DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Contract Review

OFFICE OF ACQUISITION, LOGISTICS, AND CONSTRUCTION

A Synopsis of OIG Preaward Reviews of VA Federal Supply Schedule Pharmaceutical Proposals Issued in Fiscal Year 2018

REVIEW | REPORT #19-07113-223 | SEPTEMBER 19, 2019

The mission of the Office of Inspector General is to serve veterans and the public by conducting effective oversight of the programs and operations of the Department of Veterans Affairs through independent audits, inspections, reviews, and investigations.

Report suspected wrongdoing in VA programs and operations to the VA OIG Hotline:

www.va.gov/oig/hotline

1-800-488-8244

Executive Summary

Since 1993, the VA Office of Inspector General's (OIG) Office of Contract Review has performed preaward reviews of Federal Supply Schedule (FSS) pharmaceutical proposals made to VA valued at $5 million or more.[1] The primary purposes of preaward reviews are to provide an opinion as to whether the proposal and disclosures are accurate, complete, and current. The reviews also make pricing and tracking customer recommendations based on the offeror's commercial selling practices. Preaward reports are used by contracting officers to negotiate fair and reasonable prices for the government and taxpayers.

Preaward reports are not published due to the sensitive commercial information contained in them. Thus, to promote transparency, this report provides a synopsis of the 22 preaward reviews of pharmaceutical proposals that the OIG conducted during fiscal year (FY) 2018. It details how many proposals were not accurate, complete, or current and provides summary information related to pricing and other recommendations made in the preaward reports that inform contracting officers' decisions. These 22 OIG preaward reviews collectively resulted in $386.5 million in savings for VA. The cumulative 10-year estimated contract value for the 22 proposals submitted for review was approximately $28 billion. The 22 proposals collectively included 2,040 offered drug items.

Of particular importance, one of the 22 preaward reviews recommended that no award be made in response to a pharmaceutical proposal from a "virtual" reseller with no commercial sales. As VA may receive additional proposals like this in the future, the information provided in this report can help guide consistent treatment of these types of proposals going forward.

This report is meant to provide VA and its stakeholders general information regarding the findings of the OIG's 22 preaward reviews and demonstrates the importance and the value of preaward reviews, and as such, does not contain any formal recommendations for VA response. Highlighting key data and summarizing findings from the most recent fiscal year's nearly two dozen preaward reviews will provide VA leaders with additional perspective on how its contracting personnel can make the most effective use of VA resources.

Mark A. Myers

MARK A. MYERS
Director, Healthcare Resources Division
Office of Contract Review

[1] The VA FSS program supports the healthcare acquisition needs of VA and other federal government agencies.

Contents

Executive Summary i

Abbreviations iii

Introduction 1

A Synopsis of FY 2018 Pharmaceutical Preaward Reviews 3

Appendix A: Estimated and Sustained Cost Savings for Reviews Conducted in FY 2018 10

OIG Contact and Staff Acknowledgments 11

Report Distribution 12

Abbreviations

CSP	commercial sales practices
FSS	Federal Supply Schedule
FY	fiscal year
GSA	U.S. General Services Administration
MFC	most favored customer
OCR	Office of Contract Review
OIG	Office of Inspector General

Introduction

The VA Office of Inspector General (OIG) performs preaward reviews of Federal Supply Schedule (FSS) proposals for various VA-awarded medical product contracts. VA and other government agencies spend billions of taxpayer dollars annually through VA's FSS program. The OIG's Office of Contract Review (OCR) evaluates pharmaceutical and nonpharmaceutical proposals that have an anticipated annual contract value of at least $5 million and $3 million, respectively. Preaward reviews are required by VA policy to facilitate informed decision-making and help prevent fraud, waste, and abuse.

Purpose

The findings and recommendations in OIG preaward reports are intended as a resource for VA contracting officers in negotiating fair and reasonable pricing with vendors. The purpose of OCR conducting preaward reviews is to validate the commercial disclosures required in the vendor's proposal and to identify any lower prices than offered to the government that are comparable commercial sales of the products or services. It is the responsibility of the contracting officer to negotiate the actual price with the vendor.

One of the primary acquisition programs for which the OIG provides preaward and other contract review services is VA's FSS program. The FSS program provides the government a simplified process for acquiring commercial supplies and services in varying quantities while obtaining volume discounts.[2] The purpose of this report is to provide a summary of the findings and impact of the OIG's 22 preaward reviews of FSS pharmaceutical proposals made to VA in fiscal year (FY) 2018.

Background

The U.S. General Services Administration (GSA) delegated authority to VA to award and administer nine FSS programs or schedules to support the healthcare acquisition needs of VA and other government agencies.[3] Federal agencies purchased more than $14 billion in products and services through the nine different commodity and services schedules during FY 2018.[4] Nearly 80 percent of that spending was through the FSS pharmaceutical schedule contracts.

Because of the magnitude of spending through the VA schedule program, VA has established regulations, policies, and procedures to help ensure the government is getting the best prices for pharmaceutical and other medical products and the FSS vendors are following all the terms and

[2] 41 U.S.C. § 152(3); Federal Acquisition Regulation 8.402.

[3] Federal Acquisition Regulation 8.402 General; see also, https://interact.gsa.gov/blog/va-federal-supply-schedules.

[4] VA FSS Newsletter, February 2019, Issue 63.

conditions of their FSS contracts. This included VA establishing a robust preaward and postaward contract review program.

Since 1993, the OIG's OCR has performed preaward reviews of FSS pharmaceutical proposals made to VA. Subsequently, VA established a regulation that assigned Contract Audit Services for FSS and other contracts awarded by the VA National Acquisition Center to the OIG's OCR as required.[5] Typical services include preaward and postaward reviews, public law compliance reviews, and other advisory services associated with the award and modification of the schedules and other contracts awarded by the VA National Acquisition Center.

Additionally, VA established written policy that sets forth criteria and procedures for requesting a review by the OIG of proposals and contracts submitted under or related to contracts or solicitations issued by the VA National Acquisition Center.[6] This written policy requires all FSS pharmaceutical proposals with an estimated annual contract value equal to or greater than $5 million to be submitted to the OIG for a preaward review.

[5] VA Acquisition Regulation 842.102; see also Procedural Guideline #22 – OIG Contract Review Procedures.

[6] Procedural Guideline #22 – OIG Contract Review Procedures.

A Synopsis of FY 2018 Pharmaceutical Preaward Reviews

The OIG conducted 22 preaward reviews of FSS pharmaceutical proposals during FY 2018. The main purpose of an OIG preaward review is to assist the VA's contracting office or authorized component (referred to as contracting activity) in establishing and maintaining fair and reasonable pricing on the awarded FSS contract.[7] This is accomplished through three primary review objectives:

1. Provide an opinion as to whether the commercial sales practices (CSP) disclosures in the proposals are accurate, complete, and current
2. Evaluate offered prices and rebates and provide pricing recommendations
3. Determine if the proposed tracking customers are appropriate for price reductions clause purposes

The cumulative 10-year estimated contract value for the 22 proposals submitted for review was approximately $28 billion. The 22 proposals collectively included 2,040 offered drug items. The OIG preaward reviews are generally limited to offered items that represent at least 75 percent of historical government sales. The 22 proposals included the review of 241 of the 2,040 offered items, yet represented approximately $22 billion of the total 10-year estimated contract value ($28 billion). The OIG's reported findings in each of the 22 issued pharmaceutical preaward reviews are summarized in the following sections.

Evaluation of Commercial Sales Practices Disclosures

The OIG's preaward reviews found CSP disclosures to be accurate, complete, and current for only five of the 22 proposals. This means that these five proposals were reliable for determining negotiation objectives and ultimately fair and reasonable pricing using the commercial pricing information in the CSP disclosures. Among the remaining 17 proposals, 16 were not accurate, complete, or current and could not reliably be used for negotiations until the noted deficiencies were corrected and resubmitted by the offeror. For one proposal, the OIG recommended that the contracting specialist not award the contract due to the nature of the vendor's proposal.

Government contracts generally require competition among vendors to ensure that awarded prices are fair and reasonable. For FSS contracts, there is no competition among bidders at the time of the award. Under the FSS program, vendors disclose their commercial prices and terms and conditions on the CSP form in FSS proposals. This disclosed information is used by the

[7] "Contracting activity" refers to the agency component designated by the agency head that is delegated broad acquisition authority (Federal Acquisition Regulation § 2.101).

contract specialist to evaluate the proposed prices, set the negotiation objectives, and determine whether the offered prices are fair and reasonable. Therefore, it is critical that CSP disclosures are accurate, complete, and current, so VA can make a fair and reasonable price determination.

The CSP section of the FSS pharmaceutical solicitation includes instructions on what the offeror should disclose to the government.[8] The instructions state if the offeror is proposing prices that are better than or equal to the most favored customer (MFC) prices, then those customers and MFC prices are to be disclosed.[9] If that is not the case, the offeror is required to disclose all commercial prices that are equal to or better than those prices offered to the government and to disclose all customers or customer categories who are receiving those prices.

Additionally, the offeror is required to provide enough information as to how customers may earn prices or discounts that are better than offered to the government. If there are any deviations to the CSP disclosures or exceptions to the disclosed commercial prices that are lower than offered, the offeror may be required to disclose that information to the government.

If an offeror is a reseller with no significant commercial sales, the respective manufacturer(s) of the offered items should provide CSP disclosures in accordance with the CSP instructions. Because for one proposal the OIG recommended not awarding the contract, Table 1 lists the findings and their occurrences among the 16 proposals with CSPs that were found not accurate, complete, or current.

Table 1. Commercial Sales Practices Findings

CSP findings	Occurrences among the 16 proposals
1. Incorrect most favored customers disclosed	7
2. Incorrect most favored customer prices/discounts disclosed	3
3. Discount ranges disclosed without required information	4
4. All most favored customers were not disclosed	1
5. All discounts equal to or better than offered not disclosed	2
6. Rebates to pharmacy benefit managers not disclosed	3

Source: Analysis of CSP disclosures
Some proposals may have more than one occurrence, so numbers will not sum to total.

The common reasons for the first five CSP findings listed in Table 1 included the offeror making errors, not understanding the CSP instructions, or expressing a difference of opinion about what should have been disclosed in the CSP (for example, excluding distributor pricing that is lower than offered because they are not considered comparable to the government).

---

[8] VA FSS Solicitation No. M5-Q50A-03-08, Attachment 02 – Vendor Response Document.

[9] MFC is defined as the commercial customer who receives the best up-front discount.

Other reasons or explanations for disclosed discounts being incorrect included the MFC or other commercial contract pricing expiring after the proposal was submitted for review; the wholesaler acquisition cost price list on which MFC prices are based expiring; or the disclosed MFC prices excluding the effect of rebates. Wholesaler acquisition cost prices are usually prices established by manufacturers before discounts or rebates or any other price concessions are applied.

Pharmacy benefit managers were not disclosed as customers because offerors either were directed by the contract specialist to exclude them or the vendor determined that they were not actual customers as they do not take possession of the products that are being sold. These customers do not negotiate up-front prices; instead, they negotiate rebate payments from manufacturers. Rebates are generally applied to the wholesaler acquisition cost prices, and retail pharmacy utilization data is used to determine a certain amount paid to pharmacy benefit managers to influence a preferred formulary placement. A formulary is a list of prescription drugs used by doctors to identify drugs that provide the best value.

The ultimate price paid by pharmacy benefit managers for drugs via the retail pharmacy is unknown. However, these rebate payments reduce a manufacturer’s revenue from sales of products. The CSP instructions make no exception for pharmacy benefit manager rebates and should be included in CSP disclosures.

Evaluation of Offered Prices

Among the 22 proposals reviewed, the OIG determined that prices offered to the government were higher than the MFC prices in 16 proposals and lower than or equal to the MFC prices in five proposals. Offered prices in one proposal were not considered for review due to the nature of the vendor’s proposal.[10]

The OIG made recommendations for lower prices than offered for 11 proposals, resulting in total recommended cost savings of approximately $516 million. The 11 proposals with lower-than-offered price recommendations included 120 of the 241 sampled items (49.8 percent) that were reviewed. Rebates were not offered among the proposals reviewed. However, price recommendations among three proposals included the effect of rebates because the OIG determined that the FSS was meeting purchase requirements for the respective rebates based on historical sales data.

Of the 22 pharmaceutical proposals that were submitted to the OIG for review, the VA National Acquisition Center awarded nine contracts with sustained cost savings of approximately $386.5 million (75 percent of recommended cost savings) over the life of the contract. Additionally, VA did not award the one proposal that was not considered for review because of the vendor’s business arrangement. Approximately 91 percent of the sustained cost savings resulted from one

[10] This proposal was not reviewed because the offeror did not meet the vendor definition in the VA FSS solicitation. This proposal is discussed later in the report.

review. See appendix A for more information regarding the dollar impact of the OIG's preaward reviews.

The objective of the FSS program is to achieve MFC pricing or better for the government. GSA states that the government will seek to obtain the offeror's best price (the best price given to the MFC). However, the government recognizes that the terms and conditions of commercial sales vary and there may be legitimate reasons why the best price is not achieved.[11] Additionally, GSA and Federal Acquisition Regulations indicate that the benefit of the FSS program is competitive, market-based pricing that leverages the volume buying power of the entire federal government.[12]

Furthermore, GSA states that when establishing negotiation objectives and determining price reasonableness, the contract specialist must compare the terms and conditions of the FSS solicitation with the terms and conditions of agreements with the offeror's commercial customers, and when determining the government's price negotiation objectives, the aggregate volume of anticipated purchases, among other factors, must be considered.[13]

When evaluating offered prices, the OIG considers the objective of the FSS program and implements GSA and Federal Acquisition Regulations guidance when making price recommendations. Table 2 provides a summary of reasons some offerors chose not to offer MFC prices among the proposals reviewed.

Table 2. Rationale for Not Offering MFC Prices

Rationale	Occurrences
Not meeting sales volume requirements	3
Not committing to purchase requirements	3
Not providing required market share	1
Not meeting formulary and sole source purchasing requirements	2
Not meeting formulary requirements	1
Most favored customer prices restricted to a customer type	3
No Adequate reason	3
Total	**16**

Source: Analysis of offered prices

In some cases, the offerors' arguments were valid for not offering MFC pricing to the government. However, in many instances, the respective arguments were weakened by the offerors' inconsistent pricing practices or not considering the government's sales volume.

[11] GSA Manual 538.270-1(c).

[12] GSA Multiple Award Schedules Desk Reference (Spring 2019); Federal Acquisition Regulation 8.402.

[13] 48 CFR § 538.270-1(e); GSA Manual 538.270-1.

Among the 11 proposals for which the OIG recommended negotiating prices lower than offered, the government's overall FSS sales of offered items and/or total units purchased per sampled item were greater than that of the MFCs or customers receiving a price lower than offered. In those cases, the OIG would recommend the MFC price or a price lower than offered regardless of the government's inability to commit to meeting purchase or sole source requirements because the government's historical purchases met or exceeded the committed volumes of the commercial accounts.

Evaluation of Proposed Tracking Customers

Awarded FSS contracts are firm-fixed price contracts for a period of up to 10 years, consisting of a five-year base period and up to five one-year option periods. The GSA price reductions clause is a provision that mandates reductions to the FSS contract prices based on tracking customer price reductions.[14] This contract clause requires the government and the offeror to agree upon a customer or category of customers that will be the basis of the award (tracking customer), and the government's price or discount in relationship to the identified tracking customer. This relationship shall be maintained throughout the contract period.

The OIG determined that 1,389 of the 2,040 offered items among 21 proposals included tracking customers that were not adequate for purposes of the GSA price reductions clause. For nearly 70 percent of the 1,389 offered items, vendors proposed a tracking customer that had less sales volume than the FSS sales volume, were not among the vendor's largest commercial customers, and/or received some of the highest prices given to commercial customers.

Other reasons the proposed tracking customers were not accepted were generally because the offered items were not on their contracts or they were wholesalers. Typically, wholesalers are not acceptable tracking customers because they simply pay wholesale acquisition cost prices or very minimal discounts for offered items. Therefore, wholesalers' prices would most likely increase, not decrease, during the prospective FSS contract period.

Any change in the contractor's commercial pricing or discount arrangement applicable to the identified tracking customer that disturbs this relationship shall constitute a price reduction.[15] The price reductions clause stipulates when the contractor is to report price reductions provided to the tracking customer. For example, if the government's awarded price for a product is $100 and the tracking customer's price at award is $100, the tracking ratio is one to one. If a tracking customer's price is reduced to $90, then the government's price shall be reduced to $90 to maintain the awarded tracking customer ratio of one to one. This arrangement helps ensure the government is receiving fair and reasonable pricing during the contract period.

[14] GSAM 552.238-75.

[15] GSAM 552.238-75.

For the 1,389 offered items with proposed tracking customers that were determined inappropriate, the OIG recommended different tracking customers that were generally among the offeror's largest commercial customers or MFCs. Commercial customers that generate a large sales volume and that are an offeror's MFCs, generally maintain competitive low prices. The VA National Acquisition Center was able to sustain the OIG's recommended tracking customers for 1,167 of the 1,389 items (84 percent) during negotiations.

Other Important Matters

Offerors that classify themselves as resellers, dealers, or distributors and have no commercial sales continue to present challenges for the FSS program. Historically, this issue has been more prevalent on the Medical Equipment and Supplies schedule; however, there are some indications that offers from resellers, dealers, or distributors with no commercial sales on the pharmaceutical schedule are increasing. The National Acquisition Center needs to take steps to ensure offerors without any commercial sales are legitimate resellers, dealers, or distributors and not simply representing manufacturers or other entities for the purposes of an FSS contract.

During FY 2018 the OIG received a request to conduct a preaward review of a pharmaceutical proposal from a reseller with no commercial sales. The vendor did provide CSP data from the manufacturers of the drugs. The OIG determined that the vendor did not, however, have a pricing agreement with the manufacturers for the products it was offering to sell to the government nor did it purchase any of the offered products from the manufacturers for resale.

The OIG further determined that there was no acquisition pricelist established between the offeror and its manufacturers, and the offeror does not sell the products to drug wholesalers, nor does it process any chargebacks from drug wholesalers.[16] The offered drugs are sold from the manufacturers to drug wholesalers, and chargebacks from FSS sales, under the offeror's anticipated FSS contract, are processed directly to the manufacturers. The offeror stated it receives a commission from the manufacturers on the FSS sales.

In addition, the offeror's website describes its capabilities as arranging for direct distribution to government pharmacies when the offeror's partners are uninterested or not capable of bidding directly. This statement, in concert with the fact that the offeror does not handle the product or handle the money, but rather, receives a commission from the manufacturers, makes it appear that the offeror is simply engaged by the manufacturers to manage the FSS contract on behalf of the manufacturers rather than a legitimate dealer or reseller.

[16] Drug wholesalers generally buy pharmaceuticals in bulk from manufacturers at the wholesale acquisition cost (nondiscount prices). A chargeback represents the difference between a wholesale acquisition cost and a manufacturer-negotiated contract price that the wholesaler honors when it sells products to a contract holder. Wholesalers would lose money if chargebacks were not paid back by the manufacturer.

The FSS program requires the vendor to be a manufacturer/producer, service establishment, dealer (reseller), and/or distributor. During the OIG review, the offeror described itself as a *virtual distributor*, and stated that it does not take possession or distribute any of the manufacturers' products. The offeror stated that it does not actually purchase the product or receive revenue from the sale of the product to the government and that it will basically hold and manage an FSS contract for pharmaceutical manufacturers.

Based on the findings of the preaward review, the OIG did not evaluate the reliability of the CSP or make any pricing recommendations, but issued a report recommending no award be given. The contract specialist concurred with the OIG's findings and recommendation and issued a no-award decision to the offeror.

Conclusion

The federal government spends more than $11 billion annually on pharmaceuticals through VA's FSS program. VA's robust acquisition regulations and policy governing the OIG's preaward reviews continues to demonstrate their value in helping VA identify offers with CSP disclosures that are not accurate, complete, and current. The OIG's preaward reviews demonstrate the importance of having reliable information for negotiations and determining fair and reasonable pricing. The OIG findings and recommendations contained in the preaward reports help VA contracting officers reduce the cost of drugs, saving taxpayers $386 million on proposals reviewed and awarded in FY 2018 alone.[17]

[17] The Office of Acquisition, Logistics, and Construction had no comments for inclusion in this report.

Appendix A: Estimated and Sustained Cost Savings for Reviews Conducted in FY 2018

Report count	Date issued	OCR's estimated cost savings	VA's sustained cost savings	Percentage of estimated cost savings realized	Date awarded
1	10/17/2017	$353,952,920	$352,320,848	99.5%	7/9/2018
2	11/1/2017	$14,925,958	$14,925,958	100.0%	2/14/2018
3	11/8/2017	$0	$0	Not Applicable	4/2/2018
4	11/8/2017	$0	$0	Not Applicable	2/7/2018
5	11/22/2017	$0	$0	Not Applicable	4/27/2018
6	12/21/2017	$45,750,393	$117,728	0.3%	4/9/2018
7	1/29/2018	$466,912	$0	0%	8/1/2018
8	2/1/2018	$37,149,340	$0	0%	8/15/2018
9	3/8/2018	$8,237,131	$8,237,131	100.0%	9/25/2018
10	4/11/2018	$0	$0	Not Applicable	Pending
11	4/12/2018	$0	$0	Not Applicable	8/8/2018
12	4/16/2018	$0	$0	Not Applicable	6/28/2018
13	4/17/2018	$45,967,554	$6,204,815	13.5%	11/19/2018
14	5/4/2018	$24,963	$940	3.8%	7/16/2018
15	5/15/2018	$2,654,631	$166,398	6.3%	9/10/2018
16	6/20/2018	$4,297,090	$4,297,090	100.0%	8/31/2018
17	6/28/2018	$0	$0	Not Applicable	5/6/2019
18	7/3/2018	$0	$0	Not Applicable	Pending
19	8/9/2018	$2,509,291	$227,611	9.1%	9/26/2018
20	8/30/2018	$0	$0	Not Applicable	9/25/2018
21	9/5/2018	$0	$0	Not Applicable	No Award
22	9/19/2018	$0	$0	Not Applicable	Pending
Total		**$515,936,183**	**$386,498,519**	**74.9%**	

Source: OIG reports and VA National Acquisition Center contract files
Note: OCR's estimated cost savings is the difference between offered prices and OIG recommended prices multiplied by a historical order volume and extrapolated over a 10-year contract period. VA's sustained cost savings is the estimated cost savings based on the final prices awarded by the contracting officer. Overall, VA was able to sustain nearly 75 percent of the total estimated cost savings among preaward reviews that had lower-than-offered price recommendations. The OIG recommended that VA accept offered prices in 10 reports, and one report recommended no award because the offeror did not meet the definition of a vendor in VA's solicitation.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Review Team	Joseph Houston Cliff Rybick Mike Wazybok

Report Distribution

VA Distribution

Office of the Secretary
Veterans Benefits Administration
Veterans Health Administration
National Cemetery Administration
Assistant Secretaries
Office of General Counsel
Office of Acquisition, Logistics, and Construction
Board of Veterans' Appeals

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
House Committee on Oversight and Reform
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget

OIG reports are available at www.va.gov/oig.

.