

JUSTIFICATION FOR OTHER THAN FULL AND OPEN COMPETITION
VA797N-13-R-0019
IN ACCORDANCE WITH FAR 6.302-1
For REMOTE MONITORING SYSTEM

(1) Agency & Contracting Activity:

Department of Veterans Affairs
National Acquisition Center
Hines, IL 60141

(2) Action:

Sole Source Justification to contract with Medtronic, Inc., for a requirements type contract with one (1) year base period and four (4) one (1) year option periods.

The VA National Cardiac Device Surveillance Program (VANCDSP) was established as a national special program by the Patient Care Service in 2003 to provide remote monitoring of implanted cardiac devices (ICD, pacemakers and CRT) with such functionality.

(3) Item Description:

Medtronic, Inc., implanted cardiac devices are covered by the terms and conditions of this contract and any devices newly approved by FDA for which Medtronic, Inc., offers remote monitoring.

(4) Statutory Authority:

41 U.S.C. 253(c) authorizes, under certain conditions, contracting without providing for full and open competition. Only one responsible source and no other supplies or services will satisfy the agency's requirements.

(5) Unique Qualifications:

The Prosthetics Sensory Aids Service (PSAS) has determined that the need for the remote monitoring system from Medtronic, Inc., and is required for the following reasons:

- Remote monitoring allows close follow-up of device function without clinic visits. At present, devices from about 15,000 veterans are being remotely monitored by VANCDSP. Each device vendor (manufacturer) has its own proprietary technology for communication with its devices and remote transmission of the interrogated data. Accordingly, a separate contract with Medtronic, Inc., is required for remote monitoring of its own devices.

(6) Publication of Pre-Solicitation Notice:

A Pre-solicitation – Notice of Intent to Negotiate a Sole Source contract was published in Federal Business Opportunities (FedBizOpps) website (numbered VA797N-13-R-0019, dated 8/2/2013).

(7) Fair & Reasonable Pricing:

Historically, pricing for remote monitoring over telephone land lines has been at no cost. Prices for cellular adaptaters and services have ranged from \$450.00 to \$849.00 per device as a one time fee for the life of the patient and are determined to be fair & reasonable.

(8) Market Research:

Past market research was conducted and determined that no vendors offer a universal remote monitoring system that could monitor any manufacturer's device.

(9) Other Facts Supporting "Other Than Full and Open Competition":

PSAS's defibrillators (ICD), pacemakers and cardiac resynchronous therapy devices (CRT) Integrated Product Team (IPT) is made up of clinical experts in the field of cardiac care. The members of the group work directly with patients in prescribing these devices and are aware of the products offered in the commercial market place. It is the user group's medical determination that no other company can offer the medical advantages for VA patients of the Medtronic, Inc., specific remote monitoring devices that are being sought under this sole source procurement.

(10) Other Sources:

While there are other remote monitoring devices in the commercial market place, no other remote monitoring system possesses the unique and patented features of the Medtronic, Inc., monitoring device which will be used solely to monitor Medtronic, Inc., manufactured cardiac implants.

(11) Actions to Overcome Barriers to Full & Open Competition in Future Procurements:

Future technology may offer opportunities for companies to develop universal remote monitoring devices and thus, increase competition. Plus, all future procurements will continue to be advertised in the Federal Business Opportunities website for the purpose of obtaining competition.

(12) Certification:

I hereby certify that the foregoing justification and the supporting data (signed certification) for other than full and open competition is accurate and complete to the best of my knowledge and belief.

Timothy M. Richards 8-13-2013
Timothy M. Richards Date
Contracting Officer

Ronald E. Jenkins 8/19/13
Ronald E. Jenkins Date
Chief, Medical/Surgical Branch, National Contract Service

Steven A. Thomas 8/21/13
Steven A. Thomas Date
Director of National Contracts Service

I have reviewed the justification for other than full & open competition and have no legal objection.

Maura Brown 8/21/13
Maura Brown Date
Attorney
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Approve () Do Not Approve ()

Craig Robinson 8/22/13
Craig Robinson Date
Associate Deputy Assistant Secretary
for National Healthcare Acquisitions
Department of Veterans Affairs
National Acquisition & Logistic Center