



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

RESPONSE REQUIRED

May 1, 2020

Katelyn Carroll
800 North Justice Street
Hendersonville, NC 28791

Conditional Approval

Project ID #: B-11860-20
Facility: Pardee Mobile Mammography
Project Description: Develop mobile mammography services
County: Henderson
FID #: 200140

Approved Capital Expenditure: \$865,249
Conditions of Approval: See Attachment A
Approved Timetable: See Attachment B
Last Date to Appeal: June 1, 2020
Required State Agency Findings: Enclosed

Dear Ms. Carroll:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has conditionally approved the above referenced certificate of need application. This decision was made after review of the application or applications if the review was competitive, consideration of the Certificate of Need Law and regulations promulgated thereunder, the State Medical Facilities Plan, written comments if any, responses to comments if any, and other publicly applicable information.

The conditional approval is valid only for the approved capital expenditure shown above. If the capital cost will exceed the approved capital expenditure amount by more than 115%, the applicant must first obtain a new certificate of need.

Response to the conditions in Attachment A should be attached to emails addressed to the Project Analyst and the Co-signer no later than 35 days from the date of the decision. Failure to respond within this time period may result in the Agency determining not to issue a certificate of need for the project referenced above.

The timetable for completion of the project is the timetable outlined in the certificate of need application, unless an adjustment has been made by the Agency because the review period was extended. The approved timetable for this project is found in Attachment B.

Note: The applicant shall not begin developing this project until after the certificate of need has been issued and the certificate of need will not be issued until the applicant has documented that all conditions that must be met prior to issuance of the certificate of need have been met. Furthermore, if the project requires that plans be submitted to the Construction Section, those plans will not be reviewed or approved until after the certificate of need has been issued.

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: 2704 Mail Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

The Certificate of Need law provides that any affected person has thirty (30) days after the date of the decision to file a petition for a contested case on this approval. Further, if you are aggrieved by any of the conditions you may file a petition for a contested case hearing in accordance with N.C. Gen. Stat. §150B, Article 3. 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. Effective October 1, 2009, OAH requires a filing fee with submittal of petitions for contested cases. Please direct all questions regarding this fee to the OAH Clerk's Office (919-431-3000).

N.C. Gen. Stat. §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:

Lisa G. Corbett
Department of Health and Human Services,
Office of Legal Affairs,
Adams Building – Room 154
2001 Mail Service Center
Raleigh, North Carolina, 27699-2001

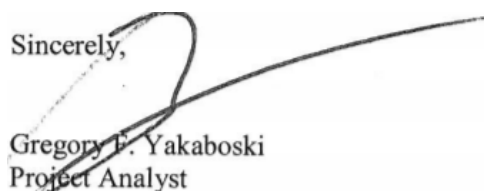
It is requested that a copy of the petition also be served on the Agency.

The certificate of need will not be issued before the completion of thirty day appeal period which ends on the date shown above. If a contested case petition is filed with OAH within the thirty day appeal period, the certificate will not be issued until the appeal is resolved.

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 this office if any clarification of this decision is required.

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

Sincerely,



Gregory F. Yakaboski
Project Analyst

greg.yakaboski@dhhs.nc.gov



Gloria C. Hale
Team Leader
gloria.hale@dhhs.nc.gov

Enclosures:

Attachment A: Conditions of Approval
Attachment B: Approved Timetable
Required State Agency Findings

cc: Radiation Protection Section

Attachment A
Conditions of Approval

1. Pardee Imaging, LLC shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Pardee Imaging, LLC shall materially comply with the last made representation.
2. Pardee Imaging, LLC shall develop a diagnostic center consisting of one mobile mammography unit.
3. Pardee Imaging, LLC, as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section Q, Form F.1a of the application and that would otherwise require a certificate of need.
4. The acquisition of the mobile mammography unit shall constitute development of a mobile diagnostic program and shall not result in the creation of a diagnostic center located at any of the host sites.
5. 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, Pardee Imaging, 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.
6. Pardee Imaging, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to insurance of the certificate of need.

Attachment B
Approved Timetable

1. Drawings Completed _____ November 1, 2020
3. Equipment Ordered _____ December 1, 2020
4. Equipment Installed _____ May 1, 2021
5. Equipment Operational _____ June 1, 2021
6. Building / Space Occupied _____ May 1, 2021
7. Licensure Obtained _____ July 1, 2021
8. Services Offered (required) _____ July 1, 2021
9. Medicare and / or Medicaid Certification Obtained _____ July 1, 2021
10. Facility or Service Accredited _____ July 1, 2021
11. First Annual Report Due* _____ October 1, 2022