(OMB control number: 0938–0046); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 7,828; *Total Annual Responses:* 138,000; *Total Annual Hours:* 138,000. (For policy questions regarding this collection contact Lisa Rees at (816) 426–6353).

Dated: December 12, 2022.

William N. Parham, III

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

[FR Doc. 2022–27233 Filed 12–14–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10527, CMS–10260, CMS–10836 and CMS–855A]

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 February 13, 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–10527 Annual Eligibility Redetermination, Product Discontinuation and Renewal Notice

CMS–10260 Medicare Advantage and Prescription Drug Program: Final Marketing Provisions in 42 CFR 422.111(a)(3) and 423.128(a)(3)

CMS–10836 Medicare Plan Performance Warning Information

CMS–855A Medicare Enrollment Application for Institutional Providers

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:* Annual Eligibility Redetermination, Product Discontinuation and Renewal Notice; *Use:* Section 1411(f)(1)(B) of the Affordable Care Act directs the Secretary of Health and Human Services (the Secretary) to establish procedures to redetermine the eligibility of individuals for premium tax credits on a periodic basis in appropriate circumstances. Section 1321(a) of the Affordable Care Act provides authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, qualified health plans (QHPs) and other components of title I of the Affordable Care Act. Under section 2703 of the Public Health Service Act (PHS Act), as added by the Affordable Care Act, and former section 2712 and section 2741 of the PHS Act, enacted by the Health Insurance Portability and Accountability Act of 1996, health insurance issuers in the group and individual markets must guarantee the renewability of coverage unless an exception applies.

The 2014 final rule ''Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges'' (79 FR 52994, September 5, 2014), provides that an Exchange may choose to conduct the annual redetermination process for a plan year (1) in accordance with the existing procedures described in 45 CFR 155.335; (2) in accordance with procedures described in guidance issued by the Secretary for the applicable benefit year; or (3) using an alternative procedure proposed by the Exchange and approved by the Secretary. The 2014 final rule established a renewal and reenrollment hierarchy at 45 CFR 155.335(j) to minimize potential enrollment disruptions. The 2016 final rule ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017'' (81 FR 12204, March 8, 2016) amended the enrollment

hierarchy to further minimize potential disruptions of enrollee eligibility for cost-sharing reductions.

The guidance document ''Guidance on Annual Eligibility Redetermination and Re-enrollment for Exchange Coverage for 2019 and Later Years'' contains the procedures that the Secretary is specifying for the coverage year, as noted in (2) above, and specifies that these procedures will be used by all Exchanges using the federal eligibility and enrollment platform, unless otherwise specified in future guidance or rulemaking.

The 2014 final rule also amended the requirements for product renewal and re-enrollment (or non-renewal) notices to be sent by QHP issuers in the Exchanges and specifies content for these notices. The guidance document ''Updated Federal Standard Renewal and Product Discontinuation Notices, and Enforcement Safe Harbor for Product Discontinuation Notices in Connection with the Open Enrollment Period for Coverage in the Individual Market in the 2020 Benefit Year'' provides standard notices for product discontinuation and renewal to be sent by issuers of individual market QHPs and issuers in the individual market.[1]

The federal standard notices to be sent by issuers of individual market QHPs and issuers in the individual market have been revised to improve consumer understanding and update out-of-date information. The revised notices in this information collection will be required for notices provided in connection with coverage beginning in the 2024 plan year.

Issuers in the small group market may use the draft federal standard small group notices released in the June 26, 2014 bulletin ''Draft Standard Notices When Discontinuing or Renewing a Product in the Small Group or Individual Market'', or any forms of the notice otherwise permitted by applicable laws and regulations. States that are enforcing the guaranteed renewability provisions of the Affordable Care Act may develop their own standard notices for product discontinuances, renewals, or both, provided the state-developed notices are at least as protective as the federal standard notices. *Form Number:* CMS–10527 (OMB control number: 0938–1254); *Frequency:* Annually; *Affected Public:* Private Sector, State, Local, or Tribal Governments; *Number of Respondents:* 1,340; *Total Annual Responses:* 5,881; *Total Annual Hours:* 72,147. (For policy questions regarding this collection contact Usree Bandyopadhyay at 410–786–6650.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Advantage and Prescription Drug Program: Final Marketing Provisions in 42 CFR 422.111(a)(3) and 423.128(a)(3); *Use:* CMS requires MA organizations and Part D sponsors to use the standardized documents being submitted for OMB approval to satisfy disclosure requirements mandated by section 1851 (d)(3)(A) of the Act and § 422.111 for MA organizations and section 1860D–1(c) of the Act and § 423.128(a)(3) for Part D sponsors. The regulatory provisions at §§ 422.111(b) and 423.128(b) require MA organizations and Part D sponsors to disclose plan information, including: service area, benefits, access, grievance and appeals procedures, and quality improvement/assurance requirements. MA organizations and sponsors may send the ANOC separately from the EOC, but must send the ANOC for enrollee receipt by September 30. The required due date for the EOC is 15 days prior to the start of the AEP.

CMS requires MA organization and Part D sponsors to submit marketing materials to CMS for review prior to the MA organization or sponsor distributing those materials to the public. In section 1851(h), paragraphs (1), (2), and (3) establish this requirement for MA organizations. Section 1860D–1(b)(1)(B)(vi) directs Part D sponsors to follow the same requirements in section 1851(h) that MA organizations must follow for this purpose. *Form number:* CMS–10260 (OMB control number: 0938–1051); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 800; *Number of Responses:* 48,439; *Total Burden Hours:* 13,568. (For questions regarding this collection contact Elizabeth Jacob at 410–786–8658).

3. *Type of Information Collection Request:* New collection (Request for new OMB control number); *Title of Information Collection:* Medicare Plan Performance Warning Information; *Use:* The Centers for Medicare & Medicaid Services (CMS) is seeking approval to collect information to assist in the Agency's response to two reports from the Department of Health and Human Services Office of the Inspector General (OIG) related to how the agency conveys information on plan performance.

CMS is conducting this research to respond to OIG's recommendations related to sharing additional information with beneficiaries on plan performance in a clear and accessible format, particularly related to information which may warn or caution beneficiaries about plan performance issues. CMS is seeking to learn more about how beneficiaries, caregivers, and the intermediaries who assist them use and understand the information CMS currently makes (or may make) available, as well as to assess their interest in accessing this information. *Form number:* CMS–10836 (OMB control number: 0938–New); *Frequency:* Annually; *Affected Public:* Individuals and Households; *Number of Respondents:* 288; *Number of Responses:* 288; *Total Burden Hours:* 497. (For questions regarding this collection contact Elizabeth Goldstein at 443 845–6993).

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Enrollment Application for Institutional Providers; *Use:* The primary function of the CMS–855A Medicare enrollment application is to gather information from a certified provider or certified supplier that tells us who it is, whether it meets certain qualifications to be a health care provider, where it practices or renders services, the identity of its owners, and other information necessary to establish correct claims payments.

In addition, on July 26, 2022, CMS published in the **Federal Register** a proposed rule titled ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating'' (CMS–1772–P) (87 FR 44502). This proposed rule outlined requirements that rural emergency hospitals (REHs)—a new Medicare provider type established pursuant to Section 125 of Division CC of the Consolidated Appropriations Act, 2021—must meet in order to bill Medicare for REH services. This

[1] Updated Federal Standard Renewal and Product Discontinuation Notices, and Enforcement Safe Harbor for Product Discontinuation Notices in Connection with the Open Enrollment Period for Coverage in the Individual Market in the 2020 Benefit Year (July 30, 2019) available at: *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Updated-Federal-Standard-Notices-and-Enforcement-Safe-Harbor-for-Discontinuation-Notices-PY2020.pdf.* This bulletin was revised on July 31, 2020 to add a link to the federal standard notices to be used beginning in the 2021 plan year: *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Updated-Federal-Standard-Notices-for-coverage-beginning-in-the-2021-plan-year.pdf.*

information collection request addresses the burden associated with the completion of the applicable CMS–855A by REHs in order to enroll in Medicare.

As part of this request, and as described in the supporting statement, we also seek approval for additional changes to the CMS–855A. These changes principally (though not exclusively) involve the collection of information related to the provider's ownership. *Form Number:* CMS–855A (OMB control number: 0938–0685); *Frequency:* On occasion; *Affected Public:* Business or other for-profits, not-for-profit institutions; *Number of Respondents:* 1,340; *Total Annual Responses:* 5,881; *Total Annual Hours:* 72,147. (For policy questions regarding this collection contact Frank Whelan at 410–786–1302.)

Dated: December 9, 2022.

William N. Parham, III,

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

[FR Doc. 2022–27166 Filed 12–14–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3728]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Collection of Conflict-of-Interest Information for Participation in Food and Drug Administration Non-Employee Fellowship and Traineeship Programs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 17, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0882. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Collection of Conflict-of-Interest Information for Participation in Food and Drug Administration Non-Employee Fellowship and Traineeship Programs

OMB Control Number 0910–0882—Extension

Section 742(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379l(b)) allows FDA to conduct and support intramural training programs through fellowship and traineeship programs. Prospective participants in these programs must complete financial disclosure forms to determine if there is a conflict of interest that would preclude participation. These new forms provide FDA with information about financial investments and relationships from non-employee scientists who participate in FDA fellowship and traineeship programs. Participants in FDA fellowship and traineeship programs will be asked for certain information about financial interests and current relationships: (1) description of the financial interest; (2) the type of financial interest (*e.g.,* stocks, bonds, stock options); (3) if the financial interest is an employee benefit from prior employment; (4) value of financial interest; (5) who owns the financial interest (*e.g.,* self, spouse, minor children); (6) employment relationship with an FDA significantly regulated organization (SRO); and (7) service as a consultant to an FDA SRO, and/or proprietary interest(s) in one of more product(s) regulated by FDA, including a patent, trademark, copyright, or licensing agreement. The purpose of the financial information is for FDA to determine if there is a conflict of interest between the Fellow's or Trainee's financial and relationship interests and their activities at FDA. The collection of information is mandatory to participate in FDA's fellowship and traineeship programs.

In the **Federal Register** of July 7, 2022 (87 FR 40537), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Oak Ridge Institute for Science and Education Fellowship	500	1	500	1	500
Traineeship Program	500	1	500	1	500
Reagan Udall Fellowship at FDA	50	1	50	1	50
Total					1,050

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.