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]

**BILLING CODE 4120–01–P**

## 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) debarring 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–

0333. An application will be placed in the docket and, unless submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

**FOR FURTHER INFORMATION CONTACT:** Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 306(b)(2)(B)(ii)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(ii)(I)) permits FDA to debar an individual if it finds that the individual: (1) Has been convicted of a felony that involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense and (2) based on the conviction and other information, the individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that the person may violate requirements under the FD&C Act relating to drug products.

On April 24, 2009, Fleming, the president of, and sole physician at, Fleming Heart and Health Institute, P.C. (FHHI), pled guilty to one felony count of healthcare fraud, in violation of 18 U.S.C. 1347 and 2, and one felony count of mail fraud, in violation of 18 U.S.C. 1341 and 2. On August 20, 2009, the U.S. District Court for the District of Nebraska entered a judgment of conviction against Fleming on these counts and sentenced Fleming to 5 years of probation.

Fleming's convictions stemmed from two separate actions. Fleming, through his practice at FHHI, performed various imaging studies and submitted reimbursement claims to Medicare and Medicaid. Fleming pled guilty to one count of felony healthcare fraud in violation of 18 U.S.C. 1347 and 2 for conduct related to the submission of a reimbursement claim. Fleming admitted to knowingly executing and attempting to execute a scheme to defraud Medicare and Medicaid healthcare benefit programs in connection with the delivery of and payment for healthcare benefits, items, and services, namely by submitting payment claims for tomographic myocardial perfusion imaging studies that he did not actually perform. Fleming also pled guilty to one count of felony mail fraud in violation of 18 U.S.C. 1341 and 2 for conduct relating to money paid him to conduct a clinical study of a soy chip food product for the purpose of evaluating health benefits. As Fleming admitted during his guilty plea, he received approximately $35,000 for conducting a clinical trial, but he fabricated data for certain subjects.

By letter dated November 18, 2013, FDA's Office of Regulatory Affairs (ORA) notified Fleming of its proposal to debar him for 10 years from providing services in any capacity to a person having an approved or pending drug product application. The proposal explained that the proposed debarment period was based on both felony fraud convictions. ORA stated that these convictions establish Fleming's disregard for his professional obligations and the law and provide reason to believe that, if he were to provide services to a person that has an approved or pending drug application, he may violate requirements under the FD&C Act relating to drug products. Therefore, ORA found that Fleming was subject to debarment under section 306(b)(2)(B)(ii)(I) of the FD&C Act.

The proposal noted that the maximum debarment period for each offense is 5 years and that FDA may determine whether debarment periods for multiple offenses should run concurrently or consecutively. The proposal outlined findings concerning the four relevant factors that ORA considered in determining the appropriateness and period of debarment, as provided in section 306(c)(3) of the FD&C Act: (1) The nature and seriousness of any offense, (2) the nature and extent of management participation in any offense, (3) the nature and extent of voluntary steps to mitigate the impact on the public, and (4) prior convictions under the FD&C Act or other acts involving matters within FDA's jurisdiction. ORA found that the first three were unfavorable factors and that the last was a favorable factor for Fleming. The notice concluded that ''the unfavorable factors cumulatively far outweigh the sole favorable factor.'' Accordingly, FDA determines that debarment is appropriate, and that the 5-year period of debarment for each of the two offenses should be served consecutively, resulting in a total debarment period of 10 years.

Fleming timely responded to the proposal to debar and requested a hearing. Fleming's response included multiple documents in which he raises variations of two central arguments, namely that: (1) His guilty plea ''does not state a crime'' and (2) he is ''actually innocent.'' Fleming contends that his guilty plea was a ''holographic plea'' to protect his children.

Under the authority delegated to him by the Commissioner of Food and Drugs, the Director of the Office of Scientific Integrity (OSI) has considered Fleming's request for a hearing. Hearings are granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)).

OSI has considered Fleming's arguments and concludes that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing.

## II. Arguments

Fleming submitted multiple documents in support of his arguments that his guilty plea ''does not state a crime'' and that he is ''actually innocent.'' However, section 306(l) of the FD&C Act defines conviction as when a Federal or State court's judgment of conviction or when a Federal or State court's acceptance of a guilty plea. In Fleming's ''Petition to Enter a Plea of Guilty,'' he stated that he understood the charges against him and that he was voluntarily entering his guilty plea. The court entered a judgment of conviction after accepting Fleming's guilty plea. Federal court is the proper venue for any challenge to Fleming's guilty plea based on a claim of actual innocence, not this remedial proceeding. OSI carefully reviewed Fleming's submission in its entirety, and Fleming does not dispute that the court entered a judgment of conviction or that the court accepted his guilty plea; therefore, Fleming's arguments regarding his actual innocence fail to raise a genuine and substantial issue of fact warranting a hearing.

Under section 306(b)(2)(B)(ii)(I) of the FD&C Act, FDA has the authority to debar an individual convicted of certain Federal felonies, involving, among other things, fraud, if FDA finds that the individual has demonstrated a pattern of conduct giving reason to believe that he may violate requirements under the FD&C Act relating to drug products. The relevant factual issues are whether Fleming was, in fact, convicted of a felony involving fraud and whether there is reason to believe that he may violate requirements under the FD&C Act relating to drug products. Fleming does not dispute that he pled guilty to felony healthcare fraud and felony mail fraud or that, based on these convictions, there is reason to believe that he may violate requirements under the FD&C Act relating to drug products. Therefore, Fleming has failed to raise a genuine and substantial issue of fact warranting a hearing regarding whether he is subject to debarment.

Fleming's response included one argument that may be construed to be a challenge to ORA's proposed findings on the nature and seriousness of his offense. Fleming appears to claim that the imaging studies he performed on his patients were safer than the imaging studies he billed to Medicare and Medicaid. In the proposal to debar, in evaluating the nature and seriousness of the offenses, ORA noted that Fleming was convicted of two felonies, healthcare fraud and mail fraud. ORA considered that he billed Medicare and Medicaid for procedures other than those that he had performed, that he falsified clinical trial data, and that his actions ''have the potential for causing significant loss of public confidence in the healthcare system.'' Fleming's actions took place over a period of several months and demonstrated multiple instances of fraud. While Fleming contends that he performed safer imaging studies than those billed, FDA must weigh this claim against the serious nature of the fraud he committed. Construing Fleming's argument in a light most favorable to him, whether he performed safer imaging studies does not sufficiently counter the very serious nature of fraudulent conduct and is not enough to establish that a shorter debarment period would be appropriate.

Based on the factual findings in the proposal to debar and on the record, OSI finds that a 5-year debarment period for each felony offense is appropriate. The nature and seriousness of Fleming's offense, Fleming's managerial participation, and his lack of voluntary steps to mitigate the impact on the public weigh in favor of debarment. Although Fleming does not appear to have prior criminal convictions involving matters within FDA's jurisdiction, a debarment period of 5 years for each felony conviction is appropriate. As noted in the proposal to debar, the conduct underlying the offenses involved submitting claims for payment for procedures other than the procedures Fleming performed and falsifying clinical trial data, and ''[t]he conduct that form[ed] the basis of [his] conviction occurred in the course of [his] profession and showed disregard for the obligations of [his] profession and the law.'' Based on the pattern of fraudulent conduct, FDA has reason to believe that Fleming may violate the requirements under the FD&C Act relating to drug products. Furthermore, given that Fleming has offered no arguments challenging the proposed determination regarding the extent to which his debarment periods should run concurrently or consecutively, OSI further determines that the 5-year debarment period for each felony conviction should run consecutively, resulting in a total debarment of 10 years.

## III. Findings and Order

Therefore, the Director of OSI, under section 306(b)(2)(B)(i)(I) of the FD&C Act and authority delegated to him by the Commissioner of Food and Drugs, finds that: (1) Fleming has been convicted of a felony which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense and (2) based on the conviction and other information, Fleming has demonstrated a pattern of conduct giving reason to believe that he may violate requirements under the FD&C Act relating to drug products. FDA considered the applicable factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 10 years is appropriate.

As a result of the foregoing findings, Fleming is debarred for 10 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application, who knowingly uses the services of Fleming, in any capacity during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Fleming, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Fleming during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: September 25, 2018.

**George M. Warren,**

*Director, Office of Scientific Integrity.*

[FR Doc. 2018–21210 Filed 9–27–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–D–3304]**

### The Special 510(k) Program; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft