

Quality Reporting System (PQRS) and the Electronic Prescribing Incentive (eRx) Program Data Assessment, Accuracy and Improper Payments Identification Support; *Use:* The incentive and reporting programs have data integrity issues, such as rejected and improper payments. This four year project will evaluate incentive payment information for accuracy and identify improper payments, with the goal of recovering these payments. Additionally, based on the project's results, recommendations will be made so that we can avoid future data integrity issues.

Data submission, processing, and reporting will be analyzed for potential errors, inconsistencies, and gaps that are related to data handling, program requirements, and clinical quality measure specifications of PQRS and eRx program. Surveys of Group Practices, Registries, and Data Submission Vendors (DSVs) will be conducted in order to evaluate the PQRS and eRx Incentive Program. Follow-up interviews will occur with a small number of respondents. *Form Number:* CMS-10519 (OMB control number: 0938-1255); *Frequency:* Annually; *Affected Public:* Business or other for-profits; *Number of Respondents:* 115; *Total Annual Responses:* 115; *Total Annual Hours:* 201. (For policy questions regarding this collection contact Timothy Jackson at 410-786-4006.)

**2. Type of Information Collection Request:** New collection (Request for a new OMB control number); *Title of Information Collection:* Data Collection for Medicare Beneficiaries Receiving Beta Amyloid Positron Emission Tomography (PET) for Dementia and Neurodegenerative Disease *Use:* In the Decision Memorandum #CAG-00431N issued on September 27, 2013, CMS determined there is sufficient evidence that the use of beta amyloid PET is promising in 2 scenarios: (1) to exclude Alzheimer's Disease (AD) in narrowly defined and clinically difficult differential diagnoses; and (2) to enrich clinical trials seeking better treatments or prevention strategies for AD. CMS will cover one beta amyloid PET scan per patient through Coverage with Evidence Development under section 1862(a)(1)(E) of the Social Security Act, in clinical studies that meet specific criteria established by CMS. Clinical studies must be approved by CMS, involve subjects from appropriate populations, and be comparative and longitudinal. Radiopharmaceuticals used in the scan must be FDA approved. Approved studies must address defined research questions established by CMS.

Clinical studies in this National Coverage Determination (NCD) must adhere to the designated timeframe and meet standards established by CMS in the NCD. Consistent with section 1142 of the Social Security Act, the Agency for Healthcare and Quality (AHRQ) supports clinical research studies that CMS determines meet specifically identified requirements and research questions.

To qualify for payment, providers must prescribe beta amyloid PET for beneficiaries with a set of clinical criteria specific to each cancer. Data elements will be transmitted to CMS for evaluation of the short and long-term benefits of beta amyloid PET to beneficiaries and for use in future clinical decision making. *Form Number:* CMS-10583 (OMB control number: 0938-NEW); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profit); *Number of Respondents:* 300; *Total Annual Responses:* 3,700; *Total Annual Hours:* 6,475. (For policy questions regarding this collection contact Stuart Caplan at 410-786-8564).

Dated: September 22, 2015.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-4178-N]

#### Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2016

**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, 2016. The calendar year 2016 AIC threshold amounts are \$150 for ALJ hearings and \$1,500 for judicial review.

**DATES:** *Effective Date:* This notice is effective on January 1, 2016.

**FOR FURTHER INFORMATION CONTACT:** Liz Hosna (*Katherine.Hosna@cms.hhs.gov*), (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 amount in controversy (AIC) threshold amounts for Administrative Law Judge (ALJ) hearing requests and judicial review at \$100 and \$1,000, 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 (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. 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 405.1006(b) and (c). 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 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 940(b)(2) of the MMA applies the AIC adjustment requirement to Medicare Part C appeals by amending section 1852(g)(5) of the Act. The implementing regulations for Medicare Part C appeals are found at 42 CFR 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 422, subpart M and 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 previously, 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 423, subparts M and U. The regulations at § 423.562(c) prescribe 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, §§ 423.1970 and 423.1976 of the Part D appeals rules discuss the AIC threshold amounts for ALJ hearings and judicial review. Section 423.1970(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. Sections 423.1976(a) and (b) allow a Part D enrollee to request judicial review of an ALJ or Medicare Appeals Council (MAC) decision if, in part, the AIC meets the threshold amount established annually by the Secretary.

**II. Provisions of the Notice—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 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 2016**

The AIC threshold amount for ALJ hearing requests will remain at \$150 and the AIC threshold amount for judicial review will rise to \$1,500 for CY 2016. These amounts are based on the 50.125 percent increase in the medical care component of the CPI, which was at 297.600 in July 2003 and rose to 446.773 in July 2015. The AIC threshold amount for ALJ hearing requests changes to \$150.125 based on the 50.125 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 2016 AIC threshold amount for ALJ hearings is \$150.00. The AIC threshold amount for judicial review changes to \$1,501.25 based on the 50.125 percent increase over the initial threshold amount of \$1,000. This amount was rounded to the nearest multiple of \$10, resulting in the CY 2016 AIC threshold amount of \$1,500.00 for judicial review.

**C. Summary Table of Adjustments in the AIC Threshold Amounts**

In the following table we list the CYs 2012 through 2016 threshold amounts.

	CY 2012 \$	CY 2013 \$	CY 2014 \$	CY 2015 \$	CY 2016 \$
ALJ Hearing .....	130	140	140	150	150
Judicial Review .....	1,350	1,400	1,430	1,460	1,500

**III. 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.*).

Dated: September 10, 2015.  
**Andrew M. Slavitt,**  
*Acting Administrator, Centers for Medicare & Medicaid Services.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Proposed Projects:*  
*Title:* Head Start Eligibility Verification.  
*OMB No.:* 0970-0374.  
*Description:* The Office of Head Start (OHS) within the Administration for