



Office of Health Care Access

Final Decision

Applicants: OssaTron Services of New England, L.P.; HealthSouth Surgery Centers of Bridgeport, Danbury, and Hartford; Connecticut Foot Surgery Center

Docket Number: 02-550

Project Title: Mobile OssaTron/Orthotripsy Service

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

Filing Date: November 15, 2002

Decision Date: December 6, 2002

Default Date: February 13, 2003

Staff: Steven Lazarus and Laura Jaworski

Project Description: OssaTron Services of New England, L.P.; the HealthSouth Surgery Centers of Bridgeport, Danbury, and Hartford; and the Connecticut Foot Surgery Center (“Applicants”) propose the establishment of a mobile OssaTron/orthotripsy service at a proposed total capital expenditure of \$350,000.

Nature of Proceedings: On November 15, 2002, the Office of Health Care Access (“OHCA”) received the Certificate of Need (“CON”) application of OssaTron Services of New England, L.P.; the HealthSouth Surgery Centers of Bridgeport, Danbury, and Hartford; and the Connecticut Foot Surgery Center to establish a mobile OssaTron/orthotripsy service at a proposed total capital expenditure of \$350,000. The Applicants are health care facilities or institutions as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

OHCA’s authority to review and approve, modify or deny this proposal is established by Section 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

Each finding of fact included in this Final Decision has been taken from the CON application and related CON filings, or from other external sources of information. A source reference is included with each finding of fact. All CON applicants must attest to the accuracy and correctness of the information submitted to OHCA as part of the CON application process.

Clear Public Need

Impact on the Applicant's Current Utilization Statistics Contribution of the Proposal to the Quality and Accessibility of Health Care Delivery in the Region

1. OssaTron Services of New England, L.P. ("OssaTron New England") is a limited partnership whose general partner is HealthTronics Orthotripsy Management Company, L.L.C., a wholly owned subsidiary of HealthTronics Surgical Services, Inc. ("HealthTronics"). HealthTronics, located on 1841 West Oak Parkway in Marietta, Georgia, was incorporated in Georgia in 1995 for the purpose of providing non-invasive treatment for certain orthopedic and urologic conditions. HealthTronics either forms operating partnerships with physicians or sells devices used to treat patients. HealthTronics is the vendor of the OssaTron equipment. *(August 15, 2002, Letter of Intent, November 8, 2002, CON Application, pages 99 and 123, and November 26, 2002, 2001 Annual Report, page 9, downloaded from the "Investor Relations" section of the HealthTronics website, [http://www.corporateir.net/ireye/ir_site.zhtml?ticker=HTRN &script= 700](http://www.corporateir.net/ireye/ir_site.zhtml?ticker=HTRN&script=700))*
2. The HealthSouth Surgery Centers of Bridgeport, Danbury, and Hartford ("HealthSouth") are licensed outpatient surgical facilities located, respectively, at 4920 Main Street in Bridgeport, Connecticut; 73 Sandpit Road in Danbury, Connecticut; and 100 Retreat Avenue in Hartford, Connecticut. The Connecticut Foot Surgery Center ("CFSC") is a licensed surgical outpatient facility located on 318 New Haven Avenue in Milford, Connecticut. Collectively, these sites are referenced as the "host facilities." *(August 15, 2002, Letter of Intent and November 8, 2002, CON Application, page 8)*
3. The Applicants propose to establish a mobile orthotripsy service whereby the OssaTron equipment will be transported amongst the host facilities. OssaTron New England's relationship with the host facilities will be a leasing arrangement for the space in which the equipment will be located. *(August 15, 2002, Letter of Intent)*
4. The orthotripsy service will focus on the treatment of plantar fasciitis cases that have existed for at least six months and have not responded to conventional treatment methods. *(November 8, 2002, CON Application, page 2)*
5. The OssaTron is a device that uses extracorporeal shock wave therapy ("ESWT") for the treatment of plantar fasciitis, a condition that causes chronic heel pain. *(November*

8, 2002, *CON Application, pages 2 and 127 and November 26, 2002, 2001 Annual Report, page 9*, downloaded from the "Investor Relations" section of the HealthTronics website, http://www.corporateir.net/ireye/ir_site.zhtml?ticker=HTRN&script=700)

6. On October 12, 2000, HealthTronics received approval from the United States Food and Drug Administration for the distribution of the OssaTron. At present, the only FDA-approved use of the OssaTron is for the treatment of plantar fasciitis. (*August 15, 2002, Letter of Intent and November 8, 2002, CON Application, pages 99 and 127*)
7. The Applicants state that although the service may draw patients from the entire State of Connecticut, patients are primarily expected to come from the municipalities in which the host facilities are located, Bridgeport, Danbury, Hartford, and Milford, as well as proximate communities. (*November 8, 2002, CON Application, page 4*)
8. The Applicants' utilization projections for chronic heel pain procedures are 100 in year one, 300 in year two, and 500 in year three. (*November 8, 2002, CON Application, page 124 and November 15, 2002, Completeness Responses, page 2*)
9. The Applicants base the volume projections upon American Podiatric Medical Association statistics that indicate that there were approximately 38,600,000 nationwide cases of heel pain in 2000. The Applicants estimate that 2% of this total will have surgery for chronic plantar fasciitis, producing a national total of 772,000 patients. The Applicants extrapolate that Connecticut's population is roughly 2% of this number, for a total of 15,400 potential OssaTron patients in the state. Assuming 1-2% of the potential patient population receives the service, the Applicants project 100 patients initially will use the service. (*November 15, Completeness Responses, page 2*)
10. The Applicants' projections take into account the finite patient population for the service (specifically, chronic plantar fasciitis cases that have existed for six months and have not responded to alternative treatment methods), evolving physician familiarity with orthotripsy, and limitations concerning the coordination of insurance coverage for a new service in the marketplace. (*November 8, 2002, CON Application, pages 2 and 4*)
11. Orthotripsy service is currently unavailable in Connecticut. Therefore, the Applicants state that their project will have no affect upon existing providers. (*November 8, 2002, CON Application, pages 4 and 5*)
12. The hours of operation of the three HealthSouth centers are Monday through Friday, 7:30 am through 5:00 pm. The CFSC's regularly scheduled hours are Tuesday, Thursday, and Friday, 7:30 am through 3:30 pm, with flexible scheduling, subject to patient utilization requirements, on Monday and Wednesday. The OssaTron will be transported amongst the host facilities on a regularly scheduled basis so that patients can be seen during normal business hours. The Applicants anticipate that the equipment will rotate on a daily basis, spending one day at each facility. The schedule is subject to modification to address patient scheduling demands. (*November 15, 2002, Completeness Responses, pages 1 and 2*)

13. Patients receiving orthotripsy treatment remain the patients of the treating physicians. Patient care is the primary responsibility of the individual physicians, as well as a responsibility of the host facilities. *(November 8, 2002, CON Application, page 14)*

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

14. The proposal has a total capital expenditure of \$350,000. The breakdown of capital costs is as follows: \$250,000 for the purchase of medical equipment; \$50,000 for the cost of the transportation vehicle for the equipment; and \$50,000 for space lease costs. *(November 8, 2002, CON Application, page 10)*
15. The proposal will be funded entirely through OssaTron Services New England's equity. The \$350,000 equity contribution will be derived initially from the contributions made to the partnership (OssaTron New England), as well as investments made by the other partners in OssaTron New England. The host facilities will not provide any equity for the project *(November 8, 2002, CON Application, pages 11 and 12, and November 15, 2002, Completeness Responses, page 3)*
16. The Applicants project excess revenues incremental to the project of \$35,000, \$371,000, and \$712,000 for Fiscal Years 2003, 2004, and 2005, respectively. *(November 8, 2002, CON Application, page 124)*
17. OssaTron New England will bill the technical component of the service. Certified physicians will bill for their own professional services. *(November 8, 2002, CON Application, page 8)*
18. HealthTronics will provide a technician who will accompany and assist in the installation and operation of the equipment. *(November 8, 2002, CON Application, page 7 and November 15, 2002, Completeness Responses, page 4)*
19. The Applicants' projected payer mix for the first three years of operation associated with the CON proposal is as follows:
(November 8, 2002, CON Application, page 13)

Table 1: Payer Mix Percentages

Payer Source	Year One	Year Two	Year Three
Medicare	0%	2%	3%
Medicaid	0%	1%	2%

TriCare	1%	4%	5%
Commercial Insurers	45%	48%	50%
Self-Pay	14%	8%	5%
Workers Compensation	25%	25%	25%
Uncompensated	15%	12%	10%
Total Payer Mix	100%	100%	100%

20. A cost comparison between ESWT and invasive, surgical procedures yields total costs of \$6,650 for ESWT treatments and \$16,500 for invasive, surgical plantar fasciotomy procedures. These figures take into account surgeon charges, facility and technical costs, anesthesia charges, after-care costs, and lost productivity for recovery time. (*November 8, 2002, CON Application, page 5 and November 8, 2002, CON Application, "Cost Comparison: Extracorporeal Shock Wave Treatment (ESWT) for Chronic Proximal Plantar Fasciitis"*)
21. If volume projections are achieved, the Applicants' rates are sufficient to cover the proposed capital expenditure and operating costs. (*November 8, 2002, CON Application, page 124*)

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

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

22. There is no State Health Plan in existence at this time. (*November 8, 2002, CON Application, page 2*)
23. The Applicants have adduced evidence that this proposal is consistent with their long-range plans. (*November 8, 2002, CON Application, page 2*)
24. The Applicants state that their proposal will remedy economic, geographic, and transportation barriers in that patients seeking orthotripsy service, which is currently unavailable in Connecticut, would have to incur travel expenses to other states to receive such service. (*November 8, 2002, CON Application, pages 3 and 5*)
25. The proposal will affect the Applicants' teaching and research responsibilities in that the additional component of operations will enable the host facilities to expand students' experiences via on-site teaching and research initiatives. (*November 8, 2002, CON Application, page 8*)
26. The Applicants assert that the distinguishing characteristic of their patient/physician mix is that this proposal will serve a unique patient population, one that has not responded to existing treatment alternatives. (*November 8, 2002, CON Application, page 8*)

27. The Applicants have sufficient technical and managerial competence to provide efficient and adequate services to the public. *(November 8, 2002, CON Application, pages 5-24, 124 and November 15, 2002, Completeness Responses, Exhibits A and B)*

Rationale

OssaTron Services of New England, L.P.; the HealthSouth Surgery Centers of Bridgeport, Danbury, and Hartford; and the Connecticut Foot Surgery Center propose the establishment of a mobile OssaTron/orthotripsy service. The total capital expenditure associated with this project is \$350,000.

OssaTron Services of New England, L.P. proposes to establish a mobile orthotripsy service whereby the OssaTron equipment will be transported among the four outpatient surgical facilities located in Bridgeport, Danbury, Hartford, and Milford. The OssaTron is a non-invasive, non-surgical, FDA-approved device used for the treatment of plantar fasciitis, or chronic heel pain. The OssaTron is only approved for such procedures.

The Applicants base their utilization projections on a finite patient population. Specifically, this population includes plantar fasciitis cases that have existed for six months and have not responded to alternative treatment methods. The Applicants base their projections upon American Podiatric Medical Association statistics that indicate approximately 38,600,000 nationwide cases of heel pain in 2000, and estimations that roughly 2% of this national total will have surgery for plantar fasciitis. Using these projections, as well as extrapolations of Connecticut's population, the Applicants' utilization volumes for chronic heel pain procedures are 100, 300, and 500 for years one through three of the project, respectively. In addition, a cost comparison between orthotripsy treatments and surgical plantar fasciotomies, including surgeon charges, lost productivity for recovery time, anesthesia charges, and facility, technical, and after-care costs, reveals that non-invasive ESWT treatments are less costly. Given that orthotripsy service is currently unavailable in Connecticut, OHCA finds that this initiative will improve the overall quality of care to patients in this region.

The capital expenditure associated with the project is \$350,000. The project will be funded entirely through the equity of OssaTron Services of New England, L.P. ("the partnership"). The equity contribution will be derived from the contributions made to the partnership, as well as investments made by the other partners in OssaTron Services of New England, L.P. The host facilities will not provide any equity for the project. Excess revenues incremental to the project are \$35,000, \$371,000, and \$712,000 for Fiscal Years 2003, 2004, and 2005, respectively. Therefore, OHCA finds that the proposal is financially feasible.

Based on the foregoing Findings and Rationale, the Certificate of Need Application of OssaTron Services of New England, L.P.; the HealthSouth Surgery Centers of Bridgeport, Danbury, and Hartford; and the Connecticut Foot Surgery Center to establish a mobile OssaTron/orthotripsy service, at a total capital expenditure of \$350,000, is hereby GRANTED.

Order

OssaTron Services of New England, L.P.; the HealthSouth Surgery Centers of Bridgeport, Danbury, and Hartford; and the Connecticut Foot Surgery Center are hereby authorized to establish a mobile OssaTron/orthotripsy service, at a total capital expenditure of \$350,000, subject to the following conditions:

1. This authorization shall expire December 6, 2003. Should the Applicants' project not be completed by that date, the Applicants must seek further approval from OHCA to complete the project beyond that date.
2. The Applicants shall not exceed the approved capital expenditure of \$350,000. In the event that the Applicants learn of potential cost increases or expect that the final project costs will exceed those approved, the Applicants 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:
December 6, 2002

Signed by:
Mary M. Heffernan
Commissioner