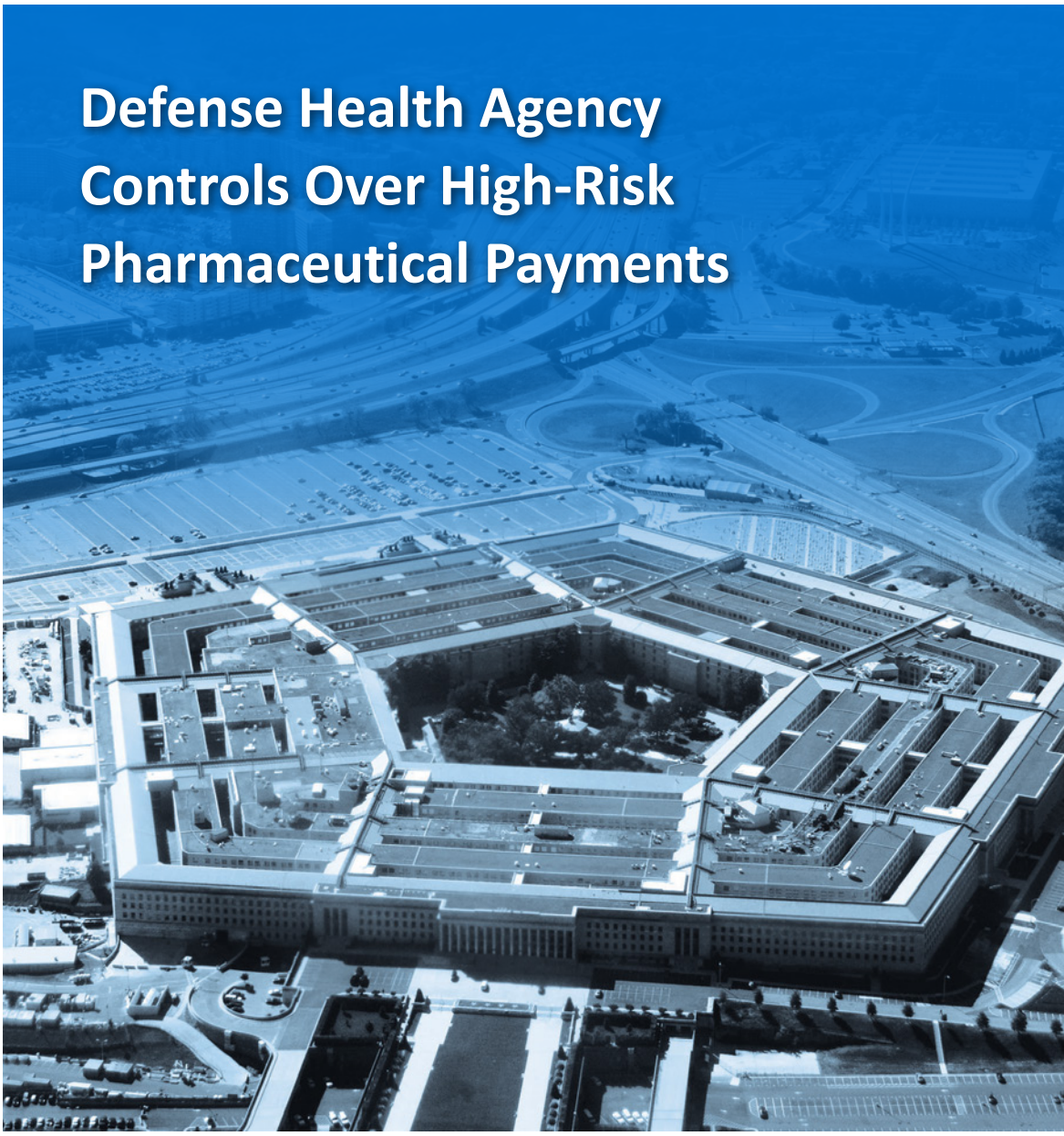
Report No. DODIG-2018-033

INSPECTOR GENERAL

U.S. Department of Defense

NOVEMBER 16, 2017

Defense Health Agency Controls Over High-Risk Pharmaceutical Payments



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Results in Brief

Defense Health Agency Controls Over High-Risk Pharmaceutical Payments

November 16, 2017

Objective

We determined whether the Defense Health Agency (DHA) developed controls to identify health care pharmaceutical payments at high risk of fraud or abuse. We focused on controls to prevent and detect potentially fraudulent or abusive claims for pharmaceuticals. The DHA defines "abuse" as any practice that is inconsistent with accepted practice which results in a claim, unnecessary costs, or payment for services or supplies not medically necessary and appropriate, or that fail to meet professionally recognized standards for health care providers. "Abuse" includes deception or misrepresentation by a provider in relation to a TRICARE claim. We also reviewed the process for approving and implementing new controls.

Background

The DHA is responsible for ensuring the effective implementation of the DoD Pharmacy benefit, taking into consideration beneficiary satisfaction, cost effectiveness, and evidence-based best practices. DHA personnel analyze claims data to identify rising pharmacy costs and develop controls, such as prior authorization requirements or quantity limits, to contain rising costs. Prior authorization controls require the health care provider to validate the need for a specific drug before approval of a prescription claim and quantity limit controls restrict the beneficiary to a maximum amount of a drug unless a health care provider certifies that the beneficiary requires additional quantities.

Background (cont'd)

In May 2015, in response to rapidly increasing costs for compound drugs, the DHA implemented an expedited process to place new prior authorization requirements for drugs used as compound ingredients. Compound drugs result from combining or altering two or more ingredients to create a customized medication. As a result of the new requirements, costs for compound drug claims dropped from $497 million in April 2015 to $10 million in June 2015. In addition, the DHA reported in 2016 it recovered over $106 million in civil settlements and criminal judgments due to compound drug fraud.

The prior authorization requirements for compound ingredients did not apply to individual drugs when not used in a compound. We initiated this audit to determine if DHA had adequate controls to identify individual drugs at high risk of fraud or abuse and prevent potential losses like those that occurred with compound drugs.

Finding

The DHA used data analytics, trend reports, and industry publications to identify drugs with increasing costs. The DHA also placed quantity limits and prior authorization requirements on high-risk drugs. We tested beneficiary claims for six drugs that the DHA had placed the quantity limits and prior authorization requirements. We determined that the DHA, through the Pharmacy Benefit Manager, effectively implemented the controls for the six drugs: Namzaric, Diclofenac 3% Gel, Namenda XR, Lidocaine 5% Ointment, Otrexup, and Lidocaine-Prilocaine Cream. However, while the DHA reduced the risk for fraudulent claims payments for those drugs, the DHA often took more than 6 months to implement new quantity limits or prior authorization requirements for other drugs. The DHA could further reduce the risk of paying fraudulent claims on drugs by developing an expedited process that uses the authorities provided in Federal regulations to implement new quantity limits in a timely manner to combat rapidly escalating drug costs. The DHA could implement temporary quantity limits when the DHA first identifies

Results in Brief

Defense Health Agency Controls Over High-Risk Pharmaceutical Payments

Finding (cont'd)

rapidly rising costs. Quantity limits could control rising costs in a timely manner until the Pharmacy and Therapeutics Committee develops permanent solutions. Although Federal regulations allow the DHA Director to implement new quantity limits without multiple reviews, the Director did not use this authority because she required a Pharmacy and Therapeutics Committee recommendation for new quantity limits.

Recommendation

We recommend that the Director, DHA, implement procedures allowing expedited placement of temporary quantity limits to address future instances of rapidly rising drug costs until the Pharmacy and Therapeutics Committee develops solutions that are more permanent.

Management Comments and Our Response

The Director, DHA, agreed, stating that in July 2017, the DHA implemented updated administrative authorities to allow temporary actions, including quantity limits, in advance of more permanent solutions. We confirmed that the DHA updated its processes to allow implementation of new quantity limits prior to Pharmacy and Therapeutics Committee review. Therefore, the recommendation is closed. Please see the Recommendations Table on the next page.

Recommendations Table

Management	Recommendation Unresolved	Recommendation Resolved	Recommendation Closed
Director, Defense Health Agency	None	None	1

Note: The following categories are used to describe agency management's comments to individual recommendations.

- **Unresolved** – Management has not agreed to implement the recommendation or has not proposed actions that will address the recommendation.
- **Resolved** – Management agreed to implement the recommendation or has proposed actions that will address the underlying finding that generated the recommendation.
- **Closed** – OIG verified that the agreed upon corrective actions were implemented.


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November 16, 2017

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

SUBJECT: Defense Health Agency Controls Over High-Risk Pharmaceutical Payments
(Report No. DODIG-2018-033)

We are providing this report for your information and use. We considered management comments on a draft of this report when preparing the final report. Comments from the Defense Health Agency conformed to the requirements of DoD Instruction 7650.03; therefore, we do not require additional comments. The Defense Health Agency identified drugs with rising costs and implemented new controls in response to the rising costs. The controls were effective for the six drugs we reviewed. We conducted this audit in accordance with generally accepted government auditing standards. 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

We determined whether the Defense Health Agency (DHA) developed adequate controls to identify health care pharmaceutical payments at high risk of fraud or abuse. We focused on controls established to prevent and detect fraudulent or abusive claims for pharmaceuticals. The DHA defines "abuse" as any practice that is inconsistent with accepted sound fiscal, business, or professional practice, which results in a TRICARE claim, unnecessary costs, or TRICARE payment for services or supplies that are not medically necessary and appropriate, or that fail to meet professionally recognized standards for health care providers. The term "abuse" includes deception or misrepresentation by a provider, or any person or entity acting on behalf of a provider in relation to a TRICARE claim.[1] We also reviewed the process for approving and implementing new controls to prevent payment of fraudulent and abusive claims. See Appendix A for the scope, 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 the DoD's managed health care program for active duty service members, retirees, and eligible family members and survivors. TRICARE is a combination of military hospitals and clinics and the Civilian Health and Medical Program of the Uniformed Services. The TRICARE program provides health care services to beneficiaries throughout the U.S. as well as overseas.

Pharmacy Benefits

Federal law authorizes TRICARE's pharmacy benefits program, which covers retail, mail order, and military treatment facility prescription services.[2] The DHA contracted with a pharmacy benefit manager (PBM) to provide claim processing, a network of retail pharmacies, and mail order prescription services. DHA personnel stated that the DHA goal is to provide TRICARE beneficiaries with appropriate cost-effective medications.

[1] TRICARE Operations Manual 6010.56-M, February 1, 2008.

[2] Section 1074g, title 10, United States Code (10 U.S.C. § 1074g).

DHA Pharmacy Operations

The DHA Pharmacy Operations Division is responsible for ensuring the effective implementation of the DoD Pharmacy benefit, taking into consideration beneficiary satisfaction, cost effectiveness, and evidence-based best practices. The Pharmacy Operations Division staff analyzes claims data and collaborates with the PBM to identify rising pharmacy costs.

Federal law requires that a Pharmacy and Therapeutics (P&T) Committee develop a uniform formulary—a list of brand name and generic drugs that TRICARE covers.[3] The P&T Committee develops the uniform formulary based on clinical and cost effectiveness, periodically reviewing the formulary and making recommendations to the Director, DHA, regarding the formulary as it deems necessary and appropriate. The P&T Committee's duties also include making recommendations for prior authorization requirements and quantity limits. The P&T Committee is made up of representatives from the DoD, the U.S. Coast Guard, and the Department of Veterans Affairs. Federal law requires the P&T Committee to meet at least quarterly.

The Federal law also requires that a Beneficiary Advisory Panel (BAP) review and comment on the P&T Committee recommendations for implementing or changing the uniform formulary. The BAP members represent the views of eligible covered beneficiaries, TRICARE contractors, and network providers. The BAP members meet after each P&T Committee meeting. The Director, DHA, must consider BAP recommendations on uniform formulary and prior authorization requirements before implementing P&T Committee recommendations across the Military Health System.

The TRICARE PBM implements prior authorization and quantity limit controls during claims processing. Prior authorization controls require the health care provider to validate the need for a specific drug before approval of a prescription claim. The purpose of these controls is to ensure that a drug is cost effective and appropriate for a particular medical condition. Quantity limit controls restrict the beneficiary to a maximum amount of a drug unless a health care provider certifies that the beneficiary requires additional quantities.

Controls Over Compound Drugs in the TRICARE Pharmacy Program

Compound drugs 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

[3] 10 U.S.C. § 1074g.

swallow pills. In May 2015, in response to rapidly increasing costs for compound drug claims, the DHA implemented an expedited process to place new prior authorization requirements on drugs used as compound ingredients.

In a prior report, we identified that the new controls were generally effective, with compound drug claim costs dropping from $497 million in April 2015 to $10 million in June 2015.[4] However, it took the DHA 28 months to implement the new controls due to feedback from beneficiaries, Congress, compound pharmacists, and pending action by the Food and Drug Administration. The DHA reported in 2016 it recovered over $106 million in civil settlements and criminal judgments due to compound drug fraud.

The new controls applied to compound drugs did not apply to individual drugs when not used as compound ingredients. Therefore, we initiated this audit to determine whether the DHA had controls in place to identify individual drugs at high-risk of fraud or abuse and prevent potential losses like those that occurred with compound drugs. For this audit, we tested controls for six high-risk drugs: Namenda XR, Namzaric, Diclofenac 3% Gel, Lidocaine 5% Ointment, Lidocaine-Prilocaine Cream, and Otrexup Auto-Injector. See Appendix B for a description of each drug.

Review of Internal Controls

DoD Instruction 5010.40 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.[5] The DHA controls over identification and prevention of high-risk drug claims payments were effective as they applied to the audit objective.

[4] Report No. DODIG-2016-105, Controls Over Compound Drugs at the Defense Health Agency Reduced Costs Substantially, but Improvements Are Needed, July 1, 2016.

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

Finding

The DHA Developed Controls to Identify and Prevent High-Risk Pharmaceutical Payments

DHA officials used data analytics, trend reports, and industry publications to identify increasing costs that could be indicators of potential fraud. The DHA implemented processes to identify drugs at high-risk of fraud or abuse and used the P&T Committee to develop and recommend controls such as quantity limits and prior authorization requirements. We tested claims for six high-risk drugs with quantity limits and prior authorization requirements and determined that the DHA, through the PBM, effectively implemented the controls for those six drugs. While the DHA reduced the risk for fraudulent and abusive claims payments for those drugs, it could further reduce the risk of paying fraudulent or abusive drug claims. Specifically, the DHA could develop an expedited process that uses the authorities provided in Federal regulations to implement new quantity limits in a timely manner to combat rapidly escalating drug costs. Although Federal regulations allow the Director, DHA, to implement new quantity limits without multiple reviews, the Director did not use this authority because she required a P&T Committee recommendation for new quantity limits. In addition, the DHA often took more than 6 months to implement new quantity limits or prior authorization requirements due to multiple reviews.

The DHA Identified Increasing Costs, and Developed and Implemented Controls to Limit Costs and Prevent Fraud and Abuse

The DHA used data analytics, cost and trend reports, and industry publications to identify drugs with rising costs and those at high risk of fraud or abuse. DHA personnel then developed potential options for controlling costs such as establishing quantity limits, and requiring prior authorization before dispensing the drugs. The P&T Committee reviewed and discussed the options during its quarterly meeting. The P&T Committee recommended the Director, DHA, implement the new quantity limits and prior authorization requirements. DHA personnel stated while they recognized that these controls could prevent fraud and abuse, cost control was the primary factor in P&T Committee recommendations.

In FYs 2015 and 2016, the P&T Committee recommended new prior authorization requirements for 124 drugs and new quantity limits for 60 drugs. For example, DHA personnel stated they made recommendations for new controls based on their observations that pharmacy claims for Diclofenac 3% gel and Lidocaine 5% ointment had increased, potentially due to fraud or abuse. Subsequently, in August 2015, the P&T Committee recommended a prior authorization requirement for Diclofenac 3% gel and a quantity limit on Lidocaine 5% ointment.

We statistically sampled retail and mail order claims for three drugs with new prior authorization requirements and beneficiaries who received three drugs with new quantity limits.[6] We tested 535 claim line items from the samples for which the DHA paid $257,194. The claims that we statistically reviewed represent 52,683 FY 2016 claim line items with payments totaling over $23.8 million. We found no instances where the PBM improperly bypassed the DHA prior authorization requirements and quantity limit controls for the claims we tested. For example, we reviewed 113 claims for Namenda XR, 9 claims for Namzaric and 217 claims for Lidocaine 5% ointment and determined that the DHA, through its PBM, properly processed prior authorizations and adhered to quantity limits before dispensing the drugs. See Appendix B for additional information on our sampling and testing procedures.

The DHA Could Reduce the Risk of Fraudulent or Abusive Claims by Implementing Quantity Limits More Timely

The DHA effectively used quantity limits and prior authorization requirements to reduce the risk for fraudulent or abusive claims. However, the DHA process to develop and implement new quantity limits and prior authorization controls often took more than 6 months because the new controls went through multiple reviews. The DHA could further reduce this risk by implementing temporary quantity limits when the DHA first identifies rapidly rising costs. Temporary quantity limits could regulate costs until the P&T Committee develops permanent solutions.

For example, from October 2015 through January 2016, the DHA paid $338,280 for 166 claims for Lidocaine 5% Ointment with quantities exceeding 300 grams for a 30 or fewer-day supply. After the DHA implemented the quantity limit of 300 grams per 30 days in February 2016, the paid claims dropped to 15 totaling

[6] The drugs selected for Prior Authorization testing were Namenda XR, Namzaric, and Diclofenac 3% Gel; the drugs selected for Quantity Limit testing were Lidocaine 5% Ointment, Lidocaine-Prilocaine Cream, and Otrexup Auto-Injector. See Appendix B for a description of each drug.

$5,813 for the remaining 8 months of FY 2016. The compound drug controls that the DHA, through the PBM, implemented in May 2015 demonstrated that an expedited process for implementing new controls effectively and efficiently could control rising costs. For example, DHA personnel used data analytics to identify a sudden increase in costs for a drug used in a compound, with two pharmacies billing over $224,000 in a single week. The DHA placed a prior authorization requirement on that drug in April 2016, and in May 2016, billings for that drug had decreased below $2,100 per week. However, the DHA only uses this expedited process for drugs used as compound ingredients. The DHA reported that in 2016 it recovered over $106 million due to compound pharmacy fraud. An expedited and repeatable process to contain costs for non-compound drugs could prevent future losses due to fraud or abuse.

Federal Regulations and DHA Policies Require Multiple Reviews

The DHA could develop an expedited process that uses the authorities provided in Federal regulations to implement new quantity limits in a timely manner to combat rapidly escalating drug costs.[7] The lengthy process for implementing new quantity limit and prior authorization controls occurred because proposed changes to the pharmacy program went through multiple levels of review prior to approval and implementation. The Director, DHA, reviewed P&T Committee and BAP recommendations before approving new quantity limits and prior authorization requirements. The DHA had taken more than 6 months from identifying the need for a new quantity limit or prior authorization control to review and approval by the Director, DHA. Additionally, Federal regulations permit the Director, DHA, to delay implementation of new controls for up to an additional 180 days.[8] For example, in October 2015 the Director, DHA, approved new prior authorization and quantity limit controls identified before the August 2015 P&T Committee meeting. The DHA implemented the new controls in February 2016, more than 6 months after the DHA identified the need for the new controls. DHA personnel stated that delaying implementation allowed time to notify beneficiaries and providers, reducing potential negative impact on beneficiaries affected by the change.

The DHA could implement temporary quantity limits when the DHA first identifies rapidly rising costs. Quantity limits could control rising costs in a timely manner until the P&T Committee develops permanent solutions. Although the DHA Director requires a P&T Committee recommendation for new quantity limits,

[7] Title 32 Code of Federal Regulations section 199.21 (2016) (32 CFR sec. 199.21 [2016]).

[8] 32 CFR sec. 199.21 (2016).

Federal regulations do not require a P&T Committee recommendation.[9] The Federal regulations require the Director, DHA, to establish procedures for the effective management of the pharmacy benefits program, which can include restrictions on the quantity of drugs included under the benefit. Therefore, the Director could modify the DHA review process to recommend and approve temporary quantity limits for high-risk drugs when the DHA first identifies rapidly rising costs. An expedited process for implementing temporary quantity limits could help prevent increasing costs and reduce the risk of paying potentially fraudulent and abusive claims. The DHA should implement procedures to allow expedited placement of temporary quantity limits to address future instances of rapidly rising drug costs until the P&T Committee develops solutions that are more permanent.

Therefore, the Director could modify the DHA review process to recommend and approve temporary quantity limits for high-risk drugs when the DHA first identifies rapidly rising costs.

Conclusion

The DHA developed controls to identify increasing drug claims costs and implemented quantity limits and prior authorization requirements to limit costs and reduce the potential for fraud and abuse. However, the DHA could implement new quantity limits that would further reduce the risk of paying fraudulent or abusive claims. When the DHA implemented controls over compound drugs in 2015, it demonstrated that an expedited process for placing new prior authorization requirements over high-risk drugs could effectively reduce costs. However, the DHA did not have an expedited process for implementing new controls over non-compound drugs when increasing costs indicate that new controls may be necessary.

Recommendation, Management Comments, and Our Response

Recommendation 1

The Director, Defense Health Agency, should implement procedures allowing expedited placement of temporary quantity limits to address future instances of rapidly rising drug costs until the Pharmacy and Therapeutics Committee develops solutions that are more permanent.

[9] 32 CFR sec. 199.21 (2016).

Defense Health Agency Comments

The Director, DHA, agreed with the recommendation, stating that in May 2017 the P&T Committee updated DHA administrative authorities to allow temporary actions, including quantity limits, in advance of more permanent solutions. The Director said that the DHA implemented the updates in July 2017.

Our Response

Comments from the Director addressed all specifics of the recommendation. We confirmed that in May 2017 the P&T Committee recommended updates to existing P&T processes due to increasing complexity of the TRICARE pharmacy benefit and the need for quick decisions. The updates included implementation of new quantity limits without prior P&T Committee review. The Acting Deputy Director, DHA, approved the Committee's recommendations on July 27, 2017. Therefore, the recommendation is closed.

Appendix A

Scope and Methodology

We conducted this performance audit from June 2016 through September 2017 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 accomplish our audit objective, we visited and interviewed the following officials:

- DHA Pharmacy Operations Directorate, Falls Church, Virginia, and San Antonio, Texas;
- DHA Program Integrity Office, Aurora, Colorado; and
- TRICARE PBM, St. Louis, Missouri.

We reviewed:

- 10 U.S.C. §1074g;
- 32 CFR sec. 199.21 (2016);
- TRICARE Operations Manual 6010.56-M, February 1, 2008; and
- TRICARE PBM contract.

We also reviewed the minutes from FYs 2015 and 2016 P&T Committee meetings to determine when the Committee recommended new prior authorization and quantity limit controls, to establish a list of drugs affected by the controls, and to identify criteria for claims approval for drugs with the controls.

To test whether prior authorization and quantity limit controls effectively prevented improper payments, we used FY 2015 P&T Committee meeting minutes to identify three drugs each with new prior authorization and quantity limit controls that became effective in FY 2016. We obtained FY 2016 pharmacy claims data from the Pharmacy Data Transaction Service to select a statistical sample for each drug. The claims that we statistically reviewed represent 52,683 FY 2016 claim line items with payments totaling over $23.8 million. We compared claims data to PBM documents to determine if the PBM effectively implemented the controls. See Appendix B for a detailed discussion of sampling and testing.

Use of Computer-Processed Data

We used computer-processed data obtained from the Military Health System Data Repository to test whether DHA controls effectively prevented improper claims. We used FY 2016 claims data to develop a statistical sample of TRICARE pharmacy claims to test the quantity limits and prior authorization controls. We compared data, including information that identified beneficiaries, drugs prescribed, and quantities of each drug prescribed, from Military Health System Data Repository claims subject to quantity limit or prior authorization controls to supporting documents obtained from the PBM. For the purpose of this audit, we concluded that the data obtained from the Military Health System Data Repository were reliable.

Use of Technical Assistance

The DoD OIG Quantitative Methods Division provided a statistical sample of TRICARE pharmacy claims for control testing. See Appendix B for a summary of the sampling methodology.

Prior Coverage

During the last 5 years, the Government Accountability Office (GAO) and the DoD OIG issued four reports discussing the TRICARE Pharmacy program. Unrestricted GAO reports can be accessed at http://www.gao.gov. Unrestricted DoD OIG reports can be accessed at http://www.dodig.mil/pubs/index.cfm.

GAO

GAO-15-768, "TRICARE PHARMACY PILOT, Improved Monitoring Needed with Expansion of Pilot Requirements," September 2015

> The GAO found that the DOD had not fully monitored availability nor the timeliness and accuracy of covered brand maintenance medications prescriptions filled for the TRICARE for Life Pharmacy Pilot. The GAO recommended that the DOD develop a monitoring plan as part of its expansion planning documents.

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

The GAO found that TRICARE's payments for certain compounded drugs under its pharmacy and medical benefit were inconsistent with its regulations and were typically more generous than those of Medicare and the Department of Veterans Affairs; and its payment for compounded drugs that contain bulk drug substances was inconsistent with its regulations. The GAO recommended that the DOD align TRICARE's payment practices for compound drugs with applicable regulations covering the TRICARE program.

DoD OIG

Report No. DoDIG-2016-105, "Controls Over Compound Drugs at the Defense Health Agency Reduced Cost Substantially, but Improvements Are Needed," July 1, 2016

The DoD OIG found that after the DHA implemented controls to screen compound ingredients, controls were being manually bypassed by the PBM because PBM personnel did not follow standard operating procedures and the adjudication system was inappropriate. The DHA agreed to implement recommendations.

Report No. DoDIG-2013-108, "The TRICARE Mail Order Pharmacy Program Was Cost Efficient and Adequate Dispensing Controls Were in Place," July 24, 2013

The DoD OIG found that the TRICARE Mail Order Pharmacy Program was more cost efficient than retail network pharmacies, and that adequate controls over dispensing drugs through the program were in place.

Appendix B

Summary of Sampling Methodology for Claims Data

With the assistance of the DoD OIG Quantitative Methods Division, we used a statistical sample to project whether controls that the DHA implemented in response to rising costs were effective. We nonstatistically selected three drugs for prior authorization testing and three drugs for quantity limit testing. Factors we used to determine which drugs to test included history of rapidly increasing costs, potential for fraudulent claims, and implementation date of the new controls. The DHA paid over $26.5 million for 71,069 FY 2016 retail and mail order claims for the six drugs selected for control testing. For prior authorization testing, we selected a statistical sample of claim line items for prescriptions dispensed after the implementation date of the new controls. The drugs selected for prior authorization tests included:

- Diclofenac 3% Gel—used to treat a skin problem known as actinic or solar keratosis that is caused by long-term sun exposure;
- Namzaric—used to treat the symptoms of moderate to severe Alzheimer's disease; and
- Namenda XR—used to treat dementia (memory loss) caused by Alzheimer's disease.

Because Namzaric and Namenda XR are both brand names containing the same ingredient, we combined them for selecting the sample. The implementation date for the prior authorization controls over the three drugs was February 3, 2016.

For testing quantity limits, we selected a statistical sample of beneficiaries who had claims for prescriptions dispensed after the implementation date of the new controls.[10] The drugs selected for quantity limit tests included:

- Lidocaine 5% Ointment—provides a temporary relief of pain associated with skin injuries, such as minor burns, abrasions (scrapes), and insect bites;
- Lidocaine-Prilocaine Cream—applied to the skin to reduce pain from injections and other medical procedures; and
- Otrexup Auto-Injector—an injectable medication to treat psoriasis (skin disease) and rheumatoid arthritis.

[10] For quantity limit testing, we sampled beneficiaries then tested all claims for each beneficiary who received the selected drugs to determine if quantity limit controls were effective for individual claims as well as multiple claims over time.

For each beneficiary selected, we examined all claims for the three selected drugs subject to the new quantity limit controls. The implementation date for the quantity limit controls over the three drugs was February 3, 2016. The Quantitative Methods Division provided us with a statistical sample for each of the six drugs selected for testing based on implementation date of the new control to ensure that we only tested claims that were subject to the new controls. However, we learned that implementation of controls over three of the drugs occurred later than we projected. Therefore, we removed claims from the samples for Lidocaine 5% Ointment, Lidocaine-Prilocaine Cream, and Otrexup Auto-Injector. Removing claims from the Lidocaine-Prilocaine Cream and Otrexup samples reduced the sample sizes below the number required to make a statistical projection for these drugs.

Sample Testing

For each claim line item selected for prior authorization testing, the beneficiary was required to obtain authorization from a health care provider prior to approval of the claim. The control only applied to beneficiaries with new prescriptions written after the February 3, 2016 implementation date. Beneficiaries did not require a prior authorization if they had existing prescriptions or other health insurance.[11] We determined that every claim line item in our sample that required prior authorization included the appropriate authorization. We conclude with 90-percent confidence that the error rate in the population is less than or equal to 5 percent for Namenda XR and Namzaric. We cannot project the results for Diclofenac Sodium 3% Gel due to the limited sample size. See Table 2 below for the results of prior authorization sample testing.

Table 1. Results of Prior Authorization Control Testing

Control	Drug	Claim Line Items in Sample	Prior Authorization Required	Prior Authorization Obtained
Authorization	Namenda XR*	113	18	18
	Namzaric*	9	1	1
	Diclofenac 3% Gel	21	4	4
Total		**143**	**23**	**23**

* Namenda XR and Namzaric are therapeutically equivalent and were considered within the same control test.

Source: The DoD OIG.

[11] TRICARE is the secondary payer for beneficiaries with other health insurance and pays the TRICARE portion of the claim after the other health insurance provider has approved and paid the claim.

For each beneficiary selected for quantity limit testing, we determined whether the beneficiary received quantities exceeding the limits without authorization. We tested for excess quantities both in individual and multiple claims. For example, beneficiaries are limited to 300 grams of Lidocaine 5% Ointment each 30 days; therefore, we examined each claim to determine if the control failed due to multiple claims approved within the 30-day period.[12] We found that records for each beneficiary that exceeded the quantity limits for the three drugs we tested contained appropriate authorization for the excess quantities. Because the control test for Lidocaine quantity limits passed, we conclude with 90-percent confidence that the error rate in the population is less than or equal to 5 percent. We cannot project the results for Lidocaine-Prilocaine Cream and Otrexup Auto Injector due to the limited sample size. See table 3 below for the results of quantity limit control testing.

Table 2. Results of Quantity Limit Control Testing

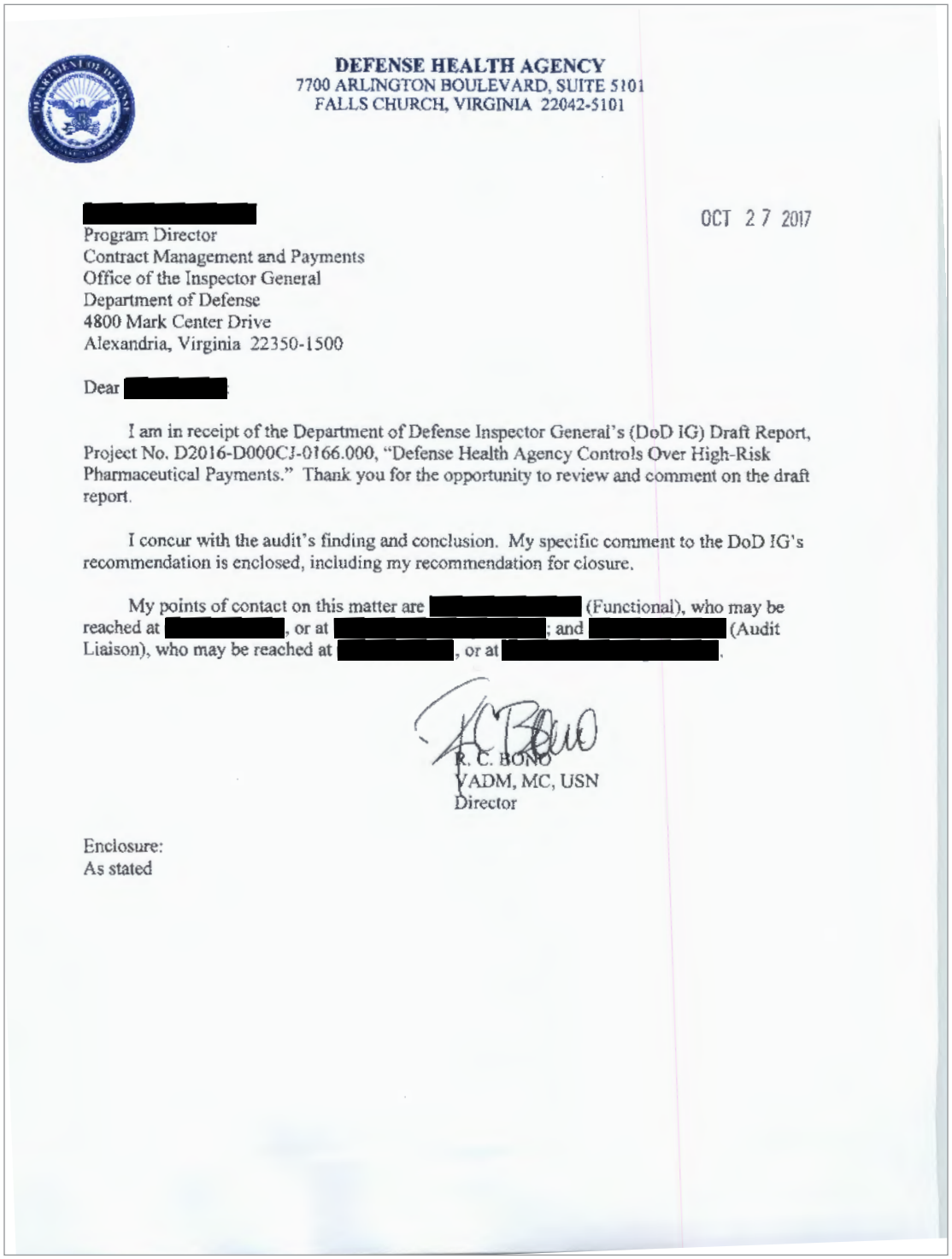
Control	Drug	Beneficiaries in Sample	Exceeded Quantity Limit	Authorized by Health Care Provider
Quantity Limit	Lidocaine 5% Ointment	138	1	1
	Lidocaine-Prilocaine Cream	42	1	1
	Otrexup	36	7	7
Total		**216**	**9**	**9**

Source: The DoD OIG.

[12] TRICARE permits prescription refills when the beneficiary has used 75 percent of the prescribed medication. We considered beneficiaries who exceeded quantity limits solely due to the refill date to be compliant with quantity limit controls.

Management Comments

Defense Health Agency



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[redacted]
Program Director
Contract Management and Payments
Office of the Inspector General
Department of Defense
4800 Mark Center Drive
Alexandria, Virginia 22350-1500

OCT 27 2017

Dear [redacted]

I am in receipt of the Department of Defense Inspector General's (DoD IG) Draft Report, Project No. D2016-D000CJ-0166.000, "Defense Health Agency Controls Over High-Risk Pharmaceutical Payments." Thank you for the opportunity to review and comment on the draft report.

I concur with the audit's finding and conclusion. My specific comment to the DoD IG's recommendation is enclosed, including my recommendation for closure.

My points of contact on this matter are [redacted] (Functional), who may be reached at [redacted], or at [redacted]; and [redacted] (Audit Liaison), who may be reached at [redacted], or at [redacted].

R. C. BONO
VADM, MC, USN
Director

Enclosure:
As stated

Defense Health Agency (cont'd)

Response to Draft Report

Report # / Project #: D2016-D000CJ-0166.000

Report Title: Defense Health Agency Controls over High-Risk Pharmaceutical Payments

Recommendation: 1 of 1

Recommendation: The Director, Defense Health Agency, should implement procedures allowing expedited placement of temporary quantity limits to address future instances of rapidly rising drug costs until the Pharmacy and Therapeutics Committee develops solutions that are more permanent.

DoD Response: Concur. The Defense Health Agency implemented the recommendation on July 27, 2017. At the May 2017 meeting of the DoD Pharmacy and Therapeutics Committee, the administrative authorities, or temporary actions that may be taken in advance of a permanent solution, were updated to include placement of quantity limits based on non-clinical factors. Recommend Closure.

Detailed information is attached with this response.

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Defense Health Agency (cont'd)

Pharmacy and Therapeutics Committee Processes and Recommendations/Approval Authorities

Issue:
The DoD Pharmacy and Therapeutics (P&T) Committee has granted certain administrative authorities to allow the Defense Health Agency Pharmacy Operations Division, Formulary Management Branch to manage the TRICARE pharmacy benefit. One such example pertains to determining quantity limits for medications.

Background:
Quantity limits are recommended for a variety of reasons, including safety issues (to comply with FDA package labeling), to ensure appropriate follow-up with the provider (e.g., narcotic antagonists), to limit quantities for costly medications requiring frequent dosage changes for adverse effects (e.g., oncology drugs), and for stockpiling and abuse purposes. Differing quantity limits may be in place for the TRICARE pharmacy dispensing points of service, including Military Treatment Facilities, TRICARE Mail Order Pharmacy, and Retail Network. Quantity limits do take into account FDA-approved dosing regimens.

At the May 10-11, 2017 DoD Pharmacy and Therapeutics Committee meeting, the administrative authorities for the Formulary Management Branch was updated. The Committee meeting minutes were subsequently signed by RADM Colin Chinn, acting Deputy Director, DHA, for RADM R.C. Bono on July 27, 2017.

The May 2017 P&T Committee meeting minutes are found at the following link: https://health.mil/About-MHS/Other-MHS-Organizations/DoD-Pharmacy-and-Therapeutics-Committee/Meeting-Minutes.

The P&T Committee administrative functions from the meeting minutes are as follows: "Management of the TRICARE pharmacy benefit requires a wide variety of actions, with various levels of involvement of the DoD P&T Committee, the Beneficiary Advisory Panel (BAP), and the Director, DHA. In May 2005 when the UF Rule was implemented, the P&T Committee developed a comprehensive list of the functions associated with formulary management and categorized each into one of three decision pathways, depending on the level of involvement required. Since May 2005, several new regulatory authorities have expanded the responsibilities of the P&T Committee, resulting in increasing complexity of the TRICARE pharmacy benefit, and the need for quick determination of issues.

The Committee reviewed an updated list of previously approved functions/actions since 2005 to manage the benefit. Operations are categorized according to the following processes: administrative functions (day-to-day maintenance not requiring DoD P&T Committee review); formulary recommendations requiring DoD P&T Committee review and approval by the Director, DHA; and formulary changes requiring DoD P&T Committee review and approval of the Committee's recommendations by the Director, DHA, after considering comments from the Beneficiary Advisory Panel (BAP). The updated list of functions is found in Appendix G."

The pertinent questions relating to the Quantity Limits are highlighted.

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Appendix G—Pharmacy and Therapeutics Committee Processes and Recommendations/Approval Authorities

Process	Function
Administrative (not part of DoD P&T Committee process; Beneficiary Advisory Panel (BAP) comments not required; Director, DHA, approval not required) Responsible parties include: TPharm4 (Mail Order Pharmacy and Retail Pharmacy Network) Contracting Officer Representative (CORs), DHA Pharmacy Program, DHA Office of General Counsel, and Pharmacy Operations Division Formulary Management Branch (FMB) staff	▪ Identification of new FDA-approved medications, formulations, strengths, package sizes, fixed-dose combinations, etc. ▪ If situation unclear, determination as to whether a new FDA-approved medication is covered by TRICARE. ▪ If situation unclear, determination as to whether a new FDA-approved medication is part of the pharmacy benefit (e.g., IV infusions). ▪ If situation unclear, determination as to whether a new FDA-approved medication is suitable for dispensing through the Mail Order Pharmacy (e.g., Accutane with proof of negative pregnancy testing requirements). ▪ Calculating and implementing quantity limits (QLs). The QLs will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making changes to QLs as needed based on non-clinical factors such as changes to packaging (e.g., medication previously available in boxes of 5 now only available packaged in boxes of 8). ▪ Establishing adjudication edit limitations (Pharmacy Data Transaction Service [PDTS]), which are set well above the clinical maximum and are intended to prevent entry errors (e.g., entering a quantity of 17 for a 17-gram inhaler for which the actual unit of measure is 1 inhaler) or are intended to limit diversion. ▪ Implementing prior authorization (PA) requirements if already established through the DoD P&T Committee process for a given medication or class of medications. The PA criteria will be reviewed by the DoD P&T Committee at the next meeting. ▪ Implementing step therapy (automated PA criteria) for a new entrant to a medication class if already established through the DoD P&T Committee process. The entrant will be designated as "non step preferred" (i.e., behind the step). The step therapy criteria for the new entrant will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making minor changes to PA forms or Medical Necessity (MN) forms NOT involving changes to underlying criteria, such as correcting contact information or rewording clinical questions. ▪ Making changes to PA criteria, MN criteria, QLs and any associated documents to accommodate new FDA-approved indications or to respond to changes in FDA-recommended safety limitations (changes will be reviewed by DoD P&T Committee at next meeting). ▪ Applying general MN criteria to drugs newly approved by the FDA after August 26, 2015 (previously known as "innovator drugs"), as outlined in the August 2015 DoD P&T Committee meeting minutes. ▪ Designated drugs newly approved by the FDA after August 26, 2015, with no formulary alternatives to adjudicate as Uniform Formulary (Tier 2 copayment), after consultation with a DoD P&T Committee physician member or MHS specialist prior to formal vote from the DoD P&T Committee. All newly-approved drugs, including those that the Pharmacy Operations Division has determined have no formulary alternatives will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the February 2016 DoD P&T

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	Committee meeting minutes. ▪ Establishing temporary specific PA criteria or MN criteria for select drugs newly approved by the FDA after August 26 2015, to be implemented at the time of product launch, after consultation with a DoD P&T Committee physician member or MHS specialist, prior to formal vote by the DoD P&T Committee, as outlined in the February 2016 DoD P&T Committee meeting minutes. All temporary specific PA or MN criteria will be reviewed by the DoD P&T Committee at the next meeting. The temporary specific PA or MN criteria will only be active until the formal P&T Committee process is complete. Implementation of permanent criteria will become effective upon signing of the DoD P&T Committee minutes. All users who have established temporary specific PA or MN criteria will be "grandfathered" when the permanent criteria become effective, unless directed otherwise. ▪ Establishing drug class definitions for maintenance medications as part of the Expanded MTF/Mail Order Pharmacy Initiative (EMMPI). ▪ Exempting NF medications from the requirement for TRICARE Mail Order Pharmacy dispensing where Trade Agreements Act (TAA) conflicts preclude purchase for use by the Mail Order Pharmacy, for products that will be discontinued from the market, or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ Exempting medications or classes of medications previously identified for addition to the Expanded MTF/Mail Order Pharmacy Initiative from the requirement for Mail Order Pharmacy dispensing in cases where Trade Agreements Act conflicts preclude purchase for use by the Mail Order Pharmacy, for products that will be discontinued from the market, or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ After consultation with the Chair of the DoD P&T Committee, implementing "brand over generic" authorization and PA criteria for drugs with recent generic entrants where the branded product is more cost effective than the generic formulations. The branded product will continue to be dispensed, and the generic product will only be available upon prior authorization. The branded product will adjudicate at the Tier 1 copayment at the Retail Pharmacy Network and Mail Order Pharmacy. The "brand over generic" authority will be removed when it is no longer cost effective to the MHS. These actions will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the May 2016 DoD P&T Committee meeting minutes. ▪ Designating "line extension" products to retain the same formulary status and any applicable PA/step therapy or MN criteria as the "parent" drug. Line extensions will be reviewed by the DoD P&T Committee at the next meeting. Line extensions are defined as having the same FDA-approved indication as the parent drug, and must be from the same manufacturer. Line extensions may also include products where there are changes in the release properties of parent drug; for example, an immediate release preparation subsequently FDA-approved as a sustained release or extended release formulation, available from the same manufacturer as the parent drug. The line extension definition is outlined in the May 2014 and November 2016 DoD P&T Committee meeting minutes. ▪ Removing medications withdrawn from the U.S. market from Basic Core Formulary (BCF) or Extended Core Formulary (ECF) listings and other documents.

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	▪ Providing clarifications to existing BCF/ECF listings in the event of market entrant of new dosage strengths, new formulations, new delivery devices (e.g., Handi-Haler vs. Respimat inhaler) or manufacturer removal/replacement of products (e.g., mesalamine Asacol changed to Delzicol). BCF clarifications of this type will be reviewed by the DoD P&T Committee at the next meeting. ▪ Providing clarifications to existing listings on the BCF or ECF to designate specific brands/manufacturers when a national contract (e.g., joint DoD/VA, Defense Logistics Agency) is awarded for a given product. ▪ Other functions as necessary to accomplish the functions listed above; for example, making changes to PDTS coding forTPharm4, communicating status of medications as part of the pharmacy or medical benefit to Managed Care Support Contractors (MCSCs), and making changes to the DHA www.health.mil website. ▪ Adding or removing products from the Specialty Agent Reporting List that have previously been designated by the DoD P&T Committee. The Specialty Agent Reporting List is maintained for purposes of monitoring specialty drug utilization trends and spends, and is based on the definition of a specialty drug previously agreed upon by the DoD P&T Committee at the August 2014 meeting.
Approval by Director, DHA, required based on DoD P&T Committee recommendations and BAP comments	▪ Classification of a medication as nonformulary on the Uniform Formulary (UF), and implementation plan (including effective date). ▪ Establishment of PA requirements for a medication or class of medications, a summary/outline of PA criteria, and implementation plan (including effective date). ▪ Changes to existing PA criteria (e.g., due to the availability of new efficacy or safety data). ▪ Discontinuation of PA requirements for a drug. ▪ Clarification of a medication as nonformulary due to NDAA Section 703 regulations, and implementation plan (effective date). ▪ Establishing pre-authorization criteria for drugs recommended as nonformulary due to NDAA Section 703 regulations. ▪ Addition or deletion of over-the-counter (OTC) drugs to the UF, and designating products recommended for a copayment waiver. ▪ Removal of copayments or reducing copayments for an individual drug (e.g., branded product available at the Tier 1 copayment). ▪ Designating individual generic drugs as nonformulary (Tier 3 copayment).

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Approval by Director, DHA, required based on DoD P&T Committee recommendations (not required to be submitted to BAP for comments)	▪ Establishment of QLs for a medication or class of medications, deletion of existing QLs, or changing existing quantity limits based on clinical factors (e.g., new clinical data or dosing regimens). ▪ Establishment and changes of MN criteria for nonformulary drugs. ▪ Addition or deletion of medications listed on the BCF or ECF. ▪ Addition or deletion of drugs or drug classes on the Expanded MFT/Mail Order Pharmacy Initiative Program. ▪ For OTC products added or deleted from the UF, adding or removing the requirement for a prescription waiver. ▪ Including or excluding drugs or drug classes from the Mail Order Pharmacy auto-refill program. ▪ Exempting NF medications from the requirement for dispensing from the Mail Order Pharmacy (e.g., schedule II drugs, antipsychotics, oncology drugs, or drugs not suitable for dispensing from the Mail Order). ▪ Addition or deletion of drugs or drug classes from the Clinical Services Drug List, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies.

Acronyms and Abbreviations

BAP	Beneficiary Advisory Panel
DHA	Defense Health Agency
P&T	Pharmacy and Therapeutics
PBM	Pharmacy Benefit Manager

Whistleblower Protection
U.S. Department of Defense

The Whistleblower Protection Ombudsman's role is to educate agency employees about prohibitions on retaliation and employees' rights and remedies available for reprisal. The DoD Hotline Director is the designated ombudsman. For more information, please visit the Whistleblower webpage at www.dodig.mil/programs/whistleblower.

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