

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA241-17-AP-1716

1. **Contracting Activity:** Department of Veterans Affairs, Network Contracting Office 1 (NE).
2. **Nature and/or Description of the Action Being Processed:** Togus VA Medical Center, Psychology department, intends to continue to lease the Deep Transcranial Magnetic Stimulator (TMS). Depression is a highly disabling condition that affects nearly 12% of Americans with a higher prevalence in the Veteran population. The devastating impact of untreated depression in the Veteran population is well-known and includes an impairment in functioning, exacerbation of medical comorbidities, substance abuse and suicide. Despite the availability of many effective treatments for depression, many patients do not respond to antidepressant medication and/or find the side effects intolerable. The American Psychiatric Association's Guidelines for the treatment of depression now list deep repetitive TMS (rTMS) as a potential "next step" after one failed antidepressant trial. Deep rTMS is established as a safer less intrusive alternative to electroconvulsive therapy (ECT) and other more invasive procedures, which side effects and requirement for general anesthesia limit its use. This is a follow-on requirement to contract number VA241-14-C-0117. Purchase Request Number 402-17-2-7302-0015. Base Year \$51,800.00. Base plus 3 Option Years total \$200,005.99.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Brainsway offers a turnkey package which includes the required caps, installation, maintenance and staff training. The system is stand alone and does not require special infrastructure. Our priority will be treating vulnerable populations, including female veterans of childbearing age, OIF/OEF veterans and homeless veterans. Providing new and innovative treatments such as deep rTMS is one way the VA remains a national leader in providing comprehensive mental health services for its patients. The Brainsway lease package includes the Deep TMS research system, stimulator system, blinding system, 40 individual patient cap kits, installation, training and technical support.
4. **Statutory Authority Permitting Other than Full and Open Competition:**
 - (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

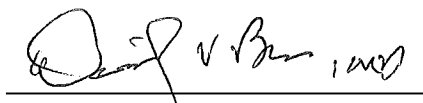
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** The Brainsway Deep Transcranial Magnetic Stimulator (TMS) is a highly specialized system that uses a unique H-coil technology based on patents developed by the National Institute of Health (NIH) and is approved by the FDA for treatment of Major Depressive Disorder (MOD). Standard TMS coils stimulate only superficial cortical areas of the brain roughly 1cm deep, whereas treating depression requires direct stimulation of deeper brain regions. Brainsway's H-coil technology is "highly specialized" and surpasses the standard TMS coils and directly stimulates target areas located deep within the brain and has been scientifically proven to be superior over superficial or surface TMS. Brain Research and Development Services LTD. (Brainsway) has secured the National Institute of Health (NIH) patents for this unique technology. They are the only company worldwide that manufactures the machine and H-coil cap required for the treatment. Accordingly, Brainsway is the only firm capable of providing the supplies and services described 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 (FAR 6.302-1(a)(2)(ii).
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Market research was conducted by the Mental Health Service to ensure product, cost and patient outcomes of treatment is desirable and acceptable for VA Maine HCS and VHA. No other company or manufacturer is able to provide this service. The Contracting Officer performed additional Market Research and verified Brainsway is the only company that manufactures, distributes and provides the supplies for the Deep TMS System. Only one other company, Neurostar, produces a similar product however their product produces only a superficial TMS and the TMS sessions on the Neurostar system is 40 minutes per session where the Brainway system is 20 minutes per session.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** Price analysis is not able to be conducted by comparison, since Brainsway is the only company that manufactures the deep TMS system and is the only company that provides the supplies to operate the machine at this time. Pricing is based on catalog pricing with substantial discounts applied (30.56% the first year and 45.65% for years 2-4) and is considered fair and reasonable.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** The Mental Health Service did extensive searches to locate other potential companies, yet Brainsway is the only company that manufactures the machine and supplies for which to operate. No other alternate equipment or acceptable

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 3: Request for Sole Source Justification Format >\$150K

substitutes for this safe and effective treatment are available. The Brainway system has been found to be the most beneficial means of fulfilling the needs of the Togus VAMC.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** This treatment has shown positive results in the intended population and has the potential to help many veterans in Maine who are suffering from depression. Deep TMS is conducting additional studies on other illnesses that will likely gain support in the US in coming years. Deep TMS is approved for use in Europe for the treatment for PTSD and neuropathic pain. VA Maine HCS is interested in these emerging studies, especially Deep TMS' potential for treating PTSD and will explore potential research implications for all veterans throughout VHA.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Brainsway USA Inc..
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:**
Brainsway is the only manufacturer of the equipment, and is well suited for our Veteran population. With subsequent option years to this contract, market research will be conducted to evaluate if other companies can meet our needs and we will seek out competition if we find alternatives that can facilitate our needs if/when another machine is marketed.
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.
(This signature is the requestor's supervisor, fund control point official, chief of service, someone with responsibility and accountability)



Name
Title
Facility

6 March 17
Date

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 3: Request for Sole Source Justification Format >\$150K

13. Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP. This part is filled out by Contracting Staff as part of the Justification

- a. **Contracting Officer's Certification (required)**: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Richard Coutermarsh
Contracting Officer
NCO 1, Manchester VAMC

3/7/2017

Date

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

Lorrie Baines
Branch Chief, Services Team 1
NCO 1,

3/10/2017

Date