number. Each participant will receive up to two survey reminders starting one week after the initial survey link is sent, for two consecutive weeks. There are minor differences in survey content for the control and intervention groups.

Each participant will create a profile in the database upon enrollment. This database will collect initial demographic and contact information, informed consent signatures, and information about the participant's navigation pattern through Crush. Any information entered directly into Crush interactive features will not be stored in the system. The database only collects web analytics data about page visits and duration of each visit by User Identification (ID) and Internet Protocol (IP) address. Web analytics will only be collected from participants navigating Crush and only when they are logged in as users. Web analytics are generated for any Web site and are a standard evaluation mechanism for assessing the traffic patterns on Web pages. This technology permits development of an objective and quantifiable measure that tracks and records participants' exposure to Crush. This study component does not entail any response burden to participants.

Findings will be used to inform the development and delivery of effective health communications.

OMB approval is requested for one year. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 802.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Avg. burden per response (in hrs.) |
|---|---|---|---|---|
| Girls 14–18 years old | Screener Questions | 3,000 | 1 | 1/60 |
| | Enrollment Questions | 1,200 | 1 | 5/60 |
| Intervention Group | Baseline Survey | 600 | 1 | 15/60 |
| | 3-Month Survey | 480 | 1 | 10/60 |
| | 6-Month Survey | 384 | 1 | 15/60 |
| Control Group | Baseline Survey | 600 | 1 | 15/60 |
| | 3-Month Survey | 480 | 1 | 10/60 |
| | 6-Month Survey | 384 | 1 | 15/60 |

**Leroy A. Richardson,**

*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2016–03687 Filed 2–22–16; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–1637–N]**

### Medicare Program; Public Meetings in Calendar Year 2016 for All New Public Requests for Revisions to the Healthcare Common Procedure Coding System (HCPCS) Coding and Payment Determinations

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the dates, time, and location of the Healthcare Common Procedure Coding System (HCPCS) public meetings to be held in calendar year 2016 to discuss our preliminary coding and payment determinations for all new public requests for revisions to the HCPCS. These meetings provide a forum for interested parties to make oral presentations or to submit written comments in response to preliminary coding and payment determinations. The discussion will be focused on responses to our specific preliminary recommendations and will include all items on the public meeting agenda. As indicated in this notice, we are reorganizing public meeting content under two main headings: (1) Drugs/Biologics, Radiopharmaceuticals/Radiologic Imaging Agents, and (2) Durable Medical Equipment (DME) and Accessories; Orthotics and Prosthetics (O & P); Supplies and Other.

**DATES:** *Meeting Dates:* The following are the 2016 HCPCS public meeting dates:

1. Tuesday, May 17, 2016, 9:00 a.m. to 5:00 p.m., eastern daylight time (e.d.t.) (Drugs/Biologicals, Radiopharmaceuticals/Radiologic Imaging Agents).

2. Wednesday, May 18, 2016, 9:00 a.m. to 5:00 p.m., e.d.t. (Drugs/Biologicals, Radiopharmaceuticals/Radiologic Imaging Agents).

3. Thursday, May 19, 2016, 9:00 a.m. to 5:00 p.m., e.d.t. (Drugs/Biologicals, Radiopharmaceuticals/Radiologic Imaging Agents).

4. Wednesday, June 1, 2016, 9:00 a.m. to 5:00 p.m., e.d.t. (Durable Medical Equipment (DME) and Accessories; Orthotics and Prosthetics (O & P); Supplies and Other).

5. Thursday, June 2, 2016, 9:00 a.m. to 5:00 p.m., e.d.t. (Durable Medical Equipment (DME) and Accessories; Orthotics and Prosthetics (O & P); Supplies and Other).

*Deadlines 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 are as follows:

- May 3, 2016 for the May 17, 2016, May 18, 2016 and May 19, 2016 public meetings.
- May 18, 2016 for the June 1, 2016 and June 2, 2016 public meetings.

*Registration Deadline for Attendees that are Foreign Nationals:* All Foreign National visitors must present a valid passport as proof of identification. Attendees that are foreign nationals (as described in section IV. of this notice) are required to identify themselves as such, and provide the necessary information for security clearance (as described in section IV. of this notice) to the public meeting coordinator at least 21 business days in advance of the date of the public meeting the individual plans to attend. Therefore, the registration deadlines for attendees that are foreign nationals are as follows:

- April 28, 2016 for the May 17, 2016, May 18, 2016 and May 19, 2016 public meetings.
- May 12, 2016 for the June 1, 2016 and June 2, 2016 public meetings.

*Registration Deadlines for all Other Attendees:* All individuals who are not foreign nationals who plan to enter the building to attend the public meeting must register for each date that they plan on attending. The registration

deadlines are different for each meeting. Registration deadlines are as follows:

- May 10, 2016 for the May 17, 2016, May 18, 2016 and May 19, 2016 public meetings.
- May 24, 2016 for the June 1, 2016 and June 2, 2016 public meeting dates.

*Deadlines for Requesting Special Accommodations:* Individuals who plan to attend the public meetings and require sign-language interpretation or other special assistance must request these services at least two weeks in advance of the meeting date, by the following deadlines:

- May 3, 2016 for the May 17, 2016, May 18, 2016 and May 19, 2016 public meetings.
- May 18, 2016 for the June 1, 2016 and June 2, 2016 public meetings.

Requests for Special Accommodation may be made within the on-line registration located at *www.cms.hhs.gov/medhcpcsgeninfo* or by contacting Judi Wallace at (410) 786–3197 or *JudiWallace@cms.hhs.gov* or Nathan Helman at (410) 786–4602 or *NathanHelman@cms.hhs.gov*.

When a request for Special Accommodations is made separate from the on-line registration, it is also necessary to complete the online registration to gain access to the facility.

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

**ADDRESSES:**

*Meeting Location:* The public meetings will be held in the main auditorium of the central building of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

*Submission of Written Comments:* Written comments may either be emailed to *JudiWallace@cms.hhs.gov* or *NathanHelman@cms.hhs.gov* or sent via regular mail to Judi Wallace or Nathan Helman, HCPCS Public Meeting Coordinators, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5–09–14, Baltimore, MD 21244–1850.

**FOR FURTHER INFORMATION CONTACT:** Judi Wallace at (410)786–3197 or *JudiWallace@cms.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

## 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 this notice for new DME are in response to the mandate of section 531(b) of BIPA. As part of HCPCS reform, we expanded the public meeting forum to include all public requests as of the 2005–2006 coding cycle (70 FR 15340, March 25, 2005).

It is our intent to distribute any materials submitted to us to the HCPCS workgroup members for their consideration. CMS and the HCPCS workgroup members require sufficient preparation time to review all relevant materials. Therefore, we are implementing a 10-page submission limit and firm deadlines for receipt of any presentation materials a meeting speaker wishes us to consider. For this reason, our HCPCS Public Meeting Coordinator will only accept and review presentation materials received by the deadline for each public meeting, as specified in the **DATES** section of this notice.

## II. Meeting Registration

### *A. Required Information for Registration*

The following information must be provided when registering:

- Name.
- Company name and address.
- Direct-dial telephone and fax numbers.
- Email address.
- Special needs information.

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 the HCPCS Public Meeting Coordinator regarding needs for audio/visual support. To avoid disruption of the meeting and ensure compatibility with our systems, tapes and disk files are tested and arranged in speaker sequence well in advance of the meeting. We will accept tapes and disk files that are received by the deadline for submissions for each public meeting as specified in the **DATES** section of this notice. Late submissions and updates of electronic materials after our deadline cannot be accommodated.

*Please note CMS' page limit for primary speaker presentation materials. The sum of all presentation materials and additional supporting documentation may 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 public meeting date,* in which case, we would like a copy of the complete publication as soon as possible. This exception applies only to the page limit and not the submission deadline.

The materials may be emailed or delivered by regular mail to the HCPCS Public Meeting Coordinators as specified in the **ADDRESSES** section of this notice. The materials must be emailed or postmarked no later than the deadline specified in the **DATES** section of this notice. Individuals will need to provide 35 copies if materials are delivered by mail.

2. ''5-Minute Speakers''

To afford the same opportunity to all attendees, 5-minute speakers are not required to register as primary speakers. However, 5-minute speakers must still register as attendees by the deadline set forth under ''Registration Deadlines for all Other Attendees'' in the **DATES** section of this notice. Attendees can sign up only on the day of the meeting to do a presentation of up to 5 minutes. Individuals must provide their name, company name and address, contact information as specified on the sign-up sheet, and identify the specific agenda item that they will address.

### *C. Additional Meeting/Registration Information*

Please note that all of the CMS' 2016 HCPCS public meetings will begin at 9:00 a.m. each day as noted in the **DATES** section of this notice.

The product category reported in the HCPCS code application by the applicant may not be the same as that assigned by us. Prior to registering to attend a public meeting, all participants are advised to review the public meeting agendas at *www.cms.hhs.gov/medhcpcsgeninfo* which identify our category determinations, and the dates each item will be discussed. Draft agendas, including a summary of each

request and our preliminary decision will be posted on our HCPCS Web site at *www.cms.hhs.gov/medhcpcsgeninfo* at least 4 weeks before each meeting.

Additional details regarding the public meeting process for all new public requests for revisions to the HCPCS, along with information on how to register and guidelines for an effective presentation, will be posted at least 4 weeks before the first meeting date on the official HCPCS Web site at *www.cms.hhs.gov/medhcpcsgeninfo.* The document titled ''Guidelines for Participation in Public Meetings for All New Public Requests for Revisions to the Healthcare Common Procedure Coding System (HCPCS)'' will be made available on the HCPCS Web site at least 4 weeks before the first public meeting in 2016 for all new public requests for revisions to the HCPCS. Individuals who intend to provide a presentation at a public meeting need to familiarize themselves with the HCPCS Web site and the valuable information it provides to prospective registrants. The HCPCS Web site 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 used to make coding determinations for all the products, supplies, and services that are coded in the HCPCS.

The HCPCS Web site 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.

A summary of each public meeting will be posted on the HCPCS Web site by the end of August 2016.

## III. Presentations and Comment Format

We can only estimate the amount of meeting time that will be needed since it is difficult to anticipate the total number of speakers that will register for each meeting. Meeting participants should arrive early to allow time to clear security and sign-in. Each meeting is expected to begin promptly as scheduled. Meetings may end earlier than the stated ending time.

### *A. Oral Presentation Procedures*

All primary speakers must register as provided under the section titled ''Meeting Registration.'' Materials and writings that will be used in support of an oral presentation should be submitted to the HCPCS Public Meeting Coordinator.

The materials may be emailed or delivered by regular mail to the HCPCS Public Meeting Coordinator as specified in the **ADDRESSES** section of this notice. The materials must be emailed or postmarked no later than the deadline specified in the **DATES** section of this notice. Individuals will need to include 35 copies if materials are delivered by mail.

### *B. Primary Speaker Presentations*

The individual or entity requesting revisions to the HCPCS coding system for a particular agenda item may designate one ''primary speaker'' to make a presentation for a maximum of 15 minutes. Fifteen minutes is the total time interval for the presentation, and the presentation must incorporate any demonstration, set-up, and distribution of material. 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 speaker by increments of less than 15 minutes.

Individuals designated to be the primary speaker must register to attend the meeting using the registration procedures described under the ''Meeting Registration'' section of this notice and contact one of the HCPCS Public Meeting Coordinators, specified in the **ADDRESSES** section. Primary speakers must also separately register as primary speakers by the date specified in the **DATES** section of this notice.

### *C. ''5-Minute'' Speaker Presentations*

Meeting attendees can sign up at the meeting, on a first-come, first-served basis, to make presentations for up to 5 minutes on individual agenda items. Based on the number of items on the agenda and the progress of the meeting, a determination will be made at the meeting by the meeting coordinator and the meeting moderator regarding how many ''5-minute speakers'' can be accommodated and/or whether the 5-minute time allocation would be reduced, to accommodate the number of speakers.

### *D. Speaker Declaration*

On the day of the meeting, before the end of the meeting, all primary speakers and 5-minute speakers must provide a brief written summary of their comments and conclusions to the HCPCS Public Meeting Coordinator.

Every primary speaker and 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.

### *E. Written Comments From Meeting Attendees*

Written comments will be accepted from the general public and meeting registrants anytime up to the date of the public meeting at which a request is discussed. Comments must be sent to the address listed in the **ADDRESSES** section of this notice.

Meeting attendees may also submit their written comments at the meeting. Due to the close timing of the public meetings, subsequent workgroup reconsiderations, and final decisions, we are able to consider only those comments received in writing by the close of the public meeting at which the request is discussed.

## IV. Security, Building, and Parking Guidelines

The meetings are held within the CMS Complex which is not open to the general public. Visitors to the complex are required to show a valid Government issued photo identification at the time of entry. As of October, 10, 2015, visitors seeking access to federal agency facilities using their state-issued driver's license or identification cards must present proper identification issued by a state that is compliant with the REAL ID Act of 2005, (Pub. L. 109–13, 119 Statute 302, enacted on May 11, 2005), or a state that has received an extension. What constitutes proper identification and whether a driver's license is acceptable identification for accessing a federal facility may vary, based on which state issued the driver's license. For detailed information, please refer to the Department of Homeland Security (DHS) Web site at *http://www.dhs.gov.* When planning to visit a federal facility, visitors who have further questions about acceptable forms of identification are encouraged to contact the facility to determine acceptable identification. In addition, all Foreign National visitors must present a valid passport as proof of identification.

Visitors will also be subject to a vehicle security inspection before access to the complex is granted. Participants not in possession of a valid identification or who are in possession of prohibited items will be denied access to the complex. Prohibited items on federal property include but are not limited to, alcoholic beverages, illegal narcotics, explosives, firearms or other dangerous weapons (including pocket knives), dogs or other animals except

service animals. Once cleared for entry to the complex participants will be directed to visitor parking by a security officer.

To ensure expedited entry into the building it is recommended that participants have their government ID and a copy of their written meeting registration confirmation readily available and that they do not bring large/bulky items into the building. Participants are reminded that photography on the CMS complex is prohibited. CMS has also been declared a tobacco free campus and violators are subject to legal action. In planning arrival time, we recommend allowing additional time to clear security. Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The invited guests may not enter the building earlier than 45 minutes before the convening of the meeting each day.

Guest access to the complex is limited to the meeting area, the main entrance lobby, and the cafeteria. If a visitor is found outside of those areas without proper escort they may be escorted off of the premises. Also be mindful that there will be an opportunity for everyone to speak and we request that everyone waits for the appropriate time to present their product or opinions. Disruptive behavior will not be tolerated and may result in removal from the meetings and escort from the complex. No visitor is allowed to attach USB cables, thumb drives or any other equipment to any CMS information technology (IT) system or hardware for any purpose at any time. Additionally, CMS staff is prohibited from taking such actions on behalf of a visitor or utilizing any removable media provided by a visitor.

We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a presentation. Special arrangements and approvals are required at least 2 weeks prior to each public meeting to bring pieces of equipment or medical devices. These arrangements need to be made with the public meeting coordinator. It is possible that certain requests made in advance of the public meeting could be denied because of unique safety, security or handling issues related to the equipment. A minimum of 2 weeks is required for approvals and security procedures. Any request not submitted at least 2 weeks in advance of the public meeting will be denied.

Foreign National Visitors are defined as Non-US Citizens, and non-lawful permanent residents, non-resident aliens or non-green-card holders.

Attendees that are foreign nationals must identify themselves as such, and provide the following information for security clearance to the public meeting coordinator by the date specified in the **DATES** section of this notice:

- Building to Visit/Destination.
- Visit start date, start time, end date, end time.
- Visitor full name.
- Gender.
- Visitor Title.
- Visitor Organization/Employer.
- Citizenship.
- Birth Place (City, Country).
- Date of Birth.
- ID Type (Passport or State Department ID).
- Passport issued by Country.
- ID (passport) Number.
- ID (passport) issue date.
- ID (passport) expiration date.
- Visa Type.
- Visa Number.
- Purpose of Visit.

Dated: February 2, 2016.

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2016–03703 Filed 2–22–16; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–D–4852]**

### Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is extending the comment period provided in the notice entitled ''Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability'' that appeared in the **Federal Register** of January 26, 2016. That notice announced the availability of a draft guidance for industry and FDA staff and requested comments by March 28, 2016. FDA is extending the draft guidance's comment period by 30 days in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period for the draft guidance ''Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices'' published on January 26, 2016 (81 FR 4303), by an additional 30 days. Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 28, 2016.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted,