



## Office of Health Care Access Certificate of Need Application

### Final Decision

**Hospital:** Saint Mary's Hospital

**Docket Number:** 03-30094-CON

**Project Title:** Establishment of Wound Care and Hyperbaric Oxygen Therapy Services

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

**Filing Date:** August 13, 2003

**Decision Date:** September 15, 2003

**Staff:** Steven Lazarus

**Project Description:** Saint Mary's Hospital ("Hospital") proposes to establish wound care and hyperbaric oxygen therapy services at a total proposed capital expenditure of \$438,800.

**Nature of Proceedings:** On August 13, 2003, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application of Saint Mary's Hospital seeking authorization to establish wound care and hyperbaric oxygen therapy services at a total proposed capital expenditure of \$438,800. The Hospital is a health care facility or institution 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 application is established by Section 19a-638, C.G.S. The provisions of this section, 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

#### Impact on the Hospital's Current Utilization Statistics

#### Contribution of the Proposal to the Accessibility and Quality of Health Care Delivery in the Region

1. Saint Mary's Hospital ("Hospital") is an acute care hospital located at 56 Franklin Street, Waterbury Connecticut. *(May 20, 2003, Letter of Intent)*
2. The Hospital proposes to establish wound care and hyperbaric oxygen therapy services ("HBOT"), which includes the acquisition of three monoplace hyperbaric chambers for hyperbaric oxygen therapy ("HBOT"). *(August 13, 2003, Certificate of need Application, page 2)*
3. The proposed program's hours of operation will be 7:00 a.m. to 5:00 p.m. Monday through Friday and 8:00 to 12:00 p.m. on Saturdays. The program is available 24-hour per day, 7-day per week service for emergencies. *(August 13, 2003, Certificate of need Application, pages 3)*
4. The Hospital will contract with National Outpatient Resources, LLC to provide all necessary equipment, training and chamber operators. *(August 13, 2003, Certificate of need Application, page 3)*
5. The Hospital based the need of this proposal on the following:
  - a. The specific clinical needs of the patients currently seen at the Hospital's outpatient specialty clinics, emergency department and inpatient services who cannot readily receive these services within a reasonable distance of Waterbury.
  - b. The increasing number of patients at risk of chronic wounds due to the aging population and growing incidence and prevalence of obesity and diabetes within the greater Waterbury population.
  - c. The need to increase convenient access to care for patients suffering from both acute and chronic health pathologies (other than chronic wounds) for which HBOT is an indicated and approved treatment. *(August 13, 2003, Certificate of need Application, page 4)*
6. Typical HBOT treatment regimen includes 5 visits per week for 30 to 60 days. *(August 13, 2003, Certificate of need Application, page 4)*
7. Patients are required to travel to Norwalk Hospital, Hartford Hospital, Griffin Hospital or Bay State Medical Center in Springfield, Massachusetts to receive HBOT services. Actual driving times for patients traveling one way from within the service area to existing HBOT facilities average one hour to the facility at Griffin Hospital and two hours to Baystate Medical Center in Massachusetts. It is difficult for the wound treatment patients to travel to these facilities for treatment and compliance becomes an issue. *(August 13, 2003, Certificate of need Application, page 4)*

8. The Hospital's service area consists of Waterbury, Wolcott, Beacon Falls, Prospect, Naugatuck, Cheshire, Oxford, Southbury, Middlebury, Watertown, Bethlehem, Morris, Plymouth, Thomaston and Woodbury. *(August 13, 2003, Certificate of need Application, pages 4&5)*
9. Currently, approximately 700 patients are treated annually for chronic wound or associated pathologies at the Hospital or its outpatient specialty clinics. *(August 13, 2003, Certificate of need Application, page 4)*
10. The Centers for Medicare & Medicaid Services recently approved HBOT service for severe diabetic foot ulcerations unresponsive to thirty days of therapy. *(August 26, 2003, Supplemental Information, Need Assessment page 1)*
11. The Hospital utilized the following assumptions in projecting the need for the proposed program: *(August 26, 2003, Supplemental Information, Need Assessment pages 1 and 2)*
  - a. The population of the service area was approximately 298,685 in 2002 and is projected to increase to 305,000 in 2007. The service area's Medicare population was approximately 42,560 in 2002 and is projected to increase to 44,000 in 2007.
  - b. The ethnic and socio-economic composition of Waterbury's service area contains a higher percentage of Hispanics, African Americans, American Indians and lower income families than the state average.
  - c. The general population with diabetes in the service area is 12.9% (ethnically and socio-economically adjusted).
  - d. Diabetes in the general population of service area greater than 15 years old is 30,400. *(August 26, 2003, Supplemental Information, Need Assessment page 1)*
12. In addition to wound care, the following diagnoses have been approved for Medicare reimbursement for HBOT treatment: acute arterial disease, transmetatarsal amputation with primary closure, deep debridement, crush/trauma injuries, grafts or flaps that are non-healing/slow healing surgical sites, recalcitrant osteomyelitis, radiation necrosis, compartment syndrome, burn cases, necrotizing fasciitis or abdominal gangrene, and carbon monoxide poisoning. *(August 26, 2003, Supplemental Information, Need Assessment page 3)*

13. Using hospital data and epidemiological literature, the Hospital identified 7,815 potential residents of the service area in need of wound care and/or HBOT services. The categories are as follows:

**Table 1: Potential Number of Patients**

Category	# Residents
Diabetic foot ulcerations secondary to neuropathy ischemia	2,740
Diabetic and non-diabetic venous stasis ulcerations	1090
Severe Decubitis Ulcerations	2540
Contra-lateral limb amputation	55
Other Categories of HBOT services	1,390
<b>Total</b>	<b>7,815</b>

*(August 26, 2003, Supplemental Information, Need Assessment pages 1-4)*

14. Using state, national statistics and epidemiological literature, Hospital discharge diagnosis and procedures data, the Hospital projects the following volume of patients for HBOT therapy:

**Table 2: Projected Actual HBOT Patients for Years One through Three**

Year	Wound Care	HBOT With Wound Care	HBOT W/O Wound Care	Total HBOT Patients
One	<ul style="list-style-type: none"> <li>429 patients or 6.7% of present diagnosed and undiagnosed chronic wound population</li> <li>339 Wound Care patients only</li> </ul>	21% of Wound Care population in first year to HBOT= approximately 90 patients	Approximately 10 non-wound care patients	100
Two	<ul style="list-style-type: none"> <li>631 patients or 9.8% of present diagnosed and undiagnosed chronic wound population</li> <li>523 Wound Care patients only</li> </ul>	17.1% of Wound Care Population in second year to HBOT= approximately 108 patients	Approximately 12 non-wound care patients	120
Three	<ul style="list-style-type: none"> <li>865 patients or 13.4% of present diagnosed and undiagnosed chronic wound population</li> <li>757 Wound Care patients only</li> </ul>	12.5% of Wound Care population in third year to HBOT= approximately 108 patients	Approximately 12 non-wound care patients	120

15. The projected number of visits associated with the proposal are listed below:

**Table 3: Projected Number of Visits**

	Projected Visits 2004	Projected Visits 2005	Projected Visits 2006
Wound Treatments Without HBOT	3,390	5,235	7,569
Wound Treatments after HBOT Termination	500	600	600
<b>Total Wound Care Visits</b>	<b>3,890</b>	<b>5,835</b>	<b>8,169</b>
HBOT Not Related to Wound Care	350	420	420
Wound Care Treatments With HBOT with daily care	3,150	3,780	3,780
<b>Total Visits HBOT</b>	<b>3,500</b>	<b>4,200</b>	<b>4,200</b>

- Note: 1. First year hyperbaric patients with or without wound care represents an average of 100 patients who will receive an average of 35 days of therapy.  
2. Second year hyperbaric oxygen therapy patients with or without wound care represents 120 patient who will receive an average of 35 days of therapy.  
*(August 26, 2003, Supplemental Information, Substituted page 7)*

16. The projected number of number procedures associated with the proposal are listed below:

**Table 4: Projected Number of Procedures**

	2004 Projected Procedures	2005 Projected Procedures	2006 Projected Procedures
Minor Surgical Wound Debridement Procedures	3,890	5,835	8,169
Hyperbaric Treatments With or Without Wound Care	3,500	4,200	4,200
Consults and Other	973	1,362	1,907
<b>Total HBOT (units) only</b>	<b>3,500</b>	<b>4,200</b>	<b>4,200</b>
<b>Total Non-HBOT</b>	<b>4,863</b>	<b>7,197</b>	<b>10,076</b>

- Note: Wound Care treatments with HBOT may consist of wound dressing changes.  
*(August 26, 2003, Supplemental Information, Substituted page 12)*

17. The Hospital conducted telephone interviews with existing HBOT facilities and found there are no lengthy waiting lists at this time. However, often the available times are too early or too late for the population in need of treatment. *(August 13, 2003, Certificate of need Application, page 8)*

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

18. The proposal includes the following cost components:

**Table 5: Total Proposed Capital Cost**

<b>Component</b>	<b>Cost</b>
Medical Equipment (Purchase)	\$298,000
Construction/Renovation	\$140,000
<b>Total Capital Expenditure</b>	<b>\$438,800</b>

*(August 13, 2003, Certificate of need Application, page 14)*

19. NOR will finance the capital expenditure through a cost per treatment basis. *(August 13, 2003, Certificate of need Application, Attachment H, Management Services Agreement)*
20. The Hospital projects incremental gains from operations related to the proposal of \$686,000 for FY 2004, \$858,000 for FY 2005 and \$929,000 for FY 2006. *(August 13, 2003, Certificate of need Application, Financial Proforma)*

**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.:

21. There is no State Health Plan in existence at this time. *(August 13, 2003, Certificate of need Application, page 3)*
22. The Hospital has adduced evidence that this proposal is consistent with the Hospital's long-range plan. *(August 13, 2003, Certificate of Need Application, page 3)*
23. The Hospital has improved productivity and contained costs through group purchasing and development of a Hospital Performance Improvement Plan. *(August 13, 2003, Certificate of Need Application, page 13)*
24. This proposal will not result in changes to the Hospital's teaching and research responsibilities. *(August 13, 2003, Certificate of Need Application, page 13)*
25. There are no distinguishing or unique characteristics of the Hospital's patient/physician mix related to this proposal. *(August 13, 2003, Certificate of Need Application, page 13)*
26. The Hospital has sufficient technical and managerial competence to provide efficient and adequate service to the public. *(August 26, 2003, Supplemental Information, Substituted page 12)*

## Rationale

Saint Mary's Hospital ("Hospital") proposes to establish wound care and hyperbaric oxygen therapy services, which includes the acquisition of three monoplace chambers for hyperbaric oxygen therapy ("HBOT"). The Hospital will contract with National Outpatient Resources, LLC ("NOR") to provide all necessary equipment, training and chamber operators.

The Hospital based the need for this proposal on the specific needs of the patients currently seen at the Hospital's outpatient specialty clinics, emergency department and inpatient services who cannot receive wound care and HBOT services within a reasonable distance of Waterbury. Also, there is an increasing number of patients at risk of chronic wounds due to the aging population and growing incidence and prevalence of obesity and diabetes within the Hospital's service area. Finally, there is a need to increase convenient access to care for the patients suffering from both acute and chronic health pathologies (other than chronic wounds) for which HBOT is an indicated and approved treatment.

The Hospital's need methodology used in projecting the service area need for a wound care center is based upon the estimated incidence rate of diabetes, the percentage of elderly, and the ethnic and socio-economic composition of its service area. Using hospital data and epidemiological literature, the Hospital identified 7,815 potential residents of the service area in need of wound care and/or HBOT services. These patients would require treatment for several conditions including diabetic foot ulcerations, venous stasis ulcerations, severe decubitus ulcerations, contra-lateral limb amputations and non-wound conditions that require HBOT services. The Hospital projects that during the first year of operation a total 429 patients will be treated and that will increase to 631 patients in year two and 865 patients in year three. Additionally, the Hospital projects 3,890 wound care visits and 3,500 HBTO visits during the first year of operation, increasing to 8,169 wound care and 4,200 HBOT visits by the third year. The projections indicate that there is sufficient need for the proposal

The proposal will remedy a geographic barrier to access by providing HBOT services within the Hospital's service area. There are no other providers of wound care services in the service area. Patients are required to travel to Norwalk Hospital, Hartford Hospital, Griffin Hospital or Bay State Medical Center in Springfield, Massachusetts to receive HBOT services. Actual driving times for patients traveling one way from within the service area to existing HBOT facilities average one hour to the facility at Griffin Hospital and two hours to Baystate Medical Center in Massachusetts. Since typical HBOT treatment regimen includes 5 visits per week for 30 to 60 days, it is difficult for the wound treatment patients to travel to these facilities for treatment and compliance becomes an issue. OHCA concludes that since patients receiving HBOT treatments have complicated medical problems and are often frail, it is critical that the service be located close to the patients' town of residence. The establishment of the proposed Center with

HBOT services addresses this concern and will improve both the quality and accessibility of wound care service in the region.

The proposal has a total capital expenditure of \$438,000, which includes \$298,800 for medical equipment and \$140,000 for construction/renovation. NOR will finance the capital expenditure through a cost per treatment basis. The Hospital projects incremental gains from operations related to the proposal of \$686,000 for FY 2004, \$858,000 for FY 2005 and \$929,000 for FY 2006. If volume projections are achieved, the Hospital's rates are sufficient to cover the proposed capital expenditure and operating costs associated with the project. OHCA concludes that the CON proposal is financially feasible and cost-effective.

Based on the foregoing Findings and Rationale, the Certificate of Need application of Saint Mary's Hospital to establish wound care and hyperbaric oxygen service, which includes the acquisition of three monoplace chambers for hyperbaric oxygen therapy, at a total capital expenditure of \$438,000, is hereby GRANTED.



## Order

Saint Mary's Hospital ("Hospital") is hereby authorized to establish a wound care center, which includes the acquisition of three monoplace chambers for hyperbaric oxygen therapy, at a total capital expenditure of \$438,000, subject to the following conditions:

1. This authorization shall expire on September 15, 2004. Should the Hospital's project not be completed by that date, the Hospital must seek further approval from OHCA to complete the project beyond that date.
2. The Hospital shall not exceed the approved capital expenditure of \$438,000.

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:  
September 15, 2003

Signed by:  
Mary M. Heffernan  
Commissioner

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