



DEPARTMENT OF VETERANS AFFAIRS
National Acquisition Center
Denver Acquisition & Logistics Center
555 Corporate Circle
Golden, CO 80401

**JUSTIFICATION AND APPROVAL FOR OTHER THAN FULL AND OPEN COMPETITION
HOME TELEHEALTH SERVICE ONLY BRIDGE CONTRACT**

Identification Number: Sole-Source Contract for Service-Fees with Medtronic Care Management Services, LLC (previously Cardiocom)

1. Identification of the agency, contracting activity, and specific identification of the document as a justification for other than full and open competition.

The Department of Veterans Affairs (VA), Office of Acquisition and Logistics, National Acquisition Center, Denver Acquisition and Logistics Center (DALC) proposes to issue a sole source contract to Medtronic's on a basis of other than full and open competition for the Department of Veterans Affairs (VA), Veterans Health Administration (VHA), Office of Connected Care (OCC). In February 2017, four contracts were awarded for Home National Telehealth. Out of the four awarded contracts, one contract has been terminated for failure to meet Trade Act Agreement (TAA) requirements. The three remaining contractors are currently in the process of achieving Authority to Operate (ATO), which involves passing stringent security scan involving HL7 data transmission and two of those contractors are awaiting substantial transformation rulings from Customs and Border Protection (CBP). All contractors have experienced delays in passing the required security scans. Due to the aforementioned, the original go-live date for the contract of August 1, 2017 has been pushed back to October 15, 2017. The program requires a minimum of three months to transition 90,000 patients off of the legacy Medtronic's equipment, to the new Home Telehealth equipment and service fees. The current Medtronic contract reaches term on November 14, 2017, which will only leave 30 days to transition the 90,000 patients. This is unachievable logistically and would cause a lapse in services to over 90,000 veterans currently in the Home Telehealth program. The original contract provided for commodities and services to support the program. This bridge contract would be only for the general service fee CLIN to support the devices already in the field. There would be a 78 day period of performance to allow the program to transition the 90,000 Veterans by January 31, 2018.

2. The nature and/or description of the action being approved.

This action will be a sole source contract action with a 78 day period of performance to the following contractor:

Medtronic Care Management Services, LLC (MCMS) (previously named Cardiocom, LLC)
7980 Century Blvd.
Chanhassen, MN 55317-8000

3. A description of the services required to meet the agency's needs.

Veterans use the home technologies to upload vital signs, clinical question responses, and other measurements that can help them self-manage their condition and alert to the need for active care/case management, including referral for clinic and/or hospital care. This data includes, but is not limited to the following: blood glucose, blood pressure, pulse, temperature, weight, pain, and pulse oximetry. All these

measurements are obtained from peripheral devices (except pain which is subjective and manually entered using a Likert Scale). Peripheral devices are provided with the HT platform and transmit this data by wired or wireless connection, or self-reported manual entry. The data that is collected on the HT platform is sent to a Care Coordinator Web Viewer (CCWV) managed on each Contractor's server at the VA Data Centers in Austin, TX. The monitoring information is then available to the care coordinators (CC) through a web based platform for the purposes of managing the health conditions of the Veterans.

The HT devices automatically send all data collected each day to a contractor owned server that is located within the secure VA hosted environment. In addition to vital sign data, this same data acquisition/transmission/ storage/management system presents patients with a series of questions each day in the form of Disease Management Protocols (DMPs). These DMPs help the Veteran understand their medical condition, communicate symptoms and modify behaviors to prevent the need for emergency room visits and hospital admissions. To substantiate that Veteran patients who receive care in their own homes are satisfied with this mode of care and do not suffer a diminution of health status, VHA also administers a patient satisfaction survey through the home telehealth platforms approximately every three months.

The vital signs, DMP responses, and patient satisfaction survey responses are collected on the HT platforms. Requests for this data originate from the contractor's server within the secure VA hosted environment and the results from the HT platform are transmitted back to the contractor's server within the secure VA hosted environment. Once received, the vital sign and DMP data are stored on the server and then forwarded to VA clinicians over the VA intranet to the VHA clinician desktops where this secure data can be viewed via a secure browser. This data is displayed by panels of patients and by individual patient. Software algorithms on the contractor servers prioritize patients according to the risk level of their condition based upon responses to the DMPs and the relationships of vital sign data thresholds. The Clinical Web Viewers are unique to each contractor.

4. The statutory authority permitting other than full and open competition.

The statutory authorities permitting other than full and open competition is FAR 6.302-1, Only one responsible source and no other supplies or services will satisfy agency requirements.

5. A statement demonstrating the unique qualifications of the proposed contractor or the nature of the action requiring the use of the authority.

Medtronic Care Management Services, LLC (MCMS) was awarded a contract under the previous Home Telehealth Solicitation issued by the VA's National Acquisition Center, effective May 2011. Although six contracts were awarded, MCMS remains as the only contractor for the current program; thus providing equipment and support services for their equipment to 100% of the patients in the program. Three of the previous contracts were not renewed for a variety of issues, regarding inability to meet the information technology requirements and associated security breaches. One contractor confirmed that they no longer were participating in HT and resultantly downsized that branch of their company. One contractor's contract expired, and even with an option remaining on their previous extension, the program office decided it was in the best interest of the government not to exercise that option as they only supported a small portion of the Veteran population in the HT program. Additionally, Medtronic's is the only contractor capable of providing service to their proprietary Hub's.

6. A description of efforts to ensure that offers were solicited from as many potential sources as is practicable. Include whether or not a FedBizOps (FBO) announcement was made and what response, if any, was received, or include the exception under FAR 5.202 if not synopsis. Describe whether any additional or similar requirements are anticipated in the future.

For this sole-source bridge contract no other sources have been considered. Four new contract awards were made February 1st, 2017 after an arduous evaluation process. The new contract awards were accomplished via an IPT, under full and open competition in accordance with all applicable FAR sections, clauses, and provisions.

7. The anticipated dollar value of the proposed acquisition, including options if applicable, and a determination by the Contracting Officer that the anticipated cost to the Government will be fair and reasonable.

The estimated value of services will be approximately \$2,883,742.81 for the 78 day bridge contract. The Contracting Officer has determined that the current Medtronic's contract price(s) are fair and reasonable because they were established within a competitive environment and the Contracting Officer will only award a service fee bridge contract at the same rate as the general service fee rates on the new contract awaiting ATO. The bridge contract is expected to be awarded at pricing identical to the base year pricing for Medtronic's service fee under their current contract.

8. A description of the market research conducted and the results.

Revised market research was not required for this sole source period because the new HT solicitation has a complete market research report included in the solicitation file. Additionally, the Contracting Officer documented the best value determination of the competition that was received.

9. Any other facts supporting the use of other than full and open competition.

Informal planning for the new solicitation commenced in June 2013 and the official Integrated Product Team (IPT) started in December 2013. The acquisition plan included a reasonable schedule of issuing the Request for Proposal in June 2015 and award of four new contracts in December 2015. This plan allowed for approximately six months for new vendors to complete their IT infrastructure requirements to receive orders. However, in June 2015, the IPT was notified that VHA Prosthetic and Sensory Aid Service (PSAS) would no longer pay for the general service fees in the contracts because they are not prosthetic items. Given that these fees amount to about half of the program costs, the solicitation was put on hold until Office of Care Coordination (OCC) acquired the required funding.

The decision by VHA to require PSAS to continue funding the entire HT program took several months causing the solicitation issue date to be delayed until November 4, 2015. As a result of the solicitation, 15 proposals were received December 28, 2015. The evaluation included several phases and teams including information technology/security and clinical before submitting the consensus reports to the contracting officer for the best value determination. The lengthy evaluation process along with the two pre-award GAO protests delayed the contract awards significantly from the original plan. The original 5 year contract with MSMC (previously Cardiocom) received an extension of six (6) months, with an option for an additional six (6) months. The previous extension was approved on January 7th, 2016 under the authority of 6.302-2. Both options have been exercised, and the second Option expired May 14th, 2017. A separate justification was prepared for an

additional six (6) month extension which will expire on November 14, 2017. These are separate justification.

A lapse in service would require the 90,000 veterans to visit their local VAMC or CBOC for their care. In an already over-burdened VA health care system, this is not an acceptable situation and the government would be seriously harmed. There would be additional expenses for each veteran to travel to the nearest VAMC or CBOC to have vital signs taken; it is to be noted that many veterans in the HT program require daily vital signs or biometric readings. If Veterans do not have access to their HT systems to report their vital signs and biometric readings, there is significant patient safety risk that a Care Coordinator will not have visibility of a patient that may require constant care. Finally, there are approximately 1,500 VHA telehealth coordinators and support staff who would have no patients to take care of during the lapse in service.

Issuing this bridge contract ensures that the 90,000 veterans receive care and OCC and the DALC can adequately manage the transition to the new contracts.

10. A listing of any sources that expressed a written interest in the acquisition.

The following contractors were awarded under the 2015 solicitation for the HT program and would have interest in this extension:

1 Vision, LLC
1 Discover Place,
Martinsburg WV, 25403-1844

Care Innovations, LLC
3721 Douglas Blvd Suite 100,
Roseville, CA 95661-4243

Iron Bow Technologies, LLC
4800 Westfields Blvd Suite 300,
Chantilly, VA 20151-2299

Medtronic Care Management Services, LLC
7980 Century Blvd.,
Chanhassen, MN, 55317-8000

11. A statement of any actions the agency may take to remove or overcome any barriers to competition, if subsequent acquisitions are anticipated.

As mentioned previously, four new contract awards were made February 1st, 2017. Consequently, barriers to competition have already been removed for subsequent acquisitions.

12. Requirements Certification. I certify that the information contained in this justification for other than full and open competition is accurate and complete to the best of my knowledge and belief.

John S.
Peters 102903
John Peters
Deputy, Telehealth Services
Office of Connected Care (10P8)

Digitally signed by John S. Peters 102903
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@va.gov, cn=John S. Peters 102903
Date: 2017.09.14 14:44:58 -0400

09/14/17

Date

13. Approvals in accordance with FAR 6.304 and VAAR 806.304-1.

Contracting Officer's Certification: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Kyle M. Shaffer
941726
Kyle Shaffer
Contracting Officer
Denver Acquisition and Logistics
Center (DALC)

Digitally signed by Kyle M. Shaffer 941726
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Date: 2017.09.14 13:00:25 -0600

09-14-2017

Date

a. I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

KIP A. SHEPPARD
441377
Kip Sheppard
Acting Chief, Acquisition Division
Denver Acquisition and Logistics
Center (DALC)

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Date: 2017.09.14
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Date

b. NAC Competition Advocate: 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 for other than full and open competition.

Murbach,
Sandra
For Craig Robinson
Associate Deputy Assistant Secretary
for National Healthcare Acquisition,
Head of Contracting Activity

Digitally signed by Murbach, Sandra
DN: dc=gov, dc=va, ou=Entities,
ou=InternalStaff, cn=Murbach,
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9/15/2017

Date