



Office of Health Care Access Certificate of Need Application

Final Decision

Hospital: Saint Vincent's Medical Center

Docket Number: 07-31060-CON

Project Title: Establishment of Ambulatory Wound Care Services and Outpatient Hyperbaric Oxygen Therapy Services in Trumbull

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

Filing Date: March 11, 2008

Decision Date: May 23, 2008

Default Date: June 9, 2008

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Project Description: Saint Vincent's Medical Center ("Hospital") proposes to establish ambulatory wound care services and outpatient hyperbaric oxygen therapy services in Trumbull at a total proposed capital expenditure of \$650,000.

Nature of Proceedings: On March 11, 2008, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application of Saint Vincent's Medical Center ("Hospital") proposal to establish ambulatory wound care services and outpatient hyperbaric oxygen therapy services in Trumbull at a total proposed capital expenditure of \$650,000. 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 *Connecticut Post* on November 14, 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 1, 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. Saint Vincent's Medical Center ("Hospital") is an acute care hospital located at 2800 Main Street, Bridgeport, Connecticut (*February 1, 2008, Initial CON Application, page 159*)
2. The Hospital provides wound related services in a variety of settings including the inpatient units, Emergency Department, outpatient clinics, walk-in centers, the physical therapy/whirlpool areas. (*February 1, 2008, Initial CON Application, page 8 and March 11, 2008, Completeness Response, page 6*)
3. The following towns are within the service area of the Hospital:

Bridgeport	Easton	Fairfield	Milford	Monroe
Newtown	Norwalk	Shelton	Stratford	Trumbull
Wilton	Weston	Westport		

(February 1, 2008, Initial CON Application, page 11)
4. The Hospital proposes to establish a wound care center and relocate its existing chronic wound care services to the new center. In addition, the Hospital proposes to provide outpatient hyperbaric oxygen therapy service ("HBOT"), an integral component of a wound care program. (*February 1, 2008, Initial CON Application, pages 7 and 8*)
5. The Hospital based its proposal on the following factors:
 - a. Service area demographic trends, including growth and aging of the population, will lead to an increase in the number of residents with chronic wounds;
 - b. Private practice physicians affiliated with the Hospital have requested a comprehensive chronic wound care clinic with HBOT;
 - c. The Hospital's current outpatient wound care services are geographically dispersed and not standardized;
 - d. The quality of outpatient chronic wound care treatment can be enhanced through the delivery of a multi-disciplinary comprehensive wound care center.

(February 1, 2008, Initial CON Application, pages 7 and 8)

6. The Hospital stated that many wound care patients are elderly or suffer from chronic illnesses such as diabetes or circulatory disorders and travel is difficult. These patients require frequent dressing changes, medication application and in some cases HBOT. It is difficult for these patients to travel to multiple locations to obtain different aspects of their wound care therapy. *(March 11, 2008, Completeness Response, page 3 and 4)*
7. Many physicians do not have the expertise or necessary resources to provide wound care treatment in their offices. HBOT involves equipment and space requirements that most private physicians are unable to provide in their private practice. *(February 1, 2008, Initial CON Application, page 12)*
8. Due to the ongoing master facility plan construction and the absence of sufficient on-campus space, the Hospital proposes to locate its wound care center at 115 Technology Drive in Trumbull. This location also houses several other Hospital-affiliated physicians. *(February 1, 2008, Initial CON Application, pages 8 and 9)*
9. The Hospital developed the following projected patient demand in its service area:

Table 1: Projected Patient Demand in Hospital's Service Area

	Total Number of Persons	Projected Patient Demand
Estimated Service Area Population in 2011	574,099	
Number of Diabetics (7% of population) ¹	40,187	
Number of Diabetics with Diabetic Ulcers at 15% of diabetics ²		6,028
Number of Persons with Venous Stasis Ulcers at 0.33% of population ³		1,895
Number of Persons with Decubitus Ulcers at 0.85% of population ⁴		4,880
Total Project Patient Demand in Service Area:		12,802

¹ Centers for Disease Control and Prevention, National Diabetes Fact Sheet, United States, 2005

² Dr. Rollins, CMS Presentation, 2005

³ Rakel: Conn's Current Therapy 2005. 57th edition, Elsevier. 1994; 167(Suppl): 37S-41S

⁴ MedPar data study, 2005, Dr. Rollins CMCS presentation, 2005, and Costs in medical vs. surgical patients. Nursing Economics 1999; 17:263-271.

(February 1, 2008, Initial CON Application, page 16)

10. The availability of oxygen to cells in the wound area and the presence of adequate blood flow are important factors to the healing process. Oxygen plays a critical role in the formation of collagen, the growth of new capillaries and the control of infection. *(February 5, 2008, Initial CON Submission, page 99)*

11. Approximately 10% of those diabetics that develop ulcers may require HBOT. Patients other than diabetics that may receive HBOT include those with slow and non-healing wounds who may have:
- a. Peripheral vascular disease;
 - b. Compromised amputation sites;
 - c. Non-healing traumatic wounds;
 - d. Vascular insufficiency ulcers;
 - e. Refractory osteomyelitis;
 - f. Radiation tissue damage;
 - g. Select infections; and
 - h. Compromised skin grafts and flaps.

(February 1, 2008, Initial CON Application, pages 16 and 17)

12. The Hospital reported the following number of visits with wound care specific codes by location and by fiscal year:

Table 2: Visits with Wound Care Specific Codes by Location and by Fiscal Year

Facility Type	Town	Fiscal Year			
		2005	2006	2007	2008*
Inpatient	Bridgeport	172	166	179	186
ED	Bridgeport	113	127	139	110
Family Health Center	Bridgeport	82	84	103	78
Walk-In Center	Bridgeport	43	53	55	44
Walk-In Center	Shelton	82	84	103	78
Walk-In Center	Fairfield	63	69	91	92
Walk-In Center	Monroe	0	17	43	36
Other Outpatient	Bridgeport	44	65	53	160
Total Visits		601	671	786	834

* Annualized numbers, based on first six months.

(March 11, 2008, Completeness Response, page 6)

13. The Hospital reported the following number of visits with wound care related codes by location and by fiscal year:

Table 3: Visits with Wound Care Related Codes by Location and by Fiscal Year

Facility Type	Town	Fiscal Year			
		2005	2006	2007	2008*
Inpatient	Bridgeport	349	401	413	212
ED	Bridgeport	479	524	564	274
Family Health Center	Bridgeport	308	489	432	217
Walk-In Center	Bridgeport	43	49	64	28
Walk-In Center	Shelton	99	75	99	45
Walk-In Center	Fairfield	55	63	57	46
Walk-In Center	Monroe	0	19	35	22
Other Outpatient	Bridgeport	179	175	233	148
Total Visits		1,512	1,795	1,897	992

* Annualized numbers, based on first six months.

(March 11, 2008, Completeness Response, page 6)

14. The Hospital has projected the following volume statistics for the first three years of operations:

Table 4: Projected Number of Patients and Treatments

	Year 1	Year 2	Year 3
Wound Patients	333	467	495
HBOT Patients	35	44	50
Wound Care Visits	3,000	4,206	4,458
HBOT Treatments	3,318	4,183	4,800

Assumption: The initial penetration rate for years 1, 2, and 3 are assumed to be 2.6%, 3.6%, and 3.9% of the service area population. Penetration rates are based on National Healing's previous experience in establishing new programs.

(February 5, 2008, Initial CON Submission, page 18 and 19)

15. The Hospital is proposing to install two monoplace HBOT chambers which each have an annual capacity of 30 patients per year or a total of 60 patients for the two chambers combined. Each single chamber has a capacity of 3 slots per day. Each patient requires 24 treatments per year. The average treatment time is 120 minutes and approximately 20 minutes is required to clean and prepare the chamber between patients. (March 11, 2008, Completeness Response, pages 4 and 5)
16. National Wound Care and Hyperbaric Services, Inc. ("National Healing"), a specialized wound care company, will assist the Hospital in the establishment and ongoing management of the proposed program. National Healing provides wound and disease management solutions for hospitals, wound treatment centers, and ADA approved

Diabetes Centers and Lymphedema programs. *(February 1, 2008, Initial CON Application, page 8)*

17. Under the Strategic Agreement for Integrated Wound Care Center between SVMC and National Healing, for a monthly management fee, as well as a per-treatment fee wound care services and HBOT treatments, National Healing will provide the following services to the Hospital's wound care center:
 - a. Day-to-day management and supervision over operations of the program and the personnel;
 - b. Provision of the Program Director and the Office Coordinator;
 - c. Consultative support and quality reviews;
 - d. Access to and reports regarding Outpatient Prospective Payment;
 - e. Proprietary outcome tracking software;
 - f. Initial education seminar for physicians and staff and ongoing training;
 - g. Community awareness and education plan for the program;
 - h. Staff competency testing;
 - i. Operations and Clinical Policies and Procedures Manuals; and
 - j. Periodic internal clinical reviews to assure that national standards are being met or exceeded.

(March 11, 2008, Completeness Response, pages 4 and 5)
18. The proposed program will operate Monday through Friday during regular business hours. A panel of physician specialists, including general and vascular surgeons, podiatrists, plastic surgeons, and nursing and support staff will provide the proposed services. *(February 1, 2008, Initial CON Application, page 8)*
19. All participating physicians will attend training provided by National Healing and will adhere to mutually agreed upon clinical pathways. *(February 1, 2008, Initial CON Application, page 9)*
20. Norwalk Hospital is an existing provider of HBOT in the proposed service area. Bridgeport Hospital¹ will be opening its HBOT within 2008. Bridgeport Hospital, with its proposed 12-person chamber, can accommodate 360 patients based on 30 patients per chamber per year. The combined capacity of SVMC and Bridgeport Hospital is 420 patients per year. *(February 1, 2008, Initial CON Application, page 19 and March 11, 2008, Completeness Response)*
21. Patients who currently require HBOT are referred to Griffin, Danbury or Norwalk Hospitals. The Hospital stated that travel to these three hospitals is difficult for wound care patients and patient compliance is an issue. Therefore, some patients who need the therapy will actually not receive it due to the burden of frequent travel. *(May 9, 2008, Response Letter)*

¹ Bridgeport Hospital in its application for HBOT, Docket Number 06-30863-CON, identified a total of 443 diabetic patients alone in the primary service that will require hyperbaric oxygen therapy. Bridgeport Hospital also identified between 188 and 195 individuals who will require HBOT based on a review of its inpatient discharges with wound related diagnoses.

**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**

22. The proposal includes the following cost components:

Table 5: Total Proposed Capital Expenditure

Component	Amount
Equipment	
Major Medical	\$185,000
Other Medical	\$22,100
Non-medical	22,900
Construction/Renovation	420,000
Total Capital Expenditure	\$650,000

(February 1, 2008, Initial CON Application, page 24)

23. The Hospital is leasing 3,621 square feet of space on the ground floor of the building. The renovations will include building exam rooms, a waiting area, nurse's station, and the two hyperbaric chambers. The use of the chamber will require an oxygen tank be located in an adjacent parking lot. *(February 1, 2008, Initial CON Application, page 25)*

24. 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 Revenues, Expenses, and Gains by Fiscal Year with the Proposal

Incremental Operating	2008*	2009	2010	2011
Revenues:				
Medicare	\$ 158,000	\$ 689,000	\$ 880,000	\$ 952,000
Medicaid and Other Medical Assistance	16,000	72,000	91,000	99,000
Non-government	67,000	288,000	366,000	399,000
Total Incremental Operating Revenues	241,000	1,049,000	1,337,000	1,450,000
Expenses:				
Salaries and Fringe Benefit	106,000	348,000	416,000	429,000
Professional/Contracted/ Purchased Services	109,000	456,000	575,000	626,000
Supplies and Drugs	21,000	48,000	60,000	65,000
Other Operating Expenses	76,000	180,000	183,000	186,000
Total Incremental Operating Expenses	312,000	1,032,000	1,234,000	1,306,000
Total Gain	\$(71,000)	\$ 17,000	\$ 104,000	\$ 144,000

* Based on starting April 2008.

(March 11, 2008, Completeness Submission, page 86)

25. The Hospital will bill for the technical portion of the proposed services. Physicians participating in the service will bill their professional services separately. *(February 1, 2008, Initial CON Application, page 24)*
26. A new cost center will be established. The units of service will be visits for wound care and hyperbaric treatments. *(February 1, 2008, Initial CON Application, page 24)*
27. The Hospital will finance the proposal through its equity from operating funds. *(February 1, 2008, Initial CON Application, page 26)*
28. The Hospital's current payer mix is based on the gross patient review from those patients reported in Tables 2 and 3. These patients received wound care services, including those with minor or acute wounds treated in either the clinic or Emergency Department. The proposed service will focus on the treatment of complex, chronic wounds which appear far more frequently in an older population. The Hospital's current and projected payer mix for the proposal, based on gross patient revenue is reported in the following table:

Table 7: Current and Three-Year Projected Payer Mix

Payer Mix	Current	Projected		
	FY 2008	FY 2009	FY 2010	FY 2011
Medicare	40%	68.0%	68.0%	68.0%
Medicaid	24%	6.5%	6.5%	6.5%
TriCare (CHAMPUS)	0%	0%	0%	0%
Total Government	64%	74.5%	74.5%	74.5%
Commercial Insurers	24%	21.6%	21.6%	21.6%
Uninsured	11%	3.1%	3.1%	3.1%
Workers Compensation	1%	0.8%	0.8%	0.8%
Total Non-Government	36%	25.5%	25.5%	25.5%
Total Payer Mix	100%	100%	100%	100%

(February 1, 2008, Initial CON Application, page 27)

29. The Hospital is reimbursed 41% of charges by Medicare, and 45% by Medicaid and the commercial insurers. *(February 1, 2008, Initial CON Application, page 10)*
30. There is no State Health Plan in existence at this time. *(February 1, 2008, Initial CON Application, page 10)*
31. The Hospital has adduced evidence that this proposal is consistent with the Hospital's long-range plan. *(February 1, 2008, Initial CON Application, page 10)*
32. The Hospital has improved productivity and contained costs through group purchasing, energy conservation, reengineering, the application of technology, and has performed environmental improvements and standards. *(February 1, 2008, Initial CON Application, page 22)*

33. This proposal will not result in changes to the Hospital's teaching and research responsibilities. *(February 1, 2008, Initial CON Application, page 23)*
34. There are no distinguishing or unique characteristics of the Hospital's patient/physician mix related to this proposal. *(February 1, 2008, Initial CON Application, page 23)*
35. The Hospital has sufficient technical and managerial competence to provide efficient and adequate service to the public. *(February 1, 2008, Initial CON Application, pages 135 to 157)*
36. The Hospital's rates are sufficient to cover the proposed capital and operating costs associated with the proposal. *(February 1, 2008, Initial CON Application, page 206)*

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.

Saint Vincent's Medical Center ("Hospital") is an acute care hospital located at 2800 Main Street in Bridgeport, Connecticut. The Hospital currently provides wound-related services in a variety of settings including the inpatient units, Emergency Department, outpatient clinics, walk-in centers, and physical therapy/whirlpool area. The Hospital proposes to establish a wound care center at 115 Technology Drive in Trumbull, Connecticut. The Hospital will relocate its existing chronic wound care services to the new center and will establish an outpatient hyperbaric oxygen therapy ("HBOT") program with two monoplace chambers at the new center.

The Hospital based the need for the proposal on enhancing the availability of comprehensive outpatient chronic wound care services. Currently, the Hospital's ambulatory wound care services are geographically dispersed. Many wound care patients are elderly or suffer from chronic illnesses such as diabetes or circulatory disorders, making travel to multiple locations for various wound care therapies difficult. Furthermore, HBOT is an integral component of a comprehensive wound care program, and the addition of HBOT will provide an additional treatment option for patients with slow and non-healing wounds. OHCA concludes that the establishment of the proposed comprehensive wound care center with an HBOT program will improve both the quality and accessibility of outpatient wound care services in the proposed service area.

The proposal has a total capital expenditure of \$650,000, which will be financed with equity from operating funds. During the startup year of FY 2008, the Hospital projects an incremental loss from operations related to the proposal of \$(71,000). In subsequent years, the Hospital projects incremental gains of \$17,000 in FY 2009, \$104,000 in FY 2010, and \$144,000 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 outpatient wound care services.

Order

Based on the foregoing Findings and Rationale, the Certificate of Need application of Saint Vincent's Medical Center ("Hospital") to establish ambulatory wound care services and outpatient hyperbaric oxygen therapy services in Trumbull, at a total capital expenditure of \$650,000, is hereby GRANTED, subject to the following conditions.

1. This authorization shall expire on May 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 \$650,000. 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

Date

Cristine A. Vogel
Commissioner

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