

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2006

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 adjustments to the AIC threshold amounts will be effective for requests for ALJ hearings and judicial review filed on or after January 1, 2006. The 2006 AIC threshold amounts are \$110 for ALJ hearings and \$1090 for judicial review.

DATES: *Effective Date:* January 1, 2006.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Section 1869(b)(1)(E) of the Social Security 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 (Medicare Modernization Act "MMA"), amended section 1869(b)(1)(E) to require the AIC threshold amounts for ALJ hearings and judicial review 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 the July of the preceding 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 Social Security Act [42 U.S.C. 1395ff(b)(1)(E)], is included in the applicable implementing regulations, 42 CFR part 405, subpart I, at section 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**. 42 CFR 405.1006(b)(2). In order to be entitled to a hearing before an ALJ, a party must meet the AIC requirement. 42 CFR 405.1006(c). Similarly, a party must meet the AIC requirement at the time judicial review is requested for the court to have jurisdiction over the appeal. 42 CFR 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 Social Security Act [42 U.S.C. 1395w-22(g)(5)]. The implementing regulations for Medicare Part C appeals are found at 42 CFR part 422, subpart M. Specifically, sections 422.600 and 422.612 discuss the AIC threshold amounts for ALJ hearings and judicial review. Section 422.600 grants any party, 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 940(b)(2) of the MMA also amended section 1876(c)(5)(B) of the Social Security Act [42 U.S.C. 1395ff(c)(5)(B)] to make section 1869(b)(1)(E) applicable to certain beneficiary appeals within the context of health maintenance organizations and competitive medical plans. The applicable implementing regulations for Medicare Part C appeals set forth in Subpart M of 42 CFR part 422 and 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) regarding Part D appeals to the Social Security Act [42 U.S.C. 1395w-104(h)(1)]. 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 Social Security Act [42 U.S.C. 1395w-22(g)(4), (g)(5)] in a similar manner as MA organizations. As noted above, the annually adjusted AIC threshold requirement was added to section 1852(g)(5) 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 section 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. More specifically, sections 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 if the AIC meets the threshold amount established annually by the Secretary.

II. AIC Adjustment Formula and the 2005 and 2006 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.

A. Calendar Year 2005

The AIC threshold amount for ALJ hearing requests remained at \$100 and the AIC threshold amount for judicial review rose to \$1,050 for the 2005 calendar year. The amounts were based on the 4.5 percent increase in the medical care component of the CPI from

July of 2003 to July of 2004 as published by the Bureau of Labor Statistics, Department of Labor. The CPI level was at 297.6 in July of 2003 and rose to 311 in July of 2004. This change accounted for the 4.5 percent increase. The increase in the AIC threshold for ALJ hearing requests would have changed to \$104.50 based on the 4.5 percent increase. Section 940 of the MMA requires, however, that the increase be rounded to the nearest \$10 if the increase is not a multiple of \$10. Therefore, after rounding, the 2005 AIC threshold amount for ALJ hearings remained at \$100. The AIC threshold amount for judicial review changed to \$1,045 based on the 4.5 percent increase. This amount was rounded to the nearest multiple of \$10, resulting in a 2005 AIC threshold amount of \$1,050.

The 2005 AIC threshold amounts were published in the preamble to the Interim Final Rule, 70 FR 11423 (March 8, 2005), regarding "Changes to the Medicare Claims Appeal Procedures." In addition, this information was previously made available to the public through a change to the Medicare Claims Processing Manual. CMS Change Request 3127, Revisions and Corrections to Chapter 29 of the IOM, Claims Processing Manual—Appeals § 30.8 (Nov. 26, 2004).

B. Calendar Year 2006

The AIC threshold amount for ALJ hearing requests has risen to \$110 and the AIC threshold amount for judicial review has risen to \$1,090 for the 2006 calendar year. These new amounts are based on the 8.9 percent increase in the

medical care component of the CPI from July of 2003 to July of 2005. The CPI level was at 297.6 in July of 2003 and rose to 324.1 in July of 2005. This change accounted for the 8.9 percent increase. The increase in the AIC threshold amount for ALJ hearing requests changes to \$108.90 based on the 8.9 percent increase. In accordance with section 940 of the MMA, this amount is rounded to the nearest multiple of \$10. Therefore, the 2006 AIC threshold amount for ALJ hearings is \$110. The AIC threshold amount for judicial review changes to \$1,089 based on the 8.9 percent increase. This amount was rounded to the nearest multiple of \$10, resulting in a 2006 AIC threshold amount of \$1,090.

C. Summary Table of Adjustments in the AIC Threshold Amounts

TABLE 1.—AMOUNT-IN-CONTROVERSY THRESHOLD AMOUNTS

	CY 2004	CY 2005	CY 2006
ALJ Hearing	\$100	\$100	\$110
Judicial Review	1000	1050	1090

*CY—Calendar Year.

Dated: January 9, 2006.

Ann C. Agnew,

Executive Secretary to the Department.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Health and Nutrition Examination Survey III (NHANES) DNA Specimens: Guidelines for Proposals To Use Samples and Cost Schedule

AGENCY: Centers for Disease Control and Prevention (CDC), Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Health and Nutrition Examination Survey (NHANES) is a program of periodic surveys conducted by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC). Examination surveys conducted since 1960 by NCHS have provided national estimates of the health and nutritional status of the U.S. civilian non-institutionalized population. To add to the large amount of information collected for the purpose of describing the health of the population, blood lymphocytes were

collected in NHANES III in anticipation of advances in genetic research.

The lymphocytes have been stored and maintained at the Division of Laboratory Sciences (DLS) at the National Center for Environmental Health (NCEH), CDC. The collection of lymphocytes was begun in the second phase of the survey (1991–1994) because of the significant advances in the rapidly evolving field of molecular biology that were occurring during the planning phase of this survey. CDC is making DNA samples from these specimens available to the research community for genetic analyses. Specimens are available from approximately 7,159 participants in the second phase of NHANES III. No cell lines will be made available.

This program has been previously announced (Tuesday, June 1, 1999 [64 FR 29321]; Thursday, August 8, 2002 [67 FR 51585]). The purpose of this notice is to announce a fourth category for proposals for use of these specimens, add an additional secondary review of approved applications and provide a new proposal schedule. For final proposal guidelines and requests or letters of intent, please contact Ms. Oraegbu or go to <http://www.cdc.gov/nchs/about/major/nhanes/dnafnlgm2.htm>.

All interested researchers are encouraged to submit letters of intent. No funding is provided as part of this

solicitation. Proposals will be reviewed by a technical panel and approved applications will be reviewed by an internal Secondary Review Committee, which will perform a programmatic review based on the results of the peer review for technical merit. The primary purpose of the Secondary Review Committee is to factor in the scientific and technical results from the first level of review, important programmatic considerations such as program priorities, program relevance, and other criteria germane to this announcement and to CDC. The secondary review panel will be comprised of senior CDC scientists, who will advise the Director, NCHS, on the approved applications. Projects approved by both reviews will be submitted to the NCHS Ethics Review Board for final approval.

Approved projects that do not obtain funding on their own will be canceled. A more complete description of this program follows.

DATES:

- Letter of Intent Receipt: February 13, 2006.
- Submission of Proposals: March 14, 2006.
- Scientific Review: April 13, 2006.
- Secondary Review: May 15, 2006.
- Ethics Review Board: July 12, 2006.
- Notification of approval: August 1, 2006.
- Anticipated distribution of samples: December 11, 2006.