Medicare—Supplementary Medical Insurance Program)

Dated: September 25, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–23996 Filed 9–27–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4158–N]

Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2013

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, 2013. The calendar year 2013 AIC threshold amounts are $140 for ALJ hearings and $1,400 for judicial review.

EFFECTIVE DATE: This notice is effective on January 1, 2013.

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 $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 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/Medicare Advantage Appeals

Section 940(b)(2) of the MMA applies the AIC adjustment requirement to Medicare Part C (MA) appeals by amending section 1852(g)(5) of the Act. The implementing regulations for Medicare Part C (MA) 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) 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 previously, 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 part 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 MAC decision if, in part, 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 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.

B. Calendar Year 2013

The AIC threshold amount for ALJ hearing requests will increase to $140 and the AIC threshold amount for judicial review will rise to $1,400 for CY 2013. These updated amounts are based on the 40.04 percent increase in the medical care component of the CPI from July 2003 to July 2012. The CPI level was at 297.600 in July 2003 and rose to 416.759 in July 2012. This change accounted for the 40.04 percent increase. The AIC threshold amount for ALJ hearing requests changes to $140.04 based on the 40.04 percent increase. In accordance with section 940 of the MMA, this amount is rounded to the nearest multiple of $10. Therefore, the CY 2013 AIC threshold amount for ALJ hearings is $140. The AIC threshold amount for judicial review changes to $1,400.40 based on the 40.04 percent increase. This amount was rounded to the nearest multiple of $10, resulting in the CY 2013 AIC threshold amount of $1,400 for judicial review.

C. Summary Table of Adjustments in the AIC Threshold Amounts

In the following table we list the CYs 2009 through 2013 threshold amounts.

	CY 2009	CY 2010	CY 2011	CY 2012	CY 2013
ALJ Hearing	$120	$130	$130	$130	$140
Judicial Review	1,220	1,260	1,300	1,350	1,400

III. Collection of Information Requirements

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, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–23992 Filed 9–27–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0961]

Agency Information Collection Activities; Proposed Collection; Comment Request; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection entitled ''Environmental Impact Considerations.''

DATES: Submit either electronic or written comments on the collection of information by November 27, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Environmental Impact Considerations—21 CFR Part 25 (OMB Control Number 0910–0322)—Extension)

FDA is requesting OMB approval for the reporting requirements contained in the FDA collection of information ''Environmental Impact Considerations.''

The National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4347) states national environmental objectives and imposes upon each Federal Agency the duty to consider the environmental effects of its actions. Section 102(2)(c) of