



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

August 3, 2020

Lisa Griffin
llgriffin@novanthealth.org

Exempt from Review - Response to COVID-19

Record #: 3326
Facility Name: Novant Health Clemmons Medical Center
FID #: 080517
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Extension of deadline to remove existing CT scanner from service for up to 60 days following installation of approved replacement CT (Record #3147 Replace existing CT)
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 July 28, 2020 with additional information of August 3, 2020, the above referenced proposal is consistent with Executive Order 130. Therefore, you may proceed to utilize the existing CT scanner for up to 60 days following the installation of the approved replacement CT scanner.

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

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

## Inman, Celia C

---

**From:** Griffin, Lisa L <lgriffin@novanthealth.org>  
**Sent:** Monday, August 3, 2020 12:18 PM  
**To:** Inman, Celia C  
**Subject:** RE: [External] NHCMC CT Replacement Request

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Celia,

It does relate to a CT Scanner and not a Simulator. That was an error on my part. It is also the only CT Scanner currently in operation at Clemmons Medical Center.

I can add that as services are opening back up after the initial pause for the COVID-19 pandemic, Clemmons is working through a backlog of procedures and increasing volumes involving CT procedures. Along with implementing and training on the replacement CT, the use of the existing CT prior to its disposal would be extremely beneficial.

Let me know if you have any other questions.

Thank you,

*Lisa Griffin*  
(704) 351 - 1132

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**From:** Inman, Celia C <celia.inman@dhhs.nc.gov>  
**Sent:** Monday, August 3, 2020 11:37 AM  
**To:** Griffin, Lisa L <lgriffin@novanthealth.org>  
**Subject:** RE: [External] NHCMC CT Replacement Request

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Lisa,  
I need some clarification on this request.

First, in the re: line, you refer to replacement of CT Scanner, as does the attached replacement exemption. However, in the body of the letter, you refer to it as a CT Simulator. Which is it that we are talking about.

Next, if we are talking about a CT scanner, is this the only CT scanner that Novant Health Clemmons Medical Center currently operates?

Finally, can you add any additional information that would help to justify your request?

The above information will help the Agency evaluate your request.  
Thanks,

**Celia C. Inman**

Project Analyst, Certificate of Need  
Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section  
NC Department of Health and Human Services

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**Know the 3 Ws. Wear. Wait. Wash.**  
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Office: 919-855-3873  
[celia.inman@dhhs.nc.gov](mailto:celia.inman@dhhs.nc.gov)

809 Ruggles Drive, Edgerton  
2704 Mail Service Center  
Raleigh, NC 27603

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**From:** Griffin, Lisa L <[lgriffin@novanthealth.org](mailto:lgriffin@novanthealth.org)>  
**Sent:** Tuesday, July 28, 2020 1:14 PM  
**To:** Inman, Celia C <[celia.inman@dhhs.nc.gov](mailto:celia.inman@dhhs.nc.gov)>  
**Cc:** Waller, Martha K <[martha.waller@dhhs.nc.gov](mailto:martha.waller@dhhs.nc.gov)>; Flores, Disraeliza <[Disraeliza.Flores@dhhs.nc.gov](mailto:Disraeliza.Flores@dhhs.nc.gov)>  
**Subject:** [External] NHCMC CT Replacement Request

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Celia,

Attached is a letter related to the replacement of the CT at Novant Health Clemmons Medical Center and our request to extend the use of the existing CT while the new CT is fully operationalized.

Please let me know if you have any questions or need more information regarding this request. Also, respond this this has been received.

Thanks for your consideration,

**Lisa Griffin**  
Manager, Operational Planning  
Novant Health, Inc.  
(704) 351 - 1132

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**Via Electronic Mail**

July 28, 2020



Celia Inman, Project Analyst  
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

2095 Frontis Plaza Boulevard  
Winston-Salem, NC 27103

Re: Novant Health Clemmons Medical Center FID # 080517  
Replacement of CT Scanner – Extension of Existing Scanner Usage  
Health Service Area II/ Forsyth County

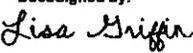
Dear Ms. Inman:

On November 27, Novant Health Clemmons Medical Center (NHCMC) submitted a replacement equipment exemption request for a CT scanner. The Agency approved the request on November 27, 2019. Please see Exhibit A attached for the Agency request letter and response, without attachments. The replacement CT scanner (the "New CT") is projected to be in operation in the first part of September 2020. Pursuant to N.C. Gen. Stat. § 131E-176(22a), NHCMC is required to sell or dispose of the existing CT scanner (the "Existing CT") when the New Simulator is installed. NHCMC respectfully requests a 60-day extension (the "Extension Period") to dispose of the Existing CT. The Extension Period would run from the time the New CT is installed and made operational. Thus, for a limited period of time, NHCMC proposes to operate both the New CT and the Existing Simulator.

The extension of time allows for NHCMC to train its imaging staff on the upgraded New CT while continuing to provide services to patients at NHCMC with no downtime and no need to temporarily add the unnecessary expense of contracting for mobile CT services. The COVID-19 pandemic has impacted construction timelines and the scheduling of procedures such that the additional time will also ensure access to CT scans while the Existing CT is being replaced. NHCMC is already approved for a second CT scanner per a No Review Determination dated November 8, 2019. Please refer to Attachment B for the Agency request letter and response. This second CT is to be installed in the room to be vacated by the Existing CT once the 60-day extension is approved and this unit is de-installed by the vendor.

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

Sincerely,

DocuSigned by:  
  
297DCB23ABC445B...

Lisa Griffin  
Manager, Operational Planning

Enclosures

# ATTACHMENT A



**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**

November 27, 2019

Lisa Griffin [lgriffin@novanthealth.org](mailto:lgriffin@novanthealth.org)  
Andrea Gymer [agymer@novanthealth.org](mailto:agymer@novanthealth.org)

**Exempt from Review – Replacement Equipment**

**Record #:** 3147  
**Facility Name:** Novant Health Clemmons Medical Center  
**FID #:** 080517  
**Business Name:** Forsyth Memorial Hospital, Inc.  
**Business #:** 755  
**Project Description:** Replace existing CT scanner  
**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 November 26, 2019, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(f). Therefore, you may proceed to acquire without a certificate of need the Siemens Edge 128 CT scanner to replace the Siemens Somatom Definition AS20, Serial # 66411, CT scanner. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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

Sincerely,

*Celia C. Inman*  
Celia C. Inman  
Project Analyst

*Martha J. Frisone*  
Martha J. Frisone  
Chief

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

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



November 26, 2019

**Via Email**

2085 Frontis Plaza Boulevard  
Winston-Salem, NC 27103

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

Re: Novant Health Clemmons Medical Center  
Replacement of CT Scanner  
Clemmons, North Carolina (FID # 080517; Forsyth County)

Dear Ms. Inman:

Novant Health Clemmons Medical Center (NHCMC) intends to replace an existing CT scanner located in the Radiology Department at the hospital in Clemmons, North Carolina. The existing CT scanner acquired in 2012 when the hospital was first opened only has a 20-slice capability and to maintain consistency and standards within Novant Health facilities, the seven-year old CT scanner is in need of upgrading. Therefore, NHCMC is seeking to replace the existing scanner with a 128-slice scanner. See **Attachment A** for the Equipment Quote including the removal and trade-in of the existing unit indicated on page 1 and page 4. Also included in the Equipment Costs is an injector.

The existing CT scanner is still in use, as reported on the Annual License Renewal Application (LRA) in **Attachment B**. 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 \$1,493,957<sup>1</sup>. See **Attachment C** for the Project Capital Cost Form.

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) NHCMC will replace the existing CT scanner 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) NHCMC seeks to replace comparable medical equipment currently in use at project costs 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.

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

Re: NHCMC Replacement of CT Scanner  
November 26, 2019  
Page 2

In support of our request, please find attached:

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

NHCMC'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 \$1,493,957. 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 NHCMC'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 [lgriffin@novanthealth.org](mailto:lgriffin@novanthealth.org)

Sincerely,



Lisa Griffin  
Manager, Operational Planning  
Novant Health, Inc.

Enclosures

# ATTACHMENT B



**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

November 8, 2019

Lisa Griffin  
llgriffin@novanthealth.org

**No Review**

**Record #:** 3110  
**Facility Name:** Novant Health Clemmons Medical Center  
**FID #:** 080517  
**Business Name:** Forsyth Memorial Hospital, Inc.  
**Business #:** 755  
**Project Description:** Acquire a CT scanner for less than \$750,000  
**County:** Forsyth

Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in that correspondence is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

You may need to contact the Agency’s Acute and Home Care Licensure and Certification and Radiation Protection Sections to determine if they have any requirements for development of the proposed project.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

*Celia C. Inman*  
Celia C. Inman  
Project Analyst

*Martha J. Frisone*  
Martha J. Frisone  
Chief

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

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

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



November 1, 2019

2085 Frontis Plaza Boulevard  
Winston-Salem, NC 27103

**Via Email**

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

Re: Novant Health Clemmons Medical Center  
Request for "No Review" Determination to Acquire 2<sup>nd</sup> CT Scanner  
Clemmons, North Carolina (FID # 923174; Forsyth County)

Dear Ms. Inman:

Novant Health Clemmons Medical Center (NHCMC) intends to acquire a second CT scanner at its campus in Clemmons, North Carolina. This new scanner will be Siemens SOMATOM Definition AS with a 64-slice configuration and will be installed in the room in the Radiology Department vacated by the existing CT scanner after it has been replaced in a new room. The notice of the replacement of the existing CT scanner (also known as CT1) will be sent under separate cover. See Attachment A for the equipment quote. The proposed equipment and related construction costs will not exceed the cost threshold of \$750,000 for Major Medical Equipment acquisitions as defined in N.C.G.S. §131E-176(14o). See Attachment B for the Project Capital Costs Summary.

NHCMC is requesting a determination from the Certificate of Need Section that this proposed project with total costs, including equipment and all related capital costs of \$641,116 is not considered Major Medical Equipment and, as such, is not subject to CON review.

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

Sincerely,

A handwritten signature in cursive script that reads "Lisa Griffin" with a small "go" written below the end of the name.

Lisa Griffin  
Manager, Operational Planning  
Novant Health, Inc.

Enclosures

**From:** [Griffin, Lisa L](#)  
**To:** [Inman, Celia C](#)  
**Cc:** [Waller, Martha K](#); [Flores, Disraeliza](#)  
**Subject:** [External] NHCMC CT Replacement Request  
**Date:** Tuesday, July 28, 2020 1:14:16 PM  
**Attachments:** [NHCMC CT Extension Ltr 07.28.20.pdf](#)

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Celia,

Attached is a letter related to the replacement of the CT at Novant Health Clemmons Medical Center and our request to extend the use of the existing CT while the new CT is fully operationalized.

Please let me know if you have any questions or need more information regarding this request. Also, respond this this has been received.

Thanks for your consideration,

***Lisa Griffin***

Manager, Operational Planning  
Novant Health, Inc.  
(704) 351 - 1132

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