



OFFICE OF INSPECTOR GENERAL

UNITED STATES POSTAL SERVICE

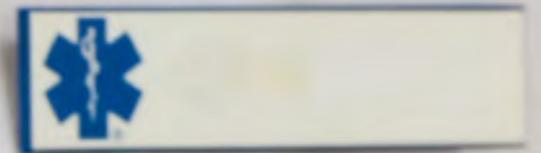
Workers' Compensation Compound Drug Costs

Management Advisory

Report Number
HR-MA-16-003

March 14, 2016

Pharmacist





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UNITED STATES POSTAL SERVICE

Highlights

In CBY 2015, the total number of Postal Service employees with compound drug prescriptions increased to 50,204 — nearly three times the number in CBY 2011

Background

Enacted in 1916, the Federal Employees' Compensation Act (FECA) provides medical, compensation, death, and vocational rehabilitation benefits to civilian federal employees who sustain injuries or disease. In fiscal years (FYs) 2014 and 2015, FECA provided over \$1 billion in annual workers' compensation benefits to U.S. Postal Service workers.

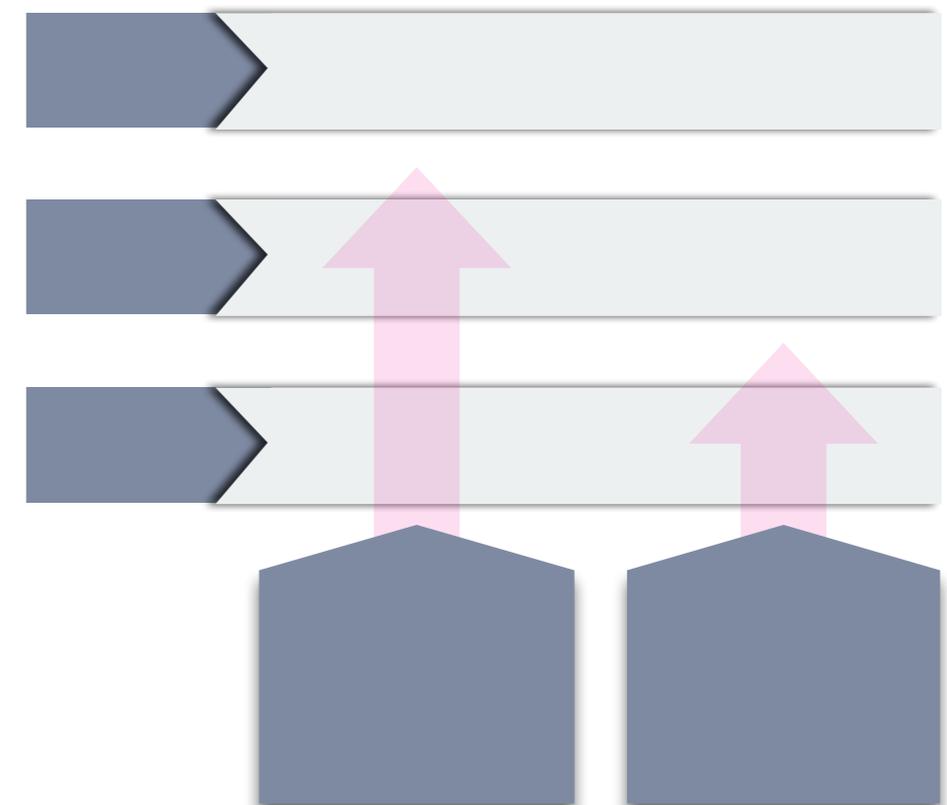
The U.S. Department of Labor (DOL) Office of Workers' Compensation Program (OWCP) administers the FECA for the Postal Service and the federal government, including costs for medical treatment and drugs. The Postal Service reimburses the DOL for benefits paid out for a chargeback year (CBY) starting from July of the preceding year to June of the current year. The Postal Service pays about 39 percent of the federal government's total workers' compensation administrative expenses.

OWCP allows charges for compound drugs, which are created when licensed pharmacists, physicians, and others acting under the supervision of licensed pharmacists combine, mix, or alter ingredients of drugs to tailor them to individual patients. The Food and Drug Administration (FDA) does not monitor or approve compound drugs, or test their effectiveness or safety.

Our objective was to assess the Postal Service's worker's compensation compound drug costs.

What The OIG Found

The Postal Service's workers' compensation compound drug costs escalated to over \$98.7 million for CBY 2015, a \$68.6 million increase over CBY 2014. During the same period, the Postal Service's administrative expenses for compound drugs increased to \$5.1 million, a \$3.6 million increase. The costs for compounds have continued to escalate. For the first 6 months of CBY 2016





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As a result, we estimated the Postal Service incurred over \$81.8 million in excessive compound drug costs and nearly \$4.1 million in excessive administrative fees for FYs 2014 and 2015.

(July 2015 through December 2015), the Postal Service has incurred \$85.7 million in compound drug costs, with another \$71 million forecasted through the end of the year. These unprecedented increases were due to the higher costs of compound drugs, the rising number of compound drug prescriptions, and fraud.

Generally, compound drugs are more costly than other drugs. In 2012, the National Council on Prescription Drug Programs permitted pharmacies to separately bill for each ingredient in a compound drug. Subsequently, more pharmacies began compounding drugs, which created shortages in ingredients and increased the cost. In CBY 2015, the total number of Postal Service employees with compound drug prescriptions increased to 50,204 — nearly three times the number in CBY 2011.

In response to the dramatic increase in compound drug costs nationwide, various government agencies and private entities began to examine these costs and implement best practices for managing them. The U.S. Department of Defense evaluated these costs and made an alarming discovery: Doctors were prescribing and charging for compound drugs without seeing patients. In a massive workers' compensation scheme in California, doctors were paid to prescribe compound drugs that patients did not need. In one case, a 5-month-old baby died after coming in contact with a compound transdermal cream prescribed for his mother.

In 2015, TRICARE, the military health insurance program, restricted compound drugs in an effort to curtail fraud, reduce costs, and provide more consistent and safe drugs for its beneficiaries. Similarly, state and private entities have implemented restrictions such as: 1) reimbursement caps on prescriptions, 2) fee schedules for compound drugs, 3) mandatory use of pharmacy benefits managers, 4) formularies (lists of prescription drugs covered by prescription drug plans), and 5) pre-authorizations for payment.

The Postal Service experienced escalated compound drug related costs because the DOL did not implement best practices to manage these costs. As a result, we estimated the Postal Service incurred over \$81.8 million in excessive compound drug costs and nearly \$4.1 million in excessive administrative fees for FYs 2014 and 2015. We also estimated that if the DOL does not implement best practices to control compound drug costs, these costs and the related administrative fees could accumulate to over \$1.2 billion and over \$60.3 million, respectively, over the next 3 years.

Although the Postal Service has expressed that it would like to reduce and better manage compound drug costs, it is limited because it is mandated to use the DOL to handle workers' compensation drug costs. For its part, the DOL has full authority to implement all of the best practices mentioned above. But, the DOL has no incentive to do so, and DOL officials have not been receptive to adopting these or other best practices. In addition,



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DOL stated if a doctor approves the compound drug they assume it is necessary and will reimburse the costs.

The Postal Service is so concerned about rising drug costs and DOL's inaction that, in October 2015, it requested an adjustment and withheld \$68.6 million in payment for its workers' compensation chargeback bill. According to Postal Service officials, the \$68.6 million represented compound drug cost increases potentially attributable to fraud and abuse that OWCP had a duty to prevent. In December 2015, the DOL denied the Postal Service's request. While Postal Service officials disagreed with the DOL's determination, they paid the outstanding \$68.6 million.

Until the DOL implements best practices to manage drug costs and ensure safe drugs, the Postal Service will continue to incur excessive and unnecessary costs and injured workers could be at an increased risk of harm.

What The OIG Recommends

We recommend the chief human resources officer and executive vice president continue to coordinate with the DOL to identify and implement best practices for controlling compound drug costs and authorizing payments for only FDA approved drugs. In addition, we recommend Human Resources, in coordination with Government Relations, inform and educate Congress on the impact of DOL's failure to address escalating compound drug costs on the Postal Service.

Transmittal Letter



OFFICE OF INSPECTOR GENERAL
UNITED STATES POSTAL SERVICE

March 14, 2016

MEMORANDUM FOR: JEFFREY WILLIAMSON, CHIEF HUMAN RESOURCES
OFFICER AND EXECUTIVE VICE PRESIDENT

E-Signed by Janet Sorensen
VERIFY authenticity with eSign Desktop


FROM: Janet M. Sorensen
Deputy Assistant Inspector General
for Revenue and Resources

SUBJECT: Management Advisory Workers' Compensation Compound
Drug (Report Number HR-MA-16-003)

This report presents the results of our review of the Postal Service's workers' compensation compound drug costs (Project Number 16RG001HR000).

We appreciate the cooperation and courtesies provided by your staff. If you have any questions or need additional information, please contact Monique P. Colter, director, Human Resources and Support, or me at 703-248-2100.

Attachments

cc: Corporate Audit and Response Management

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Findings

The Food and Drug Administration (FDA) does not monitor or approve compound drugs, and their effectiveness and safety have not been scientifically tested like other FDA approved drugs.

Introduction

This report presents the results of our self-initiated review of workers' compensation compound drug costs (Project Number 16RG001HR000). Our objective was to assess the U.S. Postal Service's workers' compensation compound drug costs. See [Appendix A](#) for additional information about this report.

In fiscal years (FYs) 2014 and 2015, the Federal Employees' Compensation Act (FECA) provided over \$1 billion in annual workers' compensation benefits to Postal Service workers for personal injury, disease, or death sustained while working. The U.S. Department of Labor (DOL) Office of Workers' Compensation Program (OWCP) administers the FECA for the Postal Service and the federal government, including costs for medical treatment and drugs. The Postal Service reimburses the DOL for benefits paid and pays an administrative fee based on the total cost of workers' compensation. The Postal Service pays for about 39 percent of the federal government's total workers' compensation administrative expenses.

The OWCP allows charges for compound drugs, which are created when licensed pharmacists, physicians, and others acting under the supervision of a licensed pharmacist combine, mix, or alter ingredients of drugs tailored to the needs of individual patients. The Food and Drug Administration (FDA) does not monitor or approve compound drugs, and their effectiveness and safety have not been scientifically tested like other FDA approved drugs.

In 2012, the National Council on Prescription Drug Programs, which sets standards for billing practices, permitted pharmacies to bill for all ingredients in compound drugs. Prior to 2012, pharmacies could only charge for the most expensive ingredient. The reason for the billing change was to allow pharmacies to collect the full cost of making a compound drug.

Summary

The Postal Service's workers' compensation compound drug costs and related administrative fees paid to the DOL for administering the drug payments escalated to over \$98.7 million and \$5.1 million, respectively, for chargeback year (CBY) 2015.¹ This was an unprecedented increase of over \$68.6 million and \$3.6 million, respectively, from CBY 2014.² The costs for compounds have continued to escalate. For the first 6 months of CBY 2016 (July 2015 through December 2015), the Postal Service has incurred \$85.7 million in compound drug costs, with another \$71 million forecasted through the end of the year. The increases were due to the higher costs of compound drugs, the rising number of compound drug prescriptions for employees on workers' compensation, and fraud.

These escalated costs to the Postal Service occurred because the DOL did not implement best practices used by other government agencies and state and private entities to manage compound drug costs and ensure safe drugs. The practices include reimbursement caps, fee schedules, mandatory use of pharmacy benefit managers, formularies,³ and pre-authorizations for payment.

As a result, we estimate the Postal Service has incurred over \$81.8 million in excessive compound drug costs and nearly \$4.1 million in excessive administrative fees for FYs 2014 and 2015. We also estimate that if the DOL does not implement best practices to control compound drug costs, these costs and the related administrative fees could accumulate to over \$1.2 billion and over \$60.3 million, respectively, over the next 3 years.

¹ July 1, 2014 through June 30, 2015.

² July 1, 2013 through June 30, 2014.

³ A formulary is a list of prescription drugs covered by a prescription drug plan or another insurance plan offering prescription drug benefits.

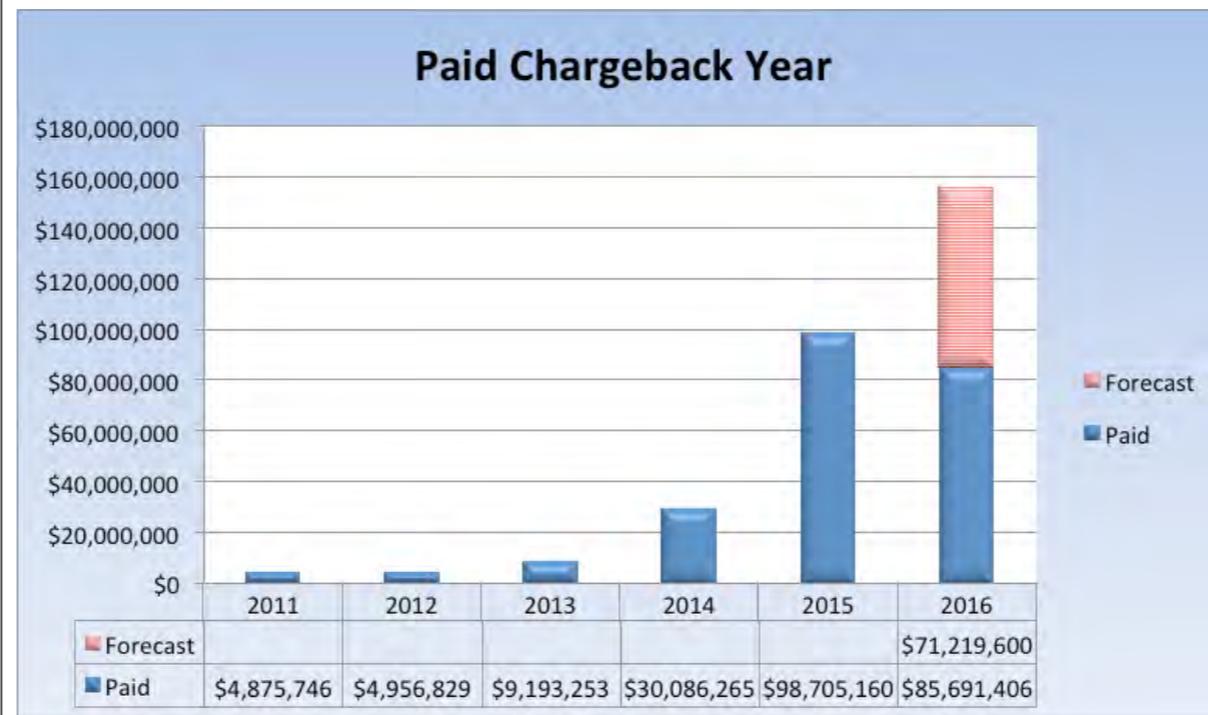
Although the Postal Service would like to reduce and manage the compound drug costs of its self-funded workers' compensation program, its efforts are limited because it is mandated to use the DOL to handle workers' compensation drug costs. For its part, the DOL has full authority to implement all of the best practices mentioned above to curtail fraud, reduce cost, and provide consistent and safe drugs. However, the DOL does not have an incentive to do so, and DOL officials have not been receptive to implementing these or other best practices.

Workers' Compensation Compound Drug Cost

The Postal Service's workers' compensation compound drug costs and related administrative fees paid to the DOL for administering the drug payments escalated to over \$98.7 million and \$5.1 million, respectively, for CBY 2015.⁴ This was an unprecedented increase of over \$68.6 million in compound drug costs and \$3.6 million in related administrative expenses from CBY 2014.⁵

While the number of paid medical cases has stayed relatively stable at about 100,000 annually for the past 5 years, compound drug costs have increased 1,924 percent, growing from about \$5 million to about \$100 million from CBYs⁶ 2011 to 2015. The costs for compounds have continued to escalate. For the first 6 months of CBY 2016 (July 2015 through December 2015), the Postal Service's has incurred \$85.7 million in compound drugs costs, with another \$71 million forecasted through the end of the year (see Graph 1).

Graph 1. Compound Costs by Chargeback Year



Source: U.S. Postal Service Office of Inspector General (OIG).

⁴ July 1, 2014, through June 30, 2015.

⁵ July 1, 2013, through June 30, 2014.

⁶ Claims the DOL pays on behalf of Postal Service employees and the assessed administrative fee for the period July 2009 through June 2010.

About 8 percent of all prescriptions were for compound drugs, representing 6 percent of prescription costs in CBY 2011. In CBY 2015, compound drug prescriptions increased to 34 percent, and 53 percent, of all prescription costs.

Similarly, in CBY 2015, the Postal Service’s compound drug prescriptions totaled 50,808, which was almost three times more than in CBY 2011. Also, 50,204 employees received prescriptions for compound drugs in CBY 2015, about three times more than the 17,722 employees who received compound drug prescriptions in CBY 2011.

Further, the number of employees receiving multiple compound drug prescriptions grew rapidly in CBY 2015. We noted over 600 employees with multiple compound drug prescriptions as of CBY 2015, compared to fewer than 100 employees for CBYs 2011 through 2014. (See Graph 2 for the number of compound drug prescriptions and the number of employees with compound drug prescriptions.)

Graph 2. Number of Employees with Compound Drug Prescriptions



Source: OIG.

About 8 percent of all prescriptions were for compound drugs, representing 6 percent of prescription costs in CBY 2011. In CBY 2015, compound drug prescriptions increased to 34 percent, and 53 percent, of all prescription costs (see Table 1).

Table 1. Compound Drug Prescription and Cost Percentages

Chargeback Year	Compound Drug Percentages	
	Prescriptions	Costs
2011	8%	6%
2012	10%	6%
2013	13%	10%
2014	22%	27%
2015	34%	53%

Source: OIG.

The daily cost of compound drugs went from \$257,039 in January to \$405,318 in September, causing the average to rise to over \$390,000 in a 9-month period.

The escalation is even more evident in calendar year (CY) 2015’s workers’ compensation “daily spend” for compound drugs. The daily cost of compound drugs went from \$257,039 in January to \$405,318 in September, causing the average to rise to over \$390,000 in a 9-month period (see Table 2).

Table 2. Calendar Year 2015 Workers’ Compensation Paid Amount and Daily Spend

CY 2015	Paid Amount	Daily Spend
January	\$7,968,196	\$257,039
February	\$9,107,694	\$325,275
March	\$9,423,679	\$303,990
April	\$14,444,550	\$481,485
May	\$12,223,481	\$394,306
June	\$11,815,181	\$393,839
July	\$15,816,701	\$510,216
August	\$13,657,009	\$440,549
September	\$12,159,539	\$405,318
Total / Average	\$106,616,030	\$390,224

Source: OIG

In April 2015, the Postal Service experienced a 53 percent spike in the workers’ compensation “paid amount” when it went from over \$9 million to over \$14 million. This was after TRICARE made an announcement on March 12, 2015, that it was going to restrict compounds. This change may have caused compound pharmacies to shift their business from TRICARE to Postal Service workers’ compensation employees.

Administrative Fees

The FECA mandates that the Postal Service use the DOL to administer its workers’ compensation program and pay its “fair share” of administrative expenses. The DOL is responsible for administering all program operations from determining eligibility to compensating service providers, including allowing for and reimbursing compound drugs. The DOL bases the administrative fee it charges the Postal Service on a percentage of the total FECA benefits paid and not the actual costs to administer the Postal Service workers’ compensation program. The secretary of labor determines the “fair share” methodology, based on a percentage of total workers’ compensation benefits paid. In CBY 2015, the “fair share” was 5 percent. The FECA does not allow the Postal Service the option to negotiate this fee or the opportunity to change the methodology for calculating it.

As total benefits costs increase, so does the administrative fee. For example, in CBY 2015, the administrative fee was \$71.5 million, or 5 percent of the \$1.4 billion in total workers’ compensation benefits costs. The increase in compound drug costs from CBYs 2014 to 2015 was over \$68.6 million alone, which cost the Postal Service an additional \$3.6 million in administrative fees.

These extraordinary cost increases were due to the higher costs of compound drugs and the rising number of compound drug prescriptions for employees on workers’ compensation. In general, the cost of compound drugs has increased because the

National Council on Prescription Drug Programs in 2012 permitted compounding pharmacies to bill for all ingredients. With this incentive, more pharmacies began compounding drugs, which created shortages in the ingredients and increased the cost. Additionally, the number of employees with compound drug prescriptions grew from 17,722 in CBY 2011 to 50,204 in CBY 2015, a threefold increase.

Best Practices

The Postal Service's unprecedented increases in compound drug costs and related administrative fees of \$68.6 million and \$3.6 million, respectively, from CBYs 2014 to 2015 occurred because the DOL did not implement best practices used by other government agencies and state and private entities. For example,

- **Reimbursement Caps:** Ohio and Georgia established reimbursement caps for compound drugs. Specifically, Ohio caps reimbursement for compounds at \$600 and sets compounding dispensing fees at \$12.50 for non-sterile drugs and \$25 for sterile drugs. Georgia limits reimbursements to a maximum of three ingredients.
- **Fee Schedules:** California, Colorado, Florida, Idaho, Tennessee, Texas, Washington, and Wyoming require compound drugs to be billed on a fee schedule with a cap on each prescription.
- **Pharmacy Benefit Managers:** Most workers' compensation programs, such as those of New York and California, establish mandatory use of pharmacy benefits managers (PBM) that are used to capture prescription network discounts, conduct drug utilization reviews, and administer formularies to reduce overall pharmacy costs. While the Postal Service has its own PBM, its workers' compensation employees are not required to use it. In fact, Postal Service officials stated most of the compound drugs are being provided by pharmacies outside of the Postal Service PBM. The DOL does not use a PBM and limits what PBMs can do. According to the DOL, PBMs may not establish formularies and are limited in their ability to control costs through drug utilization reviews.
- **Drug Formularies:** Texas and Washington use drug formularies to control drug costs.
- **Pre-authorization:** Oklahoma and Pennsylvania require pre-authorization for compound drugs.

Additionally, some insurance companies have prohibited compound drug coverage. TRICARE, the military health insurance program, saw similar increases in compound drugs costs from CBYs 2012 to 2015. A closer look into compounds revealed that doctors were prescribing and charging for compound drugs without seeing the patients. In May 2015, TRICARE established that it would only reimburse pharmacies for FDA approved ingredients in compound drugs. Initially, compound drug use decreased, but shortly after the policy change, pharmacies changed their composition of compounds and use began to rise again. TRICARE, then, had its PBM⁷ implement the "commercial reject" list⁸ of compound ingredients. The commercial reject list excluded reimbursement for compound ingredients the PBM manager, considered overpriced with no additional clinical benefit used for private business clients. This resulted in a decrease in compound expenses from about \$1 billion in a 4-month period to nearly \$4 million for a 1-month period.

⁷ A large pharmacy benefits manager for both public and private entities.

⁸ "Commercial reject" list is a list of compound ingredients for which payment will not be approved.

According to Postal Service officials, the DOL did not effectively administer or manage workers' compensation compound drug costs and failed to prevent abusive or fraudulent activity.

The DOL has full authority to implement all of the best practices mentioned above to curtail fraud, reduce costs, and provide consistent and safe drugs. However, DOL does not have an incentive to do so, and DOL officials have not been receptive to implementing these or other best practices. In addition, DOL stated if a doctor approves the compound drug they assume it is necessary and will reimburse the costs.

Postal Service Actions

The Postal Service has repeatedly asked the DOL, since January 2015, to explain why medical costs were escalating so rapidly. DOL management responded that the increase was “simply the law of averages catching up”. In June 2015, DOL advised in a meeting that another federal agency had raised similar concerns and they were looking into it. In September 2015, the Postal Service held another meeting with DOL to share OIG’s compound drugs analytical results and TRICARE’s implementation of a new compound drug policy. To our knowledge, the DOL has taken no action in response to the September meeting. We are continuing to provide information to DOL OIG on this issue.

The Postal Service is so concerned about the rising compound drug cost and DOL’s position to take no action that on October 15, 2015, the Postal Service officials requested an adjustment and withheld the \$68.6 million payment for its workers’ compensation chargeback bill. According to Postal Service officials, the DOL did not effectively administer or manage workers’ compensation compound drug costs and failed to prevent abusive or fraudulent activity. The Postal Service also provided the DOL with best practices implemented by other entities to reduce the rising cost of compound drugs. See [Appendix B](#) for a copy of the letter sent to the DOL.

In December 2015, the DOL denied the Postal Service’s adjustment request, stating the Postal Service must pay the \$68.6 million since “there is no legal basis for removing costs from the chargeback bill after OWCP has already paid those costs.” The DOL mentioned OWCP does provide for credits and adjustments for specific reasons; however, they are applied to the subsequent chargeback bill and not the current bill. In addition, the DOL mentioned the Postal Service neglected to provide support that OWCP failed to detect and prevent widespread pharmacy compound fraud. See [Appendix C](#) for a copy of the letter from the DOL.

In January 2016, Postal Service management disagreed with the DOL’s interpretation and stated the OWCP regulations do allow for an adjustment with a “written request directly to the OWCP National Office accompanied by a complete explanation for the basis of the agency objection”. Although, the Postal Service agreed to pay the outstanding \$68.6 million; they asked it be considered as an adjustment to the 2016 annual chargeback bill. See [Appendix D](#) for a copy of the letter sent to the DOL.

Investigative Actions

Compound drugs have been investigated by various agencies. The OIG’s Office of Investigations has opened over 17 investigations regarding compound pharmacies. Its ongoing investigations to date have shown incidents of fraud, waste, and abuse. For example:

- Patients received compound drugs at their house they did not expect.
- Compound drugs were prescribed to patients without instructions on how and when to use the drugs, how much to use, or whether the compound drugs will have adverse reactions to other medications they are taking.

- Some patients received compound drugs from five or more different pharmacies.
- Pharmacies appear to have financial ties to the providers in violation of the Anti-Kickback Statute.

Additionally, the DOL's Office of Inspector General has reported⁹ that DOL claim examiners needed additional training to detect and prevent improper payments and ensure payment accuracy. Furthermore, in a massive workers' compensation scheme identified by local authorities in California, doctors were paid to prescribe compound drugs that patients did not need. In one case, a 5-month-old baby died after coming in contact with a compound transdermal cream prescribed for his mother.

Because the DOL did not implement best practices used by other government agencies and state and private entities to manage compound drug cost and ensure drug safety, we estimate the Postal Service has incurred \$81.8 million in excessive compound drug costs and \$4.1 million in excessive administrative fees for FYs 2014 and 2015. We also estimate that if the DOL does not implement best practices to control compound drug costs, the Postal Service's costs and the related administrative fees could accumulate to over \$1.2 billion and over \$60.3 million, respectively, over the next 3 years.

⁹ OWCP's Efforts To Detect And Prevent FECA Improper Payments Have Not Addressed Known Weaknesses, Report Number: 03-12-001-04-431, dated February 15, 2012.

Recommendations

We recommend management continue to coordinate with the U.S. Department of Labor to identify and implement best practices for controlling compound drug costs; and inform and educate Congress on the impact of the Department of Labor's failure to address escalating compound drug costs.

We recommend the chief human resources officer and executive vice president:

1. Continue to coordinate with the U.S. Department of Labor to identify and implement best practices for controlling compound drug costs and to authorize payment for only Food and Drug Administration approved drugs.
2. In coordination with Government Relations, inform and educate Congress on the impact of the Department of Labor's failure to address escalating compound drug costs on the Postal Service.

Management's Comments

Management agreed with the finding and recommendations. In subsequent correspondence, management agreed with the monetary impact. Management reiterated the DOL is the sole administrator of the FECA; therefore, they have no authority to impose administrative controls on the claims process. In addition, they stated the concern is more than just costs; they are also concerned about the health and safety of Postal Service employees.

In regard to recommendation 1, management stated they will continue to urge the DOL to implement common sense administrative controls to eliminate abusive and fraudulent compound drug prescriptions. Management stated implementation of this recommendation is immediate and ongoing, and in subsequent correspondence indicated the recommendation would be implemented by March 18, 2016.

In regard to recommendation 2, management stated it will work to inform and educate members of Congress about the uncontrolled compound drug problem, the DOL's failure to address the problem, and the effect, financial and otherwise, DOL's failure is having on the Postal Service and its employees. In addition, they reiterated the issues raised in the report can and should be resolved without congressional intervention. Management indicated implementation of this recommendation is immediate and ongoing, and in subsequent correspondence stated the recommendation would be implemented by March 18, 2016.

See [Appendix E](#) for management's comments, in their entirety.

Evaluation of Management's Comments

The OIG considers management's comments responsive to the recommendations and corrective actions should resolve the issues identified in the report.

All recommendations require OIG concurrence before closure. Consequently, the OIG requests written confirmation when corrective actions are completed. All recommendations should not be closed in the Postal Service's follow-up tracking system until the OIG provides written confirmation that the recommendations can be closed.

Appendices

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Appendix A: Additional Information

Background

In FYs 2014 and 2015, the FECA provided over \$1 billion in annual workers' compensation benefits to Postal Service workers. Enacted in 1916, the FECA provides medical, compensation, death, and vocational rehabilitation benefits to civilian federal employees who sustain injuries — including occupational disease — because of their employment with the federal government.

The DOL OWCP administers the FECA for the Postal Service, including costs for medical treatment and drugs. The Postal Service reimburses the DOL for benefits paid out and pays an administrative fee based on the total cost of workers' compensation. The Postal Service pays for about 39 percent of the federal government's total workers' compensation administrative expenses.

According to the FDA, 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 example, compound drugs are used when individuals are allergic to a filler ingredient or need a different method of delivery, i.e. children may need a liquid form of a medication because they cannot swallow pills.

Because compound drugs are not mass-produced, the FDA does not monitor and approve them. In addition, compound drug effectiveness and safety have not been scientifically tested like their commercial counterparts. Most compounded drugs do not provide any additional clinical value over FDA-approved alternatives that are readily available to patients at far lower costs. The most common compounds in workers' compensation are “topical” — creams, gels, or ointments that are applied to the skin and are intended to manage pain.

In 2012, the National Council on Prescription Drug Programs, which sets standards for billing practices, permitted compounding pharmacies to bill for all ingredients. Prior to 2012, pharmacies could only charge for the most expensive ingredient. The reason behind the billing change was to allow pharmacies to collect the full cost of making a compound drug.

Objective, Scope, and Methodology

Our objective was to assess the Postal Service's workers' compensation compound drug costs. To accomplish our objective, we:

- Interviewed appropriate Postal Service Headquarters personnel.
- Analyzed workers' compensation data for compound drug prescriptions and costs for FYs 2011 through 2015.
- Analyzed the Postal Service's pharmacy benefit manager's compound drug costs for non-federal clients and compared them to Postal Service's compound drug costs.
- Researched industry best practices.
- Reviewed Postal Service and FDA policies and procedures on compound drugs.
- Interviewed the Postal Service's pharmacy benefit manager.

- Interviewed OIG investigative specialists.
- Reviewed federal laws and regulations related to workers' compensation.

We conducted this review from October 2015 through March 2016 in accordance with the Council of the Inspectors General on Integrity and Efficiency, *Quality Standards for Inspection and Evaluation*. We discussed our observations and conclusions with management on March 1, 2016, and included their comments where appropriate.

We assessed the reliability of the DOL workers' compensation data by interviewing an agency official knowledgeable about the data and conducting limited data testing. We determined the data sufficient and reliable for this report.

Prior Audit Coverage

The OIG did not identify any prior audits or reviews related to the objective of this audit.

Appendix B: Fiscal Year 2015 Chargeback Bill Adjustment Request

JEFFREY C. WILLIAMSON
Chief Human Resources Officer
and Executive Vice President



October 15, 2015

Leonard J. Howie III,
Director, Office of Workers' Compensation Programs,
Office of Workers' Compensation Programs, National Office
200 Constitution Avenue, NW, Suite S-3524
Washington, DC 20210

Re: Fiscal Year 2015 Chargeback Bill Adjustment Request

Mr. Howie:

With this letter, the United States Postal Service (Postal Service) formally requests an adjustment to its fiscal-year-2015 chargeback billing statement, dated August 15, 2015.¹ The U.S. Department of Labor, Office of Workers' Compensation Programs (OWCP) is solely responsible for administering the Federal Employees' Compensation Act (FECA) claims process. As such, OWCP has a fiduciary duty to employing agencies like the Postal Service, to take reasonable measures to prevent fraudulent claims and charges. But in fiscal year 2015, OWCP failed to detect or prevent large increases to the Postal Service's medical costs, which were almost certainly caused by widespread pharmacy-compounding fraud. Because OWCP, and not the Postal Service, was responsible for preventing such fraud, the Postal Service now requests that these increases be removed from its 2015 chargeback bill.

Congress has assigned sole responsibility for interpreting, administering, and enforcing FECA to the Secretary of Labor.² The Secretary of Labor has in turn delegated that responsibility to OWCP. OWCP, therefore, is the sole administrator of the federal government's workers' compensation program, including the FECA claims process. OWCP alone adjudicates compensation claims; determines agency liabilities; and evaluates requests for medical services, treatment, and supplies.

Employing agencies, on the other hand, play a relatively minor role in the claims process. The claims process is non-adversarial, meaning that the employing agency has little to no involvement. Moreover, once a claim is approved, the employing agency has no right to decide whether the claimant receives any particular medical service, treatment, or product. Rather, the authority to make that decision lies solely with OWCP. As a result, the employing agency cannot directly control its medical costs; it must instead rely on OWCP to impose reasonable cost controls.

Over the last three years, the Postal Service's medical costs have increased exponentially, largely because of sharply rising pharmacy-compounding costs. As a non-appropriated agency, the Postal Service must reimburse OWCP for the cost of medical services, treatment, and supplies provided to eligible claimants out of its own generated operating revenues. In fiscal years 2013, 2014, and 2015, those costs were largely flat—with the notable exception of

¹ See U.S. Dep't of Labor, Injury Compensation for Federal Employees Handbook 79 (1999); Department of Federal Employees' Compensation Procedure (DFEC) Manual § 5-0700(6).

² 5 U.S.C. § 8145.

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pharmacy-compounding costs, which increased by a factor of eleven in just two short years without any apparent justification. In fiscal year 2013, the Postal Service's pharmacy-compounding costs totaled only \$9 million. But in 2014, they rose to \$30 million: a single-year increase of \$21 million. And in 2015, they inflated to nearly \$99 million: a single-year increase of approximately \$69 million.

The Postal Service was not alone in seeing its pharmacy-compounding costs skyrocket. Rather, both private and public insurers have been saddled with ever-increasing pharmacy-compounding costs. For example, over the last two years, Blue Cross and Blue Shield and UnitedHealth both saw their pharmacy-compounding costs quintuple.

Similarly, between May 2014 and May 2015, TRICARE saw its pharmacy-compounding costs balloon from \$42 million per month to \$300 million per month. Department of Defense officials have publically said that most of TRICARE's increased costs were the result of nationwide kickback schemes, under which pharmacy compounders paid physicians to prescribe expensive compound drugs to TRICARE beneficiaries. Likewise, in several high-profile cases, pharmacy compounders have victimized state workers' compensation programs. For instance, in June 2015, fifteen chiropractors, pharmacists, and financial brokers were indicted for participating in a scheme to bill California's workers' compensation program for millions of dollars in fraudulent pharmacy-compounding charges.

Many of the entities targeted by such schemes have reacted by adopting common-sense safeguards. For example, in May 2015, TRICARE adopted a new claim-screening process, eliminated certain compounding pharmacies from its network, and began tracking spending on a daily basis. Likewise, in 2011, California reformed its workers'-compensation-reimbursement process to reduce pharmacy-compounding costs. Among other things, it required that compound drugs be billed on an individual-ingredient basis. It also pegged reimbursement rates to the prescribing physician's office's "Documented Paid Price." Other workers' compensation programs have also acted to reign in pharmacy-compounding. For example, Ohio capped reimbursements for compound drugs through its workers' compensation program to \$600. And Louisiana required compound drugs to be billed under the same reimbursement formula as generic drugs.

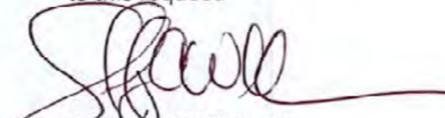
The Postal Service lacks the authority to adopt similar reforms. Instead, it must rely on OWCP to police the FECA-claims process and to reign in fraudulent charges. OWCP, however, has consistently failed to control—or even recognize—exploding pharmacy-compounding costs. To the Postal Service's knowledge, OWCP has not adopted any measure to limit compounding costs or to combat compounding fraud. Indeed, OWCP failed to act even after the Postal Service brought the issue to its attention. After the Postal Service received its first-quarter chargeback report for fiscal year 2015, it asked OWCP why its medical costs had risen so quickly. In response, OWCP stated that the increase was "simply [attributable to] the law of averages catching up." Later, after receiving additional quarterly reports, the Postal Service again noted and questioned the alarming cost increases. But on each occasion, OWCP failed to explain or address the increases. It was only once the Postal Service conducted its own investigation that it determined the increased costs were due almost entirely to surging pharmacy-compounding charges.

As the sole administrator for FECA, OWCP plays a crucial gatekeeping function. It bears responsibility for policing the claims process and for preventing fraud, waste, and abuse. It failed, however, to perform that function when it did not detect or prevent dramatic year-over-year increases in pharmacy-compounding charges. As a result of that failure, the Postal Service incurred exponential increases to its 2015 chargeback bill.

Accordingly, the Postal Service now requests that OWCP adjust the Postal Service's chargeback payment to remove the 2015 pharmacy-compounding increase. Specifically, the Postal Service asks that OWCP reduce its bill by \$68,622,202.55—the total increase in compounding costs between fiscal years 2014 and 2015.

The total amount due by the Postal Service under the terms of the fiscal-year-2015 chargeback billing statement is \$1,443,960,010.17. With this letter, the Postal Service is remitting partial payment of the fiscal-year-2015 chargeback billing statement in the amount of \$1,375,338,716.62. The Postal Service has withheld \$68,622,202.55 from the total amount due, pending a written decision by OWCP on this request for adjustment.

I am available for discussion if necessary. Otherwise, I look forward to receiving your response to this request.



Jeffrey C. Williamson

cc: Megan J. Brennan
Ronald A. Stroman
Joseph Corbett
Thomas J. Marshall

Appendix C: Department of Labor's Response to Fiscal Year 2015 Chargeback Bill Adjustment Request

U.S. Department of Labor

Office of Workers' Compensation Programs
Washington, DC 20210



DEC - 9 2015

File Number:

Jeffrey C. Williamson
Chief Human Resources Officer
and Executive Vice President
United States Postal Service
475 L'Enfant Plaza, SW Room 9021
Washington, DC 20260

Re: Fiscal Year 2015 Chargeback Bill Adjustment Request

Dear Mr. Williamson:

Thank you for your letter, dated October 15, 2015, concerning your Fiscal Year 2015 chargeback. It is clear that the United States Postal Service (USPS) has given significant thought to the prevalence and growing cost of compound medications, and the impact of these costs on the federal workers' compensation system. In response to the manner in which USPS has been impacted by these increasing costs, you requested that the Department of Labor (DOL) remove pharmacy charges from your FY 2015 chargeback. The rationale you provide for requesting the removal of these charges is that the Office of Workers' Compensation Programs (OWCP) "failed to detect or prevent large increases to [USPS]' medical costs, which were almost certainly caused by widespread pharmacy-compounding fraud." You also provided notice that USPS is withholding over \$68 million dollars in federal workers' compensation costs that OWCP paid from the Employees' Compensation Fund (the Fund) during chargeback year 2015.

After considering your request, I must report that there is no legal basis for removing costs from the chargeback bill after OWCP has already paid those costs from the Fund. OWCP must comply with the Federal Employees' Compensation Act (FECA). FECA requires OWCP to submit a statement of the total costs of benefits paid on behalf of USPS' injured workers. USPS (as an agency or instrumentality not dependent on an annual appropriation) is then required to make the deposit to the Fund during the first fifteen days of October. USPS' own statute explicitly provides that USPS has a mandate to pay the workers' compensation costs when presented the statement of total costs and benefits paid by OWCP (39 U.S.C. § 2003).

Regarding USPS' decision to withhold a portion of the chargeback payment, the FECA statute does not give agencies discretion to withhold part of its payment. OWCP does, as part of its calculation of the chargeback bill, provide credits or reductions for payment received under specific circumstances (FECA subrogation, criminal restitution, civil settlements, and where an employee is incorrectly coded to an agency). However, when these credits or adjustments are authorized, they are made to the subsequent chargeback statement and not to the statement for the fiscal year at issue. Here, since there is no provision in law that permits partial payments, nor does this fall within the chargeback bill calculation, the decision to withhold payment for properly billed charges is inconsistent with FECA's statutory payment requirements and our chargeback procedures.

As your longstanding partner in providing benefits for injured workers, OWCP understands the strain that the cost of compound medications produce on agency budgets. However, the assertion that these large increases were the result of "widespread pharmacy-compounding fraud" that OWCP "failed to detect or prevent" are unsupported and, as stated above, cannot justify our removal of the charges, nor can it support withholding a portion of the USPS payment to the Fund.

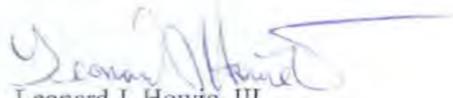
USPS and OWCP have worked together over the years on instances of suspected fraud. Our respective Office of Inspectors General (OIG) have collaborated on several successful criminal and civil prosecutions that have resulted in OWCP being reimbursed through settlement or restitution, followed by a reduction in the subsequent USPS chargeback statement. We would welcome the opportunity to work with USPS if you are aware of or become aware of any suspected instances of improper medical billing practices.

Lastly, your letter appears to suggest that USPS should not pay the costs of compound medication because OWCP should not authorize the payment of pharmacy-compounding drugs at all. This suggestion, if captured accurately, is contrary to DOL's final authority in the allowance or denial of payments under FECA. Even if agencies were to disagree with OWCP's approval of providing compound medications or with the current policy of paying such prescriptions for FECA-accepted conditions, OWCP's determinations are precluded from review by another agency (5 U.S.C. § 8128(b)).

In summary, under both FECA and USPS' own authorizing statute, once a chargeback bill has been provided to USPS, there is an absolute requirement that USPS pay the chargeback as billed. When OWCP makes payments on behalf of injured workers, our fiduciary duty to the Employees' Compensation Fund requires us to collect chargeback so the Fund remains viable for the benefit of FECA claimants. In support of that duty, it is OWCP's responsibility to collect all monies paid from every responsible agency. If payment is withheld, we are required to pursue all available remedies.

Since there is no legal basis for USPS to withhold payment, I must deny the request to remove the charges and USPS should immediately forward the remaining amount of the chargeback bill.

Sincerely,



Leonard J. Howie, III

Director

Office of Workers' Compensation Programs

cc: Gary A. Steinberg, Deputy Director, Office of Workers' Compensation Programs
Douglas C. Fitzgerald, Director, Federal Employees' Compensation
Thomas G. Giblin, Associate Solicitor Division of Federal Employees' and
Energy Workers' Compensation Office of the Solicitor
Geoffrey Kenyon, Principal Deputy Chief Financial Officer
Melissa Bomberger, Labor Branch Chief, Office of Management and Budget

Appendix D: Postal Service's Letter to Department of Labor's Response to Fiscal Year 2015 Chargeback Bill Adjustment Request

JEFFREY G. WILLIAMSON
Chief Human Resources Officer
and Executive Vice President



January 6, 2016

Mr. Leonard J. Howie III
Director,
Office of Workers' Compensation Programs
Office of Workers' Compensation Programs,
National Office
200 Constitution Avenue, NW, Suite S-3524
Washington, DC 20210-0001

Dear Mr. Howie:

SUBJECT: Postal Service's Response — OWCP's Denial of Fiscal Year 2015 Chargeback Bill Adjustment Request by the Postal Service

This is in response to your letter dated December 9, 2015, in which you denied the Postal Service's request for a \$68 million adjustment to its fiscal year (FY) 2015 chargeback bill. Although we disagree with a number of points in your letter, we are now forwarding the remaining \$68 million payment. We maintain that the Postal Service should not be held responsible for the payment. The payment is largely attributable to pharmacy-compounding fraud, which the Office of Workers' Compensation Programs (OWCP) failed to detect and prevent.

Your letter indicated that "there is no legal basis for removing costs from the chargeback bill after the OWCP has already paid those costs". We disagree, the OWCP does, in fact, have the authority to remove those costs. The OWCP administers and enforces the Federal Employees' Compensation Act (FECA), and as FECA's administrator, it has the authority to adjust an agency's annual chargeback bill. The OWCP's regulations explicitly provide for such adjustments. Specifically, they direct agencies to ask for adjustments by sending a written request "directly to the OWCP National Office" accompanied by "a complete explanation for the basis of the agency's objection."¹

On October 15, 2015, we submitted a request to the OWCP National Office for an adjustment to the Postal Service's FY2015 chargeback bill, as directed by the OWCP regulations. We fully explained the basis of our request, namely, that the additional \$68 million in pharmacy-compounding costs added to our FY2015 bill was unjustified and likely attributable to fraud and abuse. The OWCP has the duty to prevent such fraud and abuse. To the extent that the OWCP now claims it lacks the authority to grant our request, we disagree.

¹ U.S. Dep't of Labor, Injury Compensation for Federal Employees Handbook 79 (1999); Department of Federal Employees' Compensation Procedure (DFEC) Manual § 5-0700(6).

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We are even more troubled by your apparent refusal to acknowledge the possibility that the explosive growth in pharmacy-compounding charges is problematic, and by your failure to recognize that you have any responsibility to investigate the issue or to take proactive steps to attack the problem. In our request, we highlighted what we suspect to be rampant pharmacy-compounding fraud and abuse, which caused our annual chargeback bill to spike in FY2015. However, instead of addressing our concern, you merely dismissed it as "unsupported" and suggested the fact that since the OWCP made the payment for these charges that is the end of the inquiry, and that the Postal Service should have no further recourse even in the face of potential fraud. That approach is unacceptable to the Postal Service.

The numbers alone are a powerful indication of a serious problem that warrants further action on your part. In FY2013, the Postal Service's total cost attributable to pharmacy-compounding fraud and abuse was \$9 million. In FY2014, the cost jumped to \$30 million—a year-over-year increase of \$21 million or more than 200 percent. Then in FY2015, the cost ballooned to \$99 million, an 11-fold increase over the FY2013 cost. The cost has continued to soar; in the first five months of chargeback year 2016 alone, the Postal Service's pharmacy-compounding cost has surpassed \$65 million. At that pace, this year's compounding cost will exceed \$156 million—\$147 million more than the cost billed just three years ago.

Even standing alone, these increases suggest the serious possibility of fraud and abuse. But we have not asked you to act solely based on the increases themselves. Instead, we also provided you with corroborating evidence which, coupled with the increases, demonstrates the prospect of widespread fraud and abuse. Specifically, on September 17, 2015, we met with representatives from the OWCP and the Postal Service's Office of Inspector General (OIG) to present preliminary findings from the OIG's investigation into pharmacy-compounding fraud. The OIG's findings demonstrated severe and systemic abuse. For example, the OIG found that a significant number of pharmacies had financial ties to prescription providers, violating the Anti-Kickback Statute.² The majority of patients who received compound drugs from those pharmacies was not expecting them, had not asked for them, and had not been instructed on how to use them. Many of the prescriptions were refilled automatically, resulting in patients receiving far more medication than they could ever use. Even phone calls to the pharmacies and prescription providers failed to stop the prescriptions.

In response, it appears that you have merely paid the escalating costs and passed them on to the Postal Service. And you have done so at a time when several national insurance providers and state workers' compensation programs have responded to the crisis by restricting compounding reimbursements and implementing responsible administrative controls. For example, TRICARE has implemented a series of reforms aimed at eliminating unwarranted pharmacy-compounding costs: it has adopted a new-claims screening process, eliminated certain pharmacies from its network, and begun tracking expenses on a daily basis. State workers' compensation programs have taken similar, commonsense measures, such as restricting or capping reimbursements. The Postal Service has repeatedly asked what similar preventive steps are being taken by the OWCP. To date, you have not identified any such steps.

In your letter, you expressed no concern and simply wrote that the OWCP has the "final authority in the allowance or denial of payments under FECA". You also suggested that the Postal Service had no right to object to improper payments made on its behalf.

² 42 U.S.C. § 1320a-7b(b).

While you are correct that the OWCP enjoys the authority to allow or deny FECA payments, you are wrong that the Postal Service has no right to object. With authority comes responsibility. The OWCP is responsible for administering the FECA program; and as the program's administrator, the OWCP owes a fiduciary duty to agencies like the Postal Service, which bear the burden of the OWCP's choices. Your response suggests that the OWCP is unconcerned with how its choices affect those agencies that rely on it to exercise reasonable care. We hope that suggestion was inadvertent, or that we have misinterpreted your letter.

In sum, your letter failed to address, let alone resolve, the issues we raised in our request. Nevertheless, our first priority is—and always has been—the health and well-being of our employees. We therefore submit to you the remaining \$68 million of our FY2015 chargeback bill.

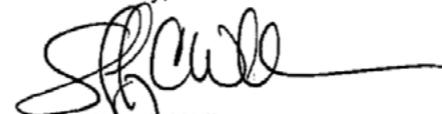
Although we are paying the bill in full, we reiterate that the Postal Service should not be held responsible for costs attributable to fraud and abuse. Since our last letter, we discussed with you the possibility that the OWCP would afford the Postal Service relief from these unjustified costs in future bills. Similarly, in your letter, you suggested that the OWCP could apply our requested adjustment to next year's annual chargeback bill. If you can provide such relief, we ask that you do so. We also ask that you adjust our 2016 or 2017 bill to remove the unjustified \$65 million we have already incurred in chargeback year 2016, as well as any additional compounding costs we incur over the remainder of the year. If you need additional information with regard to any of these requests, including information on a case file by case file basis, we would be happy to provide it.

As we explained in our first request, because the OWCP is the sole FECA administrator, the Postal Service has limited ability to control its own pharmacy-compounding costs. Nevertheless, we will take every measure within our power to lower or eliminate those costs. In order to better plan and coordinate our efforts with you, we ask that you provide us with the following information:

1. A detailed explanation as to the steps the OWCP took in FY2015 to mitigate pharmacy-compounding fraud and abuse.
2. A detailed explanation as to the steps the OWCP plans to take in FY2016 and beyond to mitigate pharmacy-compounding fraud and abuse.
3. Please identify the additional information or documentation required from the Postal Service to grant our request for an adjustment to our 2016 annual chargeback bill, as discussed more fully above.

We look forward to receiving your responses to these questions, and to continuing our discussions in this regard.

Sincerely,



Jeffrey C. Williamson

cc: Megan J. Brennan
Ronald A. Stroman
Joseph Corbett
Thomas J. Marshall

Appendix E: Management's Comments

Jeffrey C. Williamson
Chief Information Officer
Washington, DC 20503



March 10, 2016

Lori Lau Dillard
Director, Audit Operations
1735 North Lynn Street
Arlington, VA 22209-2020

SUBJECT: Management Advisory Workers' Compensation Compound Drug (Report Number HR-MA-16-DRAFT)

This memorandum responds to your audit report regarding workers' compensation compound-drug costs. In your report, you made two recommendations. Postal Service management agrees with both recommendations and offers the following supplemental responses.

Recommendation 1:

Continue to coordinate with the U.S. Department of Labor (DOL) to identify and implement best practices for controlling compound-drug costs and to authorize payment for only Food and Drug Administration (FDA) approved drugs.

Management Response:

Postal management agrees with this recommendation. Management will continue to urge the DOL to implement commonsense administrative controls to eliminate abusive and fraudulent compound-drug prescriptions.

As noted in your report, the DOL is the sole administrator of the Federal Employees Compensation Act (FECA). As such, the DOL has exclusive control over the FECA-claims process. It alone approves or denies claims submitted through that process. By contrast, the Postal Service has no authority to approve or deny any FECA claims, nor does it have any authority to impose administrative controls on the claims process. Rather, the Postal Service is required by law to pay the claims billed to it by the DOL. The Postal Service therefore cannot unilaterally control its own compound-drug costs. Only the DOL can control these costs.

The issues raised in your report, however, concern more than just costs; they also concern the health and safety of postal employees. As the report notes, compound-drugs are not monitored or approved by the FDA. Accordingly, their safety and medical efficacy have not been tested. Indeed, some compound-drugs have been proven to affirmatively harm patients, however, in at least one case, they contributed to a patient's death.

Jeffrey C. Williamson
Chief Information Officer
Washington, DC 20503

The Postal Service's first priority is, and always has been, the health and safety of its employees. However, because the DOL controls the FECA-claims process, the Postal Service cannot alone protect its employees from the risky compound drugs they receive through that process. As a result, postal employees will remain at risk until the DOL adopts a set of commonsense "best practices" to restrict compound-drug prescriptions.

Postal management has repeatedly urged the DOL to adopt such practices. It has also asked the DOL to disclose what, if anything, it is doing to combat abusive and fraudulent compound-drug prescriptions. However, to date, the DOL has not responded to the Postal Service's inquires. Nor has the DOL indicated when, or if, it plans to respond.

Nevertheless, management will continue to urge the DOL to adopt best practices, such as the practices you identified in your report. Without such practices, the Postal Service's compound-drug costs will continue to increase and its employees will remain at risk. Management considers that risk unacceptable, and so it will do everything in its power to persuade the DOL to act.

Target implementation date: Immediate and ongoing.

Responsible management official: Vice President, Employee Resource Management.

Recommendation 2:

In coordination with Government Relations, inform and educate Congress on the impact of the DOL's failure to address escalating compound-drug costs on the Postal Service.

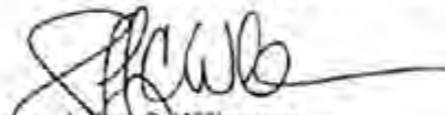
Management response:

Postal management agrees with this recommendation. It will therefore work to inform and educate members of Congress about the uncontrolled compound-drug problem, the DOL's failure to address that problem, and the effect, financial and otherwise, that DOL's failure is having on the Postal Service and its employees.

Although we agree with your recommendation, we note that the issues you raised in your report can and should be resolved without congressional intervention. As the sole FECA administrator, the DOL already has ample authority to adopt the best practices you identified. The DOL needs no additional authority to police the FECA-claims process. Indeed, it is already obligated to do so. Accordingly, while we will work to inform and educate members of Congress about these issues, we see no need for affirmative congressional action or new legislation to address these issues at this point in time.

Target implementation date: Immediate and ongoing.

Responsible Management Official: Director, Government Relations and Public Policy.



Jeremy C. Williamson

cc: Mr. Stroman
Ms. Rettinhouse
Ms. Haring
Corporate Audit and Response Management



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