

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: ___VA770-18-AP-0311

1. *Contracting Activity:* Consolidated Mail Outpatient Pharmacy Leavenworth, KS the Department of Veterans Affairs Network 15 Contracting Office (NCO), 3450 S. 4th St Trafficway, Leavenworth, KS 66048 is the contracting agency. Supplies will be purchased for the CMOP Chelmsford location at 10 Industrial Avenue Chelmsford, MA 01824-3610.
761-18-2-014-0132

LINE 1 - XH509 – GLUCOSE SENSOR ENLITE MMT-7008

- NDC/PART# MMT-7008A
- QUANTITY OF REQUEST: 288
- SUPPLIER: MEDTRONIC

Enlite Sensor

Enlite™ Glucose Sensors have an electrode inserted just under the skin and measure glucose values which are relayed to the pump and CGM monitor. Enlite combines improved performance and is designed for comfort and ease of use.

Please note: The Enlite Sensor must be combined with the Guardian 2 Link transmitter/MiniLink transmitter to wirelessly transmit glucose readings to the MiniMed 640G/VEO insulin pump. You must complete a Continuous Glucose Monitoring (CGM) start with your healthcare professional team before using this product. Be sure to discuss questions specific to your health and treatments with a healthcare professional.

One button insertion process
Up to 6 days use
Indicated for Children and Adults

The estimated Purchase Order value is for this request for this item is \$

LINE 2 - XJ024 - GLUCOSE SENSOR (3) GUARDIAN MMT-7020

- NDC/PART# - MMT-7020(A)
- Quantity of Request: 288

- SUPPLIER: MEDTRONIC

The Guardian Sensor (3) is intended for use with the Medtronic MiniMed® 670G system to continuously monitor glucose levels in persons with diabetes. It is intended to be used for detecting trends and tracking patterns in persons aged fourteen years and older, and to be used by the MiniMed 670G system to automatically adjust basal insulin levels. It is indicated for use as an adjunctive device to complement, not replace, information obtained from standard blood glucose monitoring devices. The sensor is intended for single use and requires a prescription. The Guardian Sensor (3) is indicated for 7 days of continuous use.

The estimated Purchase Order value is for this request for this item is \$

2. 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;

Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority): Products have been prescribed for patients by VA Physicians. Pharmacy employees do not have the training and/or authority to countermand physician orders. "Brand Specific" products are the same thing as "dispense as written" on a physician prescription. No NDC substitutions are permitted. In the VA, Pharmacy Benefits Management (PBM) has determined that CMOP IDs in the National Drug File (NDF) will most always identify "brand specific" products in the VA PRINT NAME. This is not always inclusive where a particular NDC has been determined to be "formulation specific" by clinical evaluation performed by the PBM or in the case where only one product in the marketplace has been identified to contain the specific ingredients to match the product code.

3. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: *This will be released on FBO.GOV as an unrestricted item*

4. Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable: : The IGCE contains the estimated cost to the government and serves as the recognition of F&R

5. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted: Products were searched in the NAC and GSA catalog and none of the items were found to be on contract.

6. Any Other Facts Supporting the Use of Other than Full and Open Competition: Due to physician prescribed devices, the need to compete for this brand name specific item will result in Veterans receiving the appropriate items for the prescribed use.

7. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: NA

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: There were no actions taken to remove or overcome barriers as these are brand name specific items prescribed by a physician and no generic or other item will meet the needs of the government.

8. 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.

_____ Not Needed _____
Diana Walters Date
Title Inventory Mgt Supervisor
Facility VA CMOP Chelmsford

Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP:](#)

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

_____ Date
Name Lori Nichols Fellows
Title Contracting Officer
Facility NCO 15 (CMOP)

b. **One Level Above the Contracting Officer (Required over\$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

_____ Date
Name James Justus
Supervisor (CMOP)
NCO 15 (CMOP)

c. **VHA SAO HCA Review and Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (if over \$68 million) or approve (\$700K to \$68 million) for other than full and open competition.

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Sole Source Justification Format >\$150K

_____ Not Needed _____
Name Date
VHA Head of Contracting Activity (HCA)

- d. **VHA Senior Procurement Executive Approval (over \$68 million)**: I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

_____ Not Needed _____
Jan R. Fry Date
Deputy Assistant Secretary for Acquisition and Logistics
Senior Procurement Executive (SPE)
Department of Veterans Affairs