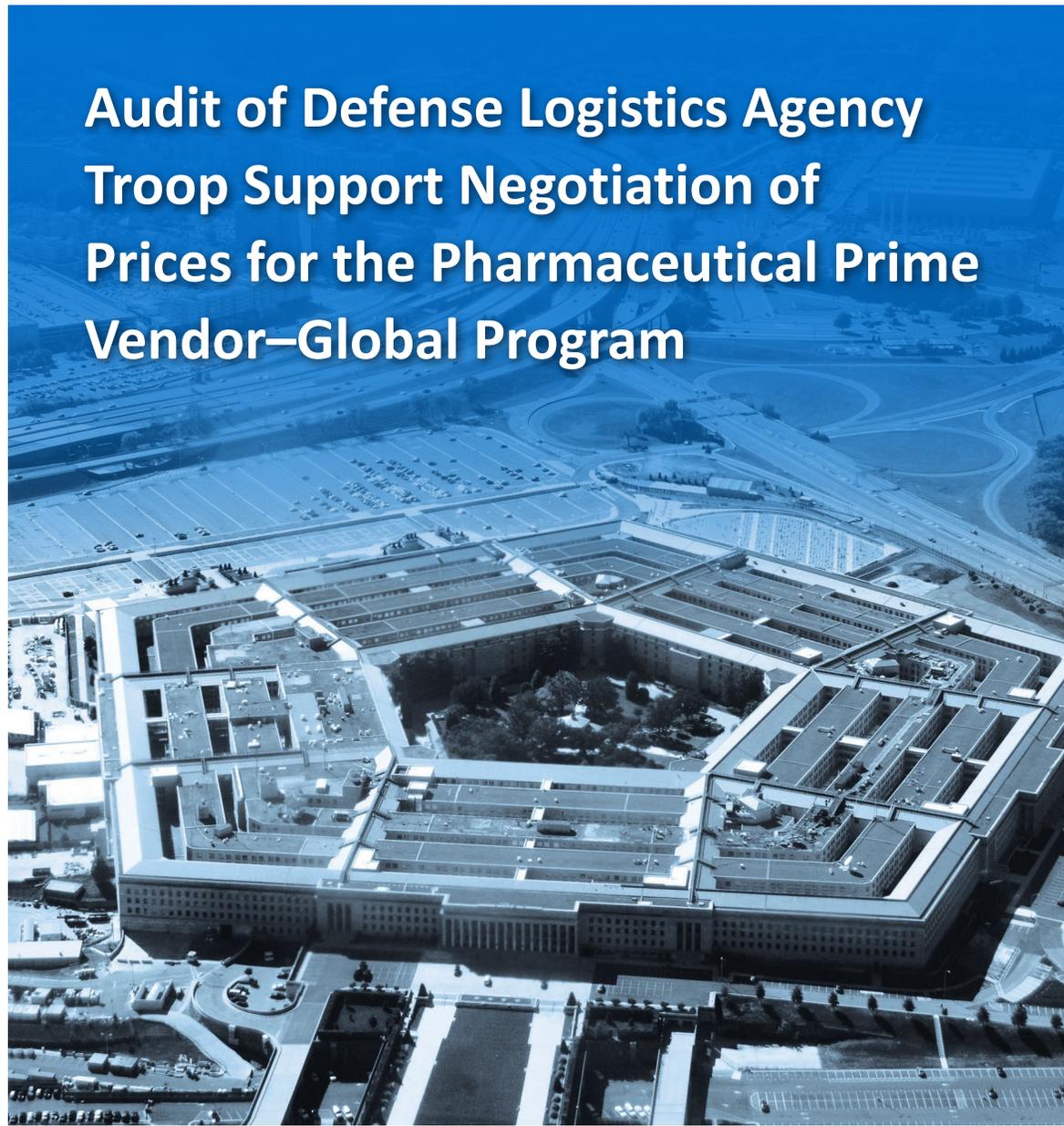




INSPECTOR GENERAL

U.S. Department of Defense

AUGUST 9, 2019



Audit of Defense Logistics Agency Troop Support Negotiation of Prices for the Pharmaceutical Prime Vendor–Global Program

INTEGRITY ★ INDEPENDENCE ★ EXCELLENCE





Results in Brief

Audit of Defense Logistics Agency Troop Support Negotiation of Prices for the Pharmaceutical Prime Vendor–Global Program

August 9, 2019

Objective

We determined whether the Defense Logistics Agency (DLA) Troop Support could improve its negotiations of pharmaceutical prices.

Background

The DLA Troop Support Pharmaceutical Prime Vendor–Global program provides the global distribution of pharmaceuticals and related products directly to customers in the DoD and other Government agencies. The prime vendor provides the pharmaceuticals directly to the customer, eliminating the need for DLA Troop Support to manage large inventories of perishable pharmaceuticals.

The Defense Health Agency (DHA) supports the delivery of health care to 9.4 million uniformed service members and their families. The DHA maintained the Military Health System Data Repository of pharmaceutical insurance claim data including the pharmaceutical's National Drug Code, which is a unique 11-digit number used to identify the pharmaceutical. The Military Health System Data Repository includes the amounts paid to retail pharmacies and quantities dispensed from both the DoD health care facilities and non-DoD sources, such as retail pharmacies, which are not subject to the Buy American or Trade Agreements Acts. We used the DHA data to calculate the median (middle) amount paid by the DoD, patients, and other health insurers for each pharmaceutical to compare to DLA Troop Support's program prices.

Background (cont'd)

Between November 13, 2014, and May 12, 2017, the DoD and other Government agencies ordered 20,675 different pharmaceutical National Drug Codes and related supplies valued at \$5.1 billion from DLA Troop Support's program. We identified 6,615 pharmaceutical National Drug Codes, with orders valued at \$329.5 million, where the program price was higher than the median amount paid by the DoD, patients, and other health insurers for each prescription filled based on the DHA's pricing data from the Military Health System Data Repository.

Finding

We determined that DLA Troop Support established prices for the Pharmaceutical Prime Vendor–Global program based on Government prices, such as the Veterans Affairs Federal Supply Schedule, or the prime vendor's pricing agreements, which allowed the prime vendor to distribute the supplier's products at an agreed-to price. DLA Troop Support officials compared the prices from the pharmaceutical prime vendor's pricing agreements to the average wholesale price, which is an industry pharmaceutical pricing benchmark. We determined that additional pricing data were available from the DHA that DLA Troop Support could have used to assist with negotiating lower prices for some pharmaceuticals.

DLA Troop Support stated that its ability to obtain the prices in DHA's pricing data was affected by the Buy American Act and Trade Agreements Act, which limits potential sources of pharmaceuticals and reduces competition. The pharmaceutical prices from DHA's pricing data were from retail pharmacies, which were not subject to the limitations of these Acts. Another limitation affecting DLA Troop Support's ability to negotiate lower prices was that it could not guarantee sales to its suppliers with distribution and pricing agreements in exchange for quantity discounts or price breaks.

Because DLA Troop Support had to comply with the Acts, DLA Troop Support may not have been able to achieve the same prices as reflected in DHA's pricing data. However,



Results in Brief

Audit of Defense Logistics Agency Troop Support Negotiation of Prices for the Pharmaceutical Prime Vendor–Global Program

Finding (cont'd)

the DLA Troop Support could have used the pricing data from DHA to assist with negotiating lower prices for some pharmaceuticals in the program. Based on our calculations, DHA's median amounts paid for the same quantity of pharmaceuticals were \$137.1 million less than DLA Troop Support's prices for the 6,615 pharmaceutical National Drug Codes.

Recommendation

We recommend that the DLA Director require the DLA Troop Support Commander to coordinate with the DHA to obtain pricing data from the Military Health System Data Repository and use the data to evaluate existing and future prices when negotiating pharmaceutical prices.

Management Comments and Our Response

Comments from the DLA Acquisition Deputy Director, responding for the DLA Director, addressed the specifics of the recommendation to coordinate with the DHA to obtain pricing data from the Military Health System

Data Repository and to use the data to evaluate prices when negotiating pharmaceutical prices. The recommendation is resolved but will remain open until we verify that the DLA and DHA have signed a memorandum of agreement to officially establish their coordination.

Additionally, the Deputy Director stated that the DLA could not concur with the DoD OIG assertion that the Agency could achieve potential savings of \$137 million by adopting the recommendation. We revised the report to clarify that we were not asserting the DLA could achieve potential savings of \$137.1 million. The \$137.1 million cited in the report is the difference between DLA Troop Support's prices and DHA's median amounts paid. The intent of the report was to highlight another source of pricing data that DLA Troop Support should consider when establishing pharmaceutical prices that could result in lower prices.

Please see the Recommendations Table on the next page for the status of all recommendations.

Recommendations Table

Management	Recommendations Unresolved	Recommendations Resolved	Recommendations Closed
Director, Defense Logistics Agency	None	Yes	None

Please provide Management Comments by November 8, 2019.

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.





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

August 9, 2019

MEMORANDUM FOR DIRECTOR, DEFENSE LOGISTICS AGENCY

**SUBJECT: Audit of Defense Logistics Agency Troop Support Negotiation of Prices
for the Pharmaceutical Prime Vendor-Global Program
(Report No. DODIG-2019-109)**

This final report provides the results of the DoD Office of Inspector General's audit. We previously provided copies of the draft report and requested written comments on the recommendation. We considered management's comment on the draft report when preparing the final report. These comments are included in the report.

The Defense Logistics Agency Acquisition Deputy Director, responding for the DLA Director, agreed to address the recommendation presented in the report; therefore, the recommendation is considered resolved and open. As described in the Recommendation, Management Comments, and Our Response section of this report, the recommendation may be closed when we receive adequate documentation showing that all agreed-upon actions to implement the recommendations have been completed. Therefore, please provide us within 90 days your response concerning specific actions in process or completed on the recommendation. Your response should be sent to either followup@dodig.mil if unclassified or rfunet@dodig.smil.mil if classified SECRET.

If you have any questions, please contact Ms. Theresa S. Hull at (703) 604-9312, (DSN 664-9312).

A handwritten signature in cursive script, reading "Theresa S. Hull", is positioned above the typed name.

Theresa S. Hull
Assistant Inspector General for Audit
Acquisition, Contracting, and Sustainment

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Introduction

Objective

We determined whether the Defense Logistics Agency (DLA) Troop Support could improve its negotiations of pharmaceutical prices. See Appendix A for a discussion of the scope and methodology and prior audit coverage related to the objective.

Background

Defense Logistics Agency

The DLA, headquartered at Fort Belvoir, Virginia, provides the Army, Marine Corps, Navy, Air Force, other Federal agencies, and partner nation armed forces with logistics, acquisition, and technical services. The DLA provides nearly all of the consumable items U.S. military forces need to operate, including medical supplies.

DLA Troop Support, located in Philadelphia, Pennsylvania, is one of the DLA's Major Subordinate Commands. DLA Troop Support provides medical supplies and equipment, including pharmaceuticals, to customers and warfighters to achieve global missions. DLA Troop Support also provides customers and warfighters with food, textiles, construction material, and industrial hardware.

DLA Troop Support Pharmaceutical Prime Vendor–Global Program

DLA Troop Support's Pharmaceutical Prime Vendor–Global program provides the global distribution of pharmaceuticals and related products directly to customers, such as the DoD and other Government agencies. The program provides customers with a single source from which to obtain pharmaceuticals to support both their day-to-day and war readiness materiel needs in order to rapidly respond to contingency, wartime, and humanitarian operations. The prime vendor provides the pharmaceuticals directly to the customer, eliminating the need for DLA Troop Support to manage large inventories of perishable pharmaceuticals. Customers can place two types of orders; routine orders for day-to-day requirements that are delivered within 24 hours, and emergency orders that are delivered within 6 hours.

On November 13, 2014, DLA Troop Support contracting officials awarded the program contract (SPE2DX-15-D-1000) to the prime vendor. The contract has an estimated maximum value of \$22.4 billion and a period of performance of up to 10 years, consisting of a 30-month base period and three 30-month options. DLA Troop Support established the program's distribution fee as a 12.04-percent discount off

the pharmaceutical prices.¹ Our review focused on the base period of the contract from November 13, 2014, to May 12, 2017. During the base period of the program, customers placed 10.5 million orders for 20,675 different pharmaceuticals and related supplies, valued at \$5.1 billion.² On May 3, 2017, DLA Troop Support exercised the contract's first option period, extending the contract for another 30 months from May 13, 2017, to November 12, 2019.

Pharmaceutical Pricing Considerations

Buy American Act and Trade Agreements Act

Pharmaceuticals and pharmaceutical supplies offered through the program must comply with the Buy American Act and the Trade Agreements Act, as applicable.³ The Acts require products to be made within the United States or designated country unless an exception applies per the Federal Acquisition Regulation (FAR) or Defense Federal Acquisition Regulation Supplement.⁴ According to DLA Troop Support officials, the Trade Agreements Act prevents them from obtaining competition and lower priced pharmaceuticals manufactured in certain foreign countries, such as India and China, that retail pharmacies, such as CVS or Rite Aid, are not restricted from purchasing.

National Drug Codes

Pharmaceutical suppliers are required to provide the U.S. Food and Drug Administration with a current list of all pharmaceuticals intended for commercial distribution. These pharmaceuticals are uniquely identified by 11-digit National Drug Codes (NDCs) that consist of the following three segments.

- 1. Labeler Code**—assigned by the U.S. Food and Drug Administration and identifies the labeler, which is the business that manufactures, repackages, relabels, or distributes under its own name, the pharmaceutical.
- 2. Product Code**—assigned by the labeler and identifies the pharmaceutical strength, dosage form, and formulation.
- 3. Package Code**—assigned by the labeler and identifies the type of packaging and quantity of pharmaceutical in the package.

DLA Troop Support used these NDCs to identify and price the pharmaceuticals sold through the program.

¹ The discounted distribution fee of 12.04 percent only applied to the prime vendor program prices based on Government contracted prices. The discounted distribution fee did not apply to program prices based on the prime vendor's pricing agreements, and to customers with annual purchases less than \$250,000.

² Of the \$5.1 billion, non-DoD customers accounted for slightly more than 5 percent of the total order value.

³ Sections 8301-8305, title 41, United States Code and sections 2501-2582, title 19, United States Code, respectively.

⁴ FAR Part 25, "Foreign Acquisition," Subpart 25.1, "Buy American – Supplies," 25.103, "Exceptions;" Subpart 25.4, "Trade Agreements;" and Defense Federal Acquisition Regulation Supplement Subpart 225.1, "Buy American – Supplies," 225.103, "Exceptions;" and Subpart 225.4, "Trade Agreements."

Average Wholesale Price

The “average wholesale price” is a pharmaceutical industry price benchmark. This benchmark is used to determine pricing and reimbursement of prescription pharmaceuticals by third parties, such as the Government. The average wholesale price, often compared to a “list price,” is not a true representation of actual market prices. The company that provided average wholesale prices to DLA Troop Support for pharmaceuticals stated that its published average wholesale price was not an average of actual wholesale prices and was not derived from, nor did it reflect, the actual prices paid for drugs. Instead the average wholesale prices were based on pricing information reported by the pharmaceutical suppliers that the vendor did not verify for accuracy.

Defense Health Agency Military Health System Data Repository

The Defense Health Agency (DHA) supports the delivery of integrated, affordable, and high quality health services to 9.4 million Military Health System beneficiaries, which consists of active duty personnel, military retirees, and their families. The Military Health System Data Repository (MDR) is the centralized data repository that captures, archives, validates, integrates, and distributes DHA corporate health care data worldwide. The MDR receives and validates data from the DoD’s worldwide network of more than 260 health care facilities and from non-DoD data sources, such as retail pharmacies, which are not subject to the Buy American or Trade Agreements Acts. The MDR includes data on the reimbursement amounts paid to retail pharmacies by the DoD and other health insurers and beneficiary copayments. The MDR also supports interagency data sharing with the Departments of Veterans Affairs and Health and Human Services.

Audit Scope

We used the DHA’s MDR reimbursement amounts paid to retail pharmacies by the DoD’s contracted pharmacy benefits manager in our audit of the program. The pharmacy benefits manager reimbursed the retail pharmacies using one of three methods:

- retail pharmacy’s usual and customary cash price,
- discounts from the average wholesale price, or
- maximum allowable charge intended to represent the market cost for a group of generic pharmaceuticals.

According to DHA’s pharmacy benefits manager, it used the method that resulted in the lowest reimbursement amount for retail claims. We also included the reimbursements made by other health insurers and the beneficiary’s copayment in our audit.

Based on our audit, we identified 6,615 pharmaceutical NDCs, with orders valued at \$329.5 million, where the program price was higher than the median amount paid from the DHA's MDR data. The \$329.5 million represented 6.5 percent of the \$5.1 billion in total purchases from the program. We then examined the top 19 pharmaceutical NDCs out of the 6,615 pharmaceuticals in our review to determine how DLA Troop Support established the prices for those pharmaceuticals. See Appendix B for a list of the top 19 pharmaceutical NDCs.

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 We did not identify any internal control weakness associated with DLA Troop Support's negotiation of pharmaceutical prices. However, DLA Troop Support could improve its negotiation process by using additional pricing data to potentially negotiate lower prices. We will provide a copy of the report to the senior official responsible for internal controls at DLA Troop Support.

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

Finding

DLA Troop Support Could Use Other Data When Negotiating Pharmaceutical Pricing

Between November 2014, and May 2017, the DoD purchased 20,675 pharmaceutical NDCs through the DLA Pharmaceutical Prime Vendor-Global program, valued at \$5.1 billion. We determined that DLA Troop Support established prices based on Government prices, such as the Veterans Affairs Federal Supply Schedule (VA FSS), or the prime vendor's pricing agreements, which allowed the prime vendor to distribute the supplier's products at an agreed-to price. DLA Troop Support officials compared the prices from the pharmaceutical prime vendor's pricing agreements to the average wholesale price, which is an industry pharmaceutical pricing benchmark. We determined that additional pricing data were available from the DHA that DLA Troop Support could have used to assist with negotiating lower prices for some pharmaceuticals.

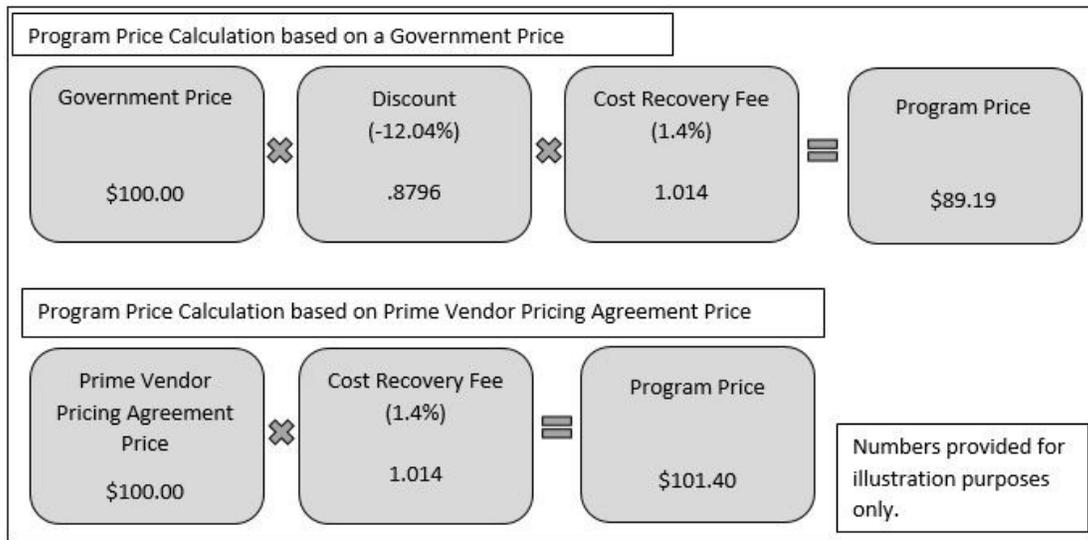
DLA Troop Support stated that its ability to obtain the prices in DHA's pricing data was affected by the Buy American Act and Trade Agreements Act, which limits potential sources of pharmaceuticals and reduces competition. The pharmaceutical prices from DHA's pricing data were from retail pharmacies, which were not subject to the limitations of these Acts. Another limitation affecting DLA Troop Support's ability to negotiate lower prices was that it could not guarantee sales to its suppliers with distribution and pricing agreements in exchange for quantity discounts or price breaks.

Because DLA Troop Support had to comply with the Acts, DLA Troop Support may not have been able to achieve the same prices as reflected in DHA's pricing data. However, the DLA Troop Support could have used the pricing data from DHA to assist with negotiating lower prices for some pharmaceuticals in the program. Based on our calculations, DHA's median amounts paid for the same quantity of pharmaceuticals were \$137.1 million less than DLA Troop Support prices for the 6,615 pharmaceutical NDCs.

DLA Troop Support Established Pharmaceutical Prices

Between November 2014, and May 2017, the DoD purchased 20,675 pharmaceutical NDCs through the DLA Pharmaceutical Prime Vendor–Global program, valued at \$5.1 billion. DLA Troop Support officials provided a list of available pharmaceuticals and the base prices to the prime vendor on a daily basis to establish program prices. We determined that DLA Troop Support established pharmaceutical base prices for the program based on Government prices, such as the VA FSS, or the prime vendor’s pricing agreements.⁶ The base price is the product’s price before any program fees are applied. The prime vendor was then responsible for calculating the final price that the DoD and other Government agencies paid for the pharmaceuticals using one of two methods depending on how DLA Troop Support officials set the pharmaceutical’s base price. See the Figure and the following examples for an illustration of the two methods that the prime vendor used to calculate the final price.

Figure. Prime Vendor Method to Calculate Final Price of Pharmaceuticals



Source: DLA Troop Support.

Method to Determine VA Federal Supply Schedule Prices

For program prices based on other Government prices, the final price was determined as the Government price, less the prime vendor’s discounts, plus DLA Troop Support’s cost recovery fee. For example, from February 2015 to May 2017, DLA Troop Support established the price of a package of ibandronate sodium (treats osteoporosis) at \$130.00 based on a Government price from

⁶ Prime vendor pricing agreements were agreements between the prime vendor and pharmaceutical suppliers that allow the prime vendor to distribute the supplier’s products at an agreed to price.

the VA FSS. The prime vendor applied a discount of 12 percent that reduced the price by \$15.65, and then added DLA Troop Support's cost recovery fee of \$1.60, for a final program price of \$115.95.

Method to Establish Pricing Agreements

When establishing program prices based on pricing agreements, DLA Troop Support officials evaluated the prime vendor's pricing agreement against the average wholesale price. DLA Troop Support officials explained that they sought to obtain at least a 15-percent discount off the pharmaceutical's average wholesale price. For example, the price of a 100-count bottle of ursodiol (treats gallstones) from the prime vendor's pricing agreement was \$510.24, DLA Troop Support officials established this price based on a 30.6-percent discount off of the average wholesale price. The final price was then determined by adding DLA Troop Support's cost recovery fee of \$7.14 for a final program price of \$517.38.

Additional Pricing Data May Be Available for Negotiating Pharmaceutical Prices

According to DLA Troop Support officials, they used the best pricing data available to them. However, additional pricing data were available from DHA that DLA Troop Support officials could have incorporated into their negotiations with suppliers to assist them in obtaining lower prices for some pharmaceuticals. Specifically, DHA's MDR contains data on prescription pharmaceuticals dispensed to uniformed service members and their families at DoD health care facilities and retail pharmacies. The MDR includes pharmaceutical NDCs, quantities dispensed, and the amount paid for the prescription.

DLA Troop Support officials could have used the DHA's MDR pricing data to negotiate lower prices for pharmaceuticals on the program. For example, on January 2, 2015, DLA Troop Support officials established the price of a 500-count bottle of verapamil hydrochloride (treats high blood pressure) at \$1,266.80. However, according to the MDR data, the price paid per bottle was \$87.89. Therefore, the DLA Troop Support could have obtained a price that was up to \$1,178.91 lower by incorporating DHA pricing data into its negotiations. The DoD could have paid approximately almost \$1 million less on the purchase of 808 bottles of verapamil hydrochloride between January 2015, and March 2017.⁷

⁷ Savings does not include the prime vendor's discount or DLA Troop Support's cost recovery fee.

In another example, DLA Troop Support officials established the price of dorzolamide hydrochloride and timolol maleate (treats eye conditions) at \$56.25 per 10-milliliter bottle in December 2014. However, according to the MDR data, the price paid per bottle was \$15.85. Although DLA Troop Support officials could not guarantee the supplier any sales, they could have incorporated the MDR pricing data to negotiate a price up to \$40.40 lower. Had DLA Troop Support used the MDR pricing data, the DoD could have paid approximately \$950,000 less for the 23,447 bottles it purchased between December 2014 and May 2017. See Table 1 for additional examples where DLA Troop Support could have incorporated MDR data points to negotiate lower prices.

Table 1. Difference Between DLA Troop Support’s Program Prices and MDR Prices

Pharmaceutical Name	National Drug Code	Established Program Price	MDR Price	Difference
Bupropion Hydrochloride (treats depression)	00378200905	\$874.74	\$340.33	\$534.41
Ursodiol (treats gallstones)	42806050301	510.24	388.88	121.36
Rizatriptan Benzoate (treats migraines)	00378370259	119.21	16.90	102.31
Ibandronate Sodium (prevents and treats osteoporosis)	60505279500	130.00	45.97	84.03

Source: The DoD OIG.

DLA Troop Support Had Limitations During Negotiations With Suppliers

According to DLA Troop Support officials, limitations affected their ability to obtain lower prices during negotiations. For example, DLA Troop Support stated that its ability to obtain the prices in DHA’s pricing data was affected by the Buy American Act and Trade Agreements Act, which limits potential sources of pharmaceuticals and reduces competition. The pharmaceutical prices from DHA’s pricing data were from retail pharmacies, which were not subject to the limitations of these Acts. Another limitation affecting DLA Troop Support’s ability to negotiate lower prices was that it could not guarantee sales to its suppliers with distribution and pricing agreements in exchange for quantity discounts or price breaks.

DLA Troop Support’s Compliance With the Buy American Act and Trade Agreements Act May Have Cost DoD Savings

The Buy American Act and Trade Agreements Act requires DLA Troop Support to purchase supplies made within the United States, or a designated country. The requirement of the Acts prevented DLA Troop Support from considering

U.S. Food and Drug Administration approved pharmaceuticals manufactured in countries, such as China and India, which are two of the largest manufacturers and exporters of generic pharmaceuticals. According to DLA Troop Support officials, domestic and designated foreign country suppliers were aware of the Trade Agreements Act requirement and their prices were higher because they did not have to compete with pharmaceuticals from China and India. DLA Troop Support did not provide any specific examples for us to review.

Guarantees of Sales Could Impact Pharmaceutical Prices

DLA Troop Support stated that it could not guarantee sales to its suppliers with distribution and pricing agreements. Unlike the national contracts, which guaranteed suppliers sales in return for lower prices, the DLA Troop Support could not offer the same guarantee to all of its suppliers because the FAR states that agreements cannot state or imply any agreement by the Government to place future orders.⁸ DLA Troop Support's ability to guarantee sales could have an impact on the prices that suppliers would agree to charge. For example, in November 2014, DLA Troop Support established the price for a bottle of fluticasone propionate (treats allergies) as \$6.25 based on a VA national contract.⁹ In January 2015, the VA national contract, which guaranteed the supplier sales expired and DLA Troop Support established a price of \$28.47 per bottle based on the prime vendor's pricing agreement, which did not guarantee the supplier any sales. However, in April 2015, a new national contract, which guaranteed sales was awarded to a different supplier for fluticasone propionate at a price of \$2.93 per bottle.¹⁰ The new national contract holder's previous price with no guaranteed sales had been \$25.92. See Table 2 for a comparison of the two supplier's prices for fluticasone propionate with and without guaranteed sales and the difference.

Table 2. Supplier Prices for Fluticasone Propionate With and Without Guaranteed Sales

	Supplier 1	Supplier 2
Price With Guaranteed Sales	\$6.25	\$2.93
Price Without Guaranteed Sales	28.47	25.92
Difference	22.22	22.99

Source: DLA Troop Support.

⁸ FAR Part 16, "Types of Contracts," Subpart 16.7, "Agreements."

⁹ The National Drug Code for this example is 50383070016.

¹⁰ The National Drug Code for this example is 60429019515.

DLA Troop Support Could Establish Lower Pharmaceutical Prices by Incorporating Other Pricing Data Into Pharmaceutical Negotiations

The use of other pricing data during negotiations could help the DLA Troop Support obtain lower prices for the Pharmaceutical Prime Vendor–Global program.

Although DLA Troop Support had to comply with the Acts, the DLA Troop Support could have used the pricing data from DHA to assist with negotiating lower prices for some pharmaceuticals in the program. Based on our calculations, DHA's median amounts paid for the same quantity of pharmaceuticals were \$137.1 million less than DLA Troop Support prices for the 6,615 pharmaceutical NDCs we reviewed.

See Table 3 for a summary of the 6,615 pharmaceutical NDCs grouped by the total difference in price. Based on this data, \$34 million of the \$137.1 million is attributable to just 38 pharmaceuticals. See Appendix A for further discussion of the methodology. The DLA Director should require the DLA Troop Support Commander to coordinate with the DHA to obtain pricing data from the MDR and use the data to evaluate existing and future prices when negotiating pharmaceuticals.

Table 3. Pharmaceutical NDCs Grouped by Total Difference in Price

Range of Total Price Difference Per NDC	Number of Pharmaceutical NDCs	Total Amount DoD Paid	Total MDR Price	Total Difference in Price
Greater than or equal to \$750,000	19 ¹	\$39,774,872	\$16,992,377	\$22,782,495
\$500,000 to \$749,999	19	18,516,951	7,300,479	11,216,472
\$100,000 to \$499,999	259	128,169,207	72,586,748	55,582,459
\$10,000 to \$99,999	1,200	110,870,836	72,279,693	38,591,143
\$1,000 to \$9,999	2,154	28,069,497	20,056,937	8,012,560
Less than \$1,000	2,964	4,088,899	3,222,253	866,646
Total	6,615	\$329,490,263²	\$192,438,487	\$137,051,775

¹ See Appendix B for a list of the 19 Pharmaceutical NDCs with a total difference in price of \$750,000 or more.

² Total does not equal the actual sum because of rounding.

Source: DoD OIG.

Management Comments on the Finding and Our Response

The DLA Acquisition Deputy Director, responding for the DLA Director, provided the following comment on the finding. For the full text of the Deputy Director's comments, see the Management Comments section of the report.

Defense Logistics Agency Comments

The DLA Acquisition Deputy Director noted there were several differences in opinion between the DLA and DoD OIG audit team regarding the methodology and analysis techniques used to develop the finding. Therefore, the Deputy Director stated that the DLA could not concur with the DoD OIG assertion that the Agency could achieve potential savings of \$137 million by adopting the recommendation for the following reasons:

- The MDR data the DoD OIG used as pricing benchmarks are reimbursement rates for families of drugs, and not the actual commercial price of any one drug audited.
- The MDR reimbursement rates were based on an array of government and commercial pricing points that are legally unattainable by DLA because of the Buy American and Trade Agreements Acts and other statutory or regulatory requirements.
- The DoD OIG only considered instances where the MDR was lower than the DLA price and did not consider the majority of the instances where the MDR reimbursement rate was higher than the DLA price.
- The DoD OIG did not consider DLA prices for equivalent generic alternatives DLA offered for the specific drugs audited where prices were the same or lower than the MDR reimbursement rates.

Our Response

We revised the report to clarify that we were not asserting the DLA could achieve potential savings of \$137.1 million. The \$137.1 million cited in the report is the difference between DLA Troop Support's prices and DHA's median amounts paid during the same time period. The intent of the report was to highlight another source of pricing data that DLA Troop Support should consider when establishing pharmaceutical prices, which could result in lower prices. Regarding the differences in opinion related to our methodology and analysis techniques used to develop the finding:

- We understand that the reimbursement amounts are not the actual price the pharmacy paid to obtain the pharmaceutical. However, the reimbursement rates can serve as an indicator to assist DLA Troop Support in identifying and negotiating lower pharmaceutical prices.

- We agree that DLA Troop Support had to comply with the Acts; however, DLA Troop Support could still use the pricing data from DHA to assist with negotiating lower prices for some pharmaceuticals in the program.
- We focused our audit on identifying opportunities for DLA Troop Support to use another source of data, specifically DHA's MDR, in order to assist with negotiating future prices for pharmaceuticals. Therefore, we focused on instances where the MDR was lower than the DLA Troop Support price.
- We did consider instances where DLA Troop Support obtained lower prices for viable equivalent generic alternatives. For example, of the 6,615 pharmaceutical NDCs, we reviewed the top 19 and identified DLA Troop Support had lower priced generic alternatives for four pharmaceutical NDCs in the program. However, three of those four lower priced alternatives were not truly alternatives. Rather, they were the same pharmaceuticals repackaged by another company.¹¹ For example, for the verapamil hydrochloride discussed earlier in the report, we determined that DLA Troop Support had established a price for an alternate of just \$33.94 for a 500-count bottle. However, based on a review of the alternate pharmaceutical's packaging we determine it was the exact same pharmaceutical that DLA Troop Support had on its program for \$1,266.80, with a different label.

Management Action Taken

As a result of the audit, DLA Troop Support officials updated their draft memorandum of agreement on Medical Logistics Collaboration and Support with the DHA to obtain relevant retail pricing data for negotiating pharmaceutical prices. The purpose of the agreement was to define the overarching roles and responsibilities of the DLA and DHA in the successful implementation of the Defense Medical Logistics Program to enhance the readiness of the U.S. warfighter. The agreement stated that the DLA and DHA shared a strategic vision of partnering to provide rapid and reliable sustainment of health care delivery that covered all aspects of medical logistics support, including pharmaceuticals.

In addition, the agreement addressed DLA and DHA responsibilities, and timeframes for providing retail pricing data in support of negotiating and establishing pharmaceutical prices. According to the agreement, the DLA is responsible for using the total buying power of the DoD and Federal partners and using all available information, including reimbursement rates, to negotiate favorable delivered prices for medical material. Together, the DLA and DHA

¹¹ According to Title 21 Code of Federal Regulations section 207.1 (2019), a repackaged pharmaceutical is a pharmaceutical that is removed from its container and placed into a different container without manipulating, changing, or affecting the composition, or formulation of the pharmaceutical.

maintain responsibility to support timely and accurate sharing and synchronization of data and information. The agreement stated that the DHA will provide the DLA retail pricing data on a monthly basis. DLA Troop Support officials stated that they are negotiating with DHA officials to finalize the agreement.

Recommendation, Management Comments, and Our Response

We recommend that the Defense Logistics Agency Director require the Defense Logistics Agency Troop Support Commander to coordinate with the Defense Health Agency to obtain pricing data from the Military Health System Data Repository and use the data to evaluate existing and future prices when negotiating pharmaceuticals.

Defense Logistics Agency Comments

The DLA Acquisition Deputy Director, responding for the DLA Director, agreed with the recommendation. The Deputy Director stated that DLA and the Defense Health Agency were negotiating a Memorandum of Agreement that would enable DLA to obtain DHA MDR reimbursement data on a monthly basis. In anticipation of the Memorandum of agreement the Executive Director for DLA Troop Support Contracting and Acquisition Management also issued a reminder to their acquisition specialists to consider all available data when evaluating prices. DLA Troop Support Medical officials revised their Pharmaceutical Pricing Desk Procedures to mandate the use of MDR data as an additional pricing point for consideration when making future fair and reasonable price determinations.

Our Response

Comments from the Deputy Director addressed all specifics of the recommendation; therefore, the recommendation is resolved but will remain open. We will close this recommendation after we verify that the DLA and the DHA have signed the memorandum of agreement to officially establish their coordination.

Appendix A

Scope and Methodology

We conducted this performance audit from April 2017 through May 2019 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 findings and conclusions based on audit objectives. We believe that the evidence obtained provided a reasonable basis for our finding and conclusions based on our audit objective.

Pharmaceutical NDCs Reviewed

To answer our audit objective, we reviewed DLA Troop Support's established prices for pharmaceuticals purchased through its Pharmaceutical Prime Vendor-Global program. We compared those prices to the median (middle) amount paid by the DoD, patients, and other health insurers for each prescription filled based on DHA pricing data from the MDR. We obtained data on 10.5 million orders for 20,675 different pharmaceutical NDCs and related supplies that the DoD and other Government agencies made during the base period of the contract, November 13, 2014, and May 12, 2017, valued at \$5.1 billion, from DLA Troop Support's program.

We determined that the DHA maintained a repository of pharmaceutical insurance claim data on the amounts paid and quantities dispensed for 51,099 NDCs. Of these NDCs, 14,346 matched with the 20,675 pharmaceutical NDCs and related supplies ordered from DLA Troop Support's program. In addition, the DoD orders for the 14,346 pharmaceutical NDCs accounted for over 80 percent of the total value of the program's orders. Therefore, we used the pricing data from the DHA MDR to evaluate DLA Troop Support's pharmaceutical prices.

Based on our calculation, we determined that for 6,615 pharmaceutical NDCs valued at \$329.5 million, (6.5 percent of the \$5.1 billion in total purchases) DHA's median amount paid was lower than DLA's program price. We selected the 19 pharmaceutical NDCs with a total difference in price of at least \$750,000 or more for additional review. Specifically, we reviewed how DLA Troop Support officials established the prices, and whether they were based on a Government price or the prime vendor's pricing agreements. For the pharmaceuticals with prices based on the prime vendor's pricing agreements, we reviewed DLA Troop Support's analysis to determine the reasonableness of the prices. See Appendix B for a list of the top 19 pharmaceutical NDCs reviewed. For the remaining 7,731 pharmaceutical NDCs, we did not identify any potential savings based on a comparison to the DHA MDR data.

Interviews and Documentation

To determine whether DLA Troop Support could improve its negotiations of pharmaceutical prices, we interviewed DLA Troop Support officials at Philadelphia, Pennsylvania. We discussed contract SPE2DX-15-D-1000, the Pharmaceutical Prime Vendor–Global program’s background, how the program was managed, and DLA Troop Support’s process for establishing pharmaceutical prices. We also interviewed DHA officials to discuss the data collected by the MDR.

We reviewed DLA Troop Support contract SPE2DX-15-D-1000 and modifications, statement of work for the contract, program prices, terms and conditions for pricing agreements, and internal pharmaceutical pricing guidance. In addition, we reviewed the DoD delivery orders for pharmaceuticals. We also reviewed the DHA MDR data on pharmaceutical NDCs and quantities dispensed, and the amount paid by the DoD, patients, and other health insurers.

We reviewed the following criteria.

- Sections 2501-2582, title 19, United States Code
- Section 8126, title 38, United States Code
- Sections 8301-8305, title 41, United States Code
- FAR Part 6, “Competition Requirements,” Subpart 6.1, “Full and Open Competition,”
 - 6.101, “Policy,” and
 - 6.102, “Use of Competitive Procedures”
- FAR Part 8, “Required Sources of Supply and Services,” Subpart 8.4, “Federal Supply Schedules,” FAR 8.404, “Use of Federal Supply Schedules”
- FAR Part 16, “Types of Contracts,” Subpart 16.7, “Agreements”
- FAR Part 25, “Foreign Acquisition”

Pharmaceutical NDC Price Evaluations

To determine whether DLA Troop Support officials could improve their negotiation of pharmaceutical prices we obtained technical assistance from our Quantitative Methods Division with evaluating DLA Troop Support’s program prices. Specifically, the Quantitative Methods Division assisted the audit team with analyzing the DHA MDR data for pharmaceuticals dispensed by retail pharmacies from October 1, 2014, through May 12, 2017. The Quantitative Methods Division also organized over 405 million transactions by pharmaceutical NDCs and date into one 3-month period from October 1, 2014, through December 31, 2014, and five 6-month periods from January 1, 2015, through June 30, 2017.

The Quantitative Methods Division then identified the median amount paid by the DoD, patients, and other health insurers for each NDC by finding the midpoint between all prices paid per pharmaceutical unit during each of the six periods. We then used the median amount paid as a reference point for evaluating the program's prices. We calculated the difference between the DHA reference point price (median amount paid) and the program's prices to calculate the total difference in price of \$137.1 million.

Use of Computer-Processed Data

We used computer-processed data from DLA Troop Support and the DHA to determine whether DLA Troop Support officials were managing the program to control health care costs for the DoD. Specifically, we obtained the quantities ordered and the prices paid from DLA Troop Support's Corporate Data for Medical Intelligence Application. We assessed the reliability of this data by selecting a statistical sample of orders. We then compared the sampled orders to source documents from DLA Troop Support to verify the date, item quantities ordered, and prices paid. As a result, we determined that the computer-processed data from DLA Troop Support were sufficiently reliable to support our finding and conclusions.

We also obtained payment information for pharmaceuticals dispensed according to DHA's MDR. We assessed the reliability of this data by comparing a random sample of pharmaceuticals dispensed and amounts paid to prescription source documents. As a result, we determined that the computer-processed data from the DHA MDR were sufficiently reliable to support our finding and conclusions.

Use of Technical Assistance

The DoD Office of Inspector General Quantitative Methods Division helped the audit team calculate the median amount paid to retail pharmacies based on DHA MDR data per pharmaceutical unit and evaluate the program's prices.

Prior Coverage

During the last 6 years, the Government Accountability Office issued one report and the DoD Office of Inspector General issued two relevant reports discussing the pricing of pharmaceuticals. Unrestricted GAO reports can be accessed at <http://www.gao.gov>. Unrestricted DoD OIG reports can be accessed at <http://www.dodig.mil/reports.html/>.

GAO

Report No. GAO-13-358, "Prescription Drugs: Comparison of DoD and VA Direct Purchase Prices," April 2013

The GAO determined that when comparing brand name and generic drug prices, the DoD obtained lower prices than the Department of Veterans Affairs for brand name drugs but paid higher prices for generic drugs.

DoD OIG

Report No. DODIG-2018-033, "Defense Health Agency Controls Over High-Risk Pharmaceutical Payments," November 16, 2017

The DoD OIG determined that the DHA used data analytics, trend reports, and industry publications to identify drugs with increasing costs, and worked with its Pharmacy Benefit Manager to effectively implement controls for six drugs. Although the DHA reduced the risk for fraudulent claims payments for the drugs, the DHA often took more than 6 months to implement the controls for other drugs.

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 determined that it was generally more cost efficient to obtain pharmaceuticals through the TRICARE Mail Order Pharmacy Program than from retail pharmacies, for the aspects of the program that were reviewed.

Appendix B

Pharmaceutical NDCs with a Total Difference in Price of \$750,000 or More

The table below identifies 19 pharmaceutical NDCs with a total difference in price of at least \$750,000 compared to the DHA MDR reference point price.

Pharmaceutical Name and Use ¹	National Drug Code	Total Paid By the DoD	Total DHA MDR Reference Point Price ²	Total Difference in Price
Fluticasone Propionate (treats allergy symptoms)	50383070016	\$4,990,709	\$1,257,293	\$3,733,416
Ursodiol (treats gallstones)	42806050301	2,961,546	970,752	1,990,794
Oxycodone and Acetaminophen (relieves moderate to severe pain)	00406052301	4,963,023	3,385,763	1,577,260
Ibandronate Sodium (prevents and treats osteoporosis)	60505279500	2,608,386	1,104,294	1,504,092
Tretinoin (treats acne)	66530025420	1,962,692	646,725	1,315,967
Bupropion Hydrochloride (treats depression)	00378200905	1,875,117	624,420	1,250,697
Tamsulosin Hydrochloride (treats symptoms of an enlarged prostate)	00228299611	2,016,542	861,352	1,155,190
Amoxicillin (treats infections caused by bacteria)	00093416173	2,384,048	1,355,364	1,028,684
Dorzolamide Hydrochloride and Timolol Maleate (treats eye conditions, including glaucoma)	50383023310	1,339,262	321,081	1,018,181
Verapamil Hydrochloride (treats high blood pressure)	00378141105	1,039,442	66,569	972,873
Ursodiol (treats gallstones)	00527132601	1,767,370	880,929	886,441
Tretinoin (treats acne)	43478024220	1,161,856	289,192	872,663
Myorisan (treats severe acne)	61748030413	1,880,334	1,048,021	832,313
Sulfamethoxazole and Trimethoprim (treats infections caused by bacteria)	65862049647	1,163,769	350,941	812,828
Claravis (treats severe acne)	00555105786	1,134,647	345,817	788,830

Pharmaceutical NDCs DLA Troop Support Could Negotiate Lower Prices for up to \$750,000 or More (cont'd)

Pharmaceutical Name and Use ¹	National Drug Code	Total Paid By the DoD	Total DHA MDR Reference Point Price ²	Total Difference in Price
Phenazopyridine Hydrochloride (treats symptoms of urinary tract infections)	51293081001	2,166,511	1,384,010	782,501
Low-Ogestrel (prevents pregnancy)	52544084728	2,247,304	1,490,437	756,867
Tretinoin (treats acne)	66530025520	1,209,213	456,579	752,634
Rizatriptan Benzoate (treats migraines)	00378370259	903,102	152,839	750,264

¹ Because we identified pharmaceuticals by NDC, some pharmaceutical names appear more than once.

² The reference point price was based on the total quantity of pharmaceuticals ordered by the DoD multiplied by the applicable MDR price, the prime vendor's discount, and cost recovery rate as applicable.

Source: The DoD OIG.

Management Comments

Defense Logistics Agency



DEFENSE LOGISTICS AGENCY
HEADQUARTERS
8725 JOHN J. KINGMAN ROAD
FORT BELVOIR, VIRGINIA 22060-6221

JUL 03 2019

MEMORANDUM FOR ASSISTANT INSPECTOR GENERAL (ACQUISITION,
CONTRACTING, AND SUSTAINMENT)

SUBJECT: Response to Office of the Inspector General Draft Report "Audit of Defense Logistics Agency Troop Support Negotiation of Prices for the Pharmaceutical Prime Vendor Global Program" (Project No. D2017-D000AH-0120.000)

DLA appreciates the opportunity to review and comment on the entirety of the audit report, and we concur with the overall DOD OIG recommendation for coordinating with the Defense Health Agency (DHA) on pharmaceutical pricing. It is standard DLA practice to maximize the use of all available and relevant information when evaluating prices for pharmaceuticals on behalf of our customers. However, we note for the record that there were several differences of opinion between the Agency and the audit team concerning the methodology and analysis techniques used for the development of the findings. As a result, DLA cannot concur with the DOD OIG assertion that the Agency could achieve potential savings of \$137 million by adopting the recommendation, for the following reasons:

- a. The Military Health System Data Repository (MDR) data used by the DOD OIG as pricing benchmarks are reimbursement rates for a family of drugs, and not the actual commercial price of any one drug audited by the DOD OIG.
- b. As pointed out in the DOD OIG's draft report, the MDR reimbursement rates are based on an array of government and commercial pricing points, with conditions and circumstances that are legally unattainable by DLA because of the Buy American and Trade Agreements Acts and other statutory or regulatory requirements.
- c. The DOD OIG considered only instances where the MDR was lower than the DLA price and disregarded the majority of the instances where the MDR rate was higher than the DLA price.
- d. The DOD OIG did not consider DLA prices for the viable equivalent generic alternatives DLA offered for the specific drugs audited by the DOD OIG that had pricing equal to or lower than the MDR reimbursement rates.

Regardless of these differences of opinion, DLA is committed to continually improving the processes in place to ensure the Agency obtains the best value for products and services in support of the Warfighter. DLA has incorporated the report's recommendations into existing processes and procedures, as demonstrated by the actions detailed in our response.

Defense Logistics Agency (cont'd)

The point of contact for this audit is [REDACTED]


ROXANNE J. BANKS
Deputy Director, DLA Acquisition

Attachment:
As stated

Defense Logistics Agency (cont'd)

Recommendation

We recommend that the Defense Logistics Agency Director require the Defense Logistics Agency Troop Support Commander to coordinate with the Defense Health Agency to obtain pricing data from the Military Health System Data Repository and use the data to evaluate existing and future prices when negotiating pharmaceuticals.

DLA's Response to Recommendation Concur. DLA and the Defense Health Agency are negotiating a Memorandum of Agreement that will enable DLA to obtain DHA MDR reimbursement data on a monthly basis. In anticipation of that Memorandum of Agreement, the DLA Troop Support Acquisition Executive signed a communication to the workforce on June 28, 2019, reminding them to consider all available data, including reimbursement rates, when evaluating prices. DLA Troop Support Medical also modified its Pharmaceutical Pricing Desk Procedures on June 28, 2019 to mandate the use of MDR data as an additional pricing point to consider when its Contracting Officers make future fair and reasonable price determinations. DLA believes once the Memorandum of Agreement is finalized, the actions taken will have addressed and met the intent of the report's recommendation and request closure.

Defense Logistics Agency (cont'd)



DEFENSE LOGISTICS AGENCY
TROOP SUPPORT
700 ROBBINS AVENUE
PHILADELPHIA, PENNSYLVANIA 19111-5092

June 28, 2019

**MEMORANDUM FOR: CONTRACTING POLICY MEMORANDUM
DISTRIBUTION LIST**

SUBJECT: Sources of Information for Price Reasonableness Determinations

**REFERENCES: DFARS 212.209 Determination of price reasonableness, PGI
215.402 Pricing policy**

It is an industry and government best practice to utilize all available sources of pricing data for comparison when determining a price to be fair & reasonable. I remind all Acquisition Specialists to study and use the Department of Defense Guidebook for Acquiring Commercial Items when evaluating prices.

As stated in the Guidebook, "The Contracting Officer must obtain and consider all information necessary when making a determination concerning whether the price is fair and reasonable. When evaluating the proposed price of a commercial item, start with government resources, which includes databases, reports, publications, experts, etc."¹

DLA Troop Support Contracting staff are required to stay informed about current industry trends to include market-driven pricing. When making independent fair and reasonable price determinations prices, Contracting Officers must seek and consider all available sources of pricing information, such as contract history, commercial price lists, pricing benchmarks, reimbursement rates and pricing data utilized by other government agencies, etc.

A handwritten signature in black ink that reads "William J. Kenny".

WILLIAM J. KENNY
Executive Director
Troop Support Contracting
and Acquisition Management

¹ Department of Defense Guidebook for Acquiring Commercial Items
(https://www.acq.osd.mil/dpap/cpic/cp/docs/Guidebook_Part_B_Commercial_Item_Pricing_20180126.pdf)

Defense Logistics Agency (cont'd)

SOP – PPV DAPA

Standard Operating Procedure for Reviewing Items for Addition to a Pharmaceutical Distribution and Pricing Agreement (DAPA)

1. PURPOSE AND SCOPE

1.1 Purpose

The purpose of the Pharmaceutical DAPA Program is to establish a pricing agreement with the supplier, on an item-by-item basis, for items that are needed by DoD Pharmaceutical Prime Vendor customers but are not covered under another Government contracting vehicle.

The purpose of this SOP is to ensure that all items placed on a Pharmaceutical DAPA have been evaluated to ensure that the Government is obtaining a fair and reasonable price, and that the file is adequately documented with the price reasonableness determination.

FAR 15.402 requires Contracting Officers to purchase supplies and services from responsible sources at fair and reasonable prices.

The FAR does not define the term "fair and reasonable price," but it implies two meanings:

- 1) The fair market value, given the prices of market transactions between informed buyers and sellers under similar competitive market conditions for deliverables with similar product, quality, and quantity requirements. (Price Analysis)
- 2) The total allowable cost of providing the product that would be incurred by a *well managed, responsible firm using reasonably efficient and economical methods of performance* plus a reasonable profit. (Cost Analysis)

The price reasonableness determination for DAPA items is based on **Price Analysis**. Per FAR 15.404-1(b), price analysis is the process of examining and evaluating a proposed price to determine if it is fair and reasonable, without evaluating its separate cost elements and proposed profit. Price analysis always involves some form of comparison with other prices.

Although many pharmaceuticals are available only from one source, they are purchased in significant quantities in the commercial market place. There are many factors that go into the purchase price for pharmaceuticals, such as committed volume and negotiated discounts as a percentage of industry benchmark pricing. The primary methods used to evaluate pricing for pharmaceutical DAPAs are:

- 1) Comparison of the offered price against the offeror's published price; and
- 2) Comparison of the offered price against the price of the same item when listed in an alternate commercial catalog (for example, the product and price catalog of major pharmaceutical wholesaler, such as those holding DLA Pharmaceutical Prime Vendor contracts).

Defense Logistics Agency (cont'd)

A standard published price utilized by the pharmaceutical industry is the Average Wholesale Price (AWP). AWP prices are published by commercial subscription data sources that operate independently from the pharmaceutical suppliers. Currently, DLA Troop Support obtains the AWP price of each pharmaceutical item through a subscription to Medi-Span. The AWP price for a pharmaceutical item is often likened to a “sticker price” – a benchmark for comparison. Traditionally, DLA Troop Support utilized AWP -15% as a benchmark for determining the Fair and Reasonable price of an item. The AWP pricing and other information obtained from these commercial sources is used as a source of additional information while researching an item, but shall not be the only comparison use in the determination of Fair and Reasonable pricing.

Since certain items are not listed in commercial data sources, particularly many over-the-counter pharmaceuticals and non-pharmaceutical items such as prescription vials and labels, the Pharmaceutical Prime Vendor Division ensures that the DAPA holder supplies other published catalog prices as a basis of comparison for the DAPA price. These procedures are explained in Section 3 below.

1.2 Scope

This SOP applies to all personnel associated with the processing, review, and approval of pharmaceutical DAPAs. The Pharmaceutical DAPA Team resides within Pricing Integrated Supplier Team (IST), Pharmaceutical Prime Vendor Division, DLA Troop Support. The Pharmaceutical DAPA Team consists of Acquisition Specialists and Business Specialists that communicate with the DAPA holders and with other entities that have a stake in the pricing of items in the Pharmaceutical Prime Vendor Program.

2. ROLES, RESPONSIBILITIES AND AUTHORITY

2.1 DAPA Administrators (Acquisition Specialists / Business Specialists assigned to the Pharmaceutical DAPA Team)

- Compare proposed DAPA prices against available pricing information to perform Fair and Reasonable determination.
REFER TO APPENDIX A – DAPA PRICING FAIR AND REASONABLE DETERMINATION
- Ensure that any DAPA offeror that is not the manufacturer of the item (distributor or dealer) has the authorization from the manufacturer to sell that company’s product. REFER TO SECTION 3.2 BELOW
- Thoroughly review the DAPA offeror’s responses in the Representations and Certifications section of the application (FDA Approval of drug, Place of Manufacture, Debarment and Suspension, etc.), and verify that that the responses are acceptable. For further information click on the “Reference Information” link within each section of the application.

Defense Logistics Agency (cont'd)

- Maintain files for each DAPA holder with copies of catalogs and any other pertinent information. DLA does not maintain hard copies of AWP prices since historic FDB files are maintained on Medical's server (R drive, FDB Folder).
- Provide information, as needed, to current and prospective DAPA holders, internal customers, customers of DLA's PPV Program, and other interested parties with respect to pricing in the Pharmaceutical Prime Vendor program

2.2 Contracting Officer (KO)

- Review DAPA logs to ensure each item has a fair and reasonable DAPA price, based on information provided by the offeror and other available pricing information for that item
- Ensure that the DAPA log for each item is documented with the price reasonableness determination
- Ensure that hard copy files are maintained for items where a catalog or other printed information was used to document price reasonableness

2.3 Integrated Supplier Team (IST) Chief

- Review a random sample of DAPAs to ensure price reasonable determinations are being adequately documented
- Provide oversight and guidance for processes contained within this SOP
- Provide information, as needed, to current and prospective DAPA holders about the requirements for fair and reasonable price determination and documentation

3. PROCEDURES AND STRATEGIES

- 3.1 The DLA Troop Support DAPA Administrator coordinates with prospective DAPA holders on providing adequate documentation to support the approval of their DAPA. Some prospective DAPA holders contact DLA Troop Support expressing interest in obtaining a DAPA. In other cases, the DAPA team contacts the prospective DAPA holder to explain the DAPA program and requests that the firm establish a DAPA due to the need for that company's product(s) by our Pharmaceutical Prime Vendor customers. In either case, the DAPA Administrator coordinates with the prospective DAPA holder to input their proposed DAPA prices into the DAPA system for review and approval by DLA Troop Support.
- 3.2 The DAPA Administrator must determine if the prospective DAPA holder is the manufacturer of the item, or is a dealer or distributor offering another firm's product. If not the manufacturer, the dealer must provide a current authorization agreement from the manufacturer (often termed "Authorized Distributor of Record", "Supply and Distribution Agreement", or "Distributor Agreement"). The DAPA Administrator shall also contact the manufacturer and confirm the authenticity of the document. If the dealer does not provide

Defense Logistics Agency (cont'd)

it, then inform the potential DAPA offeror that they must obtain a signed and dated agreement from the manufacturer to sell this product via the PPV program.

- 3.3 The DAPA Administrator must also ensure that the prospective DAPA holder provides adequate documentation to enable a price reasonableness determination. Part of the DAPA log submission by the prospective DAPA holder requires them to certify the basis for their offered price. The choices available in the Pharmaceutical DAPA log are: (1) Most Favored Customer Price or (2) Other. Appendix A (DAPA Pricing Fair and Reasonable Determination) takes into account the additional considerations surrounding each of these choices when evaluating the offered price.
- 3.4 If the DAPA offeror has not already provided the required pricing information, the DAPA Administrator requests commercial pricing information as well as any other Government pricing catalog information from the offeror, in the form of a commercial catalog or published price. In accordance with the DPAP Pricing Reference Guide:

For catalog items, the firm should include:

- A copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted;
- A copy or description of current discount policies and price lists (published or unpublished) (e.g., wholesale, original equipment manufacturer, or reseller); or
- An explanation of the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities.

In general, DLA Troop support's goal is to obtain a discount of 15% or more off of the catalog price. In certain cases where the supplier can demonstrate that no other customers can obtain the item at such a discount, the Contracting Officer may make the determination to accept a discount less than 15%.

- 3.5 The Government's objective is to obtain the offeror's best price. The Government recognizes that the terms and conditions of commercial sales vary and there may be legitimate reasons why the supplier may not be able to offer their best price to the Government. The DAPA Administrator, in conjunction with the Contracting Officer, establishes negotiation objectives based on a review of relevant data and determines price reasonableness.
- 3.6 The DAPA Administrator ensures all relevant documentation to demonstrate the fair and reasonable price determination is maintained in the DAPA system and/or the hard copy DAPA files, as appropriate.
- 3.7 The IST Chief ensures that the DAPA Team has made and documented a proper price reasonable determination, as outlined in section 2.3 above.

Defense Logistics Agency (cont'd)

4. MONITORING AND MEASURING

- 4.1 On a quarterly basis, the IST Chief reviews a random sample of DAPAs to ensure price reasonable determinations are being adequately documented.
- 4.2 To meet the Medical Acquisition Quality Review standards established in MEDSGSMNOTE 10-29, the IST Chief of the DAPA Team will keep a list of the DAPAs established. On a quarterly basis, the IST Chief will review five DAPAs selected at random and provide comments on conformance to DAPA SOP to the Prime Vendor Division Chief.
- 4.3 The IST Chief shall review the processes and procedures contained in this SOP at a minimum of every three years.

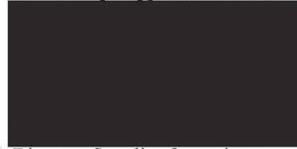
 6/27/19

IST Chief, Pricing Branch
Pharmaceutical Prime Vendor Division
DLA Troop Support

Level Higher:

 6/27/19

Chief, Pharmaceuticals Prime Vendor
DLA Troop Support Medical



Director, Supplier Operations
DLA Troop Support Medical

Defense Logistics Agency (cont'd)

APPENDIX A

APPENDIX A (DAPA Pricing Fair and Reasonable Determination) to SOP for Reviewing Items for Addition to a Pharmaceutical DAPA

1. Review the prospective DAPA holder's basis for their offered price from the DAPA log ("Most Favored Customer Price" or "Other").

1a. Most Favored Customer Price

When a DAPA Holder makes this selection for an item, they are certifying that the price offered is their "Most Favored Customer Price" given similar terms, conditions and commitment as those given by the Government under the Pharmaceutical Prime Vendor Program. Citing the price as "Most Favored Customer Price" is not a guarantee in and of itself that the Contracting Officer will determine the price as fair and reasonable; additional data is required to support this determination.

The Most Favored Customer is a customer or category of customers that receives the best discounts from the vendor's commercial price list when purchasing quantities comparable to and under similar terms and conditions to the Government's.

The offeror must provide the following information to DLA Troop Support for each item in order to justify the comparison of their offered price to their "Most Favored Customer" price:

- Total annual sales to all customers, in units and dollars (net of all discounts, rebates, and other incentives)
- Total sales at "Most Favored Customer" price
- Percent of total sales to commercial customers
- Percent of total sales to government customers

The DAPA Holder should concurrently submit this information and any other supporting documentation relating to the log to the DAPA Administrator via e-mail. If the DAPA Administrator does not receive this documentation, they shall contact the DAPA Holder by phone or e-mail and request the supporting documentation. The DAPA Administrator shall review the information to determine if it supports a determination of fair and reasonable price based on several factors, such as comparison to the offeror's "Most Favored Customer" and/or other prices previously determined to be fair and reasonable. Questions should be referred to the Contracting Officer for further evaluation. The Contracting Officer should bring any unusual cases with the IST Chief prior to making a determination or approving the DAPA.

NOTE: The amount and percentage of sales to commercial sources is critical to determine if their commercial sales practices relating to catalog prices can be accepted as a means of determining fair and reasonable prices. Ideally, if the DAPA Holder is comparing their offered price to commercial sales of the same item, then at least 75% of sales of that item should be to commercial sources. When this criterion is not met, other factors may be taken into account when determining price reasonableness, but the comparison becomes less valid.

Defense Logistics Agency (cont'd)

Often comparisons can be made to the same item provided by other manufacturers or the same manufacturer at other strengths or other package sizes that are available on the Federal Supply Schedule (FSS). When a different strength is available on the FSS, it is often possible to extrapolate the difference in price for different strengths to arrive at a fair and reasonable price. Difference in packaging sizes can be utilized by comparing the individual unit price. The Pricing and Strategy Division may be consulted for assistance with complex issues.

1b. Other

When a DAPA Holder is unable to base their offered price on an existing price that has been determined fair and reasonable, or is unable to offer the Government its most favored customer pricing, then they must choose "Other". DAPA Holders selecting "Other" must provide some other adequate rationale to explain why their price offering should be considered as being fair and reasonable by the Government. This could include, for example (1) favorable comparison to other fair and reasonable contract prices or other commercial prices for same or similar items, or (2) discount off of the offeror's own catalog price if they are not providing the "Most Favored Customer" price.

DAPA Holders are responsible with providing documentation to support the fair and reasonableness determination of their offered price concurrently to the DAPA Administrator when the log is submitted to DLA Troop Support. If no documentation is received, the DAPA Administrator shall contact the DAPA Holder by phone or e-mail and request the supporting documentation.

If the offeror is citing a discount off of their own catalog price as the basis for their offered DAPA price, they must provide the following information to DLA Troop Support for each item in order to justify the comparison of their offered price to the catalog price:

- A copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the DLA Troop Support Pharmaceutical Prime Vendor Program office
- An explanation of the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities
- The percentage of total sales made annually at the catalog price
- Total annual sales to all customers, in units and dollars (net of all discounts, rebates, and other incentives)

The DAPA Administrator shall review each item and evaluate the offered percentage discount. There is no "required" level of discount, as long as the offeror certifies that the proposed DAPA price is their lowest price offered to any commercial or public customer. Citing a particular level of discount is not a guarantee in and of itself that the Contracting Officer will determine the price as fair and reasonable; additional data is required to support this determination. Even though the price is lower than the Market Researched Best Commercial Price (BCP, explained in section 3 below), the DAPA Team still needs to determine the amount of discount the potential DAPA offeror is proposing. This step will

Defense Logistics Agency (cont'd)

help us monitor the validity of the Market Researched BCP and will assist the Contracting Officer in their Fair and Reasonableness determination.

Questions should be referred to the Contracting Officer for further evaluation. The Contracting Officer should discuss any unusual cases with the IST Chief prior to making a determination or approving the DAPA.

2. Research the Best Commercial Price (BCP) utilizing all available sources of information for the item or equivalent items available commercially.

The DAPA Administrator should consult the following resources, or other available sources of information, to obtain the best overall information about the prices being paid for the proposed DAPA item by other Government and Commercial purchasers:

2a. The online catalogs of the three main pharmaceutical wholesalers.

These wholesalers (AmerisourceBergen, Cardinal Health, and McKesson) serve as contractors in the DLA Troop Support PPV program. If pricing is available for the item in the wholesalers' online catalogs, the DAPA Administrator should take the average of these three prices to be considered as the Market Researched BCP. However, the proposed DAPA Price needs to be equal to or lower than the highest of these three prices to be considered fair and reasonable. If there is a large variance between the three prices, further research may be needed to determine if there is a packaging discrepancy or other issue. Unresolved discrepancies should be brought to the attention of the Contracting Officer for further evaluation.

2b. Reimbursement rates for the drug in the Defense Health Agency's retail pharmacy program.

The Defense Health Agency (DHA) maintains the Military Health System Data Repository (MDR), which contains information about the amounts reimbursed to the TRICARE contractors in the Home Delivery and Retail Network options of the pharmacy benefit. As MDR data becomes available to DLA, the DAPA Administrator should consider the reimbursement rate as another reference point for the price of the offered DAPA item.

2c. Online sources.

The DAPA Administrator can also consult online sources of prescription and over-the-counter medications. Some of these include www.goodrx.com, www.healthwarehouse.com, and www.walmart.com, as well as basic searches for the drug on Amazon and Google. Depending on the source, the prices quoted may be for prescriptions available to individual consumers, so may not reflect a discount available to large purchasers; or they may combine purchasing power for many consumers to get a very low price compared to other purchasers. Pay close attention to any terms and conditions that may be cited along with the prices quoted from any source that you consult.

3. Review

The goal is to obtain a price that is lower than the DAPA Holder's best price (the best price given to the most favored customer). However, the Government recognizes that the terms and

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conditions of commercial sales vary and there may be legitimate reasons why the best price cannot be achieved. DLA Troop Support DAPA Administrator shall document the file with these findings as applicable.

If the documentation submitted by the DAPA Holder is not sufficient to support a fair and reasonable price determination, the DLA Troop Support DAPA Administrator can reject the DAPA log and document the file accordingly. It is the DAPA Holder's responsibility to resubmit the requested documentation. If the documentation supplied by the offeror does not support the justification of a Fair and Reasonable price, the DAPA Administrator should provide feedback to the potential DAPA holder with their explanation.

When the offeror has provided all required information and the DAPA Administrator has performed the evaluation, then the DAPA Administrator should forward the annotated DAPA log to the Contracting Officer.

The Contracting Officer shall reject any DAPA log that does not adequately support a Fair and Reasonable price determination.

Regardless of which basis was used to evaluate the offered price, the DAPA Administrator and Contracting Officer are responsible for documenting the file with the rationale for their price reasonableness determination.

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APPENDIX B

APPENDIX B (Guidance for Contracting Officer DAPA Log Review and Approval) to SOP for Reviewing Items for Addition to a Pharmaceutical DAPA

- 1) In DMMonline Site Login page, select **DoD Medical Catalog Administration Application**
- 2) In the "Tools" menu on left side, select **Log Into Catalog Administration**
- 3) When the DAPA Management screen opens, select **PCO Log Review**
- 4) Click the dropdown box for "View Logs Assigned to:"
 - Selecting your own name will give you the list of any logs that you have already opened but not approved or returned
 - Selecting "ALL PHARM PCO GROUP" will give you the list of any logs that have been reviewed by the DAPA Administrator and waiting for KO review and approval
 - Once you make your selection click the arrow to the right of the dropdown box
- 5) This will take you to the list of logs waiting for your review

Clicking on the LOG # will take you to the first tab (Contract) of the log.
After reviewing the contents of each tab, click "Continue" at the bottom of the page.

Contract: The DAPA holder must check the appropriate button for each question or certification. If they answer with a value that is not acceptable, the box will be outlined in red on the screen. They must provide an explanation as to why they are not compliant. In some cases it is obvious. For example, for manufacturers of bottles and labels, they do not need an FDA approval for the item, so they check "No" and the box is flagged in red, but it is still acceptable.

Company: If any information about the company has been changed with this log (POC, insurance information, etc.) the new information will appear in red. There are also more questions/certifications that the company must answer. If they answer with a value that is not acceptable, the box will be outlined in red on the screen.

Tiers: Most DAPAs are available to all of our customers, so the "Current Tiers" section will say "BASE UNCOMMITTED" and the "Customers" section will say "ZZZZZZ ALL CUSTOMERS". Some DAPAs have tiered pricing (different prices for different groups of customers) or the DAPA pricing may be limited only to certain customers. This section allows them to put this information in the system, and it feeds the catalog accordingly.

Items: All items in that DAPA log will be listed, with the following code for the action that the DAPA holder wishes to take:

- N = New item
- C = Change
- D = Delete

If the DAPA Administrator has already disapproved any of the items before they sent you the log, you will see an "X" in the "Disapp" field. Clicking on the NDC for an item will take you to another screen with the detailed information for that item. You can see the buyer notes, and add PCO notes if you need to. You can also use this screen to disapprove individual items within the log by clicking the "Disapprove this item"

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box in the PCO's Review area. Make sure to click "Save" if you enter comments or click the "Disapprove" box.

After the Items tab there is not a "Continue" button at the bottom of the screen. You will need to click on the tabs across the top to get to the other screens.

Price Cert shows the price certification that the DAPA Holder selected.

DAPA Comments is not normally used. The DAPA Administrator can enter comments in this tab, but these comments will show in every log for that DAPA holder. Only enter comments here if it is something about the company that you want to see on every log. Otherwise all comments specific to that log will go in the next section ...

Log Comments: This is where the DAPA Administrator will document the information to support the changes being made to the DAPA with that log.

The Buyer Log Comments should be a summary of what changes are being made with this log (how many new items, price increases, price decreases, and item deletions) and any explanation that the company gave as to why they are making the changes.

The PCO Log Comments should have the following statement automatically populated by DMS: "Vendor has verified that the catalog/list price is current and that it represents the price or the basis for the price at which sales are being made. In accordance with DLAD 15.404-1(b)(90)(2)(iv) the price of approved items is determined fair and reasonable based on an items favorable comparison to vendor's catalog/list price."

You can add other comments that apply to the log. Click the "Submit" button below the comment box to save your comments.

The DAPA Administrator should also include a comment for each item in the **Buyer's Item Comments** field with the information to justify our fair and reasonable price determination (comparison of offered DAPA price to other available pricing, sales information, etc.). The comments for each item should also indicate where the item is manufactured. If it is not manufactured in a Trade Agreements Act (TAA) compliant country (for example, India or China), the notes should state that there is a NAD (Non-Availability Determination) on file. For example: ***The items on record #'s 1 through 3 were manufactured in India. These items have received a Non-TAA compliant waiver/memo for record that will be placed in the file.*

Log Submit: is where the KO takes action on the log.

1) *Accept Log* approves the log. If you have disapproved individual items on the Items screen, accepting the log will only approve the individual items that you are approving and not the disapproved items.

2) *Reject Log* rejects the entire log

3) *Return to Buyer* sends the log back to the DAPA Administrator. If you need them to make a correction or add additional information before you approve it, use this option, and let them know what changes you need them to make before you will approve the log.

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ADDITIONAL NOTES

Items must be listed in First Data bank (FDB) for us to accept them on a DAPA. We use the FDB record to pull in the packaging and other information that is used in our catalog.

The repackagers (Avkare, PD-RX, Liberty) and companies that make custom labels and caps (Centor) create new items/package sizes of items all of the time and try to add them to their DAPA. We need to ensure that they have submitted the information to FDB first before we approve adding the item to the DAPA.

The FDB file can be found in the Medical (R) drive. Go to the FDB folder, and then the current year, and look for the most recent version of the file (usually we receive a new file weekly).

If the DAPA holder is not the manufacturer of the item, they must provide a letter from the manufacturer of the product authorizing them to sell the product to the Government (known as a Manufacturer Distribution Agreement).

This applies mostly to the repackagers (Avkare, PD-RX, Liberty). The IST Chief stressed this to all of these vendors in 2014, and the DAPA Administrators have reinforced it with them, so they all know that DLA will not approve adding an item without it. Many times they use the same supplier for many items, so one blanket letter can cover all items from the same manufacturer. The DAPA Administrator should add a comment in the Buyer's Item Comments field indicating that they have the MDA in the file (or similar language).

Acronyms and Abbreviations

- DHA** Defense Health Agency
- DLA** Defense Logistics Agency
- FAR** Federal Acquisition Regulation
- FSS** Federal Supply Schedule
- MDR** Military Health System Data Repository
- NDC** National Drug Code
- VA** Department of Veterans Affairs

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

Congressional Liaison

703.604.8324

Media Contact

public.affairs@dodig.mil; 703.604.8324

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

