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[FR Doc. 2023–08571 Filed 4–21–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10844]

Agency Information Collection Activities: Submission for OMB Review; 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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by May 24, 2023.

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. 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:

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Small Biotech Exception; *Use:* Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (Pub. L. 117–169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (the Act). In accordance with section 1192(d)(2) of the Act, the term "negotiation-eligible drug" excludes, with respect to the initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets the requirements for the exception for small biotech drugs (the "Small Biotech Exception").

This information is required in order for CMS to accurately identify whether a given drug meets the criteria for the Small Biotech Exception in accordance with section 1192(d)(2) of the Act. To ensure that only covered Part D drugs that meet the requirements for the Small Biotech Exception are excluded from the term "negotiation-eligible drug," a manufacturer that seeks the Small Biotech Exception for its covered Part D drug ("Submitting Manufacturer") must submit information to CMS about the

company and its products in order for the drug to be considered for the exception. If the Submitting Manufacturer seeks the Small Biotech Exception for a covered Part D drug it acquired after December 31, 2021, the Submitting Manufacturer must also submit information related to the separate entity that had the Medicare Coverage Gap Discount Program agreement for the drug on December 31, 2021. The Information Collection Request Form for the Small Biotech Exception must be submitted to CMS before CMS establishes the selected drug list for initial price applicability year 2026. *Form Number:* CMS–10844 (OMB control number: 0938-New); *Frequency:* Once; *Affected Public:* Private sector, Business or other for-profit; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 68.5. (For policy questions regarding this collection contact Corey Rosenberg at 410–786–9763.)

Dated: April 19, 2023.

William N. Parham, III,

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

[FR Doc. 2023–08600 Filed 4–21–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Intent To Award a Single-Source Supplement To Provide the National Aging Network With Timely, Relevant, High-Quality Opportunities To Further Enhance Knowledge, Awareness and Models Related to Falls Prevention

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award a single-source supplement to the current cooperative agreement held by the National Council on Aging (NCOA) for the National Falls Prevention Resource Center. The purpose of this program is to advance the development and expansion of technical assistance, education, and resources to increase public awareness about the risk of falls and how to prevent them; increase the number of older adults and adults with disabilities who participate in evidence-based community falls prevention programs; and support the integration and sustainability of evidence-based falls prevention programs within community integrated health networks.

FOR FURTHER INFORMATION CONTACT: For further information or comments regarding this program supplement, contact Donna Bethge, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Aging, Office of Nutrition and Health Promotion Programs, 202-795-7659, donna.bethge@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: The purpose of this supplement is to:

- support the development of a survey of key stakeholders to determine falls prevention gaps, opportunities, and priorities in the aging network and expand the Falls Summit to capture strategies and action steps to address those gaps with nationally recognized experts in falls prevention, organizations from the health, nutrition, and aging sectors, select federal and state agencies, professional associations, corporations, and foundations that have an interest in healthy aging;
- expand upon the reach of the Falls Prevention Awareness Week to incorporate additional messaging regarding healthy aging, independence and quality of life that can be realized by moving from falls prevention awareness to action. This will include crafting new messages that will be disseminated to a broader audience to better resonate with older adults and their caregivers;
- provide further development of leaders in the falls prevention network through a fellowship program to focus on systems change to reduce falls, falls risk factors, and fall related injuries to ultimately improve the lives of older adults and save health care dollars; and
- cultivate and leverage partnerships with traditional and new partners, such as emergency medical services, paramedicine, transportation, housing, nutrition, and primary care providers to develop clinical and community collaborative best-practice frameworks and models designed to address multiple risk factors in innovative and scalable ways that would include a strong focus on increasing participation in evidence-based falls prevention programs and embedding those programs into the aging network in order to support healthy and active opportunities for older adults. This supplement would provide the resources necessary to pilot test these frameworks and models in communities.

The administrative supplement for FY 2023 will be in the amount of \$2,000,000, bringing the total award for FY 2023 to \$3,000,000.

The additional funding will not be used to begin new projects, but it will

be used to enhance existing efforts. The grantee will continue to provide appropriate, quality falls prevention resources, increase public awareness about falls prevention and the risk of falls, support the implementation of evidence-based falls prevention programs, and seek new opportunities to embed falls prevention evidence-based programs in the community.

Program Name: National Falls Prevention Resource Center.

Recipient: National Council on Aging (NCOA).

Period of Performance: The supplement award will be issued for the third year of a five-year project period of August 1, 2021, to July 31, 2026.

Total Award Amount: \$3,000,000 in FY 2023.

Award Type: Cooperative Agreement Supplement.

Statutory Authority: The Older Americans Act, Title IV; and the Patient Protection and Affordable Care Act, 42 U.S.C. 300u-11 (Prevention and Public Health Fund).

Basis for Award

National Council on Aging (NCOA) is currently funded to carry out the objectives of this project through its current cooperative agreement entitled, *National Falls Prevention Resource Center* for the period of August 1, 2021, through July 31, 2026. Since the project's implementation, the grantee has made satisfactory progress toward its approved work plan. The supplement will enable the grantee to carry their work even further, enhancing the support they provide to the Aging Network Falls Prevention Providers. The additional funding will not be used to begin new projects or activities, but rather to enhance efforts.

NCOA is uniquely positioned to complete the work called for under this project. They have an already established infrastructure and are a known and trusted organization in the Aging Network. Prior to this current award, NCOA competed and was twice awarded the *National Falls Prevention Resource Center* for the past 7 years. They have an established presence within the Aging Network. They have a comprehensive, interactive web-based repository (<https://ncoa.org/professionals/health/center-for-healthy-aging/national-falls-prevention-resource-center>) with tools and resources, including—best practices tip sheets, program and fidelity guidance, Falls Prevention Awareness Week toolkit, educational webinars, Grand Rounds recordings, articles covering topics from program implementation through sustainability, resource hubs,

policy and practice models, the Falls Free Checkup online screening tool and they maintain the national falls prevention database. Under this current award period, they are providing technical assistance and educational opportunities for the Aging Network's Falls Prevention efforts, including workgroups, webinars, and live trainings. They collaborate nationally with state falls prevention collaboratives and host the annual Age + Action Conference, a grantee gathering to explore solutions to ensure equitable aging for all, connecting with colleagues, sharing innovative ideas, and discussing policy solutions that can be achieved together on behalf of older adults. They have reached thousands of providers using their comprehensive database of SUAs, AAAs, and other Falls Prevention Program stakeholders. In addition, they have developed partnerships with organizations, universities, and other entities to provide technical assistance, education, and support for the Aging Network.

Establishing an entirely new grant project at this time would be potentially disruptive to the current work already well under way. More importantly, it could cause confusion among the Aging Network Falls Prevention Program Providers and stakeholders, which could have a negative effect on training, implementation, and support opportunities. If this supplement were not provided, the project would be unable to address the significant unmet needs of the Aging Network Falls Prevention Program.

Dated: April 18, 2023.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2023-08546 Filed 4-21-23; 8:45 am]

BILLING CODE 4154-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug