

additional fee/profit for exceptional performance in areas critical to the success of the Medicare FFS program. For example, and specific to provider satisfaction, we currently measure, evaluate, and reward MACs for the quality (accuracy, completeness, customer skills, and adherence to the Privacy Act of 1974) of their customer service representatives' responses to provider telephone calls and the providers' level of satisfaction with the MAC's Web site. The amount of award fee earned by the MAC is based on our comprehensive evaluation of the MAC's performance against specific, written quality measures and evaluation criteria.

Prior to the enactment of MACRA, the law required that MAC contracts be recompeted no less frequently than once every 5 years, which created the potential for frequent turnover in these critical contracts and disruption for Medicare providers and suppliers. With the enactment of MACRA, we are now able to renew a MAC contract for up to 10 years and reduce the potential for frequent turnover if the MAC meets or exceeds our performance objectives; conversely, we may still utilize competitive procedures sooner than 10 years in the event that a MAC does not meet our performance objectives. In concert with or in (partial or full) replacement of our award fee process, we are considering incorporating an "award term" concept into MAC contracting, meaning that we may incentivize and reward consistently, well-performing MACs with a longer-term contract (but not longer than 10 years). For example, MACs that consistently exceed our performance standards may be rewarded with a longer-term contract (up to 10 years); whereas, MACs that do not consistently exceed our performance standards may be limited to a shorter-term contract (more or less than 5 years). Therefore, we are soliciting public comment on the following questions regarding MAC incentives for exceptional performance:

- Do you have any concerns or suggestions related to development of a potential "award term" strategy and plan?
- Do you have any other suggestions for incentivizing and rewarding exceptional MAC performance?
- Are there any specific metrics or evaluation criteria that would be valuable in measuring the level and quality of the service provided by a MAC?
- Are there any specific metrics or evaluation criteria that would be valuable in measuring the level and quality of the MAC's relationships

(including education and outreach) with providers?

Section 509(c) of MACRA directs us to make some MAC performance metrics available to the public, to the extent that doing so can be done in a manner that does not compromise the competitive procurement process. Therefore, we are requesting comment on the following questions regarding MAC performance transparency:

- With regard to the MAC's quality and level of service and performance, what types or kinds of information should be published for public release?
- If we were to publish the results of the evaluation of a MAC's performance on our Web site, which types of metrics or information should be made available for public release?

We are also soliciting public comment on potential MAC jurisdictional changes. Currently, there are 12 A/B MAC jurisdictions; in 2010, we announced a plan to consolidate FFS claims operations to 10 A/B MAC jurisdictions over the course of several years. However, in 2014, we announced that we were postponing the consolidation of Jurisdictions 8 (which encompasses the states of Indiana and Michigan) and 15 (which encompasses Kentucky and Ohio) to form "Jurisdiction I" and the consolidation of Jurisdictions 5 (Iowa, Kansas, Missouri and Nebraska) and 6 (Illinois, Minnesota, and Wisconsin) to form "Jurisdiction G." For more information on our 2010 strategy for consolidating A/B MAC jurisdictions, as well as our 2014 decision to postpone the final 2 jurisdictional consolidations, see <https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/RFI-Announcement-AB-MAC-March-2014.pdf>

Accordingly, we are requesting comment on the following question:

- What would the advantages and disadvantages be if CMS completed the last two MAC consolidations?

III. Collection of Information Requirements

This request for information document does not impose any information collection requirements. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA) at 5 CFR 1320.3(h)(4), we believe it is a general solicitation of comments from the public. Therefore, it is exempt from the requirements of the PRA (44 U.S.C. 3501 *et seq.*).

IV. 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 issue a subsequent document, we will respond to the comments in the preamble to that document.

Dated: November 23, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Allergenic Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Allergenic Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 21, 2016, from 8:30 a.m. to 4 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Contact Person: Janie Kim or Denise Royster, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002, 301-796-9016 or 240-402-8158, email: Janie.kim@fda.hhs.gov or Denise.royster@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting

cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On January 21, 2016, the Committee will meet in an open session to discuss safety and effectiveness data, including challenge study endpoints, for licensure of food allergy immunotherapy products, and the clinical development of aeroallergen immunotherapy products for the prevention of respiratory allergic disease.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 6, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 29, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 31, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Janie Kim at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 15, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Risk Communication Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Risk Communication Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 16, 2016, from 9 a.m. to 5 p.m. and February 17, 2016, from 9 a.m. to 4 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Contact Person: Lee L. Zwanziger, Risk Communication Staff, Office of Planning, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 32, Rm. 3354, Silver Spring, MD 20993, 301-796-9151, FAX: 301-847-3540, email: RCAC@FDA.HHS.GOV, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On February 16 and 17, 2016, the Committee will discuss recent developments in risk communications and related sciences, and possible approaches and applications in the context of FDA communications.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 9, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on February 16, 2016, and 1 p.m. and 1:30 p.m. on February 17, 2016. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 25, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the