



Office Of Health Care Access Certificate of Need Application

Final Decision

Applicant: The Stamford Hospital

Docket Number: 03-30034

Project Title: Establish a Portable Lithotripsy Service

Statutory Reference: Section 19a-638 of the Connecticut General Statutes

Filing Date: July 2, 2003

Decision Date: August 12, 2003

Default Date: September 30, 2003

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Project Description: The Stamford Hospital (“Hospital”) proposes to establish a portable lithotripsy service on the Hospital campus, at a total capital cost of \$395,000. The Hospital will lease a Dornier Compact Delta transportable lithotripter from Allied Urological Services, LLC for the provision of the proposed lithotripsy service in the Hospital’s multi-purpose procedure rooms on designated treatment days.

Nature of Proceedings: On July 2, 2003, the Office of Health Care Access (“OHCA”) received a Certificate of Need (“CON”) application from The Stamford Hospital for the establishment of a portable lithotripsy service on the Hospital campus, at a total capital cost of \$395,000. 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 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 of the Proposal on the Applicant's Current Utilization Statistics Proposal's Contribution to the Quality of Health Care Delivery in the Region Proposal's Contribution to the Accessibility of Health Care Delivery in the Region

1. The Stamford Hospital ("Hospital") is an acute care general hospital located at West Broad Street and Shelburne Road in Stamford, Connecticut. The Hospital's total licensed bed capacity of 330 beds and bassinets includes 305 licensed beds and 25 licensed bassinets. *(July 2, 2003 CON Application, Page 164)*
2. The Hospital proposes to establish a portable lithotripsy service on the Hospital campus, at a total capital cost of \$395,000. *(July 2, 2003 CON Application, Page 2 and July 28, 2003 Supplemental CON Application Filing, Page 1)*
3. The Hospital will enter into a service and leasing arrangement with Allied Urological Services, LLC ("Allied") to provide the proposed lithotripsy service. Allied will provide a Dornier Compact Delta transportable lithotripter for the provision of the proposed lithotripsy service in the Hospital's multi-purpose procedure rooms on designated treatment days and, when necessary, on demand to serve patients suffering from kidney, ureteral and bladder stones. *(March 10, 2003 Letter of Intent, Project Description)*
4. Allied is the largest provider of shock wave lithotripsy in the New York metropolitan area, having performed over 5,000 procedures in FY 2002 at its four freestanding lithotripsy centers as well as at 14 acute care hospitals, which currently utilize the same type of portable lithotripter that the Hospital is seeking authorization to utilize. *(July 2, 2003 CON Application, Page 2)*
5. Under the proposed arrangement, X-rays and other preadmission tests, anesthesia and recovery room services related to the lithotripsy procedures will be provided by the Hospital. Allied will provide the lithotripsy equipment and certain disposable supplies as well as certified technicians to assist the treating urologist. The lithotripsy service will be available to any urologist who is licensed to practice medicine in Connecticut and who has either existing medical staff privileges at the Hospital or is eligible for temporary privileges. *(March 10, 2003 Letter of Intent, Project Description)*
6. The Hospital has not been able to provide lithotripsy services at its main campus since September 2001, when the Hospital ceased utilizing the services of Connecticut Lithotripsy, LLC, which had been granted Certificate of Need ("CON") approval under Docket Number 98-534 to provide mobile lithotripsy at nine acute care hospital sites including The Stamford Hospital. *(July 2, 2003 CON Application, Pages 3 and 4)*
7. Difficulties in scheduling patients for lithotripsy appointments in a timely fashion and other problems associated with the lithotripsy service provided by Connecticut Lithotripsy, LLC resulted in Stamford-area urologists choosing to refer their patients out-of-state to a freestanding urology center located in White Plains, New York

operated by Allied, and less frequently to other Connecticut lithotripsy providers. *(July 2, 2003 CON Application, Page 4)*

8. The need for the proposed portable lithotripsy service is based upon the following:
(July 2, 2003 CON Application, Page 2)
 - a. the consensus in the local medical community that lithotripsy is the preferred method of treatment for kidney and urinary stone disease;
 - b. the incidence rates of stone disease within the service area;
 - c. the patient benefits that will be realized by providing access to lithotripsy services at the Hospital's main campus; and
 - d. the opportunity for the Hospital to partner with an experienced, high-quality provider of lithotripsy services in an efficient and cost-effective manner.
9. The Hospital's primary service area includes the towns of Darien and Stamford, its secondary service area includes the towns of Greenwich, New Canaan, Norwalk, Westport and Wilton, and its extended service area includes the towns of Fairfield, Ridgefield and Weston. *(August 11, 2003 Supplemental CON Application Filing, Page 4)*
10. The Hospital cited medical studies estimating the prevalence of urinary stone disease at anywhere between 2% and 13% of the general population. The current population of the Hospital's service area (primary, secondary and extended) based on 2000 census data is estimated at roughly 440,000 people. Therefore, according to the Hospital, even if a conservative estimate of stone disease impacting 3% of the population was used, 13,200 people within the service area would be candidates for the proposed lithotripsy service. *(August 11, 2003 Supplemental CON Application Filing, Page 3)*
11. The Hospital also cited one published study of asymptomatic patients that determined that the cumulative 5 year probability of a symptomatic event is approximately 50% and that, of those symptomatic patients, approximately 50% passed the stone spontaneously while another approximately 50% needed a urologic procedure of some type. *(July 2, 2003 CON Application, Pages 3 and 22)*
12. The Hospital's need methodology applied the published studies' findings to the 13,200 potential stone disease patients in the Hospital's service area, yielding an estimated total of 660 people who would be candidates for lithotripsy services annually as follows: *(August 11, 2003 Supplemental CON Application Filing, Page 3)*
 - a. 13,200 potential patients times .50 equals 6,600 potential patients
 - b. 6,600 potential patients times .50 equals 3,300 potential patients
 - c. 3,300 potential patients divided by 5 years equals 660 potential patients per year

13. The Hospital believes that the estimate presented above generally comports with Solucient data for the Hospital's service area, which estimates that 532 shock wave lithotripsy procedures were performed in the Hospital's service area in 2002. *(August 11, 2003 Supplemental CON Application Filing, Pages 3 and 5)*
14. The Hospital's projected lithotripsy procedures are 10 for FY 2003, 120 for FY 2004, 144 for FY 2005 and 168 for FY 2006. *(July 2, 2003 CON Application, Page 166)*
15. The Hospital estimates that five physicians will utilize the lithotripsy service with each physician performing one lithotripsy procedure per day for a total of five procedures on each day of service. The proposed lithotripsy service will operate two days per month and will provide 10 lithotripsy procedures per month and 120 procedures per year during the first full year of operation. *(July 2, 2003 CON Application, Page 166)*
16. All Allied facilities and services are accredited by the American Lithotripsy Society, and all of the urologists rendering the professional services abide by the American Lithotripsy Society's guidelines in their daily practices. *(July 2, 2003 CON Application, Page 8)*
17. The proposed portable lithotripsy service will remedy a geographic barrier to access by providing lithotripsy on the Hospital's main campus. The proposed service will reduce scheduling backlogs at other service provider locations and will shorten the driving and public transportation distances that patients must travel while they are suffering from this painful condition, since they will no longer have to leave their local communities to access this service. *(July 2, 2003 CON Application, Page 7)*
18. The Hospital anticipates that the hours of operation for the proposed lithotripsy service will be from 7:30 a.m. to 2:00 p.m. on every other Friday each month. *(July 2, 2003 CON Application, Page 6)*

**Financial Feasibility and Cost Effectiveness 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
the Payers for Such Services**

19. The total capital cost for the CON proposal is \$395,000, which is the estimated fair market value of the transportable lithotripter to be leased by the Hospital. *(July 28, 2003 Supplemental CON Application Filing, Page 1)*
20. The CON proposal's total capital cost of \$395,000 represents the estimated fair market value of the Dornier Compact Delta transportable lithotripter that will be leased from Allied and utilized in providing the proposed lithotripsy service. *(July 28, 2003 Supplemental CON Application Filing, Pages 2 and 4)*
21. The Hospital will lease the transportable lithotripter from Allied Urological Services, LLC on a per procedure basis for lithotripsy services provided to government payers and certain Blue Cross/Blue Shield enrollees at the cost of \$1,500, which includes the services of a technologist and supplies. The Hospital and Allied will also enter into a

space, rather than equipment, lease for purposes of providing lithotripsy services to enrollees of most commercial health plans. *(July 2, 2003 CON Application, Page 11)*

22. The Hospital projects incremental revenue from operations, total operating expense and revenue over expense associated with the CON proposal as follows: *(July 2, 2003 CON Application, Pages 166 through 169)*

Table 1: Hospital's Incremental Financial Projections for FY 2003 through FY 2006

Description	FY 2003	FY 2004	FY 2005	FY 2006
Incremental Revenue from Operations	\$ 15,000	\$ 174,550	\$ 209,460	\$ 244,369
Incremental Total Operating Expense	4,000	46,854	56,225	65,595
Incremental Revenue Over Expense	\$11,000	\$127,696	\$153,235	\$178,774

23. The Hospital anticipates that the portable lithotripsy service will commence operation in September 2003. *(July 2, 2003 CON Application, Page 166)*
24. The Hospital's projected payer mix during the first three years of operation of the proposed portable lithotripsy service is as follows: *(July 2, 2003 CON Application, Page 13)*

Table 2: Hospital's Three-Year Projected Payer Mix

Payer Mix	Year 1	Year 2	Year 3
Medicare	38.0%	38.0%	38.0%
Medicaid	9.0%	9.0%	9.0%
TriCare	0.0%	0.0%	0.0%
Total Government	47.0%	47.0%	47.0%
Commercial Insurers	48.0%	48.0%	48.0%
Self-Pay	5.0%	5.0%	5.0%
Workers Compensation	0.0%	0.0%	0.0%
Total Non-Government	53.0%	53.0%	53.0%
Uncompensated Care	0.0%	0.0%	0.0%
Total Payer Mix	100.0%	100.0%	100.0%

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

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

25. There is no State Health Plan in existence at this time. *(July 2, 2003 CON Application, Page 2)*
26. The Hospital has adduced evidence that the proposal is consistent with the Hospital's long-range plan. *(July 2, 2003 CON Application, Page 2)*
27. The Hospital has improved productivity and contained costs by undertaking activities involving energy conservation, reengineering, group purchasing and the application of new technology. *(July 2, 2003 CON Application, Page 9)*

28. The proposal will not result in any change to the Hospital's teaching and research responsibilities. *(July 2, 2003 CON Application, Page 10)*
29. There are no distinguishing or unique characteristics of the Hospital's patient/physician mix related to the proposal. *(July 2, 2003 CON Application, Page 10)*
30. The Hospital has sufficient technical, financial and managerial competence and expertise to provide efficient and adequate service to the public. *(July 2, 2003 CON Application, Pages 85 through 112)*

Rationale

The Stamford Hospital ("Hospital") proposes to establish a portable lithotripsy service on the Hospital campus, at a total capital cost of \$395,000. The Hospital will enter into a service and leasing arrangement with Allied Urological Services, LLC ("Allied") to provide the proposed lithotripsy service. Allied will provide a Dornier Compact Delta transportable lithotriptor for the provision of the proposed lithotripsy service in the Hospital's multi-purpose procedure rooms on designated treatment days and, when necessary, on demand to serve patients suffering from kidney, ureteral and bladder stones.

Under the proposed arrangement between the Hospital and Allied, X-rays and other preadmission tests, anesthesia and recovery room services related to the lithotripsy procedures will be provided by the Hospital. Allied will provide the lithotripsy equipment and certain disposable supplies as well as certified technicians to assist the treating urologist. The lithotripsy service will be available to any urologist who is licensed to practice medicine in Connecticut and who has either existing medical staff privileges at the Hospital or is eligible for temporary privileges.

The Hospital's need methodology used in projecting the service area need for the proposed portable lithotripsy service is based upon the estimated incidence rate of stone disease within the Hospital's service area. The Hospital's primary service area includes the towns of Darien and Stamford, its secondary service area includes the towns of Greenwich, New Canaan, Norwalk, Westport and Wilton, and its extended service area includes the towns of Fairfield, Ridgefield and Weston.

Medical studies cited by the Hospital have estimated the prevalence of urinary stone disease at anywhere between 2% and 13% of the general population. The current population of the Hospital's service area (primary, secondary and extended) based on 2000 census data is estimated at roughly 440,000 people. The Hospital used an estimate of stone disease impacting 3% of the population representing 13,200 potential patients within the service area that would be candidates for the proposed lithotripsy service.

One published study of asymptomatic patients cited by the Hospital determined that the cumulative 5 year probability of a symptomatic event is approximately 50% and, of those symptomatic patients, approximately 50% passed the stone spontaneously while another approximately 50% needed a urologic procedure of some type. The Hospital's need methodology applied the published study's findings to the 13,200 potential stone disease

patients in the Hospital's service area, yielding an estimated total of 660 people who would be candidates for lithotripsy services annually. The estimated number of 660 patients is at approximately the same level as that reported by Solucient for the Hospital's service area, which estimates that 532 shock wave lithotripsy procedures were performed in the Hospital's service area in 2002. Therefore, OHCA finds based on the foregoing that the Hospital has demonstrated that there is a clear public need for the CON proposal.

All Allied facilities and services are accredited by the American Lithotripsy Society, and all of the urologists rendering the professional services abide by the American Lithotripsy Society's guidelines in their daily practices. The proposed portable lithotripsy service will remedy a geographic barrier to access by providing lithotripsy on the Hospital's main campus. The proposed service will reduce scheduling backlogs at other lithotripsy service provider locations and will shorten the driving and public transportation distances that patients must travel, since they will no longer have to leave their local communities to access this service. Based on the foregoing reasons, OHCA finds that the CON proposal will improve both the quality and accessibility of lithotripsy service in the region.

The proposal's total capital cost of \$395,000 represents the estimated fair market value of the Dornier Compact Delta transportable lithotripter to be leased by the Hospital. The Hospital projects lithotripsy procedures of 10 in FY 2003, 120 in FY 2004, 144 in FY 2005 and 168 in FT 2006 due to the CON proposal. The Hospital estimates that initially five physicians will utilize the lithotripsy service with each physician performing one lithotripsy procedure per day for a total of five procedures on each day of service. The proposed lithotripsy service will operate two days per month and is projected to provide 10 lithotripsy procedures per month and 120 procedures per year during the first full year of operation. In addition, the Hospital projects incremental revenue over expense of \$11,000 in FY 2003, \$127,696 in FY 2004, \$153,235 in FY 2005 and \$178,774 in FY 2006 due to the CON proposal. The Hospital's volume projections and the financial projections upon which they are based appear to be reasonable and achievable. Therefore, OHCA finds that the CON proposal is both financially feasible and cost effective.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of The Stamford Hospital to establish a portable lithotripsy service on the Hospital campus, at a total capital cost of \$395,000, is hereby GRANTED.

Order

The Stamford Hospital ("Hospital") is hereby authorized to establish a portable lithotripsy service on the Hospital campus, at a total capital cost of \$395,000, subject to the following conditions:

1. This authorization shall expire on August 31, 2005. Should the Hospital's portable lithotripsy service project not be completed by that date, the Hospital must seek further approval from OHCA to complete the project beyond that date.
2. The approved total capital cost for the Hospital's project is \$395,000.

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:
August 12, 2003

Signed by:
Mary M. Heffernan
Commissioner

MMH:ho

Table Descriptions

**The Stamford Hospital
Establish a Portable Lithotripsy Service
CON Final Decision, Docket Number 03-30034**

Table 1

Title: Hospital's Incremental Financial Projections for FY 2003 through FY 2006

The projected incremental revenue from operations for the proposal is \$15,000 in FY 2003, \$174,550 in FY 2004, \$209,460 in FY 2005 and \$244,369 in FY 2006. The projected incremental total operating expense for the proposal is \$4,000 in FY 2003, \$46,854 in FY 2004, \$56,225 in FY 2005 and \$65,595 in FY 2006. The projected incremental revenue over expense for the proposal is \$11,000 in FY 2003, \$127,696 in FY 2004, \$153,235 in FY 2005 and \$178,774 in FY 2006.

Table 2

Title: Hospital's Three-Year Projected Payer Mix

The projected payer mix remains constant in each category for the first three years of operation of the portable lithotripsy service. Total Government reimbursement is projected to account for 47.0% of total reimbursement with Medicare at 38.0%, Medicaid at 9.0% and TriCare (Champus) at 0.0%. Total Non-Government reimbursement is projected to account for 53.0% of total reimbursement with Commercial Insurers at 48.0%, Self-Pay Patients at 5.0% and Workers Compensation at 0.0%. Uncompensated Care is projected to be 0.0% of total reimbursement.