

Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection

Request: Revision of a currently approved collection; **Title of Information Collection:** Annual Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Participation Report; **Use:** The baseline data collected is used to assess the effectiveness of state early and periodic screening, diagnostic and treatment (EPSDT) programs in reaching eligible children, by age group and basis of Medicaid eligibility, who are provided initial and periodic child health screening services, referred for corrective treatment, and receiving dental, hearing, and vision services. This assessment is coupled with the state's results in attaining the participation goals set for the state. The information gathered from this report, permits federal and state managers to evaluate the effectiveness of the EPSDT law on the basic aspects of the program. The associated 30-day PRA package has been revised subsequent to the publication of the 60-day notice (78 FR 48687). **Form Number:** CMS-416 (OCN: 0938-0354); **Frequency:** Yearly; **Affected Public:** State, Local, or Tribal Governments; **Number of Respondents:** 56; **Total Annual Responses:** 56; **Total Annual Hours:** 1,568. (For policy questions regarding this collection contact Marsha Lillie-Blanton at 410-786-8856.)

2. Type of Information Collection

Request: Extension of a currently approved collection; **Title of Information Collection:** Clinical Laboratory Improvement Amendments (CLIA) Regulations; **Use:** The information is necessary to determine an entity's compliance with the Congressionally-mandated program with respect to the regulation of laboratory testing (CLIA). In addition, laboratories participating in the Medicare program must comply with CLIA requirements as required by section 6141 of OBRA 89. Medicaid, under the authority of section 1902(a)(9)(C) of the Social Security Act, pays for services furnished only by laboratories that meet Medicare (CLIA) requirements. **Form Number:** CMS-R-26 (OCN: 0938-0612); **Frequency:** Monthly, occasionally; **Affected Public:** Private sector—Business or other for-profits and Not-for-profit institutions,

State, Local or Tribal Governments, and the Federal government; **Number of Respondents:** 79,175; **Total Annual Responses:** 88,886,364; **Total Annual Hours:** 15,613,299. (For policy questions regarding this collection contact Raelene Peretto at 410-786-6876).

3. Type of Information Collection

Request: New Collection (Request for a new OMB control number); **Title of Information Collection:** Medicaid Emergency Psychiatric Demonstration (MEPD) Evaluation; **Use:** Since the inception of Medicaid, inpatient care provided to adults ages 21 to 64 in institutions for mental disease (IMDs) has been excluded from federal matching funds. The Emergency Medical Treatment and Active Labor Act (EMTALA), however, requires IMDs that participate in Medicare to provide treatment for psychiatric emergency medical conditions (EMCs), even for Medicaid patients for whose services cannot be reimbursed. Section 2707 of the Affordable Care Act (ACA) directs the Secretary of Health and Human Services to conduct and evaluate a demonstration project to determine the impact of providing payment under Medicaid for inpatient services provided by private IMDs to individuals with emergency psychiatric conditions between the ages of 21 and 64. We will use the data to evaluate the Medicaid Emergency Psychiatric Demonstration (MEPD) in accordance with the ACA mandates. This evaluation in turn will be used by Congress to determine whether to continue or expand the demonstration. If the decision is made to expand the demonstration, the data collected will help to inform us as well as our stakeholders about possible effects of contextual factors and important procedural issues to consider in the expansion, as well as the likelihood of various outcomes. Subsequent to publication of the 60-day **Federal Register** notice (78 FR 45205), there was an increase in the burden due to an increase in time assessed for reviewing medical records and the need to obtain additional informed consents for beneficiary interviews. There have also been changes made to the "Key Informant Interview Questions" for clarification purposes. **Form Number:** CMS-10487 (OCN: 0938-NEW); **Frequency:** Annually; **Affected Public:** Individuals and households; State, Local and Tribal governments; Private sector—Business and other for-profits and Not-for-profits; **Number of Respondents:** 98; **Total Annual Responses:** 2,754; **Total Annual Hours:** 2,613. (For policy questions regarding

this collection contact Negussie Tilahun at 410-786-2058.)

Dated: December 3, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013-29143 Filed 12-5-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1463-N]

Medicare Program; Semi-Annual Meeting of the Advisory Panel on Hospital Outpatient Payment (HOP Panel) March 10-11, 2014

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

ACTION: Notice.

SUMMARY: This notice announces the first semi-annual meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) for 2014. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (the Administrator) on the clinical integrity of the Ambulatory Payment Classification (APC) groups and their associated weights, and hospital outpatient therapeutic services supervision issues.

DATES: *Meeting Dates:* The first semi-annual meeting in 2014 is scheduled for the following dates and times. The times listed in this notice are Eastern Standard Time (EST) and are approximate times; consequently, the meetings may last longer than the times listed in this notice, but will not begin before the posted times:

- Monday, March 10, 2014, 1 p.m. to 5 p.m. EST
- Tuesday, March 11, 2014, 9 a.m. to 5 p.m. EST

Meeting Information Updates:

The actual meeting hours and days will be posted in the agenda. As information and updates regarding the onsite and webcasted meeting and agenda become available, they will be posted to the CMS Web site at: <http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

Deadlines

Deadline for Presentations and Comments:

Presentations and Comments can be submitted by email or hard copy as follows: Presentations or comments and form CMS-20017 submitted by email, must be in the Designated Federal Official's (DFO's) email inbox (APCPanel@cms.hhs.gov) by 5 p.m. EST, Friday, January 31, 2014. Presentations or comments and form CMS-20017 submitted hardcopy, must be received by the DFO on or before Friday, February 7, 2014. Presentations and comments that are not received by the due dates will be considered late and will not be included on the agenda. (See below for submission instructions for both hardcopy and electronic submissions.)

Meeting Registration Timeframe:

Monday, January 20, 2014 through Friday, February 21, 2014 at 5 p.m. EST.

Participants planning to attend this meeting in person must register online, during the above 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 this meeting in person should not register. No registration is required for participants who plan to view the meeting via webcast.

ADDRESSES: In commenting, please refer to file code CMS-1463-N. Because of staff and resource limitations, we cannot accept comments and presentations by facsimile (FAX) transmission.

Meeting Location and Webcast:

The meeting will be held in the Auditorium, CMS Central Office, 7500 Security Boulevard, Woodlawn, Maryland 21244-1850.

Alternately, the public may view this meeting via a webcast. During the scheduled meeting, webcasting is accessible online at: <http://cms.gov/live> or <http://www.ustream.tv>. Viewers interested in receiving the webcast from <http://www.ustream.tv> will need to type "CMS Public Events" in the search bar to access the webcast.

FOR FURTHER INFORMATION CONTACT:

Chuck Braver, 7500 Security Boulevard, Mail Stop: C4-05-17, Woodlawn, MD 21244-1850. Phone: (410) 786-3985. Email: APCPanel@cms.hhs.gov.

Mail hardcopies and email copies to the following addresses: Chuck Braver, DFO, CMS, CM, HAPG, DOC—HOP Panel 7500 Security Blvd., Mail Stop:

C4-05-17, Woodlawn, MD 21244-1850. Email: APCPanel@cms.hhs.gov.

Note: We recommend that you advise couriers of the following information: When delivering hardcopies of presentations to CMS, call (410) 786-4532 or (410) 786-6719 to ensure receipt of documents by appropriate staff.

News Media: Representatives must contact our Public Affairs Office at (202) 690-6145.

Advisory Committees' Information Lines: The phone number for the CMS Federal Advisory Committee Hotline is (410) 786-3985.

Web sites:

For additional information on the Panel and updates to the Panel's activities, we refer readers to view our Web site 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 (FACA) database are also located at: <http://facasms.fido.gov/>.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary is required by section 1833(t)(9)(A) of the Social Security Act (the Act) and section 222 of the Public Health Service Act (PHS Act) to consult with an expert outside advisory panel regarding the clinical integrity of the Ambulatory Payment Classification (APC) groups and relative payment weights. The Panel (which was formerly known as the Advisory Panel on Ambulatory Payment Classification Groups) 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 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 outpatient prospective payment system (OPPS).

II. Agenda

The agenda for the March 2014 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.
- Evaluating APC group weights.
- Reviewing the packaging of OPPS services and costs, including the methodology and the impact on APC groups and payment.

- Removing procedures from the inpatient list for payment under the OPPI.

- Using single and multiple procedure claims data for CMS' determination of APC group weights.

- Addressing other technical issues concerning APC group structure.

- Recommending the appropriate supervision level (general, direct, or personal) for individual hospital outpatient therapeutic services.

The Agenda will be posted on the CMS Web site before the meeting.

III. Presentations

The presentation subject matter must be within the scope of the Panel designated in the Charter. Any presentations outside of the scope of this 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.

The Panel may use data collected or developed by entities and organizations, other than 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.

All presentations will be shared with the public. Presentations may not contain any pictures, illustrations, or personally identifiable information.

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

1. A *hardcopy* of the presentation; only hardcopy comments and presentations can be reproduced for public dissemination.

2. An *email copy* of the presentation sent to the DFO mailbox, APCPanel@cms.hhs.gov.

3. Form CMS-20017 with complete contact information that includes name, address, phone, and email addresses for all presenters and a contact person that can answer any questions and or provide revisions that are requested for the presentation.

- Presenters must clearly explain the actions that they are requesting CMS to take in the appropriate section of the form. A presenter's relationship with the organization that they represent must also be clearly listed.

- The form is now available through the CMS Forms Web site. The Uniform Resource Locator (URL) for linking to this form is as follows: <http://www.cms.hhs.gov/cmsforms/downloads/cms20017.pdf>

IV. Oral Comments

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

V. Meeting Attendance

The meeting is open to the public; however, attendance is limited to space available. 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 "Meeting Registration Timeframe" section of this notice. A confirmation email will be sent to the registrants shortly after completing the registration process.

VI. Security, Building, and Parking Guidelines

The following are the security, building, and parking guidelines:

- Persons attending the meeting, including presenters, must be pre-registered and on the attendance list by the prescribed date.
- Individuals who are not pre-registered in advance may not be permitted to enter the building and may be unable to attend the meeting.
- Attendees must present valid photo identification to the Federal Protective Service or Guard Service personnel before entering the building. Without a current, valid photo ID, persons may not be permitted entry to the building.
- Security measures include inspection of vehicles, inside and out, at the entrance to the grounds.
- All persons entering the building must pass through a metal detector.
- All items brought into CMS including personal items, for example, laptops and cell phones are subject to physical inspection.
- The public may enter the building 30 to 45 minutes before the meeting convenes each day.

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

- The main-entrance guards will issue parking permits and instructions upon arrival at the building.

VII. Special Accommodations

Individuals requiring sign-language interpretation or other special accommodations must include the request for these services during registration.

VIII. 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 Web site after the meeting.

IX. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

(Catalog of Federal Domestic Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 29, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–29185 Filed 12–5–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected

inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT:

Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Use of Antisense Oligodeoxynucleotides (ODNs) for Inhibiting JC Virus (JCV)

Description of Technology:

Progressive multifocal leukoencephalopathy (PML) is a rare, fatal demyelinating disease of the brain caused by the polyomavirus JC (JCV) under immunosuppressive conditions. It is pathologically characterized by progressive damage of white matter of the brain by destroying oligodendrocytes at multiple locations. Clinically, PML symptoms include weakness or paralysis, vision loss, impaired speech, and cognitive deterioration. The prognosis of PML is generally poor. No effective therapy for PML has been established. The current strategies to develop a PML therapy focus on blocking viral infection or inhibiting JCV replication. Antisense oligodeoxynucleotides (ODNs) that can block JCV replication and multiplication have been identified and optimized. Use of the ODNs provide a method of inhibiting JCV replication and thereby provide a treatment for PML.

Potential Commercial Applications:

- JCV/PML Therapeutics.
- JCV Diagnostics.
- JCV Kits.

Competitive Advantages:

- Low cost PML therapeutics.
- Lower cost JCV diagnostics.
- Ease of synthesis.

Development Status:

- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

Inventors: Laura B. Jaeger, Avindra Nath, Eugene O. Major (all of NINDS).

Intellectual Property: HHS Reference No. E–547–2013/0—US Provisional Application No. 61/879,833, filed 19 Sep 2013.

Licensing Contact: Peter Soukas, J.D.; 301–435–4646; ps193c@nih.gov.

Collaborative Research Opportunity: The National Institute of Neurological Disorders and Stroke is seeking statements of capability or interest from parties interested in collaborative