DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2015–0001]

Final Revised Vaccine Information Materials for Multiple Pediatric Vaccines (''Your Child's First Vaccines'')

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

ACTION: Notice

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA)(42 U.S.C. 300aa–26), the CDC must develop vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. On January 9, 2015, CDC published a notice in the **Federal Register** (80 FR 1416) seeking public comments on proposed updated vaccine information materials for multiple pediatric vaccines (''Your Baby's First Vaccines''). Following review of comments submitted and consultation as required under the law, CDC has finalized the materials. A copy of the final vaccine information materials for multiple pediatric vaccines (''Your Child's First Vaccines'') is available to download from *http://www.cdc.gov/vaccines/hcp/vis/index.html* or *http://www.regulations.gov* (see Docket Number CDC–2015–0001).

DATES: Beginning no later than March 1, 2016, each health care provider who chooses to use the multiple pediatric vaccines Vaccine Information Statement (''Your Child's First Vaccines'') when administering multiple pediatric vaccines to any child in the United States shall provide copies of the relevant vaccine information materials contained in this notice rather than the previous edition (dated October 22, 2014) in conformance with the November 5, 2015 CDC Instructions for the Use of Vaccine Information Statements prior to providing such vaccinations.

FOR FURTHER INFORMATION CONTACT: Suzanne Johnson-DeLeon (*msj1@cdc.gov*), National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop A–19, 1600 Clifton Road NE., Atlanta, Georgia 30329.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660), as amended by section 708 of Public Law 103–183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa–26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers in the United States to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program (VICP).

Development and revision of the vaccine information materials, also known as Vaccine Information Statements (VIS), have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

(1) A concise description of the benefits of the vaccine,

(2) A concise description of the risks associated with the vaccine,

(3) A statement of the availability of the National Vaccine Injury Compensation Program, and

(4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Since then, the following vaccines have been added to the National Vaccine Injury Compensation Program, requiring use of vaccine information materials for them as well: Hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, rotavirus, hepatitis A, meningococcal, human papillomavirus (HPV), and seasonal influenza vaccines. Instructions for use of the vaccine information materials are found on the CDC Web site at: *http://www.cdc.gov/vaccines/hcp/vis/index.html.*

Revised Vaccine Information Materials

The multiple pediatric vaccines information materials referenced in this notice were developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and healthcare provider organizations. Following consultation and review of comments submitted, the vaccine information materials covering multiple pediatric vaccines (''Your Child's First Vaccines'') have been finalized and are available to download from *http://www.cdc.gov/vaccines/hcp/vis/index.html* or *http://www.regulations.gov* (see Docket Number CDC–2015–0001). The Vaccine Information Statement (VIS) is ''Your Child's First Vaccines: What You Need to Know'' (publication date November 5, 2015).

With publication of this notice, as of March 1, 2016, all health care providers who choose to use the multiple pediatric vaccines Vaccine Information Statement (''Your Child's First Vaccines'') when administering multiple pediatric vaccines to any child in the United States shall provide copies of the relevant vaccine information materials contained in this notice rather than the previous edition (dated October 22, 2014) in conformance with CDC's November 5, 2015 Instructions for the Use of Vaccine Information Statements.

Dated: December 16, 2015.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2015–31990 Filed 12–18–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1653–NC]

Medicare Program; Request for Information Regarding the Awarding and the Administration of Medicare Administrative Contractor Contracts

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

ACTION: Request for information.

SUMMARY: This request for information solicits public comment on the processes and procedures that we could use to leverage new legal authorities to— incentivize and reward exceptional Medicare Administrative Contractor (MAC) contract performance; publish performance information on each MAC,

to the extent permitted by law; and make MAC jurisdictional changes.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on February 19, 2016.

ADDRESSES: In commenting, refer to file code CMS–1653–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1653–NC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1653–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Debra Bowman, (410) 786–4941. Phyllis Atkins-Mackey, (410) 786–9362. Megan Martino, (215) 861–4425. Sue Pelella, (215) 861–4245.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

For several decades after Medicare's inception in 1966, private health care insurers, known as Part A Fiscal Intermediaries (FI) and Part B carriers, processed medical claims for Medicare beneficiaries. Section 911 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) added section 1874A to the Social Security Act (the Act) to require the Secretary of Health and Human Services (the Secretary) to replace Part A FIs and Part B carriers with Medicare Administrative Contractors (MACs). This contracting reform was intended to improve Medicare's administrative services to beneficiaries and health care providers through the use of new contracting tools, including competition and performance incentives.

Currently, we award MAC contracts through use of competitive procedures in accordance with the Federal Acquisition Regulation (FAR). As authorized by the MMA, we established MACs as multistate, regional contractors responsible for administering both Medicare Part A and Medicare Part B claims. The transition from the Part A FIs and Part B carriers to MACs began in 2006, and the last FI and carrier contractor operations ended by September 2013.

We rely on a network of 16 MACs to process Medicare claims, including 12 MACs that administer both Part A and Part B claims and 4 MACs that specialize in administering Part B claims for durable medical equipment, prosthetics, orthotics, and supplies. MACs serve as the primary operational contact between the Medicare Fee-For-Service (FFS) program and approximately 1.5 million health care providers and suppliers enrolled in the program. MACs process Medicare claims, enroll health care providers and suppliers in the Medicare program, educate providers and suppliers on Medicare billing requirements, and answer provider and supplier inquiries. Collectively, the MACs process nearly 4.9 million Medicare claims each business day and disburse more than $365 billion annually in program payments.

Section 509(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) extended the maximum length of a MAC contract, inclusive of all option and renewal periods, from 5 years to 10 years. Section 509(c) of MACRA added a clause to section 1874A(b)(3)(A) of the Act that requires the Secretary, to the extent possible without compromising the process for entering into and renewing contracts with MACs, to make available to the public the performance of each MAC with respect to such performance requirements and measurement standards.

II. Provisions of the Request for Information

The Government Accountability Office (GAO) has recently noted that, now that we have accomplished the major milestone of fully implementing and transitioning to the MAC environment, we have the opportunity to consider whether some additional contracting mechanisms could be utilized to further improve MAC performance. Consistent with the new authority provided under MACRA and the recommendation provided by GAO, we are evaluating numerous elements of our MAC acquisition strategy, including potential adjustments to our MAC contract terms and conditions. The scope of our evaluation includes the processes and procedures that we use for awarding the MAC contracts and administering the MAC contracts after award.

We currently use a cost-plus-award-fee contract type for the MAC contracts, meaning that MACs are financially incentivized and rewarded with

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.

[FR Doc. 2015–32027 Filed 12–18–15; 8:45 am]

BILLING CODE 4120–01–P

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