interstate compact on Medicaid and CHIP for children, States can more readily recognize each other's eligibility determinations and reimburse out-of-state providers. As a result, they can provide more seamless Medicaid and CHIP coverage to low-income children. States currently participate in a variety of interstate compacts including one pertaining to Federal adoption assistance/Medicaid recipients entitled the ''Interstate Compact on Adoption and Medical Assistance'' (ICAMA). Further information related to ICAMA can be viewed at: *http://www.aaicama.org/cms/*.

(2) Demonstration Projects. Section 1115(a) of the Social Security Act (the Act) provides the Secretary of Health and Human Services with the authority to authorize experimental, pilot, or demonstration projects which, in the judgment of the Secretary, are likely to assist in promoting the objectives of the Medicaid statute. States can request section 1115 authority to create a standard set of benefits or eligibility coverage across States that differ from the set of benefits provided under the State plan in each of those States or to expand coverage to groups of individuals, including parents and caretaker relatives, or to provide greater flexibility in their programs. Budget neutrality is required for title XIX programs approved under section 1115 authority under the policies of the Office of Management and Budget. A recent example of how CMS used section 1115 authority was in 2005, in response to the devastation caused by Hurricane Katrina on the health care system of the Gulf coast of Louisiana and Mississippi; the Secretary was granted the authority to approve section 1115 demonstration waivers that granted States time-limited waiver authority to facilitate expedited enrollment into Medicaid and CHIP programs for survivors of Hurricane Katrina who needed to access healthcare services in locations other than their home States. Under Hurricane Katrina demonstrations, we granted time-limited waiver authorities to States for the following:

- Simplified eligibility criteria for Medicaid and CHIP eligible groups.
- Comparability/amount, duration, and scope of benefit packages.
- Simplified eligibility determination processes in order to permit evacuees to access needed health care services in their host State.

(3) State Activities under Current Law's Flexibility. States may explore current flexibility under State plan authority to improve the continuity of coverage for Medicaid and CHIP eligible children. Some of the flexibility offered under the State plan authority may be designed to improve service delivery coordination; enhance enrollment and portability arrangements; and enhance Medicaid and CHIP managed care coordination at the State and health plan levels to facilitate enrollment and portability. Under this model for example, a State may choose to align/standardize their eligibility and enrollment processes with a neighboring State in order to improve coordination of Medicaid and CHIP coverage for children.

(4) Public-Private Partnerships. States may engage in public-private partnerships in order to research or pilot initiatives that improve the portability of Medicaid and CHIP coverage for low-income children.

(5) National Children's Health Coverage Option. This model would develop a national health insurance plan for children with a minimum benefit plan to be offered by every State. Under this option, certain statutory changes would be required related to the definition of residency and eligibility criteria for children, specifically a minimum national coverage for all children under age 21 years and a change in the income standard to a specified minimum level for all children. State residency could be defined to make it easier to cover children in the State where they are living, even if they do not intend to remain there permanently or for an indefinite period.

C. Request for Comments

We request public comments on the proposed models to include the following:

(1) Advantages (benefits) and/or disadvantages (negatives) related to each of the proposed models.

(2) Best practices States may currently have in place to ensure interstate continuity and coordination of enrollment for Medicaid and CHIP children.

(3) Recommendations for new models that will facilitate coordination of enrollment, retention, and coverage for Medicaid and CHIP children.

(4) Additional comments related to programmatic operations and/or statutory changes that may be required in order to create the model process.

D. Use of Public Comments

We will review the public comments and consider the information received in the development of the model process for the coordination of enrollment, retention, and coverage for Medicaid and CHIP children who frequently move from their State of residence.

II. Provisions of the Notice With Comment

The purpose of this notice is to provide the opportunity for public input/consultation in developing a model process for the coordination of enrollment, retention and coverage for Medicaid and CHIP eligible children who, because of migration of families, emergency evacuations, natural or other disasters, public health emergencies, educational needs, or otherwise, frequently change their State of residency or otherwise are temporarily located outside the State of their residency.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 1115 of the Social Security Act.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: November 2, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E9–29724 Filed 12–17–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1416–N]

Medicare Program; First Semi-Annual Meeting of the Advisory Panel on Ambulatory Payment Classification Groups—February 17–19, 2010

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice announces the first semi-annual meeting of the

Advisory Panel on Ambulatory Payment Classification (APC) Groups (the Panel) for 2010. The purpose of the Panel is to review the APC groups and their associated weights and to advise the Secretary of the Department of Health and Human Services (DHHS) (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Administrator) concerning the clinical integrity of the APC groups and their associated weights. We will consider the Panel's advice as we prepare the proposed and final rules that would update the hospital Outpatient Prospective Payment System (OPPS) for CY 2011.

DATES: *Meeting Dates:* We are scheduling the first semi-annual meeting in 2010 for the following dates and times:

- Wednesday, February 17, 2010, 1 p.m. to 5 p.m. eastern standard time (e.s.t.) [1]
- Thursday, February 18, 2010, 8 a.m. to 5 p.m. (e.s.t.) [1]
- Friday, February 19, 2010, 8 a.m. to 12 noon (e.s.t.) [2]

[1] The times listed in this notice are approximate times; consequently, the meetings may last longer than listed in this notice, but will not begin before the posted times.

[2] If the business of the Panel concludes on Thursday, February 18, 2010, there will be no meeting on Friday, February 19, 2010.

Deadlines:

Deadline for Hardcopy Comments/ Suggested Agenda Topics—5 p.m. (e.s.t.), Monday, January 13, 2010.

Deadline for Hardcopy Presentations—5 p.m. (e.s.t.), Monday, January 13, 2010.

Deadline for Attendance Registration—5 p.m. (e.s.t.), Wednesday, February 10, 2010.

Deadline for Special Accommodations—5 p.m. (e.s.t.), Wednesday, February 10, 2010.

Submission of Materials to the Designated Federal Official

Because of staffing and resource limitations, we cannot accept written comments and presentations by FAX, nor can we print written comments and presentations received electronically for dissemination at the meeting.

Only hardcopy comments and presentations can be reproduced for public dissemination. All hardcopy presentations *must be accompanied by Form CMS–20017 (revised 01/07).* 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.*

Presenters must use the most recent copy of CMS–20017 (updated 01/07) at the above URL. Additionally, presenters must *clearly* explain the action(s) that they are requesting CMS to take in the appropriate section of the form. They must also clarify their relationship to the organization that they represent in the presentation.

Note: Issues that are vague, or that are outside the scope of the APC Panel's purpose, will not be considered for presentations and comments. There will be no exceptions to this rule. We appreciate your cooperation on this matter.

We are also requiring electronic versions of the written comments and presentations, in addition to the hardcopies.

In summary, presenters and/or commenters must do the following:

- Send both electronic and hardcopy versions of their presentations and written comments by the prescribed deadlines.
- Send electronic transmissions to the e-mail address below.
- Do not send pictures of patients in any of the documents unless their faces have been blocked out.
- Do not send documents electronically that have been archived.
- Mail (or send by courier) to the Designated Federal Official (DFO) all hardcopies, accompanied by Form CMS–20017 (revised 01/07), if they are presenting, as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice.
- Commenters are not required to send Form CMS–20017 with their written comments.

ADDRESSES: The meeting will be held in the Auditorium, CMS Central Office, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

FOR FURTHER INFORMATION CONTACT: For further information, contact: Shirl Ackerman-Ross, DFO CMS, CMM, HAPG, DOC, 7500 Security Boulevard, Mail Stop C4–05–17, Baltimore, MD 21244–1850.

Phone: (410) 786–4474.

Note: We recommend that you advise couriers of the following information: When delivering hardcopies of presentations to CMS, if no one answers at the above phone number, please call (410) 786–4532 or (410) 786–9316.

The e-mail address for comments, presentations, and registration requests is *CMS APCPanel@cms.hhs.gov.*

Note: There is NO underscore in this e-mail address; there is a SPACE between CMS and APCPanel.

News media representatives must contact our Public Affairs Office at (202) 690–6145.

Advisory Committees' Information Lines: The phone numbers for the CMS Federal Advisory Committee Hotline are 1–877–449–5659 (toll free) and (410) 786–9379 (local).

Web Sites: The following information is available on the CMS Web site at *http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage.*

Note: There is an UNDERSCORE after FACA/05(like this_); there is no space.

- Additional information on the APC meeting agenda topics
- Updates to the Panel's activities
- Copies of the current Charter
- Membership requirements.

You may also search information about the APC Panel and its membership in the FACA database at the following URL: *https://www.fido.gov/facadatabase/public.asp.*

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary is required by section 1833(t)(9)(A) of the Social Security Act (the Act) to consult with an expert, outside advisory panel on the clinical integrity of the APC groups and weights established under the Medicare hospital OPPS.

The APC Panel meets up to three times annually. The Charter requires that the Panel must be fairly balanced in its membership in terms of the points of view represented and the functions to be performed. The Panel consists of up to 15 members who are representatives of providers and a Chair.

Each Panel member must be employed full-time by a hospital, hospital system, or other Medicare provider subject to payment under the OPPS. The Secretary or Administrator selects the Panel membership based upon either self-nominations or nominations submitted by Medicare providers and other interested organizations.

All members must have technical expertise to enable them to participate fully in the Panel's work. Such expertise encompasses hospital payment systems; hospital medical care delivery systems; provider billing systems; APC groups; Current Procedural Terminology codes; and alpha-numeric Health Care Common Procedure Coding System codes; and the use of, and payment for, drugs, medical devices, and other services in the outpatient setting, as well as other forms of relevant expertise. Details regarding membership requirements for the APC Panel are found on the FACA and CMS Web sites as listed above.

The Panel presently consists of the following members:

- E. L. Hambrick, M.D., J.D., Chair, CMS Medical Officer.
- Ruth L. Bush, M.D., M.P.H.
- Dawn L. Francis, M.D., M.H.S.
- Patrick A. Grusenmeyer, Sc.D., F.A.C.H.E.
- Kathleen Graham, R.N., M.S.H.A., C.P.H.Q., A.C.M.
- David Halsey, M.D.
- Judith T. Kelly, B.S.H.A., R.H.I.T., R.H.I.A., C.C.S.
- Michael D. Mills, Ph.D.
- Thomas M. Munger, M.D., F.A.C.C.
- Agatha L. Nolen, D.Ph., M.S., F.A.S.H.P.
- Randall A. Oyer, M.D.
- Beverly Khnie Philip, M.D.
- Daniel Pothen, M.S., R.H.I.A., C.P.H.I.M.S., C.C.S.-P, C.H.C.
- Russ Ranallo, M.S., B.S.
- Michael A. Ross, M.D., F.A.C.E.P.
- Patricia Spencer-Cisek, M.S., A.P.R.N.-B.C., A.O.C.N.

II. Agenda

The agenda for the February 2010 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 OPPS.
- Using single and multiple procedure claims data for CMS' determination of APC group weights.
- Addressing other technical issues concerning APC group structure.

Note: The subject matter before the Panel will be limited to these and related topics. Issues related to calculation of the OPPS conversion factor, charge compression, pass-through payments, or wage adjustments are not within the scope of the Panel's purpose. Therefore, these issues will not be considered for presentations and/or comments. There will be no exceptions to this rule. We appreciate your cooperation on this matter.

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 to submit data for the Panel's and CMS staff's review.

III. Written Comments and Suggested Agenda Topics

Hardcopy and electronic written comments and suggested agenda topics should be sent to the DFO as specified in the **ADDRESSES** section of this notice. The DFO must receive these items by 5 p.m. (e.s.t.), Monday, January 13, 2010. There will be no exceptions. We appreciate your cooperation on this matter.

The written comments and suggested agenda topics submitted for the February 2010 APC Panel meeting must fall within the subject categories outlined in the Panel's Charter and as listed in the Agenda section of this notice.

IV. Oral Presentations

Individuals or organizations wishing to make 5-minute oral presentations must submit hardcopy and electronic versions of their presentations to the DFO by 5 p.m. (e.s.t.), Monday, January 13, 2010, for consideration.

The number of oral presentations may be limited by the time available. Oral presentations should not exceed 5 minutes in length for an individual or an organization.

The Chair may further limit time allowed for presentations due to the number of oral presentations, if necessary.

V. Presenter and Presentation Information

All presenters must submit Form CMS–20017 (revised 01/07). Hardcopies are required for oral presentations; however, electronic submissions of Form CMS–20017 are optional. The DFO must receive the following information from those wishing to make oral presentations:

- Form CMS–20017 completed with all pertinent information identified on the first page of the presentation.
- One hardcopy of presentation.
- Electronic copy of presentation.
- Personal registration information as described in the ''Meeting Attendance'' section below.
- Those persons wishing to submit comments only must send hardcopy and electronic versions of their comments, but they are not required to submit Form CMS–20017.

VI. Collection of Information Requirements

This document does not impose any 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).

VII. Oral Comments

In addition to formal oral presentations, there will be 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.

VIII. Meeting Attendance

The meeting is open to the public; however, attendance is limited to space available. Attendance will be determined on a first-come, first-served basis.

Persons wishing to attend this meeting, which is located on Federal property, must e-mail the DFO to register in advance no later than 5 p.m. (e.s.t.), Wednesday, February 10, 2010. A confirmation will be sent to the requester(s) by return e-mail.

The following personal information must be e-mailed to the DFO by the date and time above:

- Name(s) of attendee(s).
- Title(s).
- Organization.
- E-mail address(es).
- Telephone number(s).

IX. Security, Building, and Parking Guidelines

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

- Persons attending the meeting including presenters must be registered and on the attendance list by the prescribed date.
- Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting.
- Attendees must present photographic identification to the Federal Protective Service or Guard Service personnel before entering 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, such as laptops, cell phones, and palm pilots, 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.

X. Special Accommodations

Individuals requiring sign-language interpretation or other special accommodations must send a request for these services to the DFO by 5 p.m. (e.s.t.), Wednesday, February 10, 2010.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital

Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: December 11, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E9–30123 Filed 12–17–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0575]

Incorporation of New Science Into Regulatory Decisionmaking Within the Center for Devices and Radiological Health; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled: ''Incorporation of New Science Into Regulatory Decisionmaking Within the Center for Devices and Radiological Health.'' The purpose of the public meeting is to identify strategies and means for incorporating new science into the regulatory decisionmaking process within the agency's Center for Devices and Radiological Health (CDRH). New science may include novel technologies or novel uses of existing technologies, evolving information and knowledge, or new methods to support decisionmaking. FDA is seeking input on a number of specific questions regarding how CDRH should anticipate and respond to new or evolving scientific knowledge in a manner that is consistent with our mission to protect and promote the public health, and requests comments on this topic.

Dates and Time: The public workshop will be held on February 9, 2010, from 8 a.m. to 5 p.m. Persons interested in attending the meeting must register by 5 p.m. on February 3, 2010.

Location: The public meeting will be held at the Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Maggie Dietrich, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 5449, Silver Spring, MD 20993–0002, 301–796–5094, FAX: 301–847–8510, e-mail: *maggie.dietrich@fda.hhs.gov*.

Registration: Register online at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list). Provide complete contact information for each attendee, including name, title, affiliation, address, e-mail, and telephone number. Registration requests should be received by February 3, 2010. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the public meeting will be provided on a space-available basis beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Maggie Dietrich (see *Contact Person*) at least 7 days in advance.

Comments: FDA is holding this public meeting to obtain information on a number of specific questions regarding how CDRH should anticipate and respond to new or evolving scientific knowledge in a manner that is consistent with FDA's mission to protect and promote the public health. The deadline for submitting comments regarding this public meeting is February 24, 2010.

Regardless of attendance at the public meeting, interested persons may submit written or electronic comments. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Please also indicate the specific question(s) addressed. (See section II of this document.) Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's CDRH uses science to guide our regulatory decisions, including those related to premarket approval or clearance, postmarket oversight, and compliance.

CDRH faces unique challenges in that the products we regulate are constantly changing, either through incremental or disruptive advances. Simultaneously, our understanding of the products we oversee is subject to change as we obtain new scientific information or develop new methods to assess existing data.

Given the ever-changing environment in which we operate, CDRH's regulatory decisionmaking process must be able to adapt as science evolves and as new information emerges about the risks or benefits of particular medical devices or radiation-emitting electronic products. For example, in some cases, new information gathered about the risk-benefit profile of a device on the market may justify requiring additional data on similar types of devices during premarket review, in order to provide sufficient confidence in the product's safety and effectiveness. At the same time, the center seeks to foster innovation by providing industry with a reasonable degree of predictability in our regulatory pathways. Determining the optimal way to anticipate and respond to new science is an important challenge, and the center seeks public input on how to best address it.

CDRH has formed an internal Task Force on Utilization of New Science in Regulatory Decisionmaking to review how the center uses science in our regulatory decisionmaking process, and to make recommendations for enhancements. The principal goals of the Task Force are: (1) To propose systems that will allow CDRH to be ''predictably adaptive'' to new science; and (2) to identify proactive steps that CDRH can take to keep staff abreast of new science and increase our technical competence and analytic capability in order to enhance our decisionmaking.

The notion of ''predictable adaptability'' refers to having the flexibility to appropriately respond to changes in science, while doing so through a reasonably consistent process. Given that scientific knowledge is continually changing, the model of being ''predictable'' by always requiring the same type and level of scientific evidence to justify decisions will not necessarily suffice. As the scientific landscape changes, the kind of information we need in order to make well-supported decisions may change. In the past, CDRH has sometimes incorporated new science into our regulatory decisionmaking on an ad hoc, non-transparent basis. Such an approach can result in inconsistent regulatory expectations and less predictable decisionmaking.

CDRH seeks to move toward a different model of predictability: Creating and adhering to clear procedures for adapting to new science, and applying a consistent rationale for doing so in as timely and transparent a manner as is appropriate and feasible. In order to achieve this goal, the center