Office of Health Care Access
Certificate of Need Application

Final Decision

Hospital:	**The Stamford Hospital**
Docket Number:	**07-31027-CON**
Project Title:	**Establishment of Outpatient Hyperbaric Oxygen Therapy Service**
Statutory Reference:	**Section 19a-638, Connecticut General Statutes**
Filing Date:	**March 20, 2008**
Decision Date:	**April 23, 2008**
Default Date	**June 18, 2008**
Staff:	**Alexis G. Fedorjaczenko**

Project Description: The Stamford Hospital ("Hospital") proposes to establish an outpatient hyperbaric oxygen therapy service at a total proposed capital expenditure of $1,147,856.

Nature of Proceedings: On March 20, 2008, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application of The Stamford Hospital seeking authorization to establish an outpatient hyperbaric oxygen therapy service at a total proposed capital expenditure of $1,069,039. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

Pursuant to Section 19a-638, C.G.S., a notice to the public concerning OHCA's receipt of the Hospital's CON application was published in the Stamford *Advocate* on September 15, 2007. OHCA received no responses from the public concerning the Hospital's proposal. Pursuant to Section 19a-638, three individuals or an individual representing an entity with five or more people had until April 10, 2008, the twenty-first calendar day

following the filing of the Hospital's CON Application, to request that OHCA hold a public hearing on the Hospital's proposal. OHCA received no hearing requests.

OHCA's authority to review and approve, modify or deny the CON 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. The Stamford Hospital ("TSH" or "Hospital") is an acute care hospital located at 30 Shelburne Road in Stamford, Connecticut *(December 5, 2007, Initial CON Application, page 631)*

2. The Hospital operates a Wound Care Center ("WCC") which currently provides services at the Tully Health Center located at 32 Strawberry Hill Court in Stamford, that began operation in 1993. *(December 5, 2007, Initial CON Application, page 2 and March 20, 2008, Second Completeness Response, page 1)*

3. The WCC treats patients with chronic wounds stemming from diabetes, venous stasis, collagen vascular disease, ischemia, pressure and other causes. A chronic wound is defined as any wound that has not decreased in volume by 50 percent over a four-week period. *(December 5, 2007, Initial CON Application, page 2)*

4. The Hospital proposes to establish a two-chamber outpatient hyperbaric oxygen therapy service ("HBOT") as an adjunctive modality to be provided along with the interdisciplinary and comprehensive wound care services offered by the WCC. *(August 27, 2007, Letter of Intent, page 5 and December 5, 2007, Initial CON Application, page 2)*

5. The proposal also includes plans to relocate the WCC to a larger space on the 8th floor of 1351 Washington Boulevard in Stamford. *(March 20, 2008, Second Completeness Response, page 1)*

6. The Hospital's Diabetes Center and Education program is already located in the proposed Washington Boulevard site, along with Fairfield County Surgical Specialists, other physicians' offices, the Optimus Federally Qualified Health Center primary care clinics, and a number of Stamford Hospital specialty care clinics. *(March 20, 2008, Second Completeness Response, page 2)*

7. The proposed HBOT program will be a TSH service developed in conjunction with Wound Care Centers, Inc., a division of Diversified Clinical Services ("DCS"). *(August 27, 2007, Letter of Intent, Project Description)*

8. DCS currently provides the following services at the WCC:

   - Day-to-day management of the WCC;
   - Marketing expertise and collateral materials;
   - Financial and reimbursement oversight;
   - Policies and Procedures specific to wound care;
   - Clinical and quality oversight; and
   - Training, education, and certification of TSH staff.

   (December 5, 2007, Initial CON Application, page 12 and August 27, 2007, Letter of Intent)

9. The service area for the proposed service is based on the Hospital's primary service area of Stamford and Darien, and secondary service area of New Canaan, Greenwich, Norwalk, Wilton, and Westport. *(December 5, 2007, Initial CON Application, pages 4-5)*

10. The Hospital based the need to add HBOT to the services offered at the WCC on the following:

    - HBOT is now considered the optimal treatment modality for a range of chronic non-healing wounds; and
    - Improving access for patients who must follow an intensive therapy regimen.

    (December 5, 2007, Initial CON Application, pages 2-4)

11. According to the Hospital, the delivery of high doses of oxygen through HBOT has been clinically proven to speed healing and stimulate the body's own immune system to fight infection, and the medical community and third-party payers have recognized the benefits of HBOT to a degree that it is now considered the optimal treatment modality for diabetic wounds of the lower extremities, radiation necrosis (soft and bony), crush injuries/ compartment syndrome, chronic refractory osteomyelitis, compromised skin grafts, necrotizing soft tissue infections, thermal burns and other conditions. *(December 5, 2007, Initial CON Application, page 2)*

12. Typically, patients receive HBOT treatments once a day, 5 days a week, with a total of about 20-40 treatments overall (usually for a duration of about 4 weeks). *(December 5, 2007, Initial CON Application, page 3 and March 20, 2008, Second Completeness Response, page 3)*

13. The Hospital stated that because a substantial portion of the patient population requiring such treatment is frail, elderly, and suffering from other co-morbidities impairing their health and restricting their mobility, HBOT outpatient therapy is best suited for locations close to the patient's home so that they can be readily accessed by the patients. *(December 5, 2007, Initial CON Application, page 3)*

14. More than 65% of the Hospital's WCC patients in 2007 were from Stamford. Patients receiving treatment at the WCC during FY 2007 came from the following communities:

Table 1: WCC Patients by Town in FY 2007

Patient Residence	FY 2007
Stamford	65.4%
Greenwich	12.9%
Darien	5.9%
Norwalk	3.4%
New Canaan	2.2%
Westport	0.8%
Bridgeport	0.8%
Fairfield	0.7%
Other Fairfield County Towns	1.2%
Westchester County	0.8%
Outside Fairfield and Westchester Counties	5.8%
Total	100%

(March 20, 2008, Second Completeness Response, page 3)

15. TSH's actual WCC volume for FY 2001 - FY 2007 is shown in the table below:

Table 2: Actual WCC Volumes for FYs 2001-2007

	2001	2002	2003	2004	2005	2006	2007
Patients (1)	396	372	389	417	476	537	545
Total Visits	4,160	4,302	4,768	4,779	4,631	5,061	4,457

(1) "Patient" is defined as an individual accepted into the WCC's wound care program who has not been registered in the program during the 4 weeks preceding their intake. WCC's staff also performs 30-40 additional consultations annually where a patient is referred for an evaluation but it is determined that the patient is not in need of chronic wound care. These consultations are not included in the volumes above. *(December 5, 2007, Initial CON Application, page 4 and January 31, 2008, First Completeness Response, page 3)*

16. The Hospital calculated that there are approximately 320 adults diagnosed with diabetes in the primary and secondary service area who could benefit from HBOT treatment.

Table 3: Diabetic Population in the Proposed Service Area

	FY 2006
Population with Diabetes	17,838
Diabetic Population with Chronic Wounds	2,676
Diabetic Population requiring HBOT	320

Incidence Rates: Population with Diabetes 5.1%, Diabetic Pop. w/ Chronic Wounds 15%, Diabetic Pop. Requiring HBOT 12% *(December 5, 2007, Initial CON Application, page 5 and January 31, 2008, First Completeness Response, page 2)*

17. The projected utilization of the proposed HBOT program is shown below:

Table 4: Projected HBOT Volumes for Years 1-3

	Year 1	Year 2	Year 3
WCC Patient Volume (1)	532	565	600
% WCC Patients to HBOT (2)	7%	7%	7%
Volume WCC Patients to HBOT	**37**	**40**	**42**
% non-WCC Patients to HBOT (3)	4%	4%	4%
Volume non-WCC patients to HBOT	**21**	**23**	**24**
Total Number of Patients	**58**	**63**	**66**
Number of Treatments per Patient (4)	21.45	21.45	21.45
HBOT Volume	**622** (5)	**1,352**	**1,416**

(1) Year 2 & 3 volumes reflect a 6% increase per year, based on WCC's historical growth rate.
(2) DCS' experience in established wound care centers is that anywhere from 14-16% of chronic wound care patients meet the clinical criteria for HBOT; a more conservative estimate of 7% has been chosen based on DCS' experience regarding HBOT rates for centers introducing this therapy.
(3) These are patients who are not currently receiving wound care treatment at WCC; the majority are believed to be not receiving HBOT at all because of lack of proximity to the service. It is estimated that TSH will draw a proportion of patients from this subset equal to approximately 4% of the total WCC patient population, based on rates experienced by DCS at comparable centers. These referrals are expected to come from a primary care physician or specialist treating a particular condition.
(4) Most HBOT patients have between 20 and 40 treatments depending on wound severity; 21.45 treatments per patient is the average.
(5) To reflect six months of operation in the first year, TSH has divided 1,244 (projected volume for a full year of operations based on the calculations above) by 2, for a first year volume of 622.
(December 5, 2007, Initial CON Application, page 7; January 31, 2008, First Completeness Response, page 4; and March 20, 2008, Second Completeness Response, page 5)

18. Non-wound care diagnoses that are approved by CMS for HBOT treatment are: preservation of failing flap/graft, refractory osteomyelitis, radiation necrosis (radiated bone (mandible), radiated teeth, radiated soft tissue). (*March 20, 2008, Second Completeness Response, page 6)*

19. The Hospital indicated that the projected volumes are consistent with the capacity of the proposed chambers. This is based on a standard treatment time for a patient in HBOT of ninety (90) minutes, turnaround time for a chamber of fifteen (15) minutes, and physician visit time of fifteen (15) minutes for a total time per patient of 2 hours (120 minutes). In an eight (8) hour work day, approximately four (4) treatments can be provided in a single chamber, and eight (8) treatments can be provided in two chambers. (*March 20, 2008, Second Completeness Response, page 4)*

20. TSH identified Norwalk Hospital as the only HBOT provider in the proposed service area. *(December 5, 2007, Initial CON Application, page 8)*

21. The proposed HBOT service will be open Monday through Friday from 8:00 a.m. to 4:00 p.m. *(December 5, 2007, Initial CON Application, page 7)*

22. The specialized knowledge and expertise of DCS' Wound Care Centers, Inc. allows the Hospital's services to be measured against the services provided to over 200

other centers across the country; by instituting the HBOT service, TSH will be able to benchmark patient progress against regional and national averages. *(August 27, 2007, Letter of Intent, Project Description)*

23. The Hospital will meet the Clinical Practice Guidelines for wound care; Medical and Technical Directors from DCS will be on site for the initiation of the program, and will assure that all established guidelines are in place and are being adhered to. The on-site HBOT Technician and Safety Officer will be responsible for ensuring that all guidelines are adhered to on a daily basis, and the Medical or Technical Director will provide periodic on-site inspections to assure continued compliance. *(December 5, 2007, Initial CON Application, page 7)*

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

24. The proposal includes the following cost components:

Table 5: Total Proposed Capital Expenditure

Component	Cost
Medical Equipment (Purchase)	$246,039
Construction/Renovation	$850,000
Total Capital Expenditure	**$1,096,039**

(December 5, 2007, Initial CON Application, page 14)

25. The renovations connected with this proposal include construction of a concrete pad sufficient to hold a 3,000 gallon liquid oxygen tank, installation of an oxygen delivery system from the tank to the WCC, building and furnishing the HBOT suite and WCC treatment rooms, along with a reception area, nursing station, offices, and clean and dirty utility rooms. *(January 31, 2008, Completeness Response, pages 6-7)*

26. TSH will bill for the proposed service; there will be no new cost center established. *(December 5, 2007, Initial CON Application, page 13)*

27. The Hospital will finance the proposal through its equity from operating funds. *(December 5, 2007, Initial CON Application, page 15)*

28. The proposed service will be located in approximately 4,200 square feet of renovated space located on the eighth floor of 1351 Washington Boulevard in Stamford, CT, next to TSH's diabetes center. TSH anticipates that commencement of operations will be about 4 months after construction begins. *(December 5, 2007, Initial CON Application, page 14-15)*

29. The Hospital's projected incremental revenue from operations, total operating expense, and gains from operations associated with the CON proposal are as follows:

Table 6: Incremental Financial Projections for Year 1 through Year 4

Description	2008 (1)	2009	2010	2011
Incremental Revenue from Operations	$271,121	$417,108	$617,213	$658,187
Incremental Total Operating Expense	$231,309	$401,781	$494,365	$513,077
Incremental Gain from Operations	**$39,812**	**$105,874**	**$122,848**	**$145,110**

(1) Six months
(January 31, 2008, Completeness Response, page 9)

30. The Hospital's current and projected payer mix for the WCC, based on gross patient revenue is as follows:

Table 7: Current and Three-Year Projected Payer Mix

Payer Mix	Current	Year 1	Year 2	Year 3
Medicare	68%	68%	68%	68%
Medicaid	2%	2%	2%	2%
TriCare (CHAMPUS)	0%	0%	0%	0%
Total Government	**70%**	**70%**	**70%**	**70%**
Commercial Insurers	28%	28%	28%	28%
Uninsured	2%	2%	2%	2%
Total Non-Government	**30%**	**30%**	**30%**	**30%**
Total Payer Mix	**100%**	**100%**	**100%**	**100%**

(January 31, 2008, Completeness Response, pages 11-13)

31. The Hospital is reimbursed 31% of charges by Medicare, 25% by Medicaid, 34.4% by commercial insurers, and 7.1% by uninsured/self pay clients. *(January 31, 2008, Completeness Response, page 6)*

32. The Hospital projects the following number of treatments, by payer, for the first three years of the proposal:

Table 8: Three-Year Projected Treatment Volume

Payer Mix	Year 1	Year 2	Year 3
Medicare	423	919	963
Medicaid	12	27	29
TriCare (CHAMPUS)	0	0	0
Total Government	**435**	**946**	**991**
Commercial Insurers	174	379	396
Uninsured	12	27	28
Total Non-Government	**187**	**406**	**425**
Total Payer Mix	622	1,352	1,416

(January 31, 2008, Completeness Response, pages 11-13)

33. There is no State Health Plan in existence at this time. *(December 5, 2007, Initial CON Application, page 2)*

34. The Hospital has adduced evidence that this proposal is consistent with the Hospital's long-range plan. *(December 5, 2007, Initial CON Application, page 2)*

35. The Hospital has improved productivity and contained costs through group purchasing, energy conservation, reengineering, and application of technology. *(December 5, 2007, Initial CON Application, page 11)*

36. This proposal will not result in changes to the Hospital's teaching and research responsibilities. *(December 5, 2007, Initial CON Application, page 12)*

37. There are no distinguishing or unique characteristics of the Hospital's patient/physician mix related to this proposal. *(December 5, 2007, Initial CON Application, page 12)*

38. The Hospital has sufficient technical and managerial competence to provide efficient and adequate service to the public. *(December 5, 2007, Initial CON Application, page 10 and 560-629)*

39. The Hospital's rates are sufficient to cover the proposed capital and operating costs associated with the proposal. *(December 5, 2007, Initial CON Application, page 697)*

Rationale

The Office of Health Care Access ("OHCA") approaches community and regional need for Certificate of Need ("CON") proposals on a case by case basis. CON applications do not lend themselves to general applicability due to a variety of factors, which may affect any given proposal; e.g. the characteristics of the population to be served, the nature of the existing services, the specific types of services proposed to be offered, the current utilization of services and the financial feasibility of the proposal.

The Stamford Hospital ("Hospital" or "TSH") is an acute care hospital located at 30 Shelburne Road in Stamford, Connecticut. The Hospital operates a Wound Care Center ("WCC") which treats patients with chronic wounds stemming from diabetes, venous stasis, collagen vascular disease, ischemia, pressure, and other causes. TSH proposes to establish a two-chamber outpatient hyperbaric oxygen therapy ("HBOT") service as an adjunctive modality to be provided along with the interdisciplinary and comprehensive services offered by the WCC. The HBOT service is proposed for 1351 Washington Boulevard in Stamford, Connecticut. The Hospital currently operates its Diabetes Center at this location, and also plans to relocate the WCC to this location.

The Hospital based the need for this proposal on the effectiveness of HBOT and on improving access to this service for patients who must follow an intensive therapy regimen. HBOT is now considered the optimal treatment modality for a range of chronic non-healing wounds. According to the Hospital, the delivery of high doses of oxygen through HBOT has been clinically proven to speed healing and stimulate the body's own immune system to fight infection. Most patients who receive HBOT are treated once a day, 5 days per week, with a total of about 20-40 treatments overall; a typical patient is treated for a duration of about 4 weeks. A substantial portion of the patient population with chronic non-healing wounds is frail, elderly, and suffering from other co-morbidities impairing their health and restricting their mobility. OHCA concludes that the establishment of the proposed HBOT program will improve the quality and accessibility of wound care services in the proposed service area.

The proposal has a total capital expenditure of $1,096,039, which will be financed with equity from operating funds. The Hospital projects incremental gains from operations related to the proposal of $39,812 in FY 2008, $105,874 in FY 2009, $122,848 in FY 2010, and $145,110 in FY 2011. The Hospital's financial projections, and volumes upon which they are based, appear to be reasonable and achievable. Therefore, OHCA concludes that the CON proposal is financially feasible and will improve access to quality HBOT services.

Order

Based on the foregoing Findings and Rationale, the Certificate of Need application of The Stamford Hospital to establish hyperbaric oxygen therapy services, at a total capital expenditure of $1,096,039, is hereby GRANTED, subject to the following conditions.

1. This authorization shall expire on April 23, 2009. 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 total capital cost of $1,096,039. In the event that the Hospital learns of potential cost increases or expects that final project costs will exceed those approved, the Hospital shall notify OHCA immediately.

Should the Hospital fail to comply with any of the aforementioned conditions, OHCA reserves the right to take additional actions as authorized by law.

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

Signed by Commissioner Vogel on April 23, 2008

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Date

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Cristine A. Vogel
Commissioner

CAV:agf