

**PETITION FOR AN ADJUSTED NEED DETERMINATION FOR  
ONE UNIT OF FIXED CARDIAC CATHETERIZATION EQUIPMENT**

**Petitioner:**

Caldwell Memorial Hospital  
321 Mulberry St. SW  
Lenoir, NC 28645

**Contact:**

Mrs. Laura J. Easton  
President and CEO, Caldwell Memorial Hospital  
[Laura.Easton@unchealth.unc.edu](mailto:Laura.Easton@unchealth.unc.edu)  
(828) 757-5214

Provided via E-Mail: [DHRS.SMFP.Petitions-Comments@dhhs.nc.gov](mailto:DHRS.SMFP.Petitions-Comments@dhhs.nc.gov)  
Submitted in Advance of the DHSR Deadline Date of 7/26/17

**Petition Request**

Caldwell Memorial Hospital requests an adjusted need determination in the *2018 State Medical Facilities Plan* for one unit of fixed cardiac catheterization equipment for the Caldwell County service area.

**Caldwell Memorial Hospital**

Caldwell Memorial Hospital (CMH) is the sole hospital in the Caldwell County acute care service area with a population of over 82,800. CMH has been providing cardiac catheterization procedures since 1990 and has utilized a mobile cardiac catheterization vendor from 1990 through 2007. Beginning in 2007, CMH agreed to allow the vendor to install the cardiac catheterization equipment in the hospital under the terms of a services agreement. Subsequently, the installed equipment was replaced with new equipment in 2012. This arrangement continues today and the vendor, DLP Cardiac Partners (part of Duke LifePoint Healthcare), provides the staffing and the cardiac catheterization equipment for the diagnostic and interventional procedures. CMH cardiologists are highly trained and board-certified and the CMH nursing staff provides the pre-procedure and post-procedure care.

The *Proposed 2018 State Medical Facilities Plan* shows one unit of fixed cardiac catheterization equipment in the inventory for the Caldwell County service area. The installed unit at CMH is owned by DLP Cardiac Partners. If the services agreement is not renewed or extended, the unit could be

removed from the hospital and relocated to another service area. This situation of CMH being totally dependent on the cardiac catheterization equipment and staff provided through a contract services arrangement is uncommon because only two other hospitals in North Carolina have similar service agreements for fixed cardiac catheterization equipment. CMH's continual dependence on the contract provider is not an effective long-term arrangement as explained in this petition request.

CMH recently sent correspondence to correct the cardiac catheterization utilization data as seen in the attached letter to Division of Health Services Regulation, Acute and Home Care Licensure and Certification Section as seen in Attachment A.

### **Reasons for Requested Change**

CMH requests an adjusted need determination in the *2018 State Medical Facilities Plan* for one unit of fixed cardiac catheterization equipment. The *Proposed 2018 SMFP* includes two standard methodologies used to calculate the need for additional cardiac catheterization equipment and shared fixed cardiac catheterization equipment. Methodology 1 is applicable to service areas that have fixed cardiac catheterization equipment. Methodology 2 is applicable to service areas that do not have fixed cardiac catheterization equipment. While the cardiac catheterization equipment at CMH is categorized as a fixed unit, the equipment is technically a grandfathered unit that was previously a mobile unit in service prior to the CON regulation of cardiac catheterization equipment. Certificate of Need Exemptions were obtained to allow the equipment to be installed at CMH (please see Attachment B). This equipment is owned by DLP Cardiac Partners and could be removed from CMH and installed in another hospital which would result in Caldwell County no longer having any cardiac catheterization equipment. CMH is petitioning for an adjusted need determination because there are unique circumstances in Caldwell County that are not accounted for in the standard methodologies.

Approval of the petition would allow CMH the opportunity to submit a Certificate of Need (CON) application to acquire its own equipment. If CON approval is granted and CMH obtains its own cardiac catheterization equipment and staff, the services agreement with DLP Cardiac Partners would be discontinued. The reasons for the requested change relate to continued growth in utilization, replacement of the existing equipment, improvements to staffing arrangements and training, and attainment of cost savings. These factors are unique to the circumstances at CMH and are discussed in the following paragraphs.

**Growth in Demand and Cardiac Catheterization Utilization**

The population of Caldwell County has a 2017 median age of 43.52 years, which is considerably higher than the statewide median age of 38.6 years.<sup>1</sup> The risk for coronary heart disease increases for men starting at age 45; for women, the risk increases starting at age 55. Genetics and lifestyle also contribute to increased risk of coronary heart disease.<sup>2</sup> The population of Caldwell County also has a much higher age-adjusted heart disease death rate as compared to the North Carolina rate:

**Table 1.**

Age-Adjusted Heart Disease Death Rates per 100,000 Residents

	2001-2005	2006-2010	2011-2015
North Carolina	227.6	186.0	163.7
Caldwell County	232.4	206.3	192.6
% Variance	2.1%	10.9%	17.7%

Source: NC DHHS, State Center for Health Statistics

North Carolina Statewide and County Trends in Key Health Indicators: Caldwell County

Overall cardiac catheterization utilization at CMH has increased at a notable rate in recent years with excellent support from board-certified cardiologists John Edmunds, MD and Johnny Dy, MD. Cardiac catheterization services are provided 5 days per week. The following table reports the increase in utilization including the 2016 utilization data that was recently corrected.

**Table 2.**

<b>Cardiac Catheterization Procedures</b>	<b>2014</b>	<b>2015</b>	<b>2016*</b>
Diagnostic	148	332	308
Interventional	51	149	215
<b>Weights in SMFP Methodology</b>			
Diagnostic	1.00	1.00	1.00
Interventional	1.75	1.75	1.75
<b>Weighted Totals</b>	<b>237</b>	<b>593</b>	<b>684</b>

Sources: 2016 and 2017 SMFP and Caldwell Data (Attachment A)

<sup>1</sup> [www.osbm.nc.gov](http://www.osbm.nc.gov) accessed June 27, 2017

North Carolina Office of State Budget and Management, July 1, 2017 County Total Age Groups - Standard

<sup>2</sup> <https://www.nhlbi.nih.gov/health/health-topics/topics/cad/atrisk>  
Who is at Risk for Coronary Heart Disease?

For the period from 2014 to 2016, the weighted totals for cardiac catheterization increased by 188 percent. Current year-to-date cardiac catheterization utilization at CMH shows a **15 percent** increase over the previous year.

CMH is convinced that growth in cardiac catheterization procedures will continue in future years due to the aging population, elevated heart disease incidence, strong medical staff support and the preference for patients and families to obtain healthcare services in their home county. The opportunity for CMH to acquire fixed cardiac catheterization is supported by the positive utilization trend as well as letters of support (please see Attachment C). Also, previous requests for adjusted need determinations for cardiac catheterization equipment in Johnston, Carteret, Lee and Harnett Counties have received favorable consideration by the State Health Coordinating Council. The development of additional cardiology services in these rural counties enables these hospitals to improve patient access and supports future physician recruitment.

CMH and UNC Health Care also intend to recruit additional cardiologists in future years. To continue to meet the cardiac catheterization needs of the population, CMH plans to improve patient access for cardiac services, maintain cost effective services, make improvements to facilities and equipment and actively support staff training and cross training.

### **Replacement of Cardiac Catheterization Equipment**

The existing cardiac catheterization equipment serving CMH is a GE Innova 3100 unit (owned by DLP Cardiac Partners) that is approximately five years old. Granting the petition for an adjusted need determination would allow CMH to pursue CON approval to acquire one unit of fixed cardiac catheterization equipment (in approximately 2019) with more advanced equipment that provides greater imaging capabilities. CMH would benefit from ownership of the cardiac catheterization equipment because:

- New cardiac catheterization equipment will provide advanced capabilities and greater accuracy.
- New cardiac catheterization equipment will afford the potential for lower radiation exposure.
- An equipment maintenance agreement could be bundled with other imaging modalities to provide cost savings.

In its CON application, CMH will demonstrate that the project capital cost for the equipment acquisition is reasonable and justified.

### **Improvements to Staffing Arrangements and Training**

When cardiac catheterization services began at CMH in 1990, one of the benefits of utilizing a contract services agreement for mobile cardiac catheterization service was that the vendor supplied highly trained and capable staff. However, one drawback is that the DLP Cardiac Partners' staff is dedicated solely to working in the cardiac catheterization lab. Therefore, when there is a lull in the procedure schedule, the staff is unable to serve patients in other hospital units. Consequently, the current contract staffing arrangement is costly and inefficient.

Cardiologists would prefer to have a reliable and consistent team assigned to CMH cardiac catheterization equipment. Yet, the DLP Cardiac Partners staff at CMH has been inconsistent because the contract employees rotate to laboratories at other hospitals. Onsite management of the DLP Cardiac Partners' employees has been intermittent due to extended absences of DLP management personnel.

CMH would have no difficulty in recruiting experienced registered nurses to work in the cardiac catheterization lab that could be cross-trained to also staff the post-procedure care unit and the intensive care unit. Also, CMH is convinced that cross-trained and highly skilled nursing staff adept in working in high acuity units would provide greater patient care and support overall staffing efficiency and cost savings. Similarly, the radiology technologist assigned to the cardiac catheterization lab could be cross-trained to perform additional radiographic procedures.

This petition offers a new opportunity for CMH to develop its own cardiac catheterization lab with the active support of UNC Health Care. The cardiac catheterization lab staff would have more cross-training capabilities within CMH departments which supports greater teamwork and promotes effective communications. Also, the catheterization staff at CMH could more fully utilize the staff training resources and best practices of the cardiac catheterization labs at other hospitals within the UNC Health Care System.

### Cost Savings

CMH has achieved strong growth in utilization which could support cost savings and greater efficiency except for the fact that the current contract services agreement with DLP Cardiac Partners is costly and inefficient. Also, as discussed previously, CMH has no opportunity to cross-train staff to achieve greater productivity and cost savings. The following table and calculations provide a comparison of the overall cardiac catheterization expenses for continuing with the contract services as compared to a hospital-owned equipment and staffing arrangement for cardiac catheterization service.

CMH projects over \$500,000 per year savings with the hospital owned / hospital staffed cardiac catheterization opportunity.

**Table 3. Cost Comparison**

Expense Comparison for Contract Services vs Hospital Owned Cardiac Catheterization	Current Budget Contract Service Costs	Projected CMH Equipment & Staff Cost
Salaries	\$ -	\$ 264,576
Benefits	\$ -	\$ 56,884
Drugs	\$ -	\$ 9,634
Medical Supplies	\$ 143,902	\$ 203,293
Other Supplies	\$ 21,354	\$ 25,276
Contact Services	\$ 1,100,627	\$ -
Maintenance & Repairs	\$ -	\$ 112,557
Other Expenses	\$ -	\$ -
Depreciation	\$ -	\$ 85,785
Total Expenses	\$ 1,265,883	\$ 758,005

Source: CMH Hospital Records

### Adverse Effects if the Requested Change is Not Granted

CMH believes that, absent the proposed adjustment to the need determination, the population of the affected area (Caldwell County) will suffer adverse effects. If the requested change is not granted, CMH expects that it will struggle to maintain a cost effective cardiac catheterization service. The continued involvement of DLP Cardiac Partners unnecessarily limits how CMH provides cardiac services. Other hospitals have the option and the flexibility to replace their fixed cardiac catheterization equipment by submitting a replacement exemption notice. In contrast, CMH must modify or extend its costly services agreement with the vendor who controls both the equipment and the staffing. Other hospitals can pursue

cost savings and process improvement projects that involve cross-training of cardiac catheterization staff. CHM would not be able to pursue this option due to the restrictive terms of the service agreement.

CMH also believes that the contract services arrangement detracts from physician perceptions and future physician recruitment. Having ownership and direct control of the cardiac catheterization lab is more appealing than being dependent on a particular vendor's equipment offering and staffing availability. For example, if a cardiologist wanted to modify and extend the hours of service for a particular day of the week, this could be much more easily accomplished if the hospital owns the equipment and employs the staff. This could enable an additional patient to be scheduled on a certain day to help decrease the patient's overall length of stay. Unfortunately, without the requested change, CMH is very limited in its ability to accommodate physician schedule preferences due to the contract services arrangement.

#### **Alternatives Considered**

The petitioner considered three alternatives that include: a) maintain the status quo; b) petition for a change in the methodology; c) petition for an adjusted need determination.

Maintaining the status quo is not an effective long term alternative because CMH is dependent on a costly service agreement that limits the hospital's ability to cross-train nursing staff and radiologic technologist positions. The current arrangement is no longer satisfactory because CMH is in a highly competitive market and seeks to have an opportunity to freely compete with other hospitals in terms of equipment selection, staffing, quality and outcome measures. The continued involvement of DLP Cardiac Partners unnecessarily limits CMH in how it can provide cardiac services in the future. For example, DLP Cardiac Partners could likely obtain an equipment replacement exemption to acquire replacement equipment; CHM expects that this equipment upgrade would require a long-term commitment from the hospital to continue to utilize contract services for an extended period of time. Alternatively, DLP Cardiac Partners could determine to discontinue its contract with CMH or increase contract costs which would impact CMH's ability to meet patient care needs. CMH has a need to be financially conservative to hold down healthcare costs and provide services to the medically underserved. If CMH acquires its own cardiac catheterization equipment, DLP Cardiac Partners would be free to seek an alternative hospital site for its "grandfathered" cardiac catheterization equipment.

Petitioning for a change in the cardiac catheterization methodology is not viewed as an effective alternative by CMH because the 2016 petition by UNC Rex Healthcare to change the methodology was denied and the Agency Report advised: *“Modifying a statewide methodology for a single county does not seem warranted at this time. Facilities or service areas with special circumstances can, and have in the past, successfully submitted petitions in the summer for an adjusted need determination for their particular health service areas.”*

The selected alternative to petition for an adjusted need determination fits the unique circumstances for Caldwell County in terms of disease rates, mortality data, utilization trend data and the hospital’s commitment to enhance services and achieve cost savings. Previous requests for adjusted need determinations for other CON regulated technology have received favorable consideration by the State Health Coordinating Council.

#### **The Proposed Adjustment Would Not Result In Unnecessary Duplication**

Based on the evidence provided in this Petition, the development permitted by this Petition would not result in unnecessary duplication of health resources in the area (Caldwell County). The proposed adjustment for a need determination for one unit of cardiac catheterization equipment would provide the opportunity for CMH to pursue CON approval to acquire its own equipment and DLP Cardiac Partners could seek an alternative hospital site for its “grandfathered” cardiac catheterization equipment. The cardiac catheterization inventory for the Caldwell County service area would not increase but remain at one fixed unit. DLP Cardiac Partners has the option to relocate its cardiac catheterization equipment to a hospital that could transition from part-time mobile cardiac catheterization service.

#### **Request Is Consistent With SMFP Basic Principles**

The CMH request is consistent with the Basic Principles of the State Medical Facilities Plan regarding safety, quality, access and value. Patient safety and quality of care are important benefits of the request. The proposed cardiac catheterization equipment would have to be approved, installed and operated in accordance with the hospital construction regulations and the manufacturer’s guidelines. New cardiac catheterization equipment has more advanced x-ray tubes and design features that more effectively limit radiation exposure. CMH is committed to expand staff training and quality assurance programs with the equipment acquisition.



Patient access can be expanded through increased staff productivity, greater scheduling flexibility and physician recruitment. This would enable more patients from Caldwell County to be served at CMH and avoid traveling to more distant facilities. CMH is committed to provide patient access to cardiac services to all persons that meet the patient selection criteria, regardless of race, color, national origin, disability, age, or ability to pay.

This request holds great potential for CMH and its patients to increase healthcare value. The ownership of the equipment and the direct employment of the staff will enable CMH to cross-train the staff, improve patient outcomes, increase efficiency and reduce hospital length of stay. The goal of the petition request is to provide improved value for cardiac catheterization services so that patient outcomes are improved and the hospital services are sustainable.

### **Conclusion**

Caldwell Memorial Hospital supports the standard methodology for cardiac catheterization equipment. Yet, the standard methodology does not provide a mechanism for CMH to obtain its own cardiac catheterization equipment as a more effective alternative than being ceaselessly dependent on equipment and staff provided through a services agreement. Multiple factors support the approval of the CMH petition request including the strong growth trend of increasing utilization, the absence of other providers in the Caldwell County service area and the opportunity to improve patient access. For the reasons outlined above, the petitioner respectfully requests an adjusted need determination for one unit of cardiac catheterization equipment in Caldwell County.

**ATTACHMENT A**



June 27, 2017

Ms. Azzie Conley  
Chief, Acute and Home Care  
Licensure and Certification Section  
2712 Mail Service Center  
Raleigh, NC 27699-2712

[Azzie.Conley@dhhs.nc.gov](mailto:Azzie.Conley@dhhs.nc.gov)

Re: Correction of Cardiac Catheterization Utilization Data for Caldwell Memorial Hospital  
(License # H0061), Caldwell County

Dear Ms. Conley:

The purpose of this letter is to provide corrected cardiac catheterization utilization data for Caldwell Memorial Hospital for the period from October 1, 2015 through September 30, 2016. The cardiac catheterization utilization data submitted in the 2017 License Renewal Application (LRA) was incorrect. The corrected data is provided in the following table and is also reflected in the attached copies of the 2017 LRA.

	Diagnostic	Interventional
Number of Procedures Performed in Fixed Units on Patients Age 15 and older	308	215

Also, the cardiac catheterization service was provided five days per week. Caldwell Memorial Hospital has validated the above utilization data and it is consistent with the utilization data reported by DLP Cardiac Partners on their 2017 Cardiac Catheterization Equipment Inventory Form.

If you have any questions or concerns please call me at (828) 757-5214. Thank you for the consideration of this information.

Sincerely,

A handwritten signature in black ink, appearing to read "Laura Easton".

Laura Easton  
Chief Executive Officer

Cc: Martha Frisone [Martha.Frisone@dhhs.nc.gov](mailto:Martha.Frisone@dhhs.nc.gov)  
Paige Bennett [Paige.Bennett@dhhs.nc.gov](mailto:Paige.Bennett@dhhs.nc.gov)

Attachments

DEC 29 2016

DEC 29 2016

North Carolina Department of Health and Human Services  
Division of Health Service Regulation  
Acute and Home Care Licensure and Certification Section  
Regular Mail 2712 Mail Service Center  
Raleigh, North Carolina 27699-2712  
Overnight UPS and FedEx only: 1205 Unimad Drive  
Raleigh, North Carolina 27603  
Telephone: (919) 853-4620 Fax: (919) 715-3073

For Official Use Only  
License # H0061 Medicare # 340001  
FID #: 993051

PC \_\_\_\_\_ Date \_\_\_\_\_

License Fee: \$2,375.00

2017  
HOSPITAL LICENSE  
RENEWAL APPLICATION

Legal Identity of Applicant: Caldwell Memorial Hospital, Inc.  
(Full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service.)

Doing Business As  
(d/b/a) name(s) under which the facility or services are advertised or presented to the public:

PRIMARY: Caldwell Memorial Hospital, Inc.

Other: d/b/a Caldwell

Other: \_\_\_\_\_

Facility Mailing Address: P.O. Box 1890  
Lenoir, NC 28645

Facility Site Address: 321 Mulberry St SW  
Lenoir, NC 28645

County: Caldwell  
Telephone: (828)757-5100  
Fax: (828)757-5512

Administrator/Director: Laura J Easton

Title: PRESIDENT/CEO

(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Chief Executive Officer: Laura J Easton Title: President/CEO

(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Name of the person to contact for any questions regarding this form:

Name: Jackie Berry Telephone: (828) 757-5214

E-Mail: jackie.berry@cmhhealth.unc.edu

PAID

CK NO. 504399

DATE: 12-30-16

2,375.00 CB

2017 Renewal Application for Hospital:  
Caldwell Memorial Hospital, Inc.

License No: HC061  
Facility ID: 933651

All responses should pertain to October 1, 2015 through September 30, 2016.

8. Specialized Cardiac Services *continued* (for questions, call Healthcare Planning at 919-855-3865)

(b) Cardiac Catheterization and Electrophysiology

Cardiac Catheterization, as defined in NCGS 131E-176(2g)	Diagnostic Cardiac Catheterization ICD-10 / CPT Codes <sup>1</sup>	Interventional Cardiac Catheterization ICD-10 / CPT Codes <sup>2</sup>
1. Number of Units of Fixed Equipment		1
2. Number of Procedures* Performed in Fixed Units on Patients Age 14 and younger	<del>199</del>	<del>230</del>
3. Number of Procedures* Performed in Fixed Units on Patients Age 15 and older	308	215
4. Number of Procedures* Performed in Mobile Units		
<b>Dedicated Electrophysiology (EP) Equipment</b>		
5. Number of Units of Fixed Equipment		
6. Number of Procedures on Dedicated EP Equipment		

\*A procedure is defined to be one visit or trip by a patient to a catheterization laboratory for a single or multiple catheterizations. Count each visit once, regardless of the number of diagnostic, interventional, and/or EP catheterizations performed within that visit. For example, if a patient has both a diagnostic and an interventional procedure in one visit, count only the interventional procedure.

Name of Mobile Vendor: DLP Cardiac Partners (Installed Unit)

Number of 8-hour days per week the mobile unit is onsite: 5 8-hour days per week.  
(Examples: Monday through Friday for 8 hours per day is 5 8-hour days per week. Monday, Wednesday, & Friday for 4 hours per day is 1.5 8-hour days per week)

<sup>1</sup> Diagnostic Cardiac Catheterizations

ICD-10 PCS: 02B 3ZX, 02B 4ZX, 4A020N6, 4A020N7, 4A020N8, 4A023N6, 4A023N7, 4A023N8, B21 \_\_ ZZ

CPT Codes: 93451, 93452, 93453, 93454, 93455, 93456, 93457, 93458, 93459, 93460, 93461, 93462, 93530, 93531, 93532, 93533

<sup>2</sup> Interventional Cardiac Catheterizations

ICD-10 PCS: 02B 3ZZ, 02B 4ZZ, 02B 3ZK, 02B 4ZK, 02L73DK, 02Q53ZZ, 02Q54ZZ, 02RF0 Z, 02RF3 Z, 02RF37Z, 02RF3KZ, 02RF3H, 02RF3JZ, 02RF3KZ, 02RH3\_H, 02RH3\_Z, 02U53JZ, 02U54JZ, 02UG3JZ 5A1221Z

CPT Codes: 92920, +92921, 92924, +92925, 92928, +92929, 92933, +92934, 92937, +92938, 92941, 92943, +92944, +92973, 92986, 92987, 92990, 93386, 93581, 93582, 93583, C9600, +C9601, C9602, +C9603, C9604, +C9605, C9606, C9607, +C9608

Note: Due to the large total number of potential codes in the ICD-10-PCS system, the codes noted above are not fully comprehensive. The " " symbol, while not a character within the ICD-10-PCS system, serves as a wild card character and indicates where any other recognized character would be used. For example, in the code 027.34E for a coronary drug-eluting stent procedure, " " could be a Z for three sites treated.

**ATTACHMENT B**



North Carolina Department of Health and Human Services  
Division of Health Service Regulation  
Certificate of Need Section  
2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor  
Lanier M. Cansler, Secretary

[www.ncdhs.gov/dhsr](http://www.ncdhs.gov/dhsr)

Craig R. Smith, Section Chief  
Phone: 919-855-3875  
Fax: 919-733-8139

January 25, 2012

Todd R. Williamson  
Executive Director  
DLP Cardiac Partners, LLC  
3700 Arco Corporate Drive, Suite 450  
Charlotte, NC 28273

RE: Exempt from Review - Replacement Equipment / Caldwell Memorial Hospital / Replace fixed cardiac catheterization equipment / Caldwell County  
FID #: 933051

Dear Mr. Williamson:

In response to your letters of January 5 and January 13, 2012, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the GE Innova Optima cardiac catheterization equipment to replace the existing GE Advantx LCV+ cardiac catheterization equipment. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided. In addition, you should contact the Construction Section to determine if they have any requirements for development of the proposed project.

It should be noted that this 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 Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Handwritten signature of Les Brown in black ink.

Les Brown  
Project Analyst

Handwritten signature of Craig R. Smith in black ink.

Craig R. Smith, Chief  
Certificate of Need Section

cc: Construction Section, DHSR

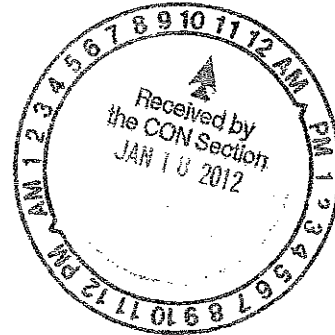


CV

## DLP Cardiac Partners, LLC

January 13, 2012

Craig Smith, Chief  
Certificate of Need Section  
NC Department of Human Resources  
Division of Facilities Services  
P.O. Box 29530  
Raleigh, NC 27626-0530



RE: Caldwell Cath Lab  
Caldwell County, NC

Dear Mr. Smith:

This letter is in follow up to the letter that was sent earlier this week and my phone call with Mr. Les Brown, about the replacement of cardiac catheterization equipment at Caldwell Memorial Hospital that has been operated by DLP Cardiac Partners ("DLP"). As noted in the first letter, the existing equipment was acquired by DLP after it was determined to be exempt from Certificate of Need Review by your office in the enclosed letter dated June 25, 2004. DLP has been planning to replace it for some time, but the existing equipment remained in service.

As we made plans to replace this equipment, we took into consideration each of the components of the Replacement Equipment Rule. The equipment that is currently in service was acquired more than three years ago, in 2004, after issuance of your letter. The data enclosed with the letter that was sent last week shows that the replacement equipment clearly meets each of the other requirements under the Rule, including its comparable technology and functionality.

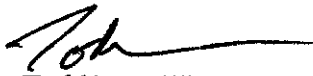
After sending the letter last week, DLP noted errors that needed to be corrected, and this letter addresses those points. One error was the omission of sales tax from the total cost, but that has been corrected on the enclosure that I am sending with this letter, and the total capital expenditure still remains under the \$2 Million threshold.

The other error concerns that date of purchase of the replacement equipment as a result of attaching an incorrect Excel spreadsheet, the date of acquisition of the replacement equipment was shown as 2008, but that is incorrect. A Purchase Order for the replacement equipment was issued on December 5, 2011, and the equipment arrived at Caldwell Memorial Hospital around December 30, but it has not been put in service to replace the existing equipment. The new replacement equipment was included on the December 5 purchase order that was issued by DLP to GE as a result of an unintentional oversight, which resulted from following our internal process to determine whether this equipment could be purchased before the year-end, under a group purchasing arrangement that DLP had in place for GE equipment. Following that internal procedure, we initiated an inquiry with our corporate office to determine if the purchase would qualify under the GPO arrangements, and when it confirmed that the purchase would qualify by issuing of a draft purchase order, we finalized the purchase order before sending the correspondence to your agency.



This error was completely inadvertent, and we regret it, because we had carefully planned our replacement of the equipment to meet the components of the Replacement Equipment Rule, as stated previously. Since the original equipment has remained in service, and has not been replaced, we trust that the inadvertent issuance of the purchase order before sending the letter to your agency will not prevent your approval of this replacement without a certificate of need. Please advise if you believe it would be helpful for us to meet with you to review and discuss this matter and answer any questions that you may have. In the meantime this letter also confirms that the equipment will not be placed in service by DLP until we have heard from your office.

Respectfully Submitted



Todd R. Williamson  
Executive Director  
DLP Cardiac Partners, LLC

enclosures

EQUIPMENT COMPARISON

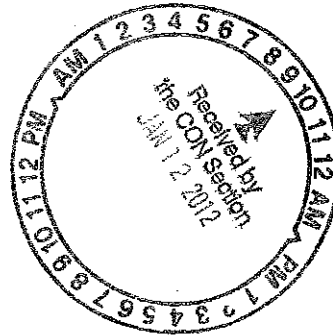
	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	cardiac cath lab	cardiac cath lab
Manufacturer of Equipment	GE	GE
Tesla Rating for MRIs	N/A	N/A
Model Number	Advantx LCV+	Innova Optima
Serial Number	527736WK2	TBD
Provider's Method of Identifying Equipment		
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	8/1/1998*	12/5/2011**
Does Provider Hold Title to Equipment or Have a Capital Lease?	Holds Title	Will hold title
Specify if Equipment Was/Is New or Used When Acquired	Used	New
Total Capital Cost of Project (Including Construction, etc.) *Use attached form*	N/A	583174***
Total Cost of Equipment	925,070	583,174
Fair Market Value of Equipment	5,000	583,174
Net Purchase Price of Equipment	N/A	583,174
Location Where Operated	Caldwell Hospital	Caldwell Hospital
Number days in Use/To be Used in N.C. Per Year	250	250
Percent Change in patient Charges (by Procedure)	N/A	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	N/A	0%
Type of Procedures Currently Performed on Existing equipment	cardiac catheterizations	N/A
Type of Pricedures New Equipment id Capable of Performing	N/A	cardiac catheterizations
* Acquisition of original equipment placed in Gaston Memorial subsequently moved to Caldwell with LORN (attached) dated 6/25/2004		
** Equipment purchase made with funds available through year end, equipment designated for Caldwell when purchased over other projected projects		
Purchase complicated by admission process to GPO as new entity needed to be set up to acknowledge pricing		
***State and County sales tax included		

**DLP Cardiac Partners, LLC**

*for*

January 5, 2011

Craig Smith, Chief  
Certificate of Need Section  
NC Department of Human Resources  
Division of Facilities Services  
P.O. Box 29530  
Raleigh, NC 27626-0530



Dear Mr. Smith:

I am writing to notify the Department that DLP Cardiac Partners, formerly MedCath Partners, intends to acquire replacement equipment defined under GS 131E-176(22a). As the Section is aware, this equipment was part of the Asset Purchase Sale by DLP from MedCath in May of 2010. This acquisition is exempt from Certificate of Need review pursuant to GS 131E-184(a)(7). The equipment to be replaced is the GE Advantx LCV+ cardiac catheterization equipment, serial number 527736WK2, which has been in service at DLP's Lab known as Caldwell Cardiology (see exhibit A).

Please note, DLP Cardiac intends only to substitute one fixed lab for another; the purpose of this submission is to meet the regulations as described in the General Statues.

As required, the existing equipment will be permanently removed from North Carolina CON and will be sold for parts to Transtate Equipment. DLP Cardiac Partners acknowledges that the above referenced existing equipment will no longer be exempt from requirements of the North Carolina Certificate of Need law and will not be used in North Carolina without first obtaining a new Certificate of Need.

Respectfully yours,

*Todd R. Williamson*

Todd R. Williamson  
Executive Director  
DLP Cardiac Partners, LLC

cc: Page Gravely, Esq.



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

June 25, 2004

Carol E. Bowen  
Moore and Van Allen  
Suite 4700 - 100 North Tryon Street  
Charlotte, NC 28202-4003

RE: No Review/ MedCath Diagnostics, LLC ("MedCath") and Caldwell Cardiology Services, LLC/  
Placement of one of MedCath's exiting cardiac catheterization equipment labs at Caldwell Memorial  
Hospital to be operated pursuant to a service agreement/Caldwell County FID #933051

Dear Ms. Bowen:

In response to your correspondence of December 16, 2003, and April 5, 2004, and information you provided in our meeting on June 11, 2004, the proposal described in your correspondence is not regulated under the Certificate of Need Law and, therefore, does not require a certificate of need. However, you should contact the Licensure and Certification Section and the Construction Section of the Division of Facility Services 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 the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in 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.

Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility LD.# (FID) if the facility is licensed.

Sincerely,

Ronald M. Loftin, Project Analyst

Lee B. Hoffman, Chief  
Certificate of Need Section

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



EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	cardiac cath lab	cardiac cath lab
Manufacturer of Equipment	GE	GE
Tesla Rating for MRIs	N/A	N/A
Model Number	Advantx LCV+	Innova
Serial Number	527736WK2	TBD
Provider's Method of Identifying Equipment		
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	8/1/1998	1/1/2008
Does Provider Hold Title to Equipment or Have a Capital Lease?	Holds Title	Will hold title
Specify if Equipment Was/is New or Used When Acquired	Used	New
Total Capital Cost of Project (Including Construction, etc.) *Use attached form*	N/A	1,328,311
Total Cost of Equipment	925,070	1,328,311
Fair Market Value of Equipment	5,000	1,328,311
Net Purchase Price of Equipment	N/A	1,328,311
Location Where Operated	Caldwell Hospital	Caldwell Hospital
Number days in Use/To be Used in N.C. Per Year	250	250
Percent Change in patient Charges (by Procedure)	N/A	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	N/A	0%
Type of Procedures Currently Performed on Existing equipment	cardiac catheterizations	N/A
Type of Pricedures New Equipment id Capable of Performing	N/A	cardiac catheterizations



North Carolina Department of Health and Human Services  
Division of Health Service Regulation  
Certificate of Need Section

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

Beverly Eaves Perdue, Governor  
Lanier M. Cansler, Secretary

[www.ncdhhs.gov/dhsr](http://www.ncdhhs.gov/dhsr)

Craig R. Smith, Section Chief  
Phone: 919-855-3873  
Fax: 919-733-8139

April 29, 2011

Jone Law Koford, Secretary  
DLP Cardiac Partners, LLC  
103 Powell Court, Suite 200  
Brentwood, TN 37027

RE: Exempt from Review/ Acquisition of the mobile diagnostic program consisting of the nine units of cardiac catheterization equipment identified in Attachment A owned by MedCath Partners, LLC by DLP Cardiac Partners, LLC

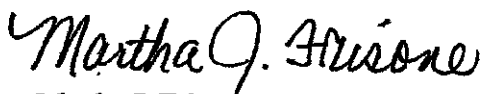
Dear Mr. Koford:

In response to your letter of April 27, 2011, the above referenced proposal is exempt from certificate of need review in accordance with G.S. 131E-184(a)(8). Therefore, DLP Cardiac Partners, LLC may proceed to acquire the above referenced health service facility without first obtaining a certificate of need.

The existing mobile diagnostic program consisting of the nine units of cardiac catheterization equipment identified in Attachment A is authorized by the terms of the August 14, 1995 Settlement Agreement (Attachment B). Operation of the nine units of cardiac catheterization equipment by DLP Cardiac Partners, LLC will also be subject to the terms of the August 14, 1995 Settlement Agreement.

It should be noted that this 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 Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

  
Martha J. Frisone  
Assistant Chief

  
Craig R. Smith, Chief  
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR



# Attachment A

AS OF 7/19/04	6/27/1905	Current 2007	2008	10/1/2008	2/7/2011
29507WK6	29507WK6	29507WK6	29507WK6	29507WK6	29507WK6
Charlottesville Mobile route	CLT Mobile / Forsyth	CLT Mobile / Forsyth	CLT Mobile / Forsyth	CLT Mobile / Forsyth	CLT Mobile / Forsyth
28539VP4	28539VP4	28539VP4	28539VP4	28539VP4	28539VP4
Pardee	Pardee	Pardee	Pardee	Pardee	Pardee
27780WK3	336	336	336	336	338
Wilmington Heart Center	Duke	Duke	Duke	Duke	Duke
82824VP4	82824VP4	82824VP4	82824VP4	82824VP4	557462BU9 <sup>10</sup>
Pinhurst First Health Mobile Rte	Pinhurst First Health Mobile Rte	Pinhurst First Health Mobile Rte	Pinhurst First Health Mobile Rte	Pinhurst First Health Mobile Rte	Presbyterian Hosp. Mathews
577482	577482	577482	577482	578218BU8	578218BU8
Wilmington Heart Center	Wilmington Heart Center	Wilmington Heart Center	Wilmington Heart Center	Wilmington Heart Center	Wilmington Heart Center
527738WK2	527738WK2	527738WK2	527738WK2	527738WK2	527738WK2
Caldwell Memorial	Caldwell Memorial	Caldwell Memorial	Caldwell Memorial	Caldwell Memorial	Caldwell Memorial
4180140	4180140	4180140	4180140	4180140	4180140
Grace Hospital	Grace Hospital	Grace Hospital	Grace Hospital	Grace Hospital	Grace Hospital
54280VP5	54280VP5	54280VP5	54280VP5	54280VP5	54280VP5
Greensboro Heart Center	Greensboro Heart Center	Greensboro Heart Center	Greensboro Heart Center	Greensboro	ENC Mobile Route
55330VP5	55330VP5	402411BU3	402411BU3	402411BU3	402411BU3
Eastern North Carolina Mobile	ENC Mobile Route	ENC Mobile Route	ENC Mobile Route	ENC Mobile Route	ENC Mobile Route

<sup>1</sup> Forsyth Review Letter dated 2/8/05  
<sup>2</sup> No Review Letter dated 1/14/05  
<sup>3</sup> No Review Letter dated 12/2/05 and Equipment Notice  
<sup>4</sup> No Review Letter dated 10/19/04  
<sup>5</sup> No Review Letter dated 7/19/01  
<sup>6</sup> No Review Letter dated 8/25/04  
<sup>7</sup> No Review Letter dated 8/25/04  
<sup>8</sup> No Review Letter dated 7/19/01  
<sup>9</sup> Notice Letter dated 12/14/05  
<sup>10</sup> No Review Letter dated 5/26/10  
<sup>11</sup> No Review Letter dated 8/4/10

**ATTACHMENT C**



Bernhardt  
Furniture  
Company  
1839 Morganton Blvd  
P. O. Box 740  
Lenoir, North Carolina  
28645 - 0740  
828.758.9811

July 13, 2017

Mrs. Laura J. Easton  
President and CEO  
Caldwell Memorial Hospital  
321 Mulberry St. SW  
Lenoir, NC 28645

RE: Letter of Support for Caldwell Memorial Hospital's Petition for Cardiac Catheterization Equipment

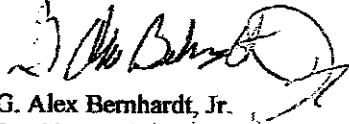
Dear Mrs. Easton:

I support approval of the Caldwell Memorial Hospital petition for a need determination in the *2018 State Medical Facilities Plan* for cardiac catheterization equipment. Caldwell Memorial Hospital currently depends on a contract services provider to obtain the equipment and staffing for cardiac catheterization procedures. The contract services arrangement is not cost effective. Also, the cardiac equipment will need to be upgraded within the next few years.

Caldwell Memorial Hospital deserves the opportunity to improve quality of care with more advanced imaging capabilities. It would be ideal for the cardiac catheterization nursing staff to be directly employed by the hospital so that they can be cross-trained to work multiple nursing units. The proposal is supported by continued growth in cardiac procedures and the recruitment of additional physicians.

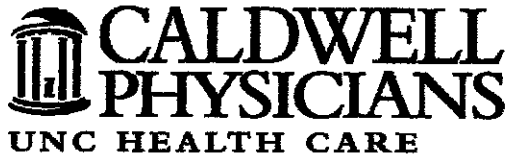
In summary, I strongly support the approval of the Caldwell Memorial Hospital petition request. Please let me know if I can provide additional information.

Sincerely,



G. Alex Bernhardt, Jr.  
President and CEO  
Bernhardt Furniture Company  
Lenoir, North Carolina

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**Robbins Cardiology**  
inside Robbins Medical Park  
322 Mulberry St., SW  
Suite F  
Lenoir, NC 28645  
Office: 828.757.6462  
Fax: 828.757.6490

July 12, 2017

Mrs. Laura J. Easton  
President and CEO  
Caldwell Memorial Hospital  
321 Mulberry St. SW  
Lenoir, NC 28645

RE: Caldwell Memorial Hospital's Petition for Cardiac Catheterization Equipment

Dear Mrs. Easton:

Caldwell Memorial Hospital intends to submit a petition for a need determination in the *2018 State Medical Facilities Plan* for one unit of cardiac catheterization equipment. As a board certified cardiologist and the Medical Director of the Cardiac Catheterization service, I strongly support the approval of the petition request.

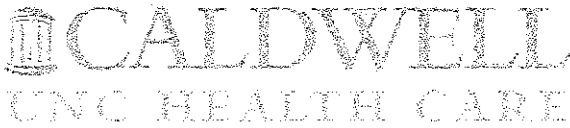
The volume of cardiac catheterization procedures has increased substantially in the past two years and the contract service is no longer cost effective. Caldwell Memorial Hospital should no longer be dependent on a contract service for cardiac catheterization procedures. We have excellent nursing staff and radiological technologists at the hospital who have advanced training and skills and we also have access to tremendous clinical training programs. The cardiac catheterization nursing staff should be directly employed by the hospital and cross-trained to work in the post-procedure cardiac unit as well as the intensive care unit.

Please include this letter of support with the petition request and let me know if I can provide additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "John Edmunds", written over a horizontal line.

Dr. John Edmunds  
Chief of Medicine  
Medical Director of Cardiac Catheterization



July 13, 2017

Mrs. Laura J. Easton  
President and CEO  
Caldwell Memorial Hospital  
321 Mulberry St. SW  
Lenoir, NC 28645

RE: Letter of Support for Caldwell Memorial Hospital's Petition for Cardiac Catheterization Equipment

Dear Mrs. Easton:

I am writing to express my support for the Caldwell Memorial Hospital petition for a need determination in the *2018 State Medical Facilities Plan* for cardiac catheterization equipment. As the Chief of the Medical Staff at Caldwell Memorial Hospital, I am pleased to report that the hospital is making great strides in improving the hospital's facilities and equipment.

For many years, Caldwell Memorial Hospital has been dependent on a contract services provider to obtain the equipment and staffing for cardiac catheterization procedures. The existing cardiac equipment at the hospital will need to be upgraded within the next few years. The current contract services arrangement is not cost effective due to the contract staff that is solely dedicated to the procedure room. If a cardiac catheterization procedure is rescheduled or delayed, the contract staff cannot be assigned to other nursing units within the hospital.

The Caldwell Memorial Hospital petition offers the hospital an opportunity to improve quality of care with more advanced imaging capabilities and newer technology that reduces radiation exposure. It will also be most beneficial for the cardiac catheterization nursing staff to be directly employed by the hospital and cross-trained to work in the post-procedure cardiac unit as well as the intensive care unit. Caldwell Memorial Hospital predicts continued growth in cardiac procedures and intends to recruit an additional cardiologist. I also understand that the hospital would utilize its own cardiac catheterization equipment and staff to provide clinical training programs through its agreements with local colleges and universities.

For all of these reasons, I strongly support the approval of the Caldwell Memorial Hospital petition request. Please let me know if I can provide additional information.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jeffrey P. Keverline'.

Jeffrey P. Keverline, MD  
Chief of Staff  
Caldwell Memorial Hospital