publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *October 27, 2014:*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR,* Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. The term ''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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Cost Sharing Reduction Reconciliation; *Use:* Under established Department of Health and Human Services (HHS) regulations, qualified health plan (QHP) issuers will receive estimated advance payments of cost-sharing reductions throughout the year. Each issuer will then be subject to a reconciliation process at the end of the benefit year to ensure that HHS reimburses each issuer only for actual cost sharing. This proposed collection establishes the data elements that a QHP issuer would be required to report to HHS in order to establish the cost-sharing reductions provided on behalf of enrollees for the benefit year. Comments were received and addressed in a Response to Comments document. *Form Number:* CMS–10526 (OMB control number: 0938–NEW); *Frequency:* Annually; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 295; *Total Annual Responses:* 4 million; *Total Annual Hours:* 2,469. (For policy questions regarding this collection contact Patricia Meisol at 410–786–1917.)

2. *Type of Information Collection Request*: Revision of a currently approved information collection; *Title of Information Collection:* Medicaid Incentives for Prevention of Chronic Disease (MIPCD) Demonstration; *Use:* Under section 4108(d)(1) of the Affordable Care Act, we are required to contract with an independent entity or organization to conduct an evaluation of the Medicaid Incentives for Prevention of Chronic Disease (MIPCD) demonstration. The contractor will conduct state site visits, two rounds of focus group discussions, interviews with key program stakeholders, and field a beneficiary satisfaction survey. Both the state site visits and interviews with key program stakeholders will entail one-on-one interviews; however each set will have a unique data collection form. Thus, each evaluation task listed above has a separate data collection form and this proposed information collection encompasses six data collection forms. The purpose of the evaluation and assessment includes determining the following:

- The effect of such initiatives on the use of health care services by Medicaid beneficiaries participating in the program;
- The extent to which special populations (including adults with disabilities, adults with chronic illnesses, and children with special health care needs) are able to participate in the program;
- The level of satisfaction of Medicaid beneficiaries with respect to the accessibility and quality of health care services provided through the program; and
- The administrative costs incurred by state agencies that are responsible for administration of the program.

Subsequent to the initial OMB approval issued January 23, 2014, we have added two Administrative Cost forms to the information collection. The burden estimates for this information collection have been revised to account for the burden associated with the new forms. *Form Number:* CMS–10477 (OMB control number: 0938–1219); *Frequency:* Annually; *Affected Public:* Individuals and Households, Private sector—Business or other for-profits and Not-for-profit institutions, State, Local or Tribal Governments; *Number of Respondents:* 4,706; *Total Annual Responses:* 4,706; *Total Annual Hours:* 2,236. (For policy questions regarding this collection contact Jean Scott at 410–786–6327.)

Dated: September 23, 2014.

Martique Jones,

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

[FR Doc. 2014–22980 Filed 9–25–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4175–N]

Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2015

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, 2015. The calendar year 2015 AIC threshold amounts are $150 for ALJ hearings and $1,460 for judicial review.

DATES: This notice is effective on January 1, 2015.

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 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. 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 2015

The AIC threshold amount for ALJ hearing requests will rise to $150 and the AIC threshold amount for judicial review will rise to $1,460 for CY 2015. These amounts are based on the 46.480 percent increase in the medical care component of the CPI level, which was at 297.600 in July 2003 and rose to 435.924 in July 2014. The AIC threshold amount for ALJ hearing requests changes to $146.48 based on the 46.480 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 2015 AIC threshold amount for ALJ hearings is $150.00. The AIC threshold

amount for judicial review changes to $1,464.80 based on the 46.480 percent increase over the initial threshold amount of $1,000. This amount was rounded to the nearest multiple of $10, resulting in the CY 2015 AIC threshold amount of $1,460.00 for judicial review.

C. Summary Table of Adjustments in the AIC Threshold Amounts

In the following table we list the CYs 2011 through 2015 threshold amounts.

	CY 2011	CY 2012	CY 2013	CY 2014	CY 2015
ALJ Hearing	$130	$130	$140	$140	$150
Judicial Review	1,300	1,350	1,400	1,430	1,460

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).

Dated: September 11, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–22625 Filed 9–25–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0037]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On July 08, 2014, the Agency submitted a proposed collection of information entitled ''Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0540. The approval expires on August 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: September 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22981 Filed 9–25–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0075]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Good Laboratory Practice Regulations for Nonclinical Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 (PRA).

DATES: Fax written comments on the collection of information by October 27, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0119. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Good Laboratory Practice Regulations for Nonclinical Studies—21 CFR Part 58 (OMB Control Number 0910–0119)—Extension

Sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348, 355, 360b, 360e) and related statutes require manufacturers of food additives, human drugs and biological products, animal drugs, and medical devices to demonstrate the safety and utility of their product by submitting applications to FDA for research or marketing permits. Such applications contain, among other important items, full reports of all studies done to demonstrate product safety in man and/or other animals. In order to ensure adequate quality control for these studies and to provide an adequate degree of consumer protection, the Agency issued good laboratory practice (GLP) regulations for nonclinical laboratory studies in part 58 (21 CFR part 58). The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOPs), test and control articles, quality assurance, protocol and conduct of a safety study, records and reports, and laboratory disqualification.

Part 58 requires testing facilities engaged in conducting toxicological studies to retain, and make available to regulatory officials, records regarding compliance with GLPs. Records are maintained on file at each testing facility and examined there periodically by FDA inspectors. The GLP regulations