

**STATEMENT OF THE
OFFICE OF INSPECTOR GENERAL
DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES
HEARING ON
THROUGH THE LOOKING GLASS: RETURN TO PPV
JUNE 6, 2012**

Chairman Miller and members of the Committee, thank you for the opportunity to discuss the results of a recent Office of Inspector General (OIG) report dealing with Pharmaceutical Prime Vendor (PPV) Fast Pay System and provide an update on our continuing work to review purchases that were allegedly made in violation of the PPV contract. The OIG is represented by Ms. Linda A. Halliday, Assistant Inspector General for Audits and Evaluations; Ms. Maureen Regan, Counselor to the Inspector General; Mr. Gary Abe, Director, OIG's Seattle Office of Audits and Evaluations; and Mr. Michael Grivnovics, Director of the OIG's Office of Contract Review, Federal Supply Service Division.

BACKGROUND

In 1994, VA implemented the PPV program to reduce the costs for storing and distributing pharmaceutical supplies. The McKesson Corporation was awarded the most recent PPV contract that expired on May 9, 2012. VA competitively awarded McKesson a long-term contract effective August 10, 2012; a bridge contract was established to ensure continuation of services in the interim. Use of the PPV is mandatory for VA pharmacies and optional for certain Other Government Agencies (OGAs) and authorized users, such as the Indian Health Service (IHS) and State Veterans Homes. In fiscal year (FY) 2011, VA purchased approximately \$4.3 billion pharmaceuticals from the PPV. The PPV contract is for distribution services only. Pharmaceutical pricing is established through Federal Supply Schedule (FSS) and other national contracts awarded by VA's National Acquisition Center (NAC). Except for local Veterans Integrated Service Network (VISN) contracts, contract pricing data in the PPV purchasing system is entered by VA, not McKesson. The issue that arose in 2011 was that VA and other agencies were using the PPV contract improperly to purchase pharmaceuticals and other items open market. A related issue was whether the fast payment procedures in the PPV contract resulted in a lapse in controls regarding the purchasing and receipt of products.

The Federal Acquisition Regulation (FAR) allows the use of fast payment procedures to help agencies meet payment timeliness requirements of the Prompt Payment Act. The PPV contract defines the Fast Pay system as an expedited payment procedure whereby payments are made to the PPV within 48 hours of shipment of an order. The current PPV contract requires all VA PPV orders to be processed using the Fast Pay system. The Fast Pay system procedures generally occur in the following sequence:

authorization and ordering; receipt of the invoice; payment approval and authorization; disbursement of funds; and receipt and acceptance of items ordered.

Fast Pay allows agencies to authorize and pay vendors after the vendor's invoice is received but prior to receipt and acceptance of the order. Payments are made when the invoice is received, based on the vendor's certification that it has delivered the supplies on the invoice and will remedy deficiencies in the supplies it delivers. The reliability of the Fast Pay system depends on promptly verifying that purchased items have been received, ensuring that receiving reports and payment documents match, and correcting discrepancies after payments have been made.

VA's Fast Pay system uses a U.S. Bank credit card-like account to pay the PPV for each VA pharmacy ordering facility's prime vendor purchases. When the PPV fills a facility's order, U.S. Bank processes the purchase through the facility's Fast Pay account using an electronic interface between the prime vendor and U.S. Bank. U.S. Bank pays the PPV each day for the orders it receives and transmits a daily transaction file of purchases to VA's Financial Services Center (FSC).

The FSC staff reviews the files before transmitting payment information to VA's Financial Management System (FMS). The FSC staff issues a single payment to U.S. Bank for the prior day's purchases from the PPV then charges each facility's prime vendor obligation account for the payment amount of the billed PPV pharmaceutical supplies. Facilities then reconcile payments made to the PPV with their prime vendor orders.

REVIEW OF THE CONTROLS FOR THE PHARMACEUTICAL PRIME VENDOR FAST PAY SYSTEM

In this report, which was done at the request of the Committee and the VA Secretary, we reviewed the internal controls of VA's Fast Pay System, specifically assessing the adequacy of VA's internal controls in support of the provisions of the PPV contract. We focused on the ordering, receipt of pharmaceuticals, and payment activities. Specifically, we examined the controls at four Consolidated Mail Outpatient Pharmacies (CMOPs), four VA Medical Centers (VAMCs) pharmacies, the payment controls at the FSC and the NAC, along with reviewing a sample of invoices. We also reviewed a sample of orders placed by Other Government Agencies¹.

Our review found:

- VA was consistently providing payments to the PPV within 48 hours from the prime vendor's shipment of an order.
- VA was paying the accurate amount for actual goods received.

¹ In February 2012, VA reported that State Veterans Homes, Howard University Hospital, the Indian Health Service, Bureau of Prisons, Peace Corps, U.S. Public Health Service, and Department of Homeland Security used the PPV contract.

- VA was processing payments to the PPV in accordance with laws, regulations, and current terms of the PPV contract.
- VA was reimbursed by other Government agencies in a timely and accurate fashion.
- VA did not have reliable controls to ensure timely correction of improper payments and the controls were not sufficient to reduce the risk of program fraud or abuse.

Accurate Prices for Actual Goods Received

Each week, at the eight VA facilities we reviewed, the staff reconciled their prime vendor purchases with summary payment reports provided by the FSC, ensuring that payment amounts were correct. VA financial management staff also researched FMS transactions that had been rejected during payment processing by the FSC and monitored the facility's PPV obligations. We did not identify reconciliations that were not resolved or unresolved exceptions such as open items on reconciliations, or rejected transactions that were not paid timely.

Seven of the eight ordering facilities had sufficient controls in place to ensure that pharmaceutical purchases were checked against invoices at delivery and discrepancies corrected.

Consistent Compliance with Federal Laws

We found VA uses Fast Pay provisions of the Prompt Payment Act to meet contractual requirements to pay the PPV within 48 hours of shipment of an order.

Other Government Agencies Reliance on PPV

The PPV contract allows other entities to use the PPV program and the Fast Pay system. According to FSC officials, only the Indian Health Service (IHS) used the Fast Pay system. In FY 2011, IHS purchased about \$46 million in pharmaceutical supplies, representing about 1 percent of the total \$4.3 billion of PPV purchases. We did not review PPV items purchased by OGAs that did not use VA's Fast Pay System because no VA funds were at risk of loss to VA.

IHS reimbursements were paid in the correct amounts, and IHS reimbursed VA within an average of 23 days from the date an order was placed. We considered IHS reimbursements to VA timely based on the Prompt Payment Act requirement that payment be made within 30 days.

Resolving Inaccurate Payments

Controls over corrections of overpayments are critical under the Fast Pay system since corrections are identified and adjustments made after payments are processed. In addition to our eight facilities, we reviewed procedures for identifying and resolving overpayments at the NAC and the Pharmacy Benefit Management (PBM) Services. We found no evidence that all of these responsibilities were properly executed.

PBM's business practice is to review prices for all pharmaceutical items purchased from the PPV each month, beginning 3 months after the purchase. For example, purchases made in July 2011 would be reviewed in October 2011. This delay allows sufficient time for price adjustments initiated by purchasing activities or the PPV to be adjusted to reflect correct amounts. PBM provides the NAC contracting officer a monthly price analysis, which shows differences between amounts paid and the contract prices for specific pharmaceutical items. The contracting officer is responsible for resolving PPV pricing anomalies.

PBM staff completed their March 2011 pricing analysis in August 2011 (2 months late). Their price analysis for April 2011 purchases was completed in December 2011 (5 months late). According to PBM officials, they reprioritized their work because the NAC's PPV contracting officer was not timely resolving potential pricing differences identified by the PBM and completing additional analyses would only have increased the contracting officer's backlog.

The process of resolving potential pricing differences, which the NAC put in place, had stopped. As a result, VA was at risk of not processing appropriate pricing adjustments. The total value of potential pricing differences identified by PBM for the monthly reviews of PPV purchases from December 2009 through April 2011 was approximately \$46.4 million. The contracting officer stated the primary reason for the delay in resolving pricing differences with the PPV was that he needed to use that time to prepare the future PPV contract. While we found that PBM and NAC controls did not reliably ensure timely correction of potential pricing differences, our subsequent work in the ongoing review of PPV open market purchases for FY 2011 has shown that these potential pricing differences had been satisfactorily resolved through the credit and rebilling process.

Facility pharmacy staff made timely payment corrections for overpayments. According to PPV records, the PPV reimbursed VA pharmacy facilities a total of approximately \$23.5 million (.5 percent of \$4.3 billion) in overpayment corrections and about \$15.4 million (.4 percent) in return credits in FY 2011. Pricing corrections occur for several reasons, such as retroactive price adjustments, item count errors, and product returns. For example, a retroactive price adjustment is required when the PPV changes a price of an item on January 5, 2012, but applies it to all purchases of that item from January 1, 2012. We determined that controls at VA facility pharmacies were considered adequate and that facility pharmacy staff made timely payment corrections for overpayments.

Protection Against Possible Fraud and Other Abuses

As the highest area of risk, we assessed pharmacy ordering and receiving operations to address whether VA has established controls to reduce the risk of fraudulent payments and other program abuses for PPV. At each pharmacy, we assessed whether the ordering and receiving duties of pharmacy staff were adequately segregated.

In general, we determined controls were not effective in mitigating the risk of program fraud. Segregation of duties is a strong fundamental control in ordering and receiving functions. Duties such as ordering supplies, receiving supplies, making payments, and certifying funding should be assigned to separate individuals to the greatest extent possible. By separating certain duties within an organization, no single employee should be in the position to perpetrate and conceal fraud. For example:

- Three of four VAMC pharmacies needed to strengthen controls to ensure an adequate segregation of duties existed. They did not segregate duties among different staff to prevent any one individual from having the ability to both order and receive non-controlled pharmacy supplies. With regard to controlled substances, at the four VAMC pharmacy the duties were properly segregated.
- The four CMOPs had adequate controls to segregate duties among designated ordering officers and staff who verified that ordered items were received. Controls in place were working effectively to ensure ordering officers and receiving staff held separate system access keys to log into the prime vendor account. At no point were individuals allowed to perform ordering and receiving functions. VA policy requires CMOPs establish unique individual user identification and passwords for all functions related to inventory maintenance and control, to include ordering and receiving on the PPV and CMOP automated inventory systems.

QUANTIFYING OPEN MARKET AND PRICING ISSUES

Currently we are completing our review of PPV purchases for FY 2011. The purpose of the review is to quantify the open market sales, identify reasons why items were not purchased through existing contracts, and evaluate whether VA was overcharged for items on contract. We also reviewed purchasing data for December 2011, to verify the accuracy of the reported 0.4 percent in open market purchases for that month and validate whether controls implemented in November 2011 were effective in controlling open market purchases. In addition, we are reviewing open market purchases to determine whether they violated procurement laws and regulations and whether the purchases were in compliance with the *Trade Agreements Act*. We expect to issue a final report in July 2012. We also have reviewed the new PPV contract to determine if additional terms and conditions will reduce open market purchases.

FY 2011 Open Market Purchases

Our review found that it is not possible to easily quantify open market purchases by simply reviewing purchasing data captured for a specific period of time. Due to delays in processing new pricing through contract modifications and entering the information into the PPV system, purchasing information is updated continually by McKesson through a system of credits and rebills. This process corrects data relating to whether the item was on contract versus open market and adjusts the price paid to reflect the correct contract pricing.

We identified \$4.3 billion in overall reported sales in FY 2011 of which approximately \$290 million was identified as open market because there was no underlying contract number listed in the appropriate data field. Approximately \$283 million of the \$290 million represented pharmaceutical purchases and remaining \$7 million represented medical/surgical items.

We selected 100 of the top pharmaceutical items identified as open market for review, which represented \$108 million (43 percent) of the open market pharmaceutical purchases.

- We found that 43 of the 100 items (\$63 million) were on contract at the time of purchase. This represents 58 percent of the dollar value of 100 items in our sample. Of the 43 items, 29 (\$36 million) were sold at the contract price. The 14 remaining items (\$27 million) were sold at a price that exceeded the contract price with potential overcharges of \$9.4 million. However, upon further review, we found that \$5.5 million of the potential overcharges was due to product allocation², not overcharging, and the remaining \$3.9 million related to delays in contract pricing adjustments, which appear to have been corrected through the credit and rebilling process.
- We determined that 48 of the 100 items were not on contract for all or part of FY 2011. These items represented \$36 million (33 percent) of the open market purchases in our sample. We identified comparable items on FSS contracts for 15 of the 48 items (\$9.1 million). For 12 of the 15 items, (\$7.6 million), the FSS prices were lower. However, we found that many of the comparable items on FSS were not available at the time of purchase due to manufacturer shortages and backorder issues. We concluded that for those items that a comparable FSS product was available, VA paid \$904,000 more than it would have paid if the contract item had been purchased. Although the prices paid for the remaining 3 items (\$1.5 million in purchases) were less than the FSS price, the items should have been purchased from the FSS as required by VA policy. We could not identify with any degree of certainty a comparable item on FSS for the remaining 33 items (\$26.6 million). These items were purchased at McKesson's list price.
- We also identified 9 items (\$8.6 million) that were on FSS but purchased at open market prices through the PPV. Most of these were covered or branded drugs on FSS at the Federal Ceiling Price, which is the highest price VA can pay when purchasing from the manufacturer or the manufacturer's authorized distributor. Because the FSS contractor elected not to participate in the PPV program, the PPV is not required to offer the FSS price. These purchases resulted in up to \$4.8 million in overpayments. We have not identified a legitimate reason to justify purchasing these products open market through the PPV instead of the manufacturer. We initially identified this problem through our post-award reviews

² For some pharmaceuticals VA is guaranteed a fixed quantity. VA can purchase additional quantities but those would be at open market prices.

and raised this issue to VA in 2007 and again in 2011. In 2007, we were told that the PPV purchasing system was changed to block purchasers from buying these products through the PPV. However, in 2011, when we found the problem continuing, we learned that at VA's request the system allows the purchaser to override the block.

We concluded that McKesson has done a good job of correcting pricing through credits and rebilling when the PPV database is updated by VA to include changes in contract pricing. However, we believe delays in identifying and correcting contract pricing are caused by poor communication between PBM and the NAC's FSS and National Contracts divisions.

Review of December 2011 Purchases

We reviewed the accuracy of VA's reported 0.4 percent in open market sales through the PPV contract for December 2011. However, we found the procedures implemented in November 2011 did not preclude or prohibit open market purchasing. Instead, open market purchases were shifted from the PPV contract to other financing accounts. We reviewed purchases through the new open market purchasing system and identified approximately \$7 million in purchases, which represented 2.0 percent of the total purchases by VA through McKesson. The percentage of open market purchases by VA through McKesson was approximately 2.4 percent, not 0.4 percent as reported. Our review of open market purchasing trends under the new system was inconclusive because a large number of the products were actually on contract.

In addition to reviewing the purchases identified in the FY 2011 data as open market, we sampled items identified as contract sales. We did not find significant problems with overcharging. As with the open market items, corrections are made over time as adjustments to the contract price are awarded and entered into the PPV system.

Open Market Issues

Based on our review and our ongoing pre-award and post-award audits of FSS contracts, we believe that open market purchasing through the PPV is impacted by several factors including items not on contract but needed to provide care, a growing number of product allocations and shortages necessitating purchasing items at non-contract prices, and purchasing items through the PPV for convenience instead of buying direct from manufacturers who do not participate in the PPV program. A growing number of items are not on contract because there is no requirement that manufacturers offer generic drugs on FSS contracts. In addition, a growing number of products are no longer manufactured in the United States or a designated country and thus cannot be offered on contract due to *Trade Agreement Act* requirements. We are currently reviewing open market purchases to determine whether the purchasers violated Federal procurement laws and regulations, including the *Trade Agreements Act*.

Review of Terms and Conditions in Recently Awarded PPV Contract

We also reviewed the changes made to the new PPV contract to determine if such changes will preclude open market purchasing and if prices paid for products previously classified as open market will be fair and reasonable. The new PPV contract states non-contract (open market) items are excluded from the PPV contract and Ordering Officers are prohibited from buying open market items through the PPV contract. Generic items that are not on a Federal government contract and have a published Wholesale Acquisition Cost (WAC), are approved by the Food and Drug Administration, and are compliant with the *Trade Agreements Act*, can now be purchased through the PPV contract at a price negotiated prior to award. These products are known as WAC Based Priced Generics (WBPG). For the most part, open market purchases should decrease significantly with the availability of WBPGs. However, open market purchases can still occur by buying such open market products via a different payment account. Such purchases are not considered a PPV purchase because they are not processed through the PPV account.

We are also concerned that FSS vendors who sell generic products may remove their products from their FSS contracts and have them sold by the PPV as WBPGs. The FSS will no longer receive a discount off the FSS vendor's list price but will pay the listed WAC price less a discount equal to the awarded distribution fee. Based on our experience conducting pre-award reviews of proposals for FSS contracts, we have concerns whether the negotiated PPV price for these generic products is fair and reasonable.

CONCLUSION

VA has implemented controls to provide timely and accurate payments for pharmaceutical items processed through VA's Fast Pay system as well as following laws, regulations, and policies. However, system controls to identify and correct pricing differences by the PPV and to reduce the risk of fraud and other program abuses were either not in place or were not effective. Without strong system controls, VA risks paying the incorrect price for pharmaceuticals as well as increasing their vulnerability to program fraud.

Our review of open market purchases found that the open market purchases were significantly less than originally stated. We found that McKesson was doing a good job of adjusting prices through credits and rebillings to ensure that contract items are purchased at contract prices when VA provides data. It is not uncommon for pricing changes to be implemented months after the fact due to delays in contract modifications that result in retroactive pricing. In addition, due to product shortages and allocations, VA does not always get contract pricing.

Mr. Chairman, this concludes our statement and we would be pleased to answer any questions you or other members of the Committee may have.