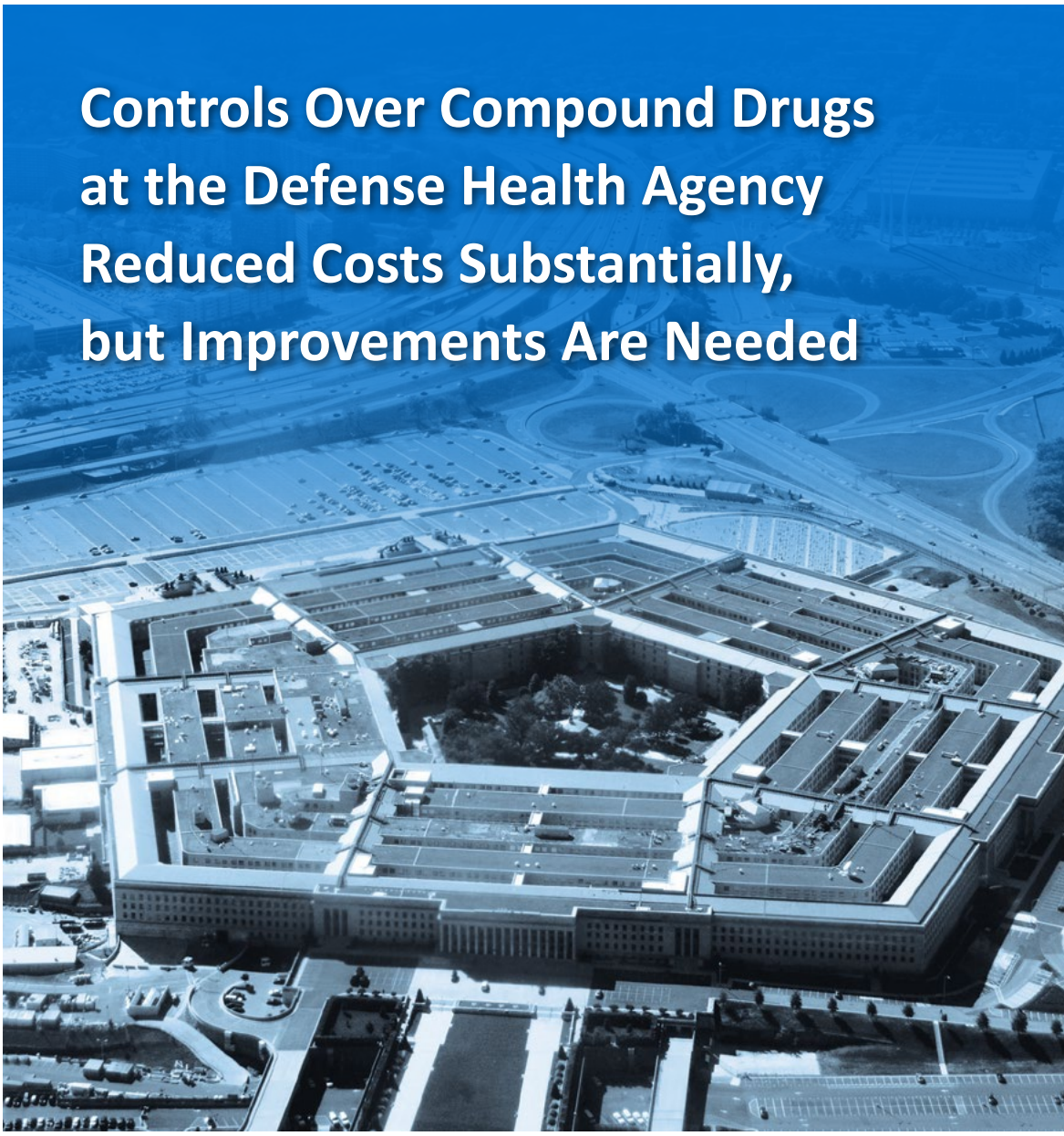
Report No. DODIG-2016-105

INSPECTOR GENERAL

U.S. Department of Defense

JULY 1, 2016

Controls Over Compound Drugs at the Defense Health Agency Reduced Costs Substantially, but Improvements Are Needed



INTEGRITY ★ EFFICIENCY ★ ACCOUNTABILITY ★ EXCELLENCE

INTEGRITY ★ EFFICIENCY ★ ACCOUNTABILITY ★ EXCELLENCE

Mission

Our mission is to provide independent, relevant, and timely oversight of the Department of Defense that supports the warfighter; promotes accountability, integrity, and efficiency; advises the Secretary of Defense and Congress; and informs the public.

Vision

Our vision is to be a model oversight organization in the Federal Government by leading change, speaking truth, and promoting excellence—a diverse organization, working together as one professional team, recognized as leaders in our field.

For more information about whistleblower protection, please see the inside back cover.

Results in Brief

Controls Over Compound Drugs at the Defense Health Agency Reduced Costs Substantially, but Improvements Are Needed

July 1, 2016

Objective

Our objective was to determine whether the Defense Health Agency (DHA) implemented adequate controls over payments for compound drugs.

Compound drugs are pharmaceutical products that result from combining, mixing, or altering two or more ingredients to create a customized medication for an individual patient.

Finding

After costs for compound drugs rapidly increased, DHA personnel implemented controls in May 2015 to screen compound ingredients, which reduced costs from approximately $497 million in April 2015, to $10 million in June 2015.

However, we determined that DoD's pharmacy benefit manager (PBM) (Express Scripts, Inc.) incorrectly paid 40 of 47 compound drug claims[1] we reviewed which had non-covered ingredients, even after the new controls were implemented. This occurred because PBM personnel did not follow their standard operating procedures, and their claims adjudication system inappropriately allowed claims with prior authorizations and claims where beneficiaries had both Medicare and TRICARE coverage to bypass screening against a list of non-covered ingredients.

[1] We nonstatistically selected 47 compound drug claims, valued at $146,061.43, out of 61,543 compound drug claims, valued at $16.6 million, with excluded ingredients.

Visit us at www.dodig.mil

Finding (cont'd)

- For 4 of the 40 compound drug claims, PBM personnel did not follow their recently implemented standard operating procedures for not issuing a prior authorization for compound refills requested early.
- For 2 of the 40 compound drug claims, the PBM's claims adjudication system did not recognize whether the prior authorization was for a compound drug prescription or single ingredient.
- For 1 of the 40 compound drug claims, the PBM's claims adjudication system did not differentiate between a prior authorization for one compound drug prescription versus another.
- For 33 of the 40 compound drug claims, the PBM's claims adjudication system allowed compound drug claims covered by Medicare to automatically bypass the controls for checking ingredients against the exclusion list when a pharmacist entered the override code to accept payment for covered ingredients only.

As a result, DHA, through the PBM, made at least $99,468.80 in potential improper payments for 40 of 47 compound drug claims, valued at $146,061.43, with excluded ingredients. See Appendix B for a summary of potential monetary benefits.

Recommendations

We recommend the Director, DHA:

- Require the PBM to ensure its personnel are properly trained in the standard operating procedures for compound drug claims requested to be filled before the approved refill date.
- Verify that controls are effective to ensure that prior authorizations issued for single ingredients do not automatically authorize other compounds with those ingredients.
- Require the PBM to perform a clinical prior authorization review for all new compound drug prescriptions submitted with excluded ingredients.

Results in Brief

Controls Over Compound Drugs at the Defense Health Agency Reduced Costs Substantially, but Improvements Are Needed

Recommendations (cont'd)

- Require the PBM to ensure that they screen all compound Medicare claims through the controls for excluded ingredients.
- Review and pursue appropriate action on the claims in our sample where we identified potential improper payments.
- Review all paid compound drug claims with prior authorizations, and paid claims with Medicare coverage, and initiate action to collect improper payments if necessary.

Management Comments and Our Response

The Director, DHA, agreed with all six recommendations. However, the comments from the Director partially addressed or did not address two of the recommendations, and the Director did not respond to potential monetary benefits. Therefore, we request the Director DHA, provide additional comments to this report by August 1, 2016. Please see the Recommendations Table on the next page.

Recommendations Table

Management	Recommendations Requiring Comment	No Additional Comments Required
Director, Defense Health Agency	1, 3	2, 4, 5, 6

Please provide Management Comments by August 1, 2016.


INSPECTOR GENERAL
INTEGRITY
EFFICIENCY
DEPARTMENT OF DEFENSE

INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
4800 MARK CENTER DRIVE
ALEXANDRIA, VIRGINIA 22350-1500

July 1, 2016

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
DIRECTOR, DEFENSE HEALTH AGENCY

SUBJECT: Controls Over Compound Drugs at the Defense Health Agency Reduced Costs Substantially, but Improvements Are Needed (Report No. DODIG-2016-105)

We are providing this report for review and comment. In May 2015, Defense Health Agency personnel implemented controls to screen compound ingredients, which reduced costs from approximately $497 million in April 2015, to $10 million in June 2015. However, the pharmacy benefit manager incorrectly paid 40 of 47 claims reviewed with non-covered ingredients after the new controls were implemented. During the audit, we identified that the pharmacy benefit manager paid at least $99,468.80 in potential improper payments for excluded compound drug ingredients that could be used for future requirements. We conducted this audit in accordance with generally accepted government auditing standards.

We considered management comments on a draft of this report when preparing the final report. DoD Instruction 7650.03 requires that recommendations be resolved promptly. The Director, Defense Health Agency, partially addressed or did not address two of the recommendations, and did not address the potential monetary benefits. Therefore, we request the Director, Defense Health Agency, provide additional comments in response to the report by August 1, 2016.

Please send a PDF file containing your comments to audityorktown@dodig.mil. Copies of your comments must have the actual signature of the authorizing official for your organization. We cannot accept the /Signed/ symbol in place of the actual signature. If you arrange to send classified comments electronically, you must send them over the SECRET Internet Protocol Router Network (SIPRNET).

We appreciate the courtesies extended to the staff. Please direct questions to me at (703) 604-9187.

Michael J. Roark
Assistant Inspector General
Contract Management and Payments

Contents

Introduction

Objective

Our objective was to determine whether the Defense Health Agency (DHA) implemented adequate controls over payments for compound drugs. See Appendix A for the scope and methodology and prior audit coverage.

Background

Defense Health Agency and the TRICARE Program

The DHA, an agency under the control, authority, and direction of the Assistant Secretary of Defense (Health Affairs), manages the TRICARE program. TRICARE is DoD's managed health care program for active duty service members, retirees, and their families and survivors. TRICARE is a blend of the military's direct care system of hospitals and clinics and the Civilian Health and Medical Program of the Uniformed Services.

Pharmacy Benefits

In FY 2000, Congress authorized TRICARE's pharmacy benefits program, which covers retail and mail-order prescription services, and pharmaceutical agents provided in support of home health care. TRICARE administers this program through contractors. Express Scripts Inc. is TRICARE's pharmacy benefit manager (PBM) contractor for the retail pharmacy and mail-order prescription services. Express Scripts Inc. is responsible for providing a retail pharmacy network, mail-order pharmacy services, claims adjudication, and pharmacy benefit management services for the 9.6 million beneficiaries who belong to the TRICARE Pharmacy Program.

Compound Drugs

Compound drugs are pharmaceutical products that result from combining, mixing, or altering two or more ingredients to create a customized medication for an individual patient. For example, a compound could be a liquid form of a drug for someone who cannot swallow pills. More recent examples of compounds include custom topical creams for scars and pain.

Compound drugs are not approved by the U.S. Food and Drug Administration (FDA). According to FDA personnel, if an approved drug product is modified such that it is no longer within the scope of its FDA approval, the resulting drug is a new, unapproved drug. For example, if new ingredients are added to an FDA-approved drug or the approved drug is mixed or combined with another approved drug, the

new drug is no longer FDA-approved. They also stated compound drugs do not need to have their safety and effectiveness demonstrated before they are marketed. FDA personnel stated the FDA does not have a mechanism for evaluating whether the ingredients used in compounding, or the resulting compounded product, is safe and effective for any particular use.

TRICARE Compound Drug Claims Reviewed

The PBM paid 442,677 compound drug claims from October 1, 2014, to April 30, 2015, valued at approximately $1.5 billion, before DHA implemented the exclusion list in May 2015. We nonstatistically selected 50 of these claims (valued at $736,442.11) and only performed a limited review to determine which ingredients the PBM would no longer pay for under the new controls.

After DHA implemented the new controls, the PBM paid 140,561 compound drug claims from May 1, 2015, to September 30, 2015, valued at approximately $116 million. To test the exclusion list, we determined whether the PBM paid claims with excluded ingredients. Of the 61,543 claims (valued at $16.6 million) with excluded ingredients, we nonstatistically selected 47 claims (valued at $146,061.43) for review. Of those 47 claims, 14 claims (valued at $119,304.86) had prior authorizations, and 33 claims (valued at $26,756.57) were Medicare claims.[2]

Review of Internal Controls

DoD Instruction 5010.40[3] requires DoD organizations to implement a comprehensive system of internal controls that provides reasonable assurance that programs are operating as intended and to evaluate the effectiveness of the controls. We identified internal control weaknesses within the DHA's controls over compound payments. Specifically, we found that DHA paid for non-covered ingredients for claims with prior authorizations and claims where the beneficiary had coverage with both TRICARE and Medicare. We will provide a copy of the report to senior officials responsible for the internal controls at DHA.

[2] A joint payment occurs when a TRICARE beneficiary also has Medicare coverage, when Medicare is the primary insurer for pharmacy claims, and when TRICARE becomes the secondary payer.

[3] DoD Instruction 5010.40, "Managers' Internal Control Program Procedures," May 30, 2013.

Finding

Defense Health Agency Controls Over Payments of Compound Drugs Substantially Reduced Costs, but Improvements Are Needed

After costs for compound drugs rapidly increased, DHA personnel implemented controls in May 2015 to screen compound ingredients, which reduced costs from approximately $497 million in April 2015, to $10 million in June 2015.

However, we determined that DoD's PBM incorrectly paid 40 of 47 compound drug claims[4] we reviewed which had non-covered ingredients, even after the new controls were implemented in May 2015. This occurred because PBM personnel did not follow their standard operating procedures, and their claims adjudication system inappropriately allowed claims with prior authorizations and claims where beneficiaries had both Medicare and TRICARE coverage to bypass screening against a list of non-covered ingredients.

- For 4[5] of the 40 compound drug claims, PBM personnel stated they did not follow their recently implemented standard operating procedures for PBM personnel to stop issuing administrative prior authorizations for compound refills requested early.
- For 2 of the 40 compound drug claims, the PBM's claims adjudication system did not recognize whether the prior authorization was for a compound prescription or single ingredient.
- For 1 of the 40 compound drug claims, the PBM's claims adjudication system did not differentiate between a prior authorization for one compound prescription versus another.
- For 33 of the 40 compound drug claims, the PBM's claims adjudication system allowed compound drug claims covered by Medicare to automatically bypass the PBM's controls for checking ingredients against the exclusion list when a pharmacist entered the override code to accept payment for covered ingredients only.

As a result, DHA, through the PBM, made at least $99,468.80[6] in potential improper payments for 40 of 47 compound drug claims, valued at $146,061.43, with excluded ingredients. See Appendix B for a summary of potential monetary benefits.

[4] We nonstatistically selected 47 compound drug claims, valued at $146,061.43, out of 61,543 compound drug claims, valued at $16.6 million, with excluded ingredients.

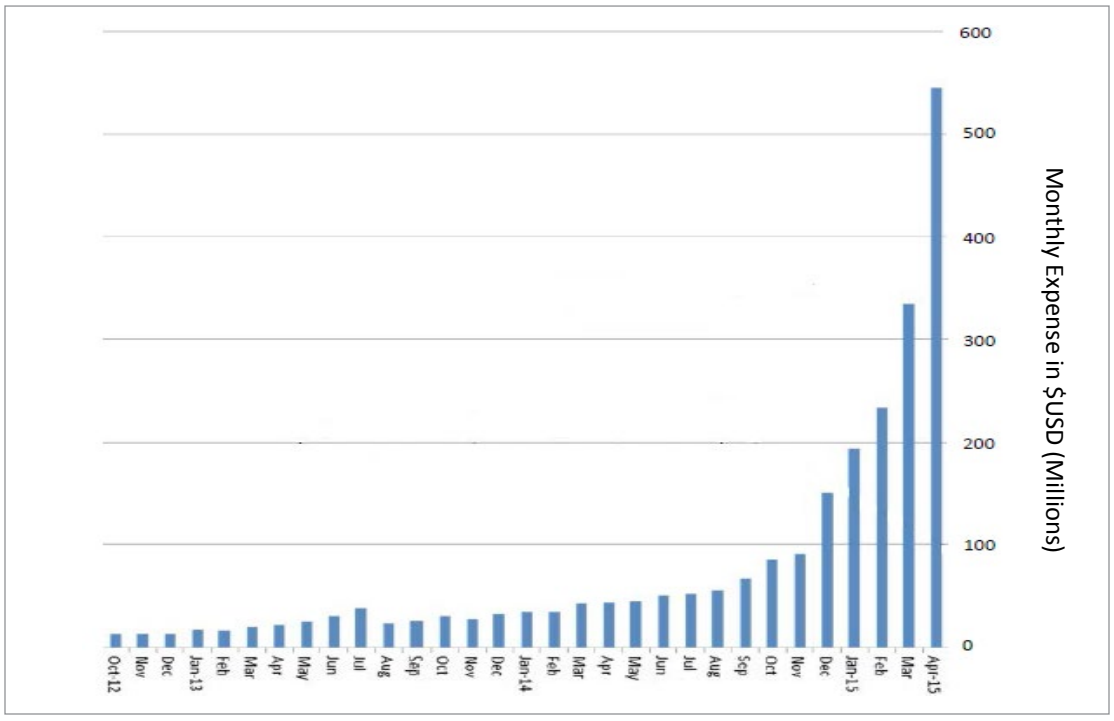
[5] As a result of the PBM incorrectly issuing a prior authorization for one of the compound drug claims, the PBM also incorrectly paid for a refill of that compound. Additionally, the PBM revised controls that addressed the cause for three of the four claims in May 2015.

[6] We were unable to determine the amount DHA overpaid for 22 of the Medicare claims because Medicare does not identify the cost of each individual ingredient in the claim.

History of Compound Drugs in the Defense Health Program

In early FY 2013, the costs TRICARE incurred for compound drugs began to rise significantly. According to DHA personnel, the PBM identified this trend and raised the issue to DHA. DHA personnel, concerned about TRICARE's dramatic increase in payments for compound drugs and the "high potential for inappropriate use," asked the PBM to perform an in-depth review of compound drug cost and usage. The PBM completed the review in January 2013. According to DHA personnel, in April 2013, DHA leadership determined that it would not reimburse for some ingredients in compound drugs. According to DHA personnel, in July 2013, after receiving feedback from beneficiaries, Congress, and compound pharmacists, the Assistant Secretary of Defense (Health Affairs) directed DHA personnel to review policy and delay implementation of excluding some ingredients from payment until at least February 2014. Additionally, in December 2013, DHA delayed the drug screening process beyond February 2014 until the FDA reviewed and published an approved list of bulk drug ingredients. DHA continued to review its policy and work with advisory committees on how to handle compound drugs. However, as of March 2015, the FDA still had not published a list of approved compound ingredients. Figure 1 demonstrates the increase in TRICARE spending on compound drugs.

Figure 1. TRICARE Monthly Spending on Compound Drugs October 2012 Through April 2015



Source: DHA

According to PBM personnel, in October 2014, the PBM implemented a compound drug exclusion list for their commercial clients, and some private insurers, such as Blue Cross Blue Shield, implemented restrictions on their compound drug coverage. After costs rose to approximately $322 million, in March 2015, the Director, DHA, authorized the PBM to implement a compound drug screening process for TRICARE beginning in May 2015.

DHA Implemented Controls to Screen Compound Drugs

After costs for compound drug claims rapidly increased, in May 2015, DHA implemented, through the PBM, controls to screen all compound drug ingredients against an exclusion list of non-covered drugs. PBM personnel stated this list referred to as the "exclusion list" is the PBM's proprietary list of ingredients that they determined pharmacies use in questionable compounds. According to PBM personnel the ingredients on the exclusion list are generally bulk powders that are not FDA-approved items. PBM pharmacists and clinicians developed and maintained the list. The PBM updates the exclusion list quarterly, or more often when necessary, with approval from DHA. Finally, PBM personnel added that DHA is responsible for determining the best course of action to ensure beneficiaries are made aware of impending changes to their prescription coverage.

PBM personnel stated this enhanced screening consists of comparing all the ingredients listed in the compound drug prescription to the list of drugs on the exclusion list. They explained that when pharmacists submit claims for compound prescriptions to the PBM electronically for payment, the PBM's claims adjudication system reviews the ingredients included in the compounds against the exclusion list. Furthermore, if all ingredients are covered by TRICARE, the PBM should process and pay the claims. They also stated if the compounds include any ingredients on the exclusion list, the claims are not paid and are automatically rejected. Finally, they stated the pharmacies receive reject messages, and have the option to:

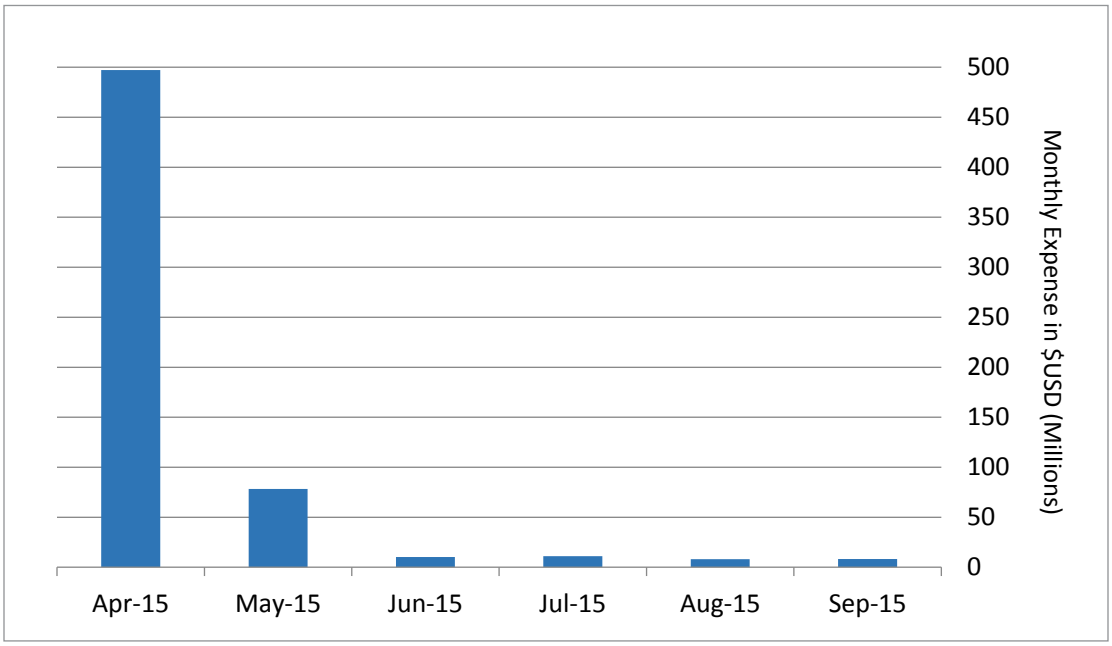
- remove or substitute non-covered ingredients with a covered ingredient, or contact the prescriber to have them prescribe a new drug;
- request a prior authorization for the compound drug, if they cannot substitute for the non-covered ingredients or prescribe a different drug; or
- enter a request to override the claim and only accept reimbursement for covered ingredients.

For each of the claims reviewed, the pharmacist requested the override and accepted reimbursement for only covered ingredients or had an approved prior authorization.

Defense Health Agency Controls Implemented for Compound Drugs Were Generally Effective

DHA controls to screen compound ingredients significantly reduced compound prescription costs. Figure 2 demonstrates that TRICARE spending on compound drug costs decreased after DHA implemented controls in May 2015.

Figure 2. TRICARE Monthly Spending on Compound Drugs April 2015 Through September 2015



The controls, implemented in May 2015, reduced costs from approximately $497 million in April 2015, to $10 million in June 2015.

We reviewed 50 compound drug claims, valued at $736,442.11, that the PBM paid before DHA implemented controls over compound drugs. Table 1 shows examples of the costs of compound drug ingredients from claims paid from October 1, 2014, to April 30, 2015. Each of the ingredients illustrated below was on the exclusion list, and after May 2015 were no longer covered when used in a compound drug.

*Table 1. Costs of Ingredients From Paid Claims That TRICARE No Longer Covered After May 2015 When Used in a Compound**

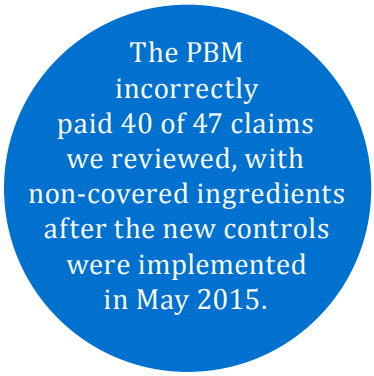
Compound Drug Ingredient Name	Amount Paid Before the May 2015 Controls Were Implemented	Covered in a Compound After the May 2015 Controls Were Implemented*
Hyaluronic Acid Sodium Salt Powder	$17,543.54	No
Collagenase Powder	12,431.97	No
Fluticasone Propionate Powder	11,512.95	No
Methylcobalamin Powder	3,906.69	No
Flurbiprofen Powder	3,787.51	No
Ethoxy Diglycol Liquid	3,602.84	No
Gabapentin Powder	3,378.18	No
Tobramycin Sulfate Powder	3,103.91	No

* According to PBM personnel, these ingredients are no longer covered by TRICARE for use in a compound unless the PBM approves a prior authorization.

For example, in one claim, the PBM paid $17,543.54 for the ingredient hyaluronic acid sodium salt powder before implementing the controls, and after implementing the controls, the PBM would not cover the drug. Of the 307 ingredients included in the 50 compounds, 242 ingredients valued at $212,089.99 were for ingredients now excluded from payment when used in a compound drug.

Pharmacy Benefit Manager Paid for Non-Covered Compound Ingredients

Although DHA implemented a list of non-covered compound ingredients, the PBM incorrectly paid 40 of 47 claims we reviewed, with non-covered ingredients after the new controls were implemented in May 2015.



Compound Drug Claims With Prior Authorizations Bypassed Exclusion List

The PBM processed and paid for excluded ingredients on seven compound drug claims where the PBM issued prior authorizations. Specifically, the PBM paid for excluded ingredients on claims that it incorrectly granted prior authorizations for, which included:

- four prescriptions that were filled before the approved refill date;
- two compound drug claims with ingredients approved to be filled individually, but not approved for use in compound prescriptions; and
- one compound drug claim with an ingredient approved to be included in a specific compound prescription, but not for the compound included in the claim.

According to PBM personnel, the PBM issues an administrative or clinical prior authorization to allow a prescription to process and pay through the claims adjudication system. They stated the PBM issues an administrative prior authorization to allow a prescription to process through the system for reasons other than clinical necessity. For example, if a patient needs a prescription refilled before the approved refill date, PBM personnel would issue an administrative prior authorization to allow the prescription be filled early.

PBM personnel perform a clinical review for a specific drug or compound to ensure it is safe, effective, medically necessary, and cost-effective for a patient. PBM personnel stated a clinical prior authorization allows the PBM's claims adjudication system to process and pay for any approved ingredients in the prescription.

Prior Authorizations for Compound Prescriptions Refilled Early Bypassed Exclusion List

The PBM paid for excluded ingredients on four compound drug claims because PBM contact center personnel entered override codes for prescriptions filled before the approved refill date. Specifically, PBM personnel stated contact center personnel incorrectly entered override codes, which created an administrative prior authorization that bypassed the controls for checking ingredients against the exclusion list. Table 2 illustrates the ingredients paid for one of the claims, demonstrating that the PBM overpaid the pharmacy by $54,567.37 for two excluded ingredients on the claim.

Table 2. Prior Authorization Claim Where PBM Paid for Two Excluded Ingredients

Ingredient Name	Ingredient on Exclusion List	Amount Correctly Paid	Amount Incorrectly Paid
Ketotifen Fumarate Powder	Yes	$0.00	
Versabasea Cream	Yes	0.00	
Nifedipine Powder	Yes	0.00	
Tranilast Powder	Yes	0.00	
Pentoxifylline Powder	Yes	0.00	
Tretinoin Powder	Yes	0.00	
Salicylic Acid Powder	Yes	0.00	
Fluticasone Propionate Powder	Yes		$32,370.48
Hyaluronic Acid Sodium Salt Powder	Yes		22,196.89
Propylene Glycol Liquid	No	20.46	

In total, the PBM overpaid $88,279.73 for the four claims. PBM personnel acknowledged the problem and stated they corrected it within the first two weeks of implementing the new controls. PBM personnel stated they took action to correct the problem by implementing new standard operating procedures for PBM contact center personnel to discontinue issuing administrative prior authorization overrides for prescriptions filled early.

However, the PBM incorrectly processed and paid for an excluded ingredient on one claim after they implemented the corrective action. PBM personnel stated they incorrectly paid for the excluded ingredient because PBM personnel did not follow the new standard operating procedures they developed as a corrective action. DHA should require the PBM to ensure its personnel are properly trained in the standard operating procedures for compound drug claims requested to be filled before the approved refill date.

Prior Authorizations for Individual Drugs Applied to Compound Prescriptions

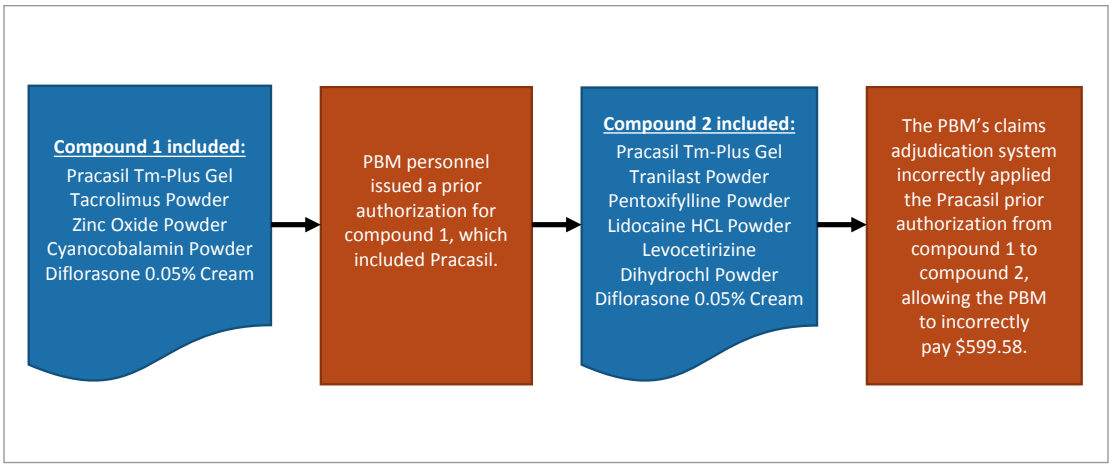
The PBM also paid for excluded ingredients in two compound drug claims where PBM personnel issued prior authorizations for the patient to receive a drug, but did not issue a prior authorization for the drug to be used as an ingredient in a compound. For example, two claims had clinical prior authorizations issued in 2012 to allow a beneficiary to have a brand-name drug for their prescription instead of the generic version, according to the PBM. Then in 2015, the beneficiary submitted a claim for a compound prescription that included the previously authorized drug. The ingredient was on the PBM's exclusion list when used in a compound, and therefore the PBM's claims adjudication system should not have processed and paid for the ingredient. However, according to the PBM, the PBM's claims adjudication system allowed compound drug claims with any clinical prior authorizations to bypass the controls for checking ingredients against the exclusion list. This occurred because the system did not previously recognize whether a prior authorization was for a compound prescription or a single ingredient. As a result, the PBM incorrectly paid a total of $3,718.94 for the excluded ingredients in both compound drug claims.

PBM personnel stated they implemented a system change that required PBM personnel to input whether the prior authorization was for a compound prescription or a single ingredient. The change would prevent the system from paying for individual ingredients filled in a compound prescription. However, PBM personnel did not provide any system-testing documentation to support the corrective action. DHA should verify that controls are effective to ensure that prior authorizations issued for single ingredients do not automatically authorize compounds with those ingredients.

Prior Authorizations for Compound Ingredients Applied to New Compounds Without Clinical Review

The PBM paid for an excluded ingredient in one compound drug claim where the PBM did not perform a clinical review of the new compound. Specifically, the PBM's claims adjudication system applied a prior authorization issued for a specific compound ingredient to the same ingredient in another compound without PBM personnel clinically reviewing the new compound. Figure 3 illustrates the process of PBM personnel issuing a prior authorization for one compound and the PBM's claims adjudication system incorrectly applying the compound's prior authorization to a different, non-approved compound.

Figure 3. Prior Authorization for Compound 1 Applied to Compound 2



As illustrated above, PBM personnel issued a prior authorization for the excluded ingredient Pracasil in compound 1. However, when the beneficiary submitted a claim for a different compound, compound 2 (which also included Pracasil), the PBM's claims adjudication system automatically paid for the excluded ingredient because Pracasil was previously authorized for that beneficiary in compound 1. When issuing a clinical prior authorization for a compound, PBM personnel conduct a review on the entire compound and then document the prior authorization on each ingredient in the compound when approved. Because PBM personnel documented the prior authorization on the ingredient level versus the compound, the ingredients can be paid for in other compound prescriptions even though a clinical review was not performed and a prior authorization was not approved for the other compounds. This occurred because the PBM's claims adjudication system

This occurred because the PBM's claims adjudication system could not differentiate between prior authorizations for one compound prescription versus another when the compounds contained at least one of the same approved ingredients.

could not differentiate between prior authorizations for one compound prescription versus another when the compounds contained at least one of the same approved ingredients. As a result, the PBM incorrectly paid $599.58 for the excluded ingredient in the claim.

PBM personnel stated they do not have a mechanism to track prior authorizations by specific prescriptions or compounds because pharmacists can change prescription numbers each time they refill the prescription, which would make it difficult to track. DHA should require the PBM to perform a clinical prior authorization review for all new compound drug prescriptions submitted with excluded ingredients.

Medicare Compound Claims Bypassed the Exclusion List

The PBM incorrectly paid 33 claims with excluded ingredients for Medicare compound drug claims. This occurred because claims covered by Medicare automatically bypassed the PBM's controls for checking ingredients against the exclusion list when a pharmacist entered the override code to accept payment for covered ingredients only. DHA guidance[7] states that TRICARE's cost-sharing of medications through a Medicare part D prescription drug plan is subject to the double coverage provisions found in Federal guidance. Federal guidance[8] states if a TRICARE beneficiary also has Medicare coverage, Medicare is the primary insurer for pharmacy claims, and TRICARE becomes the secondary payer. The guidance also states that the total amount payable for care may not exceed the total amount that would be paid if payment for that care were made solely under TRICARE. Finally, the DHA guidance states that TRICARE will make no payment for services and supplies that are not a benefit under TRICARE, regardless of any action Medicare may take on the claim.

This occurred because claims covered by Medicare automatically bypassed the PBM's controls for checking ingredients against the exclusion list...

[7] TRICARE Reimbursement Manual 6010.58-M, February 1, 2008, chapter 4, section 4, "Specific Double Coverage Actions."

[8] 32 Code of Federal Regulations, section 199.8 (2015), "Double Coverage."

The PBM's claims adjudication system processed Medicare claims differently, depending on what ingredients Medicare approved on the claim. When the beneficiary submitted a compound prescription to TRICARE and Medicare covered the primary ingredient,[9] Medicare covered the costs subject to the beneficiary meeting their Medicare deductible. If the beneficiary met their Medicare deductible, Medicare paid some or all of the compound drug costs and TRICARE paid any remaining balance without screening the ingredients against the exclusion list. If the beneficiary did not meet their Medicare deductible, Medicare paid nothing and TRICARE covered the amount the beneficiary was responsible for, again without screening the ingredients against the exclusion list. Table 3 illustrates where the PBM paid for six excluded ingredients in a Medicare claim.

Table 3. Medicare Claim Where the PBM Paid for Six Excluded Ingredients

Ingredient Name	Covered by Medicare	Ingredient on Exclusion List	Pharmacy-Submitted Costs	Medicare-Approved Costs
Lidocaine Powder	No	Yes	$13.50	
Tranilast Powder 100%	No	Yes	6.09	
Pentoxifylline Powder	No	Yes	12.60	
Diflorasone 0.05% Ointment	Yes	No	2,788.71	
Levocetirizine Dihydrochl Powder	No	Yes	466.83	
Tranilast Powder 100%	No	Yes	24.07	
Salt Durable Cream Base	No	Yes	348.00	
Total			**$3,659.80**	**$3,207.54***

* The Medicare coordination-of-benefits form only provides an overall total approved amount for the claim and does not break down the approved cost of each ingredients.

Medicare covered the primary ingredient, Diflorasone 0.05% Ointment, and valued the claim at $3,207.54. Although Medicare approved the claim, it paid nothing, leaving the $3,207.54 as the patient's responsibility. Accordingly, TRICARE as the secondary payer paid the remaining balance. However, the PBM should have screened the compound ingredients against the exclusion list and only paid for TRICARE-approved ingredients. We were unable to determine the amount DHA overpaid for 22 of the 33 Medicare claims because Medicare does not identify the approved cost of each individual ingredient in the claim.

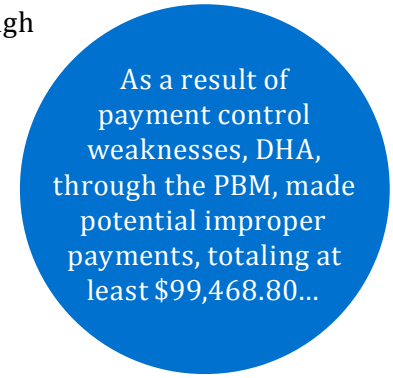
[9] According to GAO, a primary ingredient is the most expensive ingredient in a compound.

In addition, for 11 of the 33 compound claims, the PBM paid more than it would have if the PBM had processed the claim with TRICARE as the primary insurer. As valued by Medicare, the PBM paid $20,544.79 for 11 claims. However, if TRICARE was the primary payer, TRICARE would have valued the claims at $13,674.24, meaning TRICARE overpaid the 11 claims by $6,870.55. For example, on one claim, two of the four ingredients were on the exclusion list. Medicare valued the claim at $3,536.06, and paid nothing on the claim. As a result, the PBM paid the remaining $3,536.06 under TRICARE. However, had the claim been processed through the PBM's claims adjudication system, and had TRICARE only paid for the TRICARE-approved ingredients, the claim would have been valued at $2,503.13.[10] Therefore, the PBM overpaid the claim by $1,032.93.

PBM personnel acknowledged the system weakness and stated the errors resulted from a coding defect in the claims adjudication system that allowed the Medicare claims to automatically bypass the controls for checking ingredients against the exclusion list. DHA should require the PBM to screen all Medicare compound claims through the controls for excluded ingredients.

Defense Health Agency Made Potential Improper Payments As a Result of Control Weaknesses

As a result of payment control weaknesses, DHA, through the PBM, made potential improper payments, totaling at least $99,468.80, for excluded compound drug ingredients for 40 of 47 claims, and DoD expended funds that could have been used to fund other health care requirements. Table 4 illustrates the number and amount of potential improper payments by cause.



[10] Value was calculated based on zero dollar payment for the two excluded ingredients and the TRICARE discounted rate for the two covered ingredients.

Table 4. Potential Improper Payments

Cause of Potential Improper Payments	Number of Claims	Potential Improper Payment
Prescriptions filled early	4	$88,279.73
Prescriptions with ingredients approved individually, but not for use in compounds	2	3,718.94
Prescriptions with ingredients approved for a compound, but not for the compound included in the claim	1	599.58
Claims bypassed the exclusion list when Medicare covered ingredients	33*	6,870.55
Total	**40**	**$99,468.80**

* We were unable to determine the amount DHA overpaid for 22 of the 33 Medicare claims because Medicare does not identify the cost of each individual ingredient in the claim.

Additional potential improper payments may also exist in claims with prior authorizations and claims with Medicare coverage that we did not review.

Additional potential improper payments may also exist in claims with prior authorizations and claims with Medicare coverage that we did not review.

Federal guidance[11] defines an improper payment as any payment that should not have been made or that was made in an incorrect amount under statutory, contractual, administrative, or other legally applicable requirements. The guidance further defines incorrect amounts as overpayments or underpayments that are made to eligible recipients. DHA should review and pursue appropriate action on the claims in our sample where we identified potential improper payments. DHA should also conduct a review of all paid compound drug claims with prior authorizations, and paid claims with Medicare coverage, and initiate action to collect improper payments if necessary.

Conclusion

In early FY 2013, the costs TRICARE incurred for compound drugs began to rise significantly. In April 2013, DHA leadership initially determined that it would not reimburse for some ingredients in compound drugs. However, according to DHA personnel, after receiving feedback from beneficiaries, Congress, and compound pharmacists, the Assistant Secretary of Defense (Health Affairs) directed DHA personnel to review policy and delay implementation of excluding some ingredients from payment. Additionally, in December 2013, DHA delayed the drug screening process until the FDA reviewed and published an approved list of bulk drug

[11] Financial Management Regulation volume 4, chapter 14: "Improper Payments."

ingredients. DHA continued to review their policy and work with advisory committees on how to handle compound drugs. However, as of March 2015, the FDA still had not published a list of approved compound ingredients. DHA controls, implemented in May 2015, to screen compound ingredients significantly reduced the cost of compound prescriptions. However, after DHA implemented the new controls, the PBM still paid for non-covered ingredients in some claims because their claims adjudication system inappropriately allowed some compound claims with prior authorizations and Medicare coordination of benefits to bypass a list of non-covered ingredients. As a result, DHA, through the PBM, made potential improper payments for excluded compound drug ingredients, and DoD expended funds that could have been used to fund other health care requirements.

Recommendations, Management Comments, and Our Response

Recommendation 1

We recommend that the Director, Defense Health Agency, require the Pharmacy Benefit Manager to ensure its personnel are properly trained in the standard operating procedures for compound drug claims requested to be filled before the approved refill date.

Director, Defense Health Agency Comments

The Director, DHA, agreed, stating ESI updated the policy and trained personnel in proper application of standard operating procedures regarding compound claims. The Director also stated information on the corrective action was previously provided to the DoD audit team.

Our Response

Comments from the Director, DHA, partially addressed the specifics of the recommendation. Although DHA stated the contractor developed standard operating procedures and trained personnel, we identified a claim, as discussed in the report, where the PBM incorrectly processed and paid for an excluded ingredient after ESI implemented the standard operating procedures. During our review, PBM personnel stated they incorrectly paid for the excluded ingredient because PBM personnel did not follow the new standard operating procedures they developed as a corrective action. Therefore, we request the Director, DHA, provide additional comments on how the PBM will ensure its personnel are properly trained on the new standard operating procedures for compound drug claims requested to be filled before the approved refill date.

Recommendation 2

We recommend that the Director, Defense Health Agency, verify that controls are effective to ensure that prior authorizations issued for single ingredients do not automatically authorize compounds with those ingredients.

Director, Defense Health Agency Comments

The Director, DHA, agreed, stating ESI made a system change in October of 2015 that no longer allows approved prior authorizations to apply to both single-ingredient claims and compound claims.

Our Response

Comments from the Director, DHA, addressed the specifics of the recommendation and no further comments are required.

Recommendation 3

We recommend that the Director, Defense Health Agency, require the Pharmacy Benefit Manager to perform a clinical prior authorization review for all new compound drug prescriptions submitted with excluded ingredients.

Director, Defense Health Agency Comments

The Director, DHA, agreed, stating for 1 of the 40 compounds reviewed, the PBM's claims adjudication system did not differentiate between the prior authorization for one compound versus the prior authorization for another. She further stated ESI implemented a system change in October 2015, identifying between prior authorizations applied to single-ingredient drug claims and compound claims.

Our Response

Comments from the Director, DHA, did not address the specifics of the recommendation. The corrective action the Director discussed in her response addressed no longer allowing approved prior authorizations to apply to both single-ingredient claims and compound claims. However, the PBM's claim adjudication system cannot differentiate between authorizing the same drug used in different compounds. Therefore, we ask the Director, DHA, to provide additional comments on how she will ensure that PBM personnel clinically review and issue a prior authorization for each compound with excluded ingredients.

Recommendation 4

We recommend that the Director, Defense Health Agency, require the Pharmacy Benefit Manager to ensure that they screen all compound Medicare claims through the controls for excluded ingredients.

Director, Defense Health Agency Comments

The Director, DHA, agreed, stating ESI is in the process of developing a system change to only allow reimbursement on non-excluded ingredients in a Medicare compound claims.

Our Response

Comments from the Director, DHA, addressed all the specifics of the recommendation and no further comments are required.

Recommendation 5

We recommend that the Director, Defense Health Agency, review and pursue appropriate action on the claims in our sample where we identified potential improper payments.

Director, Defense Health Agency Comments

The Director, DHA, agreed, stating the final report would be the basis for DHA's contracting officer to direct ESI to take action and initiate appropriate recoupment actions if established.

Our Response

Comments from the Director, DHA, addressed all the specifics of the recommendation and no further comments are required.

Recommendation 6

We recommend that the Director, Defense Health Agency, conduct a review of all paid compound drug claims with prior authorizations, and paid claims with Medicare coverage, and initiate action to collect improper payments if necessary.

Director, Defense Health Agency Comments

The Director, DHA, agreed, stating the final report would be the basis for DHA's contracting officer to direct ESI to take action and initiate appropriate recoupment actions if established.

Our Response

Comments from the Director, DHA, addressed all the specifics of the recommendation and no further comments are required.

Management Comments on Potential Monetary Benefits

Management Comments Required

The Director, DHA, did not respond to the potential monetary benefits in the report. We request the Director, DHA, provide comments to the final report on the potential monetary benefits.

Appendix A

Scope and Methodology

We conducted this performance audit from July 2015 through May 2016 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Review of Documentation and Interviews

To obtain information and source documentation related to the adequacy of DHA controls over payments for compound drugs, we visited or interviewed personnel from:

- Express Scripts Inc., St. Louis, Missouri;
- DHA Pharmacy Operations Division, Falls Church, Virginia;
- DHA Program Integrity, Aurora, Colorado;
- Government Accountability Office (GAO), Atlanta, Georgia; and
- FDA, Silver Spring, Maryland.

Additionally, we evaluated documentation against applicable criteria. Specifically we reviewed:

- 10 United States Code § 1074g;
- 38 United Stated Code § 8126;
- 32 Code of Federal Regulations §199;
- Financial Management Regulation, volume 4, chapter 14: "Improper Payments," June 2015;
- TRICARE Operations Manual 6010.56-M, February 1, 2008;
- TRICARE Policy Manual 6010.57-M, February 1, 2008;
- TRICARE Reimbursement Manual 6010.58-M, February 1, 2008; and
- TRICARE Systems Manual 7950.2-M, February 1, 2008.

To accomplish our objective, we evaluated the PBM's claims adjudication process, the prior authorization process, and the coordination of benefits on Medicare claims, and we reviewed a nonstatistical sample of claims.[12]

[12] We did not compare the PBM's performance with its contract requirements, nor did we evaluate the DHA's administration of the PBM contract.

Claims Adjudication Process

We reviewed the PBM's claims adjudication process, including the exclusion list. We gathered information about how pharmacies electronically submit compound drug claims, the criteria applied to the claims adjudication process, and the options available to pharmacies and providers to allow excluded ingredients to be processed and paid. We also observed the procedures the PBM used to process and pay compound claims in its claims adjudication system.

Alternatives, Appeals, and Prior Authorization Process

We obtained documents from and interviewed DHA and PBM personnel about actions TRICARE beneficiaries could take in the event of an initial compound drug claim denial. We reviewed the appeals process and documents supporting a decision to reverse a denial on grounds of medical necessity. We also reviewed how PBM personnel approved clinical and administrative prior authorizations, the impact of those classifications on the claims adjudication process, and documents supporting the prior authorization.

Medicare Coordination of Benefits

We obtained documents from and interviewed PBM personnel about how the PBM processes claims when beneficiaries had both TRICARE and Medicare benefits. We determined the significance a TRICARE/Medicare enrollee status had on the claims adjudication process, and how the TRICARE/Medicare claims were categorized.

Universe and Samples

From October 1, 2014, to April 30, 2015, the PBM paid 442,677 compound drug claims, valued at approximately $1.5 billion. We nonstatistically selected 50 claims, valued at $736,442.11, that the PBM paid from October 1, 2014, to April 30, 2015. We selected claims with different compound ingredient mixtures so we could determine if the drugs listed in the claims would be paid or rejected under the new controls implemented in May 2015. For each claim, we queried each ingredient against the newly implemented exclusion list to identify which ingredients were on the exclusion list and would no longer be paid.

From May 1, 2015, to September 30, 2015, the PBM paid 140,561 compound drug claims, valued at approximately $116 million. We also compared the ingredients in all compound claims, processed after DHA implemented controls, against the exclusion list to determine if the PBM paid any claims with excluded ingredients.

Of the 61,543 claims (valued at $16.6 million) with excluded ingredients, we nonstatistically selected 14 claims with prior authorizations (valued at $119,304.86), and 33 Medicare claims (valued at $26,756.57) for review. For each of the claims, we determined why the PBM paid the ingredient and requested documentation supporting the payment.

Use of Computer-Processed Data

We used computer-processed data provided by the PBM from their claims adjudication system to perform this audit. Specifically, we used paid compound claims data obtained from the PBM for FY 2015. To determine the reliability of the processing of the paid claims, we compared the ingredients in all compound claims, processed after DHA implemented controls to the PBM's excluded ingredients list, and determined if the PBM paid any claims with excluded ingredients. We used a data-matching analysis to test a nonstatistical sample of claims with excluded ingredients to source documentation supporting the payment, such as prior authorizations, clinical review documentation, and Medicare payment detail. Based on the validation steps performed, we determined that the data were sufficiently reliable to support the audit findings.

Prior Coverage

During the last 5 years, the GAO issued three reports discussing Compound Drugs. Unrestricted GAO reports can be accessed at http://www.gao.gov.

GAO

GAO-15-85, "Payment Practices Vary Across Public Programs and Private Insurers, and Medicare Part B Policy Should Be Clarified," October 2014

GAO-15-64, "TRICARE's Payment Practices Should Be More Consistent With Regulations," October 2014

GAO-13-702, "Clear Authority and More Reliable Data Needed to Strengthen FDA Oversight," July 2013

Appendix B

Summary of Potential Monetary Benefits

Recommendation	Type of Benefit*	Amount of Benefit	Account
1	Internal Controls. This prepayment control will help prevent DHA from paying compound drug claims with incorrectly issued prior authorizations for compounds refilled early.	Undeterminable. Amount is subject to future years of compound drug claims that were not paid because of incorrectly issued prior authorizations.	97X0130
2	Internal Controls. This prepayment control will help prevent DHA from paying compound drug claims with prior authorizations incorrectly coded as a single ingredient versus a compound ingredient.	Undeterminable. Amount is subject to future years of compound drug claims that were not paid because of prior authorizations being incorrectly coded as a single ingredient.	97X0130
3	Internal Controls. This prepayment control will help prevent DHA from paying compound drug claims without a clinical prior authorization.	Undeterminable. Amount is subject to future years of compound drug claims that were not paid because of not having a clinical prior authorization performed on the compound.	97X0130
4	Internal Controls. This prepayment control will help prevent DHA from paying Medicare compound drug claims with excluded ingredients.	Undeterminable. Amount is subject to future years of compound drug claims that were not paid because they were not screened for excluded ingredients.	97X0130
5	Internal Controls. This post payment control will identify improper payments for compound claims in our audit sample.	Funds put to better use of at least $99,468.80 for FY 2015 compound drug claims reviewed in our sample.	97X0130
6	This post payment control will identify improper payments for compound drug claims with prior authorizations and compound drug claims with Medicare coverage.	Undeterminable. Amount is subject to the results of DHA or its contractor's review of compound drug claims paid.	97X0130

* Potential monetary benefits are funds put to better use or questioned costs.

Management Comments

Defense Health Agency Comments

DEFENSE HEALTH AGENCY
7700 ARLINGTON BOULEVARD, SUITE 5101
FALLS CHURCH, VIRGINIA 22042-5101

JUN 21 2016

[redacted]
Contract Management and Payment
4800 Mark Center Drive
Alexandria, Virginia 22350-1500

Dear [redacted]

I am in receipt of the Department of Defense (DoD) Inspector General (IG) Draft Report, Project No. D2015-D000CJ-0219.000, "Controls Over Compound Drugs at the Defense Health Agency Reduced Costs Substantially, but Improvements Are Needed." Thank you for the opportunity to review and comment on the draft report.

Overall, I concur with the audit's findings and conclusion. My specific response to the DoD IG recommendations are enclosed, including recommendations for closing three areas.

My points of contact on this matter are [redacted]

Sincerely,

FOR
R. C. BONO
VADM, MC, USN
Director

Enclosure:
As stated

Defense Health Agency Comments (cont'd)

DEPARTMENT OF DEFENSE INSPECTOR GENERAL DRAFT REPORT ON PROJECT NO. D2015-D000C1-0219.000 "CONTROLS OVER COMPOUND DRUGS AT THE DEFENSE HEALTH AGENCY REDUCED COSTS SUBSTANTIALLY, BUT IMPROVEMENTS ARE NEEDED"

RESPONSE TO RECOMMENDATIONS

Recommendation 1.: Require the Pharmacy Benefit Manager to ensure its personnel are properly trained in the standard operating procedures for compound claims requested to be filled before the approved refill date.

DOD Response: We concur with the recommendation. ESI updated the policy and trained personnel in proper application of standard operating procedures regarding compound claims. This information was previously provided to the DoD-IG. Recommend closure.

Recommendation 2.: Verify that controls are effective to ensure that prior authorizations issued for single ingredients do not automatically authorize compounds with those ingredients.

DOD Response: We concur. ESI made a system change in October of 2015 to correct this issue. The system change implemented no longer allows approved PAs to apply to both single ingredient claims and compound claims. Recommend closure.

Recommendation 3.: Require the Pharmacy Benefit Manager to perform a clinical prior authorization review for all new compound drug prescriptions submitted with excluded ingredients.

DOD Response: We concur with recommendation. For 1 of the 40 compounds reviewed by the DOD IG the PBM claims adjudication system did indeed not differentiate between the PA for one compound vs. the PA for another. A system change implemented in October 2015, created separation between PAs applied to single ingredients/drug claims and compound claims, therefore, this issue has been resolved. Recommend closure.

Recommendation 4: Require the Pharmacy Benefit Manager to ensure that they screen all compound Medicare claims through the controls for excluded ingredients.

DOD Response: DHA has addressed this issue with ESI who is in the process of developing a system change to only allow reimbursement on non-excluded ingredients in a Medicare OHI compound claim.

Recommendation 5.: Review and pursue appropriate action on the claims in our sample where we identified potential improper payments.

1

Defense Health Agency Comments (cont'd)

DOD Response: We concur with recommendation. The Final DoD IG report would be the basis for the contracting officer's direction to ESI to take action. If a basis for recoupment is established DHA will work with ESI to initiate appropriate actions.

Recommendation 6.: Conduct a review of all paid compound drug claims with prior authorizations, and paid claims with Medicare coverage and initiate action to collect improper payments if necessary.

DOD Response: We concur with recommendation. The Final DoD IG report would be the basis for the contracting officer's direction to ESI to take action. If a basis for recoupment is established DHA will work with ESI to initiate appropriate actions.

Acronyms and Abbreviations

DHA Defense Health Agency
FDA U.S. Food and Drug Administration
GAO Government Accountability Office
PBM Pharmacy Benefit Manager

Whistleblower Protection
U.S. Department of Defense

The Whistleblower Protection Enhancement Act of 2012 requires the Inspector General to designate a Whistleblower Protection Ombudsman to educate agency employees about prohibitions on retaliation, and rights and remedies against retaliation for protected disclosures. The designated ombudsman is the DoD Hotline Director. For more information on your rights and remedies against retaliation, visit www.dodig.mil/programs/whistleblower.

For more information about DoD IG reports or activities, please contact us:

Congressional Liaison
congressional@dodig.mil; 703.604.8324

Media Contact
public.affairs@dodig.mil; 703.604.8324

For Report Notifications
http://www.dodig.mil/pubs/email_update.cfm

Twitter
twitter.com/DoD_IG

DoD Hotline
dodig.mil/hotline

DEPARTMENT OF DEFENSE | INSPECTOR GENERAL

4800 Mark Center Drive
Alexandria, VA 22350-1500
www.dodig.mil
Defense Hotline 1.800.424.9098