

Greer, Leslie

From: Martone, Kim
Sent: Wednesday, June 28, 2017 3:48 PM
To: Hansted, Kevin
Cc: Olejarz, Barbara; Greer, Leslie
Subject: FW: Linac CON Modification Request.
Attachments: Middlesex Hospital CON Modification Request 15-31985-CON.PDF

Kimberly R. Martone

Director of Operations, Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13 CMN, Hartford, Connecticut 06134
Phone: 860-418-7029 Fax: 860-418-7053
Email: Kimberly.Martone@ct.gov Website: www.ct.gov/ohca



From: Paul E. Knag [mailto:PKNAG@murthalaw.com]
Sent: Wednesday, June 28, 2017 3:47 PM
To: Martone, Kim
Subject: Linac CON Modification Request.

Here is Middlesex's modification request, per our discussion. We are also overnighting hard copy.

Please let us know if you need further information.

Paul

PAUL E. KNAG | PARTNER

Direct: 203-653-5407 | Fax: 860-240-5711 | Mobile: 203-561-6438 | pknag@murthalaw.com

MURTHACULLINA

Murtha Cullina LLP | Attorneys at Law | www.murthalaw.com
177 Broad Street | Stamford | CT | 06901

Boston Office: 99 High Street | Boston, MA 02110-2320
Direct: 617-457-4066 | Main: 617-457-4000



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PAUL E. KNAG
203.653.5407 DIRECT TELEPHONE
860.240.5711 DIRECT FACSIMILE
PKNAG@MURTHALAW.COM

June 28, 2017

Ms. Kimberly Martone
Director of the Office of Health Care Access
410 Capital Avenue
MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Middlesex Hospital – Modification of Previously Authorized Certificate of Need

Dear Ms. Martone,

Per our conversation, please see Middlesex Hospital's enclosed request for a modification of the Certificate of Need previously authorized by the Agreed Settlement entered into on April 20, 2016, regarding 15-31985-CON.

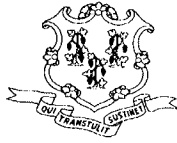
Please feel free to contact me by telephone at 203-653-5407 or by email at pknag@murthalaw.com with any questions or concerns. Thank you for your consideration.

Regards,



Paul E. Knag

Enclosure



**State of Connecticut
Office of Health Care Access
Form for Modification of a Previously
Authorized Certificate of Need**

All persons who are requesting a modification to a previously authorized Certificate of Need must complete this form. Completed forms should be submitted to the Director of the Office of Health Care Access, 410 Capitol Avenue, MS#13HCA, P.O. Box 340308, Hartford, Connecticut 06134-0308.

SECTION I. PETITIONER INFORMATION

If more than 2 Petitioners, please attach a separate sheet of paper and provide additional information in the format below:

	Petitioner	Petitioner
Full legal name	Middlesex Hospital	
Doing Business As		
Name of Parent Corporation	Middlesex Health System, Inc.	
Mailing Address, if Post Office Box, include a street mailing address for Certified Mail	28 Crescent Street Middletown, CT 06457	
Petitioner type (e.g., P for profit and NP for Not for Profit)	NP	
Name of Contact person, including title	Vincent Capece, CEO	
Contact person's street mailing address	28 Crescent Street Middletown, CT 06457	
Contact person's phone, fax and e-mail address	860-358-6150	

SECTION II. GENERAL PROPOSAL INFORMATION

a. Title of Previously Authorized Project and Associated Docket Number(s):

Acquisition of a Non-Hospital Based Linear Accelerator: 15-31985-CON

b. Location of proposal (Town including street address):

250 Flat Rock Place, Westbrook, CT 06498

c. Type of Modification Request:

Change in the Scope of the Authorized Certificate of Need Project

Extension of CON Expiration Date

Change in a CON Order Condition (*other than to extend expiration date*)

Other – Describe: _____

SECTION III. IF REQUESTING A CHANGE IN THE SCOPE OF AUTHORIZED PROJECT:

a. Provide a one page description of the requested change in the scope of a previously authorized Certificate of Need project and provide a detailed rationale for such change:

SECTION IV. IF REQUESTING AN EXTENSION OF THE CON EXPIRATION DATE:

a. Certificate of Need expiration date per CON Final Decision: _____

b. Requested revised CON expiration date: _____

c. Rationale for increased time to fully complete and implement the authorized project:

**SECTION V. IF REQUESTING A CHANGE IN A CON FINAL DECISION CONDITION
(other than extension of the CON expiration date)**

a. Identify the CON Condition that you are requesting to be revised or vacated.

3.b. of the Order requires Middlesex Hospital to “acquire a dedicated CT-scanner with simulation capabilities at its Shoreline site.” The Hospital requests this condition to be revised to state that the CT scanner can be used for other purposes when it is not needed for simulation services.

b. Provide the rationale for such requested change:

Middlesex Hospital received Certificate of Need approval to add a non-hospital based linear accelerator to its Shoreline facility via an Agreed Settlement Order, 15-31985-CON. The Agreed Settlement Order (the “Order”) required Middlesex Hospital to acquire a CT-scanner with simulation capabilities (“CT-scanner 2”). With the addition of this CT-scanner patients are able to receive all necessary cancer treatment at the Shoreline facility. Overall, the Office of Health Care Access’ approval will result in increased access to cancer services on the Shoreline.

When this Order was issued, Middlesex Hospital did not believe that having a “dedicated” scanner meant that it could not use CT-scanner 2 as a back-up for the Shoreline facility’s non-cancer patients if CT-scanner 1 experienced unexpected downtime or as a back-up scanner in the event of overflow. However, the Office of Health Care Access has since advised otherwise.

As mentioned above, and in accordance with the Order, Middlesex Hospital acquired CT-scanner 2, with simulation capabilities, at its Shoreline facility. For the reasons described below, Middlesex Hospital requests a change in the Order, to state that CT-Scanner 2 may be used for other purposes when it is not in use and/or is not scheduled to provide any simulation services. Under this proposal, CT-scanner 2 will continue to be dedicated to the Shoreline’s cancer patients. However, in order to maximize CT-scanner 2’s use and minimize unnecessary health risks and inconvenience for patients, we propose that Middlesex Hospital should be allowed to use CT-scanner 2 for other purposes, such as when the other CT scanner at the Shoreline facility (“CT-scanner 1”) experiences unexpected downtime due to maintenance or as overflow back-up when there an influx of patients requiring scans and CT-scanner 1 is occupied. The Shoreline facility has two technologists on-site to accommodate such use. Middlesex Hospital believes that this proposed modification is in accordance with the Office of Health Care Access’ commitment to access to care as well as its commitment to reduction in health care expenditures.

Since the issuance of the Order, the need for such utilization has increased. CT-scanner 1 has shown growth in the number of scans it performs per year, at a rate of roughly two percent (2%) per year. This increased utilization means that there are times when patients needing a CT-scan cannot be accommodated on a timely basis due to the volume experienced by CT-scanner 1. Middlesex Hospital installed CT-scanner 1 at the Shoreline facility on August 6, 2009, making it eight (8) years old. According to data from the ECRI Institute, CT-scanner 1 has a life expectancy of seven (7) years. Thus, CT-scanner 1 is already past its useful life. While Middlesex Hospital intends to replace CT-scanner 1, it plans to not do so until 2019.

However, unfortunately, as time passes, CT-Scanner 1 continues to need increased work orders, resulting in unexpected down time to the machine. By way of explanation, over the last five (5) years, CT-scanner 1 has experienced 406 hours of down-time, not including any downtime experienced during the evening hours. Currently, when patients need a CT-scan, but CT-scanner 1 is undergoing maintenance; such patients are transferred to a different facility. This requires that patients who may be experiencing health conditions, such as a stroke or other issues requiring a CT scan, need to be diverted to another facility due to such downtime. These transfers out of the facility lead to increased risks to a patient's health and result in a loss of quality in service. However, if CT-scanner 2 could be utilized for CT-scans when it is otherwise dormant due to no scheduled simulations, patients would not need to be transferred, thereby minimizing patient inconvenience, increasing patient outcomes and increasing patient access to CT-scan services.

Ultimately, this change in the Order will reduce expenditures to the health care system and improve access and care for patients. Thus, in order to continue to improve access to care at Middlesex Hospital's Shoreline facility, reduce down time, accommodate increased volume and reduce transfers, we propose to use CT-scanner 2 for non-simulation purposes, when it is not otherwise scheduled to perform simulations.

SECTION VI. OTHER

- a. Submit a completed CON Modification Affidavit.
- b. Identify any other pertinent changes to the findings of facts upon which the original CON authorization was based as a result of this requested modification.

As stated above, Middlesex Hospital believed that the Order permitted its use of CT-scanner 2 for times when CT-scanner 1 needed back-up for overflow or for when CT-scanner 1 experienced unexpected downtime. However, we were recently told otherwise by OHCA. Additionally, the volume for CT-scanner 1 has increased and the machine has outlasted its useful life and has been experiencing down time.

- c. Identify what has been accomplished to date in terms of full project implementation.

The Linac and the CT Scanner have been delivered and are being readied for operation, in contemplation of full implementation in the fall.


CON MODIFICATION AFFIDAVIT

Applicant: Middlesex Health System, Inc.

Project Title: Acquisition of a non-hospital-based linear accelerator

I, Vincent G. Capece, Jr. President + CEO
(Name) (Position – CEO or CFO)

of Middlesex Health System, Inc. being duly sworn, depose and state that the information provided in this CON Modification form is true and accurate to the best of my knowledge.


Signature

6/27/17
Date

Subscribed and sworn to before me on June 27, 2017


Notary Public/Commissioner of Superior Court

Abby Ann Cole, Notary Public
My Commission Expires
January 31, 2020

My commission expires: _____

Greer, Leslie

From: Greer, Leslie
Sent: Thursday, June 29, 2017 2:57 PM
To: 'matthews@wiggins.com'
Cc: Hansted, Kevin; Martone, Kim; Olejarz, Barbara
Subject: Modification Notification
Attachments: 17-31985-MDF Decision.pdf

Tracking:	Recipient	Delivery
	'matthews@wiggins.com'	
	Hansted, Kevin	Delivered: 6/29/2017 2:57 PM
	Martone, Kim	Delivered: 6/29/2017 2:57 PM
	Olejarz, Barbara	Delivered: 6/29/2017 2:57 PM

Attorney Mathews,

Attached is a notification of a modification received @ the Office of Health Care Access.

Thank you,

Leslie M. Greer
Consumer Information Representative (PPT)
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS#13HCA, Hartford, CT 06134
Phone: (860) 418-7013 Fax: (860) 418-7053
Website: www.ct.gov/ohca



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Raul Pino, M.D., M.P.H.
Commissioner

Office of Health Care Access

June 29, 2017

Rebecca A. Mathews, Esq.
Wiggin & Dana, LLP
One Century Tower
265 Church Street
P.O. Box 1832
New Haven, Connecticut 06508-1832

RE: Docket Number 17-31985-MDF: A Request for Modification of the
Certificate of Need authorized under Docket Number 15-31985-CON
Middlesex Hospital

Dear Attorney Mathews:

On June 29, 2017, OHCA received a request for a modification from Middlesex Hospital. The request is to modify Condition 3 of the CON. A copy of the complete modification request can be found on OHCA's website.

This letter is to inform you that OHCA will take action upon the request for modification. If you would like to submit any comments regarding this matter, please do so in writing to OHCA by 4:30 PM on Friday, July 21, 2017.

Sincerely,

Kimberly Martone
Director of Operations



Phone: (860) 418-7001 • Fax: (860) 418-7053
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
www.ct.gov/dph

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Olejarz, Barbara

From: Hansted, Kevin
Sent: Tuesday, July 25, 2017 6:57 AM
To: Olejarz, Barbara
Subject: FW: OHCA Modification Request # 17-31985-MDF

Please add to the record.

Kevin T. Hansted
Staff Attorney
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue
Hartford, CT 06134
Phone: 860-418-7044
kevin.hansted@ct.gov



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From: Capece, Vin [mailto:vin.capece@midhosp.org]
Sent: Monday, July 24, 2017 12:22 PM
To: Hansted, Kevin <Kevin.Hansted@ct.gov>
Subject: Re: OHCA Modification Request # 17-31985-MDF

Mr. Hanstead,

In response to your request, please see the following chart, which shows the utilization numbers of the CT Scanner located at 250 Flat Rock Place, Westbrook, Connecticut (CT Scanner 1, as defined by the Modification Request).

Year	2012	2013	2014	2015	2016
------	------	------	------	------	------

Shoreline CT	Actual Shoreline CT Volume	5995	6296	6554	7365	7854
-------------------------	----------------------------------	------	------	------	------	------

Please let me know if you have any additional questions.

Regards,

Vincent Capece

Vincent G. Capece, Jr.
President/CEO

Middlesex Hospital
28 Crescent Street
Middletown, CT 06457
office: 860-358-6150
fax: 860-346-5485
www.middlesexhospital.org



On Fri, Jul 21, 2017 at 1:33 PM, Hansted, Kevin <Kevin.Hansted@ct.gov> wrote:

Good afternoon Mr. Capece:

I am in receipt of your modification request pertaining to the CT scanner located at 250 Flat Rock Place, Westbrook Connecticut. In the modification request it states that the utilization of CT scanner 1 has increased roughly 2% per year. Please provide me with the utilization numbers for CT scanner 1 for the last 5 years.

Thank you,

[Kevin T. Hansted](#)

Staff Attorney

Office of Health Care Access

Connecticut Department of Public Health

410 Capitol Avenue

Hartford, CT 06134

Phone: [860-418-7044](tel:860-418-7044)

kevin.hansted@ct.gov



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If you have received this message in error, please notify Middlesex Health System by sending a reply email to the sender or calling the Middlesex Hospital Privacy Office Hotline at 860-358-4630 and then delete this email and all attachments.

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Greer, Leslie

From: Olejarz, Barbara
Sent: Monday, July 31, 2017 11:34 AM
To: vin.capece@midhosp.org; pknaq@murthalaw.com
Cc: matthews@wiggin.com
Subject: Modification Decision
Attachments: 17-31985-MDF decision.pdf

7/31/17

Attached is the Modification Decision for Docket Number 17-31985-MDF, Middlesex Hospital

Barbara K. Olejarz
Administrative Assistant to Kimberly Martone
Office of Health Care Access
Department of Public Health
Phone: (860) 418-7005
Email: Barbara.Olejarz@ct.gov



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

Final Decision

Modification of a Previously Authorized Certificate of Need

Applicant: Middlesex Hospital
28 Crescent Street, Middletown, CT

Docket Number: 17-31985-MDF

Project Description: Modification of previous Certificate of Need
authorization 15-31985-CON

Procedural History: On April 20, 2016, the Office of Health Care Access (“OHCA”) issued a Certificate of Need (“CON”) to Middlesex Hospital under Docket Number 15-31985-CON, for the acquisition of non-hospital based linear accelerator. Included with the CON was a requirement that Middlesex Hospital acquire a dedicated CT scanner with simulation capabilities.

On June 29, 2017, OHCA received a Request for Modification from Middlesex Hospital seeking to modify Condition 3.b. of the CON. As required by Conn. Gen. Stat. § 19a-639b(b), OHCA noticed this request on its website for 30 days and notified the other parties involved. OHCA did not receive any written comments or requests for a public hearing. Deputy Commissioner Addo reviewed the entire record in this matter.



Phone: (860) 418-7001 • Fax: (860) 418-7053
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Hartford, Connecticut 06134-0308
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Findings of Fact

1. The CON issued under Docket Number 15-31985-CON (the “CON”), by way of an Agreed Settlement, required Middlesex Hospital to acquire a dedicated CT scanner with simulation capabilities (“CT scanner 2”) for its shoreline facility located at 250 Flat Rock Place, Westbrook, Connecticut (“Shoreline Facility”).
2. OHCA intended for CT scanner 2 to be used exclusively for cancer patients at the Shoreline Facility.
3. At the time the Agreed Settlement was executed, Middlesex Hospital did not believe that having a “dedicated” scanner meant that it could not use CT scanner 2 as a back-up for the Shoreline Facility’s non-cancer patients if its other CT scanner (“CT scanner 1”) experienced unexpected downtime or to cover overflow.
4. Since the issuance of the CON, OHCA has advised Middlesex Hospital that CT scanner 2 was to be used only for cancer patients at the Shoreline Facility.
5. CT scanner 1 has shown a consistent increase in the number of scans it performs each year. The chart below shows the specific volumes:

Shoreline CT	Year	2012	2013	2014	2015	2016
	Actual Shoreline CT Volume	5995	6296	6554	7365	7854

Discussion

Connecticut General Statutes § 4-181a (b) provides in relevant part: “On a showing of changed conditions, the agency may reverse or modify the final decision, at any time, at the request of any person or on the agency’s own motion.” Middlesex Hospital has sufficiently demonstrated a change in conditions based upon its interpretation of the language contained in the Agreed Settlement versus OHCA’s interpretation. Additionally, although minimal, the increase in volume for CT scanner 1 also constitutes a change in conditions. It should be noted that the minimal increase in volume would not alone be enough to grant a modification of the original CON. However, in order to increase access for the patients at the Shoreline Facility, OHCA deems it appropriate to approve Middlesex Hospital’s request to allow for the use of CT scanner 2 on all patients, not just cancer patients.


Order

Based upon the foregoing, the request to modify the CON issued under Docket Number 15-31985-CON is hereby **APPROVED**. Condition 3.b. is hereby revised as follows:

- b. acquire a CT-scanner with simulation capabilities at its Shoreline site for use on cancer and non-cancer patients,

All other conditions entered under Docket Number 15-31985-CON remain in effect.

7/31/2017
Date


Yvonne T. Addo, MBA
Deputy Commissioner

Olejarz, Barbara

From: Microsoft Outlook
To: pknaq@murthalaw.com; vin.capece@midhosp.org; matthews@wiggin.com
Sent: Monday, July 31, 2017 11:34 AM
Subject: Relayed: Modification Decision

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

pknaq@murthalaw.com (pknaq@murthalaw.com)

vin.capece@midhosp.org (vin.capece@midhosp.org)

matthews@wiggin.com (matthews@wiggin.com)

Subject: Modification Decision

Olejarz, Barbara

From: Capece, Vin <vin.capece@midhosp.org>
To: Olejarz, Barbara
Sent: Monday, July 31, 2017 11:42 AM
Subject: Read: Modification Decision

Your message

To:
Subject: Read: Modification Decision
Sent: Monday, July 31, 2017 11:42:11 AM (UTC-05:00) Eastern Time (US & Canada)

was read on Monday, July 31, 2017 11:42:09 AM (UTC-05:00) Eastern Time (US & Canada).

User, OHCA

From: Clarke, Ormand
Sent: Friday, December 22, 2017 1:44 PM
To: vin.capece@midhosp.org
Cc: User, OHCA; Roberts, Karen; Clarke, Ormand
Subject: Certificate of Need ("CON") to Middlesex Hospital under Docket Number 15-31985-CON, for the acquisition of non-hospital based linear accelerator.

Vincent G. Capence, Jr.,
President/Chief Executive Officer
Middlesex Health Systems, Inc.,
28 Crescent Street,
Middletown, CT 06457
P: 860-358-6150 E-mail: vin.capece@midhosp.org

RE: Certificate of Need ("CON") to Middlesex Hospital under Docket Number 15-31985-CON, for the acquisition of non-hospital based linear accelerator.

Dear Mr. Capence:

On April 20, 2016, the Office of Health Care Access ("OHCA") issued a Certificate of Need ("CON") to Middlesex Hospital under Docket Number 15-31985-CON, for the acquisition of non-hospital based linear accelerator. Subsequent to this issuance of the Agreed Settlement, OHCA issued a modification under Docket Number 15-31985-CON -MDF to allow for the Acquisition of a CT-scanner with simulation capabilities at its Shoreline site for use on cancer and non-cancer patients.

It has been OHCA's recognition from media reports and Middlesex Hospital's web-based announcements that the entity has commenced operation since October, 2017. In order to be consistent with the key requirements of the CON, OHCA requests an update on the program's operation according to conditions two and three as described below:

Condition #2, in part: "...Middlesex shall provide OCHA with written notification of its ceasing regularly scheduled operation of the Varian within thirty (30) days of such cessation."

Condition # 3, in part: "Middlesex shall provide OHCA with written notification that it has completed each of the actions listed in subsections (a) through (c) above not more than thirty (30) days of its completion of each."

OHCA respectfully requests a formal update for the record under Docket Number 15-31985-CON in relation to conditions 2 and 3 of Docket Number 15-31985-CON as cited above, by January 20, 2018. Please indicate what the hospital's status with the agreed upon requirements of Conditions #2 and #3.

If there are any questions related to this request, please do not hesitate to contact me.

Respectfully,

Ormand Clarke
Health Care Analyst

Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13HCA, P.O. Box 340308, Hartford, CT 06134-0308
P: (860) 418-7047 / F: (860) 418-7053 / E: ormand.clarke@ct.gov



December 18, 2017

Ms. Kimberly Martone, Director of Operations
State of Connecticut
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

Re: *Certificate of Need Docket Number 15-31985*

Dear Ms. Martone:

The purpose of this letter is to provide written notification to OHCA regarding notification requirements outlined in Docket Number 15-31985-CON. The applicant for this CON is Middlesex Hospital regarding a request to acquire a non-hospital based linear accelerator ("LINAC") at our Shoreline site.

Item #2 in the approval indicates that "the Varian may be employed only during periods when the Novalis LINAC is inoperable due to Maintenance, repair or other unavoidable interruptions in service, *or as needed to ensure the Varian maintains its functionality.*" Middlesex has ceased regularly scheduled operation of the Varian 2100 LINAC as of November 20, 2017. After careful review, and in consultation from both the manufacturer and independent physicists, we have determined that modest daily use is needed to ensure the LINAC maintains safe functionality. This will allow the 2100 to provide backup for the Novalis LINAC, in the event the Novalis becomes inoperable due to extended maintenance, repair, or other unavoidable interruptions in service.

Item#3 in the approval has several requirements which are addressed below:

- A. Middlesex has secured a contract with .decimal to acquire IMRT compensator devices per patient specific needs.
- B. Middlesex has acquired a GE Discovery RT CT scanner with simulation capabilities at the Shoreline site.
- C. Middlesex has the ability to fabricate immobilization devices at its Shoreline site.
- D. Middlesex has spent considerable time and effort coordinating a full complement of Cancer Care services at its Shoreline site. These services mirror the services offered at the Cancer Center location in Middletown and include: medical oncology, infusion, radiation oncology, 3D mammography and other diagnostic imaging equipment, full laboratory services, social work and related counseling support, dietician support, speech and language pathologist support, nurse navigation services, survivorship services, genetic counseling services and integrative medicine modalities.

28 Crescent Street
Middletown, Connecticut 06457-3650

tel 860 358-6110
fax 860 346-5485

- E. On-site physician services include medical oncology, surgical oncology, radiation oncology, radiologists, radiation technologists, physicists, nurses and other medical professionals to meet the complex needs of the cancer patient from diagnosis through treatment into survivorship.

Finally, Middlesex will continue to comply with ongoing data submissions required as outlined in Items #4 - 9 for the next three years.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read "Vincent G. Capece, Jr.", with a large, stylized circular flourish at the end.

Vincent G. Capece, Jr.
President/CEO

VGC:aac

User, OHCA

From: Clarke, Ormand
Sent: Monday, January 29, 2018 11:39 AM
To: Vin Capece
Cc: Roberts, Karen; User, OHCA
Subject: RE: Certificate of Need ("CON") to Middlesex Hospital under Docket Number 15-31985-CON, for the acquisition of non-hospital based linear accelerator.

Vincent G. Capece, Jr.,
President/Chief Executive Officer
Middlesex Health Systems, Inc.,
28 Crescent Street,
Middletown, CT 06457
P: 860-358-6150 E-mail: vin.capece@midhosp.org

RE: Certificate of Need ("CON") to Middlesex Hospital under Docket Number 15-31985-CON, for the acquisition of non-hospital based linear accelerator.

Dear Mr. Capece:

On April 20, 2016, the Office of Health Care Access ("OHCA") issued a Certificate of Need ("CON") to Middlesex Hospital under Docket Number 15-31985-CON, for the acquisition of a non-hospital based linear accelerator. Subsequent to the issuance of the Agreed Settlement, OHCA issued a modification under Docket Number 17-31985-MDF to allow that the CT-scanner with simulation capabilities at its Shoreline site can be used on both cancer and non-cancer patients.

Thank you for your letter of December 18, 2017 regarding Conditions #2 and #3 of the Agreed Settlement. However, OHCA requires further information and/or clarification regarding the status of this project. Please respond to the following as it pertains to your December 18, 2017 letter:

- 1) What was the date of the start of operation (for scheduled patients) for the new Linear Accelerator at the Shoreline campus?
- 2) In your letter you indicated that although the Varian 2100 unit "ceased regularly schedule operation" on November 20, 2017, that unit is being used for "modest daily use" in order to maintain its functionality. As the continued use of that unit is limited by the parameters of Condition #2, OHCA requests further clarification regarding the use of the term "modest daily use." Is the Varian being scheduled on a regular basis daily? How many patients each day are specifically scheduled on this unit?

Please file a response to the above by February 9, 2018. It is requested that any response submitted to OHCA should continue to be delivered to the general inbox at OHCA@ct.gov, as in prior instances.

Respectfully,

Ormand Clarke
Health Care Analyst
Office of Health Care Access

Connecticut Department of Public Health
410 Capitol Avenue, MS #13HCA, P.O. Box 340308, Hartford, CT 06134-0308
P: (860) 418-7047 / F: (860) 418-7053 / E: ormand.clarke@ct.gov



User, OHCA

From: Clarke, Ormand
Sent: Thursday, February 01, 2018 9:12 AM
To: User, OHCA
Subject: FW: Certificate of Need ("CON") to Middlesex Hospital under Docket Number 15-31985-CON, for the acquisition of non-hospital based linear accelerator.

From: Capece, Vin [mailto:vin.capece@midhosp.org]
Sent: Monday, January 29, 2018 11:54 AM
To: Clarke, Ormand <Ormand.Clarke@ct.gov>
Subject: Re: Certificate of Need ("CON") to Middlesex Hospital under Docket Number 15-31985-CON, for the acquisition of non-hospital based linear accelerator.

Mr. Clarke,

We will be sure to address your additional questions by February 9th.

Thank you.

Vincent G. Capece, Jr.
President/CEO

Middlesex Hospital
28 Crescent Street
Middletown, CT 06457
office: 860-358-6150
fax: 860-346-5485
www.middlesexhospital.org



On Mon, Jan 29, 2018 at 11:38 AM, Clarke, Ormand <Ormand.Clarke@ct.gov> wrote:

Vincent G. Capece, Jr.,
President/Chief Executive Officer
Middlesex Health Systems, Inc.,
28 Crescent Street,
Middletown, CT 06457

P: [860-358-6150](tel:860-358-6150) E-mail: vin.capece@midhosp.org

RE: Certificate of Need (“CON”) to Middlesex Hospital under Docket Number 15-31985-CON, for the acquisition of non-hospital based linear accelerator.

Dear Mr. Capece:

On April 20, 2016, the Office of Health Care Access (“OHCA”) issued a Certificate of Need (“CON”) to Middlesex Hospital under Docket Number 15-31985-CON, for the acquisition of a non-hospital based linear accelerator. Subsequent to the issuance of the Agreed Settlement, OHCA issued a modification under Docket Number 17-31985-MDF to allow that the CT-scanner with simulation capabilities at its Shoreline site can be used on both cancer and non-cancer patients.

Thank you for your letter of December 18, 2017 regarding Conditions #2 and #3 of the Agreed Settlement. However, OHCA requires further information and/or clarification regarding the status of this project. Please respond to the following as it pertains to your December 18, 2017 letter:

- 1) What was the date of the start of operation (for scheduled patients) for the new Linear Accelerator at the Shoreline campus?

- 2) In your letter you indicated that although the Varian 2100 unit “ceased regularly schedule operation” on November 20, 2017, that unit is being used for “modest daily use” in order to maintain its functionality. As the continued use of that unit is limited by the parameters of Condition #2, OHCA requests further clarification regarding the use of the term “modest daily use.” Is the Varian being scheduled on a regular basis daily? How many patients each day are specifically scheduled on this unit?

Please file a response to the above by February 9, 2018. It is requested that any response submitted to OHCA should continue to be delivered to the general inbox at OHCA@ct.gov, as in prior instances.

Respectfully,

Ormand Clarke

Health Care Analyst

Office of Health Care Access

Connecticut Department of Public Health

[410 Capitol Avenue](#), MS #13HCA, P.O. Box 340308, Hartford, CT 06134-0308

P: [\(860\) 418-7047](tel:(860)418-7047) / F: [\(860\) 418-7053](tel:(860)418-7053) / E: ormand.clarke@ct.gov



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User, OHCA

From: Clarke, Ormand
Sent: Friday, February 09, 2018 2:44 PM
To: User, OHCA
Subject: FW: Middlesex Hospital - Response Letter CON Docket Number 15-31985
Attachments: MH Response to OHCA CON Docket #15-31985 02.08.18.pdf

Follow Up Flag: Follow up
Flag Status: Completed

From: Cole, Abby [mailto:abby.cole@midhosp.org]
Sent: Thursday, February 8, 2018 4:12 PM
To: Clarke, Ormand <Ormand.Clarke@ct.gov>
Cc: Martone, Kim <Kimberly.Martone@ct.gov>
Subject: Middlesex Hospital - Response Letter CON Docket Number 15-31985

Mr. Clarke:

Please find attached a letter from Vincent Capece, President/CEO at Middlesex Hospital, regarding Certificate of Need Docket Number 15-31985.

The original of this letter will be sent to you via U.S. mail.

Thank you.

Abby Cole

Abby Cole
Administrative Staff Supervisor
Executive Assistant to Vincent G. Capece, Jr., President/CEO
Notary Public

Middlesex Hospital
28 Crescent Street
Middletown, CT 06457
office: 860-358-6150
fax: 860-346-5485
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February 8, 2018

Mr. Ormand Clarke, HealthCare Analyst
State of Connecticut
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

Re: *Certificate of Need Docket Number 15-31985*

Dear Mr. Clarke:

Enclosed you will find the response to follow-up questions included in your email to me dated January 29, 2018 with regard to Docket #15-31985-CON.

What was the date of the start of operation (for scheduled patients) for the new Linear Accelerator at the Shoreline campus?

The first patient treatment on the Elekta LINAC in Westbrook occurred on November 1, 2017.

In your letter you indicated that although the Varian 2100 unit “ceased regularly scheduled operation” on November 20, 2017, that unit is being used for “modest daily use” in order to maintain its functionality. As the continued use of that unit is limited by the parameters of Condition #2, OHCA requests further clarification regarding the use of the term “modest daily use.” Is the Varian being scheduled on a regular basis daily? How many patients each day are specifically scheduled on this unit?

Yes, the Varian 2100 LINAC is being scheduled on a daily basis in order to achieve the modest daily use of this machine necessary to maintain its functionality, as recommended by the manufacturer and our independent physicist. When we began using the new Elekta LINAC on November 1, we gradually increased the utilization of this new machine, as dictated by the staff training schedule set forth by the manufacturer to ensure safe operating procedures for both the staff and patients. Beginning on November 20, as patients completed their course of treatment on the Varian 2100, our use of the 2100 declined accordingly. Once the decline in patient treatments on the Varian 2100 reached five patients per day, we capped treatments at this level of volume to meet the modest daily use requirement.

28 Crescent Street
Middletown, Connecticut 06457-3650

tel 860 358-6110
fax 860 346-5485

As required by sections 7, 8, and 9, we will be submitting to you data prescribed by these sections, which will detail the use of all of our LINACs since November 1, 2017. The CON does not prescribe a deadline for reporting, however, our first report will be for the partial period November 1 through December 31, 2017. As is required, subsequent reports will cover semi-annual periods from January through June and July through December. We expect to submit our first report by February 28, 2018.

If you have any further questions, please don't hesitate to contact me.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read "Vincent G. Capece, Jr.", is written over the typed name.

Vincent G. Capece, Jr.
President/CEO

VGC:aac

c: Ms. Kimberly Martone, Director of Operations

User, OHCA

From: Clarke, Ormand
Sent: Friday, February 09, 2018 2:46 PM
To: Cole, Abby
Cc: User, OHCA
Subject: RE: Middlesex Hospital - Response Letter CON Docket Number 15-31985

Follow Up Flag: Follow up
Flag Status: Completed

Thanks, Ms. Cole. Receipt confirmed.

From: Cole, Abby [mailto:abby.cole@midhosp.org]
Sent: Thursday, February 8, 2018 4:12 PM
To: Clarke, Ormand <Ormand.Clarke@ct.gov>
Cc: Martone, Kim <Kimberly.Martone@ct.gov>
Subject: Middlesex Hospital - Response Letter CON Docket Number 15-31985

Mr. Clarke:

Please find attached a letter from Vincent Capece, President/CEO at Middlesex Hospital, regarding Certificate of Need Docket Number 15-31985.

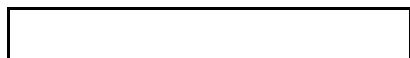
The original of this letter will be sent to you via U.S. mail.

Thank you.

Abby Cole

Abby Cole
Administrative Staff Supervisor
Executive Assistant to Vincent G. Capece, Jr., President/CEO
Notary Public

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User, OHCA

From: Clarke, Ormand
Sent: Wednesday, March 14, 2018 12:42 PM
To: User, OHCA
Subject: FW: CON Docket Number 15-31985
Attachments: OHCA CON tables Oct 1 - Dec 31 2017 final.pdf

From: Drew, Justin [mailto:justin.drew@midhosp.org]
Sent: Tuesday, March 6, 2018 3:57 PM
To: Clarke, Ormand <Ormand.Clarke@ct.gov>
Cc: Martino, Laura <laura.martino@midhosp.org>
Subject: CON Docket Number 15-31985

Mr. Clarke-

Please find the attached document regarding communication for CON Docket Number 15-31985. The tables included will be reported out by our organization for the next 3 years per the CON. Is this email to you the best way for us to send them going forward? Thank you.

Regards,
Justin Drew

Justin Drew MSN, RN
Director, Cancer Center

Middlesex Hospital Cancer Center
540 Saybrook Rd, Suite 330
Middletown, CT 06457
Office: (860) 358 - 2075
Fax: (860) 358 - 2089
www.middlesexhospital.org



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ADMINISTRATION

March 6, 2018

Mr. Ormand Clarke, HealthCare Analyst
 State of Connecticut
 Office of Health Care Access
 410 Capitol Avenue, MS#13HCA
 P.O. Box 340308
 Hartford, CT 06134

Re: **Certificate of Need Docket Number 15-31985**

Dear Mr. Clarke:

The purpose of this letter is to provide written notification to OHCA regarding the tables outlined in sections 7, 8 and 9 as outlined in Docket Number 15-31985-CON. This first report is for the partial reporting period of 10/1/17-12/31/17 as referenced in the last sentence of section 6. The applicant for this CON is Middlesex Hospital regarding a request to acquire a non-hospital based linear accelerator ("LINAC") at our Shoreline site.

Section 7 Table				
	Elekta	Novalis	Varian	Total
Berlin		27		27
Chester	43		10	53
Clinton	108	37	13	158
Colchester		33	25	58
Coventry		8		8
Cromwell		13		13
Deep River		24		24
Durham		143		143
East Haddam	15	21	6	42
East Hampton		156	50	206
East Lyme	24			24
Essex	19	6		25
Groton	30			30
Guilford	63			63
Haddam		97	71	168
Hamden			33	33
Ivoryton		77		77

28 Crescent Street
 Middletown, Connecticut 06457-3650

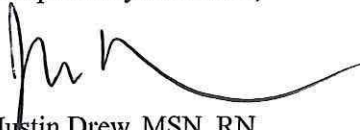
tel 860 358-6110
 fax 860 346-5485

Killingworth		31		31
Madison	63		1	64
Marlborough		75	10	85
Middlefield		77	49	126
Middletown		322	141	463
New Haven	10			10
Old Lyme	57	2		59
Old Saybrook	63	10	7	80
Outside CT		50	16	66
Portland		119	22	141
Southington		12	13	25
Vernon Rockville		24		24
Wallingford		27		27
Westbrook	98	64	9	171
Grand Total	593	1,455	476	2,524

Section 8 Table			
Time Period	Duration of Downtime	Num of Patients Affected	Reason For Downtime
10/12/17	6.5 hrs	13 patients	foil/carriage interlock
10/31/17	15 mins	1 patient	MLC issues
11/27/17	45 mins	0 patients	field light issue

Section 9 Table						
Site	Medicaid	Medicare	Commercial	Champus/Tricare	MH Employee	Total
Middletown Site	14	1,031	757	33	96	1,931
Shoreline Site		389	204			593
Total	14	1,420	961	33	96	2,524

Respectfully submitted,



Justin Drew, MSN, RN
 Director, Middlesex Hospital Cancer Center

User, OHCA

From: Clarke, Ormand
Sent: Wednesday, March 14, 2018 1:12 PM
To: Drew, Justin; User, OHCA
Cc: Clarke, Ormand
Subject: RE: CON Docket Number 15-31985

Follow Up Flag: Follow up
Flag Status: Completed

Dear Mr. Drew:

Thanks for your filings of March 6, 2018, in relation to CON Docket Number 15-31985.

The Office will review the tables and provide comments, if there is need for clarification. The current method of submission is acceptable; however, it is requested that any response submitted to OHCA should continue to be delivered to the general inbox at OHCA@ct.gov, as in prior instances.

Please do not hesitate to contact me if there are any questions.

Very Kind Regards,
Ormand.

From: Drew, Justin [mailto:justin.drew@midhosp.org]
Sent: Tuesday, March 6, 2018 3:57 PM
To: Clarke, Ormand <Ormand.Clarke@ct.gov>
Cc: Martino, Laura <laura.martino@midhosp.org>
Subject: CON Docket Number 15-31985

Mr. Clarke-

Please find the attached document regarding communication for CON Docket Number 15-31985. The tables included will be reported out by our organization for the next 3 years per the CON. Is this email to you the best way for us to send them going forward? Thank you.

Regards,
Justin Drew

Justin Drew MSN, RN
Director, Cancer Center

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540 Saybrook Rd, Suite 330
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Office: (860) 358 - 2075
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 **MIDDLESEX HOSPITAL**

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