

U.S. Department of Labor

Office of Inspector General—Office of Audit

**REPORT TO THE OFFICE OF
WORKERS' COMPENSATION
PROGRAMS**



**INTERIM REPORT ON AUDIT OF
PHARMACEUTICAL MANAGEMENT IN DOL
BENEFIT PROGRAMS**

**OWCP NEEDS BETTER CONTROLS OVER
COMPOUNDED PRESCRIPTION DRUGS**

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BRIEFLY...

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INTERIM REPORT ON AUDIT OF PHARMACEUTICAL MANAGEMENT IN DOL BENEFIT PROGRAMS

OWCP NEEDS BETTER CONTROLS OVER COMPOUNDED PRESCRIPTION DRUGS

WHY OIG CONDUCTED THE AUDIT

Congress, DOL-OIG, and the United States Postal Service have grown very concerned over the safety, rapidly escalating costs, and fraud associated with pharmaceuticals, and particularly compounded drugs, in the Federal Employees' Compensation Act (FECA) program.

In fiscal year (FY) 2016, the FECA program provided over \$3.2 billion in benefits to more than 219,000 workers injured in the performance of their duty and their survivors. The cost of prescription drugs in the FECA program rose from a reported \$183 million in FY 2011 to \$477 million in FY 2016, an increase of 161 percent. Compounded drugs accounted for most of this growth, escalating from approximately \$2 million in FY 2011 to a reported \$263 million in 2016.

WHAT OIG DID

We initiated an audit of the management of pharmaceuticals in the Office of Workers' Compensation Programs (OWCP) to determine the following:

Has OWCP effectively managed the usage and cost of pharmaceuticals in its workers' compensation programs?

This interim report reflects our work to date. Our ongoing audit may identify additional issues with respect to OWCP's management of pharmaceuticals. We will provide the complete results of our audit after we conclude our remaining work.

Our ongoing audit is assessing OWCP's controls over pharmaceuticals to determine how the agency ensures providers are qualified and have a bona fide relationship with the patient; prescriptions are medically necessary, safe and effective; prices paid are fair and reasonable; and claimants received their prescriptions. Our audit is also assessing how OWCP ensures the overall integrity of pharmaceutical benefits.

WHAT OIG FOUND

We found that OWCP has not effectively managed the use and cost of compounded pharmaceuticals in the FECA program.

In this interim report, we identify actions that could improve the management of pharmaceuticals. OWCP instituted some measures during our work, such as requiring a letter of medical necessity and prior approval for prescriptions, but needs to take additional legislative, regulatory, or policy actions. These actions include seeking statutory changes to allow the agency to remove questionable providers and to set price limitations. OWCP also needs to make regulatory changes to require prior authorization for compounded drugs, require physicians to certify medical necessity, and implement a new pricing methodology.

The remaining actions would only require policy changes, such as requiring drug exclusion lists, drug formulary lists, and limits on initial fills and refills of prescriptions. OWCP also needs to perform reviews of questionable provider practices, ensure the existence of a bona fide prescriber/patient relationship, improve its review of unusual bills, and establish an effective Program Integrity Unit. Finally, OWCP needs to ensure generic drugs and preferred providers are used when appropriate.

OWCP generally agreed with the actions we have identified to date. The agency indicated corrective actions are under consideration, in progress, or in some cases, were completed during our work.

READ THE FULL REPORT

To view the report, including the scope, methodology, and full agency response, go to:

<https://www.oig.dol.gov/public/reports/oa/2017/03-17-001-04-431.pdf>.

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U.S. Department of Labor

Office of Inspector General
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May 23, 2017

INSPECTOR GENERAL'S REPORT

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The FECA program provides workers' compensation coverage to approximately three million federal and postal workers. In fiscal year (FY) 2016, the program provided over \$3.2 billion in benefits to more than 219,000 workers injured in the performance of their duty and their survivors.

Congress, DOL-OIG, and the United States Postal Service (USPS)¹ have grown very concerned over the safety, rapidly escalating costs, and fraud associated with pharmaceuticals, and particularly compounded drugs, in the Federal Employees' Compensation Act (FECA) program. Based on these concerns, we initiated an audit of the management of pharmaceuticals in the Office of Workers' Compensation Programs (OWCP).

The objective of our work is to determine the following:

Has OWCP effectively managed the usage and cost of pharmaceuticals in its workers' compensation programs?

This is an interim report focused on the usage and cost of compounded drugs in the FECA program.

Based on our work to date, we have found that OWCP has implemented a number of additional controls in response to the compounded drugs issue. However, to provide reasonable assurance the program approves claims for prescribed drugs that are necessary and appropriate, and pays a fair and reasonable price for those drugs, the agency needs to evaluate and implement additional controls to better protect the integrity of the FECA program.

¹ USPS is the single largest agency in the FECA program. In FY 2015, USPS employees represented 22% of the employees covered by FECA and 47% of the new cases in the FECA program.

Our ongoing work may identify additional issues with respect to OWCP's management of the use and cost of pharmaceuticals in its workers' compensation programs. We will provide the complete results of our audit after we conclude our remaining work.

STATEMENT OF ISSUE

Compounding combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Although individual ingredients used in a compounded drug may be Federal Drug Administration (FDA) approved, compounded drugs in and of themselves are not FDA approved and the FDA does not verify the safety or effectiveness of the drug. The overuse and excessive costs of compounded drugs have impacted the FECA program and its customer agencies.

The FECA program's reported pharmaceutical costs increased from approximately \$183 million in FY 2011 to approximately \$477 million in FY 2016, a rise of 161 percent. Compounded drugs accounted for much of this growth, rapidly escalating from approximately \$2 million in FY 2011 to \$263 million in 2016.

USPS and Congressional Concerns

Since January 2015, USPS has questioned OWCP regarding its rapidly increasing FECA medical costs. In September 2015, as part of the ongoing conversations between the agencies, USPS provided OWCP its analytical results identifying the rapidly growing costs of compounded drugs in its agency. USPS was so concerned by the rising compounded drug costs and OWCP's inaction on the issue that in October 2015, it requested an adjustment in its yearly chargeback bill, citing OWCP's ineffective administration of the FECA program. OWCP responded that it disagreed with USPS' assertions and denied the USPS' request, stating it lacked the legal authority to adjust the chargeback amount.

In 2016, the USPS-OIG issued a management advisory to the USPS Chief Human Resources Officer on USPS' pharmaceutical costs and compounded drugs in the FECA program. The USPS-OIG management report recommended USPS work with DOL to effectively administer and manage workers' compensation compound drug costs and prevent abusive or fraudulent activity and implement best practices used by other entities to reduce the rising cost of compound drugs.

Since the issuance of USPS-OIG advisory report, several congressional committees have expressed concern over the safety, rapidly escalating costs, and fraud associated with pharmaceuticals, particularly with compounded drugs in the FECA program.

DOL OIG Initiatives

DOL OIG initiated actions within its Office of Audit (OA) and Office of Investigations (OI) regarding the management of pharmaceuticals within OWCP's benefit programs. DOL-OIG OA initiated a comprehensive review of processes and controls for pharmaceuticals in all four OWCP programs; initial information is being provided in this report. DOL OIG OI has partnered with USPS-OIG and other law enforcement agencies to pursue allegations of fraud involving compounded drugs. The OIG senior leadership has routinely met with the DOL Deputy Secretary and OWCP senior leadership to discuss initiatives to address the rising cost of compounded pharmaceuticals and the FECA program. For one initiative, OIG entered into a Memorandum of Understanding with DOL, which ensured OIG timely access to the data systems managed by the Department, including FECA data, to enhance OIG's ability to investigate allegations of fraud.

The OIG has started another new initiative whereby matters involving fraud in the FECA program are referred to DOL's suspension and debarment official once the OIG has sufficient evidence to establish potential fraudulent activity by a FECA provider. OIG has the ability to refer matters related to fraud to the DOL debarment official for consideration of any suspension or debarment remedies the debarment official deems appropriate. Based on these referrals, DOL can suspend providers from Federal Government contracting and from directly and indirectly receiving benefits of federal assistance programs prior to conviction and debar them on a government-wide basis after they are convicted, but this action is an entirely separate process from FECA's regulatory exclusion procedures.

OWCP Actions

In September 2015, OWCP started working with DOL's Office of the Solicitor to research and compile information about how other federal programs handled the processing of claims for compounded drugs. OWCP also reached out to officials at TRICARE², Department of Veterans Affairs, the Department of Health and Human Services and others to gather information about compounded drug policies and strategies. In March 2016, OWCP developed a draft Bulletin as a starting point for its eventual policy for compounded drugs.

In June 2016, OWCP issued an Action Plan to address the growing costs of compounded drugs in the FECA program. OWCP completed the first of the action items in July 2016, when it changed the reimbursement rates for prescribed drugs. OWCP's major action was the establishment of a policy and procedures requiring letters of medical necessity for compounded drugs. In September 2016 and February 2017, OWCP provided updates to the Action Plan and the status of the action items. The Action Plan is presented in Exhibit 1.

² TRICARE is the U.S. Department of Defense's military health care program for uniformed service members, including active duty and retired members and their families around the world. TRICARE provides comprehensive coverage (health plans, special programs, prescriptions, and dental plans) to all beneficiaries.

SCOPE AND METHODOLOGY OF AUDIT

In conducting this audit, we have identified key program objectives and risks for providing prescription drugs in the FECA program, reviewed the FECA law and regulations, 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. We then developed a framework of control objectives applicable to the operation of OWCP's FECA pharmaceutical benefit program. Using this framework, we assessed the information we obtained on OWCP's existing and planned controls for operating the FECA pharmaceutical program. We shared our results with OWCP management to obtain concurrence and solicit additional information relevant to understanding FECA program operations and controls.

This interim report reflects our work to date for selected areas of the control objectives framework for the FECA pharmaceutical program. Areas of the framework not included in this interim report are highlighted in grey. Our final report, when complete, will include our analyses of these additional areas of the framework.

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?

Throughout the report, we have identified action needed to improve the FECA program and its providing of pharmaceuticals. For those actions not implemented prior to the identification of the compounded drug issue and our audit of pharmaceutical benefits in OWCP’s programs, we provided graphic boxes of the actions OWCP needs to take regarding the controls discussed. Besides the action needed, the boxes identify the type action required as legislative, regulatory or policy and the status of implementing the action as implemented, in progress or not implemented.

As auditors, we have not made any sort of medical evaluations. We have reviewed laws and regulations and related control objectives and activities for FECA pharmaceutical benefits, and identified barriers to the effective management of the FECA pharmaceutical benefits program.

BACKGROUND

OWCP Role in FECA

The administration of the workers' compensation program, for federal employees and other individuals covered by FECA, is the responsibility of the Secretary of Labor. The Secretary of Labor delegated the administration of the FECA program to the Director of OWCP.

For covered employees' injured while in the performance of their duties, FECA directs the Secretary of Labor to provide services, appliances, and supplies prescribed or recommended by a qualified physician that the Secretary considers likely to cure, give relief, reduce the degree or the period of disability, or aid in lessening the amount of monthly compensation³.

OWCP uses several electronic systems to administer the FECA program. For pharmacy benefits, OWCP primarily uses its' integrated Federal Employees' Compensation System (iFECS), which contains case management information, and a contracted system for processing medical bill claims.

Compounded Drugs

Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. For medical reasons, some individuals are unable to use commercially formulated medications as prescribed and must use a compounded drug. Typically, compounded drugs are used for individuals who need:

- a specific drug combination due to allergies to certain ingredients;
- dosage that is not commercially available; or
- liquid forms of medications instead of tablet forms.

Although individual ingredients used in a compounded drug may be FDA approved, compounded drugs in and of themselves are not FDA approved and the FDA does not verify the safety or effectiveness of the drug.

³ 5 U.S.C 8103: Medical services and initial medical and other benefits.

WHAT WE FOUND

OWCP needs to implement additional processes and controls for the FECA program aimed at ensuring that the prescription drugs, including compounded drugs, it approves are medically necessary, effective, safe, and are purchased at a fair and reasonable price.

ARE PROVIDERS QUALIFIED?

OWCP has policy and procedures to ensure claimants use only qualified providers that meet FECA requirements. Specifically, OWCP's procedures ensure providers are licensed to prescribe or dispense pharmaceuticals and are not on an exclusionary list. OWCP does not ensure a doctor and claimant relationship exists prior to authorizing the reimbursement of prescriptions, nor does OWCP actively or effectively identify and take action against prescribers and pharmacists operating in a fraudulent or abusive manner.

Are licensed prescribers and pharmacists used?

OWCP has implemented controls to reimburse medical services to only those physicians and pharmacists that have met its provider enrollment requirements, which include verifying current licensure.

For prescribers, OWCP requires physicians to enroll with the OWCP's bill processing contractor prior to providing medical services. As part of the enrollment process, the bill processing contractor is required to verify enrollment information, including medical licenses, specialty and education.

For pharmacies, OWCP requires pharmacies and pharmacists to meet state and federal licensing requirements. The National Council for Prescription Drug Programs (NCPDP), a recognized industry organization, validates pharmacies and pharmacists for state and federal licensing requirements. Once validated by NCPDP, a pharmacy or pharmacist can enroll with OWCP's bill processing contractor.

Are excluded prescribers and pharmacists used?

OWCP has policy and procedures to ensure prescribers and pharmacists on exclusionary lists are not part of the FECA program. However, OWCP could take additional steps to timely remove or suspend providers identified as using questionable or fraudulent practices from the FECA program. OWCP has implemented controls to prohibit prescribers and pharmacists on federal exclusion lists from participating in the FECA program. These exclusion lists include providers convicted under criminal statutes of fraudulent activities in connection with any federal or state program. Additionally, FECA regulations allow OWCP to administratively exclude providers after going through due process with the provider.

In the absence of a criminal conviction, prior exclusion by a similar program or placement on various federal “do not pay” lists, regulations allow OWCP to exclude providers with frequent unusual or false billings through administrative means. Specifically, 20 C.F.R. §§ 10.815-10.818 identifies the grounds for initiating and excluding a provider from payments under FECA. These regulations allow OWCP to initiate procedures for excluding providers upon notification by the OIG that the OIG has reasonable cause to believe that violations of § 10.815 have occurred. These regulations do not require a conviction to occur prior to exclusion.

Is OWCP timely removing or suspending providers suspected of acting in a fraudulent or abusive manner?

OWCP could take additional steps to timely remove or suspend providers identified as using questionable or fraudulent practices from the FECA program. Currently, providers can continue to participate in the FECA program and continue to be paid for questionable services while OWCP completes its provider exclusion procedures or awaits the results of prosecution of the provider.

While FECA regulations allow OWCP to exclude a provider through administrative means, this exclusion can only be accomplished after due process. Before a provider can be excluded, OWCP must provide notice to the provider and afford the provider an opportunity for a hearing before the Department of Labor’s Office of Administrative Law Judges. This process and procedures can last several years.



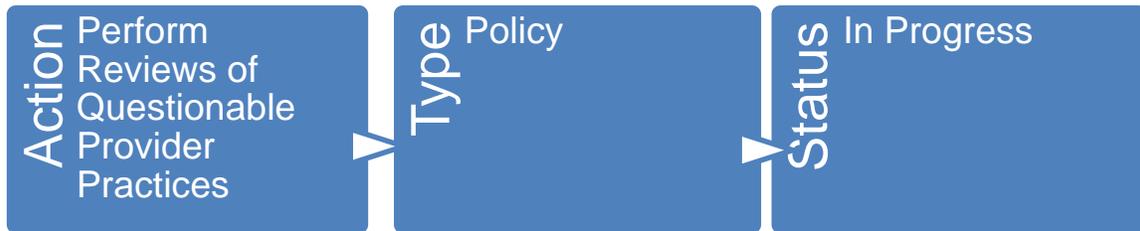
OWCP stated a legislative change would be needed to increase its ability to quickly suspend questionable providers. As part of its Action Plan, OWCP originally identified this change for future initiatives, but has since changed the status of this action item to “Reserved for Future Consideration.” In response to our draft report, OWCP stated it would work with the Department and Administration officials to evaluate seeking additional authorities by legislation. Additionally, OWCP is implementing new procedures to streamline the process to exclude providers identified as submitting suspicious billings.

As a stop gap measure, DOL OIG has begun proactively referring providers to DOL’s suspension and debarment official once the OIG has sufficient evidence to establish potential fraud by the provider. If that official decides to suspend a provider, that provider is placed on the ineligible list, effectively precluding the provider from doing business on a government-wide basis. DOL’s debarment process is separate and apart

from OWCP's provider exclusion process⁴, which identifies providers acting in a fraudulent or abusive manner and provides the basis for excluding the provider from receiving payment for services related to the FECA program.

Is OWCP reviewing providers and taking action on providers acting in a fraudulent or abusive manner?

While OWCP has policy and procedures to review providers and take action on providers acting in a fraudulent or abusive manner, OWCP is not performing these provider reviews. OWCP has taken the position that its current provider exclusion procedures are cumbersome and were not designed for pharmacy providers.

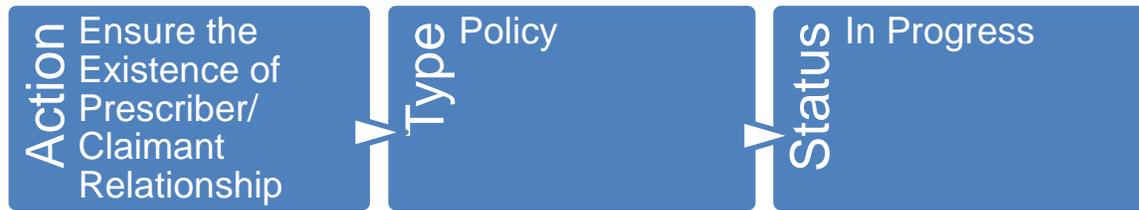


OWCP stated the section of the procedural manual on performing provider bill reviews has not been updated in some time. The provider review procedures require each and every bill to be reviewed by an OWCP staff person, a very time consuming and laborious process. OWCP stated the provider review process was not designed for pharmacy providers, but for physicians and medical services. Additionally, OWCP noted that as OWCP pharmacy benefits are “Point of Sale” transactions for authorizing and billing, the current practice would result in the claimant not being provided medications. Therefore, OWCP stated the procedures currently in place are not applicable to pharmacies. OWCP did not address this in its action plan, but stated it is implementing new procedures to perform targeted reviews of specific providers, including pharmacies, based on billing trends and reports from outside partners and the IG community. OWCP indicated it will initiate the process to exclude providers, as appropriate.

Is there a bona fide provider (prescriber) and claimant relationship?

OWCP does not ensure a bona fide prescriber and claimant relationship exists prior to paying claims for prescribed drugs. While OWCP stated FECA beneficiaries should only take medications prescribed by doctor or healthcare provider, OWCP does not have the processes or controls in place to ensure all prescriptions drugs were prescribed by the claimant’s physician or as originally prescribed.

⁴ See 20 C.F.R. §§ 10.815-10.826



OWCP reported on its website that FECA has received anecdotal reports about FECA claimants who have received compounded drugs that were not prescribed by their authorized treating physician. OWCP limits its involvement in the doctor/claimant decisions relating to medicine therapy, as OWCP interprets the FECA statute and implementing regulations as not primarily focused on managing the individual doctor/claimant decisions relating to the claimant's prescribed medicine therapy. As such, OWCP's policy for pharmacy benefits under FECA has generally been a policy of payment for any prescription claim submitted with licensed physician information and the prescription is identified as a possible treatment for the accepted injury. OWCP stated it is not the guarantor of each medical treatment and does not ensure the proper treatment for the claimant.

Currently, OWCP has the ability to review authorization requests for drugs, including compounded drugs, to ensure the request came from the claimant's treating physician. OWCP has monitoring reports that can detect unusual patterns of medical provider activity. OWCP also has the ability through medical advisors to evaluate and opine on whether claimants are receiving appropriate medical care, including whether recommended procedures, appliances or treatments are medically necessary.

OWCP did not address this in its action plan, but stated it is implementing new procedures and working with its medical bill processing contractor to require information for implementing this recommendation.

OWCP is also working with DOL-OIG investigators, who recently executed federal search warrants on several pharmacies allegedly engaged in the practice of switching non-compounded drugs to compounded drugs without medical necessity. OWCP is working to implement a pre-payment/post-payment fraud and abuse detection capability to further enhance OWCP's anti-fraud work. This fraud and abuse detection capability has been included in OWCP's new medical bill processing contract.

According to OWCP, the fraud and abuse detection capability it is developing will allow it to analyze the drug usage of claimants and review the dispensing patterns of pharmacies and prescribing physicians to identify atypical usage and prescribing practices. OWCP believes the results of such analysis will allow for additional pre-payment auditing that will result in suspending bills for further review and possible referral to the OIG for criminal investigation.

IS THE PRESCRIPTION VALID?

OWCP does not have sufficient policies and procedures in place to ensure that all prescriptions are valid, i.e., safe, effective and medically necessary for the claimant's accepted condition. OWCP verifies the claimant, the condition and the usage of certain drugs for a condition, but OWCP's policies and procedures did not effectively control the prescribing of costly and medically unnecessary compounded drugs. Recently, OWCP implemented new policies and procedures for a prior authorization process for compounded drugs, which requires OWCP's approval of the prescribing physician's certification of medical necessity for compounded drugs.

Is the claimant eligible and, if so, is the condition covered under FECA?

OWCP had policy and procedures for verifying claimants are eligible and the conditions are covered prior to reimbursement for prescription drugs, including compounded drugs. OWCP performed the verification through edit checks during the initial processing of a prescription (point of purchase) by a pharmacy.

Pharmacies submit prescription claims to OWCP's contracted pharmacy processing system. The system verifies claimant eligibility from information maintained in OWCP's case management system. OWCP's claims examiners validate the claimants' initial eligibility during the claims adjudication process based on requirements set forth in FECA and its regulations. The claims examiner is responsible for maintaining the eligibility information and updating any eligibility decisions in OWCP's case management system.

Is the prescription medically necessary?

OWCP does not ensure prescriptions are medically necessary, but relies on the prescription being from a licensed physician and verifies the prescribed drugs are possible treatments for the claimant's approved condition in its databases. In November 2016, OWCP began requiring a pre-authorization and certification of medical necessity from the claimant's physician for compounded drugs.

Is prior approval required for the prescription?

Prior to becoming aware of the compounded drug issue, OWCP did not have a pre-authorization process to review prescriptions for cost and medical necessity. In response to the growing usage and cost of compounded drugs, OWCP started requiring all claims for compounded drugs to have prior authorization before dispensing to the claimant and reimbursing the provider.



OWCP has developed a pre-authorization process that requires physicians (1) certify they recently physically examined the claimant, (2) fully explain the need for a compounded drug, and (3) certify that each ingredient in the compound is medically necessary and cost effective. This certification must be provided prior to a pharmacy providing the medication to the claimant and OWCP approving payment.

This action is **“Implemented.”** OWCP identified this action in its action plan as an action needing immediate change and OWCP completed its implementation.

Is a letter of medical necessity required and approved?

To help control the rising costs of compounded drugs, OWCP started requiring a certification of medical necessity by the prescribing physician as part of its preauthorization process.



This action is **“Implemented.”** OWCP identified this action in its action plan as an action needing immediate change and OWCP completed its implementation.

In June 2016, OWCP provided legal notice of its use of the Authorization Request Form and Certification/Letter of Medical Necessity (LMN) for Compounded Drugs (CA 26) in the Federal Register. After a comment period and receiving OMB approval in October 2016, OWCP began requiring claimants’ physicians to submit certifications of medical necessity prior to approving payments for compounded drugs. OWCP stated that its preauthorization process is modeled on TRICARE’s process, which has been successful in curtailing the use of compounded prescriptions.

For OWCP approval, the information provided by a prescribing physician on the CA-26 form is reviewed by OWCP’s contracted pharmacy technicians and either rejected based on OWCP’s criteria or forwarded to the claims examiner for final review. FECA Bulletin 17-01, issued October 14, 2016, provides guidance to claims examiners regarding the pre-authorization process for the use of compounded ingredients and how

to manage cases where a claimant is receiving such a prescription for any work-related condition. Additionally, OWCP conducted training for all FECA district offices.

During the Federal Register comment period for the proposed CA-26, LMN for Compounded Drugs, OWCP received comments from the Committee on Education and the Workforce and the Committee on Oversight and Government Reform. The following are the committees' comments provided to OWCP and Office of Management and Budget (OMB) on the preauthorization process:

- the form had a number of ambiguities meriting clarification;
- the form did not explain the screening criteria used to determine whether a compounded drug should be covered; and
- the screening process should be simplified by incorporating with the LMN a list of excluded ingredients or a commercial reject list (as TRICARE did) for those ingredients lacking clinical benefit which would preclude the need for wasteful submissions as noted in the Federal Register to minimize the burden of information collection on respondents.

Although the CA-26 form was approved by OMB, we determined it still had ambiguities, such as not having a clear definition of a compounded drug, not explaining whether physicians must complete it for both new and refill prescriptions, not having a clear definition of herbal ingredients, and not stating if the form is required to be approved before a pharmacy can dispense the compounded drug to the claimant. While the form has these ambiguities, FECA Bulletin 17-01 provides clarification regarding these items.

After OWCP implemented the LMN requirement DOL, OIG requested OWCP send a notice to all FECA claimants who had been prescribed compounded drugs. The notice advised claimants of various fraud schemes the OIG had uncovered involving compounded drugs and requested that claimants contact the OIG if they had any information about fraud in the FECA program. As a result of this fraud notice, the OIG had received in excess of 600 communications as of February, 2017.

USPS also provided comments on OWCP's Prior Approval / LMN process and identified missing items on the LMN form. However, we determined all but two were already included on the form. The items not included were: (1) questions for the physician to identify a list of commercially available products that could be used as an alternative to the requested compounded drug; and (2) a statement addressing whether there is a national drug shortage for the commercially available product. The following chart provides the list of USPS' comments on the LMN.

USPS Comments on OWCP’s Prior Approval Process

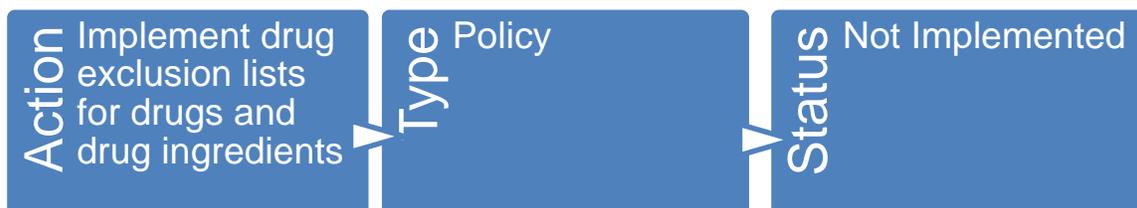
USPS Requested Action	Action Taken
The diagnosis or condition the compounded drug will treat	Yes
A list of commercially available products that could be used as an alternative to the requested compounded drug	No
A statement addressing whether there is a national drug shortage for the commercially available product	No
A list of each ingredient used in the compounded drug	Yes
Certification of the necessity for each ingredient used in the compounded drug	Yes
Certification that there is not a U.S. FDA approved drug that is more appropriate	Yes
The estimated length of the proposed therapy	Yes
Doctor’s signature certifying the compounded drug is medically necessary and cost-effective	Yes
Submission of LMN for every compounded-drug prescription submitted for reimbursement	Yes

Is the prescription safe and effective?

Prior to implementation of the LMN, OWCP did not have a process in place to confirm whether compounded drug prescriptions were safe and effective. OWCP approved prescriptions for compounded drugs if the primary ingredient was valid for the accepted condition, regardless of the additional ingredients or efficacy of the compounded drug.

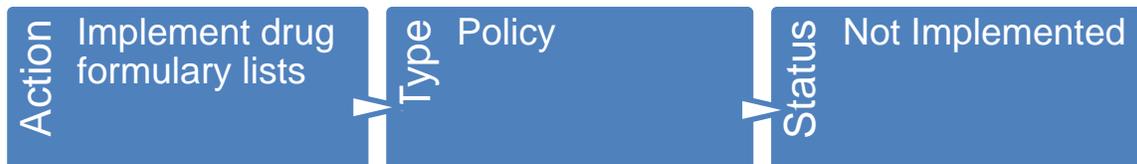
Is the prescription approved as safe in the treatment for the accepted condition?

Drug exclusion or commercial reject lists identify drugs as not being safe, effective, or cost efficient. The use of these exclusionary drug lists are industry practices that OWCP currently does not use in the FECA program, with the exception of a listing of drugs found on the FDA’s Drug Products That May Not Be Compounded. OWCP can implement the use of commercial reject lists with a policy change. FECA and its regulations do not limit OWCP’s ability to utilize exclusionary reject lists. OWCP stated it intends to implement additional exclusion lists for drugs and drug ingredients as part of contracting for a new medical billing processor and contracting for a pharmacy benefits manager (PBM).



The USPS and TRICARE discussed and suggested the use of drug reject lists with OWCP. This action is “**Not Implemented**” and OWCP does not address this in its action plan.

Additionally, formulary drugs are defined as prescribed drugs experts consider to be part of a quality treatment program that are effective, safe, and reasonably cost-effective for a specified condition. OWCP can also implement drug formulary lists with a policy change.



The USPS and TRICARE discussed and suggested the use of drug formulary with OWCP, but OWCP does not address this in its action plan. This action is “**Not Implemented.**”

ARE PRESCRIPTION PRICES FAIR AND REASONABLE?

OWCP does not have controls to ensure the prices it pays for drugs are fair and reasonable. OWCP has not effectively evaluated costs or pricing methodologies. Even though OWCP had not performed analysis on pharmaceutical costs to identify fair and reasonable prices, OWCP made changes to reimbursement structure for pharmaceuticals. OWCP should consider other methods and controls to better manage costs, such as using a different pricing methodology, a PBM, preferred and/or excluded provider lists, and performing additional reviews.

To calculate costs and reimbursement prices, FECA uses the National Drug Code (NDC)⁵, a unique universal product identifier assigned to each drug by the Food and Drug Administration (FDA). The FDA manages and publishes the list of these codes in the NDC Directory. The healthcare industry including pharmacies and insurance plans also use the NDC for identifying a drug, calculating costs and billing for drugs.

Prior to 2012, for compounded drugs, bill processing standards for the healthcare industry and OWCP only allowed pharmacies to submit bills using one NDC for each drug prescribed. For compounded drugs, pharmacies usually submitted the highest priced compounded ingredient, or used a special drug code that was not published by the FDA to process the claim. However, in 2012, these bill processing standards changed, allowing pharmacies to separately bill for each ingredient in compounded drugs. Since these changes, workers’ compensation and other medical benefit

⁵ The Drug Listing Act of 1972 requires registered drug establishments to provide the FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution.

programs have seen an increase in the usage and costs of prescribed compounded drugs.

Is OWCP using the best method for calculating pharmaceutical payments?

OWCP stated that it had not performed analysis to determine the best method calculating pharmaceutical payments when it made changes to its reimbursement pricing structure for drugs. OWCP’s policy and regulations use a fee schedule for prescription payments. The fee schedule’s payment amounts are based on a percentage of the drug’s average whole price (AWP). At its discretion, OWCP can modify the percentages, but adjusting the basis for the pricing schedule requires a regulatory change.



OWCP’s methodology for calculating drug prices is based on the AWP for pharmaceutical costs. Many in the healthcare industry have identified issues with this methodology due to the inflated bases associated with the AWP. The AWP is calculated using prices created by the manufacturer prior to discounts. This methodology allows the manufacturer to provide some customers greater discounts and artificially elevates the drug’s AWP.

This action is “**Not Implemented.**” OWCP originally identified this change for future initiatives, but has since changed the status of this action item to “Reserved for Future Consideration.”

As part of its Action Plan, on July 1, 2016, OWCP reduced reimbursements for generic ingredients in compounded drugs by 10 percent, from 70 percent of the AWP to 60 percent. Along with lowering the reimbursement percentage, OWCP created a tiered reimbursement structure for compounded drug payments that lowers the reimbursement percentage as the number of ingredients increases. Additionally, as part of its new contract for bill processing, OWCP is considering implementing a different pricing formula for all drugs, which is permissible under the current regulations.

Are lower cost alternatives considered?

OWCP has implemented other cost controls, such as requiring the use of generics, but has not assessed the effectiveness of these new cost controls.

Are generics drugs being used when appropriate?

OWCP’s policy when providing prescription drugs is to default to the generic version when available, unless otherwise specified by the physician. OWCP did not know if its policy on generics was followed as, according to OWCP, the data received from the bill processing contractor does not contain fields to capture generic medication usage.



Due to the limitations of its current medical bill processing contract, OWCP is unable to verify the implementation and effectiveness of requiring the use of generics. OWCP does not address this in its action plan, but stated it is working with its medical bill processing contractor to obtain the necessary information to verify generic drug usage.

Are preferred pharmacies used?

Although allowed by FECA regulations, OWCP does not mandate the use of preferred providers as a means for limiting pharmaceutical costs.



FECA regulations state OWCP may, at its discretion, contract for or require the use of specific providers for certain medications. Preferred providers are an industry best practice, typically used by PBMs that have negotiated better prices with certain providers. OWCP should consider implementing requirements for claimants to use preferred pharmacy providers.

This action is not in OWCP’s action plan. However, in response to our draft report, OWCP stated it is currently conducting market research on services provided by a pharmacy benefits manager, including the use of preferred providers. OWCP further stated it plans to implement the services of a pharmacy benefits manager as part of contracting for a new medical billing processor and contracting for a pharmacy benefits manager.

Can prescriptions be obtained through the Federal “ceiling price” statute?

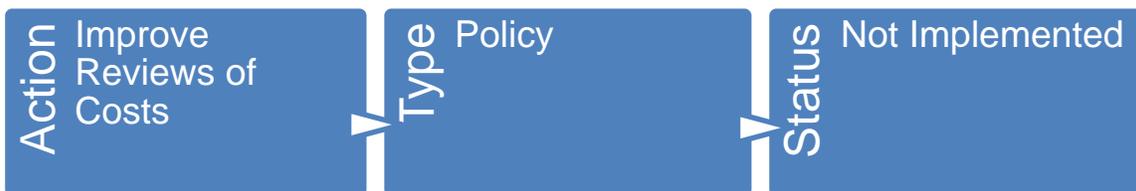
As discussed earlier in this report, OWCP needs to ensure the prices it pays for drugs are fair and reasonable. OWCP does not have the authority to set price limitations available to some similar larger programs through federal law. Through the “ceiling price” statute (38 U.S.C. § 8126), Congress mandated controls on prices that manufacturers can charge for drugs in four specific medical programs operated by the Department of Veteran’s Affairs, Department of Defense, Public Health Service, and the Coast Guard. According to OWCP, implementing such a ceiling price could potentially violate the Secretary’s obligation under FECA to provide treatment that cures, gives relief or lessens the degree of disability. Notwithstanding this reservation, OWCP stated it would work with the Department and Administration officials to evaluate seeking additional authorities by legislation.



This action is **“Not Implemented.”** This action is listed as a near-term action item; however, OWCP changed the status to reserving it for future consideration.

Are unusual bills identified and reviewed?

While OWCP has controls and edit checks to manage its medical program, the controls do not effectively manage drug costs. For example, OWCP does not have reasonable cost limit checks for identifying high or excessive drug charges requiring additional review and authorization. Currently, OWCP’s controls require claims examiners to review any medical bill over \$50,000, but point of sale pharmacy bills are not included. OWCP should require a threshold review for pharmaceuticals with a lower dollar threshold than \$50,000. Setting a more reasonable limit only requires a procedural change and additional edit checks during processing. Implementing such cost limit checks would allow OWCP to timely identify and review cost anomalies and trends.



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, and adjusts the allowable amount based on analytics for the locality of the claimant and the condition being treated. This action is not in OWCP's action plan. However, in response to our draft report, OWCP stated it is considering alternative methods in the FECA program for reviewing prescription charges exceeding a threshold.

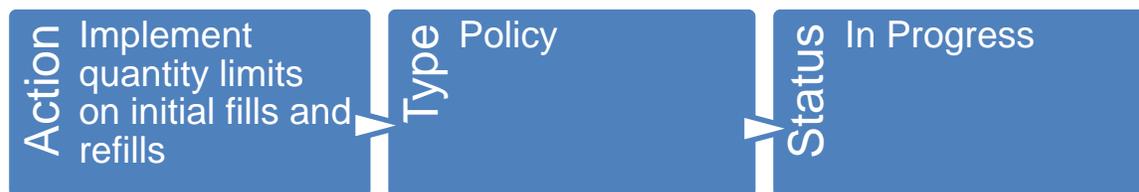
IS THE CLAIMANT PROPERLY RECEIVING THE PRESCRIPTION?

OWCP has no controls to ensure the claimant is receiving, receiving the proper quantity or is properly informed of the use and safety issues associated with the drug.

Is the claimant receiving the proper quantity of the prescribed drugs?

OWCP does not ensure the claimant receives the prescribed drug or the proper quantity needed. OWCP does not effectively limit the quantity of prescribed drugs a FECA claimant can receive, including compounded drugs. Claimants reported they received prescribed drugs in greater amounts than needed as prescriptions were being auto-filled on a regular basis.

Quantity limits allow for the timely monitoring and review for effectiveness and abuse of a treatment. As part of the OWCP Action Plan, starting July 1, 2016, OWCP set 90-day limits on initial prescriptions for compounded drugs. Prescriptions for more than 90 days may be subject to further review for medical necessity. Additionally, effective September 12, 2016, OWCP posted notice that initial fills and refills of compounded medications were to be limited to 90 days, and to only be dispensed in 30-day supplies. Similar to the Prior Approval / LMN, we found no restriction or requirement in FECA regulations regarding quantity controls. OWCP implemented the quantity and refill limits as part of the Prior Approval / LMN process.



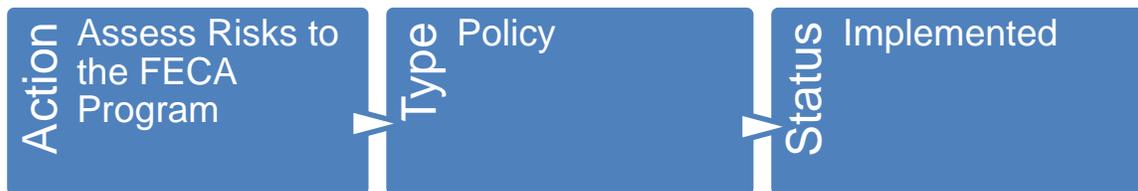
This action is **"In Progress."** As part of its Action Plan, OWCP originally identified this action as a near term action. While OWCP issued the new policies, the agency is still working with its bill processing contractor to implement the necessary controls to enforce the policy. Additionally, OWCP will need to update its procedure manual to reflect this policy change and include edit checks in the bill processing system to track refill supplies.

IS OWCP PERFORMING THE NECESSARY GENERAL MANAGEMENT AND PROGRAM INTEGRITY ACTIVITIES?

OWCP is not effectively managing pharmacy benefits in the FECA program and the controls it has implemented are not sufficient to identify and mitigate risks to the program.

Are risk assessments of the FECA program performed?

OWCP did not identify the risks associated with compounded drugs until USPS brought the escalating costs to OWCP’s attention in September 2015. In February 2016, OWCP **included** the risks associated with compounded drug costs and opioid usage in its fiscal year 2017 Enterprise Risk Management planning documents.

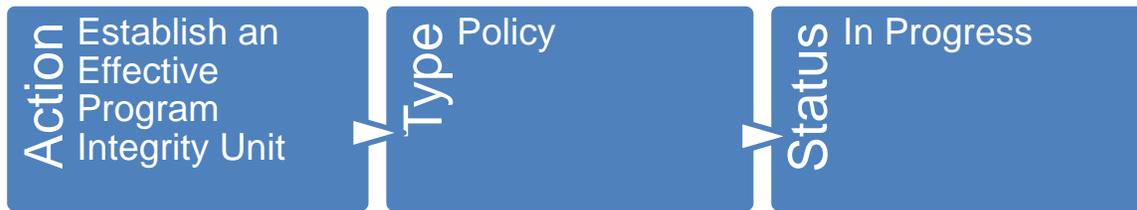


In July 2016, OMB issued Circular A-123, Management's Responsibility for Enterprise Risk Management and Internal Control, re-issuing Circular A-123, Management’s Responsibility for Internal Control, dated December 21, 2004. OMB re-emphasized the importance of having appropriate risk management processes and systems to identify challenges early, bring them to the attention of agency leadership, and develop solutions.

This action is “**Implemented.**” While not a part of its action plan, OWCP is working with the Department to identify, assess and mitigate risks in accordance with federal guidance. With the inclusion of compounded drugs in the Department’s Enterprise Risk Management FY 2017 plan, OWCP believes it is fully compliant with the circular.

Are data analytics performed to identify trends and improvements?

OWCP received funding for a Program Integrity Unit for the FECA program beginning in 2014. OWCP has not effectively used the Program Integrity Unit and its resources to identify trends, vulnerabilities and needed improvements in the FECA program. In meetings with OWCP regarding compounded drugs, OWCP was unable to provide evidence or results of the activities of the Program Integrity Unit. Specifically, the unit did not identify the rapidly increasing costs associated with compounded drugs and has not addressed fraud in the FECA program. While the number of compounded drug prescriptions and costs were escalating, OIG did not receive any referrals from the Program Integrity Unit during FY 2016. OWCP did not begin to look at issues regarding compounded drugs in the FECA program until USPS-OIG brought those issues to its attention.



OWCP and its Program Integrity Unit lacked access to data needed to effectively perform analysis on pharmaceutical benefits, including compounded drugs and generic drug usage. This data is controlled and maintained by OWCP’s bill processing contractor and OWCP is unable to obtain this data from the contractor without incurring significant charges.

Establishing an effective program integrity unit is not listed in OWCP’s action plan as the unit has been funded for several years. Since FY 2014, OWCP has received funding to implement a program integrity unit to identify areas of improper payment vulnerabilities. While OWCP originally stated a Program Integrity Unit had been implemented, OWCP, in subsequent meetings, stated the unit was not currently a group/unit with a defined mission to evaluate the program to identify program improvements or program weaknesses. OWCP was unable to provide any results from the unit.

OWCP annually requests funds to implement the Program Integrity Unit with the purpose of identifying areas of improper payment vulnerability and implementing corrective actions. The following table lists the funding for the program integrity unit by fiscal year.

FECA PROGRAM INTEGRITY FUNDING FYs 2014 - 2017

Fiscal Year	Funding
2014	\$1,360,000
2015	\$1,385,000
2016	\$1,394,000
2017 requested	\$4,101,000
Total	\$8,240,000

For FY 2017, OWCP requested approximately \$4.1 million to address program integrity issues including compounded drugs. OWCP stated it has re-focused and restructured its Program Integrity Unit, and indicated that \$2.7 million of its FY 2017 request was for the purpose of system changes and additional contractor staff required to implement additional controls over compounded drugs, such as the certification of medical necessity process.

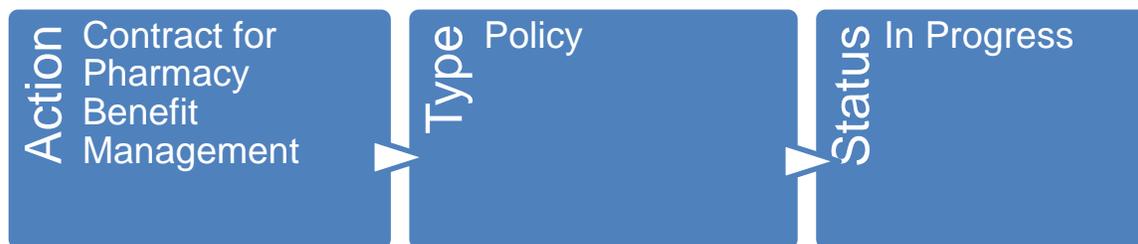
Is OWCP’s medical information adequately protected?

OWCP has implemented systems and controls to protect medical information in the FECA program. The FECA program’s medical information held by OWCP and iFECS are subject to the Privacy Act of 1974, which places certain requirements on OWCP for maintaining the records related to the FECA program as well as protecting those records from disclosure. While subject to the Privacy Act, OWCP is not subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which establishes standards for various electronic transactions (eligibility, claims status, authorizations, referrals and claims) involving personal health information. However, physicians and pharmacists participating in the FECA program and the FECA bill processing contractor are subject to HIPAA.

OIG has not audited and therefore cannot confirm the establishment of safeguards over Protected Health Information and Personally Identifiable Information in FECA's systems; however, OWCP has generally passed system security tests conducted during annual audits.

Is contracting out the pharmaceutical benefits an alternative?

While OWCP does not currently use the full services of a PBM, the agency has been using some PBM services through its medical bill processing contractor, such as screening LMNs for compounded drug prescriptions. OWCP should evaluate migrating to full-scale PBM services as a tool to control pharmaceutical costs, improve the management of treatments, and improve claimant safety. As part of its action plan, OWCP started the contracting process by publishing a Request for Information regarding the potential use of a PBM.



PBMs act as intermediaries to reduce costs by providing services such as processing prescription claims, operating mail order pharmacies, and negotiating prices with drug makers. Along with those basic services, PBMs can also provide the following:

Advantages of Using a Pharmacy Benefits Manager

Receive Prescription Network Discounts

Develop and Manage Formularies

Conduct Drug Utilization Reviews

Improve Claimant Safety – Correct Drugs Prescribed

Administer Prior Authorization Programs

Administer Employer’s Opiate and Compounded Drug Policies

Oversee Generic Prescription Policy Compliance

Monitor Costs

Conduct Trend Analyses

FECA regulations on drug pricing allow OWCP to contract out the management of pharmacy benefits. OWCP’s ability to acquire full PBM services does not require a regulatory or statutory change. Rather, it requires a contract initiation by OWCP.

The USPS and a few other agencies in the FECA program have contracted with and used some of the various services provided by a PBM. While providing cost saving services to these agencies, the PBMs are required to follow FECA policy and regulations. OWCP stated it previously discussed contracting with a PBM through an agreement with a partner agency, but determined that adding OWCP to the partner agency’s contract represented an impermissible “cardinal change” to the contract.

This action is listed as a long-term action/consideration in OWCP’s action plan. In an update to the Action Plan, OWCP stated a Request for Information for obtaining a PBM was published and OWCP will evaluate vendor responses.

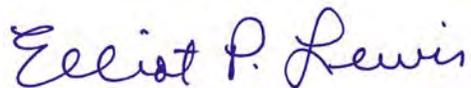
CONCLUSION

For employees injured in the performance of their duty, the Secretary of Labor is to provide services and supplies as prescribed by a qualified physician. FECA defines treatments as those services and supplies that are considered likely to cure, give relief, reduce the degree or the period of disability, or aid in lessening the amount of monthly compensation. The processes used by OWCP do not ensure pharmaceutical treatments are medically necessary or effective in treating accepted conditions. As a result, OWCP potentially has paid for costly compounded drugs and continues to be at increased risk of making further payments for drugs that are not medically necessary. To address rapidly escalating pharmaceutical costs and medical necessity issues with compounded drug prescriptions, OWCP developed an action plan to address the issues identified with compounded drugs in 2016, such as implementing a LMN process that ensures that compounded drug prescriptions are reviewed prior to dispensing and payment.

MANAGEMENT RESPONSE

The Director of OWCP generally agreed with the information in the report and provided additional information on actions taken and planned in response to the recommended actions presented in Exhibit 2 of this report. OWCP's response to the draft report is presented in its entirety in Appendix A.

We appreciate the cooperation and courtesies that OWCP personnel have extended to the Office of Inspector General during this audit. OIG personnel who made significant contributions to this report are listed in Appendix B.



Elliot P. Lewis
Assistant Inspector General
for Audit

Exhibits

Exhibit 1**OWCP's Action Plan⁶**

Actions		Status	Report Section
Previous Actions			
	OWCP reduced reimbursements for generic ingredients by 10 percent – from 70 percent of the AWP to 60 percent.	Implemented	Is OWCP using the best method for calculating pharmaceutical payments?
	OWCP created a tiered reimbursement: 50 percent of AWP for compounded drugs with three or fewer ingredients and 30 percent of AWP for compounded drugs with four or more ingredients.	Implemented	Is OWCP using the best method for calculating pharmaceutical payments?
	Initial prescriptions for periods greater than 90 days may be subject to further review for medical necessity.	Implemented	Is the claimant receiving the proper quantity of the prescribed drugs?
Immediate Actions			
	Letter of Medical Necessity. Require all claims for prescription medications that contain a compounded drug to have a completed (by the claimant's treating physician) and approved LMN.	Implemented	Is a letter of medical necessity required and approved?
	OWCP's bill processing contractor will provide an initial review and screening of the LMNs to ensure that: the form is completed; the correct boxes are checked; and the narrative portion references one of the reasons that the FDA has determined an individual might need a compounded drug.	Implemented	Is a letter of medical necessity required and approved?
Near Term Actions			
	Instituting the universal claim form	In progress	Not discussed.
	Hard coding the exception-based herbal supplements policy.	Implemented	Not discussed.
	Hard coding a 30-day limit on individual fills.	In progress	Is the claimant receiving the proper quantity of the prescribed drugs?

⁶ OWCP included obtaining access to SSA wage records as part of the action plan. This action was removed from this listing, as it does not directly relate to OWCP's management of pharmaceutical benefits or compounded drugs.

Actions		Status	Report Section
	Suspension of payment to providers under indictment for fraud or at the request of DOJ.	Not Implemented	Are excluded prescribers and pharmacists used?
	Having the authority to access the “Federal Ceiling Price” for prescription drugs.	Not Implemented	Can prescriptions be obtained through the Federal “ceiling price” statute?
Long Term Actions/ Considerations			
	Limit the cost or use of inactive ingredients, as defined by the FDA	Not Implemented	Not discussed.
	Consider implementing a different pricing formula for all drugs	Not Implemented	Is OWCP using the best method for calculating pharmaceutical payments?
	Implement a pre-payment/post-payment fraud and abuse detection capability.	In Progress	Is there a bona fide provider (prescriber) and claimant relationship?
	PBM: There may be non-compound-related benefits to OWCP having a PBM.	In Progress	Is contracting out the pharmaceutical benefits an alternative?

Exhibit 2**OIG's Recommended Actions**

Control Objective	Action	Type	Status
Is OWCP timely removing or suspending providers suspected of acting in a fraudulent or abusive manner?	Ensure Timely Removal of Questionable Providers From Program	Legislative	Not Implemented
Is OWCP reviewing providers and taking action on providers acting in a fraudulent or abusive manner?	Perform Reviews of Questionable Provider Practices	Policy	In Progress
Is there a bona fide provider (prescriber) and claimant relationship?	Ensure the Existence of Prescriber/ Claimant Relationship	Policy	In Progress
Is prior approval required for the prescription?	Require Prior Authorization for Compounded Drugs	Regulatory	Implemented
Is a letter of medical necessity required and approved?	Require Physician Certification of Medical Necessity	Regulatory	Implemented
Is the prescription approved as safe in the treatment for the accepted condition?	Implement drug exclusion lists for drugs and drug ingredients	Policy	Not Implemented
Is the prescription approved as safe in the treatment for the accepted condition?	Implement drug formulary lists	Policy	Not Implemented
Is OWCP using the best method of to calculate pharmaceutical payments?	Implement a new pricing methodology	Regulatory	Not Implemented

Control Objective	Action	Type	Status
Are generic drugs being used when appropriate?	Verify cost controls (Generic Drug Usage) Effectiveness	Policy	In Progress
Are preferred pharmacies used?	Use of Preferred Providers	Policy	Not Implemented
Can prescriptions be obtained through the Federal “ceiling price” statute?	Pursue inclusion into prices that drug manufacturers can charge	Legislative	Not Implemented
Are unusual bills identified and reviewed?	Improve reviews of costs	Policy	Not Implemented
Is the claimant receiving the proper quantity of the prescribed drugs?	Implement quantity limits on initial fills and refills	Policy	In Progress
Are risks assessments of the FECA program performed?	Assess Risks to the FECA Program	Policy	Implemented
Are data analytics performed to identify trends and improvements?	Establish an Effective Program Integrity Unit	Policy	In Progress
Is contracting out the pharmaceutical benefits an alternative?	Contract for Pharmacy Benefit Management	Policy	In Progress

Appendices

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.

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

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.

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 or 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

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

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

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.

APPENDIX B

ACKNOWLEDGEMENTS

Key contributors to this report were: Stephen Fowler (Audit Director), Dan Pompili (Audit Manager), Lisa LaRosa, Ted Lawson, and Sheila Lay

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