



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
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Division Director

October 27, 2015

Pamela A. Scott, Partner
PoynerSpruill, LLP
301 Fayetteville St, Suite 1900
Raleigh NC 27601

Exempt from Review – Replacement Equipment

Record #: 1781
Facility Name: DLP Cardiac Partners
Business Name: DLP Cardiac Partners
Business #: 2314
Project Description: Replace mobile cardiac catheterization unit

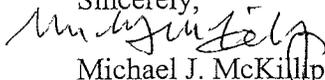
Dear Ms. Scott:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of October 15, 2015, the above referenced proposal 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, GE Innova 2000 mobile cardiac catheterization unit. This determination is based on your representations that the 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 Acute and Home Care Licensure and Certification Section 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,


Michael J. McKillip
Project Analyst


Martha J. Frisone,
Assistant Chief, Certificate of Need

cc: Kelli Fisk, Program Assistant, Healthcare Planning
Acute and Home Care Licensure and Certification Section, DHSR



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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October 15, 2015

Pamela A. Scott
Partner
D: 919.783.2954
F: 919.783.1075
pscott@poynerspruill.com

Via E-Mail and U.S. Mail

Martha Frisone
Assistant Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Exemption from Review Notification for Temporary Replacement of Existing Mobile Cardiac Catheterization Lab

Dear Ms. Frisone:

I am writing on behalf of our client, DLP Cardiac Partners (DLPCP), to inform the Healthcare Planning and Certificate of Need Section (CON Section) that DLPCP plans to temporarily replace an existing mobile cardiac catheterization lab which was recently damaged by fire, while it determines the extent of the damage and the feasibility of repair of the existing lab. More specifically, DLPCP intends to temporarily replace its GE Innova 2000 mobile cardiac catheterization lab (Serial Number 402411BU3) (ENC Lab) which has been serving sites in eastern North Carolina, with a comparable GE Innova 2000 mobile cardiac catheterization lab (Serial Number 96-0468) (Temporary Replacement Lab).

Background

DLPCP owns and operates a program of mobile cardiac catheterization labs across North Carolina which were originally acquired prior to the time the certificate of need law was amended to govern cardiac catheterization equipment and which were effectively grandfathered pursuant to a 1995 Settlement Agreement between MedCath (DLPCP's predecessor in interest) and the CON Section. As you may recall, DLPCP is part of Duke LifePoint Healthcare, a joint venture of Duke University Health System and LifePoint Hospitals. DLPCP manages cardiac cath labs throughout the U.S.

Under North Carolina law, a provider generally cannot develop or offer cardiac catheterization services, or acquire cardiac catheterization equipment without first obtaining a certificate of need. N.C. Gen. Stat. §§ 131E-176(16)f.2a and (16)f.1.3. Such activities generally constitute a "new institutional health service" which requires a CON. However, the statute detailing the cardiac catheterization services which constitute a "new institutional health service" expressly excludes "cardiac catheterization services provided on equipment furnished by a person authorized to operate such equipment in North Carolina pursuant to either a certificate of need issued for mobile cardiac catheterization equipment or a settlement agreement executed by the Department for provision of cardiac catheterization services." N.C. Gen. Stat. § 131E-176(16)f.2a. The grandfathered mobile cardiac catheterization labs operated by DLPCP, including the ENC Lab, fall within this statutory exception.

Ms. Martha Frisone
Healthcare Planning and
Certificate of Need Section
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On October 9, 2015, DLPCP's ENC Lab was travelling between sites, and blew out a tire. While the tire was being changed, the ENC Lab caught fire, causing an indeterminate (at this point) amount of damage. DLPCP currently is in the process of having the damage to the ENC Lab evaluated. It will take several weeks to determine whether the ENC Lab can be repaired and placed back into service, or whether it must be declared a total loss.

The Planned Temporary Replacement

During the interim period while the extent of damage to the ENC Lab is being determined, in order to ensure continuity of service to patients served at the ENC Lab's sites, DLPCP plans to temporarily replace the damaged ENC Lab with the Temporary Replacement Lab. This replacement will be a temporary situation until the ENC Lab is repaired and DLPCP is confident it is safe to be placed back into service (at which point the Temporary Replacement Lab would be returned to DLPCP's inventory and taken out of service in North Carolina), or DLPCP determines the ENC Lab cannot feasibly be repaired and moves forward with a permanent replacement. If DLPCP determines that it must permanently replace the ENC Lab, it will present information about any such planned permanent replacement to the CON Section at a later date.

The Temporary Replacement Lab is already owned by DLPCP as part of its existing inventory of rental cardiac cath labs, and it has not previously been in service in North Carolina. The Temporary Replacement Lab has the same technology as the ENC Lab, and will be used only to perform the same types of cardiac catheterization procedures as the ENC Lab had been performing before it was damaged. There will be no change in patient charges or operating expenses as a result of this temporary replacement. DLPCP holds title to both the ENC Lab (acquired new in April 2003) and the Temporary Replacement Lab (acquired new in September 2009).

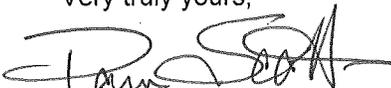
In addition to the grandfathered status of the ENC Lab, the provision of replacement equipment is exempt from Certificate of Need Review pursuant to N.C. Gen. Stat. § 131E-184(a)(7). The temporary replacement of the ENC Lab would simply maintain the status quo while the extent of the fire damage to the ENC Lab is evaluated and if feasible, repaired.

Based upon this information, we respectfully request that the CON Section confirm that the temporary replacement of the ENC Lab described above is exempt from Certificate of Need review.

Thank you for your attention to this matter. If you have any questions or need any additional information to consider this request, please do not hesitate to contact me.

With best regards, I am

Very truly yours,



Pamela A. Scott

cc: Todd Williamson, Executive Director, DLPCP