

vendor into the Board's contract writing and invoice payment system. As a result of the criteria used by the Board to evaluate proposals, the Solicitation Package may also include the Past Performance Data Sheet and Past Performance Questionnaire (Attachment I of FR 1400B) if past performance is an evaluation factor. Typically, if past performance is considered an evaluation factor, the vendor is asked to submit information on up to three previous contracts whose effort is recent and relevant to the effort required by the solicitation.

Solicitations that require the vendor to process, store, or transmit data from the Board will contain the Vendor Risk Management Offeror Questionnaire (FR 1400C). The questionnaire will be specific to the security controls surrounding the vendor's proposed application that will be used to process, store, or transmit the data. Security controls will be defined and prioritized based on the Federal Information Security Modernization Act of 2014 (FISMA) and the National Institute of Standards and Technology (NIST) Special Publication 800-53 (Security Controls and Assessment Procedures for Federal Information Systems and Organizations). In addition, for solicitations that have subcontracting opportunities and are expected to exceed \$100,000 (\$300,000 for construction), a non-covered company vendor is required to submit a subcontracting plan in its own format, with its proposal. Then, if the vendor is the chosen vendor and awarded a contract, the vendor is required to provide the quarterly Subcontracting Reports (FR 1400D) to the Board, which shall document the vendor's participation achievement on a cumulative basis. Information from the Subcontracting Report is used to assist the Board in fulfilling the requirement in Section 342(e) of the Dodd-Frank Act that requires the Board to submit to Congress an annual report regarding the fair inclusion of minorities and women in contracting.

Proposed revisions: To assist the Board's competitive vendor solicitation process, the Board is proposing to revise the FR 1400 by (1) reformatting and updating the Solicitation Package, including the Solicitation, Offer, and Award Form (SOA), Supplier Information Form, Past Performance Data Sheet, and Past Performance Questionnaire (FR 1400B); (2) adding the Vendor Risk Management Offeror Questionnaire (FR 1400C); and (3) revising the Subcontracting Report (FR 1400D) to improve clarity and gather specific information in accordance with

the Board's subcontracting goals. Lastly, the Board proposes to discontinue the use of the Request for Price Quotation Form (RFP/RFPQ). The purpose of the RFPQ form will be absorbed into the FR 1400B.

Legal authorization and confidentiality: The FR 1400A is voluntary. For prospective vendors that decide to submit proposals to the Board, the FR 1400B, 1400C, and 1400D are required to obtain a benefit, in order to be eligible for the award of a contract.

The FR 1400 is authorized pursuant to sections 10 and 11 of the Federal Reserve Act ("FRA"), and section 342(c) of the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank"). Sections 10(3) and 11 of the FRA (12 U.S.C. 243 and 248(l)) grant the Board full authority to manage its buildings and its staff. Section 10(4) of the FRA (12 U.S.C. 244) authorizes the Board to determine and prescribe the manner in which its obligations shall be incurred and its disbursements and expenses allowed and paid. Therefore, the Board can solicit proposals and seek the information in FR 1400 from prospective vendors.

Additionally, the FR 1400 is authorized by section 342(c) of Dodd-Frank (12 U.S.C. 5452(c)), which requires the Board to develop and implement standards and procedures for the review and evaluation of contract proposals and for hiring service providers that include a component that gives consideration to the diversity of a prospective vendor and the fair inclusion of women and minorities in the workforce of such vendor and any subcontractor.

A vendor generally may request confidential treatment for information submitted during the solicitation process, and the Board will review the request to determine if the data may be kept confidential under exemption 4 of the Freedom of Information Act, which protects from disclosure trade secrets and commercial or financial information (5 U.S.C. 552(b)(4)).

Board of Governors of the Federal Reserve System, September 24, 2018.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2018-21126 Filed 9-27-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10464]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by November 27, 2018.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. **Electronically.** You may send 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) that are 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.

To obtain copies of a supporting statement and any related forms for the

proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10464 Agent/Broker Data Collection in Federally Facilitated Health Insurance Exchanges

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **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.

Information Collection

1. *Title of Information Collection:* Agent/Broker Data Collection in Federally Facilitated Health Insurance Exchanges; *Type of Information Collection Request:* Revision of a currently approved collection; *Use:* The Patient Protection and Affordable Care Act, Public Law 111-148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111-152, enacted on March 30, 2010 (collectively, "Affordable Care Act"), expands access to health insurance for individuals and employees of small businesses through

the establishment of new Affordable Insurance Exchanges (Exchanges), also called Marketplaces, including the Small Business Health Options Program (SHOP). Revised requirements pertaining to agents/brokers completing Federally-facilitated Exchange (FFE) registration are discussed in the final rule published on February 27, 2015 for the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016 (CMS-9944-F). These updated requirements direct agents/brokers to submit additional fields related to basic contact information and National Producer Number (NPN). Current state licensure and relevant health lines of authority (LOA) are then validated using the National Insurance Producer Registry (NIPR) database. This ICR serves as the formal request for renewal and also includes some of the information collection requirements from the previously approved final rule. *Form Number:* CMS-10464 (OMB control number: 0938-1204); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 52,000; *Number of Responses:* 52,000; *Total Annual Hours:* 12,480. (For questions regarding this collection contact Madeline Pellish at 301-492-4390.)

Dated: September 25, 2018.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018-21171 Filed 9-27-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0333]

Richard M. Fleming; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is denying a request for a hearing submitted by Richard M. Fleming (Fleming) and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debaring Fleming for 10 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Fleming was convicted of two felonies under Federal law that

involved fraud. Additionally, Fleming has demonstrated a pattern of conduct sufficient to find that there is reason to believe that he may violate requirements under the FD&C Act relating to drug products. In determining the appropriateness and period of Fleming's debarment, FDA considered the relevant factors listed in the FD&C Act. Fleming failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: The order is applicable September 28, 2018.

ADDRESSES: Any application for termination of debarment by Fleming under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: Your application must include the Docket No. FDA-2013-N-