

Hyperbaric Oxygen Treatment Pilot Program Request for Applications

State of Indiana

APPLICATION DEADLINE: *NOVEMBER 15, 2019*

Funding Opportunity Description

The purpose of this Request for Application (RFA) is to select a medical provider for the Hyperbaric Oxygen Treatment Pilot Program established by IC 10-17-13.5. The State will make grants for the purpose of providing elective hyperbaric oxygen treatment to veterans receiving treatment under the pilot program. This pilot is a partnership between the Indiana State Department of Health (ISDH) and the Indiana Department of Veterans Affairs (IDVA).

Scope of Work

The scope of work under this RFA is meant to satisfy provisions of IC 10-17-13.5. All definitions and other provisions in the statute are applicable under this RFA. The statute mandates that the State establish a Hyperbaric Oxygen Treatment (HBOT) pilot program and select up to five (5) providers that collectively represent the various geographic areas of Indiana to provide HBOT treatment for eligible veterans. Of those prospective providers responding to this RFA, the State will select the providers which it determines can best provide HBOT services to eligible veterans. The selected providers are the only providers eligible to participate in the program.

Provider Requirements

Eligible applicants will have the following qualifications and characteristics:

- A licensed medical facility in the state of Indiana
- Which meets the Section 501 IRS code
- Which employs doctors and physical therapists licensed in Indiana under IC 25-27
- Which treats patients with long term, chronic illness, and short term care needs.

Eligible applicants must represent one of the following geographic areas of the state:

- North
- East
- West
- Central

Selected treatment providers will work with the independent evaluator of the pilot study and coordinate with other approved treatment providers to ensure consistency in the statewide pilot study.

Data Requirements: Providers must retain confidential and de-identified patient data in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and any other applicable medical records laws. All data and information from which the identify of an individual veteran cannot be reasonably ascertained must be available to the General Assembly, participating institutional review boards, participating health care providers, medical researchers and other governmental agencies. If awarded, the State may require awardees' treatment protocol be approved by an Institutional Review Board. Provider must file a quarterly status report to the State.

Provider Payment: Providers will receive reimbursement of treatment costs from funds provided by the State on a basis of monthly or quarterly invoicing. The State may pay the provider for services rendered under this pilot only if the treatment provided was based on the approved treatment plan, the drug or device used in the treatment plan has been approved for any purpose by the federal Food and Drug Administration, the veteran's health improved as demonstrated by either standardized, independent pretreatment and posttreatment neuropsychological testing, nationally accepted survey instruments and/or neurological examination or clinical examination and the State has received all pretreatment and posttreatment evaluation documentation. Payment shall be made only for diagnostic testing and hyperbaric oxygen treatment for eligible veterans. No provider may profit from services under this award. Payments will not be made after 06/30/2021.

Participant Requirements

Participants will be 18-65 years old and have been diagnosed with mild or moderate (but not severe) TBI or TBI/PTSD or PTSD by either the military (any etiology) or civilian neurologists or neuropsychologists. This diagnosis will especially include war veterans who have received the ANAM test pre- and post-deployment and had a significant decrease in their neuropsychological test scores. No restrictions or preferences shall be made based on patient demographics, including but not limited to gender, race, or ethnic origin. There is no participant payment for participation in this pilot.

Summary of Timeline

| Event: | Date: |
|---------------------------|--------------|
| RFA Posted Online | 10/17/2019 |
| Deadline for Applications | 11/15/2019 |
| Notify Award recipient | 12/02/2019 |
| Contract Start Date | 01/01/2020 |

Terms of the Contract

The State will recommend up to four (4) applicant providers to enter into grant contracts to fulfill the requirements in this RFA. The term of the grant contract shall not extend beyond 06/30/2021. At this time, no renewals of grant contracts are contemplated.

Application Instructions

The application narrative shall not exceed 30 pages with one inch margins, double spaced, Times New Roman 12-point font. Applications that exceed the page limit will be considered non-responsive and will not be entered into the review process. The budget worksheet is to be submitted with the application as a separate Excel document and does not count towards the above page limit. All required section headings are listed below. Please do not alter the format of the document. Final applications must be emailed to Rebecca Chauhan at rchauhan1@isdh.IN.gov by 5:00 p.m. on *NOVEMBER 15, 2019*.

Section 1: Application Cover Page

List the full legal name of your organization, including address and Tax ID number (EIN).

List the name, title, telephone number, email address, and signature of the following individuals within the applicant agency:

- Executive Director or Chief Executive Officer
- Project Director / Person of Contact
- Person authorized to sign legal and contractual agreements

Section 2: Project Narrative

1. Provider Qualifications

Please detail your organization's certifications and qualifications which you believe relevant in assisting the State in evaluating your proposal to treat service-related events causing traumatic brain injury or posttraumatic stress disorder. Please provide qualifications of key personnel, as well as other staffing requirements for treatment protocol.

2. Participant Eligibility & Screening

Please provide a detailed plan for determining and documenting eligibility of each veteran. How will veterans be screened for participations? Describe your enrollment process as well.

3. Treatment Protocol

Please provide a detailed protocol for treatment by Hyperbaric Oxygen Treatment for eligible veterans. The protocol should address prevention of risk of adverse events. The State requires compliance with all safety protocol required for usage of treatment equipment.

4. Individual Treatment Plans

Please provide your detailed plan for developing and submitting to the Indiana State Department of Health an Individual Treatment Plan (ITP) for each eligible veteran. The ITP will include:

- a. A detailed description of the treatment to be provided to the veteran by the provider under the treatment plan;
- b. A prescription from a health care provider;
- c. Verification that the veteran is eligible for participation in the program;
- d. Verification that the veteran voluntarily accepts treatment through the program;
- e. An estimate of the total cost of the veteran's treatment under the treatment plan;

- f. A description of the sources of funding that will be used to pay the total cost of the veteran's HBOT; and
- g. Documentation that the drug or device used in the treatment plan has been approved for any purpose by the federal Food and Drug Administration.

5. Data Confidentiality

- a. Please provide a detailed plan to keep confidential all data and information which could identify an individual veteran. De-identified participant data is required for this program.
- b. Please provide a detailed plan that, subject to the requirements of HIPAA and any other applicable medical records laws, all data and information from which the identity of an individual veteran cannot be reasonably ascertained will be available to the General Assembly, participating institutional review boards, participating health care providers, medical researchers and other governmental agencies.

6. Evaluation

Please provide your detailed plan to submit all pre-treatment and post-treatment evaluation documentation to the state department of veteran's affairs and state department of health.

Cost Proposal

The applicant should provide a budget breakdown detailing expenses per patient. Total number of patients for all providers will not exceed 15. The breakdown should be focused on clarifying how the proposed prices correspond directly to the respondent's proposed activities.

The applicant should detail as part of its Cost Proposal any special cost assumptions, conditions, and/or constraints relative to, or which impact, prices and expenses. It is of particular importance to describe any assumptions made by the respondent in the development of the respondent's application that have a material impact on expense items. A sample budget worksheet is provided as an Excel attachment. This template or similar is highly recommended for applicants.

Application Evaluation Procedure

The State evaluation team will read and score applications using a consistent scoring rubric. Applications will be evaluated based upon the proven ability of the applicant to satisfy the requirements of the RFA and execute the State pilot program to the standards of ISDH and IDVA.

Additional Applicant Resources

- Indiana HBOT Pilot Study Treatment Protocol
- Sample Budget Template Worksheet
- Indiana Code 10-17-13.5, as amended