STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

May 26, 2010

IN THE MATTER OF:

A modification of a previous Certificate of Need

Notice of Modification Final Decision
Office of Health Care Access
Docket Number 10-31262-MDF

Middlesex Hospital

A request to modify Docket Number 08-31262-CON

To: Harry Evert
Vice President
Middlesex Hospital
28 Crescent Street
Middletown, CT 06457

Dear Mr. Evert:

This letter will serve as notice of the Final Decision of the Office of Health Care Access in the above-referenced matter. On May 26, 2010, this Modification was rendered as the revised order of the Office of Health Care Access. A copy of the Final Decision is attached hereto for your information.

By Order of the
Office of Health Care Access

Cristine A. Vogel
Commissioner

CAV:md

Department of Public Health
Office of Health Care Access

A Modification of a Previously Authorized Certificate of Need

Applicant: **Middlesex Hospital**

Modification Docket Number: **10-31262-MDF**

Original Docket Number **08-31262-CON**

Decision Date: **May 26, 2010**

Procedural History: On May 14, 2009, under Docket Number 08-31262-CON, the Office of Health Care Access ("OHCA") entered into an Agreed Settlement with Middlesex Hospital ("Hospital") regarding the Hospital's request to "acquire a second Linear Accelerator ("Linac") equipped with Image-Guided Radiation Therapy ("IGRT") at Middlesex Hospital at a proposed total capital expenditure of $5,226,899." Pursuant to the Agreed Settlement, the Hospital was allowed to acquire the second linear accelerator as a replacement for the Hospital's existing linear accelerator. The Hospital was also authorized, however, to maintain the existing linear accelerator as property owned by the hospital provided that it did not utilize the existing linear accelerator for patient care. Furthermore, it was agreed that the Hospital could seek authorization to reactivate the existing linear accelerator once it achieved sufficient utilization to warrant reactivation.

In August 2009, the Hospital requested modification of the Agreed Settlement asserting that its volumes had increased. OHCA denied this modification request on September 15, 2009, indicating that there was no change in conditions warranting a modification of the Agreed Settlement. Subsequently, on April 23, 2010, the Hospital requested modification of the Agreed Settlement based upon safety concerns with respect to utilizing the second linear accelerator on certain patients and differences in the type of treatment available on each of the linear accelerators owned by the Hospital. OHCA has reviewed the Hospital's request and makes the following findings:

Findings of Fact

1. Under the Agreed Settlement, OHCA and the Hospital agreed to the following in conditions #1-4:

    1. *The Hospital's request to acquire a second Linac equipped with IGRT at Middlesex Hospital at a proposed total capital expenditure of $5,226,899 is* ***denied.***

2. *The Hospital is hereby **approved** to replace the existing Linac, located at the Hospital's Cancer Center at 536 Saybrook Road in Middletown, with the proposed Linac equipped with IGRT at Middlesex Hospital at a proposed total capital expenditure of $5,226,899.*

3. *The Applicants and OHCA agree that the existing linear accelerator may be maintained as property owned by Middlesex Hospital. The Applicants agree that the existing unit shall not be used for purposes of any direct or indirect patient care. This unit shall not be used for the scheduling of radiation therapy services or for the purpose of a back up unit during scheduled or unscheduled downtime on the new unit. No radiation therapy treatments, nor any other diagnostic or therapeutic services, may be performed using the existing unit by Middlesex Hospital or any other entity.*

4. *At the time that the Hospital finds that it has sufficient utilization to warrant the reactivation of the existing unit as a functioning Linac providing patient care services, the Hospital shall then seek a determination from OHCA. This agreed settlement does not specifically guarantee OHCA authorization in the future regarding the reactivation of the existing unit.*

2. Based upon the above conditions of the Agreed Settlement, the Hospital was allowed to own 2 Linacs but only use one of them for patient care. Further, the Hospital was allowed to seek authorization to reactivate the existing Linac unit by filing a determination with OHCA once it had achieved sufficient utilization on one unit.

3. The Hospital's existing Linac is a Varian 2100SCX that delivers intensity modulated radiation therapy ("IMRT") as well as proton electron beam irradiation and 3-dimensional conformal radiation therapy.

4. The Hospital's new Linac is a Novalis TX, which represents a major advance in radiation oncology technology, and provides image guided radiation therapy ("IGRT") as well as stereotactic radiation therapy ("SRT"), also referred to as stereotactic radiosurgery ("SRS").

5. SRS allows the delivery of extremely high and very precise radiation doses often to very small targets and was initially developed to deliver a single or very few fractions of high extremely high-dose radiation to targets in the brain.

6. The Gamma Knife is the most popular of SRS units and the Novalis TX is the product of a collaboration between BrainLab, the developers of the guidance system for the Gamma Knife, and Varian, which has pioneered the development of linear accelerators.

7. The Novalis TX has been designed to deliver SRT not only to the brain but also several extra-cranial sites. The latter is referred to as stereotactic body radiation therapy ("SBRT").

8. The Hospital indicates that it had always intended to utilize the Novalis TX for SRS and SBRT and to be able to offer IMRT with image guidance to more patients.

9. The Hospital did not, however, anticipate the rapidity with which SRT would be introduced into clinical practice and therefore, did not foresee or emphasize in the original application process that SRT would rapidly become the standard of care for a significant portion of its patient population.

10. In its current request, the Hospital indicates that SRS is the standard treatment for brain metastases as well as for may other intracranial tumors such as acoustic neuromas and meningiomas.

11. The Hospital further indicates that SBRT is becoming the standard of care for patients with stages I and II lung cancer and for patients with prostate cancer.

12. The Hospital asserts that with a single machine, it is unable to provide both conventionally fractionated radiation therapy, such as IMRT, and SRS.

13. The Hospital contends that the safe operation and delivery of stereotactic radiation therapy necessitates a commitment in time and personnel that prohibits the use of the Novalis TX for both stereotactic and conventional treatment in a department the size of the Hospital's.

14. The Hospital explains that while an IMRT treatment on the Varian 2100SCX takes 15 minutes, the application of IGRT will add another 5-10 minutes per patient and SRS can take take 1-2 hours per patient.

15. The Hospital further asserts that although the Novalis TX delivers both conventional IMRT and SBRT, it was not designed as a stand alone unit. The maximum field size on the Novalis TX is 22 x 40 cm compared to the 40 x 40 cm on the Varian 2100SCX.

16. Accordingly, patients with very large treatment volumes, such as those with Hodgkin's lymphoma or ovarian or cervical cancer, cannot be treated on the Novalis TX.

17. Therefore, if the Hospital is not allowed to continue to utilize the Varian 2100SCX, it would have to send these extremely ill patients to other treatment facilities for up to 6-8 weeks.

18. The Hospital also indicates that patients treated with palliative intent to areas such as the spine or brain are better treated on the Varian 2100SCX because if treated on the Novalis TX these patients will develop erythema of the skin (a mild sunburn) since the dose is delivered through a single field rather than multiple fields.

19. The Hospital further indicates that the long term effects, side effects, such as skin cancer, from the increased dose to the skin is unknown and therefore, it would be safer to treat these patients on the Varian 2100SCX.

20. Finally, the Hospital contends that IMRT and SBRT are fundamentally different technologies and it is not possible to go from one to the other in a single day on a single machine in a department the size of the Hospital's.

21. Accordingly, the Hospital respectfully requests that OHCA modify its decision and allow the Hospital to continue to utilize the Varian 2100SCX, in the interest of providing the safest, most effective and appropriate cancer treatments to its patients.

22. OHCA finds that the Hospital has raised legitimate safety concerns with respect to utilizing the Novalis TX on certain patients and demonstrated that the Novalis TX can not be utilized as a replacement for the Varian 2100SCX for all of its patients.

23. The Hospital also provided actual volumes on its existing linear accelerator for Fiscal Year 2009 ("FY2009"). The total volume on the Varian 2100SCX in FY2009 was 8,627 treatments.

24. The Hospital reported that it performed 7,674 procedures on the existing Linac in Fiscal Year 2008 ("FY2008") in the original CON application.

25. OHCA's concern about the decrease in volume in FY2008 was one of the factors that led to the inclusion of the condition requiring the Hospital to deactivate the existing Linac until it could achieve sufficient utilization on one Linac.

26. OHCA finds that the increase in volume on the existing Linac in FY2009 coupled with the safety concerns with respect to utilizing the Novalis TX on certain patients is sufficient evidence to justify modifying the Agreed Settlement under Docket Number 08-31262-CON.

Discussion

Based upon the foregoing, OHCA finds that it is appropriate to allow the Hospital to continue to utilize the Varian 2100SCX. The Agreed Settlement under Docket Number 08-31262 allowed the hospital to acquire the Novalis TX and to maintain the Varian 2100SCX as equipment owned by the hospital though the Hospital was not allowed to utilized the Varian 2100 SCX for treatment of its patients until it demonstrated sufficient utilization to justify reactivating the equipment. Therefore, OHCA clearly anticipated that both Linacs would eventually be utilized for patient care.

The Hospital presented legitimate safety concerns with respect to utilizing the Novalis TX for patients with certain types of cancer. At the time that OHCA and the Hospital entered into the Agreed Settlement, it was believed that the Novalis TX could be used for radiation therapy treatments on all patients and therefore, it seemed reasonable to allow the Hospital to utilize the Novalis TX until its utilization increased and justified using both the Novalis TX and the Varian 2100SCX for patient care. In its modification request, however, the Hospital has provided evidence demonstrating that certain patients, such as those with Hodgkin's lymphoma or ovarian or cervical cancer cannot be treated on the Novalis TX due to the large treatment volume. In light of this fact, the Hospital would have to send these patients to other treatment facilities if it is not allowed to continue to utilize the Varian 2100SCX. There are also safety concerns with respect to treating patients with palliative intent to areas such as the spine or brain on the Novalis TX as it could result in mild sunburn and the long term side effects, such as skin cancer, are currently unknown. OHCA finds that it would not be safe for the Hospital to utilize the Novalis TX on all of its cancer patients and therefore, the Hospital should be allowed to continue to utilize the Varian 2100SCX for its patients.

Moreover, the Hospital will be able to provide a higher quality of care to many of its patients if it is allowed to utilize the Novalis TX for SRS and SBRT procedures in light of the expanded application for patients with lung cancer and prostate cancer. The 1-2 hours required for such a procedure would undoubtedly require the Hospital to be able to utilize the Varian 2100SCX for patients requiring IMRT. Finally, the Hospital's utilization statistics from FY2009 demonstrate that the utilization of its existing linear accelerator has increased. OHCA find that the increase in volume along with the safety concerns addressed above justify modifying the order to allow the hospital to utilize both the Varian 2100SCX and the Novalis TX for patient care.

Order

Based upon the above discussion and the reasons provided in the Applicants' modification request, OHCA hereby grants the request and modifies the CON authorized under Docket Number 06-30813-CON. The Agreed Settlement under Docket Number 06-30813-CON is modified as follows:

1. The Hospital's request to acquire a second Linac equipped with IGRT at Middlesex Hospital at a proposed total capital expenditure of $5,226,899 is **approved.**

Conditions 2-4 of the Agreed Settlement are hereby VACATED. Conditions 5-8 as set forth in the CON authorization issued under Docket Number 08-31262-CON are not modified and will remain in full effect.

By Order of the
Office of Health Care Access division of the
Department of Public Health

5-26-10
Date

Cristine A. Vogel
Deputy Commissioner

CAV/md