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 2020

REVIEW | REPORT #21-00041-250 | SEPTEMBER 28, 2021

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Executive Summary

The VA Office of Inspector General (OIG) reviews proposals submitted to VA for Federal Supply Schedule pharmaceutical 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 VA National Acquisition Center's pharmaceutical Federal Supply Schedule proposals that the OIG conducted in fiscal year (FY) 2020. The 15 proposals had a cumulative 10-year estimated contract value of approximately $10 billion and included a total of 515 offered drug items. Contract specialists have completed negotiations on these proposals, and the OIG's recommendations collectively resulted in approximately $42 million in savings for VA.

This report provides 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 seven of the 15 proposals reviewed. This means that the seven proposals were reliable for determining negotiation objectives and, ultimately, fair and reasonable pricing. The remaining eight proposals could not be reliably used for negotiations until the noted deficiencies were corrected.

  Common reasons for the deficient findings 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 four proposals, resulting in total recommended cost savings of approximately $56.5 million.

- **Evaluated and suggested alternative tracking customers.** Tracking customers, either individually or as a category, may represent the vendor's largest commercial customers and serve as a benchmark. They receive price reductions to which government reductions are pegged. In the 15 proposals reviewed, the OIG determined that for 177 of the 515 offered items, vendors proposed tracking customers that were not adequate for the

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

purposes of the price reductions clause in the contracts. For example, vendors proposed tracking customers that had a lower sales volume than the Federal Supply Schedule sales volume, were not among the vendor's largest commercial customers, did not have the offered item(s) on their Federal Supply Schedule contract, or were wholesalers or distributors. For the 177 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 were accurate, complete, or current and provides summary information about pricing and the prior recommendations made to VA for those that were not. It does not propose additional recommendations for VA response.

The director of the Federal Supply Schedules Service provided comments on a draft of this report, which are included in appendix C. The director stated that the report should include the time the OIG took to complete its reviews, which would help in monitoring whether the OIG met timeliness requirements.

The OIG notes the director's concern and always strives to meet timeliness requirements. However, there are times when they are not met due to circumstances outside the OIG's control. Eight of the 15 preaward reviews were completed in less than 90 calendar days; all 15 preaward reviews were completed in an average of 107 calendar days.

Preaward reviews of pharmaceutical proposals provide great value to VA and veterans, as the FY 2020 reviews alone have saved the government over $42 million. The review team appreciates that the Federal Supply Schedules Service remains engaged with the OIG and will brief the director and any necessary staff if any new processes or procedures significantly affect the timeliness of reviews.

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Assistant Inspector General
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Contents

Abbreviations

CSP	commercial sales practice
FSS	Federal Supply Schedule
FY	fiscal year
GSA	General Services Administration
MFC	most-favored customer
OIG	Office of Inspector General

Introduction

At the request of contracting officers, the VA Office of Inspector General (OIG) reviews certain contract proposals to provide VA with medical products before VA's National Acquisition Center makes the awards. The OIG evaluates pharmaceutical proposals for Federal Supply Schedule (FSS) contracts that have an anticipated annual value of at least $5 million.[2] VA guidelines require preaward reviews to facilitate informed decision-making and help prevent waste of VA funds.

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) 2020.

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 (CSP) 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 better 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 a simplified process for acquiring commercial supplies and services in varying quantities while obtaining volume discounts.[3] The purpose of this report is to provide a summary of the findings and impact of the OIG's 15 preaward reviews of FSS pharmaceutical proposals made to VA in FY 2020.

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.[4] The goal of VA's FSS program is to leverage the entire federal

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

[3] 41 U.S.C. § 152(3); FAR 8.402.

[4] 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.[5] Federal agencies purchased more than $12.8 billion in products and services through the nine commodity and services schedules during FY 2020.[6]

The pharmaceuticals schedule is one of the nine schedules. VA's FSS program represents nearly 83 percent of the government spending on that schedule. Because of the magnitude of spending through the VA 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.[7] The written guidelines require 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] FAR 38.101(d), 8.402(a), and 8.404(d).

[6] VA National Acquisition Center, *VA FSS Newsletter*, Issue 68, March 2021, https://www.va.gov/opal/docs/nac/fss/newsletter202103.pdf.

[7] VA National Acquisition Center, Procedural Guideline 22, "OIG Contract Review Procedures," June 16, 2015.

A Summary of FY 2020 Pharmaceutical Preaward Reviews

The OIG conducted 15 preaward reviews of FSS pharmaceutical proposals during FY 2020. The main purpose of an OIG preaward review is to assist VA's FSS program in establishing and maintaining fair and reasonable pricing on the awarded FSS contract. The 15 proposals submitted for review had a 10-year estimated contract value of approximately $10 billion and included 515 offered drug items. The OIG reviewed 84 of the 515 offered items, which represented approximately $8.1 billion, or 81 percent of the total 10-year estimated contract value ($10 billion).[8]

What the OIG Did

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

1. Provide an opinion as to whether the 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 OIG's reported findings for each of the 15 issued pharmaceutical preaward reviews are summarized in the following sections:

- Evaluation of commercial sales practice disclosures
- Evaluation of offered prices
- Evaluation of proposed tracking customers

Evaluation of Commercial Sales Practice Disclosures

The OIG's preaward reviews found CSP disclosures to be accurate, complete, and current for seven of the 15 proposals. This means that these seven proposals were reliable for determining negotiation objectives and ultimately fair and reasonable pricing using the commercial pricing information in the CSP disclosures. The remaining eight proposals were not accurate, complete, or current and could not reliably be used for negotiations until the noted deficiencies were corrected.

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

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. Contract specialists use this disclosed information 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 be 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 vendor should disclose to the government.[9] The instructions state that if the vendor is proposing prices that are better than or equal to the most-favored customer (MFC) prices, those customers and MFC prices are to be disclosed.[10] If that is not the case, the vendor 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 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 that are better than those 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 vendor may be required to disclose that information to the government. If a vendor 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 lists the findings and their number of occurrences among the eight proposals with CSPs that were found not accurate, complete, or current.

[9] VA FSS Solicitation No. M5-Q50A-03-08, attachment 02, "Vendor Response Document," June 21, 2018.

[10] MFC is defined as the commercial customer that receives the best upfront discount—a vendor's net price without regard to quantity, terms, and conditions.

Table 1. Commercial Sales Practice Findings

CSP findings	Occurrences among the eight proposals
Incorrect most-favored customer prices/discounts disclosed	6
Incorrect most-favored customers disclosed	3
All most-favored customers not disclosed	1
Rebates to pharmacy benefit managers not disclosed	1
Discount ranges disclosed without required information	1
Total	**12**

Source: Analysis of CSP disclosures.
Note: Some proposals have more than one finding, so the sum does not total eight.

Common reasons for the CSP findings in table 1 generally included the vendor making pricing entry errors or unintentional omissions, misunderstanding the CSP instructions, or expressing a difference of opinion about what should have been disclosed in the CSP (for example, excluding pricing for distributors or pharmacy benefit managers that is lower than offered the government because these customers are not considered comparable to the government).[11]

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 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 MFC prices excluded the effect of rebates.

Rebates to pharmacy benefit managers were not disclosed in the vendors' CSP. Because these managers do not take possession of the products being sold and manufacturers are unaware of the final prices that the managers paid, vendors determined that pharmacy benefit managers were not actual customers and did not disclose them. However, the CSP instructions do not indicate that taking possession of a product is a requirement to be considered a customer. Pharmacy

[11] 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.

benefit managers do not negotiate up-front discounts; instead, they negotiate rebate payments from manufacturers. Rebates are generally applied to the wholesaler acquisition cost prices, where 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 used 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 up-front discounts and incentive rebates, 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 15 proposals reviewed, the OIG determined that prices offered to the government were higher than the MFC prices in seven proposals and lower than or equal to the MFC prices in eight proposals.

The OIG recommended seeking lower prices than offered for four proposals, resulting in total recommended cost savings of approximately $56.5 million.[12] The lower-than-offered prices applied to 14 of the 34 sampled items in those proposals, 17 percent of the 84 sampled items from all 15 proposals reviewed. 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 and GSA guidance when making price recommendations. Table 2 summarizes the reasons the seven vendors chose not to offer MFC prices in the proposals reviewed.

Table 2. Rationale for Not Offering MFC Prices

Rationale	Occurrences among the seven proposals
MFC prices are restricted to a customer type	3
FSS does not meet volume incentive	1
MFC sales volume is much greater than FSS sales	2
Agreement with MFC lacks wholesaler or other fees	1
MFCs are pharmacy benefit managers' customers	1

[12] As detailed below, the three remaining proposals justified higher prices based on such factors as the government not meeting MFC volume for purchases.

Rationale	Occurrences among the seven proposals
Formulary and sole-source purchasing requirements are not met	1
Total	**9**

Source: Analysis of offered prices.
Note: Some proposals contain more than one reason, so the total is greater than the number of reports with recommended cost savings.

As previously noted, in three cases, the vendors' arguments were valid for not offering MFC pricing to the government. For example, the MFC purchased a greater sales volume than the government. However, among three of the four proposals for which the OIG recommended negotiating prices that were lower than offered, the government's overall FSS sales of offered items or total units purchased per sampled item were greater than those of the MFCs or customers receiving a price lower than offered. The OIG's lower pricing recommendations resulted in the VA National Acquisition Center awarding contracts that had sustained cost savings of approximately $42 million of the recommended $56.5 million (74 percent) over the life of the contracts. Appendix A provides more information on the monetary 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 vendor'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.[13] Additionally, GSA and the Federal Acquisition Regulation state that the benefit of the FSS program is competitive, market-based pricing that leverages the volume buying power of the entire federal government.[14]

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.[15]

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 mandates reductions to the FSS contract prices based on price reductions given to what is known

[13] GSA Manual 538.270-1(c), July 26, 2021.

[14] GSA, Multiple Award Schedules Desk Reference, Spring 2019; FAR 8.402.

[15] 48 C.F.R. § 538.270-1(e); GSA Manual 538.270-1

as the tracking customer.[16] This contract clause requires the government and the vendor to agree on 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. The contract requires this relationship to be maintained throughout the contract period.

In the 15 proposals reviewed, the OIG determined that 177 of the 515 offered items included tracking customers that were not adequate for the purposes of the GSA price reductions clause. For approximately 34 percent of the 515 offered 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 item(s) on its contract, or was a wholesaler or distributor. Typically, wholesalers are not acceptable tracking customers because they 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 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 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, 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 177 offered items with proposed tracking customers that the audit team determined were inappropriate, the OIG recommended different tracking customers that were generally among the vendor's largest commercial customers or MFCs. Commercial customers that generate a large sales volume and that are a vendor's MFCs generally maintain competitive low prices. The VA National Acquisition Center was able to sustain the OIG's recommended tracking customers for 48 of the 177 items (27.1 percent) during negotiations.

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 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.

[16] GSA Manual 552.238-81, July 26, 2021.

Conclusion

The federal government spends billions of dollars annually on pharmaceuticals 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 million on proposals reviewed by the OIG in FY 2020 and awarded in FY 2020 and FY 2021.

This report provides summary information about prior recommendations made to VA; it does not propose additional recommendations for VA response.

Management Comments and OIG Response

The director of the Federal Supply Schedules Service provided comments on a draft of this report, which are included in appendix C. He stated that the OIG should include the time taken to complete preaward reviews to help monitor their timeliness and establish a baseline for improvement.

The OIG notes the director's concern and always strives to meet timeliness requirements. However, there are times when they are not met due to circumstances outside the OIG's control. Eight of the 15 preaward reviews were completed in less than 90 calendar days; all 15 preaward reviews were completed in an average of 107 calendar days.

The review team appreciates that the Federal Supply Schedules Service remains engaged with the OIG. Preaward reviews of pharmaceutical proposals provide great value to VA and veterans, as the FY 2020 reviews alone have saved the government over $42 million. The OIG will brief the director and any necessary staff at the National Acquisition Center if any new processes or procedures significantly affect the timeliness of these reviews.

Appendix A: Estimated and Sustained Cost Savings for Reviews Conducted in FY 2020

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 74 percent of the total estimated cost savings among preaward reviews for awarded contracts for FY 2020 that had lower-than-offered price recommendations. The percentage in table A.1 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 11 reports—those marked as "Not applicable."

Table A.1. Cost Savings Data

Report number	Date issued	OIG's estimated cost savings	VA's sustained cost savings	Percentage of sustained cost savings	Date awarded
1	10/2/2019	$48,645	$48,645	100.0%	9/1/2020
2	10/7/2019	0	0	Not applicable	12/19/2019
3	10/28/2019	0	0	Not applicable	1/24/2020
4	11/18/2019	0	0	Not applicable	3/10/2020
5	12/5/2019	$13,488,663	0	0.0%*	6/11/2020
6	1/15/2020	0	0	Not applicable	9/16/2020
7	4/15/2020	0	0	Not applicable	6/30/2020
8	5/8/2020	0	0	Not applicable	7/29/2020
9	5/11/2020	$11,013,708	$11,013,708	100.0%	9/17/2020
10	5/20/2020	0	0	Not applicable	7/2/2020
11	5/27/2020	0	0	Not applicable	6/18/2020
12	6/29/2020	0	0	Not applicable	8/28/2020
13	7/15/2020	0	0	Not applicable	9/2/2020
14	9/11/2020	$31,961,273	$30,952,373	96.8%	2/04/2021
15	9/18/2020	0	0	Not applicable	4/14/2021
Total		**$56,512,289**	**$42,014,726**		

Source: OIG reports and VA National Acquisition Center contract files.
** The $13,488,663 amount was not sustained by the contract specialist because the offered price for a single product was lower than the tracking customer's price. Therefore, it was determined to be fair and reasonable. Additionally, the contract specialist indicated that the product would be discontinued by the vendor once the supply was exhausted.*

Appendix B: Scope and Methodology

Scope

The review team conducted its work from October 2019 through September 2020 (FY 2020). 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 2020 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.*

Appendix C: Management Comments

Date: September 9, 2021

From: Director, Federal Supply Schedules (FSS) (003B6B)

Subj: Draft Report Comments, Pre-award Reviews of Federal Supply Schedule Pharmaceutical Proposals Issued in Fiscal Year 2020

To: Director, Healthcare Resources Division, Office of Audits and Evaluations, Office of Inspector General (OIG)

1. Thank you for the opportunity to provide comments on the Summary Pre-award Reviews of Federal Supply Schedule Pharmaceutical Proposals Issued in Fiscal Year 2020. This report and the pre-award pricing audit reports provided to FSS contracting officers are valuable tools in determining fair and reasonable pricing and ensuring compliance with contract terms and conditions.
2. The draft report does not address how long it takes for OIG to complete their audits/reviews. This piece of information should be included in the report as a statistical overview including, for example, average, median, and mode processing times in order to monitor the ability of OIG to meet the required timeframes for pre-award reviews. It is our concern that OIG should make visible the actual processing times to monitor timeliness and as a baseline to develop strategies to improve timeliness.
3. VA Federal Supply Schedules has concerns that the significant value-added results delivered by OIG are under threat of becoming an unsustainable lengthy process which prevents the program from achieving timely processing of pre-award actions. It is requested that OIG give greater emphasis in the report and consideration to lead-times when adjusting processes and resourcing.
4. We remain engaged partners with OIG and look forward to continuous improvement especially in the area of timeliness. Thank you for the opportunity to comment on this summary report.

(Original signed by)

Daniel H. Shearer
Director, Federal Supply Schedules Service

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

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