

minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by June 27, 2024.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

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 Parham at (410) 786–4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

*Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* The Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents; *Use:* Sections 1860D–2(b)(2)(E)(v)(II)–(IV) of the Act state the requirements for Part D sponsors and MA organizations in implementing the program, which include the processes for outreach to enrollees identified as likely to benefit, election, and

termination. Subsection II states that any Part D enrollee may elect into the program prior to (aa) or during (bb) the plan year. Subsection III details that PDP sponsors and MA organizations must have a mechanism in place to inform enrollees that they are likely to benefit from electing into the program at the point of sale (POS). Subsection IV (aa) states that plans must terminate a beneficiary’s participation in the program when the beneficiary fails to pay the amounts owed under this program.

CMS has developed the six materials in the attached package as model notices in order to provide standardized and consistent language for potential and active program participants, regardless of which Part D plan they may be enrolled in. CMS will require Part D plans to disseminate these notices, as appropriate, to Part D enrollees to fulfill the requirements of the Sections 1860D–2(b)(2)(E)(v)(II)–(IV) of the Act. *Form Number:* CMS–10882 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* Private, Federal Government, Business or other for profits, Not-for-profits institutions; *Number of Respondents:* 1,065; *Total Annual Responses:* 1,065; *Total Annual Hours:* 21,300. (For policy questions regarding this collection contact Michael Brown at (872) 287–1370 or [michael.brown3@cms.hhs.gov](mailto:michael.brown3@cms.hhs.gov).)

**William N. Parham, III**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2024–11676 Filed 5–24–24; 8:45 am]

**BILLING CODE 4120–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Community Living**

**Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; of the ACL Generic Information Collection for the Administration on Aging Formula Grant Programs OMB Control Number 0985-New**

**AGENCY:** Administration for Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration for Community Living (ACL) is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under the Paperwork Reduction Act of 1995. This

30-day notice collects comments on the information collection requirements related to a new information collection for the ACL Generic Information Collection (Gen IC) for the Administration on Aging Formula Grant Programs.

**DATES:** Comments on the collection of information must be submitted electronically by 11:59 p.m. (ET) or postmarked by June 27, 2024.

**ADDRESSES:** Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find the information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

**FOR FURTHER INFORMATION CONTACT:** Adam Mosey (202) 795–7631 or [Adam.Mosey@acl.hhs.gov](mailto:Adam.Mosey@acl.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, the Administration for Community Living (ACL) has submitted the following proposed collection of information to OMB for review and clearance. As a unit of the Administration for Community Living, the Administration on Aging (AoA) provides expertise on program development, advocacy, and initiatives for older Americans and their caregivers and families. Working with State agencies, local agencies, grantees, and community providers, AoA directs programs authorized by the Older Americans Act (OAA), Elder Justice Act (EJA), and other legislation that supports older adults. Through these programs multi-year State Plans and assurances, and other financial forms are needed to provide approval and oversight of grant recipients. ACL is seeking OMB approval to add a new Gen IC to ACL’s Paperwork inventory. This Gen IC will cover ACL/AoA formula grant programs for State Plans on Aging and assurances, State Plans on Adult Protective Services and assurances, and other financial forms associated with aging and APS formula grant management. Adding a Gen IC will allow for the collection of data across programmatic and financial management of the aging and APS formula grants.

**Statutory Background**

In 1965, Congress originally passed the Older Americans Act (OAA) in response to concerns by policymakers

about a lack of community social services for older adults.

The original legislation established authority for grants to states for community planning and social services, research and development projects, and personnel training in the field of aging. Changes to the OAA were made through the Supporting Older Americans Act of 2020.

This legislation reauthorized the OAA and its programs from Federal fiscal year (FFY) 2020 through 2024. The OAA provides the foundation for the national aging network, which includes the Administration on Aging (AoA), State Units on Aging (SUA), area agencies on aging (AAA), Tribal organizations, service providers, and volunteers. SUAs are an integral part of the network responsible for developing and administering a multi-year state plan that advocates for and aids older residents, their families, their caregivers, and, in many States, for adults with disabilities.

The Elder Justice Act, passed in 2010, is the first comprehensive legislation to address the abuse, neglect, and exploitation of older adults at the Federal level. The law authorized a variety of programs and initiatives to better coordinate Federal responses to elder abuse, promote elder justice research and innovation, support Adult Protective Services systems, and provide additional protections for residents of long-term care facilities. The importance of these services at the State-level and local-level is demonstrated by the fact that states significantly leverage Older Americans Act (OAA) funds to obtain other funding for these activities.

The Coronavirus Response and Relief Supplemental Appropriations Act of 2021 and the American Rescue Plan Act

provided two years of Federal funding (\$188 million in each year) to support, for the first time, the nationwide APS formula grant program authorized by the Elder Justice Act of 2010. That funding was used by States to expand or develop a variety of capabilities that were necessary to meet increased needs due to the public health pandemic, and ongoing funding is necessary to maintain the improved reach and effectiveness of APS systems beyond the pandemic.

The FY 2023 Omnibus Appropriations Bill provided, for the first time, an annual appropriation of \$15 million to continue providing Federal formula grants to State APS programs. This will be the first time State entities are required to develop and submit State plans under Section 2042 of the Elder Justice Act, 42 U.S.C. 1397m-1(b). However, States have developed spending plans for the formula funding received to date, consistent with 45 CFR 75.206(d), and to update those every three to five years.

This new Gen IC is for programmatic and financial management of the Aging and APS formula grants. The purpose of the State Plans is to document and provide the opportunity for public comment on achievements and planned activities for the multi-year plan period.

A wide range of constituents use or will use the State Plans to coordinate, monitor, evaluate, and improve Aging Network and APS support services by using the State Plans as a blueprint for service planning and delivery. Additionally, ACL leverages State Plans to understand the numerous services older adults use, and to utilize the information for advocating for the needs of older adults and those who use APS and for requesting additional funding. The purpose of the other financial forms

that are a part of this Gen IC is to facilitate OAA formula grant management.

Financial forms provide statutorily required information regarding each State's contribution to programs to ensure compliance with legislative requirements, pertinent Federal regulations, and other applicable instructions and guidelines issued by ACL. This information will be used for Federal oversight of the Aging Programs.

Based on ACL's extensive experience working with APS systems and OAA grantees on their State plans, ACL does not anticipate a significantly greater level of detail for the development of State plans for APS.

OAA and APS grantees are required to comply with all terms and conditions contained in Notices of Award (NoA) issued by ACL. When it is determined that a grantee is not in compliance with one or more of these requirements, ACL may require a grantee to submit to ACL a plan to come into compliance under a Corrective Action Plan (CAP), and any such CAP may require ACL's prior written approval, as determined by ACL. The CAP process is intended to be collaborative. Under a CAP, a grantee and ACL will jointly identify progress milestones and a feasible timeline for the grantee to come into compliance with the applicable requirement. Grantees must make a good faith effort at achieving full compliance to continue to have permission from ACL to operate under a CAP.

**Comments in Response to the 60-Day Federal Register Notice**

A 60-day notice published in the **Federal Register** on October 18, 2023, at 88 FR 71869–71871. ACL received one public comment.

Organization	Section	Comment	Response
Commonwealth of Virginia, Department for Aging and Rehabilitative Services.	Estimated Annualized Burden Table.	Noted that the burden estimates for State Plans on Aging, and State Plans on APS are too low. Recommended identification of ways to reduce reporting requirements, as well as revising burden estimates. Recommended survey of states to inform future burden estimates..	ACL appreciates the comment but declines to make changes at this time.

Estimated Program Burden: ACL estimates the burden of this collection of information as follows:

**ESTIMATED ANNUALIZED BURDEN TABLE**

Respondent/data collection activity	Form	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Unit on Aging (SUA) .....	State Plan on Aging .....	14.7	1	80	1,176
State Unit on Aging (SUA) .....	Financial Forms .....	56	5	1	280

ESTIMATED ANNUALIZED BURDEN TABLE—Continued

Respondent/data collection activity	Form	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OAA or APS Grantee .....	Corrective Action Plan (CAP) .....	75	1	8	600
Total Estimated Burden .....	.....	.....	.....	.....	2,056

Dated: May 21, 2024.

**Alison Barkoff,**

*Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.*

[FR Doc. 2024–11602 Filed 5–24–24; 8:45 am]

**BILLING CODE 4154–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2023–N–0201]

**Jessica Palacio; Denial of Hearing; Final Debarment Order**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is denying a request for a hearing submitted by Andrew S. Feldman, on behalf of Jessica Palacio (Palacio), and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debaring Palacio 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 Palacio was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product under the FD&C Act. FDA provided notice to Palacio of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Palacio submitted a request for hearing but failed to file with the Agency information and analyses sufficient to create a basis for a hearing.

**DATES:** The order is applicable May 28, 2024.

**ADDRESSES:** Any application for termination of debarment by Palacio under section 306(d) of the FD&C Act (21 U.S.C. 335a(d)) (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:* All applications must include the Docket No. FDA–2023–N–0201. 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, 240–402–7500.

• *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.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 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

**FOR FURTHER INFORMATION CONTACT:**

Karen Fikes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4232, Silver Spring, MD 20993, 301–796–9603.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 306(a)(2)(A) of the FD&C Act mandates permanent debarment if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. On January 12, 2023, following a jury trial, the U.S. District Court for the Southern District of Florida entered