

**DEPARTMENT OF VETERANS AFFAIRS**

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

**Acquisition Plan Action ID: VA260-16-AP-6942**

1. **Contracting Activity:** Department of Veterans Affairs, VISN 20 , 663- VA PUGET SOUND HEALTH CARE Medical Center  
VA Puget Sound health care, pharmacy 2237#: 663-16-4-022-3064
2. **Nature and/or Description of the Action Being Processed:**  
Medication purchase (expendable supply item) for inpatient care cancer treatment.

BICNU VIAL for injection 100MG+DILUENT, 3ML  
(Expendable supply item)

**FAR13.5 Simplified Procedures for Certain Commercial Items:** Puget Sound Healthcare Pharmacy has an unexpected increase this month in patient's receiving a transplant conditioning regimen containing carmustine. Because of the cost, we only order what we foresee using in the short term. A few patients, because of the clinical state of their disease, are being moved on to transplant sooner than anticipated. Their transplants are awaiting the arrival of this medication. The sooner it arrives, the sooner they can move on to potentially life-saving treatment. In addition, availability of this drug has been sporadic. When it is available, we try to order enough to cover multiple patient's transplants.

**Description of Supplies/Services Required to Meet the Agency's Needs:** BICNU VIAL for injection, 100MG+DILUENT, 3ML, McKesson item #2022333  
(Expendable supply item)  
Quantity: 50 vials at \$3743.60/vial for a total: \$187180.00

3. **Statutory Authority Permitting Other than Full and Open Competition:** *41 USC §3304(a)(1), as implemented by FAR 6.302-1. The specific paragraph must be cited. Most likely, only the -1 or -2 authorities will be cited. Please be aware that failure to adequately plan for future requirements does not constitute appropriate use of the unusual and compelling urgency statutory authority.*

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- (X) (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 Simplified Procedures for Certain Commercial Items:** *The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).*

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

Manufacturer does not sell direct and only source OM is McKesson Plasma and Biologics on open market account (acct# 932174) account does not accept credit cards. McKesson is the only responsible source who has the ability to meet the urgent and compelling need of the BICNU for direct Patient care.

**Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Manufacturer does not sell direct and only source OM is McKesson Plasma and Biologics on open market account (acct# 932174) account does not accept credit cards. McKesson is the only responsible source who has the ability to meet the urgent and compelling need of the BICNU for direct Patient care.

**5. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** Past purchase VA260-16-P-1265, 663-A60146, 8-4-2016, \$3,743.60/vial X 24 for a total of \$89,846.40.

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

Only one drug manufacturer and does not sell direct. This product must be purchased through McKesson the VA's prime vendor for medications open market.

**7. Any Other Facts Supporting the Use of Other than Full and Open Competition:**  
See 6.

**8. 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:**

No action, VA should try to get this medication on a contract and sole source effort is required for the planned time duration. Manufacturer does not sell direct. Can only be purchased through our primary vendor. McKesson plasma and biologics open market account (acct# 932174) account does not accept credit cards. McKesson has an established distribution network for pharmaceuticals and has the ability to get us this product by the time required.

**9. 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.

**10. Approvals in accordance with the [VHAPM, Volume 6, Chapter VI: 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.

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Name:  
Title  
Facility

9-22-2016  
\_\_\_\_\_  
Date