



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: OssaTron Services of New England, LP

Docket Number: 04-30316-CON

Project Title: Expansion of Mobile OssaTron Orthotripsy Service

Statutory Reference: Section 19a-638, Connecticut General Statutes

Filing Date: October 5, 2004

Decision Date: November 3, 2004

Default Date: January 3, 2004

Staff Assigned: Laurie Greci

Project Description: OssaTron Services of New England, LP (“Applicant”) proposes to expand its mobile OssaTron Orthotripsy Service to nine additional service sites, at no associated capital cost.

Nature of Proceedings: On October 5, 2004, the Office of Health Care Access (“OHCA”) received OssaTron Services of New England, LP’s (“Applicant”) Certificate of Need application seeking authorization to expand its mobile OssaTron Orthotripsy Service to nine additional service sites, at no associated capital cost. The Applicant is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

On July 2, 2004, the Applicant was informed that the CON application was noticed to the public in the following newspapers: *Hartford Courant*; the *Connecticut Post*; the *Middletown Press*; *The Hour* (Norwalk); and *The Waterbury Republican*. OHCA received no comments from the public concerning the Applicant’s proposal.

OHCA's authority to review and approve, modify or deny this application is established by Sections 19a-638 and 19a-639, C.G.S. The provisions of these sections, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

Findings of Fact

Clear Public Need

Proposal's Contribution to Accessibility of Health Care Delivery in the Region Impact of the Proposal on the Interests of Consumers of Health Care Services and Payers for Such Services

1. OssaTron Services of New England, L.P. ("Applicant") is a limited partnership whose general partner is HealthTronics Orthotripsy Management Company, L.L.C. (*October 5, 2004, CON Application, Exhibit 14A*)
2. The Applicant proposes to establish a transportable lithotripsy service at the following ambulatory surgery centers ("Center" or "Centers"):

Naugatuck Valley Surgery
160 Robbins Street
Waterbury, CT 06708

Johnson Surgery Center
148 Hazard Avenue
Enfield, CT 06082

HEALTHSOUTH Norwalk Surgery Center
40 Cross Street
Norwalk, CT 06851

Middlesex Outpatient Surgery Center
28 Crescent Street
Middletown, CT 06457

HEALTHSOUTH Connecticut Surgery Center
81 Gillette Street
Hartford, CT 06105

Middlesex Outpatient Center
534 Saybrook Road
Middletown, CT 06457

Saint Francis Hospital & Medical Center
114 Woodland Street
Hartford, CT 06105

UConn Health Partners
65 Kane Street
West Hartford, CT 06119

Saint Vincent's Medical Center
2800 Main Street
Bridgeport, CT 06606

(June 7, 2004, Letter of Intent, page 3)

3. Under Docket Number 02-550, OHCA granted approval to the Applicant to purchase the required OssaTron®, a device that uses extracorporeal shock wave therapy for the treatment of plantar fasciitis. The Applicant was also granted approval to establish mobile orthotripsy service to HEALTHSOUTH surgery centers in Bridgeport, Danbury, and Hartford and to the Connecticut Foot Surgery Center in Milford. *(December 2, 2002, Final Decision for Docket Number 02-550, page 2)*
4. The mobile orthotripsy service will not replace any existing services. It will only be scheduled at one of the locations to treat patients who have not responded to the conventional services already offered. *(October 5, 2004, CON Application, page 2)*
5. Under a Facility Services Agreement, the Applicant will provide the OssaTron®, staff, and other personal property required to provide orthotripsy service at each location. The equipment will be transported in the vehicle already owned for such purpose. *(October 5, 2004, CON Application, pages 16 and Attachment 14A)*
6. Each Center will provide the required certified physician to use the equipment to treat the patients. Only physicians having completed training and received certification in the utilization of the OssaTron® as required by the FDA and HealthTronics will be allowed to utilize the equipment. *(October 5, 2004, CON Application, page 8)*
7. The Centers will also be required to provide suitable rooms, equipment, and staff as necessary for the pre-operative, operative, and post-operative care of patients. *(October 5, 2004, CON Application, Attachment 14A)*
8. The Applicant projects that it will perform 2, 25, and 40 additional procedures due to the proposal in FYs 2004, 2005, and 2006. The Applicant based the projected number of additional procedures on experience in providing the service through its current authorized locations and its assessment of the proposed location based upon that experience. *(October 5, 2004, CON Application, page 16 and Financial Pro Forma)*
9. There are no additional providers of orthotripsy service in Connecticut.

**Financial Feasibility of the Proposal and its Impact on the Applicants' Rates
and Financial Condition
Impact of the Proposal on the Interests of Consumers of Health Care Services
and Payers for Such Services**

10. There is no associated capital cost for the Applicant's proposal. *(October 5, 2004, CON Application, page 12)*
11. The Applicant projects revenue incremental to the project of \$521, \$25,000, and \$40,000, for FYs 2004, 2005, and 2006, respectively. *(October 5, 2004, CON Application, Financial Pro Forma)*

12. The Applicant has recently applied for a Category 1 CPT¹ code certification. Such certification is expected to increase the number of third party payers adding orthotripsy as a covered treatment. *(October 5, 2004, CON Application, page 16)*
13. The Applicant will bill for the technical component of the service. The certified physicians will bill independently for their professional services. *(October 5, 2004, CON Application, page 11)*

Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines

The following findings are made based upon other principles and guidelines set forth in Section 19a-637, C.G.S.:

14. There is no State Health Plan in existence at this time. *(October 5, 2004, CON Application, page 3)*
15. The Applicant has adduced evidence that this proposal is consistent with its long-range plan. *(October 5, 2004, CON Application, page 3)*
16. The Applicant has not undertaken any activities in the past year that would have improved productivity and contained costs. *(October 5, 2004, CON Application, page 9)*
17. The proposal will not result in changes to the Applicant's current teaching and research responsibilities. *(October 5, 2004, CON Application, page 9)*
18. The proposal will serve a patient population not responding to existing treatment alternatives. *(October 5, 2004, CON Application, page 9)*
19. The Applicant has sufficient financial, managerial, and technical competence to provide efficient and adequate service to the public. *(October 5, 2004, CON Application, Exhibits 5D and 8(b)iii)*

¹ CPT ("Current Procedural Codes") is a trademark of the American Medical Association. The codes are used to report outpatient procedures and services. Category 1 CPT codes are reserved for those procedures that have demonstrated clinical efficacy, widespread use, and have Food and Drug Administration Approval. *(www.ama-assn.com)*

Rationale

OssaTron Services of New England, LP (“Applicant”) proposes to expand its mobile OssaTron® Orthotripsy service at no associated capital cost. The Applicant proposes to add nine additional ambulatory surgery centers in Connecticut where patients may receive the OssaTron® orthotripsy service. The equipment will be provided by the Applicant on an on-demand basis. The surgeon will use the equipment to perform the orthotripsy service on the patients. As this proposal is for the expansion of a service currently available through the Applicant, OHCA finds that the addition of nine sites will improve access to care for Connecticut residents.

The Applicant projects that it will perform an additional 2, 25, and 40 procedures during Fiscal Years 2004, 2005, and 2006. Further, the Applicant projects revenue incremental to the project of \$521, \$25,000 and \$40,000 for Fiscal Years 2004, 2005, and 2006, respectively. Based on the projected utilization for the proposal, these financial projections appear reasonable and achievable.

Based on the foregoing Findings and Rationale, the Certificate of Need application of OssaTron Services of New England, LP to expand its mobile OssaTron® Orthotripsy service to an additional nine sites in Connecticut, at no associated capital cost, is hereby **GRANTED**.

Order

The request of OssaTron Services of New England, LP to expand its mobile OssaTron® Orthotripsy Service is approved, subject to the following conditions:

1. The Applicant is authorized to provide the mobile OssaTron® Orthotripsy Service at the following ambulatory surgery centers:

Naugatuck Valley Surgery
160 Robbins Street
Waterbury, CT 06708

Johnson Surgery Center
148 Hazard Avenue
Enfield, CT 06082

HEALTHSOUTH Norwalk Surgery Center
40 Cross Street
Norwalk, CT 06851

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HEALTHSOUTH Connecticut Surgery Center
81 Gillette Street
Hartford, CT 06105

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534 Saybrook Road
Middletown, CT 06457

Saint Francis Hospital & Medical Center
114 Woodland Street
Hartford, CT 06105

UCONN Health Partners
65 Kane Street
West Hartford, CT 06119

Saint Vincent's Medical Center
2800 Main Street
Bridgeport, CT 06606

2. There is no capital expenditure associated with the proposal. In the event that the Applicant learns of potential cost increases or expects that the final project costs will alter, the Applicant shall file with OHCA a request for approval of the revised budget.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the
Office of Health Care Access

Date signed:

Signed by:

November 3, 2004

Cristine A. Vogel
Commissioner

CAV:lkg