

*Frequency of response:* Semiannual, annual.

*Total estimated burden:* 1,800 hours (per year). Burden is defined at 5 CFR 1320.3(b).

*Total estimated cost:* \$1,950,000 (per year), which includes \$1,850,000 in annualized capital/startup and/or operation & maintenance costs.

*Changes in the Estimates:* The increase in burden from the most-recently approved ICR is due to an increase in the number of new or modified sources. There is also an increase in costs due to the use of updated labor rates. This ICR uses labor rates from the most-recent Bureau of Labor Statistics report (September 2022) to calculate respondent burden costs. This ICR also adjusts the capital/startup and operation and maintenance costs from 2008 to 2022 values using the CEPCI CE Index.

**Courtney Kerwin,**

*Director, Regulatory Support Division.*

[FR Doc. 2024-01807 Filed 1-30-24; 8:45 am]

**BILLING CODE 6560-50-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10788]

#### 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 April 1, 2024.

**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-10788 Prescription Drug and Health Care Spending

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:* Prescription Drug and Health Care Spending; *Use:* On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA) was signed into law. Section 204 of title II of division BB of the CAA added parallel provisions at section 9825 of the Internal Revenue Code (the Code), section 725 of the Employee Retirement Income Security Act (ERISA), and section 2799A-10 of the Public Health Service Act (PHS Act) that require group health plans and health insurance issuers offering group or individual health insurance coverage to annually report to the Department of the Treasury, the Department of Labor (DOL), and the Department of Health and Human Services (HHS) (collectively, "the Departments") certain information about prescription drug and health care spending, premiums, and enrollment under the plan or coverage. This information will support the development of public reports that will be published by the Departments on prescription drug reimbursements for plans and coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under the plans or coverage. The 2021 interim final rules, "Prescription Drug and Health Care Spending" (2021 interim final rules), issued by the Departments and the Office of Personnel Management (OPM) implement the provisions of section 9825 of the Code, section 725 of ERISA, and section 2799A-10 of the PHS Act, as enacted by section 204 of title II of division BB of the CAA. OPM joined the Departments in issuing the 2021 interim final rules, requiring Federal Employees Health Benefits (FEHB) carriers to report information about prescription drug and health care spending, premiums, and plan enrollment in the same manner as a group health plan or health insurance issuer offering group or individual health insurance coverage.

The 2023 Prescription Drug Data Collection (RxDC) Reporting Instructions reflect changes for the 2023 reference year and beyond. As a result of removing one-time first- and second-

year implementation costs and burdens that were incurred prior to 2024, it is estimated that there will be a decrease in total three-year average annual burden from 1,684,080 to 668,952. *Form Number:* CMS-10788 (OMB Control Number: 0938-1407); *Frequency:* Annually; *Affected Public:* Private Sector; *Number of Respondents:* 356; *Number of Responses:* 356 *Total Annual Hours:* 668,952. (For policy questions regarding this collection contact Christina Whitefield at 202-536-8676.)

Dated: January 25, 2024.

**William N. Parham, III**

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

[FR Doc. 2024-01831 Filed 1-30-24; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2024-D-0361]

#### Development of Monoclonal Antibody Products Targeting SARS-CoV-2 for Emergency Use Authorization; Guidance for Industry; Correction

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

**ACTION:** Correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on December 21, 2023. The document announced the availability of a final guidance for industry entitled “Development of Monoclonal Antibody Products Targeting SARS-CoV-2 for Emergency Use Authorization.” The document was published with an incorrect docket number. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Maria Clary, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4638, Silver Spring, MD 20993-0002, 240-402-8615.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of December 21, 2023 (88 FR 88401), in FR Doc. 2023-28092, the following correction is made:

1. On page 88401, in the first column in the header of the document, and in the **ADDRESSES** section, in the second and third lines of the first paragraph, the Docket No. is corrected to read “Docket No. FDA-2024-D-0361.”

Dated: January 25, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024-01836 Filed 1-30-24; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel NIDDK Application Review: RFA-DK-23-017 (U01) and RFA-DK-23-018 (U24) Continuation of the Childhood Liver Disease Research Network (ChILDRen).

*Date:* March 21, 2024.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, NIDDK, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Cheryl Nordstrom, Ph.D., M.Ph., Scientific Review Officer, NIDDK/Scientific Review Branch, National Institutes of Health, 6707 Democracy Blvd., Room 7013, Bethesda, MD 20892, 301-402-6711, [cheryl.nordstrom@nih.gov](mailto:cheryl.nordstrom@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 25, 2024.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2024-01845 Filed 1-30-24; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK RC2 Application Review.

*Date:* March 1, 2024.

*Time:* 1:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, NIDDK, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Cheryl Nordstrom, Ph.D., M.Ph., Scientific Review Officer, NIDDK/Scientific Review Branch, National Institutes of Health, 6707 Democracy Blvd., Room 7013, Bethesda, MD 20892, 301-402-6711, [cheryl.nordstrom@nih.gov](mailto:cheryl.nordstrom@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 25, 2024.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2024-01849 Filed 1-30-24; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.