

GA 30341, Telephone: (770) 488-3953; Email: NCIPCBSC@cdc.gov.

SUPPLEMENTARY INFORMATION: Portions of the meeting as designated above will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92-463 (5 U.S.C. App.).

Purpose: The Board will: (1) Conduct, encourage, cooperate with, and assist other appropriate public health authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases, and other impairments; (2) assist States and their political subdivisions in preventing and suppressing communicable and non-communicable diseases and other preventable conditions and in promoting health and well-being; and (3) conduct and assist in research and control activities related to injury. The BSC, NCIPC makes recommendations regarding policies, strategies, objectives, and priorities; reviews progress toward injury prevention goals; and provides evidence in injury prevention-related research and programs. The Board also provides advice on the appropriate balance of intramural and extramural research, and the structure, progress, and performance of intramural programs. The Board is designed to provide guidance on extramural scientific program matters, including the: (1) Review of extramural research concepts for funding opportunity announcements; (2) conduct of Secondary Peer Review of extramural research grants, cooperative agreements, and contracts applications received in response to funding opportunity announcements as they relate to the Center's programmatic balance and mission; (3) submission of secondary review recommendations to the Center Director of applications to be considered for funding support; (4) review of research portfolios, and (5) review of program proposals.

Matters To Be Considered: The open portion of the agenda will include discussion on NCIPC Research Priorities for Addressing Adverse Childhood Experiences. The closed portion of the agenda will focus on the Secondary Peer Review of extramural research grant applications received in response to three Notice of Funding Opportunities (NOFOs): (1) RFA-CE-21-001—

“Rigorous Evaluation of Policies for their Impacts on the Primary Prevention of Multiple Forms of Violence”; (2) RFA-CE-21-003—“Grants to Support New Investigators in Conducting Research Related to Preventing Interpersonal Violence Impacting Children and Youth”; and (3) RFA-CE-21-004—“Research Grants for Preventing Violence and Violence-Related Injury (R01)”; as well as PHS 2020 Omnibus Solicitation of the NIH, CDC and FDA for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44] Clinical Trial Not Allowed). Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021-13119 Filed 6-22-21; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10137 and CMS-10174]

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 (the 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 August 23, 2021.

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, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

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-10137 Solicitation for Applications for Medicare Prescription Drug Plan 2023 Contracts
CMS-10174 Collection of Prescription Drug Data from MA-PD, PDP and Fallout Plans/Sponsors for Medicare Part D Payments

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:* Solicitation for Applications for Medicare Prescription Drug Plan 2023 Contracts; *Use:* Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application.

Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) in Subpart 3. The application requirements are codified in Subpart K of 42 CFR 423 entitled "*Application Procedures and Contracts with PDP Sponsors*."

The information will be collected under the solicitation of proposals from PDP, MA-PD, Cost Plan, Program of All Inclusive Care for the Elderly (PACE), and EGWP applicants. The collected information will be used by CMS to: (1) Ensure that applicants meet CMS requirements for offering Part D plans (including network adequacy, contracting requirements, and compliance program requirements, as described in the application), (2) support the determination of contract awards. *Form Number:* CMS-10137

(OMB control number: 0938-0936); *Frequency:* Yearly; *Affected Public:* Businesses or other for-profits, Not-for-profit institutions; *Number of Respondents:* 716; *Total Annual Responses:* 382; *Total Annual Hours:* 1,716. (For policy questions regarding this collection contact Arianne Spaccarelli at 410-786-5715.)

2. Type of Information Collection
Request: Extension of a currently approved collection; *Title of Information Collection:* Collection of Prescription Drug Event Data From Contracted Part D Providers for Payment; *Use:* The PDE data is used in the Payment Reconciliation System to perform the annual Part D payment reconciliation, any PDE data within the Coverage Gap Phase of the Part D benefit is used for invoicing in the CGDP, and the data are part of the report provided to the Secretary of the Treasury for Section 9008.

CMS has used PDE data to create summarized dashboards and tools, including the Medicare Part D Drug Spending Dashboard & Data, the Part D Manufacturer Rebate Summary Report, and the Medicare Part D Opioid Prescribing Mapping Tool. The data are also used in the Medicare Trustees Report. Due to the market sensitive nature of PDE data, external uses of the data are subject to significant limitations. However, CMS does analyze the data on a regular basis to determine drug cost and utilization patterns in order to inform programmatic patterns and to develop informed policy in the Part D program.

The information users will be Pharmacy Benefit Managers (PBMs), third party administrators and pharmacies, and the PDPs, MA-PDs, Fallbacks and other plans that offer coverage of outpatient prescription drugs under the Medicare Part D benefit to Medicare beneficiaries. The statutorily required data is used primarily for payment and is used for claim validation as well as for other legislated functions such as quality monitoring, program integrity and oversight. *Form Number:* CMS-10174 (OMB control number: 0938-0982); *Frequency:* Yearly; *Affected Public:* Businesses or other for-profits, Not-for-profit institutions; *Number of Respondents:* 739; *Total Annual Responses:* 1,499,238,090; *Total Annual Hours:* 2,998. (For policy questions regarding this collection contact Ivan Iveljic at 410-786-3312.)

Dated: June 17, 2021.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021-13194 Filed 6-22-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-E-1642]

Determination of Regulatory Review Period for Purposes of Patent Extension; GIVLAARI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for GIVLAARI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by August 23, 2021. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 20, 2021. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 23, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 23, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way: