

DEPARTMENT OF VETERANS AFFAIRS

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

1. **Contracting Activity:** Department of Veterans Affairs (VA), NC04, H.J. Heinz Facility. 2237/Purchase Request Number: 646-15-4-127-0021.
2. **Nature and/or Description of the Action Being Processed:** Brand Name Only and Only One Responsible Source - Sole Source Award to NxStage Medical, Inc.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** NxStage Medical, Inc. Hemodialysis supplies and ancillary home dialysis services. (Supplies are to be delivered directly to VA Pittsburgh Healthcare Systems (VAPHS) patient's home). The purchase of these Hemodialysis supplies is to support the treatment of an estimated 4 Patients. This will be a Base and Two Option Year Firm Fixed Price Indefinite Delivery Requirements Contract. Total estimated Contract Amount is \$76,800 per year, or \$230,400 for all three years. Period of Performance is as follows:

Base Year: 9/30/2015 - 09/29/2016

Option Year 1: 09/30/2016 - 09/29/2017

Option Year 2: 09/30/2017 – 09/29/2018

4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §3304(a)(1), as implemented by FAR 6.302-1.

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- () (2) Unusual and Compelling Urgency per FAR 6.302-2;
- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

FAR13.5 Test Program: The authority for applying the Commercial Test Program of FAR 13.5 is (Section 4202 of the Clinger-Cohen Act of 1996) and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

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

It is essential to the Government, that it purchase NxStage Medical, Hemodialysis supplies, since all VA Pittsburgh Healthcare System (VAPHS) home dialysis patients are equipped exclusively with NxStage Medical Hemodialysis machines, and according to NxStage Medical, no other company, other than NxStage Medical, sells cartridges and supplies that would be compatible and work with the NxStage Medical Hemodialysis machines, that VAPHS currently owns, and is in VAPHS patient's homes. In addition, according to NxStage, they are not aware of any other company that provides the ancillary home hemodialysis services that are part of this requirement. (See emails from NxStage in the eCMS Procurement Action Briefcase under P02). Therefore, the use of use of this brand product in this acquisition is **essential** to the Government's requirements, thereby precluding consideration of a product manufactured by another company.

It is also essential to the Government to purchase these NxStage Medical Hemodialysis supplies, since NxStage Medical, is the sole exclusive seller of their Hemodialysis supplies. (See email from NxStage in the eCMS Procurement Action Briefcase under P02).

"Accordingly, NxStage Medical is the only firm capable of providing the supplies and services described in Section 3 above, without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition and unacceptable delays in fulfilling its requirements."

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A Special Notice of Intent to Sole Source Synopsis will be posted to Fedbizopps for 3-5 days, prior to award of the Contract.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The Contracting Officer has determined that the quotes prices for the Base Year are considered fair and reasonable, since NxStage Medical has indicated they are the same they are charging other entities in the commercial market place. The Contracting Officer has also determined that the prices quoted for the two Option Years, that NxStage has indicated is 2% higher for each year, are fair and reasonable, since NxStage has indicated this is what they increase both their commercial and VA FSS prices per year, and what they are going to be requesting for a price increase to the VA FSS.

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

The Contracting Officer confirmed that NXStage sells the needed supplies to private sector entities, and sells most of the needed items off their VA FSS Contract# V797D-30208, and therefore has determined the items are commercial items.

The Contracting Officer verified with the VA FSS, that the direct home delivery services that is part of this requirement, is not authorized under the VA FSS Program, and therefore this requirement will

be treated as an open market acquisition, thus precluding consideration of the Federal Supply Schedule Contracts.

A Google Search using the words "NXSTAGE Hemodialysis Supplies" and "Hemodialysis Supplies for NXSTAGE Hemodialysis machines, did not reveal any other sources for these supplies, other than NXSTAGE. A Google Search using the words "Home Hemodialysis", did not reveal any other company names other than NxStage.

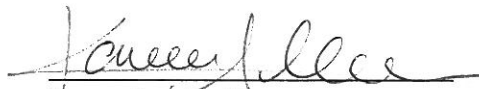
A GSA Advantage Search was not conducted, since this annual supply contract requires direct delivery to patient's homes, thus precluding the FSS from consideration.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None

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:** The VA would have to change the manufactured brand of Dialysis Machines it uses, which would result in duplicate cost and additional costs to the government, and possible delay in treatment of patients, which could be life threatening.

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.



Name: Kameen Allen

Title:

Facility: VAPHS University Drive

9/16/2015

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.

09/16/2015

Name: Michael J. Lamb

Title: Supervisory Contract Specialist

Facility: VAPHS H.J. Heinz

Date

b. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

09/16/2015

Name: Michael J. Lamb
Title: Supervisory Contract Specialist
Facility: VAPHS H. J. Heinz

Date