e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Annual Reporting of the Rape Prevention and Education (RPE) Program: CE19–1902 Cooperative Agreement—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

OMB approval is requested for three years for this new collection. The RPE Program, which provides funding to health departments in all 50 states, the District of Columbia (DC), Puerto Rico, Guam, the U.S. Virgin Islands, and the Commonwealth of Northern Mariana Islands. This ICR will collect information related to implementation and outcomes annually from recipients of the new funding opportunity CDC–RFA–CE19–1902: Rape Prevention and Education (RPE): Using The Best Available Evidence for Sexual Violence Prevention cooperative agreement. This new RPE funding opportunity differs greatly from previous funding opportunities provided by CDC through the RPE Program. Specifically, program activities differ from the previous funding cycles, and the program will be collecting information for the first time on recipient outcomes.

RPE Program recipients or designated delegates will submit data annually into the online data system, DVP Partners Portal. Recipients will monitor and report progress on their goals, objectives, and activities, as well as relevant information on the implementation of their prevention strategies, outcomes, evaluation, and state action plan.

Collecting information about the implementation and outcomes of CE19–1902 cooperative agreement through the online data system, DVP Partners Portal, is crucial to informing Sexual Violence prevention nationally; enhancing accountability of the use of federal funds; providing timely program reports and responses to information requests, such as Congressional requests mandated by the authorizing legislation; improving real-time communications between CDC and RPE recipients; and strengthening CDC's capacity to provide responsive data-driven technical assistance and to monitor and evaluate recipients' progress and performance. The only cost to respondents will be time spent responding to the survey/screener. The total estimated annualized burden hours is 440.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
RPE-funded Health Departments (State, DC, and Territories) and their Designated Delegates.	Annual Reporting—Initial Population	55	1	4	220
	Annual Reporting—Subsequent Reporting.	55	2	2	220
Total					440

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–11649 Filed 6–4–19; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1726–N]

Medicare Program; the Announcement of the Annual Advisory Panel on Hospital Outpatient Payment (HOP Panel) Meeting in August 2019 and New Panel Members

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

ACTION: Notice of meeting.

SUMMARY: This notice announces the annual public meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) for 2019. In addition, it announces 6 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 recommendations provided by the Panel will be considered as we prepare the annual updates for the hospital outpatient prospective payment system.

DATES:

Meeting Dates: The public meeting is scheduled for Monday, August 19, 2019, from 9:30 a.m. to 5:00 p.m. Eastern Daylight Time (EDT), and Tuesday, August 20, 2019, from 9:30 a.m. to 12:00 p.m. Eastern Daylight Time (EDT). The times listed in this notice 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 Meeting Registration, Presentations and Comments: Presentations or comments, and form CMS–20017 (located at *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms20017.pdf*) must be received by 5:00 p.m. EDT on Monday, July 22, 2019. Form CMS–20017 must accompany each presentation or comment submission. Presentations and comments that are not received by the due date and time or that do not include a completed form CMS–20017 will be considered late or incomplete and will not be included on the agenda. In commenting, refer to file code CMS–1726–N.

Meeting Registration Timeframe: Monday, June 24, 2019, through Monday, July 29, 2019 at 5 p.m. EDT. Participants planning to attend this meeting in person must register online, during the specified timeframe at: *https://www.cms.gov/apps/events/default.asp.*

On this web page, double click the ''Upcoming Events'' hyperlink, and then double click the ''HOP Panel'' event title link and enter the required information. Include any requests for special accommodations. *Note:* Participants who do not plan to attend the meeting in person should not register. No registration is required for participants

who plan to participate in the meeting via webcast or teleconference.

Deadline for Requesting Special Accommodations: Requests for special accommodations must be received no later than Monday, July 30, 2018 at 5:00 p.m. EDT.

ADDRESSES:

Meeting Location, Webcast and Teleconference: The meeting will be held in the Auditorium at the CMS Single Site Campus, 7500 Security Boulevard, Baltimore, MD 21244. Alternately, the public may either view this meeting via webcast or listen by teleconference. During the scheduled meeting, webcasting is accessible online at: *http://cms.gov/live.* Teleconference instructions will be available approximately one week prior to the meeting, on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html.*

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, teleconference dial-in information that will appear on the final meeting agenda, and updates to the Panel's activities, we refer readers to view our website at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html.* Information about the Panel and its membership in the Federal Advisory Committee Act database are also located at: *http://facadatabase.gov.*

Registration: The meeting is open to the public but attendance is limited to the space available and registration is required. Priority will be given to those who pre-register and attendance may be limited based on the number of registrants and the space available. Persons wishing to attend this meeting, which is located on federal property, must register by following the instructions in the **DATES** section of this notice under ''Meeting Registration Timeframe.'' A confirmation email will be sent to the registrants shortly after completing the registration process.

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 (the Act) and is allowed by section 222 of the Public Health Service Act (PHS 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.

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.* On January 26, 2018, we published a notice in the **Federal Register** entitled, ''Medicare Program; Request for Nominations to the Advisory Panel on Hospital Outpatient Payment'' (83 FR 3715). The notice solicited nominations for Panel members on a continuous basis to fill the vacancies on the Panel. The notice also stated that the Centers for Medicare & Medicaid Services (CMS) would consider the nominations submitted in response to the December 23, 2016 notice published in the **Federal Register** entitled, ''Medicare Program; Renewal of the Advisory Panel on Hospital Outpatient Payment and Solicitation of Nominations to the Advisory Panel on Hospital Outpatient Payment'' (81 FR 94378), unless they were withdrawn or the nominees' qualifications had changed. The 6 new members announced in this notice will each serve a 4-year period, with terms that begin in Calendar Year (CY) 2019 and end in CY 2023. We will 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 CY.

II. Annual Advisory Panel Meeting

A. Meeting Agenda

The agenda for the August 19, 2019 through August 20, 2019 Panel meeting will be posted on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html* approximately 1 week before the meeting. The Agenda 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 (for example, splitting APCs, moving Healthcare Common Procedure Coding System (HCPCS) codes from one APC to another, and moving HCPCS codes from new technology APCs to clinical 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 CMS's 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 ASC procedures.

B. Presentations and Comment Letters

The subject matter of any presentation and comment matter 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 the Department of Health and Human Services (DHHS) 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 comments available on the CMS 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 comments in a 508 compliant form. The 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 comments for 508 compliance and place compliant materials on the CMS website. As resources permit, we will also convert non-compliant submissions to 508 compliant forms and offer assistance to submitters who wish to make their submissions 508 compliant. All 508 compliant presentations and comments will be shared with the public onsite, webcasted, and made available on the CMS website. Those wishing to access such materials should contact the 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 comments, we will need to receive the following:

1. *An email* copy of the presentation or comments sent to the DFO mailbox, *APCPanel@cms.hhs.gov* or, if unable to submit by email, a hard copy sent to the DFO at the address noted in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

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

- The form is now 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 comments are 508 compliant.

C. Oral Comments

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

D. 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 the CMS website after the meeting.

E. Security, Building, and Parking Guidelines

The meeting is open to the public but attendance is limited to the space available. Persons wishing to attend this meeting in person must register within the noted timeframe, by following the instructions in the **DATES** section of this notice under ''Meeting Registration Timeframe.''

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. Individuals who are not registered in advance may not be permitted to enter the building and would be unable to attend the meeting. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting to allow additional time to clear security. Security measures include the following:

- Presentation of valid government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means, of all persons entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. 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 presentation or to support a presentation.

Note: Individuals who are not registered in advance may not be permitted to enter the building and would be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

II. Nominees and Membership Appointments to the Advisory Panel on Hospital Outpatient Payment

A. Panel Appointments Requirements

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 (CAHs), who advise 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 FACA guidelines.

The Panel consists of the following current members and a Chair:

- E. L. Hambrick, M.D., J.D., CMS Chairperson
- Shelly Dunham, R.N.
- Kenneth Michael Flowe, M.D., M.B.A.
- Erika Hardy, R.H.I.A.
- Karen A. Lambert
- Ruth Lande
- Scott Manaker, M.D., Ph.D.
- Agatha L. Nolen, Ph.D., D.Ph.
- Richard Nordahl, M.B.A.
- Michael Schroyer, R.N.

B. Request and Submission of the Panel Nominations

The Request for Nominations to the Advisory Panel on Hospital Outpatient Payment notice (83 FR 3715) provides for nominations to be accepted on a continuous basis to fill upcoming panel vacancies. CMS 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.*

As a result of that notice, we are announcing 6 new members to the Panel. These 6 new Panel member appointments will assure that we continue to have a Chair and up to 15 members available to attend our scheduled meeting.

New Appointments to the Panel

New members of the Panel will have terms beginning on March 1, 2019 and continuing through February 28, 2023. The new members of the Panel are as follows:

- Terry Bohlke, CPA, CMA, MHA, CASC
- Carmen Cooper-Oguz, PT, DPT, MBA, CWS, WCC
- Paul Courtney, M.D.
- Peter Duffy, M.D.
- Lisa Gangarosa, M.D.
- Michael Kuettel, M.D., MBA, Ph.D.

IV. 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.*).

Dated: May 31, 2019.

Paul Mango,

Chief Principal Deputy Administrator and Chief of Staff, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–11756 Filed 6–4–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0125]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 5, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0775. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

OMB Control Number 0910–0775—Extension

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) was signed into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding, among other things, a chapter granting FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 201(rr) of the FD&C Act (21 U.S.C.321(rr)), as amended, defines a tobacco product as any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). Section 910 of the FD&C Act (21 U.S.C. 387j) sets out premarket requirements for new tobacco products. The term new tobacco product is defined as any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007 (section 910(a)(1) of the FD&C Act).

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the FD&C Act (section 901(b) (21 U.S.C. 387a(b)) of the FD&C Act). On May 10, 2016, FDA issued that rule, extending FDA's tobacco product authority to all products that meet the definition of tobacco product in the law (except for accessories of newly regulated tobacco products), including electronic nicotine delivery systems, cigars, hookah, pipe tobacco, nicotine gels, dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28974 at 28976).

FDA refers to tobacco products that were commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007, as grandfathered tobacco products. Grandfathered tobacco products are not considered new tobacco products and are not subject to the premarket requirements of section 910 of the FD&C Act. The guidance document associated with this information collection provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007. A grandfathered