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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1778-N]

Medicare Program; Announcement of the Advisory Panel on Hospital Outpatient Payment Meeting—August 22-23, 2022

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 Calendar Year 2022. 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, which are major elements of the Medicare Hospital Outpatient Prospective Payment System (OPPS) and the Ambulatory Surgical Center (ASC) payment system; and supervision of hospital outpatient therapeutic services. The advice provided by the Panel will be considered as we prepare the annual update for the OPPS.

DATES:

Meeting Dates: The virtual meeting of the Panel is scheduled for Monday, August 22, 2022 from 9:30 a.m. to 5:00 p.m. Eastern Daylight Time (EDT) and Tuesday, August 23, 2022 from 9:30 a.m. to 5:00 p.m. 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 time.

Deadline for presentations and comments: Presentations or comment letters must be received by 5:00 p.m. EDT on Friday, August 05, 2022. Presentations or comment letters must be submitted through the “Hospital Outpatient Payment (HOP) Panel Meeting Presentation & Comment Letters” module. To access the module, go to <https://mearis.cms.gov> to register/log in, and submit your presentation or comment letter. CMS can only accept

HOP Panel Meeting presentations and comment letters that are submitted via MEARIS™. We note that with the submissions in MEARIS, CMS no longer requires the completion or submission of form CMS-20017 as part of the presentation or comment letter package. Submitters do not need to complete this form.

Presentations and comment letters that are not received by the due date and time will be considered late or incomplete and will not be included on the agenda.

Presentations and comment letters may not be revised once they are submitted. If a presentation or comment letter requires changes, a new submittal must be submitted by August 05, 2022.

ADDRESSES:

Virtual meeting location and webinar: 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>.

Advisory committee 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 located at: <https://www.facadatabase.gov>.

Virtual meeting registration: While there is no meeting registration, presenters must be identified and included as part of the MEARIS™ presentation submission process by the deadline specified above. We note that no advanced registration is required for participants who plan to view the Panel meeting via webinar, listen via teleconference, or may wish to make a public comment during the meeting.

FOR FURTHER INFORMATION CONTACT: Nicole Marcos, Designated Federal Official (DFO) by email at: APCPanel@cms.hhs.gov.

Press inquiries are handled through the CMS Press Office at (202) 690-6145.

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 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 (CY).

The Panel presently consists of members and a Chair named below.

- 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.
- Lisa Gangarosa, M.D.
- Bo Gately, M.B.A.
- Michael Kuettel, M.D., M.B.A., Ph.D.
- Scott Manaker, M.D., Ph.D.
- Brian Nester, D.O., M.B.A.
- Matthew Wheatley, M.D., F.A.C.E.P.

II. Annual Advisory Panel Meeting

A. Meeting Agenda

The agenda for the August 22, 2022 through August 23, 2022 virtual 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 only list for payment under the OPPS.
 - Using claims and cost report data for the 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 the CMS website at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups> approximately 1 week before the meeting.

B. 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>.

C. Presentations and Comment Letters

The subject matter of any presentation and comment letter must be within the scope of the Panel as 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 or 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. Presenters and commenters should reference the guidance on making documents section 508 compliant as they draft their submissions, and, whenever possible, submit their presentations and comment letters in a 508 compliant form. The section 508 guidance is available at: <https://www.cms.gov/research-statistics-data-and-systems/cms-information-technology/section508>. Presentations and comment letters should limit the use of graphs or pictures. Any use of these visual depictions must include alternate text that verbally describes what these visuals convey.

We will review presentations and comment letters for section 508 compliance and place compliant materials on our website. As resources permit, we will also convert non-compliant submissions to section 508-compliant forms and offer assistance to submitters who are making their submissions section 508-compliant. All section 508-compliant presentations and comment letters will be made available on the CMS website. If difficulties are encountered accessing the materials, contact the Designated Federal Official (DFO) in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

D. 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).

E. 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 on the CMS website after the meeting.

F. 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 CY. 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

The Panel may also include a representative of a 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 may include members that represent the interests of Critical Access Hospitals, 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 Federal Advisory Committee Act guidelines. The Secretary rechartered the Panel in 2020 for a 2-year period effective through November 20, 2022. The current charter is available on the CMS website at: <https://www.cms.gov/files/document/2020-hop-panel-charter.pdf>.

III. 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), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for

purposes of publication in the **Federal Register**.

Vanessa Garcia,

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; Office of Community Services (OCS) Community Economic Development (CED) Standard Reporting Format (Office of Management and Budget) (OMB) #0970-0386)

AGENCY: OCS, Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Request for public comments.

SUMMARY: OCS is requesting a three-year extension of the semi-annual reporting format for CED grant recipients, the Performance Progress Report (PPR),

which collects information regarding the outcomes and management of CED projects (OMB #0970-0386, expiration February 28, 2023). There are minor changes requested to the form to provide clarity to users completing the form.

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

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:
Description: OCS will continue collecting key information about projects funded through the CED program. The legislative requirement for this program is in Title IV of the Community Opportunities, Accountability and Training and Educational Services Act (COATS Human Services Reauthorization Act) of October 27, 1998, Public Law 105-285, section 680(b) as amended. The PPR

collects information regarding the outcomes and management of CED projects. OCS will use the data to critically review the overall design and effectiveness of the program.

The PPR will continue to be administered to all active grant recipients of the CED program. Grant recipients will be required to use this reporting tool for their semi-annual reports to be submitted twice a year. Through a previous renewal, the current PPR replaced both the annual questionnaire and other semi-annual reporting formats, which resulted in an overall reduction in burden for the grant recipients, significantly improved the quality of the data collected by OCS, and allowed grant recipients to become accustomed to this format. OCS seeks to renew this PPR to continue to collect quality data from grant recipients. To ensure the burden on grant recipients is not increased, but that the information collected demonstrates the full impact of the program, OCS has conducted an in-depth review of the forms and requests minor changes to the PPR to provide clarity to users filling out the form.

Respondents: Active CED Grant Recipients.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
PPR for Current OCS-CED Grant Recipients	91	2	1.5	273

Estimated Total Annual Burden Hours: 273.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Section 680(a)(2) of the Community Services Block Grant (CSBG) Act, 42 U.S.C. 9921.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-0823]

Real-Time Oncology Review; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, 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 "Real-Time Oncology Review (RTOR)." The purpose of this guidance is to provide recommendations to applicants on the process for submission of selected new drug applications (NDAs) and biologics license applications (BLAs) with oncology indications for review under RTOR.

DATES: Submit either electronic or written comments on the draft guidance by September 20, 2022 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,