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.