Current Non-Availability Determinations for Medical Nitrile Gloves and COVID-19 Tests

After determining that the global supply of medical nitrile gloves remains constrained by the COVID-19 pandemic, an extension to the March 1<sup>st</sup> non-availability determination was authorized until 11/30/2022. The extension provides acquisition flexibilities to meet national healthcare objectives via an exception to the requirements of the Trade Agreements and Buy American statute clauses for current 65 II A contract holders. This determination permits disposable medical nitrile gloves sourced from all countries except those listed in FAR subpart 25.7 - Prohibited Sources. Please visit the notification web page for further information on this exception authority, including important reminders. Similarly, a non-availability determination was issued for COVID-19 rapid diagnostic and serology/antibody tests which is in effect until 12/31/2021, unless extended. Any additional contract coverage provided by these non-availability determinations can be viewed online in the NAC’s Contract Catalog Search Tool (CCST) under the MedSurg Catalog and on GSA Advantage.

Inside FSS
News from Director Dan Shearer

An extremely relevant question of interest that we get from time to time goes as follows: Will the VA Federal Supply Schedules remain a viable source of acquisition support given the many different acquisition strategies that are out there? Like all of you, everyone serves a customer, and we know how rare it is for anyone to know exactly what our customer behavior will be. FSS serves the whole of government, Federal, State, and Local levels, and these organizations continue to pursue acquisition strategies and innovations that benefit their goals. Our customer relationships have expanded significantly since the start of COVID-19 with FSS personnel participating on VA – Integrated Process Teams while informing VA operations, logistics, and procurement through a monthly Field Notification listing of new FSS contracts awarded with important program updates. External stakeholder engagement has become second nature by working with the White House Task Force, GSA, FEMA, HHS, Bureau of Prisons, and Defense Health Agency, to name a few. In collaboration with customers, two non-availability determinations now allow global sourcing to improve customer support. As of Q3, which ended June 30, total spend against FSS contracts was...
$11.081B. There was a steady increase in quarterly spend with $3.429B in Q1, $3.791B in Q2, and $3.861B in Q3. When we extrapolate to include Q4, the total yearly spend appears to be a small percentage less than prior year spend of $15.2B, which indicates that our customers are still finding value in FSS.

While we don’t have a crystal ball, we are pressing forward to ensure we continue to provide substantial acquisition support as highlighted below.

65 I B: Pharmaceutical Public Law Season 2022 has begun and is fully supported
65 II A: Global sourcing on FSS is authorized with a non-availability determination for disposable medical nitrile gloves
621 I: Complete solicitation overhaul/refresh to be published in the next month
66 III: Solicitation refresh is planned in FY22 with an Industry Day including buying offices, contractors, and VA lab personnel to discuss improvements and issues
65 V II: Global sourcing is authorized on FSS with a non-availability determination for COVID-19 rapid diagnostic and serology/antibody tests

New Hires: Since spring 2020 we have hired 14 new employees who we are dedicated to training as quickly as possible for our mutual benefit in developing their talents and abilities.

Our viability as a program continues to rely on our collective efforts to engage and support. I thank all of you for your past efforts and in advance for many great efforts that will come in the future.

Excellence Together!

Pharm Facts!
Public Law 2022 – Important Dates & Training

We’re quickly moving into the 2022 Public Law (PL) season during which we execute annual pricing updates for all covered drugs. The timeline for this year is set as shown below, beginning with the October 1st issuance of the Dear Manufacturer Letter (DML) instructions to vendors and ending with the December 31st deadline to submit your Pharmaceutical Pricing Agreement (PPA) Addendum to FSS. The deadline to submit a Request for Modification (RFM) to effect any pre-PL season changes to your contract ended on September 15th; therefore, pricing on PL items has been frozen in preparation for the export of the PL workbook to be used by contractors in completing the 2022 annual non-federal average manufacturer price (NFAMP) calculations. Visit our Public Law web page for information on the complete process and to download critical PL documents and forms, and don’t forget to register on our training web page for one of our two sessions to be fully prepared for this PL season!
What’s New with FSS
COVID-19 Rapid Test Non-Availability Determination

On June 24th, the FSS program issued a non-availability determination which authorizes access to COVID-19 rapid diagnostic and serology/antibody tests that are not U.S.-made or designated country end products. Our customers, particularly, the Veterans Health Administration and the White House Supply Chain Task Force COVID-19 Response team, informed us of the importance of having a variety of such tests available under FSS to ensure healthcare providers have sufficient quantities of supplies to adequately function and mitigate the impact of COVID-19.

We encourage all manufacturers of COVID-19 rapid diagnostic and serology/antibody tests to submit an offer for Special Item Numbers (SINs) 555-2 and 555-8 under Schedule 65 Part VII, Invitro Diagnostics, Reagents, Test Kits and Test Sets. If you have a current contract, please submit a Request for Modification (RFM) to add the test(s). If you do not have a current contract under the Schedule 65 VII, please submit a proposal to our office for evaluation, following the guidance provided on our Electronic Acceptance of FSS Offers/Proposals web page. When submitting RFMs/proposals, please be sure to consider the following:

- COVID-19 rapid diagnostic and serology/antibody tests must be FDA approved or have been issued an Emergency Use Authorization (EUA).
- Commercial Sales Practice (CSP) data disclosures are still required. Although we are committed to expediting the review process, the contracting officer is still charged with awarding contracts with prices deemed fair and reasonable and in the best interest of the Government.
- This authority expires 12/31/2021, unless extended. If this authority is not extended, non-TA clause compliant products will be deleted from FSS contracts effective 01/01/2022. Our office will reassess the necessity of this authority beginning November 2021 and hopes to render a decision before 12/15/2021.

Our goal is to prioritize RFMs/proposals for expedited processing once a complete and responsive package is received. Read our field notification to vendors and Government ordering activities for complete details on this determination, steps to submitting an offer, how to modify your contract, and FSS points of contact.

Did You Know …
Indirect Costs Now Required for Commercial Subcontracting Plans

The Federal Register, in Federal Acquisition Circular (FAC) 2021-07, Item IV, published changes at FAR 52.219-9(d)(2)(i) and 19.704(d) to require commercial plans to include all indirect costs in their plan goals. This change will align plan goals with actual achievements reported in eSRS, allowing for direct comparisons. 52.219-9(g) has also been revised, and it now incorporates a list of excludable categories of spend, previously only found in the SBA’s regulations. These changes became effective on September 10th.

For all contractors required to maintain plans under the terms of your FSS contract, be sure that your next proposed plan includes indirect costs in the total spend, proposed category/subcategory goals, as well as in the listing of proposed products/services to be subcontracted. Additionally, make sure to submit your proposed plan on the updated template located on our Small Business Subcontracting Plan web page.
Training Center

Service Contract Labor Standards (SCLS) & Other Service Regulations: When Do They Apply?

There are a number of important services related contract clauses, including annual reporting requirements, that only apply to certain schedules/Special Item Numbers (SINs). If you are a contract holder under Schedules 621 I Professional and Allied Healthcare Staffing Services or 621 II Medical laboratory Testing & Analysis Services (also known as Reference Labs), or if you offer equipment maintenance and repair services under Schedules 65 II A and 65 II C, then this training article is for you.

**Schedules 621 I and 621 II**
The below services related clauses apply to all contracts awarded under Schedules 621 and 621 II. This includes minimum compensation requirements and wage determinations for applicable service employees performing under the FSS contract.

52.204-15 Service Contract Reporting Requirements for Indefinite-Delivery Contracts
52.222-54 Employment Eligibility Verification
52.222-41 Service Contract Labor Standards
52.222-42 Statement of Equivalent Rates for Federal Hires – Price Adjustment
52.222-43 Fair Labor Standards Act and Service Contract Labor Standards
52.222-55 Minimum Wage under Executive Order 13658
52.222-62 Paid Sick Leave under Executive Order 13706

**Schedules 65 II A and 65 II C – Equipment Maintenance & Repair SINs**
All offerors of items under equipment maintenance and repair SINs A-200 and C-100 are required to abide by these two additional, service-related contract clauses:

52.204-15 Service Contract Reporting Requirements for Indefinite-Delivery Contracts
52.222-54 Employment Eligibility Verification

There are also a number of additional services related clauses that may apply to these SINs, depending upon your commercial practices and FSS offerings. To understand when these additional clauses apply to you, answer the below, five questions. These criteria come from contract clauses 52.222-52 Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services – Certification and 52.212-3(k) Offeror Representations and Certifications- Commercial Items (also in your representations at Sam.gov).

1) Are the services offered and sold regularly to non-Governmental customers, and are they provided by the offeror to the general public in substantial quantities in the course of normal business operations?
2) Are the items of equipment to be serviced used regularly for other than Governmental purposes, and are they sold or traded by the offeror in substantial quantities to the general public in the course of normal business operations?
3) Are the equipment services furnished at prices that are, or are based on, established catalog or market prices for the maintenance, calibration, or repair of such equipment?
4) Will each employee performing services under the FSS contract spend only a small portion of his or her time (a monthly average of less than 20% of the available hours on an annualized basis) servicing the Government contract?
5) Will the offeror use the same compensation (wage and fringe benefits) plan for all service employees performing work under the FSS contract as the offeror uses for these employees and for equivalent employees servicing commercial customers?
If you answered “yes” to all of the preceding five questions then the below, additional clause applies to you.

52.222-51 Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements

If you are unable to answer “yes” to all of the preceding five questions, then the below, additional clauses (including minimum compensation requirements and wage determinations for applicable service employees) apply to you.

52.222-41 Service Contract Labor Standards
52.222-42 Statement of Equivalent Rates for Federal Hires – Price Adjustment
52.222-43 Fair Labor Standards Act and Service Contract Labor Standards
52.222-55 Minimum Wage under Executive Order 13658
52.222-62 Paid Sick Leave under Executive Order 13706

Around the VA

The GI Bill Turns 75

This year marks the 75th anniversary of the GI Bill, signed by President Franklin D. Roosevelt on June 22, 1944. The GI Bill, also known as the Servicemen’s Readjustment Act, continues to provide valuable benefits for qualifying Veterans and their family members, including education benefits for school/training, Veteran Readiness and Employment (VR&E) services, home loan assistance (including grants to meet adaptive housing needs), and health care benefits.

Since the bill’s inception, Vets have purchased approximately 24 million homes using VA home loan guaranty services, with nearly 82% of purchases being made with no down payment. Potential education and training benefit programs are offered under the Post-9/11 GI Bill and multiple other programs, including survivor and dependent benefits. In looking to the future, the VA will be implementing the Digital GI Bill (DGI), which will modernize VA technology systems, improve user experience, and optimize benefit processes.

Web Wisdom

Trade Agreements

The Trade Agreements Act applies to all FSS schedules; therefore, all offerings under FSS, unless a non-availability determination has been made, must be either U.S.-made or designated country end products as defined in FAR 52.225-5. A U.S.-made product can be either 1) an article that is mined, produced, or manufactured in the United States, or 2) an article that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. Under the trade agreements, the test to determine country of origin is substantial transformation. For services, origin is determined by the country in which the firm providing the service is established, not the location at which the services are performed. Visit our Trade Agreements web page for more information and a full listing of all designated countries.

Note that the following non-availability determinations have been made which permit products sourced from all countries except those identified as prohibited sources at FAR subpart 25.7. Authorities provided under 2 and 3 below are temporary/limited and will be extended as needed.

1) Covered Drug Products - Schedule 65 I B, SIN 42-2A
2) Disposable Medical Nitrile Gloves - Schedule 65 II A, SIN A-13e
3) COVID-19 Rapid Diagnostic & Serology/Antigen Tests - Schedule 65 VII, SINs 555-2 & 555-8
How long is a VA FSS contract?

FSS awards contracts for an initial 5-year base period. All of our schedules, with the exception of Schedule 66 III Cost Per Test Clinical Laboratory Analyzers, contain clause 52.217-9 Option to Extend the Term of the Contract which provides the potential for one, 5-year option to be exercised, bringing the full contract term to 10 years. While Schedule 65 I B Drugs, Pharmaceuticals and Hematology Related Products does contain this clause, FSS does not exercise the 5-year option but will require 65 I B contractors to submit a follow-on proposal, although short-term extensions may be granted while a new contract is being negotiated. Schedule 66 III contains clause I-FSS-163 Option to Extend the Term of the Contract (Evergreen) which provides for three potential 5-year options for a full contract term of 20 years.

REMINDER!

IFF/Report of Sales Due

4th quarter FY 2021 sales reports and Industrial Funding Fee (IFF) payments are due starting on October 1, 2021. Sales and IFF not received by November 30, 2021, are considered delinquent, and the contract is subject to administrative actions including poor performance ratings or cancellation. All VA FSS contractors are required to submit a report via the VA Sales Reporting System even if no sales occurred under the contract. The 4th quarter covers sales from July 1st – September 30th.

For more information, visit our Sales Reports & IFF page online. For assistance from our VA Sales Desk, please contact us by e-mail at FSSSales.AMMHIN@va.gov.

Contact Us!

FSS Contractors Inquiries: Please contact your assigned Contract Specialist
FSS Helpdesk: Phone (708)786-7737  E-mail: HelpDesk.ammhinfss@va.gov
FSS Small Business Liaison, Micole Stephens: Micole.Stephens@va.gov, (708)786-5156
IFF/Report of Sales (VA Sales Portal) Inquiries: FSSSales.AMMHIN@va.gov
Pharm A Chief, Trevor Martin: Trevor.Martin@va.gov, (708)786-7708
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Med Surg A Chief, James Booth: James.Booth@va.gov, (708)786-5223
Med Surg B Chief, Deborah Zuckswerth: Deborah.Zuckswerth@va.gov, (708)786-5128
PMRS Chief, Dave Hackett: David.Hackett@va.gov, (708) 786-4936
FSS Director, Dan Shearer: Daniel.Shearer2@va.gov, (708) 786-4957

To subscribe to our VA FSS Newsletter, e-mail your request to ammhinFSSPMRS@va.gov.

How are we doing? Your feedback is important to us! Please complete our Customer Survey.

Upcoming Webinars

October 19th & 28th, 2021
Public Law 2022 – 2 Repeat Sessions

October 27, 2021
Small Business Subcontracting Plan Preparation
*FY 2022, 1st Quarter
Option to Extend Package Submission Best Practices
*Dates to be announced via GovDelivery & the FSS Training Webpage

Useful Links

FSS Web Portal
VA Schedule Programs
FSS Contractors
FSS Customers
Training
Modification Request Forms (RFMs)
Contractor Responsibilities
Small Business Subcontracting
Sales Reports & IFF

VA NAC
Federal Supply Schedule
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