



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 28, 2021

Amber George
AGeorge@cpicteam.com

No Review

Record #: 3685
Date of Request: September 22, 2021
Facility Name: Raleigh Radiology Clayton
FID #: 70469
Business Name: Pinnacle Health Services of North Carolina, LLC
Business #: 1432
Project Description: Acquire a CT scanner
County: Johnston

Dear Ms. George:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law **in effect on the date of this response to your request**, the project as described 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.

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,

Kim Meymandi
Project Analyst

Micheala Mitchell
Chief

cc: Radiation Protection 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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



September 9, 2021

Ms. Micheala Mitchell
Chief, Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

RE: Request for No Review Determination for Acquisition of Diagnostic Imaging Equipment at Cardinal Points Imaging of the Carolinas/Johnston County

Dear Ms. Mitchell:

Pinnacle Health Services of North Carolina, LLC (PHSNC), doing business as Cardinal Points Imaging of the Carolinas (CPIC), intends to acquire and operate a CT scanner at its existing Johnston County diagnostic imaging center, located at 166 Springbrook Avenue, Suite 103 in Clayton. CPIC - Clayton is deemed a CON diagnostic center, as per its 2019 CON approval (Project ID # J-11746-19; see Attachment 1). PHSNC requests a determination that acquisition and operation of this CT equipment at this location does not constitute acquisition of "major medical equipment" pursuant to NCGS 131E-176(14)(o), and thus does not represent development of a "new institutional health services" and will not otherwise be subject to certificate of need (CON) review.

PHSNC plans to acquire a used GE LightSpeed VCT 64 whole body CT scanner. The purchase price for the GE system is \$55,000 (see Attachment 2). Space renovations within the imaging center are needed in order to accommodate this CT scanner and make it operational (see Attachment 3 for the contractor construction estimate. Note that not all of the \$291,680 is allocable to the CT scanner installation). Otherwise, there are no other costs that PHSNC must incur

to acquire the CT scanner and make it operational. Therefore, including the space renovation cost, delivery/rigging cost, plus the applicable 6.75% Johnston County sales tax rate, the total cost to install the CT scanner and make it operable at CPIC - Clayton is \$317,699 (\$55,000 + \$3,713 + \$10,000 + \$248,986).

NCGS 131E-176(14)(o) states "Major medical equipment". - A single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars (\$750,000). In determining whether the major medical equipment costs more than seven hundred fifty thousand dollars (\$750,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment.

(PHSNC understands that the North Carolina General Assembly recently enacted Senate Bill 462, which increased the major medical equipment threshold to \$2,000,000.)

Based on the information provided in this letter, PHSNC requests written confirmation from the Division of Health Service Regulation that this planned acquisition of the CT scanner does not require CON review, because the acquisition does not meet the definition of "major medical equipment" as specified in NCGS 131E-176(14)(o), and it does not constitute any other type of "new institutional health service" requiring a CON, as that term is defined in NCGS 131E-176(16).

I appreciate your attention to this matter. Please contact me at 919.877.5428 or ageorge@cpicteam.com regarding any questions concerning this request.

Sincerely,

Amber George

Amber George, RT, CRA
Administrator
Cardinal Points Imaging of the Carolinas

Attachments

Attachment 1



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

December 5, 2019

Amber George
5029 Falls of Neuse Road
Suite 210
Raleigh, NC 27609

Transmittal of Certificate of Need

Project ID #: J-11746-19
Facility: Raleigh Radiology Clayton
Project Description: Develop a new diagnostic center by replacing an existing digital radiology and fluoroscopy system
County: Johnston
FID #: 070469

Dear Ms. George:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) is happy to transmit your certificate of need for the above referenced project. This office will notify the appropriate Sections that the certificate of need has been issued. However, please note that it is the responsibility of the holder of the certificate of need to contact these Sections concerning the next steps to follow in the development of the approved project.

Please be aware that pursuant to N.C. Gen. Stat. §131E-181(b), you are required to materially comply with the representations made in your application for a certificate of need, or with any conditions the Agency placed on the certificate of need. **If you subsequently propose to develop the project on a site different from that named on this certificate, you must first seek and obtain approval from the Agency.** If you operate a service which materially differs from the representations made in your application for a certificate of need, or with any conditions the Agency placed on the certificate of need, including any increase in per diem reimbursement rates/charges, the Agency may bring remedial action against the holder of the certificate of need pursuant to N.C. Gen. Stat. §131E-189 and 131E-190.

The holder of a certificate of need is obligated to submit progress reports to this office as required by 10A NCAC 14C .0209. The applicant shall notify this office of any variations from the schedule or the projected capital cost of the project. During the development of the project, this office may request any additional information pertinent to the project, including additional progress reports, to determine:

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

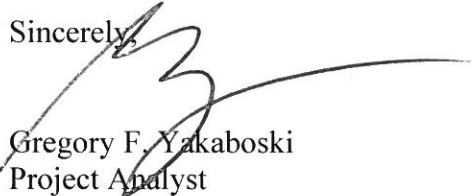
- 1) If the timetable specified on the certificate is being met;
- 2) If the amount of the capital expenditure for the development of the project is expected to exceed the maximum amount under the certificate;
- 3) If the terms and conditions of the approval are being met; and
- 4) If the project is progressing as proposed in the application.

The first progress report on this project is due January 10, 2020. Forms for the submittal of these reports are enclosed. Failure to submit any scheduled or requested progress report in a timely manner may result in the Agency withdrawing the certificate pursuant to N.C. Gen. Stat. §131E-189. If after reviewing the status of the project, the Agency determines that the holder of the certificate is not meeting the timetable and is not making a good faith effort to meet it, the Agency may withdraw the certificate in accordance with N.C. Gen. Stat. §131E-189.

Moreover, please be advised that this Agency may assess a civil penalty not to exceed \$20,000 against any person who violates the terms of a certificate of need which has been issued each time the service provided is in violation of this provision (N.C. Gen. Stat. §131E-190(f)). If for some reason, the holder of a certificate of need determines it necessary to request an increase in a per diem charge or reimbursement rate over that which was stated in the application for the certificate of need, then the holder must first contact the Agency to obtain proper instructions for initiating such a request. The request for the increase will be considered by the Agency pursuant to N.C. Gen. Stat. §131E-181(b).

Please keep us informed of the progress in the development of this project. In the future, address your Progress Reports to Michael J. McKillip, the Project Analyst for your county. Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,


Gregory F. Yakaboski
Project Analyst


Martha J. Frisone
Chief

STATE OF NORTH CAROLINA

*Department of Health and Human Services
Division of Health Service Regulation*

CERTIFICATE OF NEED

for

Project ID #: J-11746-19

FID #: 070469

ISSUED TO: Pinnacle Health Services of North Carolina, LLC

Pursuant to N.C. Gen. Stat. § 131E-177(6), 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 described below. The certificate holder shall develop the project in a manner consistent with the representations in the application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein, as documented by the periodic progress reports required by 10A NCAC 14C .0209. 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 section.

SCOPE: Develop a new diagnostic center by replacing an existing digital radiology and fluoroscopy system / Johnston County

CONDITIONS: See Reverse Side

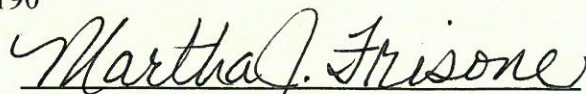
**PHYSICAL LOCATION: Raleigh Radiology Clayton
166 Springbrook Avenue, Suite 103
Clayton, NC 27520**

MAXIMUM CAPITAL EXPENDITURE: \$264,552

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: January 10, 2020

This certificate is effective as of November 26, 2019


Martha J. Frisone/Chief

CONDITIONS:

1. Pinnacle Health Services of North Carolina, LLC shall materially comply with all representations made in the certificate of need application.
2. Pinnacle Health Services of North Carolina LLC shall develop a new diagnostic center in Clayton by replacing an existing digital radiography and fluoroscopy system. Upon project completion the diagnostic center shall have no more than two ultrasound units, one mammography unit, one bone density unit and one radiography and fluoroscopy unit.
3. Pinnacle Health Services of North Carolina, LLC, as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.
4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Pinnacle Health Services of North Carolina, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Payor mix for the services authorized in this certificate of need.
 - b. Utilization of the services authorized in this certificate of need.
 - c. Revenues and operating costs for the services authorized in this certificate of need.
 - d. Average gross revenue per unit of service.
 - e. Average net revenue per unit of service.
 - f. Average operating cost per unit of service.
5. Pinnacle Health Services of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on October 31, 2019.

TIMETABLE:

- | | | |
|--------------------------------|-------|-------------------|
| 1. Equipment Ordered | _____ | December 3, 2019 |
| 2. Equipment Installed | _____ | December 24, 2019 |
| 3. Equipment Operational | _____ | January 1, 2020 |
| 4. Services Offered (required) | _____ | January 1, 2020 |
| 5. First Annual Report Due | _____ | April 1, 2023 |

Attachment 2

April 9, 2021

Mr. Paul Claus
Outpatient Imaging Affiliates, LLC
840 Crescent Centre Dr. Suite 200
Franklin, TN 37076

Dear Paul:

Medical Imaging Solutions is pleased to present the following Fair Market Value (FMV)* for the systems listed below:

Modality	Make / Model	Serial #	Fair Market Value
CT	GE LightSpeed VCT 64	427867CN7	\$55,000

* FMV based upon wholesale value, as-is, where-is.

Again, thank you for the reaching out to MIS for your needs. If you should have any questions, please do not hesitate to call anytime.

Cordially,

Trent Howell

Trent Howell
EVP Sales
Medical Imaging Solutions USA, LLC
thowell@medicalimaginggroup.com
C. 256.214.0064

Attachment 3

Trade	Value	CT %	CT Value	Future Mammo %	Future Mammo Value	Reading Room %	Reading Room Value	Admin Area %	Admin Area Value	X-ray Room %	X-ray Room Value	TOTALS
Design & Permits	\$ 28,050.00	80%	\$ 22,440.00	10%	\$ 2,805.00	5%	\$ 1,402.50	5%	\$ 1,402.50	0%	\$ -	\$ 28,050.00
Demolition & Disposal	\$ 5,970.00	80%	\$ 4,776.00	12%	\$ 716.40	3%	\$ 179.10	5%	\$ 298.50	0%	\$ -	\$ 5,970.00
Concrete	\$ 13,820.00	100%	\$ 13,820.00	0%	\$ -	0%	\$ -	0%	\$ -	0%	\$ -	\$ 13,820.00
Plumbing	\$ 9,880.00	100%	\$ 9,880.00	0%	\$ -	0%	\$ -	0%	\$ -	0%	\$ -	\$ 9,880.00
Mechanical	\$ 29,810.00	95%	\$ 28,319.50	3%	\$ 894.30	2%	\$ 596.20	0%	\$ -	0%	\$ -	\$ 29,810.00
Electrical	\$ 37,130.00	85%	\$ 31,560.50	7%	\$ 2,599.10	5%	\$ 1,856.50	2%	\$ 742.60	1%	\$ 371.30	\$ 37,130.00
Fire Alarm	\$ 5,910.00	100%	\$ 5,910.00	0%	\$ -	0%	\$ -	0%	\$ -	0%	\$ -	\$ 5,910.00
Sprinkler	\$ 6,980.00	80%	\$ 5,584.00	10%	\$ 698.00	10%	\$ 698.00	0%	\$ -	0%	\$ -	\$ 6,980.00
Metal Framing & Drywall	\$ 49,930.00	85%	\$ 42,440.50	8%	\$ 3,994.40	4%	\$ 1,997.20	3%	\$ 1,497.90	0%	\$ -	\$ 49,930.00
Paint & Stain	\$ 3,520.00	55%	\$ 1,936.00	20%	\$ 704.00	15%	\$ 528.00	10%	\$ 352.00	0%	\$ -	\$ 3,520.00
Acoustical Ceilings	\$ 5,840.00	60%	\$ 3,504.00	30%	\$ 1,752.00	10%	\$ 584.00	0%	\$ -	0%	\$ -	\$ 5,840.00
Flooring & Base	\$ 7,930.00	70%	\$ 5,551.00	20%	\$ 1,586.00	5%	\$ 396.50	5%	\$ 396.50	0%	\$ -	\$ 7,930.00
Doors, Frames & Hardware	\$ 10,920.00	90%	\$ 9,828.00	5%	\$ 546.00	5%	\$ 546.00	0%	\$ -	0%	\$ -	\$ 10,920.00
Millwork	\$ 11,940.00	70%	\$ 8,358.00	0%	\$ -	0%	\$ -	5%	\$ 597.00	25%	\$ 2,985.00	\$ 11,940.00
Glass	\$ 2,980.00	100%	\$ 2,980.00	0%	\$ -	0%	\$ -	0%	\$ -	0%	\$ -	\$ 2,980.00
Specialties	\$ 1,110.00	100%	\$ 1,110.00	0%	\$ -	0%	\$ -	0%	\$ -	0%	\$ -	\$ 1,110.00
Fire Extinguishers	\$ 150.00	100%	\$ 150.00	0%	\$ -	0%	\$ -	0%	\$ -	0%	\$ -	\$ 150.00
General Conditions	\$ 39,810.00	85%	\$ 33,838.50	7%	\$ 2,786.70	4%	\$ 1,592.40	3%	\$ 1,194.30	1%	\$ 398.10	\$ 39,810.00
Subtotal	\$ 271,680.00		\$ 231,986.00		\$ 19,081.90		\$ 10,376.40		\$ 6,481.30		\$ 3,754.40	\$ 271,680.00
Overhead & Profit	\$ 20,000.00	85%	\$ 17,000.00	7%	\$ 1,400.00	4%	\$ 800.00	3%	\$ 600.00	1%	\$ 200.00	\$ 20,000.00
Total	\$ 291,680.00		\$ 248,986.00		\$ 20,481.90		\$ 11,176.40		\$ 7,081.30		\$ 3,954.40	\$ 291,680.00

From: [Amber George](#)
To: [Mitchell, Micheala L](#); [Meymandi, Kimberly](#); [Waller, Martha K](#)
Cc: [Susan Hawkins](#)
Subject: [External] Cardinal Points Imaging of the Carolinas-Clayton Diagnostic Center-No Review Request for add'l equipment
Date: Wednesday, September 22, 2021 2:38:46 PM
Attachments: [image001.png](#)
[2021 CPIC Clayton no review letter.pdf](#)

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Good afternoon,

I hope you are all doing well and excited about the crisp fall season ahead even though there isn't much sign of it today!

Attached you will find a Request for No Review Determination for CPIC's Clayton location for your consideration.

Thank you for your time.

Be well,
Amber

Amber George, CRA, RT-R(M)
Administrator

Cardinal Points Imaging of the Carolinas
Midtown at Cedarhurst, Wake Forest, Clayton, Brier Creek

5029 Falls of Neuse Rd. Suite 210
Raleigh, NC 27609
Office: 919-877-5428
Cell: 919-332-3695
Fax: 919-877-5480
Email: ageorge@cpicteam.com



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