written summary of their comments and conclusions to *HCPCS_Level_II_Code_Applications@cms.hhs.gov* or to CMS' HCPCS staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

C. Additional Virtual Meeting/Registration Information

Prior to registering to attend a virtual public meeting, all participants are advised to review the public meeting agendas at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings* which identify our preliminary coding recommendations, and the dates each item will be discussed. All participants and other stakeholders are encouraged to begin in early October to regularly check CMS' official HCPCS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings* for publication of draft agendas, including a summary of each request and our preliminary recommendations.

All participants and other interested stakeholders are also encouraged to regularly check CMS' official HCPCS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings* for additional details regarding the public meeting process for new public requests for revisions to the HCPCS, including information on how to join the meeting remotely, and guidelines for an effective presentation. In particular, please review the document titled ''Guidelines for Participation in Public Meetings for New Public Requests for Revisions to the Healthcare Common Procedure Coding System (HCPCS)''. Individuals who intend to provide a presentation at a virtual public meeting are encouraged to familiarize themselves with the HCPCS website and the valuable information it provides to prospective registrants. The HCPCS website also contains a document titled ''Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures,'' which is a description of the HCPCS coding process, including a detailed explanation of the procedures CMS uses to make coding determinations for the items and services that are coded in the HCPCS.

The HCPCS website also contains a document titled ''HCPCS Decision Tree & Definitions,'' which illustrates, in flow diagram format, HCPCS coding standards as described in our Coding Procedures document.

III. Written Comments From Meeting Attendees

As part of CMS' response to the COVID–19 public health emergency, there is a limited presence at the CMS headquarters for receiving paper packages. Therefore, written comments from the general public and meeting registrants will only be accepted when emailed to *HCPCS_Level_II_Code_Applications@cms.hhs.gov* or to staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice any time up to 5:00 p.m. on the date of the virtual public meeting at which a request is discussed. Due to the close timing of the virtual public meetings, subsequent workgroup review, and final decisions, we are able to consider only those written submissions received by the close of business (5:00 p.m.) on the date of the virtual public meeting at which the request is discussed.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the Federal Register.

Dated: September 22, 2020.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid.

[FR Doc. 2020–21257 Filed 9–25–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3396–FN]

Medicare Program; Approval of Application by National Association of Boards of Pharmacy for Initial CMS-Approval of Its Home Infusion Therapy Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the National Association of Boards of Pharmacy for initial recognition as a national accrediting organization for home infusion therapy suppliers that wish to participate in the Medicare program. A home infusion therapy supplier that participates must meet the Medicare conditions for coverage.

DATES: The approval announced in this final notice is effective September 26, 2020 through September 26, 2024.

FOR FURTHER INFORMATION CONTACT: Christina Mister-Ward, (410) 786–2441. Shannon Freeland, (410) 786–4348. Lillian Williams, (410) 786–8636.

SUPPLEMENTARY INFORMATION:

I. Background

Home Infusion therapy (HIT) is a treatment option for Medicare beneficiaries with a wide range of acute and chronic conditions. Section 5012 of the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016) added sections 1861(iii) and 1834(u) to the Social Security Act (the Act), establishing a new Medicare benefit for HIT services. Section 1861(iii)(1) of the Act defines HIT as professional services, including nursing services; training and education not otherwise covered under the Durable Medical Equipment (DME) benefit; remote monitoring; and other monitoring services. Home infusion therapy must be furnished by a qualified HIT supplier and furnished in the individual's home. The individual must:

- Be under the care of an applicable provider (that is, physician, nurse practitioner, or physician assistant); and
- Have a plan of care established and periodically reviewed by a physician in coordination with the furnishing of home infusion drugs under Part B, that prescribes the type, amount, and duration of infusion therapy services that are to be furnished.

Section 1861(iii)(3)(D)(i)(III) of the Act requires that a qualified HIT supplier be accredited by an accrediting organization (AO) designated by the Secretary in accordance with section 1834(u)(5) of the Act. Section 1834(u)(5)(A) of the Act identifies factors for designating AOs and in reviewing and modifying the list of designated AOs. These statutory factors are as follows:

- The ability of the organization to conduct timely reviews of accreditation applications.
- The ability of the organization take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D) of the Act).
- Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.
- Such other factors as the Secretary determines appropriate.

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit HIT suppliers furnishing HIT not later than January 1, 2021. Section 1861(iii)(3)(D) of the Act defines

''qualified home infusion therapy suppliers'' as being accredited by a CMS-approved AO.

In the March 1, 2019 **Federal Register**, we published a solicitation notice entitled, ''Medicare Program; Solicitation of Independent Accrediting Organizations To Participate in the Home Infusion Therapy Supplier Accreditation Program'' (84 FR 7057). This notice informed national AOs that accredit HIT suppliers of an opportunity to submit applications to participate in the HIT supplier accreditation program. Complete applications will be considered for the January 1, 2021 designation deadline if received by February 1, 2020.

Regulations for the approval and oversight of AOs for HIT organizations are located at 42 CFR part 488, subpart L. The requirements for HIT suppliers are located at 42 CFR part 486, subpart I.

II. Approval of Accreditation Organizations

Section 1834(u)(5) of the Act and the regulations at § 488.1010 require that our findings concerning review and approval of a national AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data.

Section 488.1020(a) requires that we publish, after receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. In accordance with § 488.1010(d), we have 210 days from the receipt of a complete application to approve or deny the application.

III. Provisions of the Proposed Notice

In the April 28, 2020 **Federal Register** (85 FR 23519), we published a proposed notice announcing National Association of Boards of Pharmacy's (NABP's) request for initial approval of its Medicare HIT accreditation program. In that proposed notice, we detailed our evaluation criteria. Under section 1834(u)(5) the Act and in our regulations at § 488.1010, we conducted a review of NABP's Medicare HIT accreditation application in accordance with the criteria specified by our regulations, which included, but are not limited to the following:

- An administrative review of NABP's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its home infusion therapy surveyors; (4) ability to investigate and respond appropriately to complaints against accredited home infusion therapies; and (5) survey review and decision-making process for accreditation.
- The ability for NABP to conduct timely review of accreditation applications.
- The ability of NABP to take into account the capacities of suppliers located in a rural area.
- The comparison of NABP's Medicare home infusion therapy accreditation program standards to our current Medicare home infusion therapy conditions for coverage (CfCs).
- NABP's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and NABP's ability to provide continuing surveyor training.

++ NABP's processes, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited home infusion therapies.

++ Evaluate NABP's procedures for monitoring home infusion therapies it has found to be out of compliance with NABP's program requirements.

++ Assess NABP's ability to report deficiencies to the surveyed home infusion therapy and respond to the home infusion therapy's plan of correction in a timely manner.

++ Establish NABP's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of NABP's staff and other resources.

++ Confirm NABP's ability to provide adequate funding for performing required surveys.

++ Confirm NABP's policies with respect to surveys being unannounced.

++ Review NABP's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ Obtain NABP's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

The April 28, 2020 proposed notice also solicited public comments regarding whether NABP's requirements met or exceeded the Medicare CfCs for home infusion therapy. No comments were received in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between NABP's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared NABP's HIT accreditation requirements and survey process with the Medicare CfCs of part 486, subpart I and the survey and certification process requirements of part 488, subpart L. Our review and evaluation of NABP's HIT application, which was conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, NABP has completed revising its standards and certification processes in order to meet the condition at:

- § 486.520, to include the term ''qualified'' to meet the requirement for home infusion suppliers.
- § 486.525(a), to include the language ''qualified'' to meet the requirement for home infusion suppliers.
- § 486.525(b), to revise standard language removing the word ''shall'' from the home infusion standards.
- § 488.1010(a)(5), to provide a detailed crosswalk identifying the exact language of the organization's comparable accreditation requirements and standards.
- § 488.1010(a)(6)(i), to revise survey procedures for information gathering and investigation.
- § 488.1010(a)(6)(v), to revise procedures and timelines for notifying a surveyed or audited home infusion therapy supplier of non-compliance with the home infusion therapy accreditation program's standards.
- § 488.1010(a)(6)(vi), to revise NABP's procedures and timelines for monitoring the home infusion therapy supplier's correction of identified non-compliance with the accreditation program's standards.
- § 488.1010(6)(ix), to revise procedures for immediate jeopardy.
- § 489.13, to reflect our policies regarding when the effective period of an accreditation begins and ends.

B. Term of Approval

As authorized under § 488.1040(a), we reserve the right to conduct onsite observations of accrediting organization operations at any time as part of the

ongoing review and continuing oversight of an accrediting organization's performance. Based on the review and observations described in section III. of this final notice, we have determined that NABP's requirements for HIT meet or exceed our requirements. Therefore, we approve NABP as a national accreditation organization for HITs that request participation in the Medicare program, effective September 26, 2020 through September 26, 2024.

V. 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. Chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: September 22, 2020.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid.

[FR Doc. 2020–21261 Filed 9–25–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4191–N]

Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2021

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, 2021. The calendar year 2021 AIC threshold amounts are $180 for ALJ hearings and $1,760 for judicial review.

DATES: This annual adjustment takes effect on January 1, 2021.

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. Beginning in January 2005, the AIC threshold amounts are to be adjusted 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 the July 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 at § 405.1006(b)(2) require the Secretary of Health and Human Services (the Secretary) to publish changes to the AIC threshold amounts in the **Federal Register**. 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, sections 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 in accordance with 42 CFR 417.600(b). The Medicare Part C appeals rules also apply to health care prepayment plan appeals in accordance with 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