Desk Officer. Fax Number: (202) 395–6974.

Email: *OIRA_submission@omb.eop.gov*.

Dated: January 24, 2012.

Martique Jones,

Director, Regulations Development Group, Division-B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–1945 Filed 1–27–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–855I and CMS–855R]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection. *Title of Information Collection:* Medicare Enrollment Application for Physician and Non-Physician Practitioners. *Use:* Health care practitioners who wish to enroll in the Medicare program must complete the CMS 855I enrollment application. It is submitted at the time the applicant first requests a Medicare billing number. The application is used by the Medicare Administrative Contractor (MAC), to collect data to assure the applicant has the necessary professional and/or business credentials to provide the health care services for which they intend to bill Medicare including information that allows the MAC to correctly price, process and pay the applicant's claims. It also gathers information that allows the MAC to ensure that the practitioner is not sanctioned from the Medicare program, or debarred, suspended or excluded from any other Federal agency or program. *Form Number:* CMS–855I (OCN 0938–0685). *Frequency:* Once and Occasionally. *Affected Public:* Private Sector (Business or other for-profit and not-for-profit institutions). *Number of Respondents:* 345,000. *Total Annual Responses:* 345,000. *Total Annual Hours:* 824,000. (For policy questions regarding this collection contact Kimberly McPhillips at (410) 786–5374. For all other issues call (410) 786–1326.)

2. *Type of Information Collection Request:* New collection. *Title of Information Collection:* Medicare Enrollment Application—Reassignment of Medicare Benefits. *Use:* Health care practitioners who wish to reassign their benefits in the Medicare program must complete the CMS 855R enrollment application. It is submitted at the time the physician or non-physician practitioner first requests reassignment of his/her Medicare benefits to a group practice, as well as any subsequent reassignments or terminations of established reassignments as requested by the physician or non-physician practitioner. The application is used by the Medicare Administrative Contractor (MAC) to collect data to assure the applicant has the necessary information that allows the MAC to correctly establish or terminate the reassignment. *Form Number:* CMS–855R (OCN 0938-New). *Frequency:* Occasionally. *Affected Public:* Private Sector (Business or other for-profit and not-for-profit institutions). *Number of Respondents:* 100,000. *Total Annual Responses:* 100,000. *Total Annual Hours:* 50,000. (For policy questions regarding this collection contact Kimberly McPhillips at (410) 786–5374. For all other issues call (410) 786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office at (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *March 30, 2012:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 24, 2012.

Martique Jones,

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

[FR Doc. 2012–1951 Filed 1–27–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9970–NC]

Request for Information Regarding the Reinsurance Program Under the Affordable Care Act

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

ACTION: Request for information.

SUMMARY: This notice is a request for information (RFI) to gain market information on entities that could administer a transitional reinsurance program. This RFI will inform one or more future Requests for Proposals (RFP). This RFI solicits information about entities that could function as a reinsurance entity for the transitional reinsurance program. CMS or one or more States may contract for services required to fulfill the statutory and regulatory requirements of the reinsurance entity.

DATES: Submit written or electronic comments by February 29, 2012.

ADDRESSES: In responding, please refer to file code CMS–9970–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit responses 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 instructions under the ''More Search Options'' tab.

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–9970–NC, P.O. Box 8016, Baltimore, MD 21244–8016.

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–9970–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of 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, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

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

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Milan Shah, (301) 492–4427.

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.

We note that responses to this RFI are not offers, and cannot be accepted by the Government to form a binding contract or to issue a grant. The purpose of this RFI is to inform one or more Requests for Proposals, not to gather public comments on the proposed rules for reinsurance, risk corridors, or risk adjustment under the Affordable Care Act. Those comments have been collected and are being evaluated separately. Information obtained in response to this RFI may be used by the Government for program planning and development, or other purposes with or without attribution. Do not include any information that might be considered proprietary or confidential.

I. Background

Section 1341 of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010) (the Affordable Care Act), provides that each State must establish a transitional reinsurance program to help stabilize premiums for coverage in the individual market during the first three years of Exchange operation (2014–2016). The reinsurance program, which is a State-based program, will reduce the uncertainty of insurance risk in the individual market by making payments for high-cost cases. This program will stabilize individual market rate increases that might otherwise occur because of the immediate enrollment of individuals with unknown health status, potentially including, at the State's discretion, those currently in State high-risk pools. CMS published proposed rules for States and health insurance issuers for this reinsurance program on July 15, 2011 (76 FR 41930).

The Affordable Care Act instructs each State to establish or contract with an entity to carry out the reinsurance program. Section 1321(c)(1) of the Affordable Care Act directs the Secretary to take such actions as are necessary to implement the reinsurance program in a State if a State has not taken action necessary to do so. The reinsurance entity, whether operating under contract with a State or CMS, must be a not-for-profit organization with a tax-exempt status.

II. Request for Information

This RFI seeks comment on the entities that could carry out the transitional reinsurance program. CMS may enter into one or more contracts to fulfill the statutory and regulatory requirements of the transitional reinsurance program established under section 1341 of the Affordable Care Act depending on the workload and number of States that would require assistance. In such a case, the contractor may be tasked with one or more of the following functions:

- Collecting reinsurance contributions;
- Accepting and validating requests for reinsurance payments;
- Remitting reinsurance payments;
- Reconciling and verifying reinsurance contributions and payments;
- Maintaining records; and,
- Providing customer support to issuers.

CMS is seeking to engage formally, in a transparent and participatory manner, with entities that understand the reinsurance market, and would be able to perform the responsibilities of a reinsurance entity under the statute and associated regulations. In carrying out the transitional reinsurance program, CMS seeks to mitigate conflicts of interest (COIs) that may arise if potential market competitors operate the reinsurance program. As such, we request any information on potential COIs, and potential avenues for mitigation, from all stakeholders, including issuers and third-party administrators.

Infrastructure

1. Does your organization operate as a not-for-profit reinsurance entity in the State(s) in which you currently conduct business?

2. If your organization operates as a reinsurance entity but does not function as a not-for-profit, what steps would have to be taken to convert the organization or the part of that organization responsible for reinsurance operations into a not-for-profit entity?

What other considerations should be taken into account in connection with such a conversion?

3. What other steps must your organization take in order to be prepared to smoothly transition into a role as administrator of a new temporary reinsurance program?

4. Does your organization operate nationally or in limited geographic areas? If the latter, what are the geographic areas?

5. Would your organization be able and willing to contract with a State and/or the Federal government to operate a temporary reinsurance program?

6. Are there any State and/or local licensing requirements that must be considered by an organization operating as such a reinsurance entity?

7. What potential conflicts of interest (COIs) could arise if your organization were to operate such a reinsurance program as a not-for-profit entity? How might these COIs be mitigated?

8. For organizations that do not currently have COI mitigation programs, what steps would have to be taken to develop and execute such a program?

9. What is a reasonable amount of time for your organization to become fully operational (for example, have all systems in place to operate a reinsurance program) after the date of a contract award? What resources would be necessary?

Collection and Disbursement of Reinsurance Funds

10. Describe your organization's ability to perform the following functions:

- Collecting reinsurance contributions;
- Accepting and validating requests for reinsurance payments;
- Remitting reinsurance payments; and,
- Reconciling and verifying reinsurance contributions and payments.

11. What services related to the collection of reinsurance contributions, or disbursement of reinsurance payments to another entity would your organization need to subcontract due to a lack of capacity, expertise, or experience?

12. What COIs could arise for such potential subcontractors?

Data Collection

13. Describe current data systems that are used by your organization, including any standards, security systems, and web-based interactive structure. Are your systems compliant or have the capability of being Section 508 compliant (*http://www.section508.gov/*)?

14. Do your organization's current data systems have the capability to interface with external systems to accept data and reports? If yes, what types of interfaces are currently in place?

15. What data are currently collected by your organization related to medical costs?

16. What is your organization's current capacity for collecting and verifying claims submissions from issuers? What processes does your organization have in place to ensure confidentiality and security protections of patient information?

17. In what formats does your organization currently collect data? Can your organization support other formats? If so, which ones?

18. Would your organization need to subcontract any services related to data collection?

19. What COIs could arise for such subcontractors?

Customer Support

20. What telecommunication and technical support systems does your organization currently maintain for health insurance issuers or other commercial clients (for example, Web sites, 24-hour hotlines, helpdesk)?

21. Are your support systems compliant or have the capability of being Section 508 compliant (*http://www.section508.gov/*)?

22. Would your organization need to subcontract any services related to data collection?

23. What COIs could arise for such subcontractors?

Evaluation

24. Does your organization currently conduct evaluations of operations and activities? Do such evaluations include a financial assessment of your organization's activities?

25. What are your organization's current financial and data reconciliation processes?

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

Dated: January 20, 2012.

Charles Littleton,

Contracting Officer, Office of Acquisition and Grants Management, Centers for Medicare and Medicaid Services.

[FR Doc. 2012–1944 Filed 1–27–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Pulmonary-Allergy Drugs 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: Pulmonary-Allergy Drugs 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 23, 2012, from 8:30 a.m. to 5 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. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You'', click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Nicole Vesely, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, (301) 796–9001, Fax: (301) 847–8533, email: *PADAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1-(800) 741–8138 (301) 443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application 202450, for aclidinium bromide, sponsored by Forest Laboratories, for the proposed