

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)**

1. Contracting Activity:

Department of Veterans Affairs
Network 15 Contracting Office
3450 S. 4th Street Trafficway
Leavenworth, KS 66048

The purchase request number is: 760-15-3-050-0815
Items are to be delivered to the Leavenworth VA CMOP

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

The Leavenworth CMOP, 5000 S. 13th Street Leavenworth, KS 66048, Consolidated Mail Outpatient Pharmacy is requesting approval to purchase the BRAND NAME only per physicians determination of need for the following items: Reservoir Minimed #MMT-332A, Set infusion Minimed #MMT-399, #MMT-397, Silhouette 13MM-23" Paradigm (MMT-381), Reservoir Minimed #MMT-326A, Quick set 9mm-32" Paradigm (MMT-386), Mio 9mm-32" Clear Paradigm (MMT-975), Infusion minimed #MMT-866, and Inserter quick-serter minimed #MMT-395. The total estimated value for this request is [REDACTED]. The list below does include all drug items included in this request.

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

Reservoir, Minimed #MMT-332A

- NDC: 76300-0332-10
- Quantity: 10 per box, 820 boxes requested
- Supplier: Medtronic

Set infusion Minimed #MMT-399

- NDC: 76300-0399-10
- Quantity: 10 per box, 750 boxes requested
- Supplier: Medtronic

Set, Infusion Minimed #MMT-377

- NDC: 76300-0377-10
- Quantity: 10 per box, 100 boxes requested
- Supplier: Medtronic

Set infusion Minimed #MMT-397

- NDC: 76300-0397-10
- Quantity: 10 per box, 620 boxes requested
- Supplier: Medtronic

Silhouette 13MM-23" Paradigm, MMT-381

- NDC: 76300-0381-10
- Quantity: 10 per box, 150 boxes requested
- Supplier: Medtronic

Reservoir, Minimed #MMT-326A

- NDC: 76300-0326-10
- Quantity: 10 per box, 1,200 boxes requested
- Supplier: Medtronic

Quick-set 9MM-32" Paradigm, MMT-386

- NDC: 76300-0386-10
- Quantity: 10 per box, 250 boxes requested
- Supplier: Medtronic

Set, Infusion Minimed #MMT-371

- NDC: 76300-0371-10
- Quantity: 10 per box, 30 boxes requested
- Supplier: Medtronic

MIO 9MM-32" Clear Paradigm, MMT-975

- NDC: 76300-0975-10
- Quantity: 10 per box, 90 boxes requested
- Supplier: Medtronic

Set, infusion Minimed #MMT-866

- NDC: 76300-0866-10
- Quantity: 10 per box, 50 boxes requested
- Supplier: Medtronic

Set, infusion Minimed #MMT-864

- NDC: 76300-0864-10
- Quantity: 10 per box, 70 boxes requested
- Supplier: Medtronic

Insertor Quick-Setter Minimed #MMT-395

- NDC: 76300-0395-01
- Quantity: 10 per box, 40 boxes requested
- Supplier: Medtronic

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

- (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1; Brand name description application applies.

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

Once a physician determines that their treatment plan for a patient includes an insulin pump, the Prosthetic Department of the VA Medical Center issues a Medtronic Minimed wearable constant insulin delivery system to the patient. These devices were researched, tested, and approved by the VA as the preferred item for this treatment. Neither Medtronic or a physician will validate or waive liability of using other than Minimed products in conjunction with the issued pump. Although there are many infusion items designed to be interoperable with all pumps, Medtronic contends that they cannot ensure that the prescribed medicine is delivered when third party parts are used with their pump. According to Medtronic, manufacturer specific, non-interchangeable, parts for administering the insulin are required to ensure proper dosage.

If the CMOP National File entry has a specific brand or item number in the prescription description, the CMOP is ONLY allowed to dispense that exact item match. The VA Doctors writing prescriptions do so based on clinical need and write the prescription accordingly to provide critical patient care. The pump works in conjunction with the associated tubes to deliver the insulin as prescribed by a physician. The manufacturer cannot guarantee that the prescribed medical dose can or will be delivered as prescribed if any part of the Minimed device is NOT manufacturer approved. Not using the entire Minimed package (tubes, pump, and injection ports) could pose a threat to the patient as the prescribed amount cannot be guaranteed. The accessories are a part of a highly specialized insulin delivery system that can use other than manufacturer accessories but it is not recommended. If third party accessories are used, Medtronic cannot ensure the insulin delivery device is delivering insulin as prescribed by a physician. Based on this inability to ensure the prescribed dose is being delivered accurately, using third party accessories can put patient care in jeopardy. Mildly low blood sugar levels are somewhat common for people with diabetes; however, severely low blood sugar levels can be life-threatening. They may lead to seizures and nervous system damage. Immediate treatment is critical. It is imperative that the pump functions correctly.

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

- Thorough market research has been conducted and it has been found that Medtronic Minimed Reservoir pumps, inserts, and infusion sets are not found to be on VA NAC or GSA contract.
- There are several small business and SDVOSB wholesaler/distributors that can provide these Medtronic items on the open market.

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

- The Leavenworth CMOP anticipates the cost to the Government will be fair and reasonable based on recent prices paid by CMOP.
- There will be competition between wholesalers/distributors for the requested items.

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

- After searching NAC & GSA, there are no available contracts for any of the items requested. A search of the Center for Veteran Enterprise Vendor Information Pages indicates there are 77 SDVOSB or VOSB vendors which are engaged in the manufacture of pharmaceuticals. A query at the SBA Dynamic Search portal returned 949 possible small business vendors. However, these vendors are not engaged in manufacture, but are distributors for large business wholesalers. Because the Government is not allowed to do business using Wholesale Trade or Retail Trade NAICS codes, searches must be conducted using the manufacture NAICS code of 339112 Pharmaceutical Preparation Manufacturing.
- Acquisition History:
 - VA770-15-P-0087
 - Awarded to Veterans Healthcare Supply Solutions on February 23, 2015 in the amount of [REDACTED].
 - NAICS: 339112
 - Extent Competed: Full and Open Competition
 - Type of set aside: No set aside used
 - Socio-economic status of vendor: SDVOSB
 - VA255-15-P-1382
 - Awarded to Veterans Healthcare Supply Solutions on December 23, 2014 in the amount of [REDACTED].
 - NAICS: 339112
 - Extent Competed: Full and Open Competition
 - Type of set aside: No set aside used
 - Socio-economic status of vendor: SDVOSB

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Not applicable.

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Not applicable.

11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:**

- At this time, the physician has stated the above mentioned name brand drugs are the only brands that will meet the specific needs of the patients; however, we are still competing this amongst distributors.

12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

Robin Halstead
Inventory Management Specialist
VA CMOP Leavenworth #760

Date

13. Approvals in accordance with the [VHAPM, Volume 6, Chapter VI: OFOC SOP](#).

- a. **Contracting Officer's Certification (required)**: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Jonathan Chisholm
Contracting Officer
CMOP Acquisitions, NCO 15

Date

- b. **Director, CMOP Acquisitions (Required)** I certify the justification meets requirements for other than full and open competition.

Christine L. Scena
Director, CMOP Acquisitions
NCO 15

Date