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July 14, 2022

David S. Hardy, Esq.
Carmody, Torrance, Sandak & Hennessey, LLP
195 Church Street, 18th Floor
New Haven, CT 06510

RE: Danbury Proton, LLC
Docket Number: 20-32376-CON
Acquisition of a Proton Beam Accelerator and a Computed Tomography Simulator
Final Decision

Dear Attorney Hardy:

Enclosed please find a copy of the Final Decision rendered in the above-cited case.

Sincerely,

Lara L. Manzione

Lara L. Manzione, Esq.
Staff Attorney / HSP Manager
Lara.Manzione@ct.gov

c: Daniel J. Csuka, Esq. (daniel.csuka@ct.gov)

Encl.

Final Decision

Applicant(s): **Danbury Proton, LLC**
c/o David S. Hardy
Attorney for the Applicant
Carmody Torrance Sandak & Hennessey, LLP
195 Church Street, 18th Floor
New Haven, CT 06510

Docket Number: **20-32376-CON**

Project Title: **Acquisition of a Proton Beam Accelerator and a Computed Tomography Simulator**

The undersigned, Daniel J. Csuka, Esq., Staff Attorney / Hearing Officer for the Office of Health Strategy ("OHS"), hereby issues his final decision in Certificate of Need ("CON") Docket No. 20-32376-CON in which Danbury Proton, LLC ("DP" or the "Applicant") seeks to acquire a proton beam accelerator and a computed tomography simulator (the "Application"). This decision is issued pursuant to Connecticut General Statutes ("C.G.S.") § 4-180.

On February 28, 2022, Hearing Officer Kimberly Martone, then Deputy Director and Chief of Staff at OHS, issued a Proposed Final Decision (the "PFD"). Thereafter, the Applicant timely filed exceptions and a request for oral argument on March 16, 2022. On April 4, 2022, OHS issued a Notice of Hearing before then Executive Director Victoria Veltri, which scheduled a hearing on oral argument for April 22, 2022. The hearing proceeded as scheduled and the Applicant was provided with an opportunity to fully address any legal claims and exceptions to the PFD. Upon the close of the hearing, Executive Director Veltri took the matter under advisement. Subsequently, Executive Director Veltri designated the undersigned to issue a Final Decision.

In the PFD, Hearing Officer Martone determined that the Applicant had failed to meet its burden of proof in satisfying the statutory requirements of C.G.S. § 19a-639. Specifically, she found that the Applicant had failed to satisfy the following criteria: (2) the relationship of the proposed project to the Statewide Healthcare Facilities and Services Plan, (3) that there is a clear public need for the proposal, (4) the financial feasibility of the proposal, (5) the improvement of quality, accessibility, and cost effectiveness of the proposal, (7) and the need of the target population. Based upon this, Hearing Officer Martone recommended that the Application be denied.

In DP's Exceptions to the PFD, it made a number of arguments for why the PFD should not be adopted by OHS and why the Application should instead be granted. They can be summarized as follows: (A) the PFD misapplies the Statewide Healthcare Facilities and Services Plan (the "Plan") in that it (1) improperly applies Plan guidelines as substantive legal requirements, (2) misapplies the Plan guidelines, (3) baselessly concludes that DP's Application fails to meet one of the Plan guidelines, and (4) ignores the extent to which DP's Application, on the whole, meets

the goals of the Plan; (B) the PFD incorrectly concludes that clear public need is not met; (C) the PFD incorrectly concludes that financial feasibility is not met; (D) the PFD incorrectly concludes that the Application will not improve cost effectiveness; (E) the PFD incorrectly concludes that the identified population to be served does not have a need for the proposed services; and (F) the PFD is affected by substantive and procedural irregularities that call for fresh consideration of the issues by the Executive Director. At oral argument, the Applicant reiterated these arguments, but mostly focused on the similarities and differences between this Application and the statements set forth in the Agreed Settlement that was reached in Docket No. 19-32339-CON (Application filed by Connecticut Proton Therapy Center, LLC; Hartford HealthCare Corporation; Yale-New Haven Health Services Corporation) on April 7, 2022, which was after DP had filed its exceptions but before argument took place. The undersigned reviewed the entire DP and CPTC records both prior to and after the April 22, 2022 hearing, and was also in attendance at said hearing.

In accordance with C.G.S. § 4-180, and after review and consideration of the full record and applicable laws, the undersigned hereby adopts the PFD issued by Hearing Officer Martone as the Final Decision in this matter, with the following substantive[1] revisions and amendments:

1. Findings of Fact ("FF") 17a, 17b and 17c have been added.
2. FF 18 has been revised to state that DP intends to be an independent provider without any multi-institutional arrangement.
3. FF 30 has been clarified and made consistent with the record.
4. A paragraph has been added in the discussion preamble that explains the role of Docket No. 19-32339-CON in this proceeding and its impact on the Applicant's burden.
5. The C.G.S. § 19a-639(a)(2) discussion has been revised in response to DP's exceptions.
6. The C.G.S. § 19a-639(a)(3) discussion has been revised in response to DP's exceptions, and the table that was moved into FF 17a has been deleted. The substantive revisions clarify that DP has provided a population-based needs assessment rather than an analysis of actual patients, that DP would be new to the state, and that no letters of support have been provided from local referring physicians. References to certain of the new FFs are also included.
7. The C.G.S. § 19a-639(a)(4) discussion has been revised to include references to certain of the new FFs.
8. The C.G.S. § 19a-639(a)(5) discussion has been revised to include additional information about the cost and cost-effectiveness of proton beam therapy ("PBT") for the treatment of prostate cancer, and include citations to certain of the new FFs.
9. The C.G.S. § 19a-639(a)(7) discussion has been revised to include an additional basis on which DP has failed to establish that this criterion is met.

[1] The undersigned has also made numerous non-substantive revisions to the PFD to standardize formatting and citation to the record.

I. FINDINGS OF FACT

1. DP proposes to establish a 14,409 square foot proton beam therapy center (the "PBT Center") at 85 Wooster Heights Road, Danbury, CT 06810. Ex. A, DP CON Application, p. 10

2. DP will own the PBT Center, and a physician-owned entity headed by Dr. Yonemoto will operate the facility pursuant to a support services and medical directorship agreements. Ex. A, DP CON Application, pp. 14, 33, 75, 100-105

3. The physician-owned entity will have sole control over the PBT Center's clinical practice and will exercise their medical judgment providing direct care to patients. Ex. A, DP CON Application, p. 14

4. If the CON application is approved, the Applicant will purchase a Mevion S250i™ system with HYPERSCAN™ ("Mevion S250") proton beam radiation therapy system from Mevion Medical Systems. Ex. A, DP CON Application, p. 30

5. If the CON application is approved, DP also will purchase a Phillips IQon Spectral CT ("CT Simulator"), a dual energy CT scanner and simulator to be used exclusively for on-site treatment planning. Ex. A, DP CON Application, pp. 80, 1260-1295

6. If the CON application is approved, the Applicant will install and operate the Mevion S250 and CT Simulator at the PBT Center. Ex. A, DP CON Application, p. 30

7. In 2017, the United States Food and Drug Administration ("FDA") issued a Section 510(k) approval for use of the Mevion S250 but has not promulgated guidelines or requirements related to proton beam therapy ("PBT"). Ex. C, DP Completeness #1 Responses, pp. 1315, 2188-2189

8. The proposed PBT Center will have a three-story concrete vault that contains the MEVION S250, a reception area, consultation room, conference rooms, administrative offices, a physics office, a dosimetry office, an IT room, main electrical and control rooms, a patient device position room, exam rooms, changing rooms, a pediatrics/anesthesia suite, treatment room and a CT Simulator suite. Ex. A, DP CON Application, pp. 27-29

9. If the CON application is approved, the Applicant will apply for an Outpatient Clinic license from the CT Department of Public Health (DPH), and it will register with the State Department of Energy and Environmental Protection (DEEP) as an x-ray/accelerator facility and radioactive materials facility.[2] Ex. A, DP CON Application, p. 35

[2] 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. Ex. A, DP CON Application, p. 76

10. DP estimates that the construction and installation process will take twenty-three (23) months to complete from groundbreaking to patient treatment. Ex. A, DP CON Application, p. 32

11. The proposal will require an estimated $80 million dollar capital expenditure for the land purchase, construction of the building, equipment, furniture, interest and finance costs. Ex. A, DP CON Application, p. 57

12. Financing of the PBT Center will be sourced from the Public Finance Authority (PFA)[3] through the issuance of tax-exempt bonds[4] and DP has received a conditional underwritting committment (up to $82 million of tax-exempt bonds) from BB&T Capital Markets to participate in the financing transaction. Ex. A, DP CON Application, pp. 33, 57, 929

13. The Applicant's target population includes all Connecticut residents, but particularly those residing in the southwest region of the state and those out-of-state residents who may find the proposed Danbury location more convenient than existing centers in New York, Massachusetts and New Jersey. Ex. A, DP CON Application, p. 25

14. PBT can provide broad benefits for clinically appropriate cancer patients and is of particular benefit to those patients whose tumors have not spread and/or for those tumors located near vital and sensitive parts of the body (e.g., eye, brain and spinal cord).[5] Ex. A, DP CON Application, pp. 17-24

15. A primary benefit of PBT is that patients may experience reduced side effects when compared to other types of treatment. "This improved therapeutic ratio with proton RT (radiation therapy) most of the time involves not the improved cure of cancer but the reduction in side effects…"[6] Ex. C, DP Completeness #1 Responses, p. 2265

16. A summary of pertinent findings from journal articles[7] included in the application support the finding that PBT may result in a reduction of adverse events, side effects and possible injury to tumor adjacent tissues. Ex. A, DP CON Application, pp. 654-657

[3] PFA is a governmental entity established under the laws of the State of Wisconsin that is authorized to issue bonds, including tax-exempt bonds, in all 50 states. Ex. A, DP CON Application, p. 57
[4] A formal resolution declaring PFA's interest in financing the Center can be found in Ex. C, DP Completeness #1 Responses, p. 2186
[5] Leeman JE, Romesser PB, Zhou Y, McBride S, Riaz N, Sherman E, Cohen MA, Cahlon O, Lee N. Proton therapy for head and neck cancer: expanding the therapeutic window. Lancet Oncol. 2017 May;18(5):e254-e265. doi: 10.1016/S1470-2045(17)30179-1. Epub 2017 Apr 26. PMID: 28456587. Ex. A, DP CON Application, pp. 765-776
[6] Haffty, B., & Parikh, R. (2020). Comparison of Proton and Photon (X-ray) Therapies for Several Cancer Categories. *Rutgers Cancer Institute of New Jersey*
[7] See referenced articles – Ex. A, DP CON Application, pp. 654-657

17. The following table reflects Anthem/BCBS, United/Oxford and Aetna clinical policy determinations regarding medical necessity for PBT and tumor sites approved pursuant to each policy. Any diagnoses not covered under a carrier's policy may be subject to an appeal process.

MEDICAL NECESSITY OF PROTON THERAPY TREATMENT BY CANCER TYPE AND PAYER

Cancer Type	Payer					
	Anthem BCBS Connecticut		UHC/Oxford		Aetna	
	Policy	Appeal	Policy	Appeal	Policy	Appeal
Bone and Soft Tissue		✓		✓		✓
Brain & CNS	✓		✓		✓	
Breast		✓		✓		✓
Cervix & Uterine		✓		✓		✓
Chest & Lung		✓		✓		✓
Genitourinary		✓		✓		✓
GI (Digestive)		✓***	✓**	✓	✓**	✓***
Head & Neck	✓		✓		✓	
Lymphoma		✓		✓		✓
Other	✓*		✓*		✓*	
Skin		✓		✓		✓
Pediatric	✓		✓		✓	
Prostate		✓		✓		✓

✓*: Ocular melanomas
✓**: Unresectable hepatocellular carcinoma
✓***: Pancreatic
Ex. C, DP Completeness Responses, pp. 1308-1309

17a. The majority of the patients that DP anticipates treating will have prostate, breast or lung cancer.

APPLICANT'S PROJECTED UTILIZATION BY CANCER TYPE

		Projected Volume		
Cancer Type	**%**	**FY 2023**	**FY 2024**	**FY 2025**
Prostate	35%	73.15	97.65	118.3
Lung	20%	41.8	55.8	67.6
Breast	15%	31.35	41.85	50.7
Head and Neck	10%	20.9	27.9	33.8
Central Nervous System	5%	11.45	13.95	16.9
Other Chest	5%	10.45	13.95	16.9
Other Pelvis	5%	10.45	13.95	16.9
Other Abdominal	5%	10.45	13.95	16.9
Total Patients*		**209**	**279**	**338**

*Numbers may not add due to rounding

Ex. C, DP Completeness #1 Responses, p. 1315, Table 6; Ex. A, DP CON Application, pp. 44, 56, 61

17b. The effectiveness of PBT for the treatment of prostate cancer is at best equal to that of conventional radiation therapies ("CRT"), and at worst unclear. As such, coverage by both governmental and commercial payers is lacking. Ex. A, DP CON Application, pp. 119 (Astro); 244 (NCCN); 260, 268-269, 272 (eviCore)[8]; 615 (PCORI, no outcomes provided); 657 (no report provided); 688 (Cancer); Ex. J, DP Completeness #2 Responses, pp. 2550, 2553

17c. Prostate cancer incurs the highest average out-of-pocket cost for patients. Ex. J, DP Completeness #2 Responses, pp. 2520-2521, 2526

18. The Applicant intends to be a fully independent provider without any multi-institutional arrangement. It is not affiliated with a research facility or medical school within Connecticut and does not anticipate conducting any research studies at the PBT Center. Ex. A, DP CON Application, pp. 59, 65; Ex. D, Public Comment (CPTC/YNHHS/HHC), pp. 6-7; Ex. J, DP Completeness #2 Responses, p. 2296; Ex. O, DP Prefiled Testimony (Moyers), p. 102; Ex. S, DP Late File, pp. 4-7; Hearing Transcript, Testimony of Mr. Courtney, pp. 125-126

19. The 2012 Statewide Healthcare Facilities and Services Plan[9] states, in relevant part, that a CON application for new technology shall be consistent with the Plan if the following criteria are met:

1. The new technology is efficacious;
2. The equipment is certified for its proposed use by the United States Food and Drug Administration (FDA);

[8] Note that the introductory page of the eviCore document provides: "Health Plan medical policy supersedes the eviCore criteria when there is conflict with the eviCore criteria and the health plan medical policy." Ex. A, DP CON Application, p. 248
[9] Connecticut Statewide Health Care & Facilities Plan (October 2012), p. 67

3. Preference shall be given to proposals that involve multi-institutional arrangements;
4. Preference shall be given to proposals that place the new technology in a medical school or other teaching or research facility;
5. Before acquiring new technological equipment, applicants shall have complementary diagnostic and treatment services available to support the new program;
6. Applicants shall demonstrate that personnel who will staff the new technology are qualified and adequately trained; and
7. 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

   Ex. A, DP CON Application, pp. 12, 39-40

20. Data from the Connecticut All-Payer Claims Database ("APCD") indicates that in 2019 more than five hundred (500) claims were submitted for Connecticut residents receiving PBT 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.

21. The Applicant expects that patient self-referrals will account for 60-70% of DP patient capacity, with the remaining 30-40% to be referred by area physicians. Ex. A, DP CON Application, p. 56; Ex. C, DP Completeness #1 Responses, pp. 1297, 1312; Ex. O, DP Response to Issues, p. 5

22. The Applicant has not established any formal referral arrangements with area providers. Ex. C, DP Completeness #1 Responses, p. 1297

23. The Applicant's primary service area ("PSA") is a portion of a forty-mile (40-mile) diameter circle from the proposed PBT Center in Danbury that covers forty (40) Connecticut towns/areas[10] in the southwest region of the state and thirty-seven (37) New York cities and towns.[11] Ex. C, DP Completeness #1 Responses, pp. 1296-1297

24. DP also plans to admit patients from surrounding states who may find the Danbury location more convenient or available for admission than the closest existing centers located in New York, Massachusetts, or New Jersey. Ex. A, DP CON Application, p. 25

[10] The 40 towns in Connecticut are: Ridgefield, Georgetown, Danbury, Redding, Redding Center, Wilton, Bethel, Redding Ridge, Weston, New Canaan, Easton, Newtown, Hawleyville, Brookfield, New Fairfield, Norwalk, Stamford, Botsford, Westport, Monroe, Fairfield, Sandy Hook, Trumbull, Southport, Greens Farms, Darien, Bridgewater, Bridgeport, Stevenson, South Britain, Southbury, Cos Cob, Greenwich, Shelton, Riverside, Old Greenwich, Sherman, Roxbury, New Milford, and Stratford

[11] The 36 cities and towns in New York are: South Salem, Waccabuc, Cross River, North Salem, Pound Ridge, Goldens Bridge, Croton Falls, Brewster, Purdys, Somers, Katonah, Bedford, Bedford Hills, Lincolndale, Shenorock, Baldwin Place, Patterson, Amawalk, Mount Kisco, Granite Springs, Mahopac, Mahopac Falls, Carmel, Yorktown Heights, Jefferson Valley, Armonk, Chappaqua, Shrub Oak, Millwood, Holmes, Putnam Valley, Mohegan Lake, Crompond, Pawling, Thornwood, Ossining, and Pleasantville

25. The Applicant has reached a transfer agreement, in principle, with Danbury Emergency Medical Services, to provide any necessary emergency services to DP's patients. Ex. A, DP CON Application, pp. 39, 997-1004

26. The Applicant selected Danbury, Connecticut as the proposed PBT Center location for the following reasons:

1. the population density of Fairfield County (1,467.2/ sq. mile);[12]
2. the proximity to main interstate highways (Routes 7 and 84); and
3. the proximity to some of Connecticut's major population centers (i.e., Danbury, Stamford, Norwalk, Bridgeport, and Waterbury). Ex. A, DP CON Application, p.25

27. The Applicant plans to offer a free shuttle service throughout only the greater Danbury area, but which includes rail and bus stops, to transport patients to and from the PBT Center. Ex. A, DP CON Application, p. 27

28. The Applicant anticipates the following payer mix of patients receiving their services:

APPLICANT'S PROJECTED PAYER MIX [Proton Beam Therapy Center]

Payer	Projected					
	FY 2023		FY 2024		FY 2025	
	(Patients)	%	(Patients)	%	(Patients)	%
Medicare	77	37	103	37	125	37
Medicaid	25	12	34	12	41	12
TRICARE	6	3	8	3	10	3
Total Government	**108**	**52**	**145**	**52**	**176**	**52**
Commercial Insurers	80	38	106	38	128	38
Uninsured	3	1	3	1	3	1
Self-pay	18	9	25	9	31	9
Workers Compensation	0	0	0	0	0	0
Total Non-Government	**101**	**48**	**134**	**48**	**162**	**48**
Total Payer Mix	**209**	**100**	**279**	**100**	**338**	**100**

Ex. A, Danbury Proton CON Application, pp. 61-62

29. DP is not a Connecticut Medicaid provider but represents that it will apply to become one prior to opening the proposed PBT Center. Ex. A, DP CON Application, p. 53

30. The American Society for Radiation Oncology (ASTRO) policy currently recommends selecting patients that may clinically benefit from PBT when an emphasis on sparing the surrounding normal tissue is crucial and cannot be adequately achieved with photon (X-ray) based therapy. Ex. A, DP CON Application, p. 110

[12] https://www.census.gov/geographies/reference-files/2010/geo/state-local-geo-guides-2010/connecticut.html

31. When compared to CRT, PBT allows for reduced side effects from radiation exposure, less exposure of normal structures to radiation, and preserving quality of life for pediatric cancer survivors. Hearing Transcript, Testimony of Dr. Andrew Chang, pp.42-48

32. The reduction in side effects and the potential need for additional treatment applies across all patients eligible for PBT, with its ability to target dose placement very specifically when compared to CRT. This tissue sparing capability may enable providers to prescribe higher radiation doses.[13] Ex. A, DP CON Application, pp. 15, 71-72

33. The Applicant asserts that proton therapy's effectiveness in reducing side effects of radiation treatment may reduce overall healthcare costs due to reductions in re-treatments of incomplete care and/or the need to treat side effects. Ex. A, DP CON Application, p. 12

34. The average cost of a PBT treatment course for commercially insured patients is approximately $84,189:

AVERAGE COST[14] OF PROTON THERAPY SERVICES PER COMMERCIALLY-INSURED PATIENT[15]

	Projected			
	FY 2023	**FY 2024**	**FY 2025**	**FY 2026**
Proton Therapy	**$82,318.15**	**$83,552.92**	**$84,806.22**	**$86,078.31**

Ex. C, DP Completeness #1 Responses, p. 1304

35. The Applicant estimates that the cost of ancillary services for PBT (e.g., CT scans, clinical services, treatment planning services, dosimetry, and other services as necessary) will be approximately $19,060 for commercially-insured patients in FY 2023.[16] Ex. C, DP Completeness #1 Responses, p. 1305

[13] Jakobi, A., Stützer, K., Bandurska-Luque, A., Löck, S., Haase, R., Wack, L.-J., Mönnich, D., Thorwarth, D., Perez, D., Lühr, A., Zips, D., Krause, M., Baumann, M., Perrin, R., & Richter, C. (2015). NTCP reduction for advanced head and neck cancer patients using proton therapy for complete or sequential boost treatment versus photon therapy. *Acta Oncologica*, *54*(9), 1658–1664.

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

[15] Calculated based on DP's management experience and assumption that commercially insured patients will pay 70% more than the rates published by National Government Services. $975.13 (weighted average of the 2020 CPT rates) x 2.20 (percentage of Medicare value assumption of commercially insured payer) x 35.1 (weighted average of treatments per patient) x 1.5% annual increase = $82,318.15

[16] Calculation based on average cost of ancillary services in 2020 ($8,285,25) x 2.20 (120% more than Medicare/Medicaid patients) x 1.015 (estimated annual increase) = $19,060.15

36. The average cost of proton therapy services for self-pay patients is projected to be approximately $62,227:

AVERAGE COST[17] OF PROTON THERAPY SERVICES PER SELF-PAY PATIENT[18]

	Projected			
	FY 2023	**FY 2024**	**FY 2025**	**FY 2026**
Proton Therapy	**$60,843.85**	**$61,756.51**	**$62,682.86**	**$63,623.10**

Ex. C, DP Completeness #1 Responses, p. 1302, Table 1

37. The Applicant estimates that the cost of ancillary services for PBT (e.g., CT scans, clinical services, treatment planning services, dosimetry, and other services as necessary, etc.) will be $14,728.30 for self-pay patients in FY2023.[19] Ex. C, DP Completeness #1 Responses, p. 1303

38. In a 2017 report to Congress, an analysis of radiation treatment for cancer over a two-year period found that proton therapy was the least used modality, but also the most expensive with an average cost of $30,541.[20] Ex. J, DP Completeness #2 Responses, p. 2518

39. As an example of these higher costs, the Applicant cited a study using a microsimulation model to assess the cost effectiveness of proton-based therapy versus three-dimensional conformal radiation therapy ("3D-CRT") and intensity-modulated radiation therapy ("IMRT"). The study[21] considered head and neck cancers and found the relative treatment costs of PBT to be 2.1 times the cost of the second most expensive radiation therapy, IMRT. The study results indicated that PBT was the most effective treatment overall, but also the most expensive strategy." Ex. J, DP Completeness #2 Responses, pp. 2524-2525

40. DP projects that the proposal will help reduce PBT patients' expenses for out-of-state travel and lodging because these patients will no longer be required to travel out of state to receive proton therapy treatment. Ex. A, DP CON Application, pp. 14, 25, 54

41. Depending on multiple factors (i.e., type of cancer, tumor location, stage of cancer and the dose chosen by the radiation oncologist), patients receiving PBT can receive 2 to 10 weeks of treatment. Ex. J, DP Completeness #2 Responses, pp. 2528

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

[18] Calculated based on DP's management experience and assumption that any patients will pay 70% more than the rates published by National Government Services. $975.13 (weighted average of the 2020 CPT rates) x 1.70 (percentage of Medicare value assumption of self-pay payer) x 35.1 (weighted average of treatments per patient) x 1.5% annual increase = $60,843.85

[19] Calculation based on average cost of ancillary services in 2020 ($8,285,25) x 1.70 (70% more than Medicare/Medicaid patients) x 1.015 (estimated annual increase) = $14,728.30

[20] US Department of Health and Human Services. (2017). Report to Congress: Episodic Alternative Payment Model for Radiation Therapy Services.

[21] Ramaekers, B. L., Grutters, J. P., Pijls-Johannesma, M., Lambin, P., Joore, M. A., & Langendijk, J. A. (2013). Protons in head-and-neck cancer: bridging the gap of evidence. *International Journal of Radiation Oncology* Biology* Physics*, *85*(5), 1282-1288.

42. There are currently no established PBT centers in Connecticut; the three closest PBT centers are located at:

a. New York Proton Center, 225 East 126th Street, New York, NY 10035 (59 miles from DP's proposed Center);
b. ProCure Proton Therapy Center, 103 Cedar Grove Lane, Somerset, New Jersey 08873 (104 miles from DP's proposed Center); and
c. Francis H. Burr Proton Therapy Center, 30 Fruit Street, Boston, MA 02114 (162 miles from DP's proposed Center).

Ex. A, DP CON Application, pp. 43-44

II. DISCUSSION

The Applicant proposes to establish a PBT Center in Danbury, Connecticut, which requires the purchase of a Mevion S250. FF 4 This equipment utilizes technology not previously used in the State of Connecticut. DP also seeks to purchase a CT Simulator solely for on-site PBT planning purposes. FF 5

A brief summary of DP's exceptions and brief is set forth above. DP's main focus at oral argument was to demonstrate why, given the Agreed Settlement in Docket No. 19-32339-CON (Application filed by Connecticut Proton Therapy Center, LLC; Hartford HealthCare Corporation; Yale-New Haven Health Services Corporation), this Application should also be approved. While true that Hearing Officer Michaela Mitchell took administrative notice of this other docket at the request of DP, this did not free the Applicant from the burden of having to establish that the CON criteria are sufficiently met in this particular case.[22] To find otherwise would lead to bizarre and absurd results; a potential applicant could simply find an existing docket that matches the proposal it seeks to pursue, request that the agency take administrative notice of it, and then do little else but ride the coattails of the other applicant towards an approval. As stated in the PFD, 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. The Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Jones v. Connecticut Medical Examining Board,* 309 Conn. 727, 728-29 (2013).

C.G.S. § 19a-639(a)(1) is inapplicable because OHS has not yet adopted policies and standards as regulations.

The Application *does not meet* the 2012 Statewide Healthcare Facilities and Services Plan (the "Plan").[23] (C.G.S. § 19a-639(a)(2))

Section 19a-639(2) of the General Statutes requires that the agency consider "[t]he relationship of the proposed project to the state-wide health care facilities and services plan." The section of the Plan regarding new technology states that "[a] CON application (application) for new technology shall be consistent with the Plan if the following criteria are

[22] *See* Ex. E, CPTC/YNHHS/HHC Request to Strike; Ex. G, DP Response to Request to Strike; Ex. H, OHS Ruling on Request to Strike.
[23] https://portal.ct.gov/OHS/Health-Systems-Planning/HC-Facilities-and-Services-Plan-AB/2012-Full-Facilities-and-Services-Plan-and-Inventory

met" and then sets forth a series of seven (7) criteria that OHS considers when reviewing a CON application that involves the acquisition of equipment utilizing new technology to the state (the "New Tech Criteria"). If OHS determines that all seven (7) of the New Tech Criteria are met, then it is obligated to determine that the new technology will be consistent with the Plan. However, it does not follow from this that the reverse is true: that if a proposal does not meet one or more of the New Tech Criteria, that it is inconsistent with the Plan. Beyond these two absolutes, it is entirely within OHS' discretion what weight it gives the seven (7) New Tech Criteria, in light of the Plan as a whole, when deciding whether a proposal meets Section 19a-639(2).

OHS' CON application asks specific questions about how proposals align with the Plan. Despite the Plan having a section specifically and very apparently dedicated to the acquisition of equipment utilizing new technology to the state (Section 5.5 of the Plan at pp. 66-67), the Applicant did not address these criteria directly. And even after CPTC/YNHHS/HHC explicitly brought the existence of the New Tech Criteria to DP's attention, DP still did not directly address most of them.[24] Although it was the Applicant's burden to ensure that it addressed each of the New Tech Criteria through the provision of sufficient evidence, it left this responsibility to OHS.

Nevertheless, this statutory criterion *is not met*. First, the Applicant's proposal does not satisfy several of the New Tech Criteria that OHS uses to determine whether a proposal is consistent with the Plan. FF 19

1. The proposed new technology is efficacious;
   The proposed new technology reduces the side effects patients may experience from CRT and reduces the need for additional therapies in many patients. FF 31, FF 32 Accordingly, the proposal *demonstrates that it is efficacious* for the proposed treatment.
2. The applicant shall document that the equipment is certified for its proposed use by the United States Food and Drug Administration (FDA);
   In 2017 the United States Food and Drug Administration (FDA) issued a Section 510(k) approval for the Mevion S250. This approval *supports* the use of the proton therapy system for the Applicant's proposal. FF 7
3. If applicable,[25] preference shall be given to proposals that involve multi-institutional arrangements by contract, agreement, ownership, or other means;

[24] Ex. D, Public Comment (CPTC/YNHHS/HHC), p. 7; Ex. S, DP Late File, pp. 3-7

[25] The meaning of "if applicable" in this and the next New Tech Criterion (the "preference criteria") is ambiguous and the Plan does not articulate what is meant by the term. "If applicable" means that the rule should be applied depending on the facts and circumstances of a situation/case. 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. *Jones v. Connecticut Medical Examining Board*, 309 Conn. 727, 728-29 (2013). Preference is just that: a preference. There may be instances where the preference does not make sense. For example, if there was evidence in the record that the new technology does not typically involve more than one institution, or there are no other suitable institutions with which a partnership could be formed. Thus, the preference criteria do not require OHS to choose between two applications. Given the facts of this case and several of the statements made in CPTC/YNHHS/HHC's public

A proton beam center could involve multi-institutional arrangements, but the Applicant has not provided evidence that its proposal involves a multi-institutional arrangement for the provision of PBT. In fact, it plans to be an independent provider, which was intentional and by design. As such, it *does not satisfy* this criterion. FF 1-6, 18

4. If applicable, preference shall be given to proposals that place the new technology in a medical school or other teaching or research facility;

   A proton beam center could be placed in a medical school or other teaching or research facility, but the Applicant's proposal is to have a standalone facility. FF 18 For that reason alone, this criterion is not met. However, the Applicant's proposal also does not provide sufficient evidence of plans to conduct or participate in clinical research either. The Applicant states that it "fully intends to support" an "academic mission," and that it "intends to participate in clinical research and further academic missions in this same manner." It also states that "New York Medical College has approached Danbury Proton to discuss the possibilities of developing a teaching and research relationship." Likewise, Dr. Moyers' testimony was nonspecific.[26] None of this points to an established, concrete relationship with a medical school or other teaching or research facility. Accordingly, the proposal *fails* to satisfy this criterion. FF 1-6, 18

5. Before acquiring new technological equipment, applicants shall have complementary diagnostic and treatment services available to support the new program;

   The proposal *satisfies* this criterion by including a dual energy CT scanner and Simulator exclusively for on-site PBT Center planning that will be in place prior to the commencement of operations. FF 5

6. Applicants shall demonstrate that personnel who will staff the new technology are qualified and adequately trained;

   The proposal *demonstrates* that personnel engaged for the provision of the services are qualified. FF 2

7. Applicants shall report utilization and demographic data necessary to evaluate the technology and to facilitate state planning.

   Even though the Applicant knew or should have known of the existence of the New Tech Criteria and its duty to ensure that they

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comment letter dated March 29, 2021 (Ex. D, Public Comment, pp. 4-6), the undersigned finds that these criteria are applicable in this instance.

[26] Dr. Moyers testified, in part: "In the future, research and development, in areas such as ultra-high dose rate and rotational delivery, may further optimize patient treatments. This research and development applies not only to the beam delivery and dosimetry equipment, but also to clinical trials with patients. We also anticipate further development of treatment planning capability that could be optimized using Danbury Proton as a testbed. With Connecticut's high demand for cancer radiation treatment within its patient population and its first-rate medical practitioners and institutions, the state may serve a very valuable role in helping develop these advanced treatment techniques." Ex. O, DP Prefiled Testimony (Moyers), p. 102. This testimony appears to be a comment on the future of proton therapy generally, and how research and development may come to affect the Applicant's operations, rather than an affirmative statement regarding its plans to participate in research and development.

were fully addressed,[27] the proposal does not discuss or provide evidence concerning its plan to report this required data and therefore *fails* to meet this requirement.

The overall goals of the Plan are to be considered when evaluating a CON proposal, but they are of infinitely greater importance when there is not a section of the Plan specifically dedicated to the evaluation of a particular type of proposal. But in this instance, there is just that. The New Tech Criteria identify the main factors to be focused on and, in so doing, it is clear that this statutory criterion is not met. But even focusing on the overall goals rather than the New Tech Criteria results in the same outcome for the reasons set forth below in each of the unmet statutory criteria.

Notwithstanding this conclusion, even if the Applicant sufficiently established that this criterion was met, the Application would still be denied based on the undersigned's review of and conclusions regarding the other statutory criteria as set forth above and below.

The Applicant *has not established* that there is a clear public need for proton beam therapy as described in this proposal. (C.G.S. § 19a-639(a)(3))

In its proposal, the Applicant suggests that PBT provides superior outcomes when compared to traditional radiotherapy. The application identifies the expected utilization of PBT by type of cancer and projects that 70% of its patients will be prostate, lung and breast cancer patients. FF 17a

The proposal includes the clinical policy determinations for the three main commercial insurers in the state; however, none of these insurers' policies identify the main cancers to be treated at the PBT Center (prostate, lung and breast cancers) as medically necessary and covered by their policies. FF 17, FF 17b

The Applicant's projections are based on their experience at other PBT centers across the country and do not provide sufficient evidence to support a clear public need for the proposed facility's targeted cancer types (i.e., prostate, breast and lung). Instead, the Applicant's estimated volumes are based on national or international data, not shown to be representative of Connecticut's experience. The National Cancer Institute (NCI) and the American Society for Radiation Oncology estimate that approximately 60% of cancer patients receive radiation therapy during their course of illness[28]. The Applicant projects that in Connecticut, this would be approximately 12,180 patients.[29] The Applicant further relies on a Swedish study suggesting that between 14% and 30% of radiation-eligible patients would be eligible for PBT but fails to identify Connecticut's need.[30] In other words, unlike the CPTC proposal, the Applicant has provided a population-based needs assessment rather

[27] Ex. A, DP CON Application, pp. 12, 39-40; Ex. D, Public Comment (CPTC/YNHHS/HHC), pp. 6-7; Ex. S, DP Late File, pp. 4-7
[28] Ex. J, DP Completeness #2 Responses, p. 2563
[29] Ibid.
[30] Ex. J, DP Completeness #2 Responses, p. 2564

than an analysis of actual patients in the state who have received radiation therapy and who would likely benefit from proton therapy.

The Applicant expects that patient self-referrals will account for 60-70% of DP patient capacity, with the remaining 30-40% to be referred by area physicians.[31] FF 21 However, the Applicant would be new to the state and has not established any formal referral arrangements with area providers. FF 1-6, 9-10, 22 In fact, neither DP nor any member of the public has submitted a letter of support from a local referring physician. Therefore, the Applicant has failed to provide sufficient evidence to substantiate its projected patient volumes are reasonable and achievable.

As such, the Applicant has *failed to demonstrate* that a clear public need exists for their proposal.

The Applicant *has not satisfactorily demonstrated* that the proposal is financially feasible.
(C.G.S. § 19a-639(a)(4))

The Applicant's proposal fails to demonstrate that a clear public need for PBT exists within the state that would support the proposal's fiscal projections. The Applicant's anticipated cost of the project is approximately $80 million that the Applicant intends to finance through tax-exempt bonds. FF 12 DP expects to achieve breakeven net revenue by the third quarter of the first year of operations, with profitability by the third year of operations.

FINANCIAL ASSUMPTIONS FOR DP WITH THE PROPOSAL[32]

Description	FY 2023	FY 2024	FY 2025
Total Operating Revenue	$18,601,856	$25,174,511	$30,981,956
Total Operating Expenses	$21,521,109	$24,750,729	$25,437,477
Income/(Loss) from Operations	**($2,919,253)**	**$423,782**	**$5,544,479**

However, these financial projections are based on the Applicant's unsubstantiated volumes and associated revenue, as well as coverage decisions of commercial insurers. The proposal demonstrates that many of the cancers the Applicant intends to treat are likely to be denied coverage by commercial insurers. FF 17, FF 17b The proposal's revenue estimates assume that insurers will provide coverage for the cancers projected to represent 70% of the patients treated, but the evidence provided fails to support this claim. Instead, the Applicant provided evidence that insurers do *not* routinely cover these cancers, but that they would likely need to be appealed. FF 17, FF 17b In addition, given that insufficient evidence was provided to support the Applicant's projected volume, the associated revenues generated from those volumes cannot be validated or confirmed.

As such, given the unsupported assumptions underlying the proposal's financial projections,

[31] The Applicant has provided no data to support its anticipated self-referral percentage, instead referring to its "past experience" and alluding generally to "National Association for Proton Therapy 2017 survey data" that has not been introduced into the record. Ex. A, DP CON Application, pp. 56, 64, 73; Ex. O, DP Prefiled Testimony, p. 7.
[32] Ex. A, DP CON Application, p. 1127

the Applicant *has not* adequately demonstrated that the proposal is financially feasible.

The Applicant *has satisfactorily demonstrated* that the proposal will improve quality and accessibility but *has not satisfactorily demonstrated* that the proposal will improve the cost effectiveness of health care delivery in the region. (C.G.S. § 19a-639(a)(5))

The Applicant has provided numerous examples as to how PBT can improve quality of life for certain 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 potential side effects. FF 15, FF 16, FF 31, FF 32

There are currently no proton beam facilities in Connecticut, with the closest available in Massachusetts, New York or New Jersey. FF 42 Although the Applicant intends to draw a significant portion of its projected patient volume from the southwest region of the state and out of state, the proposed PBT Center would improve access to proton therapy services for many Connecticut residents. FF 13, FF 23

The proposal suggests that PBT will reduce overall health care costs, citing the reduction in the need for re-treatments of the cancer and/or treating side effects. FF 33 The Applicant notes one area of possible savings may be in the reduction in the number of treatment sessions, but the evidence provided states that there is inadequate data comparing the number of treatment sessions for PBT and CRT to make such an assertion. Further, the treatment cost of PBT is 2.1 times more than the second most expensive radiation therapy, IMRT. FF 39

PBT for the treatment of prostate cancer in particular has been proven to not be cost-effective (FF 17b), but in spite of this the Applicant projects that this cancer will make up 35% of its volume.[33] And prostate cancer incurs the highest average out-of-pocket cost for patients. FF 17c

Based on the evidence submitted by the Applicant, the proposal would help improve quality and accessibility, but sufficient evidence *has not been provided* to demonstrate that PBT is cost-effective compared to CRT. This is especially the case for prostate cancer, which the Applicant anticipates will account for more than one-third of its total volume. Accordingly, this criterion has not been met.

The Applicant *has shown* that there would be no significant change in the provision of health care services to the relevant populations and payer mix, including access to services by Medicaid recipients. (C.G.S. § 19a-639(a)(6))

There are currently no PBT providers within the state, and the Applicant's proposal would improve access to these services for all Connecticut residents, although the population in the southwest region of the state would experience the most significant improvement in access. FF 13, FF 23 This projected improvement in access applies across all types of payers. FF 28

The proposal estimates that 38% of its patients will have commercial insurance coverage

[33] Ex. C, DP Completeness #1 Responses, p. 1315, Table 6

which means, if an initial denial of coverage of PBT for a given cancer remains denied after appeal, the patients will be liable to pay the costs of PBT themselves. FF 17 These costs can be prohibitive for most patients in Connecticut. The proposal projects that of the population to be served 12% will be insured by Medicaid and 37% by Medicare. FF 28 Although DP is not currently a Connecticut Medicaid provider, the evidence provided shows that the Applicant intends to apply to become a Medicaid provider prior to opening the proposed PBT Center. FF 29

The evidence presented by the Applicant *does not support a finding* that the identified population to be served has a need for the proposed program. (C.G.S. § 19a-639(a)(7))

The Applicant's proposal specifies that Connecticut residents throughout the state are the intended beneficiaries of the proposal, but the predominant focus of the proposal is on patients in the southwest corner of the state and from out of state who suffer from prostate, lung and breast cancer. FF 13, FF 17a As the effectiveness of PBT for the treatment of prostate cancer is at best equal to that of CRT, and at worst unclear, 35% or more of the population that the Applicant anticipates treating do not have a need for the proposed service. FF 17, FF 17a, FF 17b

In addition, while the proposal identifies the PBT Center's proposed location as convenient for patients in Connecticut's southwest region due to the proximity of Routes 7 and Interstate 84, and details plans to operate a shuttle to connect patients using public transportation to the PBT Center, it fails to address issues that patients in other parts of the state will experience, including but not limited to transportation challenges. FF 26, FF 27 As discussed, PBT patients will likely require from 2 to 10 weeks of treatment. FF 41 For patients outside of the Applicant's proposed service area this could require a lengthy round trip for weeks, which is far less convenient than the access available to the identified population. FF 13

The proposal *demonstrates* that utilization of existing health care facilities and health care services in the Applicants' service area supports this application. (C.G.S. § 19a-639(a)(8))

The Applicant's proposal would improve access to PBT services for all Connecticut residents and, because there are currently no PBT providers within the state, the proposal will have minimal impact on Connecticut providers. FF 13, FF 42

The Applicant *has satisfactorily demonstrated* that the proposal will not result in an unnecessary duplication of existing or approved health care facilities. (C.G.S. § 19a-639(a)(9))

There are currently no existing PBT providers or services in Connecticut and, as such, the proposal will not result in a duplication of services. FF 13, FF 42

The Applicant *has satisfactorily demonstrated* that it will provide equitable access to services for Medicaid recipients or indigent persons. (C.G.S. § 19a-639(a)(10))

The Applicants will apply to become a Medicaid provider and will serve this population equitably. FF 28, FF 29 Accordingly, OHS finds that the Applicant *has satisfied this*

criterion.

The Applicant *has satisfactorily demonstrated* that the proposal will not negatively impact the diversity of health care providers and patient choice in the geographic region. (C.G.S. § 19a-639(a)(11)).

The Applicant's proposal to provide PBT in Connecticut would increase patient choice in its primary service area for radiation therapy patients because PBT would be new technology not currently available in the state. Accordingly, the Applicant has *satisfactorily demonstrated* that the proposal would improve provider diversity and patient choice in the region. FF 13, FF 42

C.G.S. § 19a-639(a)(12) in inapplicable because no consolidation is anticipated to result from the addition of the proposed service.

III. CONCLUSION

The Applicant has failed to meet its burden of proof in satisfying the statutory requirements of C.G.S. § 19a-639. Specifically, the Applicant has failed to satisfy the criteria set forth in C.G.S. § 19a-639(a) subdivisions (2) the relationship of the proposed project to the state-wide health care facilities and services plan, (3) that there is a clear public need for the proposal, (4) the financial feasibility of the proposal, (5) the improvement of quality, accessibility, and cost effectiveness of the proposal, (7) and the need of the target population.

Order

Based upon the foregoing Findings of Fact and Discussion contained herein, the Certificate of Need Application of Danbury Proton, LLC to acquire a Proton Beam Accelerator and a Computed Tomography Simulator is **DENIED**.

All of the foregoing constitutes the final Order of the Office of Health Strategy.

By Order of the
Office of Health Strategy,

July 14, 2022
Date

Daniel J. Csuka, Esq.
Staff Attorney / Hearing Officer