

submission of documentation required for long-term monitoring of competitive application projects is 14,400 hours (4,800 submissions × 3 hours).

#### VI. Homeownership Set-aside Program Applications and Certifications

FHFA estimates that Bank members will submit to the Banks an annual average of 13,000 applications and required certifications for AHP direct subsidies under the Banks' homeownership set-aside programs, and that the average preparation time for those submissions together will be 5 hours. The estimate for the total annual hour burden on members in connection with the preparation and submission of homeownership set-aside program applications and certifications is 65,000 hours (13,000 applications/certifications × 5 hours).

#### D. Public Comments Request

Written comments are requested on: (1) Whether the collection of information is necessary for the proper performance of FHFA functions, including whether the information has practical utility; (2) the accuracy of FHFA's estimates of the burdens of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on members and project sponsors, including through the use of automated collection techniques or other forms of information technology.

Dated: September 20, 2016.

**Kevin Winkler,**

Chief Information Officer, Federal Housing Finance Agency.

[FR Doc. 2016-22947 Filed 9-22-16; 8:45 am]

**BILLING CODE 8070-01-P**

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Home Owners' Loan Act (12 U.S.C. 1461 *et seq.*) (HOLA), Regulation LL (12 CFR part 238), and Regulation MM (12 CFR part 239), and all other applicable statutes and regulations to become a savings and loan holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a savings association and nonbanking companies owned by the savings and loan holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the HOLA (12 U.S.C. 1467a(e)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 10(c)(4)(B) of the HOLA (12 U.S.C. 1467a(c)(4)(B)). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 20, 2016.

A. Federal Reserve Bank of Cleveland (Nadine Wallman, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101-2566. Comments can also be sent electronically to

[Comments.applications@clev.frb.org](mailto:Comments.applications@clev.frb.org):

1. *Community Savings Bancorp, Inc., Caldwell, Ohio*; to become a savings and loan holding company through the mutual to stock conversion and acquisition of Community Savings, Caldwell, Ohio.

Board of Governors of the Federal Reserve System, September 20, 2016.

**Michele Taylor Fennell,**

Assistant Secretary of the Board.

[FR Doc. 2016-22955 Filed 9-22-16; 8:45 am]

**BILLING CODE 6210-01-P**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments

must be received not later than October 11, 2016.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001:

1. *Frank L. Carson, IV, Mulvane, Kansas*; to retain shares of Mulvane Bankshares, Inc., Mulvane, Kansas, and for approval as a member of the Carson Family Group that controls Mulvane Bankshares, Inc. Notification submitted by Sidney A. Reitz, Salina, Kansas, as trustee of Frank L. Carson, Jr. Trust No. 2; and Frank L. Carson, III Trust No. 2; to retain control of Mulvane Bankshares, Inc., and for approval as a member of the Carson Family Group. Mulvane Bankshares, Inc. controls Carson Bank, Mulvane, Kansas.

Board of Governors of the Federal Reserve System, September 20, 2016.

**Michele Taylor Fennell,**

Assistant Secretary of the Board.

[FR Doc. 2016-22956 Filed 9-22-16; 8:45 am]

**BILLING CODE 6210-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-4179-N]

### Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2017

**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, 2017. The calendar year 2017 AIC threshold amounts are \$160 for ALJ hearings and \$1,560 for judicial review.

**DATES:** *Effective Date:* This notice is effective on January 1, 2017.

**FOR FURTHER INFORMATION CONTACT:** Liz Hosna ([Katherine.Hosna@cms.hhs.gov](mailto: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 2017*

The AIC threshold amount for ALJ hearing requests will rise to \$160 and the AIC threshold amount for judicial review will rise to \$1,560 for CY 2017. These amounts are based on the 56.110 percent increase in the medical care component of the CPI, which was at 297.600 in July 2003 and rose to 464.582 in July 2016. The AIC threshold amount for ALJ hearing requests changes to \$156.11 based on the 56.110 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 2017 AIC threshold amount for ALJ hearings is \$160.00. The AIC threshold amount for judicial review changes to \$1561.10 based on the 56.110 percent increase over the initial threshold amount of \$1,000. This amount was rounded to the nearest multiple of \$10, resulting in the CY 2017 AIC threshold amount of \$1,560.00 for judicial review.

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

In the following table we list the CYs 2013 through 2017 threshold amounts.

	CY 2013	CY 2014	CY 2015	CY 2016	CY 2017
ALJ Hearing .....	\$140	\$140	\$150	\$150	\$160
Judicial Review .....	1,400	1,430	1,460	1,500	1,560

### 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 7, 2016.

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2016-23002 Filed 9-22-16; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10105]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to 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: The necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and 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 24, 2016.

**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](mailto: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 the 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](mailto: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:* Revision of a currently

approved collection; *Title of Information Collection:* National Implementation of the In-Center Hemodialysis CAHPS Survey; *Use:* Data collected in the national implementation of the In-center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey will be used to: (1) Provide a source of information from which selected measures can be publicly reported to beneficiaries as a decision aid for dialysis facility selection, (2) aid facilities with their internal quality improvement efforts and external benchmarking with other facilities, (3) provide CMS with information for monitoring and public reporting purposes, and (4) support the end-stage renal disease value-based purchasing program. *Form Number:* CMS-10105 (OMB control number: 0938-0926). *Frequency:* Occasionally; *Affected Public:* Individuals or households; *Number of Respondents:* 109,328; *Total Annual Responses:* 109,328; *Total Annual Hours:* 59,037. (For policy questions regarding this collection contact Julia Zucco at 410-786-6670.)

Dated: September 20, 2016.

**William N. Parham, III,**

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

[FR Doc. 2016-22967 Filed 9-22-16; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-D-1399]

#### Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in Food and Drug Administration Advisory Committees; Draft Guidance for the Public, Food and Drug Administration Advisory Committee Members, and Food and Drug Administration Staff; Availability; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending the comment period for the notice that