



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

September 11, 2020

Denise Gunter

denise.gunter@nelsonmullins.com

Exempt from Review

Record #: 3343

Facility Name: Novant Health Forsyth Medical Center

FID #: 923174

Business Name: Novant Health, Inc.

Business #: 1341

Project Description: Extension of deadline to remove existing CT simulator from service for an additional 90 days following installation of approved replacement CT simulator (Record # 3266 Extension of time to dispose of the existing CT simulator for up to 90 days following installation of approved replacement CT simulator Record #3023 Replace existing CT simulator)

County: Forsyth

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of **September 8, 2020**, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-176(22a). Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

However, you need to contact the Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Agency. Changes in a project include but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Sincerely,

Celia C. Inman, Project Analyst

Martha J. Frisone, Chief

cc: Acute and Home Care Licensure and Certification, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603

MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704

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September 8, 2020

Via Electronic Mail

Martha J. Frisone, Chief
Healthcare Planning and Certificate of Need Section
North Carolina Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Novant Health Forsyth Medical Center
FID # 923174
Health Service Area II
Forsyth County
Replace Existing CT Simulator

Dear Ms. Frisone:

On April 23, 2020, Novant Health Forsyth Medical Center (“NHFMC”) submitted a request that it be allowed to extend by ninety days the replacement of its Existing CT Simulator following the installation and operation of its Replacement CT Simulator. The Agency granted this request on April 28, 2020. See **Exhibit A** attached hereto (request letter and response). The Replacement CT Simulator was installed in early June 2020 and was scheduled to be removed by September 6, 2020. NHFMC plans to file a CON application in November 2020 seeking permission to retain the Existing CT Simulator permanently. In the meantime, however, NHFMC respectfully asks that it allowed to keep using the Existing CT Simulator for an additional ninety days, from September 6, 2020 until December 5, 2020.

The reasons for this request are similar to the reasons stated in our April 23 request. Although the pandemic has had an effect with postponement of cases earlier in the year, NHFMC’s cancer program continues to grow. Novant Health Kernersville Medical Center (“NHKMC”) cancer patients have their treatment planning done at NHFMC, and while those volumes declined somewhat earlier this year due to the pandemic, they are building back up again. Below is recent information about treatment volume and number of patients. Growth is particularly strong at NHFMC, with an 11%

CAGR in total volume from 2018 to 2020, and a 10.5% CAGR in total patient volumes from 2018-2020.

Forsyth Rad Onc				
	2018	2019	2020 YTD	2020 Forecast
Total Daily Treatment Volume	14586	19605	9963	19926
Special Procedures: High Dose and Brachy Therapy	406	493	364	590
Total Volume	14992	20098	10327	20516
Kernersville Rad Onc				
	2018	2019	2020 YTD	2020 Forecast
Total Daily Treatment Volume	3734	3842	1733	2146
**KMC does not perform special procedures at this time				
***Brachytherapy is our vaginal and prostate high dose procedures.				

Forsyth Rad Onc---Patients				
	2018	2019	2020 YTD	2020 Forecast
Total Patient Volume:	861	1013	577	1154
Total Patient Special Procedure Volumes: high Dose and Brachytherapy	127	145	109	176
Total Patient Volumes:	988	1158	686	1330
KMC Rad Onc -- Patients				
	2018	2019	2020 YTD	2020 Forecast
Total Patient Volume:	174	184	98	134

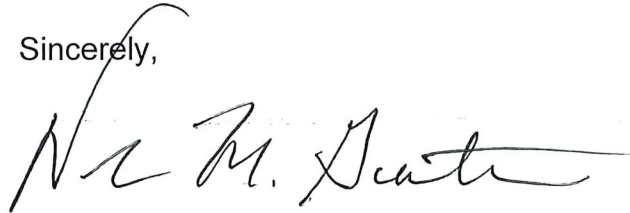
NHFMC's special procedure patient population consumes extended time slots on the simulator. By having two CT Simulators, NHFMC would be able to scan both special procedure patients as well as regular treatment patients at the same time. In order to ensure that treatment planning is always readily available at NHFMC, and to avoid any concerns about downtime, NHFMC believes it is in the best interests of the cancer patients it serves to have two simulators at NHFMC and is therefore requesting another

Martha J. Frisone
September 8, 2020
Page 3

extension. NHFMC thanks the Agency for its consideration and prompt attention to this request. If the Agency needs further information, please let me know.

With best regards.

Sincerely,

A handwritten signature in black ink, appearing to read "Denise M. Gunter". The signature is fluid and cursive, with a large initial "D" and "G".

Denise M. Gunter

Enclosure



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

April 28, 2020

Denise Gunter
Denise.gunter@nelsonmullins.com

Exemption from Review

Record #: 3266
Facility Name: Novant Health Forsyth Medical Center
FID #: 923174
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Extension of time to dispose of the existing CT simulator for up to 90 days following installation of approved replacement CT simulator (Record # 3023 Replace existing CT simulator) due to the impact of COVID-19 on simulations
County: Forsyth

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of **April 23, 2020**, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-176(22a). Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

However, you need to contact the Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Agency. Changes in a project include but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Sincerely,

Celia C. Inman
Celia C. Inman
Project Analyst

Martha J. Frisone
Martha J. Frisone
Chief

cc: Acute and Home Care Licensure and Certification, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

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April 23, 2020

Via Electronic Mail

Martha J. Frisone, Chief
Healthcare Planning and Certificate of Need Section
North Carolina Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Novant Health Forsyth Medical Center
FID # 923174
Health Service Area II
Forsyth County
Replace Existing CT Simulator

Dear Ms. Frisone:

On August 6, 2019, Novant Health Forsyth Medical Center (“NHFMC”) submitted a replacement equipment exemption request for a CT simulator. The Agency approved the request on August 19, 2019. Please see **Exhibit A** attached hereto (request letter and response, without attachments). The replacement CT simulator (the “New Simulator”) is projected to be in operation by the first week of June 2020. Pursuant to N.C. Gen. Stat. § 131E-176(22a), NHFMC is required to sell or dispose of the existing CT simulator (the “Existing Simulator”) when the New Simulator is installed. Due to the impact of the COVID-19 pandemic on cancer treatment, NHFMC respectfully requests a 90-day extension (the “Extension Period”) to dispose of the existing CT simulator. The Extension Period would run from the time the New Simulator is installed and made operational. Thus, for a limited period of time, NHFMC proposes to operate both the New Simulator and the Existing Simulator. The reasons for this request are set forth below.

CT simulation is used for treatment planning before radiation therapy takes place. Radiation therapy usually follows within one to ten days of the initial CT simulation. Many radiation therapy treatments have been paused during the COVID-19 crisis. The pause in radiation therapy treatments in turn has meant a corresponding pause in CT

Martha J. Frisone
April 23, 2020
Page 2

simulations. NHFMC anticipates a surge of patients needing CT simulation and radiation therapy once COVID-19 restrictions are eased. For example, screening mammograms have ceased during the crisis. When screening mammograms resume, NHFMC expects to see an increase in the volume of breast cancer patients who will need treatment planning. Some of these patients may need treatment on an urgent basis, depending on how long the patients were delayed in receiving their diagnosis because they were unable to have screening mammograms. NHFMC does not know precisely how many patients will be impacted, but believes it is in the best interests of patient care to ensure that patients who need treatment are not impacted by any further delays. It is also worth noting that according to Table 17C-1 of the 2020 SMFP, NHFMC has one of the top ten busiest radiation therapy programs as measured by ESTVs in North Carolina.

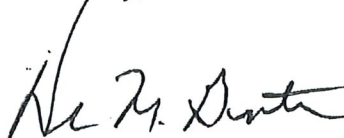
NHFMC needs to train staff on the New Simulator to a point where they are able to achieve the throughput that NHFMC has on the Existing Simulator. NHFMC expects that for at least the first 90 days of the New Simulator's tenure, throughput on the new unit will be slower than in it is with the current unit. While slower throughput likely would not have been a major issue in the pre-COVID era, it has become a significant issue now, as NHFMC faces a backlog of patients and the need to accommodate new cancer patients. As discussed above, screening mammograms have ceased, and when these restart, NHFMC expects an increase in the volume of breast cancer patients which will mean that throughput for simulation will need to increase above baseline.

A surge, by its nature, is inherently unpredictable. It is not possible to know precisely when it will arrive, how long it will last and how many patients will be impacted. But NHFMC is confident that it will happen, and the unpredictable nature of the surge supports allowing more time, rather than less time, to address the various factors such as backlog, decreased throughput and treatment of new patients. Given the highly unusual circumstances created by the pandemic, NHFMC therefore respectfully requests that the Agency approve the Extension Period described in this letter.

NHFMC thanks the Agency for its consideration and prompt attention to this request. If the Agency needs further information, please let me know.

With best regards.

Sincerely,



Denise M. Gunter

Enclosures

Received by Healthcare
Planning & CON Section
AUG -7 2019



August 6, 2019

Via Email

Celia Inman, Project Analyst, Certificate of Need
N.C. Department of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

2025 Frontis Plaza Boulevard
Winston Salem, NC 27103

Re: Novant Health Forsyth Medical Center
Replacement of CT-Simulator
Winston-Salem, North Carolina (FID # 923174; Forsyth County)

Dear Ms. Inman:

Novant Health Forsyth Medical Center (NHFMC) intends to replace an existing CT-Simulator located in the Radiation Oncology Department at the hospital in Winston-Salem, North Carolina. The existing CT-Simulator is over ten years old and is past its useful life. This CT-Simulator is still in use, as reported on the Annual License Renewal Application (LRA) in **Attachment A**. NHFMC intends to acquire a new Siemens Somatom Confidence 64-slice CT simulator. See **Attachment B** for the Equipment Quote including the removal and trade-in of the existing unit indicated at the top of Page 2. Also included are quotes for the Vision RT guidance system and LAP lasers needed for the new CT-Simulator to function. As part of the equipment cost, the vendor will provide onsite clinical training for the equipment. The total capital cost for the proposed replacement equipment project is estimated to be \$1,800,830¹. See **Attachment C** for the Project Capital Cost Summary.

The proposed project meets the definition of "replacement equipment" found in G.S. 131E-176(22a) and 10A N.C.A.C 14C.0303 for the following reasons:

- (1) NHFMC will replace the existing CT-Simulator equipment with the proposed equipment that is functionally similar and will be used for the same diagnostic purposes, although it possesses expanded capabilities due to technological improvements.
- (2) The proposed equipment will not be used to provide a new health service.
- (3) The acquisition of the proposed equipment will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.
- (4) NHFMC seeks to replace comparable medical equipment currently in use at project cost less than \$2 million.
- (5) The existing equipment was not purchased second-hand nor was the existing equipment leased.
- (6) The existing equipment will be removed from North Carolina.

¹ The project cost does not include sales, property or excise taxes as NHFMC is not subject to these taxes as a non-profit, tax-exempt organization.

Re: NHFMC Replacement of CT-Simulator
August 6, 2019
Page 2

In support of our request, please find attached:

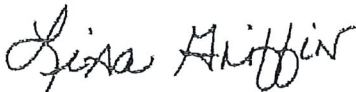
Attachment A – Excerpt of 2019 LRA
Attachment B – Vendor Equipment Quotes
Attachment C – Project Capital Costs Summary
Attachment D – Equipment Comparison chart

NHFMC's acquisition of the replacement equipment does not require a certificate of need because none of the definitions of "new institutional health services" set forth in N.C.G.S. Section 131E-176(16) apply to the proposed project. As outlined above, the total cost for the project is \$1,800,830. The proposed capital cost includes equipment, as well as studies, surveys, designs, plans, working drawings, specifications, construction installation and other activities essential to making the equipment operational.

Based on the information provided, please confirm that NHFMC's replacement equipment exemption request does not constitute a new institutional health service and is exempt from certificate of need review.

If you need additional information, please do not hesitate to contact me at (704) 384 - 3462.

Sincerely,



Lisa Griffin
Manager, Operational Planning
Novant Health, Inc.

Enclosures



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

VIA EMAIL ONLY

August 19, 2019

Lisa Griffin
lgriffin@novanthealth.org

Exempt from Review – Replacement Equipment

Record #: 3023
Facility Name: Novant Health Forsyth Medical Center
FID #: 923174
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Replace existing CT Simulator
County: Forsyth

Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of August 6, 2019, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Siemens Somatom Confidence CT Simulator equipment to replace the Philips CT Simulator, Model # 453567088051, Serial # 97370. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

Moreover, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

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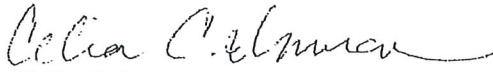
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Ms. Griffin
Page 2
August 19, 2019

separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,



Celia C. Inman
Project Analyst



Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Radiation Protection Section, DHSR

From: [Flores, Disraeliza](#)
To: [Waller, Martha K](#)
Subject: FW: [External] CON Correspondence for Forsyth County (HSA II)
Date: Tuesday, September 8, 2020 9:24:30 AM
Attachments: [20200907181259463.pdf](#)

Disraeliza Flores
Administrative Assistant
Division of Health Service Regulation
North Carolina Department of Health and Human Services

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From: Denise Gunter <denise.gunter@nelsonmullins.com>
Sent: Tuesday, September 8, 2020 9:02 AM
To: Flores, Disraeliza <Disraeliza.Flores@dhhs.nc.gov>
Subject: [External] CON Correspondence for Forsyth County (HSA II)

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Good morning,

I hope you had a nice Labor Day weekend. Attached is correspondence for Health Service Area II. Could you please let me know that you have received this? Thanks.

Nelson Mullins is continuing to monitor developments related to COVID-19, including guidance from the Centers for Disease Control and various health officials; and federal, state, and local government authorities. The firm has implemented precautionary measures and plans to ensure the continuation of all firm services to clients from both in office and remote work arrangements across our 25 geographically disperse offices. [Click here to visit the Nelson Mullins Coronavirus Resources page](#). Information described therein is subject to change.

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