

++ Copies of the organization's survey forms.

++ A description of the accreditation survey review process and the accreditation status decision-making process, including the process for addressing identified deficiencies with the accreditation requirements, and the procedures used to monitor the correction of deficiencies found during an accreditation survey.

++ Procedures for coordinating surveys with another accrediting organization (when the organization does not accredit all modalities) provided by an applicant for accreditation which the supplier provided.

++ Comprehensive information about the individuals who perform evaluations for the accreditation organization, including all of the following information:

- Detailed information about the size and composition of accreditation teams for each category of advanced medical imaging service supplier accredited.
- The number of professional and technical staff that are available for survey.
- The education, current employment and experience requirements surveyors must meet.
- The content and length of any orientation program.
- The frequency and types of in-service training provided to survey personnel.
- The evaluation systems used to monitor the performance of individual surveyors and survey teams.
- Policies and procedures regarding an individual's participation in the survey or accreditation decision process of any organization with which the individual is professionally or financially affiliated.

++ Policies and procedures used when an organization has a dispute regarding survey findings or an adverse decision.

- A description of the organization's data management and analysis capabilities in support of its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

- The organization's procedures for investigating and responding to complaints against accredited facilities, including policies and procedures regarding coordination of these activities with relevant licensing bodies and CMS.

- A description of the organization's policies and procedures for withholding or removal of accreditation status for

facilities that fail to meet the organization's accreditation standards and other actions taken by the organization in response to noncompliance with its accreditation criteria. These policies and procedures must include notifying CMS of facilities that fail to meet the requirements of the accrediting organization as required by CMS.

- The information submitted for notification of these organizations include—

++ A list of all accredited suppliers that the accrediting organization has accredited to include the type and category of accreditation currently held by each supplier, and the expiration date of each supplier's current accreditation; and

++ A list of all accreditation surveys scheduled to be performed by the organization;

- The accreditation organization must also submit the following supporting documentation:

++ A written presentation that demonstrates the organization's ability to furnish us with electronic data in ASCII comparable code.

++ A resource analysis that demonstrates that the organization's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

++ A statement acknowledging that, as a condition for approval the organization will agree to the following:

- Provide a statement agreeing to notify us, in writing, of any supplier that had its accreditation revoked, withdrawn, revised, or any other remedial or adverse action taken against it by the accreditation organization within 30 calendar days of any such action taken.
- Notify all accredited suppliers within 10 calendar days of our withdrawal of the organization's approval of designation authority.
- Notify us, in writing, at least 30 calendar days in advance of the effective date of any proposed changes in accreditation requirements.
- Permit its surveyors to serve as witnesses if we take an adverse action based on accreditation findings.
- Notify us, in writing, within 2 calendar days of a deficiency identified in any accreditation entity where the deficiency poses an immediate jeopardy to the supplier's beneficiaries or a hazard to the general public.
- Provide, on an annual basis, summary data specified by us that relates to the past years' accreditations and trends.

—Attest that the organization will not perform any accreditation surveys of Medicare participating suppliers with which it has a financial relationship with or interest.

(For further information regarding the application requirements see the November 25, 2009 (74 FR 62189) and November 30, 2009 (74 FR 62579) notices.)

We have complete our review and believe that RadSite™ has provided us with demonstrated evidence of their qualifications and ability to accredit the categories of advanced diagnostic imaging services to include computerized tomography, nuclear medicine, positron emission tomography, and magnetic resonance imaging as defined in sections 1834(e)(1)(B) and 1848(b)(4)(B) of the Act. Therefore this notice announces our approval of RadSite™ to accredit suppliers furnishing the TC of all advanced imaging modalities (that is, computerized tomography, nuclear medicine, positron emission tomography, and magnetic resonance imaging) on or after September 27, 2013.

Authority: Section 1834(e) of the Act. (Catalog of Federal Domestic Assistance Program No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: September 19, 2013.

Marilyn Tavenner,
Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-4167-N]

Medicare Program; Medicare Appeals: Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2014

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, 2014. The calendar year 2014 AIC threshold

amounts are \$140 for ALJ hearings and \$1,430 for judicial review.

DATES: This notice is effective on January 1, 2014.

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. 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 2014

The AIC threshold amount for ALJ hearing requests will remain at \$140 and the AIC threshold amount for judicial review will rise to \$1,430 for CY 2014. These amounts are based on the 42.754 percent increase in the medical care component of the CPI, which was at 297.600 in July 2003 and rose to 424.836 in July 2013. The AIC threshold amount for ALJ hearing requests changes to \$142.75 based on the 42.754 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 2014 AIC threshold amount for ALJ hearings is \$140.00. The AIC threshold amount for judicial review changes to \$1,427.54 based on the 42.754 percent increase over the initial threshold amount of \$1,000. This amount was rounded to the nearest multiple of \$10, resulting in the CY 2014 AIC threshold amount of \$1,430.00 for judicial review.

C. Summary Table of Adjustments in the AIC Threshold Amounts

In the following table we list the CYs 2010 through 2014 threshold amounts.

	CY 2010	CY 2011	CY 2012	CY 2013	CY 2014
ALJ Hearing	\$130	\$130	\$130	\$140	\$140
Judicial Review	1,260	1,300	1,350	1,400	1,430

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. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 23, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3111-N]

Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Laboratories Licensed by the State of Washington

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces that laboratories located in and licensed by the State of Washington that possess a valid license under the Medical Test Site law, Chapter 70.42 of the Revised Code of Washington, are exempt from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for a period of 6 years.

DATES: The exemption granted by this notice is effective from September 27, 2013 to September 27, 2019.

FOR FURTHER INFORMATION CONTACT: Sandra Farragut, (410) 786-3531.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

Section 353 of the Public Health Service Act (PHSA), as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100-578), which was enacted on October 31, 1988, generally provides that no laboratory may perform tests on human specimens for the diagnosis, prevention or treatment of any disease or impairment of, or assessment of the health of, human beings unless it has a certificate to perform that category of tests issued by the Secretary of the Department of Health and Human Services (HHS). Under section 1861(s) of the Social Security Act (the Act), the Medicare program will only pay for laboratory services if the laboratory has a CLIA certificate. Section 1902(a)(9)(C) of the Act requires that state Medicaid plans pay only for laboratory services furnished by CLIA-certified laboratories. Thus, although subject to specified exemptions and exceptions, laboratories generally must have a current and valid CLIA certificate to test human specimens for medical purposes noted above to be eligible for payment for those tests from the Medicare or Medicaid programs. Regulations implementing section 353 of the PHSA are contained in 42 CFR part 493.

Section 353(p) of the PHSA provides for the exemption of laboratories from CLIA requirements in states that enact legal requirements that are equal to or more stringent than CLIA's statutory and regulatory requirements. Section 353(p) of the PHSA is implemented in subpart E of our regulations at 42 CFR part 493. Sections 493.551 and 493.553 provide that we may exempt from CLIA requirements, for a period not to exceed 6 years, all state-licensed or -approved laboratories in a state if the state licensure program meets the specified conditions. Section 493.559 provides that we will publish a notice in the **Federal Register** when we grant exemption to an approved state licensure program. It also provides that the notice will include the following:

- The basis for granting the exemption.

- A description of how the laboratory requirements are equal to or more stringent than those of CLIA.
- The term of approval, not to exceed 6 years.

State of Washington's Application for CLIA Exemption of Its Laboratories

The State of Washington has applied for exemption of its laboratories from CLIA program requirements. The State of Washington submitted all of the applicable information and attestations required by § 493.551, § 493.553, and § 493.557 for state licensure programs seeking exemption of their licensed laboratories from CLIA program requirements.

Examples of documents and information submitted include: a comparison of its laboratory licensure requirements with comparable CLIA condition-level requirements (that is, a crosswalk); and a description of the following: its inspection process; its proficiency testing monitoring process; its data management and analysis system; its investigative and response procedures for complaints received against laboratories; and its policy regarding announced and unannounced inspections.

CMS Analysis of Washington's Application and Supporting Documentation

To determine whether we should grant a CLIA exemption to laboratories licensed by a state, we review the application and additional documentation that the state submits to us and conducts a detailed and in-depth comparison of the state licensure program and CLIA's statutory and regulatory requirements to determine whether the state program meets the requirements at subpart E of part 493.

In summary, the state generally must demonstrate that:

- It has state laws in effect that provide for a state licensure program that has requirements that are equal to or more stringent than CLIA condition-level requirements for laboratories.
- It has implemented a state licensure program with requirements that are equal to or more stringent than the CLIA condition-level requirements such that a