

Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, MS-H24-8, Atlanta, Georgia 30329-4027; Telephone: (404) 639-8367; Email: ACIP@cdc.gov.

SUPPLEMENTARY INFORMATION: In accordance with 41 CFR 102-3.150(b), less than 15 calendar days' notice is being given for this meeting due to the exceptional circumstances of the COVID-19 pandemic and rapidly evolving COVID-19 vaccine development and regulatory processes. The Secretary of Health and Human Services has determined that COVID-19 is a Public Health Emergency. A notice of this ACIP meeting has also been posted on CDC's ACIP website at: <http://www.cdc.gov/vaccines/acip/index.html>. In addition, CDC has sent notice of this ACIP meeting by email to those who subscribe to receive email updates about ACIP.

Purpose: The committee is charged with advising the Director, CDC, on the use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the Director of the Centers for Disease Control and Prevention and appear on CDC immunization schedules must be covered by applicable health plans.

Matters To Be Considered: The agenda will include discussions on COVID-19 vaccine safety and booster doses. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit <https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html>.

Meeting Information: The meeting will be webcast live via the World Wide Web; for more information on ACIP please visit the ACIP website: <http://www.cdc.gov/vaccines/acip/index.html>.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be

posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: Written comments must be received on or before June 18, 2021.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the June 18, 2021, ACIP meeting must submit a request at <http://www.cdc.gov/vaccines/acip/meetings/> no later than 11:59 p.m., EDT, June 16, 2021, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by 12:00 p.m., EDT, June 17, 2021. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

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Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1757-N]

Medicare Program; Virtual Public Meetings in July 2021 for New Revisions to the Healthcare Common Procedure Coding System (HCPCS) Code Set

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces the dates and times of virtual Healthcare Common Procedure Coding System (HCPCS) public meetings to be held in July 2021 to discuss our preliminary coding recommendations for new revisions to the HCPCS Level II code set.

DATES: Virtual Meeting Dates: Wednesday, July 7, 2021, 9 a.m. to 5 p.m., eastern daylight time (e.d.t.), Thursday, July 8, 2021, 9 a.m. to 5 p.m., e.d.t., and Friday, July 9, 2021, 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 that will be used in support of an oral presentation is 5 p.m., e.d.t., Friday, June 25, 2021.

Deadline for 5-Minute Speakers Registration: The deadline for registering to be a 5-Minute speaker is 5 p.m., e.d.t., Friday, June 25, 2021.

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 link specified for that meeting date. A "raise your hand" feature will be available to ask questions. A meeting link for each public meeting date will be posted in advance of the public meetings on CMS' HCPCS website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo>.

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., Friday, June 25, 2021.

Deadline for Submission of Written Comments: To be considered in formulating a final coding decision, written comments and other documentation must be received by 5 p.m., e.d.t., on the date of the virtual public meeting at which the applicable code request is scheduled for discussion.

ADDRESSES:

Virtual Meeting Location: The July 7 through 9, 2021 HCPCS public meetings will be held virtually via Zoom only. Detailed information pertaining to registering to participate via Zoom, including dial-in information for primary speakers, 5-minute speakers, and all other attendees, will be provided in a document posted 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 (PHE), written comments from the general public and meeting registrants will only be accepted when emailed to HCPCS_Level_II_Code_Applications@cms.hhs.gov before 5 p.m., e.d.t., on the date of the virtual public meeting at which a request is discussed.

FOR FURTHER INFORMATION CONTACT: 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; Constantine Markos, (410) 786-0911, Constantine.Markos@cms.hhs.gov; or HCPCS_Level_II_Code_Applications@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Guidelines for Presentation Materials and Primary Speakers: There is a 10-page submission limit for any presentation materials. All registered primary speakers will be emailed a participant ID for their individual use to join the meeting, in advance of the virtual meeting. Detailed information pertaining to registering to participate via Zoom, including dial-in information for primary speakers, will be provided in a document posted on CMS' HCPCS website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings> prior to the HCPCS public meeting. We encourage

all speakers to follow the protocols for participation as a speaker in CMS' HCPCS public meetings as detailed in this document.

Guidelines for 5-Minute Speakers: All registered 5-minute speakers will be emailed a participant ID for their individual use to join the meeting, in advance of the virtual meeting. Detailed information pertaining to registering to participate via Zoom, including dial-in information for 5-minute speakers, will be provided in a document posted on CMS' HCPCS website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings> prior to the HCPCS public meeting. We encourage all speakers to follow the protocols for participation as a speaker in CMS' HCPCS public meetings as detailed in this document.

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

I. Background

On December 21, 2000, 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 matter, we will not be conducting public meetings for coding decisions on drugs and biological products. For the 2021 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 a subsequent quarterly cycle.

II. Virtual Meeting Registration

Due to the "Notice of the Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID-19) Pandemic"¹ issued on February 24, 2021 there will not be an in-person meeting. The July 7 through July 9, 2021 HCPCS public meetings will be virtual and available for remote audio attendance and participation only via Zoom.

A. Required Information for Registration

The following information must be provided when registering online 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 regarding any needs for audio/visual support and email it to HCPCS_Level_II_Code_Applications@cms.hhs.gov. 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. Materials will only be accepted when emailed to HCPCS_Level_II_Code_Applications@cms.hhs.gov. 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

¹ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/02/24/notice-on-the-continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic/>.

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. 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 their presentation at the meeting, as well as in their written summary, whether they have 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 HCPCS_Level_II_Code_Applications@cms.hhs.gov.

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 their presentation at the meeting, as well as in their written summary, whether they have 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 written summary of their comments and

conclusions to HCPCS_Level_II_Code_Applications@cms.hhs.gov.

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 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.

CMS' official HCPCS website will include additional details regarding the public meeting process for new revisions to the HCPCS code set, including information on how to join the meeting remotely, and guidelines for an effective presentation. 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.

III. Written Comments From Meeting Attendees

As part of CMS' response to the COVID-19 PHE, written comments from the general public and meeting registrants will *only* be accepted when emailed to HCPCS_Level_II_Code_Applications@cms.hhs.gov before 5 p.m., e.d.t., on the date of the virtual public meeting at which a request is discussed.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, 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: June 9, 2021.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Tribal Maternal, Infant, and Early Childhood Home Visiting Program: Guidance for Submitting an Annual Report to the Secretary (OMB #0970-0409)

AGENCY: Office of Child Care, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), Office of Child Care (OCC) is requesting a 3-year extension of the Tribal Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program: Guidance for Submitting an Annual Report to the Secretary (OMB #0970-0409; expiration 9/30/2021). There are minor updates to the annual guidance which reflects a change in timing for the due date of the final report.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing infocollection@acf.hhs.gov. Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Section 511(e)(8)(A) of Title V of the Social Security Act requires that grantees under the MIECHV program for states and jurisdictions submit an annual report to the Secretary of Health and Human Services regarding the program and activities carried out under the program, including such data and information as the Secretary shall require. Section 511(h)(2)(A) further