• Delete item (5) of the Office of Business Integrity and Strategic Management (CAJTB) functional statement and renumber the remaining items accordingly.

Delegations of Authority

All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

(Authority: 44 U.S.C. 3101)

Dia Taylor,

Acting Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–01708 Filed 1–26–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10858, CMS–10215 and CMS–10394]

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 March 29, 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–10858 Rebate Reduction Requests under Sections 11101 and 11102 of the Inflation Reduction Act

CMS–10215 Identifying Medicaid Payment for Physician Administered Drugs

CMS–10394 Application To Be a Qualified Entity to Receive Medicare Data for Performance Measurement/Reapplication/Annual Report Worksheet

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: New collection (Request for a new OMB control number); *Title of Information Collection:* Rebate Reduction Requests under Sections 11101 and 11102 of the Inflation Reduction Act; *Use:* Under the authority in sections 11101 and 11102 of the Inflation Reduction Act of 2022 (Pub. L. 117–169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program codified in section 1847A(i) and section 1860D–14B of the Social Security Act (''the Act''), respectively. In accordance with section 1847A(i) of the Act, for calendar quarters beginning January 1, 2023, a manufacturer of a Part B rebatable drug will owe a rebate, to be deposited in the Federal Supplementary Medical Insurance Trust Fund, if the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. A ''Part B rebatable drug'' means a single-source drug or biological product (as defined section 1847A(c)(6)(D) of the Act), including a biosimilar biological product (as defined section 1847A(c)(6)(H) of the Act) but excluding a qualifying biosimilar biological product (as defined section 1847A(b)(8)(B)(iii) of the Act), for which payment is made under Medicare Part B, except such term shall not include such a drug or biological product if, as determined by the Secretary, the average total allowed charges for such drug or biological product under Part B for a year per individual that uses such a drug or biological product are less than the applicable threshold; or that is a vaccine described in subparagraph (A) or (B) of section 1861(s)(10) of the Act. In accordance with Section 1860D–14B of the Act, for each 12-month applicable period, starting with the applicable period beginning October 1, 2022, a manufacturer of a Part D rebatable drug will owe a rebate, to be deposited in the Federal Supplementary Medical Insurance Trust Fund, if the annual

manufacturer price exceeds the inflation-adjusted payment amount. Section 1860D–14B(g)(1)(A) of the Act defines a ''Part D rebatable drug,'' in part, as a drug or biological described at section 1860D–14B(g)(1)(C) that is a ''covered Part D drug'' as that term is defined in section 1860D–2(e) of the Act. The definition of a Part D rebatable drug includes generic drugs that meet certain statutory criteria (effectively sole source generics). The definition of a Part D rebatable drug does not include a drug or biological if, as determined by the Secretary, the ''average annual total cost'' for such drug or biological under Part D for a year per individual that uses such a drug or biological is less than the applicable threshold.

Sections 1847A(i)(3)(G)(ii) and 1860D–14B(b)(1)(C)(ii) of the Act require that CMS reduce or waive the inflation rebate amount owed (if any) for a Part B rebatable biosimilar biological product and generic Part D rebatable drug or biosimilar when CMS determines there is a severe supply chain disruption during a calendar quarter or applicable period, respectively, such as that caused by a natural disaster or other unique or unexpected event. CMS must also reduce or waive the inflation rebate amount owed (if any) for a generic Part D rebatable drug if CMS determines that without such reduction or waiver, the drug is likely to be in shortage in a subsequent applicable period, as required by section 1860D–14B(b)(1)(C)(iii) of the Act.

CMS does not have information necessary to determine whether manufacturers of Part B and Part D rebatable drugs should have their rebate amount reduced due to either a severe supply chain disruption or a likely shortage as required by sections 1847A(i)(3)(G)(ii), 1860D–14B(b)(1)(C)(ii), and 1860D–14B(b)(1)(C)(iii) of the Act. Some of the information and supporting documentation needed for CMS to make a determination regarding a severe supply chain disruption and the likelihood of a future shortage are held by manufacturers and are not available to CMS. As such, for CMS to determine whether there is a severe supply chain disruption or likelihood of future shortage, in accordance with sections 1847A(i)(3)(G)(ii), 1860D–14B(b)(1)(C)(ii), and 1860D–14B(b)(1)(C)(iii) of the Act, a manufacturer must submit to CMS a request for a rebate reduction along with supporting documentation. *Form Number:* CMS–10858 (OMB control number: 0938–New); *Frequency:* Once; *Affected Public:* Private sector and business or other for-profits; *Number of Respondents:* 10; *Total Annual Responses:* 20; *Total Annual Hours:* 620. (For policy questions regarding this collection contact Elisabeth Daniel at 667–290–8793.)

2. Type of Information Collection Request: Extension of currently approved collection; *Title of Information Collection:* Identifying Medicaid Payment for Physician Administered Drugs; *Use:* States are required to provide for the collection and submission of utilization data for certain physician-administered drugs in order to receive Federal financial participation for these drugs. Physicians, serving as respondents to States, submit National Drug Code numbers and utilization information for ''J'' code physician-administered drugs so that the States will have sufficient information to collect drug rebate dollars. *Form Number:* CMS–10215 (OMB control number: 0938–1026); *Frequency:* Weekly; *Affected Public:* Business or other for-profits and not-for-profit institutions); *Number of Respondents:* 26,000; *Total Annual Responses:* 39,053,932; *Total Annual Hours:* 162,074. (For policy questions regarding this collection contact Michael Forman at 410–786–2666.)

2. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Application to be a Qualified Entity to Receive Medicare Data for Performance Measurement/Reapplication/Annual Report Worksheet; *Use:* The Patient Protection and Affordable Care Act (ACA) was enacted on March 23, 2010 (Pub. L. 111–148). ACA amends section 1874 of the Social Security Act by adding a new subsection (e) to make standardized extracts of Medicare claims data under Parts A, B, and D available to QEs to evaluate the performance of providers of services and suppliers. This is the Application, Reapplication, and ARW which provides CMS with the information it needs to determine whether an organization earns approval and continues as a QE.

CMS established the Qualified Entity Certification Program (QECP) to evaluate an organization's eligibility across three areas: (1) organizational and governance capabilities, (2) addition of claims data from other sources (as required in the statute), and (3) data privacy and security. QE certification lasts for 3 years. Organizations that are interested in remaining in the QE program must submit a Reapplication that is reviewed and approved by QECP. In addition, each year QEs must submit an annual report to QECP that provides information required by statute. *Form Number:* CMS–10394 (OMB control number: 0938–1144); *Frequency:* Yearly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 40; *Total Annual Responses:* 210; *Total Annual Hours:* 17,400. (For policy questions regarding this collection contact Kari Gaare at *kari.gaare@cms.hhs.gov*).

Dated: January 24, 2024.

William N. Parham, III

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

[FR Doc. 2024–01723 Filed 1–26–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Pharmaceutical Quality (OPQ) has modified its organizational structure. This new structure was approved by the Secretary of Health and Human Services on August 10, 2023.

FOR FURTHER INFORMATION CONTACT: Michael Kopcha, Director, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–2461.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is amended to reflect reorganization of CDER, OPQ.

This reorganization changed the OPQ organizational structure from an office with nine suboffices to 10 suboffices. The former offices with divisions and branches had their branches abolished and the branch functions and resources