

**Technology and Equipment Committee  
Agency Report  
Petition for an Adjusted Need Determination for  
One Unit of Fixed Cardiac Catheterization Equipment in Caldwell County  
2018 State Medical Facilities Plan**

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***Petitioner:***

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

***Contact:***

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***Request:***

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

***Background Information:***

Chapter Two of the *Proposed 2018 SMFP* allows for “[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections.” The *SMFP* annual planning process and timeline allow for submission of petitions for changes to policies and methodologies in the spring and petitions requesting adjustments to need projections in the summer. It should be noted that any person might submit a certificate of need (CON) application for a need determination in the Plan. The CON review could be competitive and there is no guarantee that the petitioner would be the approved applicant.

Regarding cardiac catheterization equipment, in the *Proposed 2018 SMFP*, there are two standard need determination methodologies. Methodology 1 is the standard methodology for determining need for additional fixed cardiac catheterization equipment. For service areas where there is not a fixed machine, Methodology 2 is used for determining need for a shared fixed unit of equipment (that is used to perform both cardiac catheterization and angiography).

As noted in the petition, there is one unit of cardiac catheterization equipment in Caldwell County, which is currently located at CMH. While placed at the hospital, this equipment is owned and operated by DLP Cardiac Partners (DLP). Caldwell Memorial Hospital’s use of the unit under this arrangement pre-dates CON regulation of cardiac catheterization equipment. Although the equipment at CMH is categorized as ‘fixed’ in the *SMFP*, it is actually a grandfathered unit that was previously a mobile unit. In 2007, pursuant to a services agreement between DLP and CMH, the vendor installed this equipment in the hospital. In that same year, the State Health Coordinating Committee approved CMH’s request for an exemption that would allow DLP’s equipment to be regarded as a fixed machine in the *SMFP*.

***Analysis/Implications:***

The petitioner is seeking a more sustainable model for providing cardiac catheterization services in Caldwell County. In taking under consideration the aforementioned facts regarding the machine at CMH, the Agency agrees with the Petitioner’s position that the equipment is not fully under the control of the hospital and could be removed by the owner and installed elsewhere. As such, it does not constitute a true fixed machine, but would be considered a mobile unit. Therefore, Methodology 2 should be applied to determine need for a shared fixed machine in the County.

According to this methodology, if procedures exceed 240 a year “for each eight hours per week the mobile equipment is operated at that site during the 12-month period”, and no other fixed or mobile service is provided in the service area, then a need exists for one shared fixed machine. Based on data provided by DLP through the 2017 Registration and Inventory of Medical Equipment Form for Cardiac Catheterization equipment, the equipment located at CMH operates for 8 hours a day, five days a week. Over the last four years, the number of procedures performed at CMH has increased at a rate of 33.27% (see Table). Since 2013, there has only been one year that fewer than 240 procedures were performed.

**Table. Cardiac Catheterization Procedures, Weighted Totals in Caldwell County, 2013 – 2016**

	2013	2014	2015	2016	
Diagnostic	244	148	332	308	
Interventional	45	51	149	215	
Diagnostic Weights	1	1	1	1	
Interventional Weights	1.75	1.75	1.75	1.75	<b>CAGR</b>
<b>WEIGHTED TOTALS</b>	<b>289</b>	<b>237</b>	<b>593</b>	<b>684</b>	<b>33.27%</b>

*2012-2017 Registration and Inventory of Medical Equipment Forms*

***Agency Recommendation:***

The Agency supports the standard methodologies for determining need for cardiac catheterization equipment as described in the *Proposed 2018 SMFP*. Caldwell County’s single unit of cardiac catheterization equipment has been treated as ‘fixed’ in the *SMFP*; therefore, application of Methodology 1 did not result in a need determination for an additional fixed unit

for the County. However, given the unique history and ownership status of the existing equipment, the Agency finds it appropriate to use Methodology 2 to determine need for a unit of shared fixed equipment. This methodology's criteria regarding procedural volume has been met in Caldwell County.

Given available information submitted by the August 10, 2017 deadline date for comments on petitions and comments, and in consideration of the factors discussed above, the agency recommends adjusting the need determination in Caldwell County to include one unit of shared fixed cardiac catheterization equipment.