

Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways November 25, 2008:

1. *Electronically.* You may submit 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) 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.

Dated: September 18, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-4136-N]

Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2009

AGENCY: Centers for Medicare & Medicaid Services (CMS), 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, 2009. The 2009 AIC threshold amounts are \$120 for ALJ hearings and \$1,220 for judicial review.

DATES: *Effective Date:* This notice is effective on January 1, 2009.

FOR FURTHER INFORMATION CONTACT: Liz Hosna, (410) 786-4993.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1869(b)(1)(E) of the Social Security Act (the Act), as amended by section 521 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), established the AIC threshold amounts for ALJ hearing requests and judicial review at \$100 and \$1000, respectively, for Medicare Part A and Part B appeals. Section 940 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), amended section 1869(b)(1)(E) of the Act to require the AIC threshold amounts for ALJ hearings and judicial review to be adjusted annually. The AIC threshold amounts are to be adjusted, as of January 2005, by the percentage increase in the medical care component of the consumer price index 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. Section 940(b)(2) of the MMA provided conforming amendments to apply the AIC adjustment requirement to Medicare Part C (Medicare Advantage "MA") appeals and certain health maintenance organization and competitive health plan appeals. Health care prepayment plans are also subject to MA appeals rules, including the AIC adjustment requirement. Section 101 of the MMA provides for 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 Part 405, Subpart I, at § 405.1006(b). The regulations require the Secretary of the Department of Health and Human Services (the Secretary) to publish changes to the AIC threshold amounts in the **Federal Register** (§ 405.1006(b)(2)). In order 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 requirement 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 (Medicare Advantage) Appeals

Section 940(b)(2) of the MMA applies the AIC adjustment requirement to Part C (MA) appeals by amending section

1852(g)(5) of the Act. 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, 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 that any party, including the MA organization, may request judicial review if the amount in controversy 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) 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 as discussed above, apply to these appeals. The Medicare Part C appeals rules also apply to health care prepayment plan appeals.

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 101 of the MMA added section 1860D-4(h)(1) of the Act regarding Part D appeals. This statutory provision 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. As noted above, the annually adjusted AIC threshold requirement was added to section 1852(g)(5) of the Act by section 940(b)(2)(A) of the MMA. The implementing regulations for Medicare Part D appeals can be found at 42 CFR Part 423, Subpart M. The regulations impart at § 423.562(c) that unless the Part D appeals rules provide otherwise, the Part C appeals rules (including the annually adjusted AIC threshold amount) apply to Part D appeals to the extent they are appropriate. More specifically, § 423.610 and § 423.630 of the Part D appeals rules discuss the AIC threshold amounts for ALJ hearings and judicial review. Section 423.610(a)

grants 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. Section 423.630(a) allows a Part D enrollee to request judicial review of an ALJ's decision if the AIC meets the threshold amount established annually by the Secretary.

II. Annual AIC Adjustments

A. AIC Adjustment Formula and AIC Adjustments

As previously noted, section 940 of the MMA requires that the AIC threshold amounts be adjusted

annually, beginning in January of 2005, 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 of the preceding year involved and rounded to the nearest multiple of \$10.

B. Calendar Year 2009

The AIC threshold amount for ALJ hearing requests will be \$120 and the AIC threshold amount for judicial review will be \$1,220 for the 2009 calendar year. These new amounts are based on the 22.3 percent increase in the medical care component of the CPI from July of 2003 to July of 2008. The CPI level was at 297.6 in July of 2003 and rose to 363.96 in July of 2008. This

change accounted for the 22.3 percent increase. The AIC threshold amount for ALJ hearing requests changes to \$122.30 based on the 22.3 percent increase. In accordance with section 940 of the MMA, this amount is rounded to the nearest multiple of \$10. Therefore, the 2009 AIC threshold amount for ALJ hearings is \$120. The AIC threshold amount for judicial review changes to \$1,223.00 based on the 22.3 percent increase. This amount was rounded to the nearest multiple of \$10, resulting in a 2009 AIC threshold amount of \$1,220.

C. Summary Table of Adjustments in the AIC Threshold Amounts

In Table 1 below, we list the Calendar Year 2005 through 2009 threshold amounts.

TABLE 1—AMOUNT-IN-CONTROVERSY THRESHOLD AMOUNTS

	CY 2005	CY 2006	CY 2007	CY 2008	CY 2009
ALJ Hearing	\$100	\$110	\$110	\$120	\$120
Judicial Review	1050	1090	1130	1180	1,220

Key: CY = Calendar Year.

III. Collection of Information Requirements (If Applicable)

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 12, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3203–N]

Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee—November 19, 2008

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces that a public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) (“Committee”) will be held on Wednesday, November 19, 2008. The Committee generally provides advice and recommendations concerning the adequacy of scientific evidence needed to determine whether certain medical items and services can be covered under the Medicare statute. This meeting will focus on the use of computed tomography colonography (CTC), also referred to as virtual colonoscopy, as a cancer screening test for average risk individuals (See section 1861(pp) of the Social Security Act (42 U.S.C. section 1395x(pp))). The meeting will discuss the various kinds of evidence that are useful to support requests for Medicare coverage in this field. This meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

DATES: *Meeting date:* The public meeting will be held on Wednesday, November 19, 2008 from 7:30 a.m. until 4:30 p.m., e.s.t.

Deadline for Submission of Written Comments: Written comments must be received at the address specified in the **ADDRESSES** section of this notice by 5 p.m., e.s.t on October 20, 2008. Once submitted comments are final.

Deadlines for Speaker Registration and Presentation Materials: The

deadline to register to be a speaker and to submit powerpoint presentation materials and writings that will be used in support of an oral presentation, is 5 p.m., d.s.t. on Monday, October 20, 2008. Speakers may register by phone or via e-mail by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the address specified in the **ADDRESSES** section of this notice.

Deadline for All Other Attendees Registration: Individuals may register by phone or via e-mail by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5 p.m., e.s.t. on Wednesday, November 12, 2008.

Deadline for Submitting a Request for Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to contact the Executive Secretary as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than 5 p.m., e.s.t. Friday, November 7, 2008.

ADDRESSES: *Meeting Location:* The meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Blvd., Baltimore, MD 21244.

Submission of Presentations and Comments: Presentation materials and written comments that will be presented at the meeting must be submitted via e-