APPENDIX B: AGENCY'S RESPONSE TO THE REPORT

U.S. Department of Labor

Office of Workers' Compensation Programs Washington, D.C. 20210



March 16, 2023

MEMORANDUM FOR: CAROLYN R. HANTZ

Assistant Inspector General for Audit

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FROM: CHRISTOPHER J. GODFREY GODFREY

Director of Workers' Compensation Programs

SUBJECT: Draft Report: OWCP Did Not Ensure Best Prices and

Allowed Inappropriate, Potentially Lethal Prescriptions in the

FECA Program, No. 03-23-001-04-431

The purpose of this memo is to provide a response from the Office of Workers' Compensation Programs (OWCP) to the subject draft report by the Office of the Inspector General (OIG) regarding the Federal Employees' Compensation Act (FECA) Program's pharmaceutical management. I want to emphasize that this report does not reflect the *current* pharmaceutical management program within the FECA program. As this audit covers the period 2015-2020, before OWCP executed a contract with a pharmacy benefit manager (PBM), many of the recommendations have already been addressed or were in the process of being addressed before this audit began. The OWCP has addressed each OIG Recommendation indicating the status of the recommendation below.

OIG RECOMMENDATION #1: "Implement a process to ensure competitive prices for the FECA program by regularly evaluating alternate pricing methodologies and other sources—including state fee schedules, ACA FUL, NADAC, MAC lists, market research, and comparable payers—and updating its pricing methodology as appropriate."

OWCP Response: OWCP has already implemented a process to "ensure competitive pricing" through a competitive acquisition process. On February 5, 2021, the U.S. Department of Labor's Office of the Senior Procurement Executive awarded a five-year contract to a pharmacy benefit manager (PBM) for the FECA program following a competitive solicitation process that resulted in the selection of the firm (among several competitors) whose proposal offered the Government the best value to the Government, considering among other factors the pricing offered by the offerors. This contract guaranteed pharmaceutical pricing for the FECA program that was substantially lower than the FECA pharmacy fee schedule in place at the time. Implementation of the PBM by the

FECA program saved federal agencies approximately \$87.9 million on medications year over year between Fiscal Year 2021 and Fiscal Year 2022. That contract (including its price reductions) is currently in place. As OWCP continues its market research as part of future procurements, OWCP will incorporate a process to evaluate alternative pricing methods, such as those recommended, and to include such alternative pricing methods, as appropriate, in future PBM contract solicitations beginning in 2025.

OIG RECOMMENDATION #2: "Implement a process to collect drug manufacturer rebates."

OWCP Response: The OWCP agrees to evaluate whether the collection of drug manufacturer rebates is in the best interest of the Government during the next pharmacy benefit manager (PBM) solicitation. On February 5, 2021, the U.S. Department of Labor's Office of the Senior Procurement Executive (OSPE) awarded a five-year contract to a PBM for the FECA program. This contract guaranteed pricing that was substantially lower than the FECA pharmacy fee schedule in place at the time. As part of its first PBM contract, the OWCP required and collects information on drug manufacturer rebates received by the PBM. In its market research efforts, and during the next solicitation, planned for 2025, the OWCP will explore whether direct payment or pass-through of drug manufacturer rebates to OWCP is in the best interest of the Government.

OIG RECOMMENDATION #3: "Implement a process to review the effectiveness of policy changes, including: (a) documented assessment of prescription information after any changes in the authorization, approval, and/or adjudication process to ensure desired changes are achieved; and (b) documented solutions for any performance gaps identified during the review, including follow-up testing."

OWCP Response: The OWCP agrees with the OIG's recommendation. On February 5, 2021, the U.S. Department of Labor's Office of the Senior Procurement Executive awarded a five-year contract to a pharmacy benefit manager (PBM) for the FECA program. OWCP created an audit controls matrix to regularly monitor policy compliance and a quality assurance surveillance plan that monitors and reports on the overall performance of the PBM contractor. When performance gaps are identified, the OWCP documents the gaps and works with the PBM to resolve the gaps and perform necessary system testing.

OIG RECOMMENDATION #4: "Implement an ongoing pharmaceutical monitoring and alert program to identify and closely monitor significant changes in costs, prescribing patterns, utilization, sources, and new and novel prescription drugs."

OWCP Response: This recommendation has already been implemented. On February 5, 2021, the U.S. Department of Labor's Office of Procurement Services awarded a five-year contract to a pharmacy benefit manager (PBM) for the FECA program. This contract included pharmaceutical monitoring and new drug alerts by the PBM. The PBM's account management team alerts the OWCP of changes in prescription costs, drug utilization, and prescribing patterns on a monthly and quarterly basis.

OIG RECOMMENDATION #5: "Establish internal controls that identify prescription drugs payment and management issues in near-real-time, including: (a) reviewing all system data fields provided by PBM(s) and bill pay vendor(s); (b) determining any additional data fields/elements needed to monitor pharmaceutical spending and track trends over time; (c) ensuring a recurring process to receive and immediately review data from the PBM(s) and bill pay vendor(s); and (d) using that data review to report regularly to management, medical director, and staff pharmacists for collaborative identification of current and emerging issues."

OWCP Response: This recommendation has already been implemented. On February 5, 2021, the U.S. Department of Labor's Office of Procurement Services awarded a five-year contract to a pharmacy benefit manager (PBM) for the FECA program. Subsequently, the OWCP established internal controls that identify prescription drug payment and management issues in near-real-time to include immediate data access via the PBM portal and daily pricing alerts. The OWCP receives pharmacy data from the PBM on a weekly basis and has access to the PBM's near-real-time data analytics platform. The pharmacy data received are added to the OWCP's pharmacy database, which includes data extracts from Medi-Span and the National Council for Prescription Drug Programs (NCPDP).

OIG RECOMMENDATION #6: "Implement a technology solution to perform ongoing prescription-claim-level reviews in near-real-time—including contractual adherence by the PBM, prescription drug pricing discounts, and rebate guarantees—as well as to validate prescription drug pricing methodology."

OWCP Response: This recommendation has already been implemented. On February 5, 2021, the U.S. Department of Labor's Office of Procurement Services awarded a five-year contract to a pharmacy benefit manager (PBM) for the FECA program. The OWCP currently receives data extracts from the PBM on a weekly basis, which are added to the OWCP's pharmacy database. The OWCP identifies any overpayments (deviations from contractually required pricing discounts) billed by the PBM on a quarterly basis, to be processed for collection under FECA program debt collection procedures

OIG RECOMMENDATION #7: "Adopt one or more of the widely used and thoroughly vetted evidence-based clinical guidelines, such as those from the American College of Occupational and Environmental Medicine and Official Disability Guidelines, in place of treatment suites."

OWCP Response: This recommendation has already been implemented. On February 5, 2021, the U.S. Department of Labor's Office of Procurement Services awarded a five-year contract to a pharmacy benefit manager (PBM) for the FECA program. This contract included the use of a Pharmacy and Therapeutics Committee to develop and maintain a drug formulary that is based on nationally recognized guidelines, including American College of Occupational and Environmental Medicine (ACOEM) and Official Disability Guidelines (ODG), and is approved by the OWCP. Treatment suites are no longer used by the FECA program in the adjudication and management of pharmacy claims.

OIG RECOMMENDATION #8: "Develop and deliver ongoing formal training for staff involved in making pharmaceutical decisions, with documentation of participation and post-training evaluation."

OWCP Response: This recommendation has already been implemented. On February 5, 2021, the U.S. Department of Labor's Office of Procurement Services awarded a five-year contract to a pharmacy benefit manager (PBM) for the FECA program. The PBM's clinical pharmacists, physicians, and nurses, and OWCP clinical pharmacists and physicians make pharmaceutical decisions based on current clinical guidelines. The OWCP clinical pharmacists and physicians receive continuing education from major, nonprofit medical and pharmacy societies and attend annual meetings to stay abreast of important medical topics. The OWCP's clinical pharmacists and physicians also have access to major medical journals and information from other federal agencies including the U.S. Food and Drug Administration (FDA). The FECA program's medical benefit examiners and claims examiners make administrative decisions; they do not make clinical decisions.

OWCP RECOMMENDATION #9: "Add pharmacists and physicians to the FECA program for oversight and other necessary functions not assigned to the PBM."

OWCP Response: The OWCP agrees with the OIG's recommendation. The OWCP added a second clinical pharmacist in August of 2021, and a Deputy Chief Medical Officer in November of 2021. The OWCP recently approved the hiring of a third clinical pharmacist and a third physician and will initiate the hiring process in Fiscal Year 2023.

OWCP RECOMMENDATION #10: "Ensure medical and pharmaceutical experts participate in the development, monitoring, maintenance, improvement, and evaluation of the FECA pharmaceutical program."

OWCP Response: This recommendation has already been implemented. On February 5, 2021, the U.S. Department of Labor's Office of Procurement Services awarded a five-year contract to a pharmacy benefit manager (PBM) for the FECA program. Since the implementation of the pharmacy benefit manager (PBM) contract, OWCP physicians, pharmacists, and data scientists have actively collaborated with the FECA program in the development and administration of the FECA pharmacy program. The OWCP has a dedicated team within the Division of Administrative Operations (DAO), comprised of medical professionals responsible for developing policy in conjunction with the program and for providing professional oversight for the delivery of medical and pharmacy benefits. This team includes physicians, pharmacists, and data scientists who are directly managing the PBM contract, monitoring its performance, making improvements, and evaluating its overall progress in collaboration with DOL's contracting officials as appropriate.