

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>SAT)**

GLUCOSE SENSOR DEXCOM G6
Acquisition Plan Action ID: 36C770-19-AP-0940

1. Contracting Activity:

Department of Veterans Affairs
Network 15 Contracting Office (NCO 15)
3450 South 13th Street
Leavenworth, KS 66048

Department of Veterans Affairs,
VA CMOP Charleston
10 Industrial Drive
Chelmsford, MA 01824-3610

Purchase request number: **761-19-4-014-0470**

2. Nature and/or Description of the Action Being Processed:

- J&A supporting an RFQ for a - NAME BRAND ONLY - MedSurg Supply item, used in Patient Care. -
"Name Brand Only" meaning - no other like item will do.
- No Generic MedSurg Item from another manufacturer will be accepted.
- "Name Brand Only" originates with the VA Physician treating Veteran Patients
- A VA Physician has prescribed a specific Name Brand MedSurg item for Veteran use/treatment.
- Neither the CMOP nor Contracting Officer have the authority to change a Physician's prescription.
- This limits the Bids to one manufacturer but does not limit all bids from one source. –
- One Manufacturer (Name Brand) – there are several different suppliers/sources.

FAR13.5 Simplified Procedures for Certain Commercial Items:

This procurement is for MedSurg Supply Item, in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.

3. Description of Supplies/Services Required to Meet the Agency's Needs:

Manufacturer #	
Brand	GLUCOSE SENSOR DEXCOM G6
Manufacturer	DEXCOM
Country of Origin	Unknown
Application	Glucose Sensor
UNSPSC Code	
NDC	08627005303

- QTY : 1200 Boxes (BX)
- Est Value: **\$388.89**
- Delivery: 10 Days After Receipt of Order

Total Cost = \$466,668.00

Manufacturer #	
Brand	GLUCOSE SENSOR ENLITE MMT-7008A
Manufacturer	MEDTRONIC
Country of Origin	Unknown
Application	Glucose Sensor
UNSPSC Code	
NDC	76300700800

- QTY : 180Boxes (BX)
- Est Value: **\$419.00**
- Delivery: 10 Days After Receipt of Order

Total Cost = \$75,420.00

Manufacturer #	
Brand	CATH, SPEEDICATH COMPACT COLOPLAST #28702
Manufacturer	COLOPLAST
Country of Origin	Unknown
Application	Catheter
UNSPSC Code	
NDC	97621028702

- QTY : 50 Boxes (BX)
- Est Value: **\$85.80**
- Delivery: 10 Days After Receipt of Order

Total Cost = \$4,290.00

Manufacturer #	
Brand	LANCET, 28G
Manufacturer	HI-TECH
Country of Origin	Unknown
Application	Lancet
UNSPSC Code	
NDC	89134072602

- QTY : 1000 Boxes (BX)
- Est Value: **\$2.62**

- Delivery: 10 Days After Receipt of Order

Total Cost = \$2620.00

Manufacturer #	
Brand	SET,INFUSION AUTOSOFT 90 TANDEM #1002820
Manufacturer	TANDEM
Country of Origin	Unknown
Application	Infusion set
UNSPSC Code	
NDC	89152282005

- QTY : 120 Boxes (BX)
- Est Value: **\$67.74**
- Delivery: 10 Days After Receipt of Order

Total Cost = \$8128.80

4. Statutory Authority Permitting Other than Full and Open Competition:

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- () (2) Unusual and Compelling Urgency per FAR 6.302-2;
- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

FAR13.5 Simplified Procedures for Certain Commercial Items: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

- This is not a J&A for a Sole Source procurement.
- This a J&A for a Name Brand Only Item - available from multiple suppliers.
- Name Brand Only is designated under Physician's Orders.
- The attending Physician has prescribed a Name Brand: GLUCOSE SENSOR (3) GUARDIAN MMT-7020A for Veteran Patient Use.
- The CMOP facility and CMOP contracting office do not have the authority to arbitrarily change or modify the Physician's Prescription (i.e. substitute a generic brand for a name brand).
- Within the Veterans Health Administration brand name drugs and medical surgical (MedSurg) products may be prescribed by physicians when in their clinical judgment the brand name drug/MedSurg will provide a better therapeutic outcome for patients.

- Brand name drugs and MedSurg are requested when there is a clinical requirement for the drug/product or there is history of clinical requirements for the drug/product and inventory must be maintained to meet anticipated requirements.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

- Solicitation: **36C770-19-AP-0940**, GLUCOSE SENSOR DEXCOM G6 - will be posted to FedBizOps as other than full Full and Open.
- A pre-solicitation notice will be posted to FedBizOps on 8/20/2019.

7. Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:

The CO anticipates the cost will be considered fair and reasonable based on the following:

- Comparison will be made against historical purchases.
- Comparison to the IGCE.
- Internet searches of commercial product prices, which are listed.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

- Vip.Vetbiz.Va.Gov search NAICS Code 325413 shows 25 SDVOSB's capable of bidding.
- The CO has a reasonable expectation that two or more SDVOSBs will bid on this RFQ.
- CO has a reasonable expectation SDVOSB authorized vendors who sell the product or can get the product from an authorized source.
- It is not certain if vendors can get the product at the same cost as the manufacturer.
- The manufacturer is a large business and has never offered a quote in past solicitations.
- GLUCOSE SENSOR DEXCON G6 are made by DEXCOM – large business.
- Procurement exceeds the SAT threshold; nonmanufacturer rules applies therefore prohibiting the use of a set-side.
- Per the Code of Federal Regulations §121.406, the performance requirements (limitations on subcontracting) and the nonmanufacturer rule do not apply to small business set-aside acquisitions with an estimated value between the micro-purchase threshold and the simplified acquisition threshold (SAT). This allows for a SDVOSB set-aside MedSurg procurement, which solicits from SDVOSB vendors who are authorized suppliers but the not the manufacturer of the MedSurg Item.
- The nonmanufacturer rule, however, applies for MedSurg procurements over the SAT. Therefore, without a waiver in place, the solicitation (RFQ) must be released as Open Market with limited competition.
- The same SDVOSB vendors who are authorized suppliers but not the manufacturer of the product may provide a quote along with other business size classes.
- In order to request a waiver to the nonmanufacturer rule for a pharmaceutical/MedSurg procurement over the SAT, the Code of Federal Regulations §121.1203, (a), states, "Where appropriate, SBA will generally grant waivers for an individual contract or order prior to the issuance of a solicitation, or, where a solicitation has been issued, when the contracting officer provides all potential offerors additional time to respond." In addition, §121.1203, (a)(4)(i), requires a public notice to be issued on the Commerce Business Daily and the Federal Register seeking information on small business manufacturers or processors, announcing a notice of intent to waive the Nonmanufacturer Rule for that class of products and affording the public a 15-day comment period is required.
- In order to avoid pharmaceutical supply shortages at the CMOP facilities, the facilities require an average of 10 days delivery of the pharmaceutical after the receipt of the order.
- The SBA waiver processing timeline exceeds the CMOPs required delivery timelines.

