



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Audits and Evaluations

OFFICE OF ACQUISITION, LOGISTICS, AND
CONSTRUCTION

A Summary of Preaward
Reviews of VA Federal
Supply Schedule
Pharmaceutical Proposals
Issued in Fiscal Year 2021

REVIEW

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Executive Summary

The VA Office of Inspector General (OIG) reviews pharmaceutical proposals submitted to the VA National Acquisition Center for Federal Supply Schedule contracts. Specifically, the OIG reviews contracts valued annually at \$5 million or greater.¹ These preaward reviews help contract specialists negotiate fair and reasonable prices for the government and taxpayers. The reviews are not published because they contain sensitive commercial information that is protected from release under the Trade Secrets Act.

To promote transparency, this report summarizes the 15 preaward reviews of the pharmaceutical proposals that the OIG conducted in fiscal year (FY) 2021. The 15 proposals had a cumulative 10-year estimated contract value of approximately \$8.3 billion and included a total of 846 offered drug items. Contract negotiations for 12 of 15 pharmaceutical proposals have been completed as of February 2, 2022, and the OIG's recommendations collectively assisted contract specialists in obtaining \$42.6 million in contract savings for VA.

This report presents an overview of the three types of OIG actions taken related to these reviews:

- **Provided an opinion as to whether the proposal and commercial disclosures were accurate, complete, and current.** The OIG's preaward reviews found that commercial disclosures were accurate, complete, and current for four of the 15 proposals reviewed. This means four proposals were reliable for determining negotiation objectives and, ultimately, fair and reasonable pricing. The remaining 11 proposals could not be reliably used for negotiations until the noted deficiencies were corrected. Common reasons for the deficiencies included the vendor misunderstanding the instructions for disclosing information or expressing a difference of opinion about what should have been disclosed—for example, not disclosing lower prices for distributors or pharmacy benefit managers because they were not considered comparable to the government.
- **Made recommendations for pricing based on the vendor's commercial selling practices.** The OIG made recommendations for lower prices than offered for 10 of the 15 proposals, resulting in total recommended cost savings of approximately \$328.8 million. The OIG's lower pricing recommendations resulted in the Acquisition Center awarding contracts or modifications with cost savings of about \$42.6 million of the recommended \$328.8 million over the life of the contracts.
- **Evaluated and suggested alternative tracking customers.** Tracking customers, either individually or as a category, represent the vendor's largest commercial customers and serve as a benchmark for pricing changes during the life of the contract. If tracking

¹ The VA Federal Supply Schedule supports the healthcare acquisition needs of VA and other federal government agencies.

customers receive a price reduction, the government price should also be reduced. For 10 of the 15 proposals, the OIG reviewed the proposed tracking customers for all the offered items. For the remaining five proposals, the OIG reviewed the proposed tracking customers for only the sampled items.² The OIG determined that for 132 of the 626 offered items, vendors proposed tracking customers that were not adequate for the purposes of the price reductions clause in the contracts. For example, vendors proposed tracking customers that had lower sales volume than the Federal Supply Schedule sales volume, were not among the vendor's largest commercial customers, did not have the offered items on their contracts, or were wholesalers or distributors. For the same 132 items, the OIG recommended different tracking customers that were generally among the vendor's largest commercial customers or most-favored customers.

This report details how many proposals the OIG team reviewed that were accurate, complete, or current, and provides summary information about prior pricing recommendations made to VA for those that were not. It does not propose any additional recommendations that necessitate any action or VA response. A draft copy was provided to VA management who declined to provide any comment.



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² Sampled items are offered items among proposals that collectively represent at least 75 percent of total government sales of offered items in a given period. The scope for the tracking customer analysis changed from reviewing all offered items to the sampled items as it was determined to be adequate and meet the preaward objectives.

Contents

Executive Summary	i
Abbreviations	iv
Introduction.....	1
A Summary of FY 2021 Pharmaceutical Preaward Reviews	3
Appendix A: Estimated and Sustained Cost Savings for Reviews Conducted in FY 2021	9
Appendix B: Scope and Methodology	10
OIG Contact and Staff Acknowledgments	11
Report Distribution	12

Abbreviations

FAR	Federal Acquisition Regulation
FSS	Federal Supply Schedule
FY	fiscal year
GSA	General Services Administration
OIG	Office of Inspector General



Introduction

At the request of contracting officers, the VA Office of Inspector General (OIG) reviews pharmaceutical proposals for Federal Supply Schedule (FSS) contracts that have an anticipated annual value of \$5 million or more.³ These proposals are reviewed by the OIG before the VA National Acquisition Center makes contract awards. VA guidelines require preaward reviews to facilitate informed decision-making and help prevent waste of VA funds.⁴

Preaward reviews are not published because they contain sensitive commercial pricing information and data protected from release under the Trade Secrets Act. However, to promote transparency, this report provides a summary of the 15 preaward reviews of pharmaceutical proposals that the OIG conducted during fiscal year (FY) 2021.

Purpose of Preaward Reviews

The findings and recommendations in OIG preaward reviews are intended as a resource for the VA contract specialist in negotiating fair and reasonable pricing with vendors. The OIG conducts preaward reviews to validate the commercial sales practice disclosures required in the vendor's FSS proposal, to identify any lower prices than those offered to the government for products or services, and to propose alternative tracking customers when appropriate as the basis for future pricing. The contract specialist is responsible for negotiating the actual prices with the vendor and ultimately determining that the offered prices are fair and reasonable.

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 with a simplified process for acquiring commercial supplies and services in varying quantities while obtaining volume discounts.⁵ The purpose of this report is to provide a summary of the findings and effects of the OIG's 15 preaward reviews of FSS pharmaceutical proposals made to VA in FY 2021.

VA Federal Supply Schedule Program

The General Services Administration (GSA) has delegated authority to VA to award and administer nine FSS award schedules to support the healthcare acquisition needs of VA and other government agencies.⁶ The goal of VA's FSS program is to leverage the entire federal

³ VA FSS Service supports the healthcare requirements of VA and other federal government agencies by providing federal customers with access to commercial products and services.

⁴ VA National Acquisition Center, Procedural Guideline 22, "OIG Contract Review Procedures."

⁵ 41 U.S.C. § 152(3); FAR 8.402.

⁶ FAR 8.402; "VA Schedule Programs," VA Office of Procurement, Acquisition and Logistics website, accessed June 29, 2021, <https://www.va.gov/opal/nac/fss/schedules.asp>.

government's purchasing power to drive volume-based discounts that provide healthcare solutions at fair and reasonable prices to all authorized FSS users.⁷ Federal agencies purchased more than \$16.1 billion in products and services through these nine commodity and services schedules during FY 2021.

The pharmaceuticals schedule is one of the nine schedules. VA's FSS program expenditures represented nearly 82 percent of the government spending on that schedule for FY 2021. Because of the magnitude of spending through the VA FSS program, GSA and VA have established regulations, policies, and procedures to help ensure that the government receives the best prices for pharmaceutical and other medical supplies and that FSS vendors are following all the terms and conditions of their contracts. This included VA establishing a robust preaward and postaward contract review program.

Additionally, VA established written guidelines that set forth criteria and procedures for requesting an OIG review of proposals and contracts submitted under or related to contracts or solicitations issued by the VA National Acquisition Center.⁸ The written guidelines require contracting officers to submit 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.

⁷ FAR 38.101(d), 8.402(a) and 8.404(d).

⁸ VA National Acquisition Center, Procedural Guideline 22, "OIG Contract Review Procedures."

A Summary of FY 2021 Pharmaceutical Preaward Reviews

The OIG conducted 15 preaward reviews of FSS pharmaceutical proposals during FY 2021. The main purpose of an OIG preaward review is to assist VA's FSS contracting officers in establishing and maintaining fair and reasonable prices on the FSS contract they award. The 15 proposals submitted for review during FY 2021 had a 10-year estimated contract value of approximately \$8.3 billion and included 846 offered drug items. All 15 preaward reviews were completed in an average of 189 calendar days.

What the OIG Did

The OIG had three primary objectives when reviewing the 15 FSS proposals:

1. Provide an opinion as to whether the commercial sales practice 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.

To provide an opinion on the commercial sales practice disclosures and evaluate offered pricing, the OIG reviewed 147 of the 846 offered items among the 15 proposals, which represented approximately \$7.4 billion or 89 percent of the total 10-year estimated contract value (\$8.3 billion).⁹ To determine if the proposed tracking customers were appropriate, the OIG reviewed 626 offered items. For 10 of the 15 proposals, the OIG reviewed proposed tracking customers for all offered items and for the remaining five, only proposed tracking customers among sampled items were reviewed. The audit team adjusted the methodology to focus on sampled items for the tracking customer analysis during FY 2021; this adjustment aligns with preaward requirements. The sections that follow detail the OIG's results for each of the three preaward objectives.

Opinion of Commercial Sales Practice Disclosures

The OIG's preaward reviews found commercial sales practice disclosures to be accurate, complete, and current for four of the 15 proposals. This means that these four proposals were reliable for determining negotiation objectives and ultimately fair and reasonable pricing using the commercial pricing information in the disclosures. The remaining 11 proposals did not meet

⁹ The OIG preaward reviews are generally limited to offered items that represent at least 75 percent of past government sales.

these criteria and could not reliably be used for negotiations until the noted deficiencies were corrected.

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 the prices and terms and conditions of their commercial customers on the commercial sales practice form in FSS proposals. Commercial sales practice disclosures must be accurate, complete, and current because contract specialists use this information to evaluate the proposed prices, set the negotiation objectives, and determine whether the offered prices are fair and reasonable.

The commercial sales practice section of the FSS pharmaceutical solicitation includes instructions on what the vendor should disclose to the government. The instructions state that if the vendor is proposing prices better than or equal to the most-favored-customer prices, those customers and prices are to be disclosed. If that is not the case, the vendor is required to disclose all commercial prices equal to or better than those prices offered to the government and to disclose all customers or categories of customers who are receiving those prices.

Additionally, the vendor is required to provide enough information as to how customers may earn prices or discounts better than those offered to the government. If there are any deviations to the commercial sales practice disclosures or exceptions to the disclosed commercial prices that are lower than offered, the vendor may be required to disclose that information to the government. If a vendor is a reseller with no significant commercial sales, the respective manufacturers of the offered items should provide commercial sales practice disclosures in accordance with instructions. Table 1 lists the findings and their number of occurrences among the 11 proposals with commercial sales practices that the OIG found to be inaccurate, incomplete, or not current.

Table 1. Commercial Sales Practice Findings

Commercial sales practice findings	Occurrences among the 11 proposals
Incorrect most-favored-customer prices or discounts disclosed	9
Incorrect most-favored customers disclosed	2
All most-favored customers were not disclosed	5
Rebates to pharmacy benefit managers not disclosed	1
Discount ranges disclosed without required information	2

Source: Analysis of commercial sales practice disclosures.

Note: Some proposals had more than one deficiency, so the sum does not total 11.

Common reasons for the commercial sales practice findings in table 1 generally included the vendor making pricing entry errors or unintentional omissions, misunderstanding the commercial sales practice instructions, or expressing a difference of opinion about what should have been disclosed. For example, some proposals excluded pricing for distributors or pharmacy benefit managers lower than offered the government because these customers were not considered comparable to the government.¹⁰

Other reasons or explanations for disclosed commercial sales practice information being incorrect included timing issues. For example, the disclosed most-favored-customer 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 to the OIG for review. Wholesaler acquisition cost prices are usually established by manufacturers before discounts, rebates, or any other price concessions are applied. Another common error occurred when the disclosed most-favored-customer prices excluded the effect of rebates.

Rebates to pharmacy benefit managers were not disclosed by a vendor in their commercial sales practice disclosures. Because these managers do not take possession of the products being sold and manufacturers are unaware of the final prices that the managers paid, the vendor determined that pharmacy benefit managers were not actual customers and did not disclose them. However, the commercial sales practice instructions do not indicate that taking possession of a product is a requirement to be considered a customer. Pharmacy benefit managers do not negotiate upfront discounts; instead, they negotiate rebate payments from manufacturers. Rebates are generally applied to the wholesaler acquisition cost prices, and then retail pharmacy utilization data are used to determine a certain amount paid to these managers to influence a preferred formulary placement. A formulary is a list of prescription drugs that doctors use 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 that pharmacy benefit managers paid for drugs via the retail pharmacy is unknown to the OIG. However, like any upfront discount, rebates paid to pharmacy benefit managers reduce a manufacturer's revenue on sales of products. The commercial sales practice instructions make no exception for pharmacy benefit manager rebates, and they should be included in disclosures.

Evaluation of Offered Prices and Related Recommendations

Among the 15 proposals reviewed, the OIG review team determined that the prices offered to the government were higher than the most-favored-customer prices in 12 proposals and lower than

¹⁰ A pharmacy benefit manager is a third-party administrator of prescription drug programs for commercial health plans, self-insured employer plans, and government plans. These managers negotiate rebates for member insurance plans through a formulary system; they do not purchase and take possession of products as direct and indirect customers do.

or equal in three proposals. For those three proposals, report recommendations included accepting offered prices. The OIG recommended seeking lower prices than offered for 10 of the remaining 12 proposals. For two proposals, the vendors’ reasons were valid for not offering most-favored-customer pricing to the government, such as when the most-favored customer purchased more than the government. None of the contractors offered rebates to the FSS.

When evaluating offered prices, the OIG considers the objective of the FSS program and implements Federal Acquisition Regulation (FAR) and GSA guidance when making price recommendations. Table 2 summarizes the reasons the 12 vendors chose not to offer most-favored-customer prices in the proposals reviewed.

Table 2. Rationale for Not Offering Most-Favored-Customer Prices

Rationale	Occurrences among the 12 proposals
Most-favored-customer sales volume is much greater than FSS sales	2
FSS does not meet volume incentive	5
Most-favored-customer prices are restricted to a customer type	3
Most-favored customer has volume-based commitments	1
Agreement with most-favored customer lacks wholesaler or other fees	1

Source: Analysis of offered prices.

Note: Shaded row reflects the two of 12 contracts for which lower prices were not sought.

The OIG’s lower pricing recommendations resulted in the VA National Acquisition Center awarding contracts that had sustained cost savings of approximately \$42.6 million of the recommended \$328.8 million over the life of the contracts. Appendix A provides more information on the monetary impact of the OIG’s preaward reviews.

GSA and the FAR state that the benefit of the FSS program is competitive, market-based pricing that leverages the volume buying power of the entire federal government.¹¹ The objective of the FSS program is to achieve most-favored-customer pricing or better for the government. GSA states that the government will seek to obtain the vendor’s best price given to the most-favored customer, and it states that 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.¹²

¹¹ GSA, Multiple Award Schedules Desk Reference, Spring 2019; FAR 8.402 (a).

¹² GSA Acquisition Manual 538.270-1(c) Evaluation of offers without access to transactional data.

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 vendor's commercial customers. When determining the government's price negotiation objectives, the aggregate volume of anticipated purchases, among other factors, must be considered.¹³

Evaluation of Proposed Tracking Customers

After pricing has been established, it is still important to ensure that over the term of the contract, any adjustments are fairly and reasonably made for VA that are made for other 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 mandates future reductions to the FSS contract prices be based on price reductions given to what is known as the tracking customer.¹⁴ This contract clause requires the government and the vendor to agree on a customer or category of customers, known as a tracking customer, against which the government's price or discount can be linked for the purposes of potential price reductions. The contract requires this relationship to be maintained throughout the contract period.

The most-favored customer simply has received the lowest price whereas the tracking customer is used to maintain fair and reasonable pricing for the government throughout the life of the contract. If, for example, the price drops for the tracking customer, the FSS price would drop proportionally.¹⁵ As detailed below, the most-favored customer may also be the tracking customer.

For 10 of the 15 proposals, the OIG reviewed the proposed tracking customers for all the offered items. For the remaining five proposals, the OIG reviewed the proposed tracking customers for only the sampled items.¹⁶ In total, the OIG evaluated the proposed tracking customers for 626 items. The OIG determined that the proposed tracking customers for 132 of 626 items (about 21 percent) were not adequate for GSA price reductions clause purposes.¹⁷ Among the deficiencies for those 132 items, vendors proposed a tracking customer that had lower sales volume than the FSS sales volume, was not among the vendor's largest commercial customers, did not contain the offered items on its contract, or was a wholesaler or distributor. Typically, in the OIG's opinion, wholesalers are not acceptable tracking customers because they pay wholesale

¹³ GSA Acquisition Manual 538.270-1 (e) Evaluation of offers without access to transactional data.

¹⁴ GSA Acquisition Manual 552.238-81 Price Reductions.

¹⁵ For more information see VA's frequently asked questions on FSS at <https://www.fss.va.gov/faqs/csp.asp#q001>.

¹⁶ The scope for the tracking customer analysis changed from reviewing all offered items to the sampled items as it was determined to be adequate and meet the preaward objectives.

¹⁷ GSA Acquisition Manual 552.238-81 Price Reductions.

acquisition 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 a vendor's pricing arrangements with the identified tracking customer would initiate a price reduction. The price reductions clause stipulates when the contractor is to report price reductions provided to the tracking customer. For example, if the government's award 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, the price reductions clause mandates that 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 entire contract period.

For the 132 offered items with proposed tracking customers that the OIG determined were inappropriate, the OIG recommended different tracking customers that were generally among the vendor's largest commercial customers or most-favored customers. Commercial customers that generate a large sales volume and are a vendor's most-favored customers generally maintain competitive low prices. The VA National Acquisition Center was able to sustain the OIG's recommended tracking customers for seven of the 132 items during negotiations.

Selecting a tracking customer for price reduction clause purposes involves a variety of factors that can be weighted and analyzed differently. While 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 OIG's opinion, should provide long-term price protection for the government. However, the contract specialist 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 pharmaceutical items through VA's FSS program. The OIG's findings and recommendations in the preaward reviews helped VA contract specialists reduce the cost of drugs, which saved taxpayers nearly \$42.6 million over the life of proposed contracts reviewed by the OIG in FY 2021 and awarded in FY 2021 and FY 2022.

This report provides summary information about prior recommendations made to VA; it does not propose any additional recommendations that require VA response or action. A draft copy was provided to VA management who declined to provide any comment.

Appendix A: Estimated and Sustained Cost Savings for Reviews Conducted in FY 2021

The OIG’s estimated cost savings is the difference between vendor-offered prices and OIG-recommended prices, multiplied by a past 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 VA contract specialist. Overall, VA was able to sustain about \$42.6 million of the total estimated cost savings among preaward reviews for awarded contracts as of February 2, 2022, that had lower-than-offered price recommendations. The percentage of sustained cost savings in table A.1 reflects the proportion of OIG-recommended cost savings that contracting officers were able to sustain for all reviewed proposals, whether awarded or not. The OIG recommended that VA accept offered prices in five reports—those rows marked as “N/A” with an award date.

Table A.1. Cost Savings Data by Issue Date

Report number	Date issued	OIG’s estimated cost savings(dollars)	VA’s sustained cost savings(dollars)	Percentage of sustained cost savings	Date awarded
1	12/04/2020	0	\$0	N/A	06/24/2021
2	12/28/2020	2,472,751	1,644,791	66.5%	02/01/2021
3	01/04/2021	59,940	0	0%	05/18/2021
4	02/25/2021	114,437,781	20,188,816	17.6%	06/17/2021
5	03/25/2021	0	0	N/A	09/22/2021
6	03/26/2021	10,193,827	4,119,909	40.4%	08/03/2021
7	04/27/2021	0	0	N/A	05/26/2021
8	05/03/2021	0	0	N/A	11/08/2021
9	05/28/2021	83,251,853	4,668,830	5.6%	08/11/2021
10	07/28/2021	12,017,550	12,017,550	100%	09/18/2021
11	08/02/2021	86,097,886			01/31/2022
12	08/31/2021	0	0	N/A	09/22/2021
13	09/20/2021	130,166			01/31/2022
14	09/28/2021	226,370			01/31/2022
15	09/29/2021	19,956,275	0	0%	11/19/2021
Total		\$328,844,399	\$42,639,897		

Source: OIG reports and VA National Acquisition Center contract files.

Note: Numbers in table may not sum due to rounding.

Appendix B: Scope and Methodology

Scope

The review team conducted its work from October 2021 through May 2022. The scope of the review focused on summarizing the information in prior OIG preaward review reports and presenting subsequent contract award data. The team assessed relevant sources of information, including contracts obtained from VA's electronic contract management system and applicable FY 2021 FSS pharmaceutical preaward reports.

Methodology

The review team searched the VA electronic contract management system for the solicitations with OIG-prepared preaward review reports and obtained the resulting contract, if applicable. The team then summarized the data from the review reports and resulting contracts for presentation in this publication.

Fraud Assessment

The review team assessed the risk that fraud and noncompliance with provisions of laws, regulations, contracts, and grant agreements significant within the context of the review objectives could occur during this review. The team exercised due diligence in staying alert to any fraud indicators. The OIG did not identify any instances of fraud or potential fraud during this review.

Data Reliability

The review team did not obtain or rely on computer-processed data. The team also did not perform detailed fieldwork to verify the information listed in the review reports or the contracts because verification was not the focus of the review's objectives.

Government Standards

The OIG conducted this review in accordance with the Council of the Inspectors General on Integrity and Efficiency's *Quality Standards for Inspection and Evaluation*

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