



Agreed Settlement

Applicant(s): Connecticut Proton Therapy Center, LLC
932 Northrop Road
Wallingford, Connecticut 06492

Hartford HealthCare Corporation
1 State Street
Hartford, Connecticut 06103

Yale-New Haven Health Services Corporation
20 York Street
New Haven, Connecticut 06511

Docket Number: 19-32339-CON

Project Title: Acquisition of Equipment Utilizing Proton Beam Technology that has Not Previously been Utilized by the State.
Acquisition of a Computed Tomography (CT) Simulator

I. Project Description

Connecticut Proton Therapy Center, LLC (“CPTC”), Hartford HealthCare Corporation (“HHC”) and Yale-New Haven Health Services Corporation (“YNHHS”) (collectively, “Applicants”) seek authorization for the acquisition of equipment utilizing proton beam technology that has not previously been utilized in Connecticut. The Applicants also seek authorization to acquire a CT Simulator to be used with this new technology. The Applicants and the Office of Health Strategy (“OHS”) have resolved all issues in the Applicants’ application pursuant to this Agreed Settlement (“Settlement”). The Applicants and OHS are hereinafter referred to as the “Parties.”

II. Procedural History. The Parties agree to the following procedural history:

The Applicants published notice of their intent to file a Certificate of Need (“CON”) application in *The Hartford Courant* (Hartford) on September 18, 19 and 20, 2019, in the *Record Journal* (Meriden) on September 18, 19, and 20, 2019, and in the *New Haven Register* (New Haven) on September 18, 19, and 20, 2019. On December 17, 2019, the Health Systems Planning (“HSP”) unit of OHS received the CON application from the Applicants for the above-referenced project and OHS deemed the application complete on August 10, 2020.

On March 10, 2020, Governor Ned Lamont issued an emergency declaration of public health and civil preparedness in response to the COVID-19 global pandemic.¹ On March 14, 2020, Governor Lamont issued Executive Order 7B² which, in relevant part, waived public meeting and hearing requirements to mitigate the spread of COVID-19.

On October 30, 2020, OHS published notice in the *Hartford Courant*, *Record Journal* and *New Haven Register* announcing a virtual hearing on November 18, 2020. On November 5, 2020, Executive Director Victoria Veltri designated Attorney Micheala Mitchell as the Hearing Officer for the proceedings.

OHS convened the hearing on November 18, 2020, pursuant to Connecticut General Statutes (Conn. Gen. Stat.) § 19a-639a(f)(2). OHS asserts that the proceedings were not a contested case; however, they were conducted in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of Conn. Gen. Stat.). Attorney Mitchell closed the hearing record on April 15, 2021.

On August 16, 2021, Executive Director Victoria Veltri designated Kimberly Martone, Deputy Director/Chief of Staff, as the Hearing Officer for the proceedings. On August 18, 2021, the record was opened for the limited purpose of allowing the Applicants to submit clarifying information. Deputy Director/Chief of Staff Kimberly Martone closed the hearing on October 29, 2021. Subsequent to the hearing, the Parties engaged in settlement negotiations that resulted in this Settlement.

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¹ Declaration of Public Health and Civil Preparedness Emergencies. Governor Ned Lamont, March 10, 2020, <https://portal.ct.gov/-/media/Office-of-the-Governor/News/20200310-declaration-of-civil-preparedness-and-public-health-emergency.pdf?la=en>

² Executive Order 7B, Governor Ned Lamont, March 14, 2020, <https://portal.ct.gov/-/media/Office-of-the-Governor/Executive-Orders/Lamont-Executive-Orders/Executive-Order-No-7B.pdf?la=en>

III. Provisions of Law. The Parties agree that the following provisions of law apply to this matter:

The proposal constitutes the acquisition of equipment utilizing technology that has not previously been utilized in the state and the acquisition of a CT Simulator pursuant to Conn. Gen. Stat. §§ 19-638(a)(10) and (13). OHS considered the factors set forth in Conn. Gen. Stat. § 19a-639(a) prior to reaching this Settlement with the Applicants.

CON applications are decided on a case-by-case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case.

IV. Findings of Fact and Conclusions of Law. The Parties agree to the following Findings of Fact and Conclusions of Law based upon the evidence in the record, including the evidence presented at the hearing:

A. Introduction and Background

1. HHC is an integrated health system in Connecticut that includes seven acute care hospitals and an ambulatory healthcare network. Hartford Hospital is an 867-bed tertiary care teaching hospital affiliated with the University of Connecticut School of Medicine, and a Level I Trauma Center serving the New England region. Ex. A, p. 20.
2. YNHHS is a comprehensive healthcare system in Connecticut that includes five hospitals, several specialty networks and the Northeast Medical Group (“NEMG”). YNHHS is affiliated with Yale University and the Yale School of Medicine’s (“YSM”) clinical physician practice, Yale Medicine. Yale New Haven Hospital (“YNHH”) is a 1,541-bed tertiary medical center and is the primary teaching hospital for YSM. Ex. A, pp. 21, 22.
3. CPTC is a joint venture limited liability company formed between HHC and YNHHS for purposes of owning and operating a 25,000 square foot proton therapy center (“the Center”) at 932 Northrop Road in Wallingford, CT. Ex. A, pp. 23, 27.
4. HHC and YNHHS will also partner with a third party to serve as both the developer/operator of the Center and the future majority non-controlling equity owner. Ex. A, p. 24.
5. The Applicants selected Proton International “to assist with our technology selection, financing, and constructing, as well as the management and operation of the facility and for its reputation as an established and experienced developer and operator of proton centers throughout the country.” Testimony of Donna Handley, Senior Vice President, Hartford Hospital, Hearing Transcript, p. 20.

6. Following the execution of the final agreement, CPTC will be owned and operated by HHC (24.5%), YNHHS (24.5%) and Proton International, LLC (51%).³ Ex. C, pp. 815-816.
7. The Center will house a CT simulator and one-room proton therapy delivery system, exam rooms, changing rooms, physics and dosimetry work areas, administrative areas and waiting rooms. Ex. A, p. 28.
8. If this Settlement is accepted, the Applicants plan to purchase a Proteus@ONE Compact Image-Guided Intensity Modulated Proton Therapy machine -- equipment not previously used in Connecticut. Ex. A, p. 20.
9. If this Settlement is accepted, the Applicants plan to also purchase a CT Simulator to be used exclusively for proton beam therapy (“PBT”) treatment planning on-site at the Center. Ex. A, p. 76.
10. If this Settlement is accepted, CPTC shall seek licensure as an Outpatient Clinic from the Connecticut Department of Public Health (“DPH”) and shall register with the Connecticut Department of Energy and Environmental Protection (“DEEP”) as both an x-ray/accelerator and a radioactive materials facility.⁴ Ex. A, p. 31.
11. If this Settlement is accepted, construction on the Center will begin with an estimated 18 month to two (2) year construction and installation period. Ex. A, p. 29.

B. Demonstration of Need. The Parties agree to the following with respect to the issue of need:

12. The Applicants’ target population includes any Connecticut resident who requires or may benefit from receiving proton therapy. Ex. A, p. 38.
13. Research studies have concluded that proton therapy has demonstrated positive outcomes for patients when compared with traditional radiation therapy in the following specific types of cancer:
 - a. **Retinoblastoma**⁵: showed the incidence of therapy induced second malignancies was significantly different between the modalities (proton vs. photon: 0% vs 14%; P=.015).
 - b. **Pediatric oncology**⁶: decreased toxicity in tumors outside of the CNS for PBT have been reported in sarcomas, Hodgkin disease, and neuroblastoma.

³ The ownership composition reflects the proposed equity structure of CPTC after the CON is approved and Proton International’s buy-in takes place.

⁴ The Connecticut DEEP Radiation Control Unit indicated that current state regulations do not address proton therapy facilities and that the DEEP Commissioner may need to issue a special permit.

⁵ Sethi, Roshan V. et al; Second Nonocular Tumors Among Survivors of Retinoblastoma Treated with Contemporary Photon and Proton Radiotherapy. Cancer January 1, 2014, pp. 126-133.

⁶ Baglia, S. and Yock, T.: Proton Beam Therapy in Pediatric Oncology; Current Opinion-Pediatrics, Vol. 31, No. 1, Feb. 2019, pp. 28-33; Tamura, M. et al: Lifetime Attributable Risk of Radiation-induced Secondary Cancer from Proton Therapy Compared with that of Intensity-modulated X-ray Therapy in Randomly Sampled Pediatric Cancer Patients; Journal of Radiation Research; Vol. 58, No. 3, 2017, pp. 363-371; Weber, D. et al: Proton therapy for pediatric malignancies: Fact, figures and costs. A joint consensus statement from the pediatric subcommittee of

- c. **Head and neck cancer**⁷: uniquely suited for the complex anatomy of tumors and sensitive surrounding organs to avoid inflicting detrimental adverse effects on swallowing, salivation, hearing, and cosmesis.
- d. **Brain and Skull Base Tumors**⁸: has a finite range in tissue, zero exit dose, and lower integral dose resulting in better dose conformity when the therapy tolerance of surrounding organs at risk (brainstem, temporal lobes, optic nerve) is lower, or for tumors associated with long-term survival to mitigate radiation-induced adverse effects.
- e. **Esophageal Cancer**⁹: further risk reduction is achieved with proton therapy, reducing radiation dose received by the heart and lungs, lowering toxicity, and helping to prevent pneumonitis, pericarditis, and myocardial infarction.
- f. **Lung Cancer**¹⁰: shown to offer a significant dosimetric advantage in non-small cell lung cancer (“NSCLC”) over photon therapy, with a decrease in dose to vital organs at risk (“OARs”), including the heart, lungs, and esophagus.
- g. **Breast Cancer**¹¹: emerging data suggests the potential to reduce adverse effects and toxicity from radiation exposure to the lungs and heart.
Ex. A, pp. 33-36.

14. Incidence rates from 2013-2017 from the American Cancer Society® Cancer Statistics Center’s published article, *Cancer Facts & Figures 2021*, reflect that Connecticut’s cancer incidence for all Cancer sites was 504.9 for males and 449.9 for females, above the respective national rates of 489.1 and 422.4. This puts Connecticut as the 17th highest state for incidence for all cancer sites for males and 10th highest state for incidence for all cancer sites for females. <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf>

PTCOG, PROS, and EPTN; *Radiotherapy and Oncology*, 128 (2018) pp. 44-55; Ladra, M. et al: Proton therapy for central nervous system tumors in children; *Pediatric Blood & Cancer*, 2018, 65:e27046; <https://doi.org/10.1002/pbc.27046>; Huynh, M., et al; Current status of proton therapy outcome for pediatric cancers of the central nervous system – Analysis of the published literature. *Cancer Treatment Reviews*. 70 (2018) pp. 272-288.

⁷ Leeman, J. et al.: Proton therapy for head and neck cancer: expanding the therapeutic window. *Lancet Oncol* 2017; 18: e254-65.

⁸ Ahmed, S.K. et al: Protons vs Photons for Brain and Skull Base Tumors; *Seminars in Radiation Oncology*, 2017, 11.001, pp. 97-107.

⁹ Chuong, MD et al: Improving Outcomes for Esophageal Cancer using Proton Beam Therapy; *International Journal of Radiation Oncology•biology•physics*, 2016, Vol. 95, No. 1, pp. 488-497.

¹⁰ Vyfhuis, M. et al: Advances in proton therapy in lung cancer; *Therapeutic Advances in Respiratory Disease*, 2018, Vol. 12: 1-16.

¹¹ Braunstein, L.Z. and Cahlon, O.: Potential Morbidity Reduction with Proton Radiation Therapy for Breast Cancer; *Seminars in Radiation Oncology*, 2018, 138-149.

15. To estimate cancer incidences for 2018, the Applicants’ methodology begins by averaging 2012-2016 cancer incidence for cancers most likely to be treated with proton beam radiation therapy. From this, the Applicants estimated a tumor cancer base of 23,749 on an average annual basis.

TABLE 2
Connecticut Tumor Registry

State Tumor Registry			
Tumor Site	Consensus	Patients	PB Eligible
Breast	5%	4,269	128
Chest/Lung	10%	2,710	163
CNS	20%	751	90
GI	10%	3,394	204
GU	5%	4,271	128
Gyn	5%	998	30
H&N	15%	1,299	117
Lymphoma	5%	937	28
Other	5%	3,483	104
Sarcoma	10%	n/a	-
Skin	0%	1,638	-
TOTAL		23,749	992

Ex. KK, pp. 26-27

*Additional Data source confirmation: DPH Connecticut Tumor Registry; Surveillance, Epidemiology, and End Results (SEER) Program (www.seer.cancer.gov) SEER*Stat Database: Incidence – SEER Research Plus Data, 9 Registries, Nov 2020 Sub (1975-2018) – Linked To County Attributes – Total U.S., 1969-2019 Counties, National Cancer Institute, DCCPS, Surveillance Research Program, released April 2021, based on the November 2020 submission.*

16. To estimate potential volume at the proposed CPTC, HHC and YNHHS worked with in-house radiation oncologists and other experts to reach a consensus on the percentage of cancer patients receiving radiation therapy that would likely be referred for PBT, by type of cancer. HHC and YNHHS assumed that approximately 60% of these cancer patients are treated with radiation therapy and a subset of these patients would likely be referred for proton beam for specific types of cancers. Ex. KK, p. 26.

17. The number of patients by tumor site is multiplied by 60% and then multiplied by the consensus value to calculate eligible patients by cancer type. These individual amounts are then summed to estimate the statewide proton eligible patient base of 992. Ex. KK, p. 27.

18. YNHHS and HHC looked at the State Tumor Registry by tumor site and used the consensus percent to identify the number of patients that would originate from YNHHS and HHC. The remaining 10% is assumed to be patients referred to the new CPTC by other providers in the first year of operations, 15% the second year, and 20% in the thereafter. YNHHS and HHC anticipate that volumes will increase over a two-year period before reaching expected capacity. Ex. KK, pp. 26-27.

19. Consensus indicates that those who would likely be referred for PBT is between 5%-20% of non-pediatric cancer patients, averaging a 9% referral rate. Ex. KK, pp. 26-27.
20. Based on consensus, the percentage of pediatric patients that would likely be referred for proton therapy ranges from 60% for non-central nervous system cancer patients up to 80% for central nervous system cancer patients. Ex. KK, p. 27.
21. Assuming a ramp-up in volume and applying the consensus referral rates for specific types of cancers, HHC/YNHHS’s methodology results in CPTC volume estimates of approximately 208 patients in 2022 (21% of 992), 397 (40%) in 2023, 479 (48%) in 2024 and 487 (49%) in 2025.

**TABLE 3
PROJECTED UTILIZATION**

Projected Volumes		Patient Referral Source		
Fiscal Year	Patients	YNHHS	HHC	Other Providers
2022	208	99	89	21
2023	397	177	160	60
2024	479	202	181	96
2025	487	205	185	97
Total	1,571	683	615	274

Ex. C, pp. 820-821.

22. The Applicants project the following patient volumes by cancer type at the CPTC:

**TABLE 4
PROJECTED UTILIZATION BY CANCER TYPE**

Cancer Type	%	FY 2022	FY 2023	FY 2024	FY 2025
Central Nervous System (CNS)	28%	59	113	136	138
Chest/Lung	16%	34	65	79	80
Breast	14%	29	55	66	67
Head & Neck (H&N)	10%	22	41	50	50
Sarcoma	9%	19	35	43	43
Genitourinary (GU)	8%	17	33	40	41
Gastrointestinal (GI)	6%	12	22	27	27
Lymphoma	5%	10	19	23	23
Gynecological (Gyn)	3%	6	11	13	14
Other	1%	1	2	3	3
Skin	0%	0	0	0	0
Total Patients	100%	208	397	479	487

Ex. C, pp. 820-821.

23. PBT for cancers of the CNS, and head and neck tumors, which comprise 38% of the CPTC’s projected volume, is accepted as medically necessary for these patients and currently is a covered service by three of the four commercial payers (i.e., Anthem BCBS, UHC Oxford, Aetna). Ex. KK, pp. 3-4; Ex. C, pp. 849-1678.
24. The following table is a summary of the positions taken by Anthem BCBS, UHC Oxford, and Aetna, with respect to policy coverage and appeal outcomes for specific individual cases of proton therapy treatment:

**TABLE 5
PROTON THERAPY TREATMENT BY CANCER TYPE AND PAYER**

PBT Coverage by Top Commercial Insurers in Connecticut

Cancer Type	Payer							
	Anthem BCBS		UHC/Oxford		Aetna		Cigna	
	Policy	Appeal	Policy	Appeal	Policy	Appeal	Policy	Appeal
Base of Skull Tumors	✓		✓		✓		✓	
Bone & Soft Tissue		✓		✓				
Arteriovenous Malformation (AVM) or Central Nervous System Tumors	✓		✓		✓			✓
Breast		✓		✓		✓		✓
Cervix & Uterine				✓				
Chest/Lung		✓		✓				
Genitourinary				✓				
GI (Digestive)		✓		✓		✓		✓
Hepatobiliary cancer [HCC/intrahepatic cholangiocarcinoma]	✓		✓		✓		✓	
Head & Neck	✓		✓		✓			✓
Lymphoma		✓		✓				✓
Melanomas [Ocular]	✓		✓		✓		✓	
Skin				✓				
Spine (primary or metastatic tumors of the spine)		✓			✓			✓
Stage IIA Seminoma							✓	
Pancreatic		✓		✓		✓		✓
Pediatric	✓		✓		✓		✓	
Prostate				✓				
Re-irradiation	✓			✓		✓		✓

Ex. KK p.4

25. The approval rate of Medicare Advantage patients is 100% as long as the ICD-10 falls under the National Government Services Local Coverage Determination Policy (“LCD”). Ex. E, pp. 1913, 1918-1937. Per the LCD, PBT is considered “reasonable” for Medicare patients in instances where sparing the surrounding normal tissue cannot be adequately achieved with photon-based radiotherapy and is of added clinical benefit to the patient. The LCD provides examples of when PBT delivers such “added clinical benefit.” Ex. E, pp. 1922-1923.
26. The Centers for Medicare & Medicaid Services (“CMS”) LCD indications for coverage are similar to the American Society for Radiation Oncology (“ASTRO”) Model Policies for Proton Beam Therapy. ASTRO issues policy guidelines on payer coverage for proton therapy. These guidelines are described as evidence-based standards that were developed to efficiently communicate the correct coverage policies for proton therapy. Ex. A, pp. 522-541.

27. Based on CMS medical necessity requirements and published clinical data, disease sites that frequently support the use of PBT include the following:

- a. Ocular tumors, including intraocular melanomas;
- b. Tumors that approach or are located at the base of skull, including but not limited to: Chordoma Chondrosarcomas Primary or metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment or where the spinal cord has previously been irradiated;
- c. Unresectable benign or malignant central nervous system tumors to include but not be limited to primary and variant forms of astrocytoma, glioblastoma, medulloblastoma, acoustic neuroma, craniopharyngioma, benign and atypical meningiomas, pineal gland tumors, and arteriovenous malformations;
- d. Primary hepatocellular cancer treated in a hypofractionated regimen;
- e. Primary or benign solid tumors in children treated with curative intent and occasional palliative treatment of childhood tumors when at least one of the four criteria noted above apply;
- f. Patients with genetic syndromes making total volume of radiation minimization crucial such as but not limited to NF-1 patients and retinoblastoma patients;
- g. Pituitary neoplasm;
- h. Advanced staged (e.g., T4) and/or unresectable malignant lesions of the head and neck;
- i. Malignant lesions of the paranasal sinus, and other accessory sinuses; and
- j. Unresectable retroperitoneal sarcoma.

Ex. E, pp. 1922-1923.

28. Medicare coverage of PBT for the following cancers is limited to providers who have demonstrated experience in data collection and analysis with a history of publication in peer-reviewed medical literature:

- a. Unresectable lung cancers and upper abdominal/peri-diaphragmatic cancers;
- b. Advanced stage, unresectable pelvic tumors including those with peri-aortic nodes or malignant lesions of the cervix;
- c. Breast cancers;
- d. Unresectable pancreatic and adrenal tumors;
- e. Skin cancer with macroscopic perineural/cranial nerve invasion of skull base;
- f. Unresectable malignant lesions of the liver, biliary tract, anal canal and rectum;
- g. Prostate cancer, without distant metastases;
- h. Hodgkin or Non-Hodgkin Lymphoma involving the mediastinum or in non-mediastinal sites where PBT has the potential to reduce the risk of pneumonitis or late effects of radiation therapy (secondary malignancy, cardiovascular disease, or other chronic health conditions); and
- i. Re-irradiation where prior radiation therapy to the site is the governing factor necessitating PBT in lieu of other radiotherapy.

Ex. E, p. 1923.

29. Connecticut Medicaid (Husky Health Connecticut) requires prior authorization for those patients referred for proton therapy services. Connecticut Medicaid uses eviCore as its utilization manager for radiation oncology. Ex. KK, pp. 182-186. Medical necessity and patient eligibility for proton therapy services is determined using the clinical criteria established under eviCore. Ex. KK, pp. 5-6, 138-181. The ASTRO Proton Beam Therapy Model Policy recommendations, together with a review of the published evidence and guidelines, were used to develop eviCore's coverage guidelines. Ex. KK, p. 140.

30. According to eviCore's Radiation Oncology Criteria, PBT is considered medically necessary for the curative treatment of any of the following:

- Chordomas and chondrosarcomas of the base of the skull, localized and in the postoperative setting
- Uveal melanoma, when PBT is considered preferential compared to brachytherapy
- Maxillary sinus or paranasal/ethmoid sinus tumors
- Select cases of localized unresectable hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma (see Discussion section)
- Stage IIA seminoma
- Malignancies requiring craniospinal irradiation (CSI)

Ex. KK, p. 139.

31. According to eviCore's Radiation Oncology Criteria, PBT is also considered medically necessary under Medicaid guidelines for the treatment of pediatric malignancies (age less than 18 years). Ex. KK, p. 139.

32. According to eviCore's Radiation Oncology Criteria, available evidence suggests that PBT may be essentially equivalent to photons for the following malignancies and, where PBT is significantly more costly than IMRT, coverage for PBT will depend upon the applicable health benefit plan definition of medical necessity:

- Locally advanced breast cancer when treating the internal mammary nodes
- Primary central nervous system (CNS) cancer
- Esophageal cancer
- Head and neck cancer (excluding T1-T2N0M0 laryngeal cancer)
- Remaining cases of unresectable hepatocellular carcinoma and intrahepatic cholangiocarcinoma
- Hodgkin lymphoma
- Non-Hodgkin lymphoma
- Stage II-III non-small cell lung cancer
- Pancreatic cancer
- Prostate cancer (intact and postoperative)
- Retroperitoneal sarcoma
- Thymomas and thymic carcinoma

Ex. KK, pp. 139-140.

33. Because proton therapy services are not available in the State of Connecticut, the administrative review process is burdensome and a barrier to access for Medicaid patients. If a Medicaid patient who resides in Connecticut is clinically appropriate for PBT, Connecticut Medicaid must first approve the service and then negotiate a single case rate with an out-of-state PBT provider. If PBT is available in state, Connecticut Medicaid will establish its own fee schedule, which intuitively should be less burdensome and time consuming than the process of negotiating with other states' Medicaid programs. Ex. E, p. 1913.

34. The Applicants project the following patient volumes by patient age at the CPTC:

**TABLE 6
PROJECTED UTILIZATION BY AGE**

Age Range	%	FY 2022	FY 2023	FY 2024	FY 2025
0-17	5%	11	21	26	26
18-64	44%	92	176	212	216
65+	50%	105	200	241	245
Total	100%	208	397	479	487

Ex. C, p. 820.

35. The 2012 Statewide Healthcare Facilities and Services Plan states, in relevant part, that a CON application for new technology shall be consistent with the Plan if the following criteria are met:

- a. The new technology is efficacious;
- b. The equipment is certified for its proposed use by the United States Food and Drug Administration (“USFDA”);
- c. Preference shall be given to proposals that involve multi-institutional arrangements;
- d. Preference shall be given to proposals that place the new technology in a medical school or other teaching or research facility;
- e. Before acquiring new technological equipment, applicants shall have complementary diagnostic and treatment services available to support the new program;
- f. Applicants shall demonstrate that personnel who will staff the new technology are qualified and adequately trained;
- g. Applicants shall report utilization and demographic data necessary to evaluate the technology and to facilitate State planning.

Source: Connecticut Statewide Health Care & Facilities Plan (October 2012), p. 67.

36. The IBA Proteus®ONE proton system has two Section 510(k) approvals from the USFDA -- one approval is for the proton therapy system and the other is for an update to the system's control pendent. Ex. C, p. 807.
37. YNHH's Smilow Cancer Hospital and the HHC's Cancer Institute provide patients with a cancer diagnosis, treatment and access to advanced treatment options and clinical trials. Ex. A, pp. 22-23.
38. "Proton therapy is typically administered five days per week, and a course of therapy can range from one to nine weeks depending upon the type of cancer, the location of the tumor, and other patient related factors. Industry average for proton radiation therapy has been on the order of 27 daily treatments for approximately five and a half weeks." Testimony of Dr. Andrew Salner, Director of the Hartford HealthCare Cancer Institute at Hartford Hospital, Hearing Transcript, pp. 38-39.
39. Claims data indicates that in 2019 more than 500 claims were submitted for Connecticut residents receiving proton therapy treatment at out-of-state facilities. Source: CT Office of Health Strategy All-Payer Claims Database for fully insured commercial, State employees and retirees and Medicare claims only.
40. The Applicant health systems are both affiliated with medical schools, have teaching hospitals within their respective systems and provide advanced diagnosis, treatment, and clinical trials for cancer patients in the state in accordance with the statewide health care facilities and services plan.
41. The YNHHS and HHC systems have identified Connecticut residents with specific types of cancers that may benefit from proton therapy in Wallingford.
42. Current PBT patients are traveling out of state and some cancer patients will continue to be served at their existing radiology providers. However, patients with specific cancer types that are in need of a different, more appropriate level of care, will be referred to the Center voluntarily. Accordingly, there will be minimal impact on existing providers.
43. The Applicants have demonstrated clear public need for the proposal.
44. The Applicants have identified the target population as any Connecticut resident, or those from surrounding states, that may require or benefit from proton therapy services for specific types of cancers. The Applicants have not proven that all services provided will be routinely covered under clinical care guidelines by commercial carriers or by Medicare or Medicaid but have asserted that these services are being covered by payers under many circumstances and would be covered as proton beam therapy becomes more common, noting also that under certain patient-specific appeals, coverage may have been granted. While the Applicants have generally satisfied Conn. Gen. Stat. §§ 19a-639(a)(2), (3) and (7), the Applicants agree to comply with the conditions attached hereto.

C. Access. The Parties agree to the following with respect to the issue of access:

- 45. The primary service area is the State of Connecticut. Ex. A, p. 31.
- 46. CPTC will also admit patients from surrounding states. Ex. FF, p. 1.
- 47. CPTC will be open to all patients regardless of system affiliation or referral source -- non-system referrals will come in the same manner as they currently do for conventional radiation treatment. Ex. C, p. 819; Ex. FF, p. 1.
- 48. The Applicants' rationale in choosing the site in Wallingford, Connecticut is because of its central location, access to main interstate highways, availability of parking, and access to hotels in the vicinity. Ex. A, p. 42.
- 49. The Applicants used historical blended payer mix data from both the HHC and YNHHS cancer programs to model the projected payer mix for PBT services:

OHS TABLE 7
APPLICANTS' CURRENT & PROJECTED PAYER MIX [Proton Therapy Center]

Payer	Most Recently Completed FY ____		Projected					
			FY 2022		FY 2023		FY 2024	
	Volume: (indicate type)	%	Volume: (indicate type)	%	Volume: (indicate type)	%	Volume: (indicate type)	%
Medicare	N/A		83	40.0%	159	40.0%	192	40.0%
Medicaid	N/A		35	17.0%	68	17.0%	81	17.0%
TRICARE	N/A		10	5.0%	20	5.0%	24	5.0%
Total Government	N/A		128	62.0%	247	62.0%	297	62.0%
Commercial Insurers	N/A		66	31.5%	125	31.5%	151	31.5%
Uninsured	N/A		1	0.2%	1	0.2%	1	0.2%
Self-pay	N/A		2	1.0%	4	1.0%	5	1.0%
Workers Compensation /Other	N/A		11	5.3%	20	5.3%	25	5.3%
Total Non-Government	N/A		80	38.0%	150	38.0%	182	38.0%
Total Payer Mix	N/A		208	100.0%	397	100.0%	479	100.0%

Ex. A, pp. 69-70.

- 50. CPTC shall apply to be a Medicaid provider prior to opening. Ex. A, p. 50.
- 51. Traveling for proton therapy is costly for more than one parent at a time. The proposal will allow for local treatment and prevent the need for patients and families to relocate for periods

of time and divide families in order to receive treatment. Testimony of Matthew Somberg, Father of a proton therapy recipient, Hearing Transcripts, pp. 157-160.

52. The Applicants have satisfactorily demonstrated that the proposal will improve accessibility of healthcare delivery for adults and children within the state that do not have access to proton therapy services for specific types of cancer, pursuant to subsection Conn. Gen. Stat. § 19a-639(a)(5).
53. The Applicants have also indicated that they will apply to become a Medicaid provider prior to opening, so Conn. Gen. Stat. § 19a-639(a)(10) is satisfied, and § 19a-639(a)(12) is not applicable as the proposal does not reduce access to services by Medicaid or indigent patients and the proposal will not result in any consolidation.
54. In order to ensure that the proposal will increase access to Medicare, Medicaid and commercially insured recipients in accordance with Conn. Gen. Stat. § 19a-639(a)(5), which includes ensuring payer coverage for PBT services to the greatest extent possible as alluded to in Finding of Fact 44, the Applicants agree to comply with the conditions attached hereto.

D. Quality. The Parties agree to the following with respect to quality:

55. Proton therapy is a more precise and less toxic form of cancer treatment for a variety of cancers, including head and neck cancer.¹² Ex. A, pp. 44, 706; Ex. FF 26.
56. Numerous studies listed below support the potential clinical benefits of proton therapy:
 - a. reduced injury to surrounding tissues and organs;
 - b. up to 60% less radiation than is typically delivered to non-cancerous tissues;
 - c. a higher dose of radiation is delivered to the tumor, increasing the chances that all of the targeted tumor cells are destroyed;
 - d. fewer and less severe side effects; and
 - e. an increased benefit to pediatric cancer patients.
Ex. A, pp. 45, 325 Proton Therapy in Oncology a General Overview of Current Practice, Opportunities, and Challenges (2015).
57. According to a comparative study of proton and photon (x-ray) therapies, protons, compared to photons, are often able to more specifically and precisely target a tumor, yielding significant improvement to the therapeutic ratio and improved patient outcomes.¹³ Ex. C, pp. 1780-1781; Comparison of Proton and Photon (X-ray) Therapies for Several Cancer Categories Bruce Haffty, MD, Rahul R. Parikh, MD.

¹² Proton therapy for head and neck cancer: expanding the therapeutic window Jonathan E Leeman, Paul B Romesser, Ying Zhou, Sean McBride, Nadeem Riaz, Eric Sherman, Marc A Cohen, Oren Cahlon, Nancy Lee

¹³ *Intensity Modulated Proton Therapy (IMPT) also has the further advantage over older passive scatter proton systems of dispensing with treatment accessories (brass collimators and wax compensators) that were used to optimize the shaping of proton dose distributions. These technology developments have reduced facility costs and as well as occupational radiation exposures.* Comparison of Proton and Photon (X-ray) Therapies for Several Cancer Categories Bruce Haffty, MD, Rahul R. Parikh, MD

58. The summaries below focus on the cancer types/sites proposed for CPTC and provide reference studies documenting how proton therapy treatment may improve patient outcomes:

- **Central Nervous System (CNS)**: Multiple studies indicate that the use of the proton RT has been shown to decrease brain injury, improve neurocognitive function, and reduce dose to the spinal vertebral bodies, which limits growth abnormalities of the spine in children. In addition, The Massachusetts General Hospital proton group stated that disease control rates for the proton-based RT patients were improved, relative to the benchmark for the photon-based RT patients who had medulloblastoma. The 5-year progression-free survival rate was 80% and the 5-year overall survival rate was 83%.

References:

- MacEwan I, Chou B, Moretz J, Loredo L, Bush D, Slater JD. Effects of vertebral-body-sparing proton craniospinal irradiation on the spine of young pediatric patients with medulloblastoma. *Adv Radiat Oncol* 2017;2:220-7.
- Yock TI, Yeap BY, Ebb DH, et al. Long-term toxic effects of proton radiotherapy for paediatric medulloblastoma: A phase 2 single-arm study. *The Lancet Oncology* 2016;17:287-98.
Ex. KK, pp. 9-11.

- **Brain**: Radiation therapy to the brain increases neurocognitive impairments, hormone dysfunction, secondary malignancy, and deterioration in quality of life. The use of protons improves dosimetry, which is beneficial for purposes of sparing normal neurological tissue.

References:

- Arvold ND, Niemierko A, Broussard GP, et al. Projected second tumor risk and dose to neurocognitive structures after proton versus photon radiotherapy for benign meningioma. *Int J Radiat Oncol Biol Phys* 2012;83:e495-500.
- Ahmed SK, Brown PD, Foote RL. Protons vs Photons for Brain and Skull Base Tumors. *Semin Radiat Oncol* 2018;28:97-107.
Ex. KK, pp. 11-12.

- **Base of Skull**: Multiple studies have shown that base of skull chordomas radiation therapy outcomes are improved, including local control and overall survival, when using proton therapy versus photon therapy. A study of the National Cancer Database (NCDB) compared photon to proton RT where proton therapy resulted in a significantly better 5-year overall survival when used alone or after surgery for both chordomas and chondrosarcomas.

References:

- Palm RF, Oliver DE, Yang GQ, Abuodeh Y, Naghavi AO, Johnstone PAS. The role of dose escalation and proton therapy in perioperative or definitive treatment of chondrosarcoma and chordoma: An analysis of the National Cancer Data Base. *Cancer* 2019;125:642-51.
- Amichetti M, Cianchetti M, Amelio D, Enrici RM, Minniti G. Proton therapy in chordoma of the base of the skull: A systematic review. *Neurosurg Rev* 2009;32:403-16.
- Zhou J, Yang B, Wang X, Jing Z. Comparison of the Effectiveness of Radiotherapy with Photons and Particles for Chordoma After Surgery: A Meta-Analysis. *World Neurosurg* 2018;117:46-53.
Ex. KK, pp. 12-13.

- **Head and Neck**: Proton therapy can spare dose to the normal tissues and reduce toxicity that typically comes from radiotherapy for cancers of the head and neck. A group from

Memorial Sloan Kettering Cancer Center (*MSKCC*) studied patients who underwent ipsilateral irradiation for major salivary gland cancer or cutaneous squamous cell carcinoma. The study showed that the use of protons significantly reduced grade 2 acute mucositis (17% vs. 52%), nausea (11% vs. 56%), and dysgeusia (5.6% vs. 65.2%) for patients after treatment; however, it had increased grade 2 acute dermatitis (100% vs. 74%). Overall, however, proton therapy was shown to reduce side effects and risk to other organs including the oral cavity, larynx, esophagus, and parotid.

References:

- Romesser PB, Cahlon O, Scher E, et al. Proton beam radiation therapy results in significantly reduced toxicity compared with intensity-modulated radiation therapy for head and neck tumors that require ipsilateral radiation. *Radiotherapy and Oncology* 2016;118:286-92.
- McDonald MW, Liu Y, Moore MG, Johnstone PAS. Acute toxicity in comprehensive head and neck radiation for nasopharynx and paranasal sinus cancers: Cohort comparison of 3D conformal proton therapy and intensity modulated radiation therapy. *Radiation Oncology* 2016;11. Ex. KK, pp. 13-15.

- **Lung:** Radiation for lung cancer, even low doses of radiation, can cause significant damage, including damage to lung alveoli, morbidity, and mortality. Evidence shows that proton therapy is beneficial for thoracic and non-small cell lung cancer patients with stage II and III lung cancer, with better overall survival rates when treated with proton therapy than when treated with photon therapy.

References:

- Darby SC, Ewertz M, McGale P, et al. Risk of ischemic heart disease in women after radiotherapy for breast cancer. *N Engl J Med* 2013;368:987-98.
- Ghafoori P, Marks LB, Vujaskovic Z, Kelsey CR. Radiation-induced lung injury. Assessment, management, and prevention. *Oncology (Williston Park)* 2008;22:37-47; discussion 52-3.
- Higgins KA, O'Connell K, Liu Y, et al. National Cancer Database Analysis of Proton Versus Photon Radiation Therapy in Non-Small Cell Lung Cancer. *International Journal of Radiation Oncology Biology Physics* 2017;97:128-37. Ex. KK, pp. 15-17.

- **Breast:** Studies have shown that the use of proton RT spares the heart and lungs when delivering treatment to the target areas at a much greater rate than photon RT. In addition, the use of proton RT decreases side effects and increases survival rates of certain breast cancer patients.

References:

- MacDonald SM, Jimenez R, Paetzold P, et al. Proton radiotherapy for chest wall and regional lymphatic radiation; dose comparisons and treatment delivery. *Radiation oncology (London, England)* 2013;8:71.
- Jimenez RB, Goma C, Nyamwanda J, et al. Intensity modulated proton therapy for postmastectomy radiation of bilateral implant reconstructed breasts: a treatment planning study. *Radiotherapy and oncology : journal of the European Society for Therapeutic Radiology and Oncology* 2013;107:213-7.
- Patel SA, Lu HM, Nyamwanda JA, et al. Postmastectomy radiation therapy technique and cardiopulmonary sparing: A dosimetric comparative analysis between photons and protons with free breathing versus deep inspiration breath hold. *Pract Radiat Oncol* 2017;7:e377-e84.
- Mailhot Vega RB, Ishaq O, Raldow A, et al. Establishing Cost-Effective Allocation of Proton Therapy for Breast Irradiation. *Int J Radiat Oncol Biol Phys* 2016;95:11-8. Ex. KK, pp. 17-19.

- **Re-irradiation:** Studies have shown that proton re-irradiation's safety and efficacy is greater than or equal to photon re-irradiation, as proton radiation reduces the radiation dose to healthy organs and presents fewer side effects for certain patients.

References:

- Badiyan SN, Rutenberg MS, Hoppe BS, et al. Clinical Outcomes of Patients With Recurrent Lung Cancer Reirradiated With Proton Therapy on the Proton Collaborative Group and University of Florida Proton Therapy Institute Prospective Registry Studies. *Pract Radiat Oncol* 2019;9:280-8.
- Berman A, Both S, Sharkoski T. Proton re-irradiation of recurrent rectal cancer: Dosimetric comparison, toxicities, and preliminary outcomes. *Int J Particle Ther* 2014;1:2-13.
- Boimel PJ, Berman AT, Li J, et al. Proton beam reirradiation for locally recurrent pancreatic adenocarcinoma. *Journal of Gastrointestinal Oncology* 2017;8:665-74.
- Chao HH, Berman AT, Simone CB, II, et al. Multi-Institutional Prospective Study of Reirradiation with Proton Beam Radiotherapy for Locoregionally Recurrent Non-Small Cell Lung Cancer. *Journal of Thoracic Oncology* 2017;12:281-92.
- Eaton BR, Chowdhry V, Weaver K, et al. Use of proton therapy for re-irradiation in pediatric intracranial ependymoma. *Radiotherapy and Oncology* 2015;116:301-8.
- Galle JO, McDonald MW, Simoneaux V, Buchsbaum JC. Reirradiation with proton therapy for recurrent gliomas. *Int J Particle Ther* 2015;2:11-8.
- Marucci L, Lane AM, Li W, et al. Conservation treatment of the eye: Conformal proton reirradiation for recurrent uveal melanoma. *International Journal of Radiation Oncology Biology Physics* 2006;64:1018-22.
- McDonald MW, Linton OR, Shah MV. Proton therapy for reirradiation of progressive or recurrent chordoma. *International Journal of Radiation Oncology Biology Physics* 2013;87:1107-14.
- McDonald MW, Zolali-Meybodi O, Lehnert SJ, et al. Reirradiation of Recurrent and Second Primary Head and Neck Cancer With Proton Therapy. *International Journal of Radiation Oncology Biology Physics* 2016;96:808-19.
- Phan J, Sio TT, Nguyen TP, et al. Reirradiation of Head and Neck Cancers With Proton Therapy: Outcomes and Analyses. *International Journal of Radiation Oncology Biology Physics* 2016;96:30-41.
- Romesser PB, Cahlon O, Scher ED, et al. Proton Beam Reirradiation for Recurrent Head and Neck Cancer: Multi-institutional Report on Feasibility and Early Outcomes. *International Journal of Radiation Oncology Biology Physics* 2016;95:386-95.
- Verma V, Rwigema JCM, Malyapa RS, Regine WF, Simone CB, II. Systematic assessment of clinical outcomes and toxicities of proton radiotherapy for reirradiation. *Radiotherapy and Oncology* 2017;125:21-30.
- Fernandes A, Berman AT, Mick R, et al. A Prospective Study of Proton Beam Reirradiation for Esophageal Cancer. *International Journal of Radiation Oncology Biology Physics* 2016;95:483-7.
- Dionisi F, Croci S, Giacomelli I, et al. Clinical results of proton therapy reirradiation for recurrent nasopharyngeal carcinoma. *Acta Oncologica* 2019;58:1238-45.
Ex. KK, pp. 19-20.

59. The proposed proton therapy cancer treatment will enhance oncology services offered to patients by all referring providers. Ex. A, p. 44.
60. In addition to a CPTC radiation oncologist, referring physicians will remain involved in the care of patients during a course of proton therapy treatment. Ex. EE, p. 2.
61. At the conclusion of the proton therapy course of treatment, patients will be referred back to their medical oncologist and/or other physicians for appropriate follow-up care. Ex. EE, p. 2.
62. The Applicants have provided examples as to how the proton therapy will improve quality of life for cancer patients by reducing toxicity to surrounding healthy tissue and organs, emitting

less radiation, providing a higher dose to increase the chance of destroying the tumor cells, and reducing the potential side effects. Ex. P, pp. pp. 34-43, 79-81, 194-197.

63. With respect to subsection Conn. Gen. Stat. § 19a-639(a)(5), the Applicants have satisfactorily demonstrated that the proposal will improve quality and accessibility for cancer patients with specific types of cancer where PBT is clinically effective.

E. Financial Soundness. The Parties agree to the following with respect to financial soundness:

64. The proposal will require an estimated \$72,000,000 total capital expenditure to be secured through public bond financing by the Applicants. Ex. A, p. 52.

65. The public bond financing will be a private placement by Loop Capital Management with the issued bonds able to be traded and information available on the Electronic Municipal Market Access system - a letter of intent was provided to the Applicants on November 15, 2019. Ex. A, p. 765; Ex. C, p. 819.

66. The bonds will be non-recourse, thus limiting the risk to HHC, YNHHS and PI to the amount of each entity's initial investment in the CPTC (\$3 million for each health system and \$4 million for PI). Ex. Y, pp. 8-9.

67. Although an initial loss is anticipated for the first year of operation (FY 2022), CPTC will generate positive income from operations beginning in FY 2023 through FY 2025:

TABLE 8
FINANCIAL ASSUMPTIONS FOR CPTC WITH THE PROPOSAL

Description	FY 2022	FY 2023	FY 2024	FY 2025
Total Operating Revenue	\$9,277,995	\$17,687,264	\$21,318,540	\$21,683,405
Total Operating Expenses	\$9,636,707	\$17,020,143	\$17,441,782	\$17,582,685
Income/(Loss) from Operations	(\$358,711)	\$667,121	\$3,876,757	\$4,100,719

Ex. A, p. 753.

68. The Applicants have considered the financial performance of the CPTC on a total program basis. The adverse financial impact to both HHC and YNHHS will begin to be offset by the positive margins achieved by CPTC starting in year two, with financial solvency to the entire program beginning in year three (FY 2024) and continuing forward. Ex. Y, p. 4.

**TABLE 9
FINANCIAL IMPACT ON HHC AND YNHHS**

CPTC Programmatic Financial Projections			
	Year 1	Year 2	Year 3
	FY 2022	FY 2023	FY 2024
HHC	(\$1,197,266)	(\$1,886,792)	(\$1,434,466)
YNHHS	(\$1,479,204)	(\$2,324,067)	(\$1,889,050)
CPTC	(\$358,711)	\$667,121	\$3,876,757
Total Program	(\$3,035,181)	(\$3,543,738)	\$553,241

source: Financial Schedules for HHC, YNHHS and CPTC

Ex. E, p. 1917.

69. From an individual system perspective, the Applicants project that the proposal will generate incremental losses for the first four years after commencement of service due primarily to a corresponding reduction of radiation therapy visits. Despite these incremental losses, both health systems project that they will continue to achieve operational gains, overall, during this same period.

**TABLE 10
FINANCIAL ASSUMPTIONS FOR HARTFORD HEALTHCARE WITH THE PROPOSAL**

Description	FY 2022	FY 2023	FY 2024	FY 2025
Total Operating Revenue	\$4,537,323,560	\$4,662,995,496	\$4,793,695,991	\$4,927,817,257
Total Operating Expenses ¹⁴	\$4,379,716,826	\$4,501,832,288	\$4,627,476,457	\$4,756,961,779
Income/(Loss) from Operations	\$157,606,734	\$161,163,208	\$166,219,534	\$170,855,478

Ex. A, pp. 759-760

**TABLE 11
FINANCIAL ASSUMPTIONS FOR YALE-NEW HAVEN HEALTH SYSTEM WITH THE PROPOSAL**

Description	FY 2022	FY 2023	FY 2024	FY 2025
Total Operating Revenue	\$6,225,359,161	\$6,639,957,949	\$7,139,215,483	\$7,472,921,294
Total Operating Expenses ¹⁴	\$5,952,542,365	\$6,351,138,016	\$6,899,850,533	\$7,223,997,635
Income/(Loss) from Operations	\$272,816,796	\$288,819,933	\$239,364,950	\$248,923,659

Ex. A, p. 762.

70. The financial projections and resulting operating losses for HHC and YNHHS are based on conservative assumptions. These annual losses to the health systems based on conservative projections are considered immaterial to each System’s overall financial wellbeing and are also accepted willingly in the interest of advancing care for cancer patients in the state. Moreover,

¹⁴ Total Operating Expenses include salaries and wages, fringe benefits, physicians’ fees, supplies and drugs, depreciation and amortization, provision for bad debts-other, interest expense, malpractice insurance cost, lease expense, and other operating expenses. Ex. A, pp. 753, 759, 760

HHC and YNHHS are both sufficiently capitalized so that any incremental losses generated by this program can be absorbed without impact to patient care. Ex. Y, p. 5.

71. The Applicants have demonstrated that the proposal is financially feasible in accordance with Conn. Gen. Stat. § 19a-639(a)(4).

F. Cost to Consumers. The Parties agree to the following with respect to cost for consumers:

72. Below is the Applicants’ projected reimbursement for a complete delivery of proton therapy services (average 27.2 fractions) for commercially insured patients; however, there is no underlying support for this in the application as this is a new service to the state for which the Applicants do not have agreed upon reimbursement rates with commercial insurers at 230% of Medicare rates.

**TABLE 12
AVERAGE DAILY COST¹⁵ OF PROTON THERAPY SERVICES PER COMMERCIALY INSURED ADULT**

	Projected		
	FY 2023	FY 2024	FY 2025
Proton Therapy	\$73,883	\$73,883	\$73,883

^A The projected cost is calculated by taking the *base rate of all-in Medicare reimbursement (\$1,181 per fraction) multiplied by the percentage of Medicare value assumption for commercially insured payer (230%) multiplied by the average of fractions of treatments per patient (27.2).*
Ex. C, p. 811.

73. Below is the Applicants’ projected reimbursement for a complete delivery of proton therapy services (average 27.2 fractions) for self-pay patients; however, there is no underlying support for this projected rate of approximately 150% of Medicare reimbursement in the application as this is a new service to the state.

**TABLE 13
AVERAGE DAILY COST OF PROTON THERAPY SERVICES PER SELF-PAY ADULT**

	Projected		
	FY 2023	FY 2024	FY 2025
Proton Therapy	\$47,783	\$47,783	\$47,783

^A The projected cost is calculated by taking the *base rate of all-in Medicare reimbursement (\$1,181 per fraction) multiplied by the percentage of Medicare value assumption for self-pay patients (148.75%) multiplied by the average of fractions of treatments per patient (27.2).*
Ex. C, p. 810.

¹⁵ Cost is defined as the total dollar amount paid by the insurer plus client out-of-pocket costs (e.g., deductibles and co-pays).

74. All patients with commercial insurance, Medicare and Medicaid will need to go through an initial treatment authorization process.¹⁶ Ex. E, p. 1913.
75. CPTC will also employ an Insurance Coordinator who will evaluate all the Applicants' uninsured potential patients to determine eligibility and assist with enrollment with governmental and non-governmental payers. Ex. C, p. 815.
76. CPTC estimates utilization of the Insurance Coordinator will reduce the number of uninsured patients that it projects to treat annually between FY 2022 and FY 2024. Ex. C, p. 815.
77. The Center agrees that hospital facility fees will not be imposed at the CPTC, which will have a price structure similar to other licensed free-standing outpatient clinics. Ex. A, p. 51.
78. The Center shall adopt a financial assistance policy that aligns with the charitable mission of both health systems. Ex. A, p. 50.
79. The Center, pursuant to CPTC's financial assistance policy, shall provide free care to patients who earn up to 250% of the Federal Poverty Guidelines family income limit, considering household size. Ex. A, p. 50.
80. While proton therapy is potentially initially more expensive than traditional x-ray radiation therapy, the difference in cost should be offset through the reduction in the need for potential treatment of other side effects, diseases, and secondary cancers. Ex. A, p. 51.
81. One subgroup analysis of a study showed that "there was a significant reduction in 90-day adverse events associated with hospitalizations." As a result, the Applicants predict that there will be fewer hospitalizations and a corresponding reduction in costs, which would offset the increased cost of proton RT. Ex. C, p. 1799; Comparison of Proton and Photon (X-ray) Therapies for Several Cancer Categories Bruce Haffty, MD, Rahul R. Parikh, MD.
82. FTI Consulting provided a cost analysis indicating that, for pediatric cancers, PBT cost savings ranges between \$20,000 to \$33,000 per patient when assessing the total cost of care including other factors. Ex. C, p. 1725.
83. CPTC anticipates that by its third year in operation, it will be treating 479 patients per year, 150 of whom will be commercially insured. The 150 commercially insured patients are likely to be distributed amongst multiple different commercial health plans, so the Applicants predict that there will be no significant financial impact to any one payer. Ex. J, p. 1943.
84. Based on the Applicants' proposed provision of services to relevant populations, its central location in Connecticut, and the benefits of using proton therapy versus conventional radiation therapy for specific types of cancers, the Applicants have satisfied Conn. Gen. Stat. §§ 19a-639(a)(5) and (6). The proposal will have a minimal impact on cost effectiveness of health care

¹⁶ This includes submitting consultation notes, tumor site documentation based on ICD-10 coding and other documentation requested by the insurers' internal or external utilization management.

delivery in the region in accordance with Conn. Gen. Stat. § 19a-639(a)(5). In order to satisfy those criteria, the Applicants agree to comply with the conditions attached hereto.

G. Existing Providers. The Parties agree to the following regarding existing providers:

85. The Francis H. Burr Proton Therapy Center at Massachusetts General Hospital is the only proton therapy center located in New England. Ex. A, p. 41.
86. CPTC may offer proton therapy to those in need of proton therapy in Connecticut who are currently receiving PBT out of state or are receiving traditional radiation therapy for cancers that would benefit from PBT in Connecticut. Ex. A, p. 57.
87. Patients referred by their oncologist, radiation oncologist, surgeon, or other physician to CPTC for proton therapy will be those who need or would benefit from a different level of care apart from traditional radiation therapy. Ex. KK, pp. 52-53.
88. The Applicants' establishment of proton therapy services will increase the diversity of existing health care facilities in the service area for the proposed service.
89. The methodology used by the Applicants to project volume assumes that certain HHC and YNHHS cancer patients would be deemed clinically appropriate for PBT and would be referred to the CPTC for treatment instead of one of the systems' photon therapy locations.
90. Cancer patients not deemed clinically appropriate for PBT will continue with their existing providers using photon therapy. For a small population with specific cancer types, existing providers may voluntarily refer patients to CPTC for PBT. Volume is shifting minimally, however, patients are being directed to a different, more appropriate level of care for a limited set of services, in the opinion of the referring providers. The proposal will not result in any unnecessary duplication of services, and Conn. Gen. Stat. §§ 19a-639(a)(8), (9) and (11) are satisfied.
91. The Applicants have met their burden in satisfying Conn. Gen. Stat. §§ 19a-639(a)(2)-(11). In addition, Conn. Gen. Stat. § 19a-639(a)(12) is not germane to the application as the proposal does not result in any consolidation and OHS currently has no policies or regulations in place, so Conn. Gen. Stat. § 19a-639(a)(1) cannot be applied.

Order

The Applicants' request to establish a proton therapy center located at 932 Northrop Road in Wallingford, Connecticut and for the acquisition of a CT simulator is hereby **Approved** under Conn. Gen. Stat. § 19a-639(a), subject to the enumerated conditions (the "Conditions") set forth below.

All references to days in these Conditions shall mean calendar days.

1. The Parties agree that the Applicants' request to establish a proton therapy center located at 932 Northrop Road in Wallingford, Connecticut and for the acquisition of a CT simulator is hereby Approved under Conn. Gen. Stat. § 19a-639(a), subject to these enumerated conditions.
2. The CPTC shall seek and obtain approval by the Connecticut Department of Social Services ("DSS") as a Medicaid provider prior to commencing the approved service and comply with all requirements of participation following approval. The CPTC shall file documentation with OHS evidencing approval of its enrollment application. Such documentation shall be filed within thirty (30) days of approval as a Connecticut Medicaid provider.
3. The CPTC shall seek licensure as an Outpatient Clinic from the Connecticut Department of Public Health ("DPH") and will register with the Connecticut Department of Energy and Environmental Protection ("DEEP") as both an x-ray/accelerator and a radioactive materials facility prior to commencing the approved service.¹⁷ The CPTC shall file with OHS proof of said licensure and registration/special permit within thirty (30) days of commencement of operations.
4. The CPTC shall only provide proton beam services to cancer patients who are clinically appropriate as determined by their oncologist.
5. The CPTC shall file with OHS a list of commercial carriers with which it participates, as well as updated clinical policies or guidelines from these carriers that document coverage for the services authorized under this Settlement. The CPTC shall provide this information and documentation annually for a period of five (5) years, as required by Condition No. 14.
6. The CPTC will use its best efforts to obtain approval of payment from the payer for patients covered by Medicaid, Medicare, commercial or other coverage, and will work with patients to exhaust all levels of appeal if initially denied, prior to initiating the service, or if coverage is made available for a portion of the full course of treatment, prior to the continuation of treatment beyond the approved course. However, this does not preclude the CPTC from commencing and/or continuing PBT service while appeals are pending if the patient makes an informed decision to proceed with treatment for any reason including, but not limited to, a determination by the patient's physician that delaying treatment may be clinically detrimental.

¹⁷ If the Connecticut DEEP Radiation Control Unit requires a special permit, obtaining said special permit shall suffice as compliance with this condition.

7. If coverage for a patient remains denied after the exhaustion of appeal rights, or if a patient elects to proceed or continue with PBT services while appeals are pending, the CPTC shall notify said patient in writing, in easily-understood language and in the preferred language of the patient, of said denial (or potential denial) and the basis for said denial. The CPTC shall inform the patient, both verbally and in writing, that urgent/expedited appeals processes are available in such situations where the patient's life or health are in jeopardy. The CPTC shall inform the patient what the turnaround time is for such appeals and that failure to complete the appeal process may result in the patient incurring significant financial liability. The CPTC shall include reference to any expedited external review processes when available to ensure the patient is fully aware of all available coverage options prior to commencing or continuing treatment. The CPTC shall not begin or continue a course of PBT prior to documenting in writing, with written acknowledgement from the patient, that the CPTC has informed the patient of the above-referenced options, processes, and timeframes. The CPTC shall also provide such patient with a complete cost estimate for services and shall offer the patient the opportunity to apply for financial assistance under the CPTC's financial assistance policy. All decisions regarding awards of financial assistance shall be made in accordance with the CPTC's policy and such patients shall be notified in advance that not every patient whose insurance denies coverage will qualify for financial assistance. The CPTC shall also include all information about the patient's right to refuse the service or return to HHC, YNHHS, or another referring provider for alternate treatment. The Applicants shall file with OHS a copy of the form notice(s) described herein prior to commencement of operations.
8. The CPTC shall provide notification to OHS of the date of commencement of operations. Such notification shall be filed with OHS within thirty (30) days of commencement of operations.
9. Prior to commencing operations, the Applicants shall provide to OHS and the Office of the Attorney General copies of all final executed Definitive Agreements (as that Term is defined in the Letter of Intent, dated July 1, 2020, Ex. J, pp. 1948-1958) and all exhibits to those agreements. This includes the final agreement with Proton International or alternative partner. Along with the Definitive Agreements, and the Applicants shall provide OHS with a description of the final ownership interests in CPTC.
10. The Applicants are authorized to operate a one-room proton therapy delivery system at CPTC. OHS CON approval shall be required for the use of any additional proton therapy delivery system rooms at the Center.
11. The CPTC shall implement a transfer agreement with an appropriate hospital or hospitals in the event of an emergency during proton therapy treatment prior to the commencement of operations. The CPTC shall file with OHS a copy or copies of such transfer agreement(s) within thirty (30) days of commencement of operations. The existence of a transfer agreement does not preclude the CPTC from accessing emergency services via 911 and/or in accordance with the facility's emergency protocols.
12. The CPTC shall not impose any hospital facility fees related to any proton therapy treatment received at CPTC. However, for avoidance of confusion, the CPTC may employ a price structure similar to other licensed freestanding outpatient clinics. This includes the imposition

of both professional charges as well as charges for the technical component associated with performing the actual PBT services at the Center.

13. The CPTC shall, after providing proton therapy, transition patients back to their medical oncologist, radiation oncologist, and/or other members of their care team, including oncologists outside the HHC and YNHHS health systems. If the patient does not have a medical oncologist, radiation oncologist, or other pertinent physician or does not wish to return to their initial treating provider, the patient shall be referred to the appropriate provider of the patient's choosing. Patient choice of provider shall be documented in the medical record.
14. The CPTC shall, not later than January 31st of the year following the conclusion of each of the first five (5) fiscal years of operation, submit an annual report to OHS that includes the following:
 - a. Utilization by service type at CPTC;
 - b. Utilization by cancer type;
 - c. Utilization by referral source provider;
 - d. Utilization by health system (e.g., HHC, YNHHS, etc.);
 - e. Utilization by age (under 18, 18-64, 65+), gender, sex, race, ethnicity;
 - f. Number of patients by cancer type, payer, and in-network/out-of-network status who were approved and denied for PBT, in whole or in part. For those patients who are approved, the Applicants shall indicate whether they were approved directly by policy or on appeal. For those patients who are denied, the Applicants shall indicate the basis for each denial. A table similar to that included in Finding of Fact 24 may be used to report the information contained in this subsection;
 - g. Number of patients who were self-pay, in whole or in part, by cancer type (as listed in the table in Finding of Fact 24);
 - h. List of commercial carriers with which the CPTC participates, as well as updated clinical policies or guidelines from these carriers that document coverage for the services authorized under this Settlement;
 - i. Average allowed amounts for proton therapy treatment for commercial and self-pay patients;
 - j. Payer mix for CPTC by patients/visits;
 - k. Revenues and operating costs for the services authorized;
 - l. The average gross revenue per unit of service;
 - m. The average net revenue per unit of service;
 - n. The average operating cost per unit of service; and
 - o. Column One (1) (Actual Results) of OHS, Financial Worksheet B or comparable financial reporting form for CPTC.
15. For all services authorized by this Settlement, no CPTC charges for self-pay patients¹⁸ shall exceed the Medicare allowed amounts, in any year.

¹⁸ Self-pay patients shall mean uninsured patients with a qualifying financial need, as determined in accordance with the CPTC's written financial assistance policy.

16. Blended average annual increases to CPTC negotiated rates for all services authorized by this Settlement shall not exceed three percent (3%) annually for a period of five (5) years following the commencement of operations.
17. The CPTC shall prepare and adopt a written financial assistance policy that aligns with the charitable mission of both health systems. The CPTC shall file a copy of the policy with OHS prior to commencement of operations.
18. The CPTC shall engage the services of a third-party health equity expert or experts, with at least one being located in Connecticut, to ensure equity in access for individuals and develop tools to measure equity in access. This third-party health equity expert may work alone or alongside existing experts within Applicants' health systems. The CPTC shall provide notification to OHS and a copy of its agreement(s) with such third-party health equity expert(s) within thirty (30) days of commencement of operations and shall, within ninety (90) days from the submission of the agreement(s), file a plan with OHS that ensures equity in access going forward.
19. The CPTC shall prepare and adopt a policy outlining the manner in which it will assist patients in accessing transportation to/from the facility in compliance with all applicable laws. The CPTC shall file a copy of the policy with OHS prior to the commencement of operations.
20. The CPTC, upon commencement of operations, shall participate in the statewide Health Information Exchange ("HIE") d/b/a Connie to ensure patient care coordination among providers outside of the HHC and YNHHS systems.
21. The CPTC shall provide the contact information for the individual(s) responsible for submitting compliance documents and responding to compliance inquiries at the time that the first submission comes due. The CPTC shall update this information within thirty (30) days of any change to the individual(s) identified for a period of five (5) years or until the final compliance submission is filed.
22. OHS and CPTC, YNHHS and HHC agree that this Settlement, once accepted by the OHS Executive Director and finalized and adopted by OHS, represents a final agreement between OHS and CPTC, YNHHS and HHC with respect to OHS Docket No. 19-32339-CON. The execution of this Settlement, acceptance of same by the OHS Executive Director and finalization and adoption by OHS, resolve all objections, claims and disputes, which may have been raised by CPTC, YNHHS and HHC with regard to OHS Docket Number 19-32339-CON. The Applicants waive any right that they may have to challenge the terms of this Settlement once accepted by the OHS Executive Director and finalized and adopted by OHS. The Applicants also waive any right they may have to appeal and/or challenge the terms of this Settlement in any court or judicial forum once accepted by the OHS Executive Director and finalized and adopted by OHS. If the OHS Executive Director rejects this Settlement, the Applicants retain all legal right and remedies available to them, waiving none.

23. OHS may enforce this Settlement, once accepted by the OHS Executive Director and finalized and adopted by OHS, under the provisions of Conn. Gen. Stat. §§ 19a-642; 19a-653 and all other remedies available at law, with all fees and costs of such enforcement to be paid by the Applicants.
24. This Settlement, once accepted by the OHS Executive Director and finalized and adopted by OHS, shall be binding upon the Applicants and its successors and assigns.
25. This Settlement, once accepted by the OHS Executive Director and finalized and adopted by OHS, is a public document and will be reported in accordance with OHS policy and procedures, and it will be posted to its CON portal.
26. The Executive Director has complete and final discretion as to whether this executed Agreed Settlement is accepted. If this matter proceeds to a final decision by the Executive Director, the Applicants hereby waive any claim of procedural error asserting that the Executive Director's role in reviewing and considering this Agreed Settlement was inappropriate or that it prejudiced such final decision.

IN WITNESS WHEREOF, the Parties hereto, which have caused this Order to be executed by their respective officers and officials, declare the execution of this Agreed Settlement to be their free act and deed.

April 6, 2022
Date



Member Representative of
Connecticut Proton Therapy Center, LLC

April 7, 2022
Date



Member Representative of
Connecticut Proton Therapy Center, LLC

April 7, 2022
Date



Authorized Agent for
Hartford HealthCare Corporation

April 6, 2022
Date



Authorized Agent for
Yale-New Haven Health Services Corporation

April 1, 2022
Date



Daniel J. Csuka, Esq.
Staff Attorney
Office of Health Strategy

The above Agreed Settlement having been presented to the undersigned, it is hereby Ordered:

ACCEPTED / ~~REJECTED~~

April 7, 2022
Date

Victoria Veltri, JD, LLM
Executive Director
Office of Health Strategy