U.S. Department of Labor

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REPORT TO THE OFFICE OF WORKERS' COMPENSATION PROGRAMS

OWCP MUST CONTINUE STRENGTHENING MANAGEMENT OF FECA PHARMACEUTICALS, INCLUDING OPIOIDS

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U.S. Department of Labor
Office of Inspector General
Audit

BRIEFLY...

OWCP MUST CONTINUE STRENGTHENING MANAGEMENT OF FECA PHARMACEUTICALS, INCLUDING OPIOIDS

MAY 14, 2019

WHY OIG CONDUCTED THE AUDIT

DOL OIG and the United States Postal Service have grown very concerned over the rapidly increasing costs, questionable safety, and likelihood of fraud associated with pharmaceutical benefits in the Federal Employee Compensation Act (FECA) program. Dramatic increases in compounded drug costs, from $2 million in Fiscal Year (FY) 2011 to $254 million in FY 2016, and dangers related to opioid abuse have gained significant attention from Congress and the public. While the costs of compounded drugs dropped to $18 million in FY 2018, overall pharmaceutical costs remained at $262 million for over 33,000 monthly average cases, of which 42 percent included opioid prescriptions.

WHAT OIG DID

We assessed the Office of Workers' Compensation Program's (OWCP) controls for managing pharmaceutical benefits in the FECA program to answer the following question:

> Has OWCP effectively managed the use and cost of pharmaceuticals in the FECA program?

This report summarizes the complete results of our work and augments the findings in our first report, issued May 23, 2017.

READ THE FULL REPORT

http://www.oig.dol.gov/public/reports/oa/2019/03-19-002-04-431.pdf

WHAT OIG FOUND

OWCP must continue to strengthen its management of the use and cost of pharmaceuticals in the FECA program. OWCP has made progress in addressing recommendations from our first report, but more action is needed.

OWCP identified risks and implemented controls over compounded drugs and opioids, but it needs to further reduce risks for opioids. Our audit determined that OWCP's policy on opioids was too permissive, and OWCP had not developed sufficient controls to manage opioid addiction.

In addition, OWCP did not do enough to ensure it paid the best price for prescription drugs. We found OWCP had not determined if alternative drug pricing methodologies would be more competitive; had not used drug formulary lists or preferred providers; had not implemented cost-limit checks on high or excessive drug charges; and had not ensured its generic drug policy was effective.

OWCP could also do more to help ensure FECA prescriptions are safe from overuse and adverse interaction with other FECA medications. Our analysis revealed OWCP had not implemented drug utilization reviews and quantity limits on initial fills and refills of maintenance drugs; had not determined if classes of drugs other than compounded drugs and opioids should require prior authorization for medical necessity; and had not monitored claimant and prescriber relationships to ensure drugs were prescribed by attending physicians.

Finally, OWCP had not reported excluded providers to the national healthcare fraud and abuse data collection program, or accessed this data to ensure FECA providers were qualified. However, OWCP had taken actions to identify questionable providers, refer them to DOL OIG for investigation, and exclude providers convicted of fraud.

WHAT OIG RECOMMENDED

In addition to the recommendations we made in our first report, we are making 7 new recommendations for the Director of OWCP to strengthen management of pharmaceuticals in the FECA program.

TABLE OF CONTENTS

INSPECTOR GENERAL'S REPORT

Julia Hearthway
Director
Office of Workers' Compensation Programs
U.S. Department of Labor
200 Constitution Ave, NW
Washington, DC 20210

We initiated an audit of the Office of Workers' Compensation Programs' (OWCP) management of pharmaceutical benefits in the Federal Employees' Compensation Act (FECA) program in response to our concerns, as well as concerns raised by the United States Postal Service and several congressional committees, over the safety, rapidly escalating costs, and likelihood of fraud associated with pharmaceutical benefits.

In conducting this audit, we developed a framework of control objectives applicable to OWCP's management of FECA pharmaceutical benefits (see Exhibit 1: Pharmaceutical Benefits Framework). Using this framework of control objectives, we assessed OWCP's existing and planned controls for managing FECA pharmaceutical benefits so we could answer the following objective:

> Has OWCP effectively managed the use and cost of pharmaceuticals in the FECA program?

To keep stakeholders informed of the serious control issues in the FECA pharmaceutical program, we issued a report[1] in May 2017 with 16 recommended actions to improve the management of pharmaceuticals. This report summarizes the overall results of our work, makes additional recommendations to improve management of the FECA program, and reports

[1] Interim Report on Audit of Pharmaceutical Management in DOL Benefit Program: OWCP Needs Better Controls over Compounded Prescription Drugs (Report No. 03-17-001-04-431).

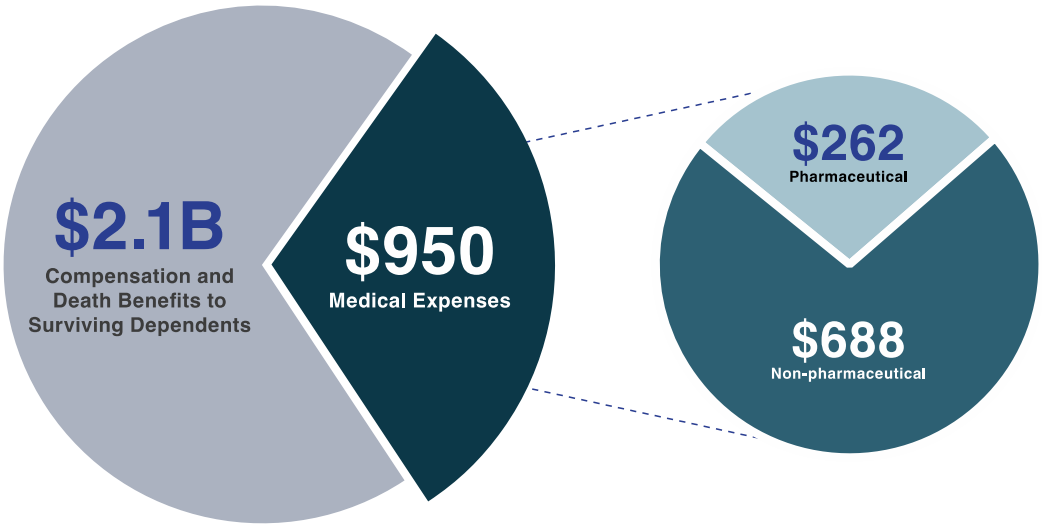
on the progress OWCP has made in addressing our previously-reported concerns.

FECA PHARMACEUTICAL SPENDING FY 2011 – FY 2018

The Federal Employees' Compensation Act provides workers' compensation benefits to Federal and postal workers around the world for employment-related injuries and occupational diseases. OWCP's Division of Federal Employees' Compensation (DFEC) has responsibility for administering the Act.

In Fiscal Year (FY) 2018, the FECA program provided about $3.1 billion in benefits. Of these benefit payments, over $2.1 billion was paid for compensation benefits and almost $950 million was paid for medical expenses, including $262 million in pharmaceutical costs.

FIGURE 1: TOTAL FECA BENEFITS PAID FY 2018 (IN MILLIONS)

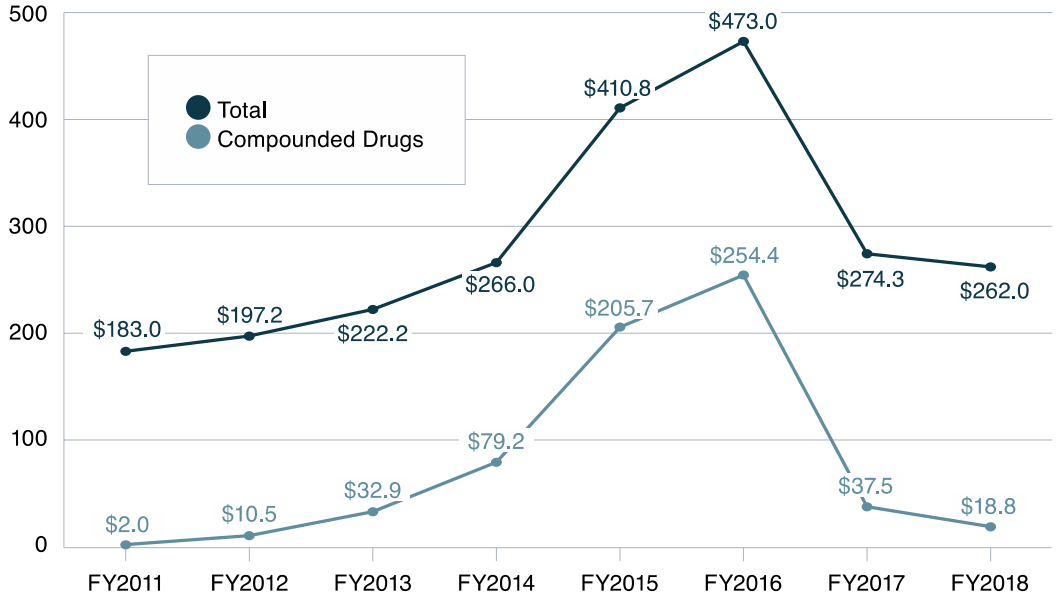


Between FY 2011 and FY 2016, the overall cost of pharmaceuticals in the FECA program rose from $183 million to $473 million. Most of the increase in pharmaceuticals were driven by compounded drugs, which escalated from $2 million in FY 2011 to $254 million in FY 2016.[2] After being made aware of the

[2] We previously reported compounded drug spending of $263 million in FY 2016 based on information provided by OWCP. In this report, we are reporting compounded drug spending data based on our analysis of OWCP's bill payment data.

dramatic increase in compounded drugs by USPS, OWCP implemented a prior certification policy for compounded drugs, which significantly decreased the total compounded drug spending from FY 2016 to FY 2018. For FY 2018, the costs of compounded drugs dropped to $18 million, while overall pharmaceutical costs remained at $262 million for over 33,000 monthly average cases, of which 42 percent included opioid prescriptions.

FIGURE 2: FECA PHARMACEUTICAL COSTS FY 2011–2018 (IN MILLIONS)



THE OPIOID CRISIS IN BRIEF

In 2017, more than 47,000 Americans died as a result of an opioid overdose and an estimated 1.7 million people in the United States suffered from substance abuse disorders related to prescription opioids. The Centers for Disease Control and Prevention (CDC) reported more than 35 percent of all U.S. opioid overdose deaths in 2017 involved a prescription opioid.

Based on CDC estimates, the total economic burden of prescription opioid misuse in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement. According to the National Safety Council, opioids also increase workers' compensation costs, increase the length of worker disability, and increase work time lost.[3]

[3] The Proactive Role Employers Can Take: Opioids in the Workplace, National Safety Council.

In October 2017, the Department of Health and Human Services declared the opioid crisis a nationwide public health emergency and the President directed all executive agencies to use every appropriate emergency authority to fight the crisis. In 2018, the Administration secured $6 billion in new funding, and awarded more than $1 billion in funding to state and local entities, to fight opioid abuse. The U.S. Secretary of Labor has expressed full support of the President's Initiative to Stop Opioid Abuse, which focuses on educating Americans to reduce demand and over-prescription, cutting off illicit drug supply chains, and helping those struggling with addiction through evidence-based treatment and recovery.

RESULTS

OWCP needs to take action to effectively manage the use and cost of pharmaceuticals in the FECA program. Specifically, OWCP needs to:

Reduce the risks associated with opioids by shortening the 60-day grace period for first fill opioid prescriptions and developing sufficient controls to help manage opioid addiction;

Obtain the best price for prescription drugs by determining if alternative drug pricing methodologies would be more competitive, implementing cost-limit checks on high or excessive drug charges, and ensuring its generic drug policy is effective;

Ensure FECA prescriptions are safe by implementing drug utilization reviews and quantity limits on initial fills and refills of maintenance drugs, determining if drugs other than compounded drugs and opioids should require prior authorization for medical necessity, and monitoring claimant and prescriber relationships to ensure drugs are prescribed by attending physicians; and

Ensure FECA providers are qualified by reporting excluded providers to the national healthcare fraud and abuse data collection program, and accessing this data to check for adverse actions against FECA providers.

OWCP has made progress in addressing the recommended actions from our first report. Recent measures taken include setting limits on initial fills and refills for opioids and non-maintenance drugs, establishing policies for alternative pain management and treatment for opioid use disorder, and improving analysis of spending patterns and questionable providers.

REDUCING THE RISKS ASSOCIATED WITH OPIOIDS

OWCP identified risks and implemented controls over compounded drugs and opioids, but it needs to further reduce risks for opioids. Our audit determined that OWCP's policy on opioids was too permissive, and OWCP had not developed sufficient controls to manage opioid addiction.

OWCP IDENTIFIED RISKS RELATED TO COMPOUNDED DRUGS AND OPIOIDS, AND IMPLEMENTED CONTROLS TO HELP ENSURE THEIR MEDICAL NECESSITY

In our first report, we found OWCP had not identified risks associated with compounded drugs until the United States Postal Service brought escalating compounded drug costs to OWCP's attention in 2015. OWCP addressed risks related to compounded drugs by requiring prior authorization and letters of medical necessity (LMN), and implementing initial fill and refill policies.[4] We recommended that OWCP continue to assess risks in the FECA program.

After we issued our report, OWCP identified opioid addiction as a risk facing the FECA program in the FY 2017 Annual Performance Report and established performance targets to reduce the number and duration of new opioid prescriptions by 10 percent from FY 2017 to FY 2019.

[4] FECA Bulletin No. 17-01, Compounded Medication Prescribing Guidelines, October 14, 2016, provided guidance on the use and management of cases where a claimant received compounded drugs for any work-related condition. OWCP began requiring an LMN from the claimant's treating physician to authorize any compounded drug prescriptions. Each LMN authorizes prescriptions for up to 90 days (to be filled every 30 days).

In June 2017, OWCP required prior authorization and LMNs, and implemented initial fill and refill policies for newly prescribed opioid use.[5] Moreover, in June 2018, OWCP implemented additional controls over long-term and high-dose opioid use.[6] Based upon a review of Morphine Equivalent Dose (MED) levels and the length of opioid use, OWCP can request an LMN from the prescribing physician.[7]

According to OWCP, its efforts have resulted in a 22 percent drop in new opioid prescriptions and a 43 percent drop in new prescriptions lasting more than 30 days.

OWCP'S CONTROLS FOR OPIOID PRESCRIPTIONS WERE TOO PERMISSIVE

After we issued our first report, we determined OWCP's initial effort to address opioids was too permissive compared to CDC's opioid guidelines.

OWCP allowed physicians to prescribe opioids to new users for up to 60 days without an LMN. However, CDC reported prescribing opioids for 3 days or less was often sufficient and that more than 7 days was rarely needed for treatment of acute pain. Additionally, CDC stated, "opioids are not first-line or routine therapy for chronic pain," outside of active cancer treatment, specialized medical care for serious illness, and end-of-life care.[8]

OWCP stated it considered multiple factors when it implemented the 60-day grace period, including: data from 2015 and 2016 that showed approximately 63 percent of claimants stopped taking opioids within 60 days; the need to provide adequate provider and claimant notice prior to requiring an LMN; and the need to balance workload between other claims and opioid claims.

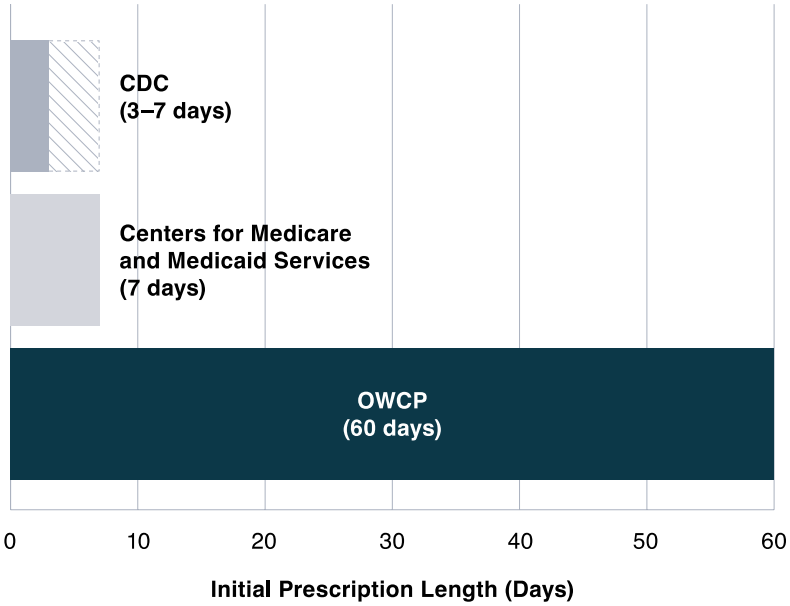
[5] FECA Bulletin No. 17-07. Opioid Prescribing Guidelines. June 6, 2017.

[6] FECA Bulletin No. 18-04. Opioid Prescribing Guidelines, Short-Term, Long-Term and High Dose Opioid Use. June 15, 2018.

[7] The MED is a measure of a claimant's daily dosage of opioids.

[8] CDC Guideline for Prescribing Opioids for Chronic Pain, found on: www.cdc.gov/drugoverdose/prescribing/guideline.html

FIGURE 3: COMPARISON OF OPIOID PRESCRIPTION GUIDELINES



A policy that is too permissive could lead to overprescribing medically-unnecessary opioids and increased costs for the FECA program, as well as needless addiction, dependency, and overdose for claimants. Safe prescribing guidelines such as shorter initial prescription length can reduce the number of claimants receiving higher than recommended doses. For example, according to the Centers for Medicare and Medicaid Services, its safe prescribing guidelines, 7 days for initial opioid prescriptions and 30 days for second prescriptions, reduced the number of Medicare beneficiaries receiving higher than recommended doses from multiple doctors by 40 percent in 2017.[9]

OWCP HAD NOT DEVELOPED CONTROLS TO MANAGE OPIOID ADDICTION

After our first report was issued, we determined OWCP did not have reliable information to allow its management to make informed decisions and evaluate FECA's performance in managing opioid dependency among FECA claimants.

[9] CMS Roadmap to Address the Opioid Epidemic, Center for Medicare & Medicaid Services, June 2018.

While OWCP used ICD-10 codes[10] to indicate opioid dependency, OWCP had not developed ways to analyze the FECA claimant population to determine how many had these accepted conditions, how long they had these conditions, and if they were receiving appropriate treatments. Instead, OWCP has been analyzing claimants for high MED levels and addressing them. However, it is still important to analyze the claimant population to ensure claimants officially diagnosed with addiction are receiving appropriate treatment.

In addition, OWCP had not ensured the ICD-10 codes for opioid addiction in the system were reliable. Attending physicians are supposed to diagnose claimants and identify the ICD-10 codes as a part of the condition related to the work injury. OWCP stated there are not too many cases with ICD-10 codes for opioid addiction because physicians do not consistently use an ICD-10 code for opioid addiction, and noted some physicians have been using a "pain management" code (with a component of it being opioid dependence) for treatment of opioid addiction instead of a code for alcohol and drug detoxification. Consequently, the total number of claimants receiving opioid addiction treatment may not have been accurate.

Our analysis of FECA data found no cases with ICD-10 codes for opioid addiction as an accepted condition and only 205 cases that had older ICD-9 codes for opioid dependency, which represented 1.4 percent of the 14,300 legacy claimants as of September 2018. OWCP has not reached out to physicians to ensure they identify appropriate ICD-10 codes for opioid addiction as part of the work injury.

Because the use of ICD-10 codes for opioid addiction as an accepted condition was inconsistent, OWCP told us it used "OPIADM" in the accepted condition field to allow treatment for opioid addiction. It developed a treatment suite[11] containing allowable opioid treatment procedures for cases coded as "OPIADM." OWCP entered "OPIADM" for all cases where an opioid was prescribed.

[10] The International Classification of Diseases (ICD) is "the international standard for reporting diseases and health conditions" and is owned and published by World Health Organization (WHO). The U.S. developed a Clinical Modification (ICD-10-CM) for medical diagnosis based on WHO's 10th Revision (ICD-10). In 2015, ICD-10-CM replaced ICD-9-CM, which has been used since 1979.

[11] A treatment suite is an automated tool OWCP uses to ensure medical procedures, including drugs, are allowable for treatment of the claimant's work-related injury.

Federal standards require management to use quality information.[12] Without adequate information on opioid addiction among FECA claimants, OWCP cannot effectively manage opioid dependency in the FECA program.

OIG'S RECOMMENDATIONS

PREVIOUS RECOMMENDED ACTIONS

In our first report, we recommended the Director of OWCP take the following actions. We have included the most recent status of management's action.

- *Require prior authorization for compounded drugs.* We **closed** this recommendation based on FECA Bulletin 17-01, issued on October 14, 2016, which established requirements for prior authorization for compounded drugs.

- *Require physician certification of medical necessity.* We **closed** this recommendation based on FECA Bulletin 17-01, issued on October 14, 2016, which established policy requiring LMNs for compounded drugs.

- *Assess risks to the FECA program.* We **closed** this recommendation based on the corrective actions described by OWCP and the risk assessment documentation provided.

NEW RECOMMENDATIONS

In this report, we are making 3 new recommendations that the Director of OWCP:

1. Work with stakeholders to develop better guidelines to shorten the 60-day grace period for first fill opioid prescriptions.

2. Implement controls to improve the reliability of the ICD-10 codes for opioid addiction, such as analyzing prescription data and reaching out to physicians when claimants have long-term prescriptions and/or high MED levels.

[12] GAO-14-704G Standards for Internal Control in the Federal Government, Principle #13, September 2014.

3. Establish procedures to conduct on-going analysis of ICD-10 codes and other related data to monitor opioid addiction and treatment.

OBTAINING THE BEST PRICE FOR PRESCRIPTION DRUGS

OWCP did not do enough to ensure it paid the best price for prescription drugs. We found OWCP had not determined if alternative drug pricing methodologies would be more competitive; had not used drug formulary lists or preferred providers; had not implemented cost-limit checks on high or excessive drug charges; and had not ensured its generic drug policy was effective.

OWCP HAD NOT ANALYZED ALTERNATIVE DRUG PRICING METHODOLOGIES

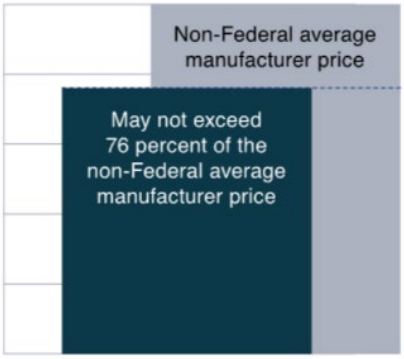
In our first report, we found OWCP had not performed an analysis to determine the best method for calculating pharmaceutical payments. OWCP implemented some changes to reduce pharmaceutical costs, such as reducing reimbursements for generic ingredients from 70 percent of the Average Wholesale Price (AWP)[13] to 60 percent, and creating a tiered reimbursement structure for compounded drugs that lowers the reimbursement percentage as the number of ingredients increases for drugs billed on or after July 1, 2016.[14] However, OWCP had not performed an analysis to determine whether a fee schedule based on the percentage of AWP was the best method for calculating payments. We also noted Federal law provides for medical programs operated by other Federal agencies[15] to negotiate with manufacturers to obtain the Federal Ceiling Price – a pharmaceutical pricing agreement that may not exceed 76 percent of the non-Federal average manufacturer price.

[13] AWP is a prescription drug pricing benchmark used throughout the healthcare industry. Although it describes the average price paid to buy a drug from a wholesaler, it does not include discounts/rebates and is not a true representation of actual market prices paid.

[14] OWCP Medical Fee Schedule. October 15, 2018.

[15] The Department of Veteran's Affairs, Department of Defense, Public Health Service, and Coast Guard.

FIGURE 4: FEDERAL CEILING PRICE



Many in the healthcare industry have identified issues with the AWP due to the inflated bases associated with this pricing methodology.[16] To better control pharmaceutical costs in FECA, we recommended in that report that OWCP (1) implement a new pricing methodology; (2) pursue inclusion into prices that drug manufacturers can charge under the Federal Ceiling Price statute; and (3) contract for pharmacy benefit management.[17]

After we issued our report, OWCP drafted a Government Reform Proposal requesting that DOL be given access to the Federal Ceiling Price through legislation. However, in November 2017, OMB responded:

> We appreciate OWCP's interest in pursuing ways to decrease drug prices, but would like to work with OWCP on alternatives to accessing the Federal Ceiling Price.

As a result, OWCP stated that while there was still value in potentially pursuing access to the Federal Ceiling Price, OWCP would be unable to support access to the Federal Ceiling Price operationally until both the pharmacy benefit manager (PBM) and FECA's new case management system were both fully implemented.

In November 2018, OWCP awarded a contract for a pharmacy benefit manager (PBM).[18] The PBM contract price was based on the Net Discount off the AWP.

[16] What is the Price Benchmark to Replace Average Wholesale Price (AWP)?, Journal of Managed Care Pharmacy, September 2010, Vol. 16, No. 7.

[17] Pharmacy benefit managers are third party administrators contracted by health plans, employers, and government entities to manage prescription drug programs on behalf of health plan beneficiaries.

[18] A bid protest was filed on January 7, 2019, with the Government Accountability Office (GAO), which triggered an automatic stay of contract performance per the Competition in Contracting Act

However, OWCP had not compared the contract price to other fee schedule options or worker compensation industry pharmaceutical costs to ensure the contracted Net Discount/Price based on the AWP was the most cost competitive.

OWCP stated:

> While several independent publishers have proposed alternatives to AWP, at this time, according to the Academy of Managed Care Pharmacy (AMCP) latest guide to Pharmaceutical Payment Methods, no comprehensive, transparent, and widely acceptable alternative to AWP has been identified for the commercial marketplace.
>
> [and]
>
> OWCP will continue to assess new commercial pricing strategies, such as value based pricing and others as they become available. OWCP will also leverage the [PBM] to perform various pharmacoeconomic analyses.

OWCP believes its pricing (percentage of AWP) has been competitive with other worker compensation programs at the state level, and changes in its pricing methods will be in tandem with the use of a PBM. OWCP plans to calculate the spread between what OWCP pays the PBM and what the PBM pays pharmacies. According to OWCP, these results will guide its pricing methods, provide insight into the PBM's pricing implementation, and help ensure OWCP's pricing structure is most advantageous to the government.

In addition to the calculation of the spread, OWCP has built some additional controls into the contract to ensure the reasonableness of the prices charged by the PBM. For example, the PBM will report on the amount of price concessions it earns from drug manufacturers and the amount of price concessions passed onto OWCP. However, these controls will only ensure OWCP pays reasonable prices in comparison to what the PBM pays. They will not ensure what OWCP pays is the most advantageous to the government. Specifically, for compounded drugs with more than three ingredients, the PBM contract specifies a significantly smaller discount than OWCP's pre-PBM pricing structure.

(CICA). On January 10, 2019, DOL approved a partial "override" of the CICA stay, allowing the performance of only certain limited services related to the approximately 3,000 claimants receiving opioid prescriptions with MED levels of 90 or higher. All other work under the PBM contract is subject to the CICA stay, which prohibits performance of that work. While GAO has dismissed the protest based on DOL agreeing to take corrective action, the CICA stay and partial override remain in effect pending the outcome of the corrective action.

OWCP needs to ensure the contract prices established in the PBM contract are competitive. Without such assurance, there is risk that the reimbursements OWCP pays the PBM will not be the most advantageous to the government. We believe OWCP should, as it intends to do, assess new pricing strategies and perform analysis to determine if the current pricing methodology is the most cost effective.

OWCP HAD NOT USED DRUG FORMULARY LISTS OR PREFERRED PROVIDERS

In our first report, we determined OWCP was not using drug formulary lists and we recommended the use of such lists be implemented. A drug formulary list is a list of prescription drugs that are safe and cost effective for a specified condition. Additionally, in our report we found OWCP did not use preferred providers and recommended OWCP implement the use of preferred providers.

The use of formulary lists and preferred providers are industry standards. Additionally, FECA regulations allow OWCP to contract for or require the use of specific providers for certain medications.[19] However, OWCP did not use drug formulary lists or preferred providers because it planned to implement them as part of its contracting for a PBM.

After we issued our report, OWCP awarded a PBM contract in November 2018 that required the implementation of a drug formulary list within 90 days of the award and the establishment of a provider network within 60 days of the award.[20] This was an important step because without formulary lists or preferred providers, OWCP cannot ensure it pays for prescriptions at the most cost effective prices.

OWCP HAD NOT PERFORMED COST-LIMIT CHECKS ON PHARMACEUTICAL BILLS FOR HIGH OR EXCESSIVE DRUG CHARGES

In our first report, we found OWCP did not have reasonable cost-limit checks for identifying high or excessive drug charges for additional review and authorization, and we recommended OWCP improve its review of costs. In response to the report, OWCP stated it was considering alternative methods to

[19] Code of Federal Regulations. Title 20, Part 10, Claims for Compensation under the Federal Employees' Compensation Act. Section 10.809, Medical Fee Schedule.

[20] These implementation dates will be delayed due to the bid protest filed in January 2019.

ensure cost effectiveness, including post-fill reviews or requiring prior authorization for prescriptions exceeding a certain dollar threshold.

FECA procedures require medical bills over $50,000 to be reviewed, and defines medical bills to include pharmacy bills.[21] OWCP's Black Lung Program currently uses additional reviews for pharmaceutical costs exceeding a threshold of $750. Similarly, a leader in the healthcare industry reviews pharmaceutical claims exceeding a threshold of $300 for efficiency and cost effectiveness.

FIGURE 5: OWCP DID NOT REVIEW PHARMACEUTICAL BILLS OVER $50,000

OWCP has not implemented a policy to review pharmaceutical bills over $50,000 or conducted any other cost-limit checks for high or excessive drug charges.

OWCP has not implemented a policy to review pharmaceutical bills over $50,000 or conducted any other cost-limit checks for high or excessive drug charges. We identified 52 FECA pharmaceutical transactions over $50,000 between FY 2016 and FY 2018, which totaled $10.7 million. During this 3-year period, OWCP paid approximately $1.9 million in pharmaceutical costs for one claimant's case. OWCP had concerns about this case because it was a high MED case and eventually referred it to DOL OIG for investigation in August 2018. OWCP explained it excluded pharmacy bills from the $50,000 review requirement because claimants may have needed the drugs immediately. For example, some high cost pharmaceuticals consisted of specialty drugs that claimants often needed immediately.

OWCP has targeted drug types that may have been problematic, such as unclassified J-code procedures and convenience kits. OWCP said it was not easy to develop edit checks to identify prescriptions by cost for review and pre-approval, and it had been unable to conduct further dollar limitation reviews

[21] DFEC Procedure Manual. Part 5, Benefit Payments. Chapter 5-0200.10.

based on other competing priorities. However, it awarded a PBM contract in November 2018 and OWCP intended to work on some options for an approval method with the PBM.

The PBM contract required the contractor, within 90 days of the award,[22] to:

> Provide the ability to deny, or refer for OWCP approval, payment of medications based on an OWCP-specified dollar threshold, specific medication (e.g., [National Drug Codes]), provider, or other criteria (e.g., case).

However, OWCP had not specified the dollar threshold. Without controls to ensure the drugs it pays for are priced fairly and reasonably, OWCP could be paying too much for pharmaceuticals and drug costs could continue to escalate.

OWCP HAD NOT PERFORMED SIGNIFICANT ANALYSIS TO ENSURE ITS GENERIC DRUG POLICY WAS EFFECTIVE

In our first report, we determined OWCP was unable to verify the implementation and effectiveness of its generic drug policy and we recommended OWCP verify the effectiveness of generic drug usage in FECA.

OWCP started receiving a file extract with generic drug indicators in December 2017. According to OWCP, it performed an initial analysis that showed about 80 percent of prescriptions it paid for were generics. Furthermore, the recently-awarded PBM contract required the use of generic equivalents where they were available and required the contractor to produce reports containing information on generic drug payments. However, OWCP has not validated the accuracy of the generic indicator codes, or performed further analysis, such as determining the justifications for the use of non-generics.

OWCP stated it will work with the PBM to develop an "informed and aggressive generic policy once the award is finalized."

OWCP has only recently initiated analysis of generic drug usage because of the current emphasis on its opioid initiatives. FECA regulations allowed the use of generic equivalents where they were available.[23] Without ensuring that lower

[22] This implementation date will be delayed due to the bid protest filed in January 2019.

[23] Code of Federal Regulations. Title 20, Part 10, Claims for Compensation under the Federal Employees' Compensation Act. Section10.809(c), Medical Fee Schedule.

cost generic options were used, OWCP may have been paying more than necessary.

OIG'S RECOMMENDATIONS

PREVIOUS RECOMMENDED ACTIONS

In our first report, we recommended the Director of OWCP take the following actions. We have included the most recent status of management's action.

- *Implement drug formulary lists and implement the use of preferred providers.*[24] We **resolved** these recommendations based on the PBM contract, which required the contractor to "recommend, develop and maintain a formulary and formulary parameters." We will close this recommendation when OWCP provides evidence the PBM contractor developed a pharmacy network and implemented a formulary list, as required by the contract.

- *Implement a new pricing methodology.* We **resolved** this recommendation based on OWCP's policy changes for generic and compounded drug pricing, prior authorization, and the award of a PBM contract in November 2018 to control costs. We will close this recommendation when OWCP establishes a policy to conduct ongoing analysis into commercial pricing strategies as they become available to ensure current pricing strategies are providing the best prices for the FECA program.

- *Verify cost controls (generic drug usage) effectiveness.* We **resolved** this recommendation based on the award of a PBM contract in November 2018 and OWCP's analysis of generic payments. We will close this recommendation when OWCP provides evidence that it is conducting a routine analysis to determine whether its generic drug policy is being effectively followed.

- *Pursue inclusion into prices that drug manufacturers can charge.* We **closed** this recommendation based on OWCP's drafted Government Reform Proposal requesting access to the Federal Ceiling Price and OMB's November 2017 response to this proposal on alternatives to accessing the Federal Ceiling Price.

[24] This is a combination of two recommended actions in our previous report.

- *Improve review of costs.* We **resolved** this recommendation based on OWCP's alternative methods to ensure cost-effectiveness of prescription medications and the award of a PBM contract in November 2018, to assist "with implementation of any further dollar limitations." We will close this recommendation when OWCP establishes a specific dollar threshold and implements a formal procedure to review pharmaceutical bills.

- *Contract for pharmacy benefit management.* We **closed** this recommendation based on the award of a PBM contract in November 2018.

NEW RECOMMENDATIONS

In this report, we are not making any new recommendations for this finding.

ENSURING FECA PRESCRIPTIONS ARE SAFE

OWCP could do more to help ensure FECA prescriptions are safe from overuse and adverse interaction with other FECA medications. Our analysis revealed that OWCP had not implemented drug utilization reviews and quantity limits on initial fills and refills of maintenance drugs. It also had not determined if classes of drugs other than compounded drugs and opioids should require prior authorization for medical necessity. Finally, OWCP had not monitored claimant and prescriber relationships to ensure drugs were prescribed by attending physicians.

OWCP HAD NOT IMPLEMENTED DRUG EXCLUSION LISTS OR DRUG UTILIZATION REVIEWS TO HELP ENSURE FECA PRESCRIPTIONS ARE SAFE

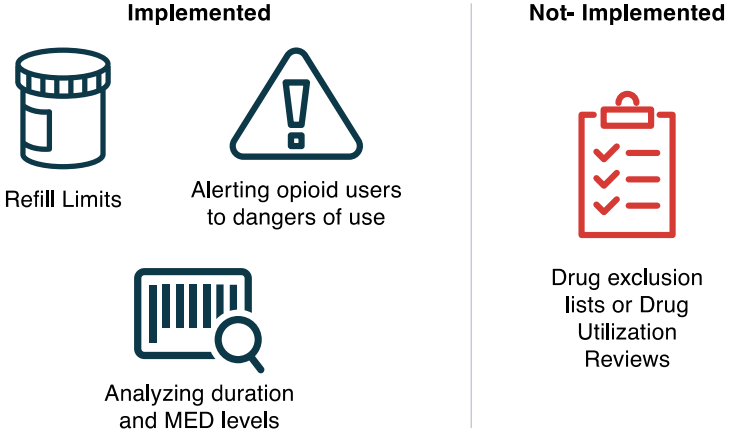
In our first report, we determined OWCP did not use drug exclusion lists, except for FDA's list of *Drug Products That May Not Be Compounded*. We recommended that OWCP implement drug exclusion lists for all drugs and drug ingredients.

After we issued our report, OWCP implemented some controls to prevent drug overuse, such as:

- Establishing refill limits for compounds and opioids;
- Alerting opioid users to the dangers of opioid use via a notice mailed to all legacy claimants and providers in July 2017, and a similar notice mailed to new entrants; and
- Analyzing the duration and MED levels of opioid prescriptions based on concerns about overuse and the "risk of addiction."

However, OWCP still has not implemented drug exclusion lists, nor has it performed drug utilization reviews to help ensure the safety of drug interaction with other drugs. Drug utilization reviews include: 1) detecting fraud, waste, and abuse patterns by providers or employees; 2) screening for situations where a certain drug should not be used due to the harm it could cause; 3) identifying duplicate prescriptions and therapeutic overlap; and 4) determining brand name versus generic use by drug category. It is critical for OWCP to perform drug utilization reviews to help ensure that drugs it pays for are safe from interaction with one another.

FIGURE 6: OWCP CONTROLS TO PREVENT DRUG OVERUSE AND INTERACTION



The use of drug exclusion lists and drug utilization reviews are industry standards. OWCP believes the pharmacy and prescriber are in the best position to evaluate individual claimant safety since they have direct access to the claimant's medical and prescription history, including non-employment related

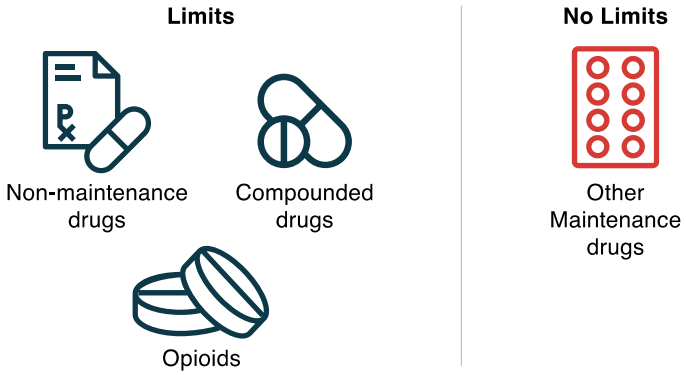
conditions, which would be unknown to OWCP. However, OWCP plans to implement drug exclusion lists and drug utilization reviews as a part of its contract with a PBM.

The recently awarded PBM contract required implementation of a drug utilization review program within 180 days of the contract award.[25] It also required the contractor's system to support OWCP-designated reference files, including exclusion lists. However, OWCP has yet to determine which exclusion lists it will use as reference or how the lists will be developed. Without the use of drug exclusion lists, OWCP cannot ensure prescribed drugs are appropriate for FECA injuries.

OWCP HAD NOT IMPLEMENTED QUANTITY LIMITS ON ALL DRUGS

In our first report, we found OWCP set quantity limits for compounded drugs, but not for all drugs. We recommended that OWCP implement quantity limits on initial fills and refills. After we issued our report, OWCP set quantity limits on opioids and non-maintenance drugs; however, OWCP has not set limits on maintenance drugs, other than compounded drugs and opioids.

FIGURE 7: OWCP QUANTITY LIMITS FOR DRUGS



According to OWCP, it had no specific policy for maintenance drugs because it wanted to encourage claimants to be compliant with their medical regimens for chronic, ongoing conditions resulting from their work-related injury. However, the PBM contract awarded in November 2018 required the contractor to recommend, develop, and maintain a formulary with parameters that could include quantity limits. At the time of this report, OWCP's approval of the PBM's formulary

[25] This implementation date will be delayed due to the bid protest filed in January 2019.

parameters was still pending for maintenance drugs. Without quantity limits for initial fills and refills, there is a risk that access to prescription drugs can be abused, even for maintenance drugs. Consequently, OWCP could pay for drugs that are not medically necessary.

OWCP HAD NOT DETERMINED IF PRIOR AUTHORIZATION SHOULD BE REQUIRED FOR OTHER DRUG CLASSES NOT COVERED BY ITS CURRENT POLICIES

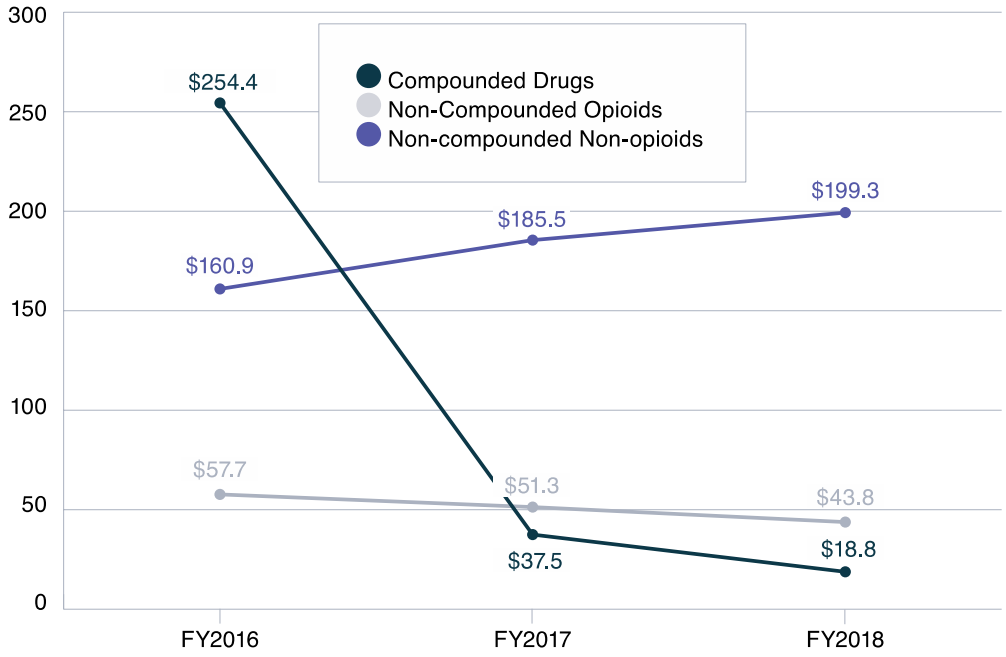
In our first report, we determined OWCP implemented requirements for prior authorization and LMNs for compounded drugs. After we issued our report, OWCP implemented additional policies requiring LMNs for opioids[26] and prior authorization for unclassified J-code procedures.[27] However, excluding herbal supplements and convenience kits, OWCP has not reviewed other classes of drugs paid for by the FECA program to determine if requiring prior authorization or LMNs would be appropriate for them.

As seen in the below chart, the cost of compounded drugs dropped from $254.4 million in FY 2016 to $18.8 million in FY 2018 following OWCP's prior authorization and LMN requirement. Similarly, the cost of non-compounded opioids dropped from $57.7 million to $43.8 million between FY 2016 and FY 2018 (OWCP's LMN requirement for opioids became effective June 2017). However, the cost of other drugs, which have no prior authorization or LMN requirement, continued to rise steadily – from $160.9 million in FY 2016 to $199.3 million in FY 2018.

[26] FECA Bulletin No. 17-07. Opioid Prescribing Guidelines. June 6, 2017.

[27] Unclassified J-code procedures can include compounded drugs, which bypass the LMN requirement for compounded drugs. FECA Circular No. 18-06. Physician Dispensed Medication (Billing for Unspecified "J Codes"). May 18, 2018.

FIGURE 8: FECA PHARMACEUTICAL COSTS FY 2016–2018 (IN MILLIONS)



Although the increase in non-compounded, non-opioid drug costs could be due to other factors, it is worth noting the lack of prior authorization is a differentiating factor between the groups that saw cost decreases compared to the group that saw a cost increase. It would be prudent for OWCP to analyze the increase in costs of these other drugs to determine if prior authorization or LMNs are warranted.

Federal standards state that management should identify, analyze, and respond to risks.[28] OWCP stated it uses treatment suites to ensure all prescription drugs are medically necessary for the accepted FECA injury. OWCP reviews pharmaceutical spend trends and utilization through its Program Integrity Unit's data analytics. In addition, OWCP has deferred any in-depth reviews of other drug classes for implementation of a prior authorization or LMN until after the implementation of its PBM.

The PBM contract awarded in November 2018 required the contractor to recommend, develop, and maintain a formulary with parameters that could include prior-authorization requirements. At the time of this report, OWCP still needed to ensure the PBM, when developing its formulary parameters,

[28] GAO-14-704G Standards for Internal Control in the Federal Government, Principle #7. September 2014.

considered all classes of drugs to determine if prior authorization or LMNs would be appropriate. Without such assurance, OWCP exposes itself to a risk that providers and claimants will prescribe and obtain drugs that may be permissible for the FECA injury, but may not be medically necessary.

OWCP DID NOT HAVE PROCESSES OR CONTROLS TO ENSURE ALL DRUGS WERE PRESCRIBED BY THE CLAIMANT'S ATTENDING PHYSICIAN

In our first report, we found OWCP established a control to provide some assurance that compounded drugs were prescribed by treating physicians. The LMN for compounded drugs required the prescriber to certify that they were the claimant's treating physician. However, OWCP did not ensure a bona fide relationship existed between the prescriber and the claimant for all prescription drugs. We recommended OWCP continue its efforts to ensure the existence of a bona fide relationship between the prescriber and the claimant.

After we issued our report, OWCP began requiring LMNs to ensure opioids were prescribed by a treating physician. However, OWCP did not verify the physician who certified the LMNs for compounded drugs and opioids was the attending physician.[29] Furthermore, for drugs other than compounded drugs and opioids, OWCP did not establish any controls to ensure a bona fide relationship existed between the prescriber and claimant. DFEC Procedure Manual 3-0400-3(a) stated:

> In general, drugs and medications which are necessary to treat an injury or occupational disease may be purchased at OWCP expense on the recommendation of the attending physician.

OWCP stated it limits its involvement in physician/claimant decisions as they relate to prescriptions. As such, OWCP's general policy has been to pay for any prescription claim submitted with physician information where the drug has also been identified as a possible treatment for the accepted injury. However, OWCP has not had the capability to verify that prescribers were the attending physicians.

This issue has been at least partially due to the fact that FECA's case management system has not contained a field for "attending physician;" therefore, a match between the prescriber and the attending physician has not

[29] An attending physician is a physician who provided an examination or treatment either before or after the injury and whose medical opinion was used to adjudicate the claim. A change in attending physician requires approval by OWCP.

been possible. OWCP also believed a real-time match between the prescriber and the attending physician prior to dispensing the medication would not be effective and did "not support DFEC's mission to provide treatment that will cure and give relief to the injured worker, consistent with 5 USC 8103."

According to OWCP, there have been various logistical and timing issues related to real-time matching prior to dispensing medications. For example, if a claimant had been treated by a physician in a large practice, any physician or nurse practitioner in the practice who had their own identification number could have prescribed the medication, rendering the match ineffective. Additionally, there have been instances when a claimant has been referred to a specialist by the attending physician, and a real-time match would have caused an appropriately prescribed drug to be rejected at the pharmacy.

FIGURE 9: OWCP DID NOT ENSURE A BONA FIDE RELATIONSHIP BETWEEN THE PRESCRIBER AND THE CLAIMANT

Without verifying if there is a bona fide relationship between the prescriber and the claimant, OWCP cannot ensure that prescriptions are safe.

Moving forward, while a real-time match might not be practical, an after-the-fact analysis would help OWCP verify if a bona fide relationship exists between a prescriber and a claimant. Recently, some states have enacted laws requiring a bona-fide prescriber/patient relationship before prescribing certain types of drugs. An after-the-fact match would help OWCP identify providers who submit prescription bills for claimants they never examined, and consequently, for whom prescriptions may be unnecessary or unsafe. For example, a group of physicians were indicted in 2016 for prescribing compounded pain medications for FECA claimants who had their personally-identifying health information misappropriated and used without their knowledge.

OIG'S RECOMMENDATIONS

PREVIOUS RECOMMENDED ACTIONS

In our first report, we recommended the Director of OWCP take the following actions. We have included the most recent status of management's action.

- *Ensure the existence of prescriber/claimant relationship.* We **resolved** this recommendation based on the corrective actions OWCP has taken related to LMNs for compounded drugs and opioids. We will close this recommendation when OWCP performs a periodic, after-the-fact match between prescribers and attending physicians to identify and review any unusual prescribing activity for potential fraud or abuse.

- *Implement drug exclusion lists for drugs and drug ingredients.* We **resolved** this recommendation based on OWCP's recent award of a PBM contract, which required implementation of exclusion lists. We will close this recommendation when OWCP develops drug exclusion lists for the PBM contractor to use as reference files in its system.

- *Implement quantity limits on initial fills and refills.* We **resolved** this recommendation based on policies OWCP implemented for filling non-maintenance medications, compounded drugs, and opioids. We will close this recommendation when OWCP implements quantity limits for maintenance drugs and formally documents its policy.

NEW RECOMMENDATIONS

In this report, we are making 2 new recommendations that the Director of OWCP:

4. Ensure the PBM implements a drug utilization review as specified in the contract.

5. Ensure the PBM, when developing its formulary, considers all classes of drugs to determine if prior authorization or LMNs would be appropriate.

ENSURING FECA PROVIDERS ARE QUALIFIED

OWCP had not reported all the excluded providers to the national healthcare fraud and abuse data collection program, or accessed this data to ensure FECA providers were qualified. However, OWCP had taken actions to identify questionable providers, refer them to DOL OIG for investigation, and exclude providers convicted of fraud.

OWCP HAD TAKEN ACTIONS TO IDENTIFY QUESTIONABLE PROVIDERS, REFER THEM TO DOL OIG, AND EXCLUDE CONVICTED PROVIDERS

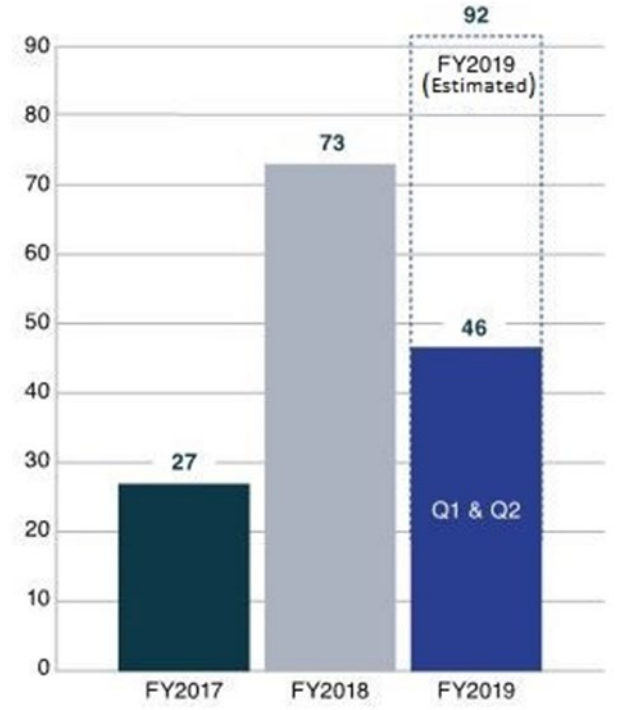
In our first report, we determined even though OWCP had policies and procedures in place for reviewing and taking action on providers who acted in fraudulent and abusive manners, OWCP did not perform these reviews because its exclusion procedures were cumbersome and not designed for pharmacy providers. We recommended OWCP perform reviews of questionable provider practices and establish an effective program integrity unit.

After we issued our report, OWCP established a program integrity unit and tasked it with reviewing and analyzing spending data to identify potential fraud cases and refer those cases to DOL OIG for investigation.[30] The Program Integrity Unit also began using data analytics and data science to proactively identify unusual payment activity and patterns to better detect and prevent fraud in the FECA program.

[30] FECA Bulletin No. 17-05. Investigations Related to Federal Employees' Compensation Act (FECA) Medical Fraud. May 8, 2017.

As a result of these efforts, OWCP significantly increased referrals to DOL OIG. OWCP made only 27 referrals to DOL OIG in FY 2017, but made 73 referrals in FY 2018, and 46 during the first six months of FY 2019.

FIGURE 10: THE PROGRAM INTEGRITY UNIT HAS SIGNIFICANTLY INCREASED REFERRALS TO DOL OIG



From FY 2016 to FY 2018, OWCP excluded 21 providers who were convicted of fraud. Additionally, OWCP expanded its authority to remove fraudulent providers by implementing a non-procurement suspension and debarment process.[31] OWCP further expanded its exclusion authority to include entities owned, managed by, or otherwise associated with convicted individuals.[32]

[31] FECA Circular No. 18-01. Application of the Department of Labor's (DOL) Suspension and Debarment Procedures to Medical Provider Payments under the Federal Employees' Compensation Act (FECA). November 29, 2017.

[32] FECA Bulletin No. 18-05. Provider Exclusion - Ownership/Management Interest and Support Services. July 3, 2018.

OWCP HAD NOT REPORTED EXCLUDED PROVIDERS TO THE HHS HEALTHCARE FRAUD AND ABUSE DATA COLLECTION PROGRAM

OWCP did not report to the U.S. Department of Health and Human Services (HHS) any of the 21 providers it excluded from the FECA program.

Congress established a national healthcare fraud and abuse data collection program that required federal agencies to report any adverse actions, including exclusions, against healthcare providers, suppliers, or practitioners.[33] HHS maintains the information in the National Practitioner Data Bank (Data Bank). The purpose of the Data Bank is to deter fraud and abuse in healthcare delivery systems by preventing practitioners from moving state to state without disclosure or discovery of first damaging performance.

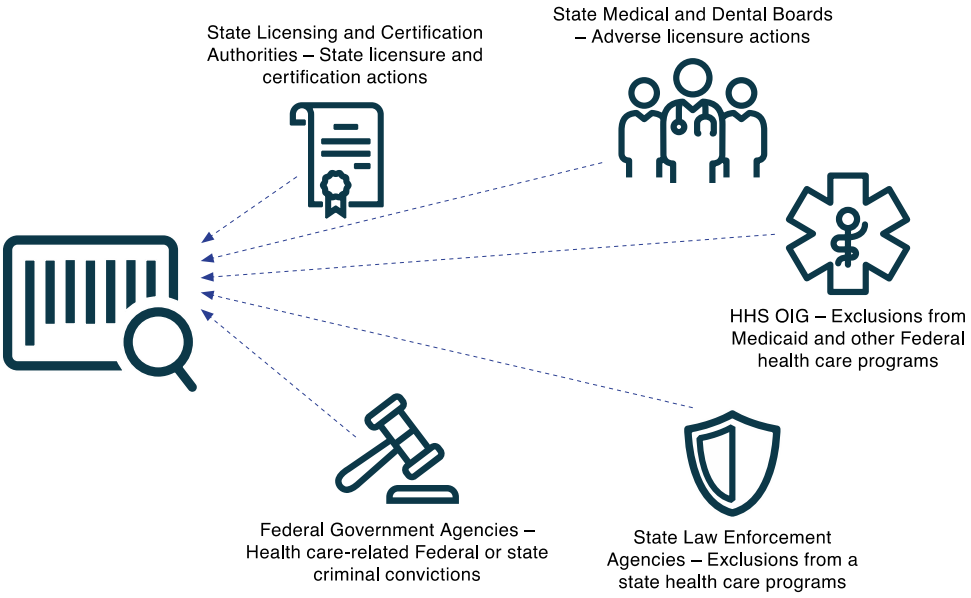
OWCP was not aware of this requirement and has reached out to HHS for guidance. Without timely reporting to the Data Bank, fraudulent providers may continue to participate in federal and state healthcare programs and potentially expose those programs to fraud and abuse.

OWCP HAD NOT USED PROVIDER INFORMATION IN THE DATA BANK TO ENSURE FECA PROVIDERS WERE QUALIFIED

After issuing our first report, we found OWCP did not use information from the Data Bank. It instead used a "List of Excluded Individuals/Entities" maintained by HHS OIG. However, this list only contained providers excluded by HHS OIG and did not contain all the adverse actions taken by other federal agencies or state licensing or certification agencies.

[33] United States Code. Title 42, Section 1320a–7e, Health Care Fraud and Abuse Data Collection Program.

FIGURE 11: OWCP DID NOT USE INFORMATION FROM THE DATA BANK



Federal law requires the information in the Data Bank to be available to agencies administering federal healthcare programs.[34] In addition to the exclusions, the Data Bank contains other information on healthcare providers, such as adverse licensing or certification actions taken by state licensing or certification agencies.

The information in the Data Bank is not free. According to its website, Data Bank charges a fee for each query performed. Consequently, OWCP needs to work with Data Bank to determine whether it is cost effective to use the information in the Data Bank. OWCP stated it has obtained information on the Data Bank and is in the process of reaching out to it for additional detail on the process to use the information. Without using currently available adverse licensing and certification information on healthcare providers, OWCP cannot ensure the providers in the FECA program are qualified.

[34] United States Code. Title 42, Section 1320a–7e, Health Care Fraud and Abuse Data Collection Program.

OIG'S RECOMMENDATIONS

PREVIOUS RECOMMENDED ACTIONS

In our first report, we recommended the Director of OWCP take the following actions. We have included the most recent status of management actions.

- *Ensure timely removal of questionable providers from the program.* We **closed** this recommendation based on the additional policies OWCP implemented to expand its authority to remove fraudulent providers from the FECA program.

- *Perform reviews of questionable provider practices.* We **closed** this recommendation based on OWCP's undertaking of targeted reviews of specific providers, including pharmacies, using billing trends and reports from other stakeholders, and the issuing of FECA Bulletin No. 17-05, which outlines procedures for identifying potential fraud cases and referring them to DOL OIG.

- *Establish an effective program integrity unit.* We **closed** this recommendation based on OWCP's restructuring of the unit by working with the Medical Bill Specialist and Fraud Liaison to identify improper billing practices, review spending patterns, and increase referrals made to DOL OIG.

NEW RECOMMENDATIONS

In this report, we are making 2 new recommendations that the Director of OWCP:

6. Report all excluded providers to HHS.

7. Determine whether it is cost effective to use the information in the Data Bank to ensure FECA providers are qualified.

SUMMARY OF OWCP'S RESPONSE

OWCP agreed with our recommendations and stated that it will continue to focus on combatting the opioid epidemic and protecting injured federal workers. It is currently working to finalize a PBM contract award, which should satisfy many of our recommendations. We included management's response to our draft report in its entirety in Appendix B.

We appreciate the cooperation and courtesies OWCP extended us during this audit. OIG personnel who made major contributions to this report are listed in Appendix C.

Elliot P. Lewis
Assistant Inspector General for Audit

EXHIBIT 1: PHARMACEUTICAL BENEFITS FRAMEWORK

- Are providers qualified?
  - Are licensed prescribers and pharmacists used?
  - Are excluded prescribers and pharmacists used?
  - Is OWCP timely removing or suspending providers suspected of acting in a fraudulent or abusive manner?
  - Is OWCP reviewing providers and taking action on providers acting in a fraudulent or abusive manner?
  - Is there a bona fide provider and claimant relationship?

- Is the prescription valid?
  - Is the claimant eligible and, if so, is the condition covered under FECA?
  - Is the prescription medically necessary?
    - Is the prescription identified as a possible treatment for the accepted condition?
    - Is prior approval required for the prescription?
    - Is a letter of medical necessity required and approved?
  - Is the prescription safe and effective?
    - Is the prescription approved as safe in the treatment for the accepted condition?
  - Is the prescription reviewed to ensure safety from overuse (e.g. drug utilization reviews)?
  - Is the claimant prescription reviewed for safety from interactions with other medications?

- Are prescription prices fair and reasonable?
  - Are prescription reimbursements calculated correctly?
  - Is OWCP using the best method to calculate pharmaceutical payments?
  - Are lower cost alternatives considered?
    - Are generics drugs being used when appropriate?
    - Are preferred pharmacies used?
    - Can prescriptions be obtained through the Federal “ceiling price” statute?
  - Are unusual bills identified and reviewed?

- Is the claimant properly receiving the prescription?
  - Did the claimant receive the prescribed drug?
  - Is the claimant receiving the proper quantity of the prescribed drugs?

  - Did the claimant receive notification or explanation of benefits regarding the payment for the prescribed drug?
  - Did the claimant receive education regarding the proper usage and possible interactions of the prescribed drug?

- Is OWCP performing the necessary general management and program integrity activities?
  - Are risks assessments of the FECA program performed?
  - Are data analytics performed to identify trends and improvements?
  - Are improper payment and fraud detection techniques employed?
  - Is OWCP's medical information adequately protected?
  - Are stakeholders and management informed of the proper information to manage and make decisions?
  - Is OWCP collecting the right information to manage the program?
  - Is OWCP management receiving the needed information to make decisions?
  - Is contracting out the pharmaceutical benefits an alternative?

APPENDIX A: SCOPE, METHODOLOGY & CRITERIA

SCOPE

Our audit covered OWCP's policies and procedures for managing prescription drugs in the FECA program as of the end of our fieldwork, which was March 4, 2019. Our analysis of FECA's bill payment data generally covered the period from FY 2016 to FY 2018. We conducted the fieldwork at OWCP National Office in Washington, DC.

METHODOLOGY

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

To answer our objective, we identified key program objectives and risks for pharmaceutical benefits in the FECA program, reviewed FECA laws and regulations, reviewed OWCP policies and procedures, and interviewed OWCP administrators, USPS-OIG officials, and representatives of healthcare organizations to understand the objectives and requirements of pharmaceutical benefit programs. Based on that understanding, we developed a framework of control objectives applicable to OWCP's management of pharmaceutical benefits in the FECA program (see Exhibit 1: Pharmaceutical Benefits Framework).

Using this framework, we assessed OWCP's existing and planned controls for managing pharmaceutical benefits in the FECA program by conducting interviews with OWCP management and reviewing supporting documentation, including OWCP's drafted Government Reform Proposal and its PBM contract; analyzed pharmaceutical costs and other bill pay data to verify implementation of controls and to identify potential areas of risk; conducted research into opioids, the opioid crisis, prescribing guidelines used by other federal agencies, requirements for reporting excluded healthcare providers, AWP costs at both the federal and state levels, and other pharmaceutical pricing benchmarks; and conducted walk-throughs of (a) the Program Integrity Unit's process for identifying and tracking potentially fraudulent providers through the use of data analytics, and (b) the OWCP bill pay system's automated edit check process used to limit fills and refills for non-maintenance drugs.

In addition, we tested a random sample of two transactions per month from October 2016 through March 2018 from a universe of 9,950 transactions to determine whether compounded drug prescriptions were supported by LMNs; tested providers convicted of fraud, and consulted with OIG Office of Investigations and Office of Legal Services, to determine if OWCP made any payments to these providers or excluded them from the FECA program; and reviewed bill pay data from FY 2016 to FY 2018 to identify high cost prescriptions over $50,000.

To keep stakeholders informed of pharmaceutical issues in the FECA program, we issued *Interim Report on Audit of Pharmaceutical Management in DOL Benefit Program: OWCP Needs Better Controls over Compounded Prescription Drugs* (Report No. 03-17-001-04-431) on May 23, 2017. The report reflected the work performed in selected areas of the framework.

This report includes the result of our work performed in all areas of the framework. To obtain concurrence and solicit additional information relevant to understanding FECA program operations and controls, we shared our results with OWCP management.

As auditors, we have not made any sort of medical evaluations. We reviewed OWCP laws, regulations, as well as other federal agency guidelines on opioids and related control objectives and activities for FECA pharmaceutical benefits, and identified barriers to the effective management of the FECA pharmaceutical benefits program.

DATA RELIABILITY

In conducting this audit, we relied on data from OWCP's bill pay and case management systems. To assess the reliability of this information, we performed tests for obvious errors in completeness, compared it to other sources where possible, and confirmed our understanding of the data through interviews and walkthroughs with agency officials. We determined that the data was sufficiently reliable to support our audit conclusions, findings, and recommendations.

INTERNAL CONTROLS

In planning and performing our audit of OWCP's management of pharmaceuticals in the FECA program, we considered internal controls that were relevant to our audit objective by obtaining an understanding of those controls and assessing control risk for the purposes of achieving our objective. The objective of our audit was not to provide assurance on the internal controls; therefore, we did not express an opinion on the internal controls as a whole. Our consideration of OWCP's internal controls relevant to our audit objective would

not necessarily disclose all matters that might be significant deficiencies. Because of the inherent limitations on internal controls, noncompliance may nevertheless occur and not be detected.

CRITERIA

- Code of Federal Regulations. Title 20, Part 10, Claims for Compensation under the Federal Employees' Compensation Act. Section10.809, Medical Fee Schedule.
- Code of Federal Regulations. Title 20, Part 10, Claims for Compensation under the Federal Employees' Compensation Act. Sections 10.815-10.826, Exclusions of Providers.
- DFEC Procedure Manual. Part 3, Medical.
- DFEC Procedure Manual. Part 5, Benefit Payments.
- FECA Bulletin No. 17-01. Compounded Medication Prescribing Guidelines. October 14, 2016.
- FECA Bulletin No. 17-05. Investigations Related to Federal Employees' Compensation Act (FECA) Medical Fraud. May 8, 2017.
- FECA Bulletin No. 17-07. Opioid Prescribing Guidelines. June 6, 2017.
- FECA Bulletin No. 18-04. Opioid Prescribing Guidelines, Short-Term, Long-Term and High Dose Opioid Use. June 15, 2018.
- FECA Bulletin No. 18-05. Provider Exclusion - Ownership/Management Interest and Support Services. July 3, 2018.
- FECA Circular No. 12-06. Bill Payment Practices and Restrictions. June 26, 2012.
- FECA Circular No. 18-01. Application of the Department of Labor's (DOL) Suspension and Debarment Procedures to Medical Provider Payments under the Federal Employees' Compensation Act (FECA). November 29, 2017.
- FECA Circular No. 18-05, Medication "Convenience" Kits and Combination Medications. February 14, 2018.
- FECA Circular No. 18-06, Physician Dispensed Medication (Billing for Unspecified "J Codes"). May 18, 2018.
- GAO-14-704G, Standards for Internal Controls in the Federal Government. September 2014.
- United States Code, Title 38, Section 8126, Limitation on Prices of Drugs Procured by Department and Certain Other Federal Agencies.
- United States Code, Title 42, Section1320a–7b, Criminal Penalties for Acts Involving Federal Health Care Programs.
- United States Code, Title 42, Section1320a–7e, Health Care Fraud and Abuse Data Collection Program.

APPENDIX B: AGENCY'S RESPONSE TO THE REPORT

U.S. Department of Labor

Office of Workers' Compensation Programs
Washington, DC 20210

MAY - 8 2019

MEMORANDUM FOR: **ELLIOT P. LEWIS**
Assistant Inspector General for Audit

FROM: **JULIA K. HEARTHWAY**
Director, Office of Workers' Compensation Programs

SUBJECT: **Office of Worker's Compensation Programs' Response to the Office of the Inspector General's Audit of Pharmaceutical Management in the FECA Program, Draft Report No. 03-19-002-04-431**

The Office of Workers' Compensation Programs (OWCP) has received the Office of Inspector General (OIG) Draft Report No. 03-19-002-04-431, "OWCP Must Continue Addressing Weaknesses in Management of FECA Pharmaceutical Benefits" for review and response addressing the findings and recommendations. The Draft Report details the progress OWCP has made since 2017 to manage the use and cost of pharmaceuticals in the FECA program. Since the OIG issued their Interim Report on this topic in May 2017, the OIG has closed most of the recommendations it contained, and the majority of the remaining recommendations will be satisfied after finalizing a Pharmacy Benefit Manager (PBM) award — a process which is currently underway.

This Draft Report makes a total of seven helpful and thoughtful new recommendations, which are outlined below along with our responses, but overall:

- As the OIG notes, OWCP has made great strides in combatting the opioid epidemic and protecting injured federal workers, and will continue to focus intensely on this issue.
- OWCP is currently working to finalize a PBM award, which will satisfy many of the new recommendations in addition to those remaining from the Interim Report. All immediately implementable recommendations will be pursued and documented before our follow-up in 60 days. Those that depend on the full contract with the PBM will be implemented as soon as practicable.
- OWCP appreciates the OIG bringing the National Practitioner Data Bank reporting requirement to our attention; OWCP will work expeditiously to close this recommendation.

1. **Recommendation:** Work with stakeholders to develop better guidelines to shorten the 60-day grace period for first fill opioid prescriptions.

   Management Response: Agree. OWCP has developed a comprehensive plan to shorten the grace period while respecting the medical needs of patients. Currently, initial opioid fills are limited to no more than a 30-day supply. A second prescription, again limited to

30 days, is allowed; after which the Division of Federal Employees' Compensation (DFEC) requires a Letter of Medical Necessity (LMN) before authorizing payment for any additional opioid medication. DFEC considered multiple factors when it implemented this policy nearly two years ago (20 months) including data available at the time showing that the majority of new entrants stopped using opioids by day 60 without any governmental intervention. Our most recent data now shows that 52% of opioid recipients stop taking opioids at or before day 15. And, it is significant to note that opioid use among injured federal workers has dramatically declined. Overall opioid use has dropped by 30% and new entrants have dropped by 24%.

Despite this population being relatively small in the FECA program, DFEC is nonetheless actively pursuing shortening its current initial time periods. We anticipate initial fills to be limited to a 7-day supply and prior approval required to extend continued opioid use beyond 30 days; we will begin implementing this change as soon as practicable and will report back in 60 days. There are really two controls that warrant attention and are part of DFEC's comprehensive plan. The first is a limit on the days' supply of an opioid prescription. This is a control that many states have implemented, with various different time frames, and it is important to also note that any state control also applies to all FECA claimants living in those states. The second control is the requirement of obtaining prior authorization for the continued prescribing of opioids. These two controls are closely related and striking the right, most effective balance for the federal injured worker population is in-line with our tailored individual approach to opioid use. Our in-depth work with opioid use among this population has presented us with a host of varied and inter-related factors that we are continuously evaluating. We are also mindful of the recent medical community opposition to other government payers who have proposed broad-brush restrictions. Accordingly, DFEC is carefully balancing these concerns, but nonetheless does anticipate introducing new time limitations later this year.

Lastly, DFEC also will ensure that it has in place the mechanisms to appropriately notify patients through real-time communications (either at the pharmacy counter or through written correspondence) that adequately alert patients of the requirements needed to obtain their necessary medication.

2. **Recommendation:** Implement controls to improve the reliability of the ICD-10 codes for opioid addiction, such as analyzing prescription data and reaching out to physicians when claimants have long-term prescriptions and/or high Morphine Equivalency Dose (MED) levels.

   Management Response: Agree. DFEC is already analyzing prescription data and reaching out to physicians when claimants have long-term prescriptions and high MED levels. DFEC has also inserted a code in the accepted condition field for all cases with a prescribed opioid that allows treatment for opioid addiction. DFEC has taken this approach because: 1) The diagnosis does not indicate the danger, the opioid usage does; and 2) DFEC cannot diagnose patients with opioid addiction as this requires medical training, examining the patients, and is reserved for the patient's physician to determine.

3. **Recommendation:** Establish procedures to conduct on-going analysis of ICD-10 codes and other related data to monitor opioid addiction and treatment.

   Management Response: Agree. DFEC already collects and monitors this information, and will institute a more standardized process for doing so moving forward.

4. **Recommendation:** Ensure the PBM implements a drug utilization review as specified in the contract.

   Management Response: Agree. Drug utilization reviews would be beneficial. Drug utilization reviews include functions such as detecting fraud, waste, and abuse patterns by providers or claimants; screening for drug/drug contraindications; identifying duplicate prescriptions and therapeutic overlap; and/or determining brand name versus generic use by drug category. The OWCP pharmacist, DFEC policy-makers, and the PBM clinicians will undertake the necessary analyses, develop appropriate drug utilization reviews as specified in the contract, and implement once a PBM award is finalized.

5. **Recommendation:** Ensure the PBM, when developing its formulary, considers all classes of drugs to determine if prior authorization or LMNs would be appropriate.

   Management Response: Agree. Drug formulary lists would be beneficial and DFEC intends to implement them with the assistance of a PBM. The OWCP pharmacist, DFEC policy-makers, and the PBM clinicians will undertake the necessary analyses (including requirements for prior authorization or an LMN), develop an informed formulary, and implement once a PBM award is finalized.

6. **Recommendation:** Report all excluded providers to HHS.

   Management Response: Agree. OWCP appreciates the OIG bringing this requirement to our attention. OWCP has confirmed this requirement with HHS, registered, and will begin reporting as soon as possible.

7. **Recommendation:** Determine whether it is cost effective to use the information in the Data Bank to ensure FECA providers are qualified.

   Management Response: Agree. OWCP is working with HHS and our medical bill pay provider to determine whether we can use this database effectively and if the associated costs are reasonable.

In addition to the seven new recommendations, the Draft Report included the status of the recommendations the OIG issued in their Interim Report on this topic in May 2017. While the OIG has closed eight of the 16 recommendations from the Interim Report, the eight remaining open/resolved recommendations are included below along with our responses.

- **Recommendations:** Implement drug formulary lists and implement the use of preferred providers.

  Status: The OIG has indicated they will close these recommendations when OWCP provides evidence the PBM contractor developed a pharmacy network and implemented a formulary list.

  Management Response: Agree. Drug formulary lists would be beneficial, and OWCP intends to implement them with the assistance of a PBM. The OWCP pharmacist, DFEC policy-makers, and the PBM clinicians will undertake the necessary analyses, develop an informed formulary, and implement once a PBM award is finalized. OWCP will also provide evidence of the PBM-developed pharmacy network once a PBM award is finalized.

- **Recommendation:** Implement a new pricing methodology.

  Status: The OIG has indicated they will close this recommendation when OWCP establishes a policy to conduct on-going analysis into commercial pricing strategies as they become available to ensure current pricing strategies are providing the best prices for the FECA program.

  Management Response: Agree. OWCP has, by regulation, adopted Average Wholesale Price (AWP) to calculate pharmacy payments and has full discretion to base its payments on a percentage of AWP. While several independent publishers have proposed alternatives to AWP, according to the latest Academy of Managed Care Pharmacy (AMCP) Guide to Pharmaceutical Payment Methods, no comprehensive, transparent, and widely acceptable alternative to AWP has been identified for the commercial marketplace (http://amcp.org/pharmaceutical-payment-guide/).

  OWCP will also continue seeking to control costs and improve safety within the existing AWP pricing methodology. Savings have resulted from changes such as the implementation of a prior-authorization requirement for compounded medications, and further changes such as utilizing a PBM will also help control costs and improve safety. Examples of PBM benefits include clinical controls, prescription management procedures and monitoring of certain medications, all of which can trigger a prior-authorization process for the pharmacy or approval and denial recommendations for the adjudicator. OWCP will also implement controls to ensure the reasonableness of the prices charged by the PBM.

- **Recommendation:** Verify cost controls (generic drug usage) effectiveness.

  Status: The OIG has indicated they will close this recommendation when OWCP provides evidence that it is conducting a routine analysis to determine whether its generic drug policy is being effectively followed.

Management Response: Agree. The OWCP pharmacist and/or physicians, DFEC policy-makers, and the PBM clinicians will work on developing an informed and aggressive generic policy once a PBM award is finalized.

- **Recommendation:** Improve review of costs.

  Status: The OIG has indicated they will close this recommendation when OWCP establishes a specific dollar threshold and implements a formal procedure to review pharmaceutical bills.

  Management Response: Agree. The OWCP pharmacist, DFEC policy-makers, and the PBM clinicians will undertake the necessary analyses to determine any appropriate thresholds and review procedures once the PBM award is finalized.

- **Recommendation:** Ensure existence of prescriber/claimant relationship.

  Status: The OIG has indicated they will close this recommendation when OWCP performs a periodic, after-the-fact match between prescribers and treating physicians to identify and review any unusual prescribing activity for potential fraud or abuse.

  Management Response: Agree. While a real-time match between prescribers and treating physicians is not practical for many reasons as the OIG indicates in their report, OWCP will develop the ability to do a periodic, appropriate post-utilization match sampling.

- **Recommendation:** Implement drug exclusion lists for drugs and drug ingredients.

  Status: The OIG has indicated they will close this recommendation when OWCP develops drug exclusion lists for the Pharmacy Benefits Management (PBM) contractor to use as reference files in its system.

  Management Response: Agree. Drug exclusion lists for drugs and drug ingredients would be beneficial. While as DOL OIG notes some limitations/exclusions have already been implemented such as on the J codes, OWCP intends to fully implement further drug exclusions through the assistance of a PBM. The OWCP pharmacist and/or physicians, DFEC policy-makers, and the PBM clinicians will undertake the necessary analyses, develop drug exclusion lists, and implement once a PBM award is finalized.

- **Recommendation:** Implement quantity limits on initial fills and refills.

  Status: The OIG has indicated they will close this recommendation when OWCP implements quantity limits for maintenance drugs and formally documents its policy.

  Management Response: Agree. For non-maintenance medications, DFEC's policy is to limit fills to 30-day increments and refills cannot be obtained until 75% of the prescription timeline has passed (See

https://www.dol.gov/owcp/dfec/FillingNonmaintenanceMeds.htm). For maintenance medications, the OWCP pharmacist and/or physicians, DFEC policy-makers, and the PBM clinicians will review quantity limits as part of formulary development, undertake any necessary analyses, and determine any appropriate policy changes once a PBM award is finalized.

APPENDIX C: ACKNOWLEDGEMENTS

Key contributors to this report were Jessy Joseph, Daniel Pompilii, Steve Sovich, Lisa LaRosa, Yung Lee, and Badara Kamara.

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