maintained and distributed via modifications of codes, modifiers and descriptions, as a direct result of data received from applicants. Thus, information collected in the application is significant to codeset maintenance.

The HCPCS codeset maintenance is an ongoing process, as changes are implemented and updated annually; therefore, the process requires continual collection of information from applicants on an annual basis. As new technology evolves and new devices, drugs and supplies are introduced to the market, applicants submit applications to CMS requesting modifications to the HCPCS Level II codeset. Applications have been received prior to HIPAA implementation and must continue to be collected to ensure quality decision-making. The HIPAA of 1996 required CMS to adopt standards for coding systems that are used for reporting health care transactions. The regulation that CMS published on August 17, 2000 (45 CFR 162.10002) to implement the HIPAA requirement for standardized coding systems established the HCPCS Level II codes as the standardized coding system for describing and identifying health care equipment and supplies in health care transactions. HCPCS Level II was selected as the standardized coding system because of its wide acceptance among both public and private insurers. Public and private insurers were required to be in compliance with the August 2000 regulation by October 1, 2002. *Form Number:* CMS–10224 (OMB control number: 0938–1042); *Frequency:* Annually; *Affected Public:* Private Sector: Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 100; *Total Annual Responses:* 100; *Total Annual Hours:* 1100. (For policy questions regarding this collection contact Kimberley Combs-Miller at 410–786–6707).

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Independent Rural Health Clinics/Freestanding Federally Qualified Health Clinics Cost Report; *Use:* Providers of services participating in the Medicare program are required under sections 1815(a), 1833(e) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. The Form CMS–222–17 cost report is needed to determine a provider's reasonable costs incurred in furnishing medical services to Medicare beneficiaries and reimbursement due to or from a provider. *Form Number:* CMS–222–17 (OMB control number: 0938–0107); *Frequency:* Annually; *Affected Public:* Private Sector: Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 1,744; *Total Annual Responses:* 1,744; *Total Annual Hours:* 95,920. (For policy questions regarding this collection contact Yaakov Feinstein at 410–786–3137).

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Organ Procurement Organization/Histocompatibility Laboratory Cost Report; *Use:* Providers of services participating in the Medicare program are required under sections 1815(a) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. The Form CMS–216–94 cost report is needed to determine a provider's reasonable costs incurred in furnishing medical services to Medicare beneficiaries and reimbursement due to or due from a provider. *Form Number:* CMS–216–94 (OMB control number: 0938–0102); *Frequency:* Annually; *Affected Public:* Private Sector: Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 102; *Total Annual Responses:* 102; *Total Annual Hours:* 4590. (For policy questions regarding this collection contact Amelia Citerone at 410–786–3901).

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Providers of services participating in the Medicare program are required under sections 1815(a) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. The Form CMS–265–11 cost report is needed to determine a provider's reasonable costs incurred in furnishing medical services to Medicare beneficiaries. *Form Number:* CMS–265–11 (OMB control number: 0938–0236); *Frequency:* Annually; *Affected Public:* Private Sector: Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 6,821; *Total Annual Responses:* 6,821; *Total Annual Hours:* 443,365. (For policy questions regarding this collection contact Gail Duncan at 410–786–7278).

Dated: September 26, 2017.

William N. Parham, III,

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

[FR Doc. 2017–20921 Filed 9–28–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1698–N]

Medicare Program; Request for Nominations to the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests

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

ACTION: Notice.

SUMMARY: This notice requests nominations to fill vacancies on the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel). The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services (DHHS) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on issues related to clinical diagnostic laboratory tests (CDLTs). As announced in the notice published in the **Federal Register** on June 16, 2017, entitled ''Medicare Program; Rechartering, Membership, and Announcement of the Advisory Panel on Clinical Diagnostic Laboratory Tests Meeting on August 1, 2017'' (82 FR 27705), the Secretary approved the rechartering of the Panel on April 25, 2017 for a 2-year period effective through April 25, 2019.

DATES: The agency will receive nominations on a continuous basis.

ADDRESSES: All nominations should be sent electronically to the following email address: *CDLTPanel@cms.hhs.gov.*

Web site: For additional information on the Panel and updates to the Panel's activities, we refer readers to our Web site at *http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

FOR FURTHER INFORMATION CONTACT: Persons wishing to nominate individuals to serve on the Panel or to

obtain further information may submit an email to the following email address: *CDLTPanel@cms.hhs.gov*.

News Media: Representatives should contact the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION:

I. Background

The Advisory Panel on Clinical Diagnostic Laboratory Tests is authorized by section 1834A(f)(1) of the Social Security Act (the Act) (42 U.S.C. 1395m–1), as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93, enacted on April 1, 2014) (PAMA). The Panel is subject to the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory panels.

Section 1834A(f)(1) of the Act directs the Secretary of the Department of Health and Human Services (the Secretary) to consult with an expert outside advisory panel established by the Secretary, composed of an appropriate selection of individuals with expertise in issues related to clinical diagnostic laboratory tests. Such individuals may include molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics.

The Panel will provide input and recommendations to the Secretary and the Administrator of CMS, on the following:

- The establishment of payment rates under section 1834A of the Act for new clinical diagnostic laboratory tests, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test; and
- The factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests.
- Other aspects of the new payment system under section 1834A of the Act.

A notice announcing the establishment of the Panel and soliciting nominations for members was published in the October 27, 2014 **Federal Register** (79 FR 63919 through 63920). In the August 7, 2015 **Federal Register** (80 FR 47491), we announced membership appointments to the Panel along with the first public meeting date for the Panel, which was held on August 26, 2015. Subsequent meetings of the Panel were also announced in the **Federal Register**. As previously noted, the Secretary approved the rechartering of the Panel on April 25, 2017, for a 2-year period effective through April 25, 2019.

The Panel charter provides that Panel meetings will be held up to 4 times annually and the Panel Chair will serve for a period of 3 years, which may be extended at the discretion of the Administrator or his or her duly appointed designee. Additionally, the Panel Chair facilitates the meeting and the Designated Federal Official (DFO) or DFO's designee must be present at all meetings.

II. Request for Nominations; Criteria for Nominees

We are requesting nominations for members to serve on the Panel. The Panel shall consist of up to 15 individuals with expertise in issues related to clinical diagnostic laboratory tests, which may include molecular pathologists, laboratory researchers, and individuals with expertise in laboratory science or health economics, with regard to issues related to the development, validation, performance, safety, and application of such tests.

Panel members serve on a voluntary basis, without compensation, according to an advance written agreement; however, for the meetings, we reimburse travel, meals, lodging, and related expenses in accordance with standard Government travel regulations.

Nominees must demonstrate personal experience with clinical diagnostic laboratory tests and services through a past or present history of direct employment with an organization that furnishes clinical diagnostic laboratory tests. (For purposes of this Panel, consultants or independent contractors shall not be representatives of clinical laboratories.)

We have special interest in ensuring, while taking into account the nominee pool, that the Panel membership is balanced under the FACA guidelines; therefore nominees will be evaluated based on expertise and factors needed to keep the balance of the Panel. These factors include, but are not limited to, geographic locations within the United States or territories; race; ethnicity; sex; disability; points of view; and area of expertise (for example, medical, scientific, financial, technical, administrative). Additionally, all nominees must have at least 5 years of experience with clinical diagnostic laboratory tests or genetic testing.

Based upon either self-nominations or nominations submitted by interested organizations, the Secretary, the CMS Administrator, or the Secretary's or CMS Administrator's designee, appoints new members to the Panel from among candidates determined to have the required expertise. Nominations will be considered as vacancies occur on the Panel. Nominations should be updated and resubmitted every 3 years to continue to be considered for Panel vacancies. New appointments are made in manner that ensures a balanced membership under FACA guidelines. Our appointment schedule will assure that we have the full complement of members for each Panel meeting.

It is not necessary for a nominee to possess expertise in all of the areas listed, but each must have a minimum of 5 years of experience and currently have full-time employment in his or her area of expertise. Generally, members of the Panel serve overlapping terms up to 3 years, based on the needs of the Panel and contingent upon the rechartering of the Panel. A member may serve after the expiration of his or her term until a successor has been sworn in. Any member appointed to fill a vacancy for an unexpired term will be appointed for the remainder of that term.

Any interested person or organization may nominate one or more qualified individuals. Self-nominations will also be accepted. Each nomination must include the following:

- Letter of Nomination stating the reason why the nominee should be considered.
- Curriculum vitae or resume of the nominee that includes the following:

++ Email address where the nominee can be contacted.

++ Title and current position.

++ Professional affiliation.

++ Home and business address.

++ Home and business telephone and or fax numbers.

++ List of areas of expertise.

- Written and signed statement from the nominee indicating that the nominee is willing to serve on the Panel under the conditions described in this notice and further specified in the Charter.
- Brief (1 page; double-spaced) biographical summary of the nominee's experience.

The top nominees will be contacted for interest and availability. Phone interviews of nominees may also be requested after review of the nominations. The Secretary, the CMS Administrator, or the Secretary's or CMS Administrator's designee will make the final decision about who will serve on the committee. Formal letters of invitation to serve on the Panel will be extended by the CMS Administrator.

To permit an evaluation of possible sources of conflict of interest, potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts.

III. Copies of the Charter

To obtain a copy of the Panel's Charter, we refer readers to our Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

IV. 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 22, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2017–20923 Filed 9–28–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4181–N]

Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2018

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, 2018. The calendar year 2018 AIC threshold amounts are $160 for ALJ hearings and $1,600 for judicial review.

DATES: This notice is applicable on January 1, 2018.

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) hearings 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 pursuant to 42 CFR 417.600(b). The Medicare Part C appeals rules also apply to health care prepayment plan appeals pursuant to 42 CFR 417.840.

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)