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| **AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT** | | | | | | | | | | | 1. CONTRACT ID CODE | | | PAGES OF PAGES | | | |
| 1 | | 5 | |
| 2. AMENDMENT/MODIFICATION NO.  **Mass Modification 0013** | | | | 3. EFFECTIVE DATE | | | | 4. REQUISITION/PURCHASE REQ. NO. | | | | 5. PROJECT NO. *(If applicable)* | | | | | |
| 6. ISSUED BY: CODE: | | | | | 003B6B | | | 7. ADMINISTERED BY *(If other than Item 6)* CODE: | | | | | | |  | | |
| Department of Veterans Affairs  National Acquisition Center  P.O. Box 76, Bldg. 37  Hines, IL 60141 | | | | | | |  | | | | | | | | | |
| 8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)* | | | | | | | | | (X) | 9A. AMENDMENT OF SOLICITATION NUMBER | | | | | | | |
|
| 9B. DATED *(SEE ITEM 11)* | | | | | | | |
|
| X | 10A. MODIFICATION OF CONTRACT/ORDER NUMBER | | | | | | | |
| 10B. DATED *(SEE ITEM 13)* | | | | | | | |
| CODE | | FACILITY CODE | | | | | | |
| 11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS | | | | | | | | | | | | | | | | | |
| The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers  is extended  is not extended.  Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:  (a) By completing Items 8 and 15, and returning     copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted;  or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified. | | | | | | | | | | | | | | | | | |
| 12. ACCOUNTING AND APPROPRIATION DATA *(If required)* | | | | | | | | | | | | | | | | | |
| **13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS.**  **IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.** | | | | | | | | | | | | | | | | | |
| (x) | A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A. | | | | | | | | | | | | | | | | |
|  | B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office,* *appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b). | | | | | | | | | | | | | | | | |
| X | C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: 52.212-4(c) Contract Terms and Conditions - Commercial Products and Commercial Services (Changes) | | | | | | | | | | | | | | | | |
|  | D. OTHER *(Specify type of modification and authority)* | | | | | | | | | | | | | | | | |
| E. **IMPORTANT**: Contractor  is not,  is required to sign this document and return  1 copies to the issuing office. | | | | | | | | | | | | | | | | | |
| 14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*  **621 II Schedule Updates: Revision of the Scope of Solicitation**  This modification is issued to incorporate changes to the Scope of Solicitation and minimum geographic coverage requirements for the above-referenced contract pursuant to Amendment 0008 under solicitation number RFP-797-FSS-04-0001-R3. Specifically, this revision allows geographic service areas to be awarded to other than nationwide coverage. | | | | | | | | | | | | | | | | | |
| Except as provided herein, all terms and conditions of the document referenced in item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect. | | | | | | | | | | | | | | | | | |
| 15A. NAME AND TITLE OF SIGNER *(Type or print)* | | | | | | 16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)* | | | | | | | | | | | |
| 15B. CONTRACTOR/OFFEROR  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *(Signature of person authorized to sign)* | | | 15C. DATE SIGNED | | | 16B. UNITED STATES OF AMERICA  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *(Signature of Contracting Officer)* | | | | | | | 16C. DATE SIGNED | | | | |
| EXCEPTION TO SF 30 STANDARD FORM 30 (REV. 11/2016)  APPROVED BY OIRM 11-84 Prescribed by GSA FAR (48 CFR) 53.243 | | | | | | | | | | | | | | | | | |

**Revised Language**

**SCOPE OF** **SOLICITATION**

The Federal Supply Schedule (FSS) program is also known as the GSA Schedules Program or the Multiple Award Schedule (MAS) Program. The FSS program is directed and managed by GSA and provides Federal agencies with a simplified process for obtaining commercial supplies and services at prices associated with volume buying. Indefinite-delivery, indefinite quantity contracts are awarded to provide supplies and services at stated prices for given periods of time. GSA has delegated authority to the VA to manage the Schedules for medical supplies under the VA FSS program.

This solicitation is for the offering of reference laboratory services for the purpose of providing medical laboratory testing for the diagnosis, prevention, or treatment of a disease or condition and to assess patient health to make clinical decisions for patient care.  This solicitation is not for facilities that only collect and/or prepare specimens nor for those facilities that only serve as a mailing service and do not perform testing services.

This solicitation is issued to establish contracts which may be used on a nonmandatory basis by eligible users, as a source of supply for the supplies or services described herein, for domestic delivery.

Domestic delivery is defined as “delivery within the 48 contiguous states, Alaska, Hawaii, Puerto Rico, Washington, DC, and U.S. territories.” Offerors may be limited to geographic service areas based upon licensing requirements or may offer nationwide delivery. This solicitation further requires that offered prices cover delivery to destinations (i.e. F.O.B. destination) located within the 48 contiguous states and the District of Columbia. Offerors can choose whether or not prices cover delivery F.O.B. destination to Alaska, Hawaii, and the Commonwealth of Puerto Rico. Additionally, the solicitation defines the number of calendar days after receipt of order (ARO) within which delivery must be made (see 552.211-78 COMMERCIAL DELIVERY SCHEDULE (MULTIPLE AWARD SCHEDULE) (FEB 1996) (TAILORED)). Offerors who cannot provide the required minimum geographic coverage, that is one state, will not be considered for award.

As specified in the solicitation, offerors shall comply with all state, federal and local regulations, licenses, permits, and accreditation necessary to manage and conduct preanalytic specimen testing services. Offerors must comply with states that require out of state licenses/permits. Therefore, laboratories conducting clinical testing on specimens originating in a state that requires an out of state license/permit must hold that state’s Department of Health (or other governing body) clinical laboratory permit, licenses, etc.  Offerors that are not compliant with the originating state’s licensing and/or permit requirement, regardless of location, will not be considered for an award for that specific state. Offerors may not subcontract to another laboratory to circumvent the

originating state’s requirement for licensing, permits, etc. The offeror, in itself, is required to meet the requirements of the solicitation without the aid of a subcontractor.

The Government retains sole discretion to determine the offeror’s capability, compliance, and to limit SINs or geographic coverage.

**Commercial Items**

Per GSA regulations at 538.271(a), MAS awards are for commercial products and services as defined in FAR 2.101.

**Special Item Numbers (SINs):** FSS solicitations set forth broad categories of accepted products/services, referred to as Special Item Numbers (SINs), listed in the Continuation of SF1449 in Vendor Response Document 02. Offerors are not required to submit their entire catalog of products/services but are free to choose which items they will offer as long as those items fall within one of the solicitation’s pre-defined SIN categories. Items that do not fall within one of these SINs are considered to be out of scope of the solicitation and cannot be awarded. An item’s acceptability under the schedule may be further restricted by a determination of fair and reasonable pricing.

Offered diagnostic testing services must be categorized under the accepted services referenced under the Special Item Numbers (SINs) and classified as a specialties or subspecialties of tests as defined under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Please note that items offered are further restricted to those tests with CPT codes. Additionally, FSS will not award any home diagnostic tests under this schedule. Home diagnostic tests/test kits may be proposed under Schedule 65 V II Invitro Diagnostics, Reagents, Test Kits and Test Sets.

**FDA Regulatory Requirements**

Reagents used to perform the tests must be FDA cleared, as appropriate, or be identified as a Laboratory Developed Test (LDT). Offerors of tests not in compliance with these requirements shall not be considered for award under this solicitation.

**New Items vs. Refurbished or “Grey Market Goods”**

This solicitation is for the award of new items only. The Contractor shall provide only new equipment and new parts for the required products described herein. Absolutely no “grey market goods” or refurbished products shall be provided under any delivery order. Grey market goods are defined as genuine branded goods sold outside of an authorized sales territory (or by non-authorized dealers in an authorized territory) at prices lower than being charged in authorized sales territories (or by authorized dealers). All equipment must be covered by a manufacturer’s warranty.

**Trade Agreements Act**

The Trade Agreements Act (<https://www.acquisition.gov/far/part-25#FAR_Subpart_25_4>) is applicable to all FSS Schedules. In exercising its authority under FAR Part 25, Foreign Acquisition~~,~~ purchases by Ordering Activities are restricted to either U.S.-made or designated country end products as defined in clause FAR 52.225-5. For the purposes of this services schedule, origin is determined by the country in which the firm providing the service is established, not the location at which the services are performed.

**Notice of Additional Requirements - Ordering Level**

In addition to the terms and conditions set forth in this solicitation, the contractor may, in the performance of orders issued under this contract, be responsible for further requirements at the ordering level. For more information on these potential, additional requirements, please see the note in Solicitation Document 01 after FAR clause 52.216-18 Ordering.

**Please note** that the VA does not promote the use of any vendor’s specific Schedule contract. Vendors should be aware that obtaining a VA Schedule contract is **not a guarantee of sales**. Vendors awarded a VA Schedule contract will need to market their supplies and services to Government customers as they would to commercial customers (see <https://www.va.gov/opal/nac/fss/marketing.asp>). A listing of eligible schedule users can be found at on GSA’s website at <http://gsa.federalschedules.com/resources/eligible-gsa-schedule-users/>.

**Current contract holders do not need to complete sections below:**

**GEOGRAPHIC COVERAGE**

1. **Current Coverage:** List the specific U.S. states, including Alaska, Hawaii, Puerto Rico, Washington D.C., and U.S. territories in which you are currently providing or have provided services ***relative to this solicitation*** in the last two years. Enter “Nationwide” if currently providing nationwide (i.e. domestic delivery) coverage.
2. **Proposed Coverage:** Offerors may propose to provide service to individual states or nationwide. Respond to each question below regarding proposed coverage. For each choice selected, you must also check the box to verify your submission of the requested supporting documentation. Please note that qualifying “*supporting documentation*” means evidence of compliance with all federal, state and local license and certification in accordance with Statement of Work, Section II General Qualifications and Sub-Factor B.1 “Organization” sub-paragraph (a)(b) - Organizational and Professional Staff. The awards must be for services provided ***relative to this solicitation*** in the last two years.
3. **Offering Nationwide (i.e. Domestic Delivery) Coverage?** YES NO

Nationwide coverage includes the 48 contiguous states, Alaska, Hawaii, Puerto Rico, Washington, DC, and U.S. territories. In order to be awarded nationwide coverage, you must be able to provide the supporting documentation *as stipulated in the Technical Proposal section,* Sub-Factor B.1 “Organization”, sub-paragraph (a) and (b) demonstrating *compliance with licensing and accreditation as required by local, state, and federal law.*

*I understand there are Out of State Laboratory requirements such as Business Registration for the State of Alabama and Out of State Laboratory Licenses/Certificates for California, Maryland (for Genetics), New York, Pennsylvania, and Rhode Island.*

*I am providing a valid and active CLIA Certificate of Accreditation*

*I have met the requirements for Out of State Laboratories and providing all required Out of State Laboratory Licenses/Certificates*

*I am providing a valid and active CLIA Certificate of Accreditation for all offered subcontractors*

*I have met the requirements for Out of State Laboratories and providing all required Out of State Laboratory Licenses/Certificates for all offered subcontractors*

**b) Excluded States?** YES If yes, respond to the following:

I am unable to obtain and/or provide the licenses/certificates for the following states that require Out of State Laboratory Licenses/Certificates

*I have properly identified each test/analysis service with their respective current procedural terminology (CPT) code.*

*If applicable, I have identified all laboratory developed tests (LDTs) appropriately.*