((2,455 + 86) × 0.05 = 127).

Following publication of the 60-day notice, the Agency identified a multiplication and rounding error in the burden calculations. The corrected estimates are reflected in this 30-day notice. This revision does not reflect a substantive or programmatic change to the information collection. Our estimated burden for the information collection reflects an overall increase of approximately 4,612 hours and a corresponding increase of 2,642 responses. We attribute this adjustment to an increase in the number of product deviations we received in FY 2024 from licensed manufacturers, unlicensed registered blood establishments and transfusion services under § 606.171. This is likely due to the issuance of the revised guidance document titled, “Biological Product Deviation Reporting for Blood and Plasma Establishments” (85 FR 14682; March 13, 2020), which provided blood and plasma establishments with revised recommendations related to BPD reporting.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18946 Filed 9–15–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–8692]

Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Pathogen-Agnostic Sequencing

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 Microbiology Devices Panel of the Medical Devices Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA. In addition, the Committee will meet to discuss and provide advice to FDA on examining the scientific, clinical, and public health dimensions of the use of pathogen-agnostic sequencing as it relates to emergency preparedness and response efforts, and to support discussion of opportunities, implementation considerations, and potential priorities for future coordination. The preparedness use could cover local and national outbreaks, known pathogens, or unknown pathogens. This meeting is being held to satisfy, in part, a requirement under the Food and Drug Omnibus Reform Act of 2022 (FDORA). The meeting will be open to the public. FDA is establishing a docket for public comment.

DATES: The meeting will be held on November 19, 2026, from 9 a.m. to 4 p.m. Eastern Time.

ADDRESSES: The public will have the option to participate, and all 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, including information regarding special accommodations due to a disability, visitor parking, and transportation 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/pUjANlAc1ZQ?feature=share>.

The address for in-person attendance is FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2026–N–8692. The docket will close on November 12, 2026. 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 November 12, 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.

Comments received on or before November 3, 2026, 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