Exchange to allow individuals to easily compare enrollee satisfaction levels between comparable plans. HHS established the QHP Enrollee Experience Survey (QHP Enrollee Survey) to assess consumer experience with the QHPs offered through the Marketplaces. The survey includes topics to assess consumer experience with the health care system such as communication skills of providers and ease of access to health care services. CMS developed the survey using the Consumer Assessment of Health Providers and Systems (CAHPS®) principles (*https://www.ahrq.gov/cahps/about-cahps/principles/index.html*) and established an application and approval process for survey vendors who want to participate in collecting QHP enrollee experience data.

The QHP Enrollee Survey, which is based on the CAHPS® Health Plan Survey, will be used to (1) help consumers choose among competing health plans, (2) provide actionable information that the QHPs can use to improve performance, (3) provide information that regulatory and accreditation organizations can use to regulate and accredit plans, and (4) provide a longitudinal database for consumer research. Based on the requirements for the QHP Enrollee Survey, CMS developed this survey to capture information about enrollees' experience with QHPs offered through an Exchange. CMS conducted in-depth formative research including: a comprehensive literature review, review of existing CMS survey instruments, consumer focus groups, stakeholder discussions, and input from a Technical Expert Panel (TEP). CMS performed a psychometric test and beta test in 2014 and 2015, respectively. CMS began fielding the QHP Enrollee Survey nationwide in 2016 and this request is to continue nationwide collection and administration of the statutorily-required survey in 2021 through 2023. These activities are necessary to ensure that CMS fulfills legislative mandates established by section 1311(c)(4) of the Affordable Care Act to develop an ''enrollee satisfaction survey system'' and provide such information on Exchange websites. *Form Number:* CMS–10488 (0938–1221): *Frequency:* Annually: *Affected Public:* Public sector (Individuals and Households), Private sector (Business or other for-profits and Not-for-profit institutions): *Number of Respondents:* 285; *Total Annual Responses:* 82,510; *Total Annual Hours:* 16,517. For policy questions regarding this collection contact Nidhi Singh Shah at 301–492–5110.

Dated: August 5, 2020.

William N. Parham, III,

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

[FR Doc. 2020–17417 Filed 8–7–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1755–N]

Medicare Program; Announcement of the Advisory Panel on Hospital Outpatient Payment Meeting

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a virtual meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) for 2020. In addition, this notice announces four new membership appointments to the Panel. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services concerning the clinical integrity of the Ambulatory Payment Classification groups and their associated weights, and supervision of hospital outpatient therapeutic services. The advice provided by the Panel will be considered as we prepare the annual updates for the hospital outpatient prospective payment system.

DATES: *Meeting date:* The virtual meeting of the Panel is scheduled for Monday, August 31, 2020, from 9:30 a.m. to 5 p.m. Eastern Daylight Time (EDT). The times listed in this notice are EDT and are approximate times. Consequently, the meetings may last longer or be shorter than the times listed in this notice, but will not begin before the posted times:

Deadline for presentations and comment letters: Presentations or comment letters, and form CMS–20017 (located at *http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms20017.pdf*), must be received by 5 p.m. EDT, Friday, August 14, 2020.

Please note that form CMS–20017 must accompany each presentation or comment letter submission. Presentations and comment letters that are not received by the due date and time, or that do not include a completed form CMS–20017 are considered late or incomplete, and cannot be included on the agenda. In commenting, refer to file code CMS–1755–N.

Meeting Registration Timeframe: All presentation or comment letter speakers, including any alternates, with items on the agenda must register electronically to our Panel mailbox, *APCPanel@cms.hhs.gov* no later than 5pm EDT, Friday, August 14, 2020.

The subject of the email should state ''Agenda Speaker Registration for HOP Panel Meeting.'' In the email, all of the following information must be submitted when registering:

- Speaker name.
- Speaker's organization or company name.
- Company or organization that the speaker is representing that submitted a presentation or comment letter that is on the agenda.
- Email addresses to which materials regarding meeting registration and instructions on connecting to the meeting should be sent.
- Registration details may not be revised once they are submitted. If registration details require changes, a new registration entry must be submitted by August 14, 2020. In addition, registration information must reflect individual-level content and not reflect an organization entry. Also, each individual may only register one person at a time. That is, one individual may not register multiple individuals at the same time.
- A confirmation email will be sent upon receipt of the registration. The email will provide information to the speaker in preparation for the meeting.
- Registration is only required for agenda speakers and alternates and must be submitted by the deadline specified above. We note that no registration is required for participants who plan to view the Panel meeting via webinar or listen via teleconference.

ADDRESSES: *Meeting location and webinar:* The meeting will be held virtually. The public may participate in this meeting via webinar, or listen-only via teleconference. Closed captioning will be available on the webinar. Teleconference dial-in and webinar information will appear on the final meeting agenda, which will be posted on our website when available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.*

News media: Press inquiries are handled through the CMS Press Office at (202) 690–6145.

Advisory committees information line: The telephone number for the Advisory Panel on Hospital Outpatient Payment Committee Hotline is (410) 786–3985.

Websites: For additional information on the Panel, including the Panel charter, and updates to the Panel's activities, we refer readers to view our website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.* Information about the Panel and its membership in the Federal Advisory Committee Act database are also located at: *https://www.facadatabase.gov.*

FOR FURTHER INFORMATION CONTACT: Elise Barringer, Designated Federal Official (DFO) (410) 786–9222, email at *APCPanel@cms.hhs.gov.* Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop: C4–04–25, Baltimore, MD 21244–1850.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of the Department of Health and Human Services (the Secretary) is required by section 1833(t)(9)(A) of the Social Security Act and is allowed by section 222 of the Public Health Service Act to consult with an expert outside panel, such as the Advisory Panel on Hospital Outpatient Payment (the Panel), regarding the clinical integrity of the Ambulatory Payment Classification (APC) groups and relative payment weights. The Panel is governed by the provisions of the Federal Advisory Committee Act (Pub. L. 92–463), as amended (5 U.S.C. Appendix 2), to set forth standards for the formation and use of advisory panels. We consider the technical advice provided by the Panel as we prepare the proposed and final rules to update the Hospital Outpatient Prospective Payment System (OPPS) for the following calendar year.

II. Meeting Agenda

The agenda for the August 31, 2020 Panel meeting will provide for discussion and comment on the following topics as designated in the Panel's Charter:

- Addressing whether procedures within an APC group are similar both clinically and in terms of resource use.
- Reconfiguring APCs.
- Evaluating APC group weights.
- Reviewing packaging the cost of items and services, including drugs and devices, into procedures and services, including the methodology for packaging and the impact of packaging the cost of those items and services on APC group structure and payment. Removing procedures from the inpatient list for payment under the OPPS.
- Using claims and cost report data for Centers for Medicare & Medicaid Services (CMS) determination of APC group costs.
- Addressing other technical issues concerning APC group structure.
- Evaluating the required level of supervision for hospital outpatient services.
- OPPS APC rates for covered Ambulatory Surgical Center (ASC) procedures.

The Agenda will be posted on our website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html* approximately 1 week before the meeting.

Meeting Information Updates

The actual meeting hours and days will be posted in the agenda. As information and updates regarding this webinar and listen-only teleconference, including the agenda, become available, they will be posted to our website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.*

III. Presentations and Comment Letters

The subject matter of any presentation and comment letter must be within the scope of the Panel designated in the Charter. Any presentations or comments outside of the scope of the Panel will be returned or requested for amendment. Unrelated topics include, but are not limited to; the conversion factor, charge compression, revisions to the cost report, pass-through payments, correct coding, new technology applications (including supporting information/documentation), provider payment adjustments, supervision of hospital outpatient diagnostic services, and the types of practitioners that are permitted to supervise hospital outpatient services. The Panel may not recommend that services be designated as nonsurgical extended duration therapeutic services. Presentations or Comment Letters that address OPPS APC rates as they relate to covered ASC procedures are within the scope of the panel, however, ASC payment rates, ASC payment indicators, the ASC covered procedures list, or other ASC payment system matters will be considered out of scope.

The Panel may use data collected or developed by entities and organizations other than Department of Health and Human Services and CMS in conducting its review. We recommend organizations submit data for CMS staff and the Panel's review.

All presentations are limited to 5 minutes, regardless of the number of individuals or organizations represented by a single presentation. Presenters may use their 5 minutes to represent either one or more agenda items.

Section 508 Compliance

For this meeting, we are aiming to have all presentations and comment letters available on our website. Materials on our website must be Section 508 compliant to ensure access to federal employees and members of the public with and without disabilities. We encourage presenters and commenters to reference the guidance on making documents section 508 compliant as they draft their submissions, and, whenever possible, to submit their presentations and comment letters in a 508 compliant form. Such guidance is available at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/Section508/508-Compliant-doc.html.* We will review presentations and comment letters for 508 compliance and place compliant materials on our website. As resources permit, we will also convert non-compliant submissions to 508 compliant forms and offer assistance to submitters who are making their submissions 508 compliant. All 508 compliant presentations and comment letters will be made available on the CMS website. If difficulties are encountered accessing the materials, please contact the Designated Federal Official (DFO) (the DFO's address, email, and phone number are provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice).

In order to consider presentations and/or comment letters, we will need to receive the following:

1. *An email* copy of the presentation or comment letters sent to the DFO mailbox, *APCPanel@cms.hhs.gov.*

2. Form *CMS–20017* with complete contact information that includes name, address, phone number, and email addresses for all presenters, comment letters, and a contact person who can answer any questions, and provide revisions that are requested, for the presentation or comment letter. Presenters and commenter letters must clearly explain the actions that they are requesting CMS to take in the appropriate section of the form. A presenter or commenter's relationship with the organization that they represent must also be clearly listed.

• The form is available through the CMS Forms website at: *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms20017.pdf.*

• We encourage submitters to make efforts to ensure that their presentations and comment letters are 508 compliant.

IV. Formal Presentations

In addition to formal presentations (limited to 5 minutes total per presentation), there will be an opportunity during the meeting for public comments as time permits (limited to 1 minute for each individual and a total of 3 minutes per organization).

V. Panel Recommendations and Discussions

The Panel's recommendations at any Panel meeting generally are not final until they have been reviewed and approved by the Panel on the last day of the meeting, before the final adjournment. These recommendations will be posted to our website after the meeting.

VI. Membership Appointments to the Advisory Panel on Hospital Outpatient Payment

The Panel Charter provides that the Panel shall meet up to 3 times annually. We consider the technical advice provided by the Panel as we prepare the proposed and final rules to update the OPPS for the following calendar year.

The Panel shall consist of a chair and up to 15 members who are full-time employees of hospitals, hospital systems, or other Medicare providers that are subject to the OPPS. The panel may also include a representative of the provider with ASC expertise, who shall advise CMS only on OPPS APC rates, as appropriate, impacting ASC covered procedures within the context and purview of the panel's scope. The Secretary or a designee selects the Panel membership based upon either self-nominations or nominations submitted by Medicare providers and other interested organizations of candidates determined to have the required expertise. For supervision deliberations, the Panel shall also include members that represent the interests of Critical Access Hospitals, who advice CMS only regarding the level of supervision for hospital outpatient therapeutic services. New appointments are made in a manner that ensures a balanced membership under the Federal Advisory Committee Act guidelines.

This notice also announces four new membership appointments to the Panel. The four new members will each serve a 4-year period, with terms that begin in Calendar Year (CY) 2020 and end in CY 2024. The Secretary rechartered the Panel in 2018 for a 2-year period effective through November 20, 2020. The current charter is available on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/2018-HOP-Panel-Charter.pdf.* The Panel presently consists of members and a Chair named below. The panel members whose names are annotated with a single asterisk (*) are members that had terms that otherwise would have expired but are continuing to serve temporarily in accordance with the charter while we search for new members. The panel members whose names are annotated with a double asterisk (**) are new members and have a 4 year term beginning on July 16, 2020 and continuing through July 15, 2024.

- E.L. Hambrick, M.D., J.D., CMS Chairperson
- Terry Bohlke, C.P.A., C.M.A, M.H.A., C.A.S.C
- Carmen Cooper-Oguz, P.T., D.P.T, M.B.A, C.W.S, W.C.C
- Paul Courtney, M.D.
- Peter Duffy, M.D.
- Shelly Dunham, R.N. (*)
- Lisa Gangarosa, M.D.
- Erika Hardy, R.H.I.A., C.D.I.P, C.C.S. (*)
- Michael Kuettel, M.D., M.B.A, Ph.D.
- Karen A. Lambert (*)
- Scott Manaker, M.D., Ph.D.**
- Brian Nester, D.O., M.B.A. **
- Bo Gately, M.B.A. **
- Matthew Wheatley, M.D., F.A.C.E.P. **

VII. Provisions of the Notice

We published a notice in the **Federal Register** on January 26, 2018, entitled ''Medicare Program; Request for Nominations to the Advisory Panel on Hospital Outpatient Payment'' (83 FR 3715). The notice solicited nominations for the Panel members on a continuous basis to fill the vacancies on the Panel. As published in this notice, CMS is accepting nominations on a continuous basis and encourages additional submissions. Any interested person or organization may nominate qualified individuals. Self-nominations from qualified individuals are also accepted. Additional information including criteria for nominees as well as submission requirements are available in the notice, which is accessible from the CMS website at: *https://www.govinfo.gov/content/pkg/FR-2018-01-26/pdf/2018-01474.pdf.*

VIII. 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.*).

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: August 4, 2020.

Lynette Wilson,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020–17398 Filed 8–5–20; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1480]

Drug-Drug Interaction Assessment for Therapeutic Proteins; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Drug-Drug Interaction Assessment for Therapeutic Proteins.'' The purpose of this guidance is to provide a systematic, risk-based approach to help sponsors of investigational new drug applications (INDs) and applicants of biologic license applications (BLAs) determine the need for drug-drug interaction (DDI) studies for a therapeutic protein (TP).

DATES: Submit either electronic or written comments on the draft guidance by November 9, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to