

STATE OF CONNECTICUT

OFFICE OF HEALTH STRATEGY

Docket No.: 20-32376-CON

Proposal: Acquisition of a Computed

Tomography ("CT") Simulator and

Technology New to the State (Statute Reference 19a-639)

Applicant: Danbury Proton, LLC (Danbury, CT)

Public/Administrative Hearing held via
Teleconference, on April 22, 2022, beginning at 10 a.m.

Held Before:

VICTORIA VELTRI, ESQ., THE HEARING OFFICER

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1 (Begin: 10 a.m.) 2 3 THE HEARING OFFICER: We're going to begin now. 4 10 a.m. And I'm going to open up here. 5 Applicant in this matter, Danbury Proton, LLC, 6 seeks to acquire equipment utilizing technology 7 not previously utilized in the state under 8 Connecticut General Statutes --9 (Interruption.) 10 THE HEARING OFFICER: Everyone should be muted, please. 11 MICHAEL GRACE: Good morning, your honor. Michael 12 Grace. 13 THE HEARING OFFICER: I'm sorry. Please mute your 14 devices. Thank you very much. I'll begin again 15 just for clarity. 16 The Applicant in this matter, Danbury Proton, 17 LLC, seeks to acquire equipment utilizing technology not previously utilized in the state 18 19 under Connecticut General Statutes Section 20 19a638(a)13. 21 Specifically, the Applicant proposes to 22 establish a proton therapy center in Danbury, 23 Connecticut, and as part of that proposal also 24 seeks to acquire a CT simulator for treatment

25

planning.

On February 28, 2022, the Hearing Officer in this matter issued a proposed final decision denying the application. On March 16, 2022, Danbury Proton filed exceptions and requested oral argument. On April 4, 2022, the Office of Health Strategy, which I'm going to refer to as OHS as we go forward, issued a notice of a hearing for The hearing before the Office of Health today. Strategy is being held right now on April 22, 2022.

My name is Victoria Veltri. I am the

Executive Director of the Office of Health

Strategy, and I will be issuing the final decision
in this matter. Also present on behalf of the
agency is Staff Attorney and Health Systems

Planning Manager, Lara Manzione; as well as Staff

Attorney and Hearing Officer Daniel Csuka.

Public Act 212, Section 149, effective July

1, 2021, authorizes an agency to hold a public
hearing by means of electronic equipment. In
accordance with the public act, any person who
participates orally in an electronic meeting shall
make a good faith effort to state his or her name
and title at the outset at each occasion that
person participates orally during an uninterrupted

dialogue or series of questions and answers. We ask that all members of the public mute the device you are using to access the hearing and silence any additional devices that are around you.

This hearing concerns only the Applicant's oral argument regarding the exceptions to the proposed final decision, and it will be conducted under the provisions of Chapter 54 of the Connecticut General Statutes.

While I cannot impose time constraints, I do not expect this to be a very long hearing, perhaps 15 to 20 minutes or so.

The certificate of need process is a regulatory process, and as such the highest level of respect will be accorded to the Applicant and to the staff of OHS. Our priority is the integrity and transparency of this process.

Accordingly, decorum must be maintained by all present during these proceedings.

This hearing is being transcribed and recorded, and the video will also be made available on the OHS website and its YouTube account.

All documents related to this hearing that have been or will be submitted to the Office of

Health Strategy are available for review through our electronic certificate of need portal, which is accessible on the OHS BON webpage.

Although this hearing is open to the public, only the Applicant and its representatives and OHS and its representatives will be allowed to make comment. Accordingly, the chat feature is disabled.

At this hearing, which is being held virtually, we ask that anyone speaking to the extent possible enable the use of video cameras when speaking during the proceedings. In addition, anyone who is not speaking shall mute their electronic devices, as I said earlier, including telephones, televisions and other devices not being used to access the hearings.

Lastly, as Zoom hopefully notified you in the course of entering the meeting, I wish to point out that by appearing on camera in this virtual hearing you are consenting to being filmed. If you wish to revoke your consent, please do so at this time. However, please be advised that the hearing will be continued to a later date if you do so.

We will proceed in the order established in

the agenda for today's hearing. I want to also remind people that this is an opportunity for oral argument only on the exceptions filed to the proposed decision. It is not an opportunity to introduce new evidence in the record or have witnesses testify.

This is an oral argument. It will probably be made by counsel for the Applicant.

So counsel for the Applicant, could you

please identify yourself for the record?

MR. HARDY: Good morning, Director Veltri. David Hardy
of Carmody, Torrance, Sandak & Hennessey for
Danbury Proton, LLC.

THE HEARING OFFICER: Good morning, Mr. Hardy. It's nice to see you.

Are there other housekeeping or procedural

issues we need to address before we start?

MR. HARDY: Director Veltri, I take it by your introductory comments that screen sharing, for example, is something that you don't want to entertain this morning?

THE HEARING OFFICER: Well, because this is purely an oral argument where it will be an oral argument, it's not really an opportunity to introduce a presentation for evidence on the records.

1	It's your opportunity to make your oral
2	argument based on what you've provided us already
3	that's in the record.
4	MR. HARDY: Sure. Understood. I just had some matters
5	that were of record that I had planned to make
6	reference to, but can proceed without them if
7	that's what you prefer.
8	THE HEARING OFFICER: I think we would prefer you to
9	just make a reference to the location in the
10	record, if you're able to do that, since we have
11	the record accessible to us as well.
12	MR. HARDY: Sure.
13	THE HEARING OFFICER: That would be helpful. Thank
14	you.
15	Any other housekeeping matters?
16	MR. HARDY: No.
17	THE HEARING OFFICER: Okay. Mr. Hardy, you may
18	introduce people if you would like who were
19	on, but obviously the oral argument will be
20	limited to counsel for the Applicant.
21	MR. HARDY: Understood. Many of the principals and
22	representatives of Danbury Proton are on this
23	Zoom, but in the interest of time, I'd just as
24	soon proceed to the argument.
25	THE HEARING OFFICER: Okay. Thank you very much.

You can begin whenever you're ready. And I again please ask everybody to ensure that you're muted and give your attention to counsel for the Applicant for uninterrupted argument.

So thank you very much.

Please go ahead, Mr. Hardy.

MR. HARDY: Well, thank you. I want to thank you,

Director Veltri, for your time this morning. And

I do want to thank the staff of OHS who has worked

under very extraordinarily challenging

circumstances over the past two years to process

Danbury Proton's certificate of need application.

And secondly, I did want to state on behalf of Danbury Proton that its very pleased that OHS has granted a certificate of need to Connecticut Proton Therapy Center in Wallingford.

The trajectory of proton therapy as the optimal mode of radiation treatment for cancer patients is undeniable, and so we're very pleased that OHS has appropriately recognized the clinical benefits of this life-saving technology as well as the need for it in our state.

And so today I intend to explain based on the record of our application why Danbury Proton's facility is critical to meeting the need for

proton therapy in this state, and to providing access to large segments of Connecticut's population who realistically will remain unserved by a single treatment room in Wallingford.

Our March 16, 2022, exceptions to the proposed decision are of record, and we stand by them. Importantly, though, those exceptions were submitted prior to the release of the April 7, 2022, decision approving the Connecticut Proton Therapy Center certificate of need. And because of that I intend to focus my remarks this morning on why the findings made in that decision call for a reconsideration of the proposed decision that has been issued for Danbury Proton.

And in particular, I want to focus on how that decision supports and establishes the importance of the Danbury Proton proposal in terms of meeting Connecticut's need and improving access for Connecticut residents with the placement of a second treatment room located in the southwest corner of Connecticut.

In many respects the Danbury Proton proposal mirrors the Wallingford proposal. Our facility organization is similar. We're working with a 501(c)(3) nonprofit who will be issuing tax exempt

bonds for the project and will be the asset owner of the project.

The experience and the credentials of Danbury Proton team are exceptional and unquestionable.

Dr. Leslie Yamamoto, Dr. Andrew Chang, and Dr.

Michael Moyers are all nationally recognized experts in their fields.

You may have read that just last week a Nevada jury awarded a family of a deceased cancer patient \$200 million based on a refusal to provide that patient with access to proton therapy.

And I mention that because, one, Dr. Chang was the expert for the family in that case. But I also mention it because I think that is an indication of where the commercial healthcare insurance landscape will be shifting, in favor of covering proton therapy, which of course is our sincere hope that that will continue to improve.

And importantly the proposed decision does recognize that Danbury Proton already has in place personnel who will staff the new technology, who are qualified, and who are adequately trained to do so. So that, that has been termed to be a nonissue for Danbury Proton.

The proposed decision also made several

favorable findings about Danbury Proton, including that it would improve healthcare quality and accessibility in our state, that it would be supported by utilization of existing healthcare facilities in our state. That it would provide equitable access to services for Medicaid recipients and indigent persons, and that it would increase the diversity of healthcare providers and would increase patient choice in our state.

So there are a number of positive findings by Danbury Proton that are contained in the proposed decision. And indeed, Danbury Proton does have overwhelming support from the Danbury community, its residents, its government and community leaders, the business community.

And I think part of the reason why that support has been generated and why you see so many people on the Zoom hearing today is that Danbury proton has been extraordinarily transparent -- I would say, comfortably transparent with the public and its supporters at every step of the way in this two-plus year process seeking a certificate of need for its facility.

As OHS is aware, the legislative delegation for Danbury, its members have all been unanimously

and ardently supportive of this project. They have written letters in support of the application. They testified at the public hearing on April 1st, and this project is shovel ready.

Should OHS change course and issue a certificate of need, this project is ready to be in a position by early 2024. Its land use approvals are in place. The Mevion equipment, that's been selected not only for its technological excellence, but also its ability to support clinical research -- it's made in Massachusetts. There's a commitment that it can meet the proposed construction schedule.

The conditional financing approvals are in place and they are ready to move forward should OHS grant Danbury Proton a certificate of need.

Now on the issue of need, the location of
Danbury was chosen due to its proximity to what is
one of the most densely populated areas of our
country, and that's comprised of both Connecticut
and New York residents. And for a sense of
perspective, if you consider that the entire
population of the state of Connecticut is 3.6
million people with the greater weight of that
population weighted toward the southwest corner,

and also consider that Danbury Proton is located within 30 miles of major population centers in Danbury, Stamford, Norwalk, Bridgeport, Waterbury; consider the fact that 98 percent of residents of Fairfield County, which is the most populous county in Connecticut, live within 25 miles of the site; these are all compelling reasons why it makes sense to locate a proton therapy treatment room in Danbury.

So again, against this backdrop of a total state population of 3.6 million people, when you look at the location of the Danbury Proton facility and you draw a circle of 25 miles around it, there's a population of about a million people. And that's on par with what we see in Wallingford, a 25-mile radius; you see about a million people.

But what happens when you draw that circle further out in Danbury from 25 miles to 50 miles, the population within that ring jumps from 1 million people to 17 million people. And if you draw it even further out to 75 miles, there's a population of 22 million.

So again, in our state with 3.6 million people the Danbury Proton proposal would be

located within 50 miles of 17 million people in an area of the state that, in contrast to much of the rest of the state, is growing and not shrinking.

And I think given the area demographics, it is not coincidental that in February of this year, the New York Proton Therapy Center announced that it is the fastest growing of the 40 proton centers in the United States.

And if you look at the history of the development of proton therapy centers, including independent centers like Danbury Proton, they have thrived in areas with far less population density, areas with population density that is not even close to what we see around Danbury.

Even if you look at Massachusetts General Hospital with its four treatment rooms, it has been forced to ration care for years now. And MGH with its four rooms is located in a smaller demographic area than Danbury Proton. So the case for need is laid out comprehensively in our record. It includes an independent report from IHS Markit. And it also includes the entirety of the record of the Connecticut Proton Therapy Center current application which was admitted and noticed as part of the record in the Danbury

Proton application.

And so on the issue of need, which of course is the paramount consideration in this process, the proposed decision concludes that the national statistics and statistics at other centers that we provided were, quote, not shown to be representative of Connecticut, and that Danbury Proton failed to identify Connecticut's need.

And our response to that conclusion is, that's simply not accurate. Danbury Proton submitted American Cancer Society statistics summarizing cancer incidents in Connecticut in support of its need in this state, and in particular the densely populated region of Southwest Connecticut.

And so the first point I would make is that OHS has now cited those very same statistics as supporting its finding a need in the Connecticut Proton Therapy Center decision.

And the second point I would make is that the Connecticut statistics, both the cancer society statistics and the tumor registry data are consistent with the broader non Connecticut specific statistical data that has been supplied.

So in our view, there's no basis upon which

to disbelieve that the distribution of Connecticut cancer patients has somehow diverged from what we see around the country in terms of the broader distribution of cancer patients. And if anything, Connecticut with its older population has a population that is more likely to require cancer treatment.

But what it comes down to in our point, in our view at this point is that the answer to the question of whether there is need for proton therapy in Danbury can now be definitively answered in the affirmative by looking out further than the decision that has been made and the findings that have been made in the Connecticut Proton Therapy Center.

And the approach that OHS took to determining need in that docket was to take the State's tumor registry and then apply census percentages developed by Hartford HealthCare and Yale radiation oncologists to conservatively determine a pool of patients in Connecticut who would be suitable and likely to receive proton therapy.

And that table is table two in the Connecticut Proton Therapy Center decision. And what that concludes, again under a conservative

projection is that there will be a need for proton therapy among 992 Connecticut patients per year -- again, 992 Connecticut patients per year as a conservative projection against table two in the Connecticut Proton Therapy Center decision.

And the decision goes on to determine that -again these 992 Connecticut patients only. This
is disregarding any potential need in New York -that Connecticut Proton Therapy Center in
Wallingford will only be able to serve 208
patients in year one, 397 patients in year two,
479 patients in year three, and 487 patients in
year four, at full capacity.

So in other words, we have a finding from OHS that among Connecticut patients alone there will be an unmet need for 784 patients in year one, an unmet need for 595 patients in year two, an unmet need for 513 patients in year three, and an unmet need for 505 patients in year four at full operational capacity.

And so when you consider that and put that in the perspective of the projected -- again conservatively projected 992 Connecticut-only patients who would be receiving proton therapy in a given year, even when you add in Danbury

Proton's capacity projected to be 338 patients per year, we still will not be meeting the need for proton therapy in our state between the two centers.

And so when you combine the two, the capacity of the two centers we will be in a much better position to meet the needs of the State, both in terms of the total demand for proton therapy but also in regard to the proportion of cancer types treated with proton therapy.

So again the combined capacity would add up to 825 patients a year, and we have a projection of 992 Connecticut patients only who will be in need of proton therapy. So we have conclusive findings that there is need for additional proton therapy capacity.

Another criticism that's leveled at Danbury
Proton in the proposed decision is that 30 to 40
percent of its patients are projected to be
referred by area providers, but Danbury Proton has
no formal arrangements with area providers. And
that is very intentional on the part of Danbury
Proton.

It will be open to all patients regardless of system affiliation or referral source. And I

think that OHS has recognized the importance of serving those patients, because what we see in the decision on Connecticut Proton Therapy Center is that there's a condition that the center in Wallingford accept patients from outside the member networks, which of course is very important.

And it's clear that OHS credited the testimony given by the representatives of Connecticut Proton Therapy Center that the vast majority of its patients are expected to come from its networks, that even under conservative projections that center could meet all of the capacity of the center using only patients from within those two networks.

That there was a projection that 80 percent of patients served at the Wallingford facility would originate from the Yale New Haven Health and Hartford HealthCare System. And we see that OHS has credited that testimony, and in the decision has supplied a projected utilization rate for the Wallingford center. And what you see at full operational capacity in 2025 is the center will be able to serve a total of 487 patients, but of those 487 patients, only 97 are projected to

originate from outside the Hartford HealthCare and Yale networks.

And so in other words, less than 20 percent of the patients who will receive treatment at that center are forecast to originate from outside the member networks. And that will result in substantial imbalance to patient access to proton therapy in our state, and here's why we say that.

If we measure the presence of the Yale New Haven and Hartford HealthCare networks in Connecticut, which we did of record -- and particularly at the hearing, in our public hearing responses, if you use hospital bed count as a metric what you see is that those two networks account for 5,177 hospital beds in our state.

All other healthcare providers' systems' independent hospitals account for 3,739 hospital beds in our state, which as it turns out, tend to be weighted toward the western and southwestern parts of our state.

And so when using these metrics, what you see is the Yale and Hartford networks accounting for 58 percent of the state's hospital bed capacity. But what we see in the approval of the certificate of need is that they're anticipating that 80

percent of their patients treated at Wallingford will originate from their own networks.

So that, that is an imbalance. And so that's, again that's the reason why Danbury Proton is so critical to meeting the State's need, not only from a total demand perspective, but also from the perspective of treating patients and meeting that need in an inequitable manner.

When you factor in the out-of-state hospitals in New York that are within the primary service of Danbury Hospital, you see a figure that is much larger than the total hospital bed count of the Yale and Hartford HealthCare Network. So again, it's just there's no questioning that there's sufficient need for these services among the patients located within the primary service area of Danbury Proton.

On the issue of cost effectiveness. Again, this appears to be a situation where there is conflict between the findings in the Connecticut Proton Therapy Center decision and the Danbury Proton proposed decision.

In the Danbury Proton decision, there is a general doubt expressed about whether or not proton therapy is cost effective, but in the

Connecticut Proton Therapy Center decision there are very clear findings and statements that -- and I'll read them.

Quote, while proton therapy is potentially initially more expensive than traditional X-ray radiation therapy, the difference in costs should be offset through the reduction in need for potential treatment of other side effects, diseases and secondary cancers. Further, there are likely to be fewer hospitalizations and a corresponding reduction in costs, which would offset the increased costs of proton therapy.

So on the issue of whether or not proton therapy is cost effective, in our view it's incumbent upon OHS to correct this conclusion in the Danbury Proton application to align with its conclusion in the Connecticut Proton Therapy decision and find that proton therapy, as it is, is on the whole cost effective for Connecticut patients.

And a related point to cost effectiveness, it has to do with the fact that there can be no question that approving a second center for which there is clear patient need will improve the cost effectiveness of proton therapy treatment for

Connecticut patients.

Having a monopoly on proton therapy controlled by the state's two largest healthcare networks without any competitive pressure is simply a prescription for high costs. And we see that out of concern for that OHS has chosen to impose cost control conditions on the Connecticut Proton Therapy Center Certificate of need. But in our view the State should have the benefit of both, both the competitive pressures and these sensible conditions that have been imposed by OHS.

And allowing a truly and intentionally independent provider with an open referral platform like Danbury Proton serving as an alternative choice for patients in our state can only yield benefits.

We do -- Danbury Proton does laud the conditions that have been imposed on the Connecticut Proton Therapy Center, and many of those conditions that have been identified are already planned for, for the Danbury Proton facility including providing insurance resources for patients and financial assistance for patients.

Danbury Proton would certainly also agree to

a cap on a rate increase, OHS apply the 3 percent cap per year or less cap on the Connecticut Proton Therapy Center. And in fact, if you look at the Danbury Proton proforma financial projections that were submitted with its application, Danbury Proton is actually based on forecasting an increase of half of that, at only 1 and a half percent per year.

And certainly, Danbury Proton would welcome the opportunity to work with the health equity expert to ensure equitable access to patients, and to provide reporting on those efforts to OHS on a regular basis.

And so I do want to state very clearly and unequivocally that we're at OHS willing to approve the Danbury Proton application. It would accept all the same conditions that have been imposed on Connecticut Proton Therapy Center as well as any others that OHS might deem appropriate for the Danbury location. And it certainly would invite and welcome discussions with OHS around those issues.

And in our view, were such a conditional approval to be provided to Danbury Proton,

Connecticut patients would receive benefits, both

the benefits of competitive pressures for care, delivery and pricing as well as the pricing mandates that OHS has developed. And in our view that's the optimum solution for Connecticut patients.

The last points I would like to touch on are in regard to access. And again, importantly OHS found in the proposed decision that Danbury Proton would improve quality and accessibility for patients in need of proton therapy. And it was rightly persuaded, as stated in the Connecticut Proton Therapy Center decision, that allowing for local treatment in a manner that does not necessitate patient and family relocation is critical to providing meaningful access to proton therapy for Connecticut patients.

And that concept has always been at the heart of Danbury Proton's application. Access to proton therapy among Connecticut patients is completely inequitable right now. Only those with financial means and the ability to travel and take time off from work can have access to proton therapy.

And at our public hearing we heard from numerous proton therapy patients who had such means testifying and pleading with OHS to make the

treatment that they were fortunate to receive meaningfully available to all Connecticut residents.

Because the truth is if you live in Norwalk or Stamford and you have to work every day, or if you don't have a car -- or even if you do, traveling to Wallingford on a daily basis for weeks on end is not a realistic option for treatment. One treatment room in Wallingford is inadequate to provide meaningful access to all residents in all corners of our state who could benefit from proton therapy.

And as things stand, our State is already behind the rest of the country in terms of access to proton therapy. And in terms of the growth we're seeing in proton therapy's utilization, the concern is that as a State we'll continue to lag behind with only one treatment room operating in our state.

So in conclusion, Director Veltri, the need for a second treatment room in the southwest corner of our state is clear. And there's no downside risk to our State in approving Danbury Proton's certificate of the application. There's only upside.

There's upside to the Danbury community.

There's upside to the state's economy. There's upside to cancer research efforts. But of course, most importantly access to this life saving and life preserving medical treatment to Connecticut patients who are unquestionably in need of it would be accomplished by granting a certificate of need for a second location in Danbury.

So on behalf of Danbury Proton, we request that you give thorough and thoughtful reconsideration to its certificate of need application. We're happy to answer any questions you may have today, or should you desire to formulate written questions, we'd be happy to provide written answers very shortly -- if that would be helpful.

And again, we would welcome discussions with OHS around any conditions that would persuade OHS to grant Danbury Proton's certificate of need application.

So again, thank you for your time this morning.

THE HEARING OFFICER: Thank you very much, Mr. Hardy.

I don't have any questions at this time. I appreciate you coming today and making your

arguments before me.

I want to let everyone know here today, first of all, I appreciate attendance. And we will be basing a decision, a final decision in this matter that I will be issuing. We will do so in accordance with Chapter 54 of the General Statutes. And if we have any followup, we will be sure to reach out to you, Mr. Hardy, on behalf of your client.

But other than that, I think I just want to thank everyone for being here today. Appreciate the respectful manner in which this was conducted and we will be back to you with a final decision or any questions we might have shortly, hopefully. So I want to thank you again for attending everyone.

And with that, would conclude the hearing for today. Thank you. Thank you very much.

Take care everybody.

MR. HARDY: Thank you.

22 (End: 10:33 a.m.)

## 1 STATE OF CONNECTICUT (Hartford County) 2 I, ROBERT G. DIXON, a Certified Verbatim Reporter, 3 and Notary Public for the State of Connecticut, do hereby certify that I transcribed the above 29 pages of 4 the STATE OF CONNECTICUT OFFICE OF HEALTH STRATEGY, PUBLIC/ADMINISTRATIVE HEARING, in Re: DOCKET NO: 5 20-32376-CON, ACQUISITION OF A COMPUTED TOMOGRAPHY ("CT") SIMULATOR AND TECHNOLOGY NEW TO THE STATE, 6 (STATUTE REFERENCE 19A-639) BY DANBURY PROTON, LLC (DANBURY, CT); held before: VICTORIA VELTRI, ESQ., THE 7 HEARING OFFICER, On April 22, 2022, via teleconference. 8 I further certify that the within testimony was taken by me stenographically and reduced to typewritten 9 form under my direction by means of computer assisted transcription; and I further certify that said 10 deposition is a true record of the testimony given in these proceedings. 11 I further certify that I am neither counsel for, related to, nor employed by any of the parties to the 12 action in which this proceeding was taken; and further, 13 that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially 14 or otherwise interested in the outcome of the action. 15 WITNESS my hand and seal the 20th day of May, 2022. 16 17 18 19 20 21 Robert G. Dixon, CVR-M No. 857 22 My Commission Expires: 23 6/30/2025 24