DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10716]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human 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 (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 May 1, 2023.

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, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

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–10716 Applicable Integrated Plan Coverage Decision Letter

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. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Applicable Integrated Plan Coverage Decision Letter; *Use:* Sections 1859(f)(8) of the Act require development of unified grievance and appeals processes for D–SNPs, to the extent feasible. We finalized the implementation of this regulation for integrated organization determinations at § 422.631, effective January 1, 2021. This rule requires applicable integrated plans to send an enrollee a written notice of any adverse decision on an integrated organization determination using a notice that is written in plain language and contains the information detailed at § 422.631(d)(1)(iii).

Applicable integrated plans as defined at § 422.561 are required to issue form CMS–10716 when a request for either a medical service or payment is denied in whole or in part after considering both the Medicare or Medicaid benefit. Applicable integrated plans issue this form to enrollees when the plan reduces, stops, suspends, or denies, in whole or in part, a request for a service or item (including a Part B drug) or a request for payment of a service or item (including a Part B drug) that the enrollee has already received. The form provides the enrollee with information regarding their right to an appeal of the applicable integrated plan's decision and the enrollee will use the instructions to navigate the appeal process. *Form Number:* CMS–10716 (OMB control number: 0938–1386); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 112; *Total Annual Responses:* 24,716; *Total Annual Hours:* 4,120. (For policy questions regarding this collection contact Kristi Sugarman Coats at 415–744–3629.)

Dated: February 23, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–04068 Filed 2–27–23; 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 on Application for Termination of Debarment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is denying Dr. Richard M. Fleming's (Dr. Fleming's) request for a hearing and denying his application for termination of debarment under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Dr. Fleming has failed to file information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is applicable February 28, 2023.

ADDRESSES: You may be submit comments at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *https://www.regulations.gov*.

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

Written/Paper Submissions

• *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 written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0333 for ''Richard M. Fleming; Denial of Hearing on Application for Termination of Debarment.'' Received comments will be placed in the docket and, except for those 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, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 comments. 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 comments 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.govinfo.gov/content/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, 240–402–7500. 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

On April 24, 2009, Dr. 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 Dr. Fleming on these counts and sentenced Dr. Fleming to 5 years of probation. In pleading guilty to those offenses, Dr. Fleming admitted that his convictions stemmed from two separate actions. Dr. Fleming, through his practice at FHHI, performed various imaging studies and submitted reimbursement claims to Medicare and Medicaid. Dr. Fleming's felony healthcare fraud related to the submission of a reimbursement claim. Dr. 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. Dr. Fleming's felony mail fraud violation related to money paid to him to conduct a clinical study of a soy chip food product for the purpose of evaluating health benefits. As Dr. 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, pursuant to section 306(b)(2)(B)(ii)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(ii)(I)), FDA's Office of Regulatory Affairs (ORA) notified Dr. Fleming of its proposal to debar him for 10 years based on those convictions. On September 28, 2018, FDA debarred Dr. Fleming for 10 years from providing services in any capacity to a person with an approved or pending drug product application. Following that debarment, Dr. Fleming made various submissions from September 2018 to October 2018, which FDA construed as a petition for reconsideration and denied on November 28, 2018.

On March 15, 2022, Dr. Fleming applied for termination of debarment pursuant to section 306(d)(1) of the FD&C Act. Absent a conviction reversal, FDA may grant an application to terminate debarment pursuant to section 306(b)(2)(B) only when ''termination serves the interests of justice and adequately protects the integrity of the drug approval process'' (see section 306(d)(3)(B)).

By letter dated July 12, 2022, ORA offered Dr. Fleming an opportunity for a hearing under 21 CFR part 12 on a proposal to deny his application for termination of debarment. In the letter, ORA stated that, considering all the favorable and unfavorable information in light of the remedial public health purposes underlying debarment, terminating Dr. Fleming's debarment would not best serve the interests of justice and would not adequately protect the integrity of the drug approval process.

Under the authority delegated by the Commissioner of Food and Drugs, the Chief Scientist has considered Dr. 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 § 12.24(b) (21 CFR 12.24(b))).

The Chief Scientist has considered Dr. Fleming's arguments, as well as the proposal to deny Dr. Fleming's application for termination of debarment and concludes that there is no genuine and substantial issue of fact requiring a hearing. Further, the Chief Scientist finds that Dr. Fleming's application does not satisfy the grounds for terminating debarment.

II. Arguments

In his response to ORA's proposal to deny his request for termination, Dr. Fleming concedes that the convictions underlying his debarment pursuant to section 306(b)(2)(B)(ii)(I) of the FD&C Act have not been reversed. FDA could therefore only terminate his debarment under section 306(d)(3)(B) if the Agency determined that such termination would serve the interests of justice and adequately protect the integrity of the drug approval process. In the application to terminate his debarment, Dr. Fleming presented three reasons for terminating his debarment: (1) that he was effectively debarred in the period between when he was convicted of the two felony offenses on which his debarment was based and when FDA finalized his debarment; (2) that he has taken training courses related to billing and ethics; and (3) that he has taken steps to prevent future mistakes in billing and collecting data.

In proposing to deny Dr. Fleming's application to terminate his debarment, ORA weighed the seriousness and nature of the offenses that led to his debarment, including his culpability, against his statements regarding other mitigating factors. After accounting for his assertions that he had effectively been debarred since his original convictions, ORA found that Dr. Fleming had not established that terminating his debarment would serve the interests of justice or adequately protect the integrity of the drug approval process. In his request for a hearing on ORA's proposal, Dr. Fleming repeats some of the arguments from his application for termination of debarment and provides some additional context related to his own views on drug regulation, the criminal justice system, and other ethical considerations. He further clarifies some of the corrective actions he has implemented with respect to patient billing.

As a preliminary matter, the Chief Scientist notes Dr. Fleming's request in his application for termination of debarment that FDA consider the time starting from when he was convicted in 2009 as ''time served.'' Dr. Fleming contended that, because he was convicted in 2009, ''the effective period of debarment has been 12+ years.'' While Dr. Fleming does not renew this argument in his request for a hearing on ORA's proposal, the timing of when he was convicted, when ORA proposed his debarment, and when FDA finalized his debarment is not in dispute. Notwithstanding his arguments to the contrary, FDA did not debar Dr. Fleming until the Agency issued the final order debarring him in September 2018. Neither his convictions nor ORA's proposal to debar him started his debarment period pursuant to the Agency's authority under section 306(b)(2)(B)(ii)(I) of the FD&C Act. He thus cannot now argue that his ultimate debarment in September 2018 had any effect whatsoever on him before that time. The Chief Scientist therefore agrees with ORA that terminating his debarment on that basis would not serve the interests of justice or adequately protect the integrity of the drug approval process.

The Chief Scientist further agrees with ORA that Dr. Fleming has not shown that terminating his debarment would serve the interests of justice or adequately protect the drug approval process—even in light of the additional assertions and arguments proffered in support of his hearing request on ORA's proposal. Both offenses underlying his debarment are felony fraud convictions related to the regulation of drugs. As noted in ORA's proposal to deny Dr. Fleming's application for termination, the pattern of fraudulent conduct on which his convictions were based calls into question his ability to comply with the FD&C Act and indicates that he poses a threat to the drug approval process if he were allowed to participate in it. In light of the conduct underlying the convictions on which Dr. Fleming's debarment was based, his assertions that he has taken some courses and adopted corrective measures relative to billing patients and collecting data do not come close to showing that terminating his debarment would serve the interests of justice and adequately protect the drug approval process in the sense contemplated by section 306(d)(3)(B)(ii). Dr. Fleming has thus presented no material factual dispute for a hearing on ORA's proposal to deny the application to terminate his debarment.

III. Conclusion

Therefore, the Chief Scientist, under authority delegated to her, denies Dr. Fleming's application for termination of debarment under section 306(d) of the FD&C Act. A hearing on this request is not necessary because there are no genuine and substantial issues of fact (see § 12.24(b)).

Any person with an approved or pending drug product application who knowingly uses the services of Dr. 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 Dr. Fleming 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 Dr. Fleming during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: February 22, 2023.

Namandjé N. Bumpus,

Chief Scientist.

[FR Doc. 2023–04003 Filed 2–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Interagency Autism Coordinating Committee.

The meeting will be open to the public for virtual viewing via NIH Videocast. Advanced registration is recommended. Individuals who plan to attend the meeting virtually and need special assistance or other reasonable accommodations to virtually view the meeting should notify the Contact Person listed below at least seven (7) business days in advance of the meeting. The open session can be accessed from the NIH Videocast website (*http://videocast.nih.gov/*).

Name of Committee: Interagency Autism Coordinating Committee.

Date: April 4, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Meeting Access: https://videocast.nih.gov/watch=49068.

Agenda: To discuss business, updates, and issues related to ASD research and services activities.

Cost: The meeting is free and open to the public.

Registration: A registration web link will be posted on the IACC website (*www.iacc.hhs.gov*) prior to the meeting. Pre-registration is recommended.

Deadlines: Written/Virtual Public Comment Due *Date:* Wednesday, March 22,