

## Information Collection

1. *Type of Information Collection Request*: Extension; *Title of Information Collection*: Health Care Reform Insurance Web Portal; *Use*: Upon collection of the data collection requirements from individual States, State health benefits high risk pools, and insurance issuers (hereon referred to as issuers), this information is processed by contractors for display on the *HealthCare.gov* website. The information that is provided helps the general public make educated decisions about their choice in organizations providing private health care insurance. Information collected quarterly from insurance issuers is used to populate the Plan Finder application to show individuals their options, to provide some profile information, and to coordinate the data collection with Oversight collections to reduce the burden on issuers and the Federal Government. Collecting information consistent with the SBC standards allows consumers to access this information in a consistent manner. *Form Number*: CMS-10320 (OMB control number 0938-1086); *Frequency*: Occasionally; *Affected Public*: State, Local, and Tribal Governments; *Number of Respondents*: 700; *Number of Responses*: 700; *Total Annual Hours*: 78,675. For questions regarding this collection contact Kimberlee Heckstall at 410-786-1647.

Dated: September 23, 2020.

**William N. Parham, III,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1740-N]

### Medicare Program; Virtual Public Meetings in October 2020 for New Public Requests for Revisions to the Healthcare Common Procedure Coding System (HCPCS) Coding for Non-Drug and Non-Biological Items and Services

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

**ACTION**: Notice.

**SUMMARY**: This notice announces the dates and time of virtual Healthcare Common Procedure Coding System (HCPCS) public meetings to be held in

October 2020 to discuss our preliminary coding recommendations for new public requests for revisions to the HCPCS Level II code set Durable Medical Equipment (DME) and Accessories, Orthotics and Prosthetics (O&P), Supplies and for non-drug and non-biological items and services.

**DATES**: *Virtual Meeting Dates*: Tuesday, October 27, 2020, 9 a.m. to 5 p.m., eastern daylight time (e.d.t.), and Wednesday, October 28, 2020, 9 a.m. to 5 p.m., e.d.t.

*Deadline for Primary Speaker Registration and Presentation Materials*: The deadline for registering to be a primary speaker, and submitting materials and writings that will be used in support of an oral presentation is 5 p.m., e.d.t., Wednesday, October 14, 2020.

*Deadline for 5-Minute Speakers Registration*: The deadline for registering to be a 5-Minute speaker is 5 p.m., e.d.t., Wednesday, October 14, 2020.

*Deadline for Registration for all Other Attendees*: All individuals who plan to attend the virtual public meetings to listen, but are not registering as a primary or 5-minute speaker, may simply join the virtual meeting on the date that they plan to attend, using the meeting attendee link specified for that meeting date.

*Deadline for Requesting Special Accommodations*: Individuals who plan to participate in the virtual public meetings and require special assistance must request these services by 5 p.m., e.d.t., Wednesday, October 14, 2020.

*Deadline for Submission of Written Comments*: Written comments and other documentation in response to a preliminary coding recommendation that are received by no later than 5 p.m. on the date of the virtual public meeting at which the code request is scheduled for discussion will be considered in formulating a final coding decision.

**ADDRESSES**: *Virtual Meeting Location*: The October 27 and October 28, 2020 HCPCS Public meetings will be held virtually via WebEx only. Detailed information pertaining to registering to participate via WebEx, including dial-in information for Primary Speakers, 5-minute speakers, and all other attendees, will be provided in CMS' "Guidelines for Participation in HCPCS Public Meetings", posted *approximately 2 weeks prior to the HCPCS Public Meeting* on CMS' HCPCS website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings>.

*Written Comments*: As part of CMS' response to the COVID-19 public health

emergency, 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 before 5 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 CMS consideration, and final decisions, we are able to consider only those written comments received by the close of business (5 p.m.) on the date of the virtual public meeting at which the request is discussed.

#### FOR FURTHER INFORMATION CONTACT:

Kimberlee Combs, (410) 786-6707, or *Kimberlee.Combs@cms.hhs.gov*;  
Irina Akelaitis, (410) 786-4602, or *Irina.Akelaitis@cms.hhs.gov*;  
Felicia Kyeremeh, (410) 786-1898, or *Felicia.Kyeremeh@cms.hhs.gov*;  
Sundus Ashar, (410) 786-0750, or *Sundus.Ashar1@cms.hhs.gov*;  
William Walker, (410) 786-5023, or *William.Walker@cms.hhs.gov*; or  
Constantine Markos, (410) 786-0911, *Constantine.Markos@cms.hhs.gov*

#### SUPPLEMENTARY INFORMATION:

*Guidelines for Presentation Materials*: There is a 10-page submission limit for any presentation materials. All registered primary speakers will be emailed a link for their individual use to join the meeting, in advance of the virtual meeting. Detailed information pertaining to registering to participate via WebEx, including dial-in information for Primary Speakers, 5-minute speakers, and all other attendees, will be provided in CMS' "Guidelines for Participation in HCPCS Public Meetings", as posted on CMS' HCPCS website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings> approximately two weeks prior to the HCPCS Public Meeting. We encourage all speakers to familiarize themselves with, and follow, protocol for participation as a speaker in CMS' HCPCS Public meetings as detailed in these guidelines.

*Guidelines for 5-minute Speakers*: All 5-Minute speakers will be emailed a link for their individual use to join the meeting, in advance of the virtual meeting. Detailed information pertaining to registering to participate via WebEx, including dial-in information for Primary Speakers, 5-minute speakers, and all other attendees, will be provided in CMS' "Guidelines for Participation in HCPCS Public Meetings", as posted on CMS' HCPCS website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings> approximately 2

weeks prior to the HCPCS Public Meeting. We encourage all speakers to familiarize themselves with, and follow, protocol for participation as a speaker in CMS' HCPCS Public meetings as detailed in these guidelines.

*Guidelines for All Other Attendees:* A "raise your hand" feature will be available to ask questions. A meeting attendee link for each public meeting date will be posted approximately 2 weeks in advance of the public meetings on CMS' HCPCS website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo>.

## I. Background

On December 21, 2000, the Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554). Section 531(b) of BIPA mandated that we establish procedures that permit public consultation for coding and payment determinations for new durable medical equipment (DME) under Medicare Part B of title XVIII of the Social Security Act (the Act). In the November 23, 2001 **Federal Register** (66 FR 58743), we published a notice providing information regarding the establishment of the public meeting process for DME. The procedures and public meetings announced in that notice for new DME were in response to the mandate of section 531(b) of BIPA.

As of 2020, we implemented changes to our HCPCS coding procedures that enable quarterly coding cycles for drugs and biological products, and bi-annual coding cycles for non-drug and non-biological items and services. To achieve the time savings necessary to implement coding for the vast majority of drugs and biological products on a quarterly cycle, as a general rule, we will not be conducting public meetings for coding decisions on drugs and biological products. For the 2020 coding cycles, for drug and biological code applicants who are dissatisfied with CMS' coding decision in a quarterly coding cycle, we provide them an opportunity to resubmit their application in the next or subsequent quarterly cycle.

## II. Virtual Meeting Registration

Due to the "Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak"<sup>1</sup> issued on March 13, 2020, there will not be an in-person meeting. The October 27 and October 28, 2020 HCPCS Public

meetings will be virtual and available for remote audio attendance and participation only via WebEx.

### A. Required Information for Registration

The following information must be provided when registering on-line to attend:

- Name.
- Company name and address.
- Direct-dial telephone.
- Email address.
- Any special accommodation requests.

A CMS staff member will confirm your registration by email.

### B. Registration Process

#### 1. Primary Speakers

Individuals must also indicate whether they are the "primary speaker" for an agenda item. Primary speakers must be designated by the entity that submitted the HCPCS coding request. When registering, primary speakers must provide a brief written statement regarding the nature of the information they intend to provide and advise CMS' HCPCS staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, regarding needs for audio/visual support. Speaker PowerPoint files are tested and arranged in speaker sequence well in advance of the meeting. We will accept emailed PowerPoint files that are received by the deadline for submissions of presentation materials as specified in the **DATES** section of this notice. We are also exploring mechanisms to successfully incorporate video clips in Primary Speaker presentation materials for our remote public meetings, and further information on that topic is forthcoming and will be published on CMS HCPCS website in advance of the October public meetings. Materials will only be accepted when emailed to [HCPCS\\_Level\\_II\\_Code\\_Applications@cms.hhs.gov](mailto:HCPCS_Level_II_Code_Applications@cms.hhs.gov) or to staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Due to the timeframe for planning and coordination of the HCPCS Public Meetings under CMS' shorter and more frequent coding cycles that started in 2020, late submissions and updates of materials after our deadline cannot be accommodated.

All presentation materials and additional supporting documentation should not exceed 10 pages (each side of a page counts as 1 page). An exception will be made to the 10-page limit only for relevant studies newly published between the application deadline and the virtual public meeting date, in which case, we request a copy of the complete publication be emailed

as soon as possible to [HCPCS\\_Level\\_II\\_Code\\_Applications@cms.hhs.gov](mailto:HCPCS_Level_II_Code_Applications@cms.hhs.gov) or to staff listed in the **FOR FURTHER**

**INFORMATION CONTACT** section of this notice. This exception applies only to the page limit and not the submission deadline.

Fifteen minutes is the total time interval for the presentation. In establishing the public meeting agenda, we may group multiple, related requests under the same agenda item. In that case, we will decide whether additional time will be allotted, and may opt to increase the amount of time allotted to the primary speaker.

Every primary speaker must declare at the beginning of the speaker's presentation at the meeting, as well as in the speaker's written summary, whether the speaker has any financial involvement with the manufacturers or competitors of any items being discussed; this includes any payment, salary, remuneration, or benefit provided to that speaker by the manufacturer or the manufacturer's representatives.

On the day of the virtual meeting, before the end of the meeting, all primary speakers must email a brief written summary of their comments and conclusions to CMS' HCPCS staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

#### 2. "5-Minute Speakers"

The deadline for registering to be a 5-Minute speaker is noted in the **DATES** section of this notice. Individuals must provide their name, company name and address, and contact information as specified in the instructions for remote participation, and identify the specific agenda item that they will address. Based on the number of items on the agenda and the progress of the meeting, a determination will be made by the meeting coordinator and the meeting moderator regarding how many "5-minute speakers" can be accommodated and whether the 5-minute allocation would be reduced to accommodate the number of speakers.

Every 5-minute speaker must declare at the beginning of the speaker's presentation at the meeting, as well as in the speaker's written summary, whether the speaker has any financial involvement with the manufacturers or competitors of any items being discussed; this includes any payment, salary, remuneration, or benefit provided to that speaker by the manufacturer or the manufacturer's representatives.

On the day of the virtual meeting, before the end of the meeting, all 5-minute speakers must email a brief

<sup>1</sup> <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

written summary of their comments and conclusions to [HCPCS\\_Level\\_II\\_Code\\_Applications@cms.hhs.gov](mailto: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](mailto: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.*

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**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