



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 30, 2021

Denise M. Gunter
Denise.gunter@nelsonmullins.com

Exempt from Review – Replacement Equipment

Record #: 3533
Date of Request: April 23, 2021
Facility Name: First Imaging of the Carolinas
FID #: 041040
Business Name: First Imaging of the Carolinas, LLC
Business #: 732
Project Description: Temporarily replace existing PET/CT scanner with a mobile PET/CT scanner
County: Moore

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need a temporary mobile PET/CT scanner to replace the existing PET/CT scanner. This determination is based on your representations that First Imaging of the Carolinas, LLC will request an exemption for a permanent replacement PET/CT scanner in the Fall of 2021, at which time the temporary replacement and the existing unit will be disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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,

[Handwritten signature of Tanya M. Saporito]

Tanya M. Saporito
Project Analyst

[Handwritten signature of Lisa Pittman] for

Lisa Pittman
Acting Chief, Certificate of Need

cc: Radiation Protection Section, DHSR
Construction 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
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

Denise M. Gunter  
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The Knollwood, 380 Knollwood Street Suite 530  
Winston-Salem, North Carolina 27103  
T: 336.774.3300 F: 336.774.3299  
nelsonmullins.com

April 22, 2021

**VIA EMAIL**

Lisa Pittman, Acting Chief  
North Carolina Department of Health and Human Services  
Division of Health Service Regulation  
Healthcare Planning and Certificate of Need Section  
809 Ruggles Drive  
Raleigh, North Carolina 27603

RE: First Imaging of the Carolinas  
Temporary Replacement of PET/CT Scanner  
Project I.D. No. H-6758-03  
FID # 943358  
Moore County  
Health Service Area V

Dear Ms. Pittman:

First Imaging of the Carolinas (“FirstHealth”) operates a fixed PET/CT scanner (the “Existing PET/CT Scanner”) in a building across the street from FirstHealth Moore Regional Hospital in Moore County. The CON for the Existing PET/CT Scanner is attached as **Exhibit A**. The Existing PET/CT Scanner is 17 years old and needs to be replaced permanently. FirstHealth intends to replace the Existing PET/CT Scanner with a new machine (the “Replacement PET/CT Scanner”) in the fall of 2021. FirstHealth intends to file a Replacement Equipment Exemption pursuant to N.C. Gen. Stat. § 131E-184 before it acquires the Replacement PET/CT Scanner.

Due to its age, the Existing PET/CT Scanner is experiencing frequent service interruptions. For example, the machine has been down for the last 12 days. This in turn causes delays in treating patients. This problem is exacerbated due to a backlog of patients (currently, about 50 patients) whose scans were postponed or cancelled due to the pandemic and have since been rescheduled.

In the meantime, to treat patients in a timely manner and reduce the backlog, FirstHealth proposes to enter into a services agreement with an out-of-state vendor who

Lisa Pittman  
April 22, 2021  
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will provide a mobile PET/CT scanner at FirstHealth Moore Regional on a temporary basis (the "Temporary PET/CT Scanner") until such time as the Replacement PET/CT Scanner is installed and ready to be operated. The parties presently anticipate that the services agreement will last six months. During the term of the services agreement, the Temporary PET/CT Scanner will remain at FirstHealth and will not travel to other locations.

When the Temporary PET/CT Scanner is ready to begin serving patients, FirstHealth will shut down the Existing PET/CT Scanner. There will never be a time when both the Existing PET/CT Scanner and the Temporary PET/CT Scanner are operating simultaneously in HSA V. When the Replacement PET/CT Scanner is ready to be operated, the Temporary PET/CT Scanner will end its service at FirstHealth. There will never be a time when both the Temporary PET/CT Scanner and the Replacement PET/CT Scanner are operating simultaneously in HSA V. Therefore, the inventory of fixed PET/CT scanners in HSA V will remain four at all times relevant to the facts described in this letter. See 2021 SMFP, page 369, Table 17F-1.

The Temporary PET/CT Scanner and the Existing PET/CT Scanner are comparable equipment under 10A N.C.A.C. 14C.0303. The Existing PET/CT Scanner has been used at least ten times in the last twelve months. The Temporary PET/CT Scanner provides the same type of scans as the Existing PET/CT Scanner. No additional health services or health service facilities will be offered or developed as a result of the proposal described in this letter. Patient charges will not be increased as a result of the proposal described in this letter.

Accordingly, FirstHealth respectfully requests that it be allowed to temporarily replace its Existing PET/CT Scanner with the Temporary PET/CT Scanner as described herein. Because this is an urgent situation, FirstHealth respectfully requests that this request be approved on an expedited basis.

Please let me know if you have any questions or need further information.

Very truly yours,



Denise M. Gunter

Enclosure

**STATE OF NORTH CAROLINA**  
 Department of Health and Human Services  
 Division of Facility Services

**CERTIFICATE OF NEED**

for

**Project Identification Number H-6758-03**

**FID# 943358**

**ISSUED TO: FirstHealth of the Carolinas, Inc.**  
**d/b/a FirstHealth Moore Regional Hospital**  
**155 Memorial Dr.**  
**Pinehurst, NC 28374**

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

**SCOPE: Renovate space in the imaging department and acquire no more than one fixed combined dedicated positron emission tomography (PET) and computed tomography (CT) scanner/Moore County**

**CONDITIONS: See Reverse Side**

**PHYSICAL LOCATION: FirstHealth Moore Regional Hospital**  
**155 Memorial Drive, Pinehurst, NC 28374**

**MAXIMUM CAPITAL EXPENDITURE: \$2,645,996**

**TIMETABLE: See Reverse Side**

**FIRST PROGRESS REPORT DUE: January 15, 2004**

This certificate is effective as of the 5th day of August, 2003.

*Geoff Hoffman*  
 \_\_\_\_\_  
 Chief, Certificate of Need Section  
 Division of Facility Services

**CONDITIONS:**

1. FirstHealth of the Carolinas, Inc. d/b/a/ FirstHealth Moore Regional Hospital shall materially comply with all representations made in its certificate of need application.
2. FirstHealth of the Carolinas, Inc. d/b/a/ FirstHealth Moore Regional Hospital shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.
3. Prior to the issuance of a certificate of need, FirstHealth of the Carolinas, Inc. d/b/a/ FirstHealth Moore Regional Hospital shall submit to the Certificate of Need Section a description of the protocols that will be established to assure that all clinical PET procedures performed are medically necessary and cannot be performed using other, less expensive, established modalities.
4. Prior to the issuance of a certificate of need, FirstHealth of the Carolinas, Inc. d/b/a/ FirstHealth Moore Regional Hospital shall document that the proposed physics personnel have training and experience in the operation and maintenance of PET scanning equipment.
5. FirstHealth of the Carolinas, Inc. d/b/a/ FirstHealth Moore Regional Hospital shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.

A letter acknowledging acceptance and compliance with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on July 28, 2003.

**TIMETABLE:**

Completion of final drawings and specifications _____	November 1, 2003
Ordering equipment _____	March 1, 2004
Contract Award _____	May 1, 2004
50% completion of construction _____	July 1, 2004
Completion of construction _____	September 1, 2004
Arrival of equipment _____	September 1, 2004
Occupancy/offering of service(s) _____	October 1, 2004

**From:** [Denise Gunter](#)  
**To:** [Tanya, Saporito](#)  
**Subject:** [External] RE: Question re: FirstHealth Exemption  
**Date:** Monday, April 26, 2021 6:49:53 PM

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**CAUTION:** External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

Hi, Tanya,

Hopefully the CON I sent you earlier clears things up. First Imaging was approved in 2004 to acquire the FirstHealth PET/CT scanner. So, the CON for the PET/CT is H-6758-03, and the approval for First Imaging to acquire that CON is Project ID H-7098-04. It probably would make sense to use the First Imaging FID.

Please let me know if you need anything else.

Thanks!



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**DENISE M. GUNTER PARTNER**  
[denise.gunter@nelsonmullins.com](mailto:denise.gunter@nelsonmullins.com)

She/Her/Hers

THE KNOLLWOOD | SUITE 530

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**From:** Tanya, Saporito <tanya.saporito@dhhs.nc.gov>  
**Sent:** Monday, April 26, 2021 4:27 PM  
**To:** Denise Gunter <denise.gunter@nelsonmullins.com>  
**Subject:** Question re: FirstHealth Exemption  
◀External Email▶ - From: [tanya.saporito@dhhs.nc.gov](mailto:tanya.saporito@dhhs.nc.gov)

Hi Denise,

Your request for an exemption for a temporary mobile PET/CT scanner replacement for the existing fixed PET/CT scanner currently operating at First Imaging of the Carolinas, Inc. has been referred to me for processing. Before I can respond, I need some additional information, please.

The letter states that First Health Imaging operates an old PET/CT scanner that it would like to temporarily replace with a mobile PET/CT scanner, until FirstHealth later requests an exemption for a permanent replacement PET/CT scanner. The Project ID # reference is H-6758-03. That Project ID number is a project that was conditionally approved for FirstHealth Moore Regional Hospital to acquire a fixed PET scanner. The FID Number associated with that Project ID # and with FirstHealth Moore Regional Hospital is 943358. According to the 2021 Hospital License Renewal Application for FirstHealth Moore Regional Hospital (FHMRH), FHMRH does not own or operate a fixed PET scanner. First Imaging of the Carolinas, Inc. is a diagnostic center that was approved pursuant to Project ID #H-7098-04, FID number 041040, to acquire and operate a PET scanner from FirstHealth of the Carolinas, Inc. (FHMRH).

Please verify that the CON Project ID# referenced in your request should be H-7098-04, and that the

FID number should be the one associated with First Imaging of the Carolinas, Inc. (041040).  
Thank you in advance. I understand the urgency behind your request and will do my best to expedite the Agency response.

Please contact me if you have additional questions. Have a wonderful day!

**Tanya Saporito, J.D.**

Project Analyst

[Division of Health Service Regulation](#), Certificate of Need  
[NC Department of Health and Human Services](#)

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Office: 919-855-3873

**[Tanya.saporito@dhhs.nc.gov](mailto:Tanya.saporito@dhhs.nc.gov)**

809 Ruggles Drive, Edgerton Building

2704 Mail Service Center

Raleigh, NC 27699-2704

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**North Carolina Department of Health and Human Services  
Division of Facility Services  
Certificate of Need Section**

2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor  
Carmen Hooker Odom, Secretary

<http://facility-services.state.nc.us>

Lee Hoffman, Section Chief  
Phone: 919-855-3873  
Fax: 919-733-8139

**RESPONSE REQUIRED**

November 16, 2004

Lynn S. DeJaco  
First Imaging Board of Managers  
155 Memorial Drive  
Pinehurst, NC 28374

RE: Conditional Approval/Project I.D. #H-7098-04/First Imaging of the Carolinas, LLC/Acquire an existing PET/CT scanner from FirstHealth Moore Regional Hospital and establish a diagnostic center/Moore County  
FID #041040

Dear Ms DeJaco:

The Certificate of Need (CON) Section, Division of Facility Services, Department of Health and Human Services has conditionally approved the above referenced Certificate of Need application. This decision was made after a review of the applications submitted for this cycle and after consideration of the Certificate of Need Statute, G.S. 131E-175 et. seq., and regulations promulgated thereunder, the State Medical Facilities Plan, and other applicable information. Attached to this letter are the required findings made with respect to your application. The applicant shall not proceed with the construction, offering or development of this project until the certificate of need is issued. Further, the Department shall not issue the certificate of need until all applicable conditions of approval that can be satisfied before issuance of the certificate of need have been met pursuant to G.S. 131E-187(a). The conditions are as follows:

1. First Imaging of the Carolinas, LLC shall materially comply with all representations made in its certificate of need application.
2. First Imaging of the Carolinas, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.
3. First Imaging of the Carolinas, LLC will continue to provide PET/CT imaging to any Medicaid patient regardless of non-reimbursement from the North Carolina Division of Medical Assistance.





Ms DeJaco  
November 16, 2004  
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4. Prior to the issuance of the certificate of need, First Imaging of the Carolinas, LLC shall submit to the CON Section documentation of the availability of engineering personnel with training and experience in the operation and maintenance of PET scanning equipment.
5. First Imaging of the Carolinas, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.

**Response to the above conditions should be submitted to the CON Section no later than 35 days from the date of the decision. Failure to respond within this time period may result in the CON Section making a determination not to issue a certificate of need for the project referenced above.**

The conditional approval is valid only for a capital expenditure of \$2,251,626. If a cost overrun occurs that exceeds the approved capital expenditure amount, a new Certificate of Need may be required as determined by G.S. 131E-176(16)(e).

The applicant should be aware that according to the Certificate of Need Statute any affected person shall have thirty (30) days after the date of decision to file a petition for a contested case on this approval. Further, if you are aggrieved by the conditions of the decision you may file a petition for a contested case hearing in accordance with G.S. 150B, Article 3, as amended. This petition must be filed with the Office of Administrative Hearings, 6714 Mail Service Center, Raleigh, North Carolina 27699-6714 within thirty (30) days of the date of this decision. G.S. 150B-23 provides that a party filing a petition must also serve a copy of the petition on all parties to the petition. Therefore, if you file a petition for a contested case hearing, you must serve a copy of the petition on the Department of Health and Human Services by mailing a copy of your petition to:

Satana T. Deberry  
Department of Health and Human Services,  
Office of Legal Affairs,  
Adams Building – Room 154  
2005 Mail Service Center  
Raleigh, North Carolina, 27699-2005

It is requested that a copy of the petition also be served on the Certificate of Need Section.

The certificate of need will not be issued before the completion of this 30-day period ending December 16, 2004. If a contested case request is received within the thirty (30) day period, the certificate will not be issued until the appeal is resolved (10A NCAC 14C .0208).

Ms DeJaco  
November 16, 2004  
Page Three

The timetable for this project will be the timetable outlined in the Certificate of Need application, unless an adjustment is made by the CON Section because the review period was extended. The timetable may not be changed for any reason prior to the issuance of the certificate if the decision is not appealed. Therefore, the timetable for this project is as follows:


Occupancy/offering of service(s) \_\_\_\_\_ January 1, 2005

If the decision is appealed, the timetable set forth in this letter will be adjusted accordingly before the Certificate of Need is issued. Please contact us if any clarification of this decision is required.

Please refer to the Project I.D.# and Facility I.D.# (FID) in all correspondence.

Sincerely,

  
Mary Edwards, Project Analyst

  
Lee B. Hoffman, Chief  
Certificate of Need Section

ME:LBH:ps

Attachment

cc: Section Chief, Licensure and Certification Section, DFS  
Medical Facilities Planning Section, DFS


CERTIFICATE OF SERVICE

I hereby certify that I have served the foregoing notice of conditional approval on the following person by placing a copy in an official depository of the United States Postal Service in a postage-paid, first class envelope addressed as follows:

Lynn S. DeJaco  
First Imaging Board of Managers  
155 Memorial Drive  
Pinehurst, NC 28374

Project ID #H-7098-04  
FID #041040

This the 16<sup>th</sup> day of November, 2004.

  
\_\_\_\_\_  
Mary Edwards, Project Analyst