

Vehicle screening is conducted and all persons in the vehicle must present a valid ID. Visitors may only enter from Security Boulevard, using the far-right entrance lane to the campus. Parking on campus is increasingly limited, and visitors are not guaranteed a parking space with registration. Visitors are encouraged to consider alternate means of arrival, such as public transportation, taxi, or other ride-share arrangements. Visitors will be required to go through x-ray screening similar to screening at a United States airport, or alternate arrangements as instructed and permitted by security.

VI. Written Comments

The primary and 5-minute speaker(s) must email a brief, written summary (one paragraph) of their comments and conclusions. Written comments from anyone, including the primary and 5-minute speaker(s), will only be accepted when emailed to the address specified in the **ADDRESSES** section of this notice by the deadline specified in the **DATES** section of this notice.

VII. Additional Information

All participants should regularly check the CMS website for updates and final agenda information at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings>.

The HCPCS section of the CMS website also includes details regarding the public meeting process for new revisions to the HCPCS Level II code set, including guidelines for an effective presentation. The HCPCS section of the CMS website also contains a document titled "HCPCS Level II Coding Procedures (PDF)," which is a description of the HCPCS Level II coding process, including a detailed explanation of the procedures CMS uses to make HCPCS Level II coding determinations.

When CMS refers to a HCPCS Level II code or HCPCS Level II coding application above, CMS may also be referring to circumstances when a HCPCS Level II code has already been issued, but a Medicare benefit category and/or payment has not been determined.

VIII. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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

Trenesha Fultz-Mimms,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2026-19015 Filed 9-15-26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-4213-N]

Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2027

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces the annual adjustment in the amount in controversy (AIC) threshold amounts for Administrative Law Judge (ALJ) hearings and judicial review under the Medicare appeals process. The adjustment to the AIC threshold amounts will be effective for requests for ALJ hearings and judicial review filed on or after January 1, 2027. The calendar year 2027 AIC threshold amounts are \$200 for ALJ hearings and \$2,000 for judicial review.

DATES: This annual adjustment takes effect on January 1, 2027.

FOR FURTHER INFORMATION CONTACT: Natasha Franklin, (410) 786-5692.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1869(b)(1)(E) of the Social Security Act (the Act) established the amount in controversy (AIC) threshold amounts for Administrative Law Judge (ALJ) hearings and judicial review at \$100 and \$1,000, respectively, for Medicare Part A and Part B appeals. Additionally, section 1869(b)(1)(E) of the Act provides that beginning in January 2005, the AIC threshold amounts are to be adjusted annually by the percentage increase in the medical care component of the consumer price

index (CPI) for all urban consumers (U.S. city average) for July 2003 to the July preceding the year involved and rounded to the nearest multiple of \$10. Sections 1852(g)(5) and 1876(c)(5)(B) of the Act apply the AIC adjustment requirement to Medicare Part C/Medicare Advantage (MA) appeals and certain health maintenance organization and competitive medical plan appeals. Health care prepayment plans are also subject to MA appeals rules, including the AIC adjustment requirement, pursuant to 42 CFR 417.840. Section 1860D-4(h)(1) of the Act, provides that a Medicare Part D plan sponsor shall meet the requirements of paragraphs (4) and (5) of section 1852(g) of the Act with respect to benefits, including appeals and the application of the AIC adjustment requirement to Medicare Part D appeals.

A. Medicare Part A and Part B Appeals

The statutory formula for the annual adjustment to the AIC threshold amounts for ALJ hearings and judicial review of Medicare Part A and Part B appeals, set forth at section 1869(b)(1)(E) of the Act, is included in the applicable implementing regulations, 42 CFR 405.1006(b) and (c). The regulations at § 405.1006(b)(2) require the Secretary of Health and Human Services (the Secretary) to publish changes to the AIC threshold amounts in the **Federal Register**. To be entitled to a hearing before an ALJ, a party to a proceeding must meet the AIC requirements at § 405.1006(b). Similarly, a party must meet the AIC requirements at § 405.1006(c) at the time judicial review is requested for the court to have jurisdiction over the appeal (§ 405.1136(a)).

B. Medicare Part C/MA Appeals

Section 1852(g)(5) of the Act applies the AIC adjustment requirement to Medicare Part C appeals. The implementing regulations for Medicare Part C appeals are found at 42 CFR part 422, subpart M. Specifically, §§ 422.600 and 422.612 discuss the AIC threshold amounts for ALJ hearings and judicial review. Section 422.600 grants any party to the reconsideration (except the MA organization) who is dissatisfied with the reconsideration determination a right to an ALJ hearing as long as the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary. Section 422.612 states, in part, that any party, including the MA organization, may request judicial review if the AIC meets the threshold requirement established annually by the Secretary.

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]

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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, PRAStaff@fda.hhs.gov.