



Office Of Health Care Access Certificate of Need Application

Final Decision

Applicant: Norwalk Hospital

Docket Number: 04-30322-CON

Project Title: Clinical Chemistry Laboratory Equipment Replacement and Automation

Statutory Reference: Section 19a-639 of the Connecticut General Statutes

Filing Date: October 8, 2004

Decision Date: December 20, 2004

Default Date: January 6, 2005

Staff Assigned: Paolo Fiducia

Project Description: Norwalk Hospital (“Hospital”) proposes to replace its existing clinical chemistry laboratory equipment with new laboratory equipment and to acquire a laboratory automation system, at a total capital expenditure of \$1,200,000.

Nature of Proceedings: On October 8, 2004, the Office of Health Care Access (“OHCA”) received a Certificate of Need (“CON”) application from Norwalk Hospital seeking authorization to replace its existing clinical chemistry laboratory equipment with new laboratory equipment and to acquire a laboratory automation system, at a total capital expenditure of \$1,200,000. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

A notice to the public regarding OHCA's receipt of the Hospital's Letter of Intent (LOI) to file its CON Application was published on June 30, 2004 in *The Hour* (Norwalk). OHCA received no responses from the public concerning the Hospital's proposal.

OHCA's authority to review and approve, modify or deny this proposal is established by Section 19a-639, 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

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. Norwalk Hospital ("Hospital") is an acute care general hospital located at 34 Maple Street in Norwalk, Connecticut. (*June 29, 2004 Letter of Intent, page 3*)
2. The Hospital proposes to replace its 10 year old clinical chemistry laboratory equipment, including therapeutic drug monitoring and toxicology equipment and also to acquire a new state-of-the-art Roche Automated Modular Laboratory System ("RAMLS"). (*October 8, 2004 CON Application, page 3*)
3. The Hospital stated the current equipment is obsolete and inadequate to meet the demands of efficient result turnaround times for patient care and quality testing. (*June 29, 2004 Letter of Intent, page 8*)
4. The proposed replacement will not only meet the growing needs of clinical laboratory testing requirements but will also incorporate special chemistry testing for hormones and tumor markers as part of the routine analysis of the laboratory. (*October 8, 2004 CON Application, page 3*)
5. The Hospital determined that the implementation of the new Clinical Chemistry Laboratory equipment will not only improve patient care but also provide safety and operational benefits as follows: (*October 8, 2004, CON Application, page 4*)
 - a. Error Reduction: Reduces human error associated with manual sample processing.
 - b. Improvement in Patient Care: Improves processing times and combined with advanced technology it accelerates results reporting to physician.
 - c. Optimization of workflow and efficiency: Automates repetitive and time-consuming specimen preparation.
 - d. Safety risks minimization: Reduces safety risks of handling biological specimens.

6. The Hospital stated that the RAMLS will simplify and automate the processing of the specimens and the delivery of samples directly to the analyzers without human intervention. *(October 8, 2004, CON Application, page 4)*
7. The Hospital stated that the RAMLS will allow for faster turnaround time of results. This gives the technologist more time to concentrate on the results that require attention and intervention, as needed. Patient safety will be enhanced by getting appropriate results to the care providers in record time. *(October 8, 2004, CON Application, page 5)*
8. The new system will include 2 Vitros Analyzers, 2 Axysm Abbott Analyzers and 1 Elecsys Roche Analyzer. *(October 8, 2004, CON Application, page 5)*
9. The proposed RAMLS will enable the Hospital to reach its goals and objectives for the Clinical Chemistry Laboratory that include: *(October 8, 2004 CON Application, Page 5)*
 - a. Reduce manual processes such as accessioning, labeling, centrifuging, decapping and aliquoting.
 - b. Consolidate workstations.
 - c. Enhance software flexibility to address:
 - Auto repeats, dilution, and reflexing
 - Auto verification and release of results by analyzer
 - Rules based decision processing
 - d. Improve capability to efficiently handle higher testing volumes.
 - e. Reduce send out testing, turnaround times, and operating expenses.
 - f. Enable the Clinical Chemistry Laboratory to offer all tests on all shifts.

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 Payers for Such Services

10. The Hospital's breakdown of the proposed total capital expenditure of \$1,200,000 for the CON proposal is as follows. *(October 8, 2004 CON Application, page 11)*

| Description | Amount |
|----------------------------------|--------------------|
| Medical Equipment (Purchase) | \$ 900,000 |
| Non-Medical Equip(Purchase) | 215,000 |
| Construction/Renovations | 85,000 |
| Total Capital Expenditure | \$1,200,000 |

11. The CON proposal's total capital expenditure of \$1,200,000 will be funded entirely from the Hospital's Operating Funds. *(October 8, 2004 CON Application, page 11)*
14. The Hospital estimates cost reductions of \$422,800, \$539,320 and \$552,673 in FY 2005, FY 2006 and FY 2007, respectively due to reagent savings, reduction of service on existing equipment, reduced send out costs, savings on lease for electsys instruments and labor savings. *(October 8, 2004 CON Application, page 11)*
15. The Hospital projects gains from operations with the project of \$171,000, \$188,000 and \$202,000 in FY 2005, FY 2006 and FY 2007, respectively. *(October 8, 2004 CON Application, page 18)*
16. The proposed renovation of 1,344 square feet of a total 3,437 square feet within the Pathology Department includes the following: *(October 8, 2004, CON Application, page 13)*
- Relocate existing laboratory equipment.
 - Demolition of existing counters, cabinets, walls, electrical, and plumbing drain lines.
 - Provide dedicated electrical service for new equipment.
 - Provide new back-up emergency power.
 - Install new floor drainage system.
 - Fabricate and install new counters for equipment previously removed.
 - Modify HVAC ductwork for new operating environment.
 - Install new floor.
 - Relocate laboratory equipment for functional operations.
17. The Hospital's projected payer mix during the first three years of implementation and/or operation of the new system is as follows: *(October 8, 2004 CON Application, page 16)*

| Payer Source | Current | Year 1 | Year 2 | Year 3 |
|--------------------------------|----------------|---------------|---------------|---------------|
| Medicare | 23% | 23% | 23% | 23% |
| Medicaid | 2% | 2% | 2% | 2% |
| Total Government Payers | 25% | 25% | 25% | 25% |
| Commercial Insurers | 67% | 67% | 67% | 67% |
| Self-Pay | 8% | 8% | 8% | 8% |
| Workers Compensation | Included | In | Commercial | |
| Total Non-Gov. Payers | 75% | 75% | 75% | 75% |
| Uncompensated Care | Included | In Self Pay | | |
| Total Payer Mix | 100% | 100% | 100% | 100% |

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.:

18. There is no State Health Plan in existence at this time. *(October 8, 2004 CON Application, page 2)*
19. The Hospital has adduced evidence that the proposal is consistent with the Hospital's long-range plan. *(October 8, 2004 CON Application, page 2)*
20. The Hospital has no teaching or research responsibilities that would be affected as a result of the proposal. *(October 8, 2004 CON Application, page 8)*
21. There are no distinguishing or unique characteristics of the Hospital's patient/physician mix related to the proposal. *(October 8, 2004 CON Application, page 8)*
22. The Hospital has implemented various activities to improve productivity and contain costs including energy conservation, reengineering of its operations, the application of new technology and group purchasing. *(October 8, 2004 CON Application, page 8)*
23. The Hospital has sufficient technical, financial and managerial competence to provide efficient and adequate service to the public. *(October 8, 2004 CON Application, page 7)*
24. The Hospital's proposal has no impact on the Hospital's current utilization of services.

Rationale

Norwalk Hospital (“Hospital”) proposes to replace its existing clinical chemistry laboratory equipment with new laboratory equipment and to acquire a laboratory automation system, at a total capital expenditure of \$1,200,000. The Hospital proposes to acquire a new Roche Automated Modular Laboratory System (“RAMLS”).

The current clinical chemistry laboratory equipment, including therapeutic drug monitoring and toxicology equipment, is 10 years old, obsolete and inadequate to meet the demands of efficient results turnaround times for patient care and quality testing. The proposed replacement will not only meet the growing needs of clinical laboratory testing requirements but will also incorporate special chemistry testing for hormones and tumor markers as part of the routine analysis of the laboratory. The Hospital determined that the implementation of the new Clinical Chemistry Laboratory equipment will not only improve patient care but also provide safety and operational benefits. The new RAMLS will provide faster turnaround time of results which will allow the technologist to concentrate on results that require attention and intervention. In addition, the new system will enable the Clinical Chemistry Laboratory to reduce manual processes such as accessioning, labeling, centrifuging, decapping and aliquoting; consolidate workstations; enhance software flexibility; improve capability to efficiently handle higher testing volumes; reduce send out testing, turnaround times, and operating expenses; and enable the Clinical Chemistry Laboratory to offer all tests on all shifts.

The CON proposal’s total capital expenditure of \$1,200,000 will be funded entirely by the Hospital’s Operating Funds. The Hospital estimates cost reductions of \$422,800, \$539,320 and \$552,673 in FY 2005, FY 2006 and FY 2007, respectively, due to reagent savings, reduction of service on existing equipment, reduced send out costs, savings on lease for elecsys instruments and labor savings. The Hospital projects gains from operations with the project of \$171,000, \$188,000 and \$202,000 in FY 2005, FY 2006 and FY 2007, respectively. 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 Norwalk Hospital to replace its existing clinical chemistry laboratory equipment with a new laboratory equipment and to acquire a laboratory automation system, at a total capital expenditure of \$1,200,000, is hereby GRANTED.

Order

Norwalk Hospital ("Hospital") is hereby authorized to replace its existing clinical chemistry laboratory equipment with new laboratory equipment and to acquire a laboratory automation system, at a total capital expenditure of \$1,200,000, subject to the following conditions:

1. This authorization shall expire on December 20, 2005. Should the Hospital's replacement laboratory equipment and acquisition of laboratory automation system project not be fully implemented 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 \$1,200,000. In the event that the Hospital learns of potential cost increases or expects that final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of the revised project 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

December 20, 2004

Signed by Cristine A. Vogel
Commissioner

CAV:pf