

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.

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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 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: