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.

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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

were realigned to their respective divisions.

The OPQ retitled four of its suboffices and retitled the majority of its divisions. The OPQ will establish the Office of Quality Assurance and within it established the Quality Assurance Staff, Learning and Professional Staff, and the Project Management Staff.

FDA, CDER, OPQ has been restructured as follows:

DCDL. ORGANIZATION. The Office of Pharmaceutical Quality is headed by the Director of Pharmaceutical Quality and includes the following organizational units:

Office of Pharmaceutical Quality (DCDL)
Office of Product Quality Assessment I (DCDLH)
Division of Product Quality Assessment I (DCDLHA)
Division of Product Quality Assessment II (DCDLHB)
Division of Product Quality Assessment III (DCDLHC)
Division of Product Quality Assessment IV (DCDLHD)
Division of Product Quality Assessment V (DCDLHE)
Division of Product Quality Assessment VI (DCDLHF)
Office of Product Quality Assessment II (DCDLB)
Division of Product Quality Assessment VII (DCDLBA)
Division of Product Quality Assessment VIII (DCDLBB)
Division of Product Quality Assessment IX (DCDLBC)
Division of Product Quality Assessment X (DCDLBD)
Division of Product Quality Assessment XI (DCDLBE)
Division of Product Quality Assessment XII (DCDLBF)
Office of Product Quality Assessment III (DCDLA)
Division of Product Quality Assessment XIII (DCDLAA)
Division of Product Quality Assessment XIV (DCDLAB)
Division of Product Quality Assessment XV (DCDLAC)
Division of Product Quality Assessment XVI (DCDLAD)
Division of Product Quality Assessment XVII (DCDLAE)
Division of Product Quality Assessment XVIII (DCDLAF)
Division of Product Quality Assessment XIX (DCDLAG)
Office of Pharmaceutical Manufacturing Assessment (DCDLD)
Division of Pharmaceutical Manufacturing Assessment I (DCDLDA)
Division of Pharmaceutical Manufacturing Assessment II (DCDLDB)
Division of Pharmaceutical Manufacturing Assessment III (DCDLDC)
Division of Pharmaceutical Manufacturing Assessment IV (DCDLDD)
Division of Pharmaceutical Manufacturing Assessment V (DCDLDE)
Division of Pharmaceutical Manufacturing Assessment VI (DCDLDF)
Office of Program and Regulatory Operations (DCDLG)
Division of Regulatory & Business Process Management I (DCDLGA)
Division of Regulatory & Business Process Management II (DCDLGB)
Division of Regulatory & Business Process Management III (DCDLGC)
Division of Regulatory & Business Process Management IV (DCDLGD)
Office of Pharmaceutical Quality Research (DCDLF)
Division of Pharmaceutical Quality Research I (DCDLFA)
Division of Pharmaceutical Quality Research II (DCDLFB)
Division of Pharmaceutical Quality Research III (DCDLFC)
Division of Pharmaceutical Quality Research IV (DCDLFD)
Division of Pharmaceutical Quality Research V (DCDLFE)
Division of Pharmaceutical Quality Research VI (DCDLFF)
Office of Policy for Pharmaceutical Quality (DCDLC)
Compendial Operations and Standards Staff (DCDLCA)
Division of Regulations and Guidance (DCDLCB)
Division of Internal Policy and Communication (DCDLCC)
Division of Editorial and Project Management (DCDLCD)
Office of Quality Assurance (DCDLJ)
Quality Assurance Staff (DCDLJ1)
Learning and Professional Development Staff (DCDLJ2)
Enterprise Project Management Staff (DCDLJ3)
Office of Quality Surveillance (DCDLE)
Division of Quality Intelligence I (DCDLEB)
Division of Quality Intelligence II (DCDLEC)
Division of Quality Intelligence III (DCDLED)
Office of Administrative Operations (DCDLI)
Administrative Analysis Staff (DCDLI1)
Administrative Operations Staff 1 (DCDLI2)
Administrative Operations Staff 2 (DCDLI3)
Administrative Operations Staff 3 (DCDLI4)
Administrative Operations Staff 4 (DCDLI5)
Financial Services Staff (DCDLI6)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete SMG can find it on FDA's website at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

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

Xavier Becerra,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request

Collection of Grants and Contracts Data the Historically Black Colleges and Universities (HBCUs) and Small Businesses May Be Interested in Pursuing (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), Office of the Director, Office of Acquisitions and Logistics Management (OALM), Small Business Program Office (SBPO), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent