JUSTIFICATION FOR OTHER THAN FULL AND OPEN COMPETITION

1. Identification of Agency/Contracting: Department of Veterans Affairs (VA)
Office of Acquisition Operations
Strategic Acquisition Center
10300 Spotsylvania Avenue, Suite 400
Fredericksburg, VA 22408

2. Description of Action: The proposed action is to establish single-award Blanket Purchase Agreements (BPAs) for brand name Fisher and Paykel Positive Airway Pressure (PAP) devices and accessories under the Medical Surgical Prime Vendor (MSPV) Program to be utilized by Veterans Health Administration (VHA) for treatment of patients with sleep apnea. PAP devices are used throughout VA, for the treatment for moderate and severe sleep apnea and have been endorsed by the American Academy of Sleep Medicine. PAP is a mode of respiratory ventilation used primarily in the treatment of obstructive sleep apnea. The MSPV formulary catalog is a list of approved healthcare commodities including medical, surgical, prosthetic, dental, laboratory, facilities/cleaning products, and textiles. The objective is to ensure availability of PAP devices for nation-wide usage and to enhance the quality of care we provide to our Veterans by leveraging spend and maximizing efficiency. The anticipated period of performance is a 1-year base with a 1-year option period.

3. Description of Supplies or Services: VHA is the largest healthcare system in the United States, providing care to 1,233 healthcare facilities, including 168 VA Medical Venters and 1,053 outpatient sites of care of varying complexity, serving more than 8.9 million Veterans each year. VHA medical centers provide a wide range of services including traditional hospital-bed services such as surgery, critical care, mental health, orthopedics, pharmacy, radiology and physical therapy. In addition, most medical centers offer additional medical and surgical specialty services including audiology, speech pathology, dermatology, dental, geriatrics, neurology, oncology, podiatry, prosthetics, urology, respiratory and vision care. Some medical centers offer advanced services such as organ transplants and plastic surgery.

The proposed action is to provide a source (or sources) for continuous supply of Fisher and Paykel PAP devices and accessories. Obstructive sleep apnea and other types of sleep breathing disorders often required long-term management with PAP. Sleep Disordered Breathing (SDB) is a collective term encompassing severe breathing abnormalities. PAP therapy is the gold standard treatment for SDB and works by creating a pneumatic splint of the upper airway, allowing continuous breathing during sleep. PAP devices draw room air through a filter, pressurize it, and release that air into flexible tubing. The tubing connects to a variety of mask interfaces (full-face masks, nasal masks, and nasal pillows) which deliver the pressurized air through the nose and/or mouth. Each component of the therapy (devices, masks, tubing, and filters) must be supplied to the Veteran. The contractor shall provide Continuous Positive Airway Pressure (CPAP), Bi-level Positive Airway Pressure (BiPAP), and Variable Positive Airway Pressure (VPAP) devices and accessories. VHA is currently providing

16 different Human Common Procedures Codes (HCPC) for supplies and 18 codes for equipment as identified in table 1 below. The total estimated value of the proposed action is $ TBD (inclusive of options).

Table 1 – HCPC and Descriptions

RESPIRATORY SUPPLIES
A7027 - COMBINATION ORAL/NASAL MASK
A7028 - REPL ORAL CUSHION COMBO MASK
A7029 - REPL NASAL PILLOW COMB MASK
A7030 - FUL FCE MSK POS ARWY PRS DEV
A7031 - FCE MSK INTFCE REP FULL MSK
A7032 - RPLT CUSHN NASL APPLIC DEV
A7033 - RPL PILLWS NASL APPLIC DEV PR
A7034 - NASL INTFCE POS ARWY PRSS DEV
A7035 - HDGR USED W/POS ARWY PRSS DEV
A7036 - CHNSTP USE W/POS ARWY PRSS DEV
A7037 - TUBING USD W/POS ARWY PRSS DEV
A7038 - FLTR DISP W/POS ARWY PRSS DEV
A7039 - FLTR NO DISP POS ARWY PRSS DEV
A7044 - ORL INTFCE W/POS ARWY PRSS DEV
A7045 - REPL EXHALATION PORT FOR PAP
A7046 - REPL WATER CHAMBER PAP DEV
RESPIRATORY EQUIPMENT
E0452 - INTERMIT ASSIS DEVICE W CPAP
E0470 - BIPAP MACHINE
E0471 - BIPAP MACHINE W B/U NONINV INT
E0472 - BIPAP MACHINE W B/U FTR INVAS
E0485 - ORAL DEVICE/APPLIANCE PREFAB
E0550 - HUMIDIF EXTENS SUPPLE W IPPB
E0555 - HUMIDIFIER FOR USE W/ REGULA
E0560 - HUMIDIFIER SUPPLEMENTAL W/ I
E0561 - HUMIDIFIER NONHEATED W PAP
E0562 - HUMIDIFIER HEATED USED W PAP
E0601 - CONT AIRWAY PRESSURE DEVICE
K0188 - FILTER DISPOSABLE WITH CPAP
S8100 - SPACER WITHOUT MASK
S8101 - SPACER WITH MASK
S8185 - FLUTTER DEVICE
S8186 - SWIVEL ADAPTOR
VA123 - BIPAP MACHINE
VA170 - CPAP/BIPAP DATA CARD

4. Statutory Authority: The statutory authority permitting other than full and open competition is 41 U.S.C. 1903 as implemented by the Federal Acquisition Regulation (FAR) Subpart 13.501(a), entitled "Special Documentation Requirements, Sole Source Acquisitions, Application for Brand Name Descriptions."

5. Rationale Supporting Use of Authority Cited Above: The products identified by brand-name herein have been determined to be the most cost effective and safest means to meet VHA' s requirement to streamline, maintain continuity of care and to standardize, or otherwise procure the required products. Procured items must match remaining in-use inventory for patient safety, standardize training, and logistics reasons. The Fisher and Paykel products are currently in use at the VA Medical Centers across the country and are a Physicians medical necessity items for use in patients homes. The objective of this action is to ensure the continuity of care, availability and consistency of products for nationwide usage and to obtain volume based, standardized pricing without having any interruption in the use of the products for the Veteran.

As such, this acquisition supports the procurement of high quality prosthetic appliances and sensory aids by the patient, to establish a supply source that will provide the contracted items for specialized healthcare services for individuals with needs for sleep apnea devices and accessories. Having a catalog of products from the three top manufacturers provides a unique solution that is already compatible with the existing system infrastructure and is already in use, to meet current business needs for the care of our Veterans. Procurement of any other item besides the required brand name items, would be cost prohibited, as the Government would incur costs for changing out equipment and supplies that are already in use, assigned to patients, and part of the patient's treatment plan.

Additional concerns are outlined and discussed below. The below rationale describes why the use of brand-name descriptions is essential to the Government's requirements, and thereby precludes consideration of a product manufactured by another company:

a. Introducing new or otherwise unfamiliar medical equipment would require the Veterans Health Administration to remove medical staff from their primary, patient care duties in order to train for other than current brand-name equipment.

b. Excluding the cost of removal of staff from primary patient care duties, the estimated cost of training on new equipment for staff and delay in patient care to ensure therapy compliance is much to extensive to attempt to award to other than what is currently in use. The acquisition cost of non-brand-name equipment, and the cost to retrain medical staff is too cost prohibitive as a feasible solution to obtain other than name-brand supplies.

c. Additional brands added to a hospital's inventory would require separate inspection/maintenance schedules as well as additional

space required to inventory multiple replacement and other consumables parts for multiple brand names. Additionally, logistics officers would be required to administer and manage multiple warranties where terms and conditions can differ drastically among competitors. Conversely, by restricting competition to the currently predominate brand name, these logistical considerations are alleviated; maintenance schedules are the same, there is no need for multiple types of replacement parts, and warranties would be the same/similar across product lines.

Procurement of any other items beside the required brand name products is detrimental to safety of the VHA patients and medical-care staff who are otherwise accustomed, fully trained, and highly proficient to use these brand name PAP devices. The product selection is currently based on "physician medical necessity and experience"; whereby, other factors that would normally affect the decision to purchase an items such as price and delivery, are not always considered when ordering. A Clinician's decision to use a particular manufacturer's PAP devices and accessories is based on the technical characteristics of the sleep apnea equipment that is expected to produce a higher quality of life for the patient and/or achieve certain therapeutic results. Soliciting for any other brand would result in substantial costs to the Government that would not be recovered. To change the manner that VHA is purchasing the PAP devices and accessories must be done in a gradual phase, to avoid any disruption in the use of the equipment and supplies for our Veterans. This may be accomplished with the long-term effort being pursued at the Denver Acquisition and Logistic Center (DALC).

6. Efforts to Obtain Competition: In accordance with (IAW) FAR 5.201, this action will be synopsized at award on Federal Business Opportunities (FBO) and the justification will be made publicly available. Market research was conducted, details of which are in the market research section of this document. This effort did not yield any additional manufacturers that can meet the Government's needs. Any quotes received shall be considered and be evaluated as to the extent capable of meeting Agency needs.

7. Determination Fair and Reasonable: The Contracting Officer will use the price analysis techniques in FAR 13.106-3 to determine that the proposed price is fair and reasonable. Additional price discounts will be sought prior to award.

8. Market Research: Market research for this procurement was conducted IAW FAR part 10, which describes the policies and procedures that govern the market research process and the requirements of 41 U.S.C. 3306(a)(1) and 41 U.S.C 3307. Market research efforts were conducted via FSS, Vendor Information Pages (VIP), MEDpdb, and the open market to determine if competition was viable for this action. VIP identified three Veteran-Owned Small Businesses capable of providing the brand name devices and accessories. First Nation Group, LLC (dba) Jordan Reses Supply Company (First Nation Group), Medical Place, Inc (Medical Place) and Veterans Medical Supply, Inc. (VMS) are authorized distributors of the brand name items. There were no other viable sources found to provide the required products. While other PAP devices and accessories exist in the market, use of alternate devices would require

extensive training and replacement cost to VA. Based on this market research, the VA's subject matter experts determined that only Fisher and Paykel products could meet the Government's requirement.

9. Other Facts: There are no other supporting facts.

10. Listing of Interested Sources: First Nation Group, Medical Place and VMS have expressed interest in the requirement.

11. Action Taken to Remove Barriers to Competition: The Government will continue to conduct market research to ascertain if there are changes in the marketplace. Competition is expected for Fisher and Paykel devices.

12. Technical and Requirements Certification: I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge and belief.