

Memorandum to the Commissioner

Applicant: The Children's Hospital Corporation
300 Longwood Ave
Boston, MA 02115

Project Number: DoN 2004039-CL

Filing Date: October 13, 2020

Introduction

This memorandum presents, for Commissioner review and action, the Determination of Need (DoN) Program's recommendation regarding a request by The Children's Hospital Corporation (Children's, or Applicant), for approval of renovations to restore areas of three of its facilities, located in Boston's Longwood area (Longwood), Lexington, and Waltham. All three locations are part of Children's hospital license. The capital expenditure for the project is \$32,971,000.

This Application is presented as a Conservation Project, which means "Construction that consists solely of a project(s) that would Sustain or Restore a Health Care Facility or service for its designated purpose, and to its original functionality, without Modernization, Addition, or Expansion." Pursuant to 105 CMR 100.210(B)(2), Factors 1, 2, and 5 do not apply to Conservation Projects. Therefore, Staff reviewed this proposal in the context of Factors 3- Compliance, 4- Financial Feasibility, and 6- Community Health Initiatives. Pursuant to 105 CMR 100.630, this Application has been delegated by the Department for review and Final Action by the Commissioner.

Background

As a specialty Academic Medical Center, in addition to providing quaternary pediatric clinical care and community service, Children's engages in training and research at multiple sites through ownership and clinical affiliations throughout Massachusetts. The three facilities that the proposed project comprises are all part of the Children's hospital license and are described separately herein. The emergency department on the Longwood campus is a Level 1 pediatric trauma center and the Children's system-wide case-mix index is 2.09, compared to the overall statewide index of 1.14.¹ Reflecting the specialty nature of the hospital, the majority of the patients come from a broad geographic distance within and beyond the Greater Boston region.²

¹ Based on FY 2018 Massachusetts Hospital Profiles, of the Center for Health Information and Analysis (CHIA). <https://www.chiamass.gov/assets/docs/r/hospital-profiles/2018/FY18-Massachusetts-Hospital-Profiles-Compendium.pdf>

² Based on FY 2018 Massachusetts Hospital Profiles from CHIA, staff calculated discharges from top 10 towns comprise only 13% of total discharges.

The Proposed Project

The projects presented within this application are designed to keep the facilities in what the Applicant describes as "good working order." Key components include:

- Bringing the compound pharmacy operations into compliance with substantial recent regulatory changes at three locations on the Longwood Campus in Boston
- Renovating designated areas, including
 - the emergency department at the Longwood Campus
 - the radiology department at Longwood Campus and Waltham
 - and other areas across the three sites.

The cumulative costs at all three sites attributed to inpatient services are \$23,638,673; the cumulative costs at all three sites attributed to outpatient services are \$8,332,327. The Applicant has allotted an additional \$1M for contingency expenditures which is customary for renovation and construction projects.

Project Components:

Pharmacy – Longwood Campus

Pharmacy renovations are a result of substantial changes to national standards of The United States Pharmacopeia – National Formulary (USP-NF) that establishes standards for compounding pharmacies.³ In Addition, the Massachusetts Board of Registration in Pharmacy⁴ is promulgating new regulations regarding compounding pharmacies. It will require that all hazardous medications be compounded using a containment hood that is separately exhausted to the exterior of the building. The Applicant states that:

"Pediatric pharmacies are uniquely affected due to much higher compounding activity. Pediatric sterile and non-sterile medications vary in size of dosing, doses are patient specific, and 70% of all doses need to be compounded and dispensed very close to administration time. Sterile medications are reconstituted and diluted."

The Applicant reports that the renovation will bring the hospital into compliance with the new standards and compliance will be verified by Plan Review within Bureau of Health Care Safety and Quality (BHCSQ). In addition, the BHCSQ currently collects Serious Reportable Events (SRE's),⁵ two of which pertain to product or device events and care management events which encompass pharmacy. They are:

³USP-NF includes over 5000 quality standards for medicines, both chemical and biologic; active pharmaceutical ingredients (APIs); and excipients (inactive ingredients). The standards in USP-NF are used to help ensure the quality of medicines and their ingredients, and to protect the safety of patients. USP is utilized in over 140 countries worldwide and integrated into the laws of more than 40 countries

⁴ Board of Registration in Pharmacy requirements regarding USP 797 and USP 800, and proposed 247 CMR 17.

⁵ <https://www.mass.gov/doc/sre-reporting-guidance-0/download>

- *Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting*
- *Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration).*

Given that Children's already reports this data to the Department, Staff does not recommend that any additional reporting by the Applicant be required related to this Project component.

The chart below depicts the three locations of the Pharmacy project.

Longwood Pharmacy		% of	Attributed
Mandell 7 Critical Care	700	13.1%	\$1,689,813
Main 6 Inpatient Oncology	3,200	59.8%	\$7,724,860
Farley 4 Outpatient Infusion	1,450	27.1%	\$3,500,327
Total	5,350	100%	\$12,915,000

Emergency Department (ED) – Longwood Campus

The ED is the largest pediatric emergency service in the state, providing 60,700 visits annually. The project involves the renovation of the triage area for incoming patients to enhance flow, as well as to ensure HIPAA /privacy and regulatory compliance.⁶ The work includes fresh paint, millwork, and replacement of furniture and equipment. It does not expand the footprint of the department. The capital required to complete this project is \$2,150,000. The project also includes the installation of lockers to store a parent or guardian's personal possessions while they are accompanying children throughout their ED stay.

Staff notes that DoN does not consider the installation of lockers to be Conservation. However, the ED project as a whole did not meet the expenditure threshold for a capital project and the other components of the ED project do meet the definition of Conservation.

Radiology Department- Waltham Campuses and Overall Imaging

Included in this project is the renovation of two diagnostic radiology rooms in Waltham.⁷ This work was identified in the Hospital's radiology facility plan, as both rooms are in need of refurbishment with no structural changes. These rooms house imaging recording systems that have reached the end their useful life and will be replaced. The capital required to complete

⁶ The renovation is taking place over four years to ensure that clinical operations can safely proceed unimpeded by the work.

⁷ It does not include any DoN required equipment.

this project is \$75,000. Also, for the continued renewal of all the Children's imaging suites an additional \$461,000 in architectural and design fees was included.

General Building Restorations – Longwood, Waltham, and Lexington Campuses

The Hospital reports that it engages in an in-depth evaluation of all major components of its buildings (substructure, superstructure, exterior enclosures, roofing, etc.) bi-annually⁸ that produces a series of priority recommendations of projects that range from those needing immediate action to future needs over the next five to ten years. This information ensures that funds from the annual capital routine budget are directed to renovation projects with the highest priority for its annual preventive maintenance and facilities renewal. It reports that generally the facilities are showing wear and tear in a variety of areas, including walls, floors, ceilings and millwork and will be replaced, repaired or modified as required. More specifically included in this project:

- **Longwood Campus** evaluation indicates that replacement and upgrades of utilities, transformers, air handlers, nurse call and facility automation systems are necessary for a capital cost of \$14,224,000.
- **Waltham Campus** evaluation indicates that upgrades to roofs, stair wells, hot water systems, sprinklers, flooring, and renewal of the utility substation, replacement of a transformer, and other small projects are necessary to maintain the facility costing \$1,945,000.
- **Lexington Campus** evaluation indicates the roof requires repairs for a cost of \$201,000.
- **Contingency** the Applicant has also submitted a \$1M contingency request to address unforeseen issues that arise during the normal course of business.

Analysis of the Project

Staff finds that the Applicant has presented sufficient information affirming that the proposed construction fits within the definitions in the DoN Regulation of Sustain and/or Restore; that this proposed Conservation Project is necessary to maintain the original functionality of the facility, and does not add any new beds, services or capacity.

Factor 3

The Applicant has certified that it is in compliance and in good standing with federal, state, and local laws and regulations, including, but not limited to M.G.L. c. 30, §§ 61 through 62H and the applicable regulations thereunder, and in compliance with all previously issued notices of Determination of Need and the terms and conditions attached therein.

⁸ Using the Infrastructure Condition Index (ICI) as defined by the U.S. Department of Commerce.

Factor 4

Under factor 4, the Applicant must demonstrate that it has sufficient funds available for capital and operating costs necessary to support the Proposed Project without negative effects or consequences to the existing patient panel. Documentation sufficient to make such finding must be supported by an analysis conducted by an independent CPA. The Applicant submitted a report performed by BDO (CPA Report).

In order to assess the reasonableness the feasibility of the projections, the CPA Report reflects a review and analysis of ~28 documents including two years of audited financial statements, current and historic cash flow for 15 years, and industry metrics,⁹ the 2016-2023 financial performance and projections prepared by management with supporting documentation, that includes underlying assumptions, and determined the projections were reasonable at the time of preparation, December 2019.

The CPA reports that revenue is from many sources¹⁰ with 79% coming from net patient service revenue (NPSR), the focus of the Proposed Projects; of that, ~66% is Hospital, and ~28% is physician's organization¹¹ NPSR. Projected revenue, based on historical statistics and reimbursement rates and incorporates annual growth rate of 3.1%. The CPA's opinion is that the projections for BCH reflect a reasonable estimation of future revenues since the projections are lower than the rates for the past two years.

The CPA also reviewed the Applicant's projected operating expenses and states that those projections are based on historical categories of *Salaries and Benefits*, and *Supplies and Other Expenses*. After review of these expenses, the CPA's reports that the projections of the Applicant are reasonable. The CPA noted that the Applicant's budget for each of the prior 15 fiscal years was met or exceeded for 13 of the 15 years and believes it is feasible that the Applicant will achieve the targets in the Projections.

The CPA added that capital expenditures for the Proposed Project represents 36.6% of the annual capital budget; it will not require debt financing; rather it will be funded through the Applicant's net assets and cash flows. As a result of its analysis, the CPA determined that "the Projections are reasonable and feasible, and not likely to have a negative impact on the patient panel or result in a liquidation of assets of Children's."

Analysis of Factor 4

As a result of information provided by the Applicant, staff finds the Applicant has reasonably met the standards of Factor 4.

⁹ For a complete list of all 28 documents see pages 6-7 of the BDO report.

¹⁰ These include research grants and contracts, contributions, teaching administration and other means.

¹¹ And the remaining 6% is from other subsidiaries.

Factor 6

The Community Health Initiative (CHI) component of the DoN regulation requires Hospital Facilities doing a Conservation project to contribute 3% of the total value of the project. For this proposed Conservation Project, the CHI contribution is \$824,275.

Summary and relevant background and context for this application

Given that this is a Conservation project and given that DPH has determined that the Applicant has complied with all DPH guidance and CHI related requirements for the previously approved project #4-3C47 which the Applicant is currently implementing, for this application the Applicant was required to:

- Submit the CHI Self-Assessment form based on the Applicant's 2018 and 2019 Community Health Needs Assessment and Implementation Strategy.
- Commit to convening the Applicant's Community Advisory Board to determine how to invest the new CHI resources required as part of this Application by using the funding strategy approved under project #4-3C47 as the basis for decision-making.

The Self-Assessment form was required to confirm that the Applicant has engaged in a process of routine community health needs assessment and community health planning sufficient to allow the Applicant to move forward with plans to invest these new CHI resources in the Special Initiatives Funding stream approved under #4-3C47. The Special Initiatives Funding stream was designed to allow for timely targeted investments in critical community health issues which are outside of the other approved funding areas.¹² The applicant reviews investments made through the Special Initiatives Funding stream with DPH to ensure consistency with prior approvals. Examples of projects funded through the Special Initiatives Funding stream include a Children's Health Policy and Advocacy Initiative, support for the Children's Mental Health Campaign to promote behavioral health equity, and most recently the Boston Childcare Support Initiative which is supporting childcare centers and family childcare providers to support COVID-19 re-opening activities.

At the September 15th, 2020 Community Advisory Board (CAB) meeting, the Applicant discussed the CHI requirement and the CAB proposed focusing efforts in two areas:

1. Family Housing Stability (through an expedited RFP process with the goal of distributed resources within 90 days post-DoN project approval) with a focus on
 - a. Education and advocacy to support effective operationalization of new housing stability resources;
 - b. Acquisition projects to preserve affordable family housing;
 - c. Staffing/infrastructure to rapidly develop and scale systems to coordinate, manage, and/or disburse new eviction prevention resources.

¹² which are Children's behavioral/mental health; stable and affordable housing; systems of support for infants, children, youth and families; healthy and safe communities

2. School-age Children Remote Learning (with a focus on behavioral health) with a goal of distributing funds within 6-9 months after a landscape scan of gaps to further refine the strategy.

These priorities will complement existing DoN strategic initiatives being implemented through DoN #4-3C47: Family Housing Stability; and Mental Health and Youth Support Systems. Under the direction of the CAB the applicant will implement focused RFP processes that engage organizations that work with priority populations of children, particularly Black and Latinx children.

Analysis of Factor 6

DPH has determined that the proposed investments meet DPH's Health Priorities standards and that the Applicant can proceed with allocating these new CHI resources to the Special Initiatives Funding stream under the direction and guidance of its Community Advisory Board and affirms that the Applicant will comply with all reporting requirements as deemed necessary by DPH.

Overall Findings

Based upon a review of the materials submitted, the Department finds that the Proposed Project of the Children's Hospital Corporation, complies with the requirements of a Conservation Project and has met applicable DoN factors 3, 4, and 6 as required in the regulation 105 CMR 100.715B(2). As a result, this Application for \$32,971,000 in capital expenditures for a Conservation Project is approved. All standard and Other Conditions apply except 100.310(A)(10).

Additional Conditions

1. Of the total required CHI contribution of \$824,275
 - a. \$206,068.75 will be directed to the CHI Statewide Initiative
 - b. \$618,206.25 will be dedicated to local approaches to the DoN Health Priorities
2. To comply with the Holder's obligation to contribute to the Statewide CHI Initiative, the Holder must submit a check for \$206,068.75 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative).
 - a. The Holder must submit the funds to HRiA within 30 days from the date of the Notice of Approval.
 - b. The Holder must promptly notify DPH (CHI contact staff) when the payment has been made.