

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 3: Request for Sole Source Justification Format >\$150K

DEPARTMENT OF VETERANS AFFAIRS

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

1. **Contracting Activity:** Department of Veterans Affairs, NCO 15, Leavenworth, KS CMOP; 13 S. Street, Leavenworth, KS 66048. This request is a Justification for Other Than Full and Open Competition for the purchase order# 760-15-1-050-0237.

2. **Nature and/or Description of the Action Being Processed:** New procurement for Medtronic MINIMED insulin pump infusion products. This request is for a firm-fixed price for the associated infusion products for the MINIMED infusion pump. The total is [REDACTED].

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

RESERVOIR, MINIMED #MMT-332A XZ835

- NDC -76300033210 (NO SUBSTITUTES)
- Quantity and Description of request: 10 per box RESERVOIR, MINIMED #MMT-332A
- Supplier: Medtronic
- The estimated Purchase Order value is for this request for this item is [REDACTED]

RESERVOIR, MINIMED #MMT-326A XV094

- NDC -76300032610 (NO SUBSTITUTES)
- Quantity and Description of request: 10 per box RESERVOIR, MINIMED #MMT-326A
- Supplier: Medtronic
- The estimated Purchase Order value is for this request for this item is [REDACTED]

RESERVOIR, MINIMED #MMT-397 XZ672

- NDC -76300039710 (NO SUBSTITUTES)
- Quantity and Description of request: 10 per box RESERVOIR, MINIMED #MMT-397
- Supplier: Medtronic
- The estimated Purchase Order value is for this request for this item is [REDACTED]

RESERVOIR, MINIMED #MMT-398 XZ670

- NDC -76300039810 (NO SUBSTITUTES)
- Quantity and Description of request: 10 per box RESERVOIR, MINIMED #MMT-398
- Supplier: Medtronic
- The estimated Purchase Order value is for this request for this item is [REDACTED]

RESERVOIR, MINIMED #MMT-399 XZ673

- NDC -76300039910 (NO SUBSTITUTES)
- Quantity and Description of request: 10 per box RESERVOIR, MINIMED #MMT-399
- Supplier: Medtronic

760-15-1-050-0237

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- The estimated Purchase Order value is for this request for this item is [REDACTED]

RESERVOIR, MINIMED #MMT-381 XV652

- NDC -76300038610 (NO SUBSTITUTES)
- Quantity and Description of request: 10 per box RESERVOIR, MINIMED #MMT-381
- Supplier: Medtronix
- The estimated Purchase Order value is for this request for this item is [REDACTED]

RESERVOIR, MINIMED #MMT-386

- NDC -76300038610 (NO SUBSTITUTES)
- Quantity and Description of request: 10 per box RESERVOIR, MINIMED #MMT-386
- Supplier: Medtronix
- The estimated Purchase Order value is for this request for this item is [REDACTED]

RESERVOIR, MINIMED #MMT-864

- NDC -76300086410 (NO SUBSTITUTES)
- Quantity and Description of request: 10 per box RESERVOIR, MINIMED #MMT-864
- Supplier: Medtronix
- The estimated Purchase Order value is for this request for this item is [REDACTED]

RESERVOIR, MINIMED #MMT-866 XT583

- NDC -763000866910 (NO SUBSTITUTES)
- Quantity and Description of request: 10 per box RESERVOIR, MINIMED #MMT-866
- Supplier: Medtronix
- The estimated Purchase Order value is for this request for this item is [REDACTED]

RESERVOIR, MINIMED #MMT-975

- NDC -76300097510 (NO SUBSTITUTES)
- Quantity and Description of request: 10 per box RESERVOIR, MINIMED #MMT-975
- Supplier: Medtronix
- The estimated Purchase Order value is for this request for this item is [REDACTED]

RESERVOIR, MINIMED #MMT-373 XZ109

- NDC -76300037310 (NO SUBSTITUTES)
- Quantity and Description of request: 10 per box RESERVOIR, MINIMED #MMT-373
- Supplier: Medtronix
- The estimated Purchase Order value is for this request for this item is [REDACTED]

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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;

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 Department of Veterans Affairs 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. Medtronic MINIMED products are issued to patients for insulin dependent patients by Prosthetics. The associated infusion products are also provided by the Medtronic MINIMED manufacturer. Neither MINIMED or a physician will validate or waive liability of using other than MINIMED products in conjunction with the issued pump. Although many infusion items designed to be interoperable with all pumps, MINIMED contends that they cannot ensure that the prescribed medicine is delivered when third party parts are used with their pump. According to MINIMED, manufacture specific, non-interchangeable, parts for administering the insulin are required to ensure proper dosage.

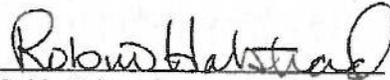
If the CMOP National File entry has a specific brand or item number in the prescription description, the CMOP is ONLY allowed to dispense that exact item match. The VA Doctors writing prescription do so based on clinical need and write the prescription according to provide critical patient care. Being a unique medical device, the pump works in conjunction with the associated tubes, and the insulin to deliver the insulin as prescribed by a physician. The manufacture 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 manufacture 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 the 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. For people at risk of low blood sugar, having a glucagon kit, a medication that raises blood sugar levels, is important. It is imperative that the pump functions correctly.

Additionally, the Metronic MINIMED has been dispensed to our Veteran Patients for a significant time period. Changing the device would incur significant cost to the VA.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: Theses items are purchased from several sources, mostly large businesses as they offer the best price for the government.

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7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The CMOP anticipates the cost to the Government will be fair and reasonable based on competition and comparison to recent prices paid by CMOP.
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 80 SDVOSB or VOSB vendors which are engaged in the manufacture of medical/surgical items. A query at the SBA Dynamic Search portal returned 945 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 Surgical and Medical Instrument Manufacturing.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Patient care cannot be compromised as serious consequences (to include death) can occur if the insulin delivery system is not properly functioning. The manufacture will not be held liable for any malfunction if third party pump accessories are used.
10. **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 medical/surgical items are the only brands that will meet the specific needs of the patients, however, we are still competing this amongst distributors.
11. **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 Procurement
Leavenworth CMOP 760

12-2-2014
Date

12. **Approvals in accordance with the FAR 6.304.**

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

Donald J.
Denno 927072

Dig2ally signed by Donald J. Denno 927072
DN: cn=denno, dc=va, ou=contracting_officer, o=927072, email=denno@va.gov, c=US, st=Denno, ou=Denno 927072
Date: 2014.12.02 13:52:11 -0600

Donald J. Denno
Contracting Officer
NCO15

Date

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- a. Director of Contracting / Designee : I certify the justification meets requirements for other than full and open competition.

Donald J.

Denno 927072

Digitally signed by Donald J. Denno 927072
DN: c=gov, dc=va, ou=Internal, ou=people,
o=92342.19200300.100.1, email=denno,
@va.gov, cn=Donald J. Denno 927072
Date: 2014.12.02 13:15:47 -0600

for Christine L. Scena
Director of Contracting
NCO15

Date

QA review
Lori Kopacz
12/2/14