DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Contract Review

OFFICE OF ACQUISITION, LOGISTICS, AND CONSTRUCTION

A Synopsis of Preaward Reviews of VA Federal Supply Schedule Pharmaceutical Proposals Issued in Fiscal Year 2019

REVIEW | REPORT #20-00010-151 | JUNE 30, 2020

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.

In addition to general privacy laws that govern release of medical information, disclosure of certain veteran health or other private information may be prohibited by various federal statutes including, but not limited to, 38 U.S.C. §§ 5701, 5705, and 7332, absent an exemption or other specified circumstances. As mandated by law, the OIG adheres to privacy and confidentiality laws and regulations protecting veteran health or other private information in this report.

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 pharmaceutical proposals made to VA valued annually at $5 million or greater.[1] The primary purposes of preaward reviews are to provide an opinion as to whether the proposal and disclosures are accurate, complete, and current, and to make pricing and tracking customer recommendations based on the offeror's commercial selling practices. Preaward reviews are used by contracting officers to negotiate fair and reasonable prices for the government and taxpayers.

Preaward reviews are not published due to the sensitive commercial information contained in them. Thus, to promote transparency, this report (the second in a series) provides a synopsis of the 19 preaward reviews of pharmaceutical proposals that the OIG conducted during fiscal year 2019. 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 reviews that inform contracting officers' decisions. Negotiations for 14 of 19 OIG preaward reviews have been completed as of May 8, 2020, and the OIG's recommendations have collectively resulted in approximately $203 million in savings for VA. The cumulative 10-year estimated contract value for the 19 proposals submitted for review was approximately $21 billion. The 19 proposals collectively included 862 offered drug items.

This report is meant to provide VA and its stakeholders general information regarding the findings of the OIG's 19 preaward reviews and demonstrate the importance and the value of preaward reviews. Accordingly, it does not contain any formal recommendations for VA response.

Highlighting key data and summarizing findings from the most recent fiscal year's 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

Abbreviations

CSP	Commercial Sales Practices
FAR	Federal Acquisition Regulation
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 non-pharmaceutical 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 reviews are intended as a resource for VA contracting officers in negotiating fair and reasonable pricing with vendors. OCR conducts preaward reviews to validate the commercial disclosures required in the vendor's proposal and to identify any lower prices than offered to the government for products or services and those situations or considerations on which the better pricing is based. 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 19 preaward reviews of FSS pharmaceutical proposals made to VA in fiscal year (FY) 2019.

Background

The U.S. General Services Administration (GSA) has delegated authority to VA to award and administer nine FSS award schedule programs to support the healthcare acquisition needs of VA and other government agencies.[3] The goal of the FSS Service is to leverage the entire federal government's purchasing power to drive volume-based discounts that provide healthcare solutions at fair and reasonable prices to all authorized FSS users.[4] Federal agencies purchased more than $15 billion in products and services through the nine different commodity and services

[2] 41 U.S.C. § 152(3); FAR 8.402.

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

[4] FAR 38.000, "Scope of Part," 38.101(d), "General," 8.402(a), "General," and 8.404(d), "Use of Federal Supply Schedules."

schedules during FY 2019.[5] Nearly 81 percent of 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 that the government is getting the best prices for pharmaceutical and other medical supplies and that FSS vendors are following all the terms and 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 OCR.[6] 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.[7] 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] FSS activity information data FY 2019, submitted by the VA National Acquisition Center.

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

[7] Procedural Guideline #22-OIG Contract Review Procedures.

A Synopsis of FY 2019 Pharmaceutical Preaward Reviews

The OIG conducted 19 preaward reviews of FSS pharmaceutical proposals during FY 2019. 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.[8] 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 19 proposals submitted for review was approximately $21 billion. The 19 proposals included 862 offered drug items. OIG preaward reviews are generally limited to offered items that represent at least 75 percent of historical government sales. The 19 proposals included the OIG's review of 136 of the 862 offered items. Those 136 items represented approximately $17 billion of the total 10-year estimated contract value ($21 billion). The OIG's reported findings in each of the 19 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 19 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. The remaining 14 proposals 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.

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 contract specialist to evaluate the proposed prices, set the negotiation objectives, and determine

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

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.[9] 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.[10] 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. Table 1 below lists the findings and their number of occurrences among the 14 proposals with CSPs that were found not accurate, complete, or current.

Table 1. Commercial Sales Practices Findings

CSP Findings	Occurrences among the 14 proposals
Incorrect most favored customers disclosed	4
Incorrect most favored customer prices/discounts disclosed	8
Discount ranges disclosed without required information	1
All most favored customers were not disclosed	3
Rebates to pharmacy benefit managers not disclosed	3
Total	**19**

Source: Analysis of CSP disclosures
Note: Some proposals may have more than one finding, so the sum will not total to 14.

Common reasons for the CSP findings in Table 1 generally include the offeror making mistakes, misunderstanding the CSP instructions, or expressing a difference of opinion about what should have been disclosed in the CSP (for example, excluding distributor or pharmacy benefit managers pricing that is lower than offered because they are not considered comparable to the government).

[9] VA FSS Solicitation No. M5-Q50A-03-08, Attachment 02- Vendor Response Document
[10] MFC is defined as the commercial customer who receives the best upfront discount.

Other reasons or explanations for disclosed CSP information being incorrect included timing issues. For example, the disclosed MFC prices, other commercial customer prices, or the wholesaler acquisition cost price list on which discounted prices were based expired before or shortly after the proposal was submitted for review. Wholesaler acquisition cost prices are usually prices established by manufacturers before discounts or rebates or any other price concessions are applied. Another common error occurs when the disclosed MFC prices excluded the effect of rebates.

Rebates to Pharmacy Benefit Managers (PBMs) are routinely not disclosed in offerors' CSP. Because PBMs do not take possession of the products being sold, offerors determined that PBMs were not actual customers and did not disclose them. However, the CSP instructions do not specify that taking possession of a product is a requirement to be considered a customer. PBMs do not negotiate upfront discounts; instead, they negotiate rebate payments from manufacturers. Rebates are generally applied to the wholesaler acquisition cost prices, where retail pharmacy utilization data is used to determine a certain amount paid to PBMs 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. Preferred formulary placement is a marketing strategy that pushes the sale of one product over another.

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

Evaluation of Offered Prices

Among the 19 proposals reviewed, the OIG determined that prices offered to the government were higher than the MFC prices in 15 proposals and lower than or equal to the MFC prices in four proposals.

The OIG made recommendations for lower prices than offered for 13 proposals, resulting in total recommended cost savings of approximately $1.17 billion. Among these 13 proposals, the OIG's OCR recommended lower than offered prices for 68 of 100 sampled items in those proposals. Only two of 19 proposals included offered rebates, which the government must earn by meeting specified volume purchasing requirements. Price recommendations for two proposals, in which rebates were not offered to the FSS, included the effect of commercial rebates because the OIG determined the government was meeting purchase requirements for the respective rebates based on historical sales.

The VA National Acquisition Center awarded 14 contracts from the 19 pharmaceutical proposals as of May 8, 2020, which comprised $941.9 million of the $1.17 billion in recommended cost savings. Contracting officers sustained cost savings of approximately $203 million of the recommended $941.9 million (22 percent) over the life of the contracts.

The low sustained rate was due to a single preaward review that contained $660.4 million of the cumulative $939.7 million in estimated cost savings. Only $6.5 million in savings was sustained because the contracting officer agreed with the contractor's assertion that the FSS does not meet the performance conditions required to obtain OIG's recommended pricing. Most of the estimated cost savings in that review were based on the difference between the offered prices and applicable MFC prices that were recommended by the OIG for sampled items. The applicable MFC prices were recommended because the OIG determined that the government generated a greater annual sales volume than the applicable MFC, and that the government had purchased more units per sampled item than the applicable MFC. The government's historical purchases met or exceeded the applicable MFC's purchasing requirements. 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 policy 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 that there may be legitimate reasons why the best price is not achieved.[11] Therefore, contracting officers should compare all terms and conditions of the FSS program to the offeror's commercial customers.[12] Additionally, GSA and Federal Acquisition Regulations state that the benefit of the FSS program is competitive, market-based pricing that leverages the buying power of the entire federal government.[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.

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

[12] 48 CFR § 538.270-1(e); GSA Manual 538.270-1.

[13] GSA Multiple Award Schedules Desk Reference (Spring 2019); FAR 8.402 – "General."

Table 2. Rationale for Not Offering MFC Prices

Rationale	Occurrences among the 15 proposals
MFC sales volume much greater than FSS sales volume	3
Not all FSS sales volume was considered for MFC prices	2
Not meeting formulary and sole-source purchasing requirements	3
MFC contract prices did not exist at time of offer	1
MFC prices restricted to a customer type	6
MFC pricing is changed quarterly	1
No reasons or inadequate reasons given	6
Total	**22**

Source: Analysis of offered prices
Note: Some proposals contain more than one rationale, so the total will not sum to 15.

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 total sales volume.

Among the proposals for which the OIG recommended VA negotiate prices lower than offered were those in which 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 recommended the MFC price or a price lower than offered regardless of the government's inability to commit to meeting minimum 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 451 of the 862 offered items among 19 proposals included tracking customers that were potentially not adequate for purposes of the GSA price reductions clause. In

[14] GSA Acquisition Manual 552.238-81

these proposals the OIG found that vendors proposed tracking customers with less sales volume than the FSS sales volume, were not among the vendor's largest commercial customers, no longer carried the respective items on its contract, and/or were wholesalers or distributors. Typically, wholesalers or distributors are not acceptable tracking customers because they pay wholesale acquisition cost prices or receive 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 and implement 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 contractor is to report the price reduction to the government contracting officer and lower the government's price 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.

For the 451 offered items with proposed tracking customers determined to be inadequate, the OIG recommended different tracking customers that were generally among the offeror's largest commercial customers, comparable to the FSS in sales volume, and/or MFCs. Commercial customers that generate a large sales volume and/or that are an offeror's MFCs generally maintain competitive low prices.

The OIG has received 14 price negotiation memorandums or contract award files that detail the results of contract negotiations. For these 14 contracts, the VA National Acquisition Center negotiated tracking customers for 64 of 231 items (28 percent) recommended by the OIG as of May 8, 2020. Selecting a tracking customer for price reduction clause purposes involves a variety of factors that can be weighted and analyzed differently. There is no authoritative guidance for selecting a tracking customer. The OIG recommends tracking customers that will provide contract item coverage and that, in the Office of Contract Review's opinion, should provide long-term price protection for the government. However, the contracting officer may decide different tracking customers provide adequate price reduction protection than those recommended by the OIG.

Conclusion

The federal government spends billions of dollars annually on pharmaceuticals through VA's FSS program. VA's robust acquisition regulations and policy governing the OIG's preaward reviews continue to demonstrate their value in helping VA identify offers with CSP disclosures

[15] GSA Acquisition Manual 552.238-81

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 reviews helped VA contracting officers reduce the cost of drugs, which saved taxpayers nearly $203 million on proposals reviewed and awarded in FY 2019.

Appendix A: Estimated and Sustained Cost Savings for Reviews Conducted in FY 2019 as of May 8, 2020

Report Count	Date Issued	OCR's Estimated Cost Savings	VA's Sustained Cost Savings	Percentage of Sustained Cost Savings	Date Awarded
1	10/5/2018	$5,822,002	$3,393,925	58.3%	9/24/2019
2	11/14/2018	0	0	Not Applicable	7/15/2019
3	12/6/2018	14,083,325	0	Not Applicable	Pending
4	12/6/2018	0	0	Not Applicable	08/09/2019
5	1/24/2019	0	0	Not Applicable	Pending
6	1/31/2019	660,433,845	6,530,906	1.0%	8/12/2019
7	2/11/2019	185,995,052	117,203,124	63.0%	8/16/2019
8	2/14/2019	325,360	325,360	100.0%	5/3/2019
9	2/15/2019	0	0	Not Applicable	9/10/2019
10	2/21/2019	73,393,219	73,388,358	100.0%	5/17/2019
11	3/21/2019	620,794	396,556	63.9%	11/26/2019
12	5/24/2019	3,529,888	0	0.0%	8/26/2019
13	7/25/2019	3,438,012	0	0.0%	9/10/2019
14	8/28/2019	6,763,592	0	0.0%	9/25/2019
15	8/30/2019	6,468,581	0	Not Applicable	Pending
16	9/5/2019	209,773,243	0	Not Applicable	Pending
17	9/18/2019	0	0	Not Applicable	12/18/2019
18	9/24/2019	0	0	Not Applicable	Pending
19	9/26/2019	1,542,971	1,542,971	100.0%	3/9/2020
		$1,172,189,884	**$202,781,200**		

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 about 22 percent of the total estimated cost savings among preaward reviews for awarded contracts as of May 8, 2020, that had lower-than-offered price recommendations. The percentage in the table above is sustained cost savings to recommended cost savings for all reviewed proposals whether awarded or not. The OIG recommended that VA accept offered prices in six reports.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4719.
Review Team	Joseph Houston Kevin Aguilar Clifton Rybick Michael 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.