APPENDIX A

OWCP'S RESPONSE

U.S. Department of Labor

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

May 5, 2017

MEMORANDUM FOR ELLIOT P. LEWIS
Assistant Inspector General for Audit

FROM: **GARY A. STEINBERG**
Deputy Director, Office of Workers' Compensation Programs

SUBJECT: **Office of Workers' Compensation Programs' Response to the Office of the Inspector General's Compounded Drug Costs Audit Report No. 03-17-001-04-431**

Thank you for allowing me the opportunity to review and respond to the findings and recommendations in your draft report regarding pharmaceuticals in the Office of Workers' Compensation Programs (OWCP) Division of Federal Employees' Compensation (DFEC). I also want to thank you for your continued interest and assistance in this area, as together we have made great strides to ameliorate the issues raised by you and our partner agencies and inspectors general. The FECA program was paying over $20 million per month for compounded drugs prior to the implementation of our change efforts in July and October 2016, and due to those changes we are now averaging approximately $2 million per month. However, I acknowledge there is more to be done and your report contains many excellent recommendations. Our responses to your "OIG Recommended Actions" (Exhibit 2 of your report) are outlined below.

1. **Control Objective**: Are excluded prescribers and pharmacists used?
Recommended Action: Ensure Timely Removal of Questionable Providers From Program
Type: Legislative
Management Response: Agree. In consultation with other Department and Administration officials, OWCP will evaluate whether to seek additional authorities by legislation. Until then, we are committed to using our current process to exclude providers to the maximum extent permissible under our statute. In an effort to streamline that process, we have developed new procedures where OWCP will use analysis from our program integrity unit as well as other sources as a starting point for initiating internal investigations of providers where suspicious billing activity is noted. After the internal investigation is completed, where appropriate, OWCP will refer the matter to the Department's OIG with recommendations for exclusion. Once the OIG concurs on our recommendations, OWCP will proceed with steps to exclude the provider from participating in the program. These procedures were developed in collaboration with the Department's OIG Office of Investigations. These new fraud procedures have been outlined in a FECA Bulletin (Investigations related to Federal Employees' Compensation Act (FECA) Medical Fraud), and are scheduled to be published in May 2017.

2. **Control Objective**: Is OWCP reviewing providers and taking action on providers acting in a fraudulent or abusive manner?
Recommended Action: Perform Provider Reviews of Questionable Provider Practices
Type: Policy
Management Response: Agree. Previously, DFEC only had a "provider on review" process wherein bills could be suspended and reviewed prior to payment if the billing practices of the provider were found to be questionable; however, this process did not work for pharmacies since they typically bill via Point-of-Sale (POS) transactions and an instantaneous decision is required. Pharmacies are considered to be a qualified provider of medical services for DFEC claims (see 20 CFR 10.5), and with DFEC's increased focus on billing practices that are questionable, misleading, deceptive or unfair for all provider types, a new process has been created in conjunction with the Department's OIG to address this shortfall. DFEC is now undertaking targeted reviews of specific providers, including pharmacies, based on billing trends and reports from outside partners and stakeholders, e.g., the employing agency IG community. When potentially fraudulent behavior is initially identified, as described in the previous section, OWCP will consult with the Department's OIG and then, based on that recommendation, OWCP will proceed with investigative and bill review work if the Department's OIG determines that such work would not interfere with an open investigation. Upon completion of any investigatory actions, if the provider's practices are found to be potentially fraudulent, OWCP will consider whether declaration of an administrative debt is appropriate and also refer the findings to the Department's OIG for review and recommendation regarding a discretionary exclusion under 20 CFR 10.817. These new procedures have been outlined in a FECA Bulletin (Investigations related to Federal Employees' Compensation Act (FECA) Medical Fraud), which is scheduled to be published in May 2017.

3. **Control Objective**: Is there a bona-fide provider (prescriber) and claimant relationship?
Recommended Action: Ensure the Existence of Prescriber/ Claimant Relationship
Type: Policy
Management Response: Agree, as this relates to compounded and other special classes of drugs. For compounded drugs the CA-26 (Letter of Medical Necessity) mandates that the physician who completes the form must certify he or she is the treating physician for the injured worker. This can also be done for drugs such as opioids.

OWCP agrees that only prescriptions where the prescriber has examined the injured worker should be paid. We have plans to implement a change to our medical bill processing system to require that prescribers submit their national provider identifier (NPI) number when submitting bills for drugs, which will identify the provider submitting the prescription. This change will take place by June 30, 2017, and beginning July 1, 2017, POS transactions will be denied for claims that do not reflect the prescriber's NPI number and/or where an NPI number is submitted in an invalid format. While this will allow OWCP to know the prescriber for each claimant's prescription, the NPI number is not currently included in the bill history extract file that is loaded into OWCP's claims management system, iFECS. OWCP will require its CBP vendor to include the NPI in the full data extract that will be provided to OWCP on a routine basis, and expects to accomplish this by November of 2017.

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In implementing other controls for prescriptions, DFEC must be mindful of its statutory obligation to see that injured workers receive services, appliances and supplies prescribed or recommended by a qualified physician that are likely to cure and give relief, among other things. An injured worker may seek many types of treatment for a work injury in addition to the treating physician who manages day-to-day care. The injured worker may be treated in various ways, for example, at emergency rooms or clinics, by specialists to whom the treating physician refers them, by physicians treating non-employment related conditions that impact treatment for the FECA injury and return to work, or a fitness-for-duty examination ordered by the employer. The FECA regulations at 20 CFR 10.316 state that "(w)hen the physician originally selected to provide treatment for a work-related injury refers the employee to a specialist for further medical care, the employee need not consult with OWCP for approval." However, OWCP has established new procedures that allow for the declaration of an administrative debt when a provider's practices are later found to be potentially fraudulent, misleading, deceptive or unfair. OWCP will also refer the findings to the Department's OIG for review and recommendation regarding a discretionary exclusion under 20 CFR 10.817.

4. **Control Objective**: Is prior approval required for the prescription?
Recommended Action: Require Prior Authorization for Compounded Drugs
Type: Regulatory
Management Response: Agree, and action is complete. FECA Bulletin 17-01 (Compounding Medication Prescribing Guidelines) was published on October 14, 2016. This bulletin outlines the CA-26 requirement for prior authorization for compounded drugs and the new policy has drastically curbed spending in that area. The FECA program was paying over $20 million per month for compounded drugs prior to the implementation of our change efforts in July and October 2016, and due to those changes we are now averaging approximately $2 million per month.

5. **Control Objective**: Is a letter of medical necessity required and approved?
Recommended Action: Require Physician Certification of Medical Necessity
Type: Regulatory
Management Response: Agree, and action is complete. FECA Bulletin 17-01 (Compounding Medication Prescribing Guidelines) was published on October 14, 2016. This bulletin outlines policy guidance for the program's requirement for a CA-26 Letter of Medical Necessity for compound medications, for which a Federal Register notice was published. This policy has proven to be effective in managing prescription practices for compounded drugs and has drastically curbed spending in that area. The FECA program was paying over $20 million per month for compounded drugs prior to the implementation of our change efforts in July and October 2016, and due to those changes we are now averaging approximately $2 million per month. With respect to the number of prescriptions approved, we experienced a decrease from 7,666 paid in June 2016 to 2,947 paid in March 2017.

6. **Control Objective**: Is the prescription approved as safe in the treatment for the accepted condition?
Recommended Action: Implement drug exclusion lists for drugs and drug ingredients

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Type: Policy
Management Response: Agree. OWCP does use treatment suites to help ensure that the medication being prescribed is considered to be effective for the accepted work-related conditions; these treatment suites are created under the supervision of the OWCP Chief Medical Officer. If a prescribed medication does not fall within the treatment suite, it is not authorized, and DFEC review is required prior to authorization. In addition, DFEC policy restricts payment of products on the FDA's publicly-available listing of *Drug Products That May Not Be Compounded.* Most recently, DFEC published FECA Bulletin 17-03 (Herbal Supplement Prescribing and Authorizing Guidelines under the Federal Employees' Compensation Act). This bulletin outlines that, due to safety concerns, DFEC's policy is to not authorize payment for herbal supplements unless a claimant's treating physician acquires prior authorization by submitting rationalized medical evidence that supports the herbal supplement's safety, effectiveness and necessity. As outlined on the CA-26 Letter of Medical Necessity, herbal supplements are then authorized only after review by OWCP Chief Medical Officer, or his designee.

OWCP agrees that drug exclusion lists for drugs and drug ingredients would be beneficial, and OWCP intends to implement these restrictions with the assistance of a Pharmacy Benefit Manager (PBM) - a priority for the agency. Organizations such as TRICARE and VA have exclusion lists and/or formularies that were developed and are maintained by their PBMs. PBMs develop commercially proven lists that are proprietary to their companies, and OWCP does not currently have the level of expertise to develop and maintain its own drug exclusion lists or formularies. The exclusions discussed above relate to banned FDA drugs and are publicly available. OWCP will continue to implement these types of restrictions. Because implementation of a PBM will require significant effort to implement and to interact with OWCP's medical bill processing vendor, OWCP plans to implement the PBM once the new medical bill processing system is in place (fall 2019). To implement prior to then would greatly increase risk to the PBM implementation effort, and would also require additional funding.

7. **Control Objective**: Is the prescription approved as safe in the treatment for the accepted condition?
Recommended Action: Implement drug formulary lists
Type: Policy
Management Response: Agree. The recommended action will be implemented when OWCP acquires the services of a PBM. PBMs maintain pharmacy and therapeutic committees, composed of actively practicing physicians, pharmacists, and administrators, that develop and maintain formularies by weighing the costs and benefits of FDA-approved drugs and drug formulations (pharmacoeconomic analysis) to determine which drugs and drug formulations offer the greatest value per dollar. Because implementation of a PBM will require significant effort to implement and to interact with OWCP's medical bill processing vendor, OWCP plans to implement the PBM once the new medical bill processing system is in place (fall 2019). To implement prior to then would greatly increase risk to the PBM implementation effort, and also require additional funding.

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8. **Control Objective**: Is OWCP using the best method of to calculate pharmaceutical payments?
Recommended Action: Implement a new pricing methodology
Type: Regulatory
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. OWCP's Central Bill Processing vendor updates AWP drug pricing information in its system on a weekly basis. When bills are processed, the most current pricing information is applied for reimbursement purposes, and then OWCP's reimbursement discounts are applied. In July 2016, OWCP implemented pricing policy changes in which we reduced the reimbursement rate for generic drugs from 70% of AWP to 60%. We also established a two-tiered reimbursement rate for compound drugs in which we pay 50% of the AWP per ingredient for compounds with three or fewer ingredients and 30% of AWP for compounds with four our more ingredients. These recent reimbursement discounts of AWP have effected significant savings, and OWCP has discretion to impose additional reductions based on this formula as deemed needed. Additional savings have resulted from implementation of a prior-authorization requirement for compounded medications and imposing restrictions on herbal supplements. Further changes such as utilizing a PBM (discussed previously) will be more effective in controlling costs and improving safety, and are permitted by our current regulations. 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.

9. **Control Objective**: Are generic drugs being used when appropriate?
Recommended Action: Verify cost controls (Generic Drug Usage) Effectiveness
Type: Policy
Management Response: Agree. DFEC does have a policy to approve only generic drugs even when a name brand is available, unless the physician specifically prescribed brand. OWCP's pharmacy point of sale system records an indication of generic drug usage; however, the generic indicator is not currently included in the bill history extract file that is loaded into OWCP's claims management system, iFECS. OWCP has begun work to require its CBP vendor to include the generic indicator in the data extract that will be provided to OWCP on a routine basis. OWCP expects to accomplish this by November 2017. OWCP's replacement contract will implement full use and reporting of the generic indicator to verify utilization and cost effectiveness.

10. **Control Objective**: Are preferred pharmacies used?
Recommended Action: Use of Preferred Providers
Type: Policy
Management Response: Agree. Preferred pharmacies are not currently used by OWCP. OWCP's regulations stipulate that, "OWCP may, in its discretion, contract for or require the use of specific providers for certain medications." OWCP is currently conducting market research for a PBM services acquisition effort. Because implementation of a PBM will require significant effort to implement and to interact with OWCP's medical

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bill processing vendor, OWCP plans to implement the PBM once the new medical bill processing vendor/system is in place in the fall 2019 timeframe. To implement PBM services prior to then would greatly increase risk to the PBM implementation effort, and would require additional funding.

11. **Control Objective**: Can prescriptions be obtained through the Federal "ceiling price" statute?
Recommended Action: Pursue inclusion into prices that drug manufacturers can charge
Type: Legislative
Management Response: Agree. A legislative change to 38 U.S.C. 8126 is necessary to have access to these limitations on pricing--the pricing for pharmaceuticals set forth in section 8126 is to date reserved for four agencies: the Department of Veterans Affairs; the Department of Defense; the Public Health Service, including the Indian Health Service; and the United States Coast Guard. In consultation with other Department and Administration officials, OWCP will evaluate whether to seek additional authorities by legislation.

12. **Control Objective**: Are unusual bills identified and reviewed?
Recommended Action: Improve reviews of costs
Type: Policy
Management Response: Agree. On a case-by-case basis, bills for medical services over $50,000 are reviewed prior to payment, and DFEC is currently reviewing this dollar limit to determine whether it should be lowered. POS prescription medication sales are exempt from this price limit processing since the POS mechanism requires an immediate pay or deny decision, but DFEC is considering alternative methods to help ensure cost-effectiveness of prescription medications, including post-fill reviews or requiring prior-authorization for prescriptions exceeding a certain dollar threshold. Additionally, quarterly spend reports are now produced and analyzed to spot payment anomalies and/or spikes based on both historical and projected outlays for providers and procedures, and compound spend is reviewed on a weekly basis. Based on these trend reports, individual providers and/or cases are reviewed to determine suspicious billing activity. Based on new provider fraud procedures, OWCP will begin to investigate providers where suspicious billing activity is noted and where appropriate, refer to the Department's OIG with recommendations for exclusion. These procedures were developed with the Department's OIG Office of Investigations, and are designed to streamline the provider exclusion process. These new fraud procedures have been outlined in a FECA Bulletin (Investigations related to Federal Employees' Compensation Act (FECA) Medical Fraud) and are scheduled to be published in May 2017.

13. **Control Objective**: Is the claimant receiving the proper quantity of the prescribed drugs?
Recommended Action: Implement quantity limits on initial fills and refills
Type: Policy
Management Response: Agree, and action is complete. Effective May 2017, DFEC instituted a new policy on filling non-maintenance medications for the treatment of work related injury or illness. The program's policy limits the fill of non-maintenance

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medications to 30-day increments. Additionally, refills cannot be obtained until 75% of the prescription timeline has passed.

14. **Control Objective**: Are risks assessments of the FECA program performed?
Recommended Action: Assess Risks to the FECA Program
Type: Policy
Management Response: Agree, and action is complete. As outlined in the report, OWCP is working with the Department to identify, assess and mitigate risks in accordance with federal guidance.

15. **Control Objective**: Are data analytics performed to identify trends and improvements?
Recommended Action: Establish an Effective Program Integrity Unit
Type: Policy
Management Response: Agree. The Program Integrity (PI) Unit has three main areas of focus: Improper Payments, Return to Work and Risky Providers. While these three areas will continue to guide the actions of the unit, e.g. the PI Unit will continue to conduct the Program's annual Improper Payments Elimination and Recovery Act Audit and in doing so identify root causes and possible solutions for improper compensation payments, DFEC has restructured the work within the PI Unit in an effort to specifically yield more tangible results related to Risky Providers. PI Analysts, working under the Branch Chief for Fiscal Operations, now work more closely with DFEC's Medical Bill Specialist and the National Office Fraud Liaison to identify potential improper or fraudulent billing practices. Quarterly spend reports are produced and analyzed to spot payment anomalies and/or spikes based on both historical and projected outlays for providers and procedures. Compound spend is reviewed on a weekly basis, and other reports are generated and reviewed based on information received from District Office staff and the IG community. If an issue is identified from any of these sources, it is logged as pending until it can be assigned. Once assigned, the PI Analyst and/or National Office Fraud Liaison reviews the data to determine if the behavior is potentially fraudulent, and if so, the new fraud protocols are implemented to track the issue through to completion. These new fraud procedures have been outlined in a FECA Bulletin (Investigations related to Federal Employees' Compensation Act (FECA) Medical Fraud), which is scheduled to be published in May 2017.

16. **Control Objective**: Is the prescription part of a formulary list?
Recommended Action: Implement drug formulary lists
Type: Procedural
Management Response: Agree. The recommended action however, cannot be taken at this time for the reasons outlined in the response to recommendations 6 and 7.

17. **Control Objective**: Is contracting out the pharmaceutical benefits an alternative?
Recommended Action: Contract for Pharmacy Benefit Management
Type: Policy
Management Response: Agree. OWCP views the acquisition of Pharmacy Benefits Manager (PBM) services as a high priority. OWCP is currently working on an acquisition effort to obtain the services of a PBM. OWCP posted a request for

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information (RFI) on the Federal Business Opportunities website on December 12, 2016. In February 2017, OWCP received 13 responses to its RFI for PBM services. OWCP completed an initial analysis of the vendor responses in late February 2017, and the agency is currently performing market research to answer several questions involving the interaction of PBM and bill processing systems. The result of this effort will inform our acquisition approach and plan. Upon review of the market research, OWCP plans to complete the development of requirements that meet the needs of all OWCP programs by the end of the calendar year.

OWCP will be moving to a new medical bill processing system in fall 2019. Because implementation of a PBM will require significant effort to implement and interact with OWCP's medical bill processing vendor, OWCP plans to implement the PBM once the new medical bill processing system is in place. To implement prior to then would not only greatly increase risk to the PBM implementation effort, but would also require additional funding through contract modifications to the existing bill processing vendor.

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