

STAFF REPORT TO THE COMMISSIONER FOR A DETERMINATION OF NEED	
Applicant Name	Beth Israel Lahey Health, Inc.
Applicant Address	20 University Road, Suite 700, Cambridge, MA 02138
Filing Date	October 20, 2023
Type of DoN Application	DoN Required Equipment
Total Value	\$34,500.00
Project Number	#BILH-23082513-RE
Ten Taxpayer Groups (TTG)	None
Community Health Initiative (CHI)	\$1,725.00 (Statewide Fund)
Staff Recommendation	Approval
Delegated Review	Commissioner Approval
<u>Project Summary and Regulatory Review</u> Beth Israel Lahey Health, Inc., with a principal place of business at 20 University Road, Suite 700, Cambridge, MA 02138, filed a Notice of Determination of Need with the Massachusetts Department of Public Health to add a second linear accelerator (“LINAC”) unit for operation at Beth Israel Deaconess Hospital - Plymouth, Inc. (“BID-P” or “Hospital”) located at 275 Sandwich St, Plymouth, MA 02360. This DoN application falls within the definition of DoN-Required Equipment and Services, which is reviewed under the DoN regulation 105 CMR 100.000. The Department must determine that need exists for a Proposed Project, on the basis of material in the record, where the Applicant makes a clear and convincing demonstration that the Proposed Project meets each Determination of Need Factor set forth within 105 CMR 100.210. This staff report addresses each of the six factors set forth in the regulation.	

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Applicant Background and Application Overview

Beth Israel Lahey Health, Inc.

The Beth Israel Lahey Health, Inc (BILH or Applicant), is a Massachusetts, non-profit, tax-exempt corporation that oversees an integrated health care delivery system comprised of teaching and community hospitals, physician groups, behavioral health providers, post-acute care providers and other caregivers serving patients in Greater Boston and the surrounding communities in Eastern Massachusetts and South Eastern New Hampshire.¹

Collectively known as “BILH Hospitals,” BILH’s member hospitals include:

Acute Hospital ²	Type (Per CHIA Category ^{a, b)}
Anna Jaques Hospital	Community Hospital
Beth Israel Deaconess Hospital–Milton	Community Hospital
Beth Israel Deaconess Hospital–Needham	Community Hospital
Beth Israel Deaconess Hospital–Plymouth	Community-High Public Payer Hospital
Beth Israel Deaconess Medical Center	Academic Medical Center
Lahey Hospital & Medical Center	Teaching Hospital
Mount Auburn Hospital	Teaching Hospital
New England Baptist Hospital	Specialty Hospital
Northeast Hospital	Community-High Public Payer
Winchester Hospital	Community Hospital

BILH operates Beth Israel Lahey Health Performance Network, LLC (BILHPN), a Massachusetts Health Policy Commission (HPC) certified Accountable Care Organization (ACO), which the Applicant states is a value-based physician and hospital network whose goal is to partner with other community hospitals and providers throughout Eastern Massachusetts to improve quality of care while managing medical costs.

Beth Israel Deaconess Hospital – Plymouth

Beth Israel Deaconess Hospital-Plymouth (“BID-P” or “Hospital”), is a 170-bed acute care hospital serving the communities of Plymouth, Carver, Kingston, Middleboro, Duxbury, Marshfield, Bourne, Pembroke, Sandwich, Halifax, and Plympton. The Hospital provides a full range of comprehensive community hospital services including primary and preventative care, emergency services, inpatient acute care, inpatient psychiatric services, and specialty services. The Hospital joined Beth Israel Deaconess in 2014.

¹ The Applicant states that an estimated five million people reside in the BILH service area.

² Beth Israel Lahey Health includes the following Hospitals: Addison Gilbert Hospital (Northeast), Anna Jaques Hospital, Beth Israel Deaconess Hospital – Milton, Beth Israel Hospital – Needham, Beth Israel Hospital – Plymouth, Beth Israel Deaconess Medical Center, Beverly Hospital (Northeast), Lahey Hospital & Medical Center, Lahey Medical Center, Peabody, Mount Auburn Hospital, New England Baptist Hospital, and Winchester Hospital.

Proposed Project

The Proposed Project would add a second LINAC unit by reactivating a dormant machine and would also include necessary renovations to the LINAC vault and control rooms to meet current DPH architectural standards. The dormant 2005 Varian2100EX LINAC was replaced with a Varian TrueBeam LINAC (currently in operation) in early 2021. Because the hospital had DoN approval for only one LINAC when the new model was put in use, the old machine was placed in a dormant state despite being fully functional. Currently, the Hospital is limited to use of a single LINAC, which the Applicant notes decreases the Hospital's ability to accommodate flexible scheduling for different procedure types, puts strain on the single machine currently in use, and risks the unavailability of services if the single LINAC experiences downtime. The Hospital asserts that the reactivation of the LINAC unit will accommodate projected demand for radiation therapy.

Factor 1

In this section, we assess if the Applicant has sufficiently addressed Patient Panel need, public health value, competitiveness and cost containment, and community engagement for this Required Equipment application.

Patient Panel³

As shown in Table 1, the BILH Patient Panel consisted of 1,324,649 patients in Fiscal Year (FY) 2023⁴. The Applicant notes that a drop in COVID testing and immunizations between 2022 and 2023 resulted in a lower number of total unique patients in FY2023.

Table 1: Overview of BILH Patient Panel

	FY2020	FY2021	FY2022	FY2023
BILH Total Unique Patients	1,219,718	1,427,711	1,633,109	1,324,649

The Applicant provided data showing that the top 15 patient origins of their Patient Panel included Plymouth, Woburn, Beverly, Peabody, Gloucester, Quincy, Boston, Cambridge, Billerica, Burlington, Dorchester, Arlington, Danvers, Medford, and Wilmington⁵. The Applicant also provided demographic data for BILH's Patient Panel, which is presented in Appendix II. Staff notes the following observations about the FY2022 data:

- **Age:** Most patients fall in the 18-64 age group (60.84%), followed by the over 65 age group at 28.09%.
- **Race:** The majority of BILH's patients self-identified as White (74.05%).
- **Ethnicity:** Over 80% of patients identify as "Not Hispanic".

³ As defined in 105 CMR 100.100, Patient Panel is the total of the individual patients regardless of payer, including those patients seen within an emergency department(s) if applicable, seen over the course of the most recent complete 36-month period by the Applicant or Holder.

⁴ For purposes of the Applicant's Patient Panel, the fiscal year is defined as July 1 through June 30.

⁵ This information is from the Center for Health Information and Analysis ("CHIA") Massachusetts Acute Care Hospital Inpatient Discharge Dataset, which is only current through the end of 2021. Therefore, the data provided is from FY21.

- **Payer Mix:** Approximately 53.23% of patients were covered by Commercial insurance, followed by Medicare (26.02%) and Medicaid (10.14%).

The Applicant provided information for BID-P's patient population, the Hospital targeted for this DoN Application. Many data points are similar to the demographics of the BILH Patient Panel. Table 2 includes information notably different from the Patient Panel data in the following areas:

- **Age:** The largest portion (35%) of BID-P's patient population is aged 65+, compared to only 28% of BILH's overall Patient Panel.
- **Race:** A higher proportion of patients identify as White (89%) compared to the BILH Patient Panel. This is consistent with the demographics of Plymouth County, as reported by the 2022 US Census.^c
- **Payer Mix:** BID-P has a larger portion covered by Medicare (31.30% at BID-P versus BILH at 26%) and Medicaid (17% at BID-P while BILH is at 10%). BID-P patients have a lower proportion of Commercially insured patients compared to the BILH Patient Panel (38.1% at BID-P and BILH at 53%).

Table 2: Beth Israel Deaconess Hospital - Plymouth Patient Population

	FY2022 Totals
Total Unique Patients	83,796
Age	
0-17	8.60%
18-25	6.10%
26-45	20.20%
46-64	30.10%
65+	35.00%
Total	100.00%
Race	
White	89.10%
African American	2.10%
American Indian or Alaska Native	0.10%
Asian	0.60%
Native Hawaiian or Other Pacific Islander	0.00%
Other ⁶	1.40%
Patient Declined	6.70%
Total	100.00%
Payer Mix	
Commercial	38.10%
Medicaid	17.10%
Medicare	31.30%
Other ⁷	13.40%

⁶ "Other" is a choice for patients to select if they do not feel that their race/ethnicity is reflected in the list of choices.

⁷ Includes self-pay, health safety net, and liability coverage other than worker's compensation for an injury event.

	FY2022 Totals
Unknown	0.10%
Total	100.00%

The Applicant also provided demographics for BID-P's Radiation Oncology patient population. It is notable that approximately three quarters of patients were over the age of 65.

Table 3: BID-P Radiation Oncology Patient Demographics

	FY2022 Totals
Total Unique Patients	436
Age	
Under 65	25.92%
Over 65	74.08%
Total	100.00%

Factor 1: a) Patient Panel Need

In this section, staff assesses if the Applicant has sufficiently addressed Patient Panel need for the Proposed Project.

Patient Panel Need

The Applicant attributes the need for reactivating its second LINAC unit to two factors:

- 1) Historical Utilization and Projected Increase in Demand
- 2) Limitations of One LINAC Unit
 - a. Longer wait to begin treatment
 - b. No backup if downtime increases on overburdened unit

1) Historical Utilization and Projected Increase in Demand

The BID-P patient population increased by 9.6% between FY20 and FY22. With respect to radiation therapy utilization, BID-P experienced an approximately 40% overall increase from FY20 to FY22 in the number new starts⁸ for All Radiation Therapy, and the Stereotactic Body Radiation Therapy ("SBRT") new starts more than doubled in recent years, as detailed in Table 4.

Table 4: BID-Plymouth Historical LINAC Utilization

Treatment type	FY2020	FY2021	FY2022
New Starts: All Radiation Therapy	311	366	436

⁸ "New starts" is the number of treatment courses.

New Starts: Stereotactic Body Radiation Therapy	15	18	46
Total LINAC Treatments ⁹	6,870	8,217	7,945

In addition to historical increases in radiation therapy volume, BID-P expects that new start volume will continue to grow as the Hospital's patients age. The likelihood of being diagnosed with cancer increases with age and the CDC estimates that more than two-thirds of all new cancers are diagnosed in patients aged 60 years and older.^d As a result of aging and increased life expectancy, BID-P anticipates that patients will present with higher incidence of cancer and more frequently require radiation therapy. These age-based demand considerations are especially important for future planning for BID-P's radiation oncology department. In Plymouth County, where the majority of BID-P's patients reside, the 65+ age cohort is projected to grow 17% between 2020 and 2025.^e Given that ~74% of patients who received radiation treatment at BID-P were ages 65+, this anticipated growth in the Plymouth region will increase the number of older adults requiring radiation therapy. Table 5 demonstrates a 23% projected increase in total new starts for all radiation therapy from FY2022-FY2028, with exponential growth expected in SBRT new starts.

Table 5: BID-Plymouth Projected Utilization

Treatment Type	FY2024	FY2025	FY2026	FY2027	FY2028
New Starts: All Radiation Therapy	466	490	509	523	536
New Starts: Stereotactic Body Radiation Therapy	66	81	91	96	101
Total LINAC Treatments	8,222	8,452	8,665	8,860	9,026

The Advisory Board Cancer Incidence Estimator expects that cancer incidence in BID-P's service area and surrounding counties will increase by 9.6% between 2020 and 2025 and by nearly 17% between 2020 and 2030.^f Additionally, the Hospital expects to see a sustained higher volume of SBRT treatments, which take longer per treatment than conventional radiation therapy, thereby decreasing the number of available appointments. The Advisory Board's Oncology Outpatient Market Estimator anticipates that the number of patients requiring SBRT in BID-P's service area and surrounding counties will increase by approximately 40% from 2020 to 2025.^g Due to the longer treatment times for SBRT and the performance of both SBRT and conventional radiation therapy on a single LINAC machine, the Hospital is currently limited in its ability to meet the demand for this form of treatment.

2) Limitations of One LINAC Unit

- a. **Longer Wait to Begin Treatment:** BID-P has experienced a significant increase in new radiation therapy patients overall, with a particular increase in SBRT patients. SBRT is a newer form of radiation therapy that is especially promising for patients who previously had limited treatment options. However, the average SBRT treatment time is currently one hour, compared to 10 minutes for more conventional forms of radiation therapy,

⁹ The total LINAC treatments is the total number of visits/treatments.

which results in less appointment availability on the single LINAC unit. While radiation services are occasionally offered outside of regular hours, the Hospital has been unable to permanently extend hours due to staff capacity, which leads to patients waiting longer to start radiation therapy so that they can schedule their treatments at a convenient time. This is particularly true for patients who are working or providing childcare. A snapshot study of wait times performed by the Hospital in 2022 revealed that the average wait time between simulation and the start of treatment rose from approximately 9 working days in 2021 to 12 working days in August 2022. A difference of even a few working days in the timeliness of radiation therapy affects the efficacy of treatment outcomes, as explored in greater detail in Factor 1b.

- b. **No Backup if Downtime Increases on Overburdened Unit:** In addition to providing schedule flexibility for patients, a second LINAC unit would provide timely access to radiation therapy if the existing LINAC experiences downtime. While the existing LINAC unit is not yet experiencing significant downtime, the downtime will inevitably increase as the machine ages and there will be no back-up machine to ensure the reliability of services. This concern is heightened by the fact that the existing unit is currently operating significantly above capacity. There were 436 new treatment starts in FY22, which is well above the recommended average of 237 patients per machine.^h This is an increase of approximately 40% from the FY2020 volume of new treatment starts. Continuing to operate the machine above capacity will put strain on the unit and hasten the increase in downtime as the machine ages. A second LINAC unit is necessary to maintain the existing LINAC for as long as possible and reduce the potential for downtime, which can cause the treatment delays addressed in the previous section.

Analysis

Staff finds that the historic and projected growth in treatments demonstrate sufficient need for a second LINAC unit at BID-P. Staff finds that providing radiation therapy across two units will decrease the strain on the current LINAC, in turn prolonging the useful life of both units. Adding a second machine will also provide patients with greater flexibility in scheduling appointments, which could improve compliance with treatment. The second unit will provide capacity to accommodate the increased number of radiation oncology patients predicted in the Primary Service Area. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1a.

Factor 1: b) Public Health Value, Improved Health Outcomes and Quality of Life; Assurances of Health Equity

In this section staff will assess if the Proposed Project adds measurable public health value in terms of improved health outcomes and quality of life for the Applicant's existing Patient Panel, while providing reasonable assurances of health equity.

Public Health Value and Health Outcomes

The Applicant asserts that the Proposed Project aims to improve health outcomes and quality of life by ensuring uninterrupted access to radiation therapy for oncology patients, thereby improving quality of life for the existing Patient Panel. To demonstrate improved public health value and quality of life, the Applicant provided a summary of literature supporting the benefits of 1) access to LINAC and 2) timely access to care close to home.

1) Access to Linear Accelerator (LINAC)

LINAC is the device most commonly used for external beam radiation treatments for patients with cancer. The machine produces high energy x-rays or electrons that can precisely target the tumor while leaving the surrounding healthy tissue intact.ⁱ The Applicant referenced an array of literature (listed in Appendix III) detailing the utility and benefits of External Beam Radiation Therapy, IMRT, and SBRT. Based on a review of the literature, LINAC is medical technology that is well-accepted as an effective cancer treatment and has the potential to provide very precise doses of radiation while minimizing side effects and damage to healthy tissue. Having uninterrupted access to this equipment will likely improve the quality of life for the Patient Panel by avoiding treatment delays caused by the limitations of scheduling on only one LINAC unit.

2) Timely Access to Care Close To Home

Radiation therapies are often performed over a period of time and require the patient to return for treatment multiple times a week, month, or over longer periods of time. Therefore, unimpeded access to care within the patient's community is necessary for improving treatment completion rates and overall outcomes. The Applicant presented a series of studies supporting the need for timely access to radiation. They noted that delays in the start time of radiation treatment over a certain number of days may be associated with worse overall survival.^j Delayed treatment start times also negatively impact patient satisfaction and experience.^k Proximity to care and minimal travel time to health care facilities become increasingly important factors for access to care as adults age because of potential barriers to transportation for those adults who no longer drive or do not have a support system for reliable transportation to appointments.^l In addition to poorer health outcomes related to the patient's specific diagnosis, there is evidence that the time spent traveling to receive health care services, as well as costs associated to traveling, physically impacts individuals and is a source of additional stress.^m The cited literature suggests that health outcomes are better when individuals live close to the health care facilities that can address the full spectrum of health care needs.

To assess the impact of the Proposed Project, the Applicant developed quality metrics and a reporting schematic, as well as metric projections for quality indicators that will measure quality of care. The measures are presented in Appendix I and will be reported to DPH on an annual basis following implementation of the Proposed Project.

Analysis: Public Health Value, Health Outcomes, and Quality of Life

Staff finds that providing unimpeded access to cancer services close to home has the potential to improve health outcomes for the Patient Panel and the greater community. The literature suggests that these treatments stop tumor growth, minimize risk of damage to healthy tissue, and may result in a reduction of side effects for the patient. The need for treatments to be accomplished multiple times

weekly for prolonged time periods makes proximity of services an important factor. Having the added capacity of a second LINAC unit helps promote treatment completion by providing the service within the local community. As a result, Staff finds that the Applicant meets the requirements of the Public Health Value: Health Outcomes part of Factor 1b.

Health Equity and Social Determinants of Health (SDoH)

The Applicant states that the Proposed Project will work to reduce health inequity through increasing and improving access to radiation oncology therapies to all members of BID-P's community, particularly for working patients with limited scheduling options. The Hospital asserts that it does not discriminate on the basis of age, race, ethnicity, gender/gender-identity, physical ability, sensory or speech limitations, or religious, spiritual, and cultural beliefs, nor a patient's ability to pay or payer source. The Applicant states that BID-P has ongoing efforts in Language Accessibility, Admission Screenings, and Data Collection to facilitate equitable access to its services.

Analysis: Health Equity and SDoH

The Applicant demonstrates efforts to achieve health equity through language accessibility, and data collection that provides a more accurate understanding of the race, ethnicity, and language of their Patient Panel. Staff finds that the Applicant has sufficiently demonstrated ongoing efforts to achieve health equity. As a result, Staff finds that the Applicant meets the requirements of the Public Health Value: Health Equity part of Factor 1b.

Factor 1: c) Efficiency, Continuity of Care, Coordination of Care

The Applicant states that the Proposed Project will improve care continuity and coordination of care for radiation oncology patients by providing uninterrupted LINAC services for BID-P patients in their community. The Applicant states that these efforts are aided by technology infrastructure, multi-disciplinary care coordination, and their ACO program.

Technology Infrastructure: BID-P's existing technology infrastructure streamlines access for patients and facilitates improved coordination of care among physicians and other professionals on a patient's care team. BID-P's EMR serves as the primary link between Radiology, specialists, and community primary care providers. The EMR provides BID-P radiologists real-time access to a patient's comprehensive medical information, including medical history, lab results, and clinical notes while they are protocoling or reading a study. Once the radiologist's report is complete, the EMR enables results and information to be available to primary care and specialty physicians across the system and integrated into the patient's EMR. The EMR also allows authorized providers outside of BID-P to view patients' records and send progress notes back for continuity of care.

Multi-disciplinary Care Coordination: BID-P coordinates a variety of supportive care services to complement active chemotherapy and radiation therapy treatment. Nutrition, speech, and swallowing evaluation/ treatment is available to patients going through radiation therapy. The Hospital's Social Work department provides access to financial, transportation, and psychiatric support services. Physical Therapy and Occupational Therapy is available as both an inpatient and

outpatient service. A multidisciplinary team including nurse practitioners, nurses, radiation therapists, dietary & speech/swallow services, and social workers meet regularly to review complex cases and coordinate efforts from medical & radiation oncology, and supportive services.

MassHealth ACO Program: BID-P participates in the MassHealth ACO Program through Beth Israel Deaconess Care Organization (BIDCO), part of Beth Israel Lahey Health Performance Network (BILHPN) and its clinically integrated network. BIDCO strives to increase access to high quality care for members who are more likely to have unmet SDoH needs than the commercially insured population. The Applicant notes that a significant portion of BIDCO's efforts to improve health care are accomplished through care coordination. Specifically, BIDCO's data analysis and risk management tools are provided to BID-P providers, including a Population Health Management Tool that helps primary care physicians monitor patients' health and manage chronic conditions. These primary care linkages will continue to enhance care for BID-P's patients, including timely access to radiology services that will be achieved through the Proposed Project.

Analysis

Staff finds that the Applicant's care coordination will contribute positively to efficiency, continuity, and coordination of care. The integration of cancer services with supportive services will likely contribute to increased patient satisfaction and support continuity and coordination of care. The Hospital's multi-disciplinary review and involvement in treatment planning create an efficient, real-time coordination of care that has the potential to improve patient outcomes. BID-P's EMR supports communication between the patient, physician, and all care team members that can foster better collaboration. Review of literature points to evidence which suggests access to integrated health information technology systems directly impacts health outcomes through reducing fragmentation and improving coordination among care providers.ⁿ Similarly other studies show that integrated health information technology systems directly affect health outcomes, as access to a single, integrated health record, can reduce errors, improve patient safety, and support better patient outcomes.^o As a result, Staff finds that the Proposed Project meets the requirements of Factor 1c.

Factor 1: d) Consultation

The Applicant has provided evidence of consultation, both prior to and after the Filing Date, with all government agencies that have licensure, certification, or other regulatory oversight, which has been done and will not be addressed further in this report. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1d.

Factor 1: e) Evidence of Sound Community Engagement through the Patient Panel

The Department's Guideline¹⁰ for community engagement defines "community" as the Patient Panel and requires that, at minimum, the Applicant must consult with groups representative of the Applicant's Patient Panel. Regulations state that efforts in such consultation should consist of engaging "community coalitions statistically representative of the Patient Panel."¹¹

¹⁰ [Community Engagement Standards for Community Health Planning Guideline.](#)

¹¹ [DoN Regulation 100.210 \(A\)\(1\)\(e\).](#)

The Applicant presented the Proposed Project presented to The Hospital's Patient Family Advisory Council (PFAC) and Hospital's Community Benefits Advisory Council (CBAC) in March 2023. The presentations covered the Applicant's proposed plans, and how the Proposed Project will benefit the Hospital's Patient Panel. Following the presentation, attendees were able to share feedback and ask the presenters questions. Discussions centered around understanding the current volume of treatment, projected increases in volume following the project, the timeline for the project, and the current hours available for treatment.

Analysis

Staff reviewed the information on the Applicant's community engagement and finds that the Applicant has met the required community engagement standard of Consult in the planning phase of the Proposed Project. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1e.

Factor 1: f) Competition on price, total medical expenses (TME), costs and other measures of health care spending

The Applicant states that the Proposed Project will compete on the basis of price, total medical expenses (TME), provider costs, and other recognized measures of health care spending by ensuring reliable access to timely outpatient cancer services in the community. The Applicant notes that the Proposed Project is an existing resource without the need for a significant capital expenditure to recommission the unit. Ensuring that access to cancer services remain available to BID-P's patients close to home and on a timely basis contributes to reducing the cost of care by preventing cost-increasing delays in treatment. Preventing long wait times, increasing scheduling flexibility, and ensuring the reliability of BID-P's radiation therapy will also guarantee that patients can receive care in the community where they live. Without the addition of a LINAC, BID-P may not be able to provide reliable and convenient radiation therapy treatments if their existing LINAC unit goes offline, resulting in the possibility that both current and future patients would need to seek services further from home and potentially outside of the BILH network.

Analysis

The Proposed Project has the potential to reduce costs by providing LINAC services on site at BID-P, saving the cost of delayed treatments. The Proposed Project also ensures access to LINAC in the Primary Service Area, ensuring access to radiation treatments close to home. Staff finds that, on balance, the requirement that the Proposed Project will likely compete on the basis of price, TME provider costs, and other measures of health care spending have been met.

Summary, FACTOR 1

As a result of the information provided by the Applicant and additional analysis, staff finds that the Applicant has demonstrated that the Proposed Project meets Factor 1.

Factor 2: Cost containment, Improved Public Health Outcomes and Delivery System Transformation

For Factor 2 the Applicant must demonstrate that the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation beyond the Patient Panel.

Cost Containment

As detailed in Factor 1f, the Proposed Project reduces capital expenses of the project by using existing equipment and ensures local, uninterrupted radiation therapy services to the Patient Panel, which can reduce overall health care costs. The Applicant asserts that there will be no change in BID-P's contracted rates for LINAC services, and no impact on costs.

Analysis: Cost Containment

Staff finds that the Applicant has adequately explained how it aligns with cost containment goals through the expansion of radiation services provided on site at BID-P with no change in contracted rates. Therefore, DoN Staff can conclude that the Proposed Project will likely meet the cost containment component of Factor 2.

Improved Public Health Outcomes

The Proposed Project will improve public health outcomes by providing patients with timely, reliable, and convenient access to radiation oncology services in the community, potentially reducing travel time as well as delays in diagnosis and treatment. Factor 1a detailed the Patient Panel need for the Proposed Project. Increased capacity and access to LINAC services answer that need by meeting current and future demands for radiation services, as well as providing timely access within the community. Improved access to these services will also further the patient care experience and patient satisfaction.

Analysis: Public Health Outcomes

Staff finds that the Proposed Project will provide the Patient Panel with timely access to radiation services, which has the potential to improve health outcomes. Timely access can reduce delays in diagnosis and treatment that can adversely impact health outcomes. A second LINAC unit ensures that radiation services will remain available to the community if one machine experiences down time, which has historically resulted treatment delays due to rescheduling. As the LINAC patient volume continues to increase, having unimpeded access to radiation treatment will be important in meeting the needs of the community. Therefore, DoN Staff can conclude that the Proposed Project will likely meet the Public Health Outcomes component of Factor 2.

Delivery System Transformation

BID-P conducts comprehensive admission screenings that address social determinants of health, including financial barriers to care, social support, housing and transportation issues, mental health problems, and other barriers to access. BID-P has ongoing screenings at the time of initial consultation, and again during the second week of treatment. Based on these assessments, appropriate interventions

are arranged as needed. Social Work referrals may be made to connect patients with services, including financial counseling, mental health services in the community, ride assistance programs, wig share programs, and physical therapy programs for patients who qualify.

Analysis: Delivery System Transformation

Central to the goal of Delivery System Transformation is the integration of social services and community-based expertise. The Applicant screens patients on relevant SDoH factors and demonstrates a variety of methods for linking patients to needed community resources. Therefore, DoN Staff can conclude that the Proposed Project will likely meet the Delivery System Transformation component of Factor 2.

Summary, FACTOR 2

As a result of the information provided, staff finds that the Proposed Project has sufficiently met the requirements of Factor 2.

Factor 3: Relevant Licensure/Oversight Compliance

The Applicant has provided evidence of compliance and good standing with federal, state, and local laws and regulations and this Factor will not be addressed further in this report. As a result of information provided by the Applicant, staff finds the Applicant has reasonably met the standards of Factor 3.

Factor 4: Demonstration of Sufficient Funds as Supported by an Independent CPA Analysis

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 a finding must be supported by an analysis by an independent CPA.

The Applicant submitted a CPA report compiled by Meyers Brother Kalicka. The CPA assessed the reasonableness¹² of assumptions used in the preparation and feasibility¹³ of the projections with regards to the Proposed Project. The CPA concluded that projections were reasonable, and that the Applicant 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.

Factor 4 Analysis

Staff is satisfied with the CPA's analysis of the Proposed Project's projections. As a result of information provided by the Applicant and additional analysis, staff finds that the Applicant has demonstrated that the Proposed Project has met Factor 4.

¹² Reasonableness is defined within the context of this report as supportable and proper, given the underlying information.

¹³ Feasibility is defined as based on the assumptions used, the plan is not likely to result in insufficient funds available for capital and ongoing operating costs necessary to support the proposed project without negative impacts or consequences to the existing Patient Panel.

Factor 5: Assessment of the Proposed Project's Relative Merit

Evaluation of 105 CMR 100.210(A)(5) shall take into account, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes, including alternative evidence-based strategies and public health interventions.

The Applicant considered and rejected two alternatives to the Proposed Project.

Alternative Option 1: Do not reactivate the second LINAC and continue to serve patients through the use of a single LINAC.

This option carries no capital expenses or additional operating costs. However, this option does not address the need of BID-P's patients to have unimpeded access to radiation therapy. This option would further limit scheduling options for patients, would limit the availability of machines for new SBRT treatment, and would place strain on the already over-capacity LINAC that the Hospital is currently using. If the LINAC was down for an extended period of time (more than a week), the patient's care could be transferred to South Shore Hospital Radiation Oncology, Good Samaritan Medical Center in Brockton, Brockton Hospital, Cape Cod Hospital, or Beth Israel Deaconess Medical Center in Boston if the patient needed to stay within the BILH system. If this were to happen, patients would likely be triaged to determine who needed to resume treatment most urgently, as the complexity and time involved with in transferring care in the middle of a treatment course is prohibitive. The Applicant notes that delays in treatment can adversely impact patient outcomes, quality of life, and patient satisfaction.

Alternative Option 2: Purchase an entirely new LINAC, rather than re-activating the existing LINAC.

This option has a capital expense of \$2,839,397 and an operating cost that would equal the Proposed Project. This alternative would achieve the same overall quality outcomes as re-activating the existing LINAC. However, purchasing a new LINAC is a costly alternative to using the existing machine and there would be delays in implementing the proposal, as the old machine would need to be removed and the new machine would need to be purchased and installed.

Analysis

Staff finds that the Applicant has appropriately considered the quality, efficiency, and capital and operating costs of the Proposed Project relative to the potential alternative. As a result of information provided by the Applicant, staff finds the Applicant has reasonably met the standards of Factor 5.

Factor 6: Fulfillment of DPH Community-based Health Initiatives Guideline

Summary and relevant background and context for this application: This project constitutes DoN-Required Equipment obtained by a hospital. Standard practice is to contribute the CHI dollars to a local CHI project and the Statewide Community Health and Healthy Aging Funds (CHHAF). Given the size of the CHI contribution (\$1,725), DPH and the Applicant have agreed that the BID-Plymouth will contribute CHI dollars solely to the Statewide CHHAF.

Findings and Recommendations

Based upon a review of the materials submitted and with the addition of certain conditions, set out below and imposed pursuant to 105 CMR 100.360(A), the Department finds that the Applicant has met each DoN factor and recommends approval of this Application for Determination of Need.

Other Conditions

1. Payment should be made out to the Massachusetts Community Health and Healthy Aging Funds in the full amount of \$1,725, and should be submitted within 30 days from the date of Notice of Approval to:

Health Resources in Action, Inc., (HRiA)
2 Boylston Street, 4th Floor
Boston, MA 02116
Attn: MACHHAF c/o Ms. Bora Toro
DoN project #: #BILH-23082513-RE

2. Please also **send a PDF image of the check** (or confirmation of payment) to DONCHI@mass.gov and dongrants@hria.org. If you should have any questions or concerns regarding payment, please contact the CHI team at DONCHI@mass.gov.

Appendix I: Measures for Annual Reporting

Outcome Measures

To assess the impact of the Proposed Project, the Applicant will report on the following outcome measures. The Applicant will report this information to the Department's DoN Program staff as part of its annual report required by 105 CMR 100.310(A)(12) following implementation of the Proposed Project. For all measures, the Applicant will provide to the program a baseline upon implementation of each project component, along with updated projections, which the program will use for comparison with the annual data submitted. Reporting will include a description of numerators and denominators.

1. **Wait Times:** The Proposed Project seeks to address the need for timely access to radiation services.

Measure: The average wait time in working days between simulation and the start of treatment for SBRT, IMRT, 3D, and Urgent radiation services.

Baseline: August 2022 wait times as listed below.

Average number of working days between Simulation and Start				
	SBRT	IMRT	3D	Urgent
August 2022	11	12	13	4

- 2. Patient Satisfaction:** Patients that are satisfied with their care are more likely to seek additional treatment when necessary.

Measure: Patient satisfaction scores will be used to determine the impact of the Proposed Project on quality of life.

Numerator = Number of top scores, such as “likely to recommend” or “highly satisfied”.

Denominator = Total number of survey respondents

Baseline: 98.2% based on 204 surveys completed by patients

Projections: 98.5-100% based on completion of 250 surveys

Monitoring: Results will be reviewed monthly by the Manager.

- 3. Treatment Access:** This measure will monitor the total number of patients who receive radiation therapy via LINAC at BID-P following implementation of the Proposed Project.

Measure: By tracking the number of patients treated using the LINAC, BID-P will be able to assess how the Proposed Project has improved access.

Baseline: 436 New Start Patients in 2022

Projections: 466 New Start Patients in 2024

Monitoring: Results will be reviewed monthly by the Manager.

Appendix II: BILH Patient Panel Demographic Profile

BILH Patient Panel Demographic Profile

	FY2022 Totals
Total Unique Patients	1,633,109
Gender	
Female	60.23%
Male	39.63%
Other ¹⁴	0.14%
Total	100.00%
Age	
0-17	11.08%
18-64	60.84%
65+	28.09%
Total	100.00%
Race	
White	74.05%

¹⁴ Patients for whom a gender is not specified or whose gender varies across visits over the time period are included in “Other.”

	FY2022 Totals
Black or African American	5.45%
American Indian or Alaska Native	0.13%
Asian	6.45%
Native Hawaiian or Other Pacific Islander	0.07%
Other ¹⁵	6.66%
Unknown	5.71%
Patient Declined	1.49%
Total	100.00%
Ethnicity¹⁶	
Hispanic/Latino	5.95%
Not Hispanic/Latino	80.38%
Patient Declined	2.91%
Unknown	7.36%
Other	3.41%
Total	100.00%
Payer Mix	
Commercial	53.23%
Medicare	26.02%
Medicaid	10.14%
Multiple Payers	2.65%
Other ¹⁷	7.96%
Unknown	0.00%
Total	100.00%

Appendix III: Literature Review

NAT'L CANCER INSTITUTE, *Radiation Therapy to Treat Cancer* (updated Jan. 8, 2019), <https://www.cancer.gov/about-cancer/treatment/types/radiation-therapy> [hereinafter NCI, *Radiation Therapy*].

Sarah Hegarty et al., *Please Place Your Seat in the Full Upright Position: A Technical Framework for Landing Upright Radiation Therapy in the 21st Century*. 12 FRONTIERS ONCOLOGY (Article) 821887 (2022).

See AM. COLL. RADIOLOGY, *ACR-ARS Practice Parameter for Intensity-Modulated Radiation Therapy (IMRT)* (2021), <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/imrt-ro.pdf>; NCI, *External Beam*.

¹⁵ As a newly merged health system, BILH has not yet fully implemented a standardized data collection methodology for BILH Hospitals. As a result, "Other" may include patients whose race and/or ethnicity varied over time, as well as patients who did not report their race and/or ethnicity. Furthermore, patients who declined to report their race and/or ethnicity might also be captured in "Unknown" or "Patient Declined". "Other" is a choice for patients to select if they do not feel that their race/ethnicity is reflected in the list of choices.

¹⁶ Ethnicity information is not available at the system-level for three hospitals: BID-Milton, BID-Needham, and BID-Plymouth. For the remaining BILH hospitals, ethnicity information is self-reported. Patients for whom ethnicity is not specified are included in "Patient Declined," "Unknown," or "Other," per the local facility's data collection methodology. Patients for whom ethnicity varies across visits over the time period are included in "Other."

¹⁷ Includes self-pay, health safety net, and liability insurance coverage other than worker's compensation for an injury event.

A Taylor & MEB Powell, *Intensity-Modulated Radiotherapy--What Is It?* 4 CANCER IMAGING 68, 68-73 (2004).

NAT'L CANCER INSTITUTE, *External Beam Radiation Therapy for Cancer* (May 1, 2018), <https://www.cancer.gov/about-cancer/treatment/types/radiation-therapy/external-beam> [hereinafter NCI, *External Beam*].

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Kavitha Prezzano et al., *Stereotactic Body Radiation Therapy for Non-Small Cell Lung Cancer: A Review*, 10 WORLD J. CLINICAL ONCOLOGY 14, 14-27 (2019); Maged Ghaly et al., *New Potential Options for SBRT in Pancreatic Cancer*, 4 CANCER MEDICINE J. (Supplement 3) 41, 41-50 (2021); Chia-Lin Tseng et al, *Spine Stereotactic Body Radiotherapy: Indications, Outcomes, and Points of Caution*, 7 GLOBAL SPINE J. 179, 179-197 (2017).

MAYO CLINIC, *Stereotactic Radiosurgery*, <https://www.mayoclinic.org/tests-procedures/stereotactic-radiosurgery/about/pac-20384526>.

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<https://www.chiamass.gov/assets/docs/r/hospital-profiles/2021/FY21-Massachusetts-Hospital-Profiles-Technical-Appendix.pdf>

^b Center for Health Information and Analysis (CHIA). *Beth Israel Lahey Health*.

<https://www.chiamass.gov/assets/docs/r/hospital-profiles/2021/hospital-health-systems/Beth-Israel-Lahey.pdf>

^c U.S. Census Bureau, "Demographic Profile, July 1, 2022 (V2022) – Plymouth County, MA," Quick Facts, accessed December 13, 2022. <https://www.census.gov/quickfacts/plymouthcountymassachusetts>

^d CTRS. FOR DISEASE CONTROL, DIV. CANCER PREVENTION & CONTROL, *Cancer Prevention During Older Adulthood* (Sept. 3, 2021), <https://www.cdc.gov/cancer/dccp/prevention/older-adulthood.htm>.

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^f *Cancer Incidence Estimator*, ADVISORY BOARD, <https://www.advisory.com/topics/oncology/2020/06/cancer-incidence-estimator> (last visited Aug. 31, 2023).

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ⁱ NAT'L CANCER INSTITUTE, *Types of Radiation Therapy*, <https://training.seer.cancer.gov/treatment/radiation/types.html>.

^j Jeremy P Harris et al., *Association of Survival With Shorter Time to Radiation Therapy After Surgery for US Patients With Head and Neck Cancer*, 144(4) JAMA OTOLARYNGOLOGY – HEAD & NECK SURGERY 349–359 (2018).

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