

PETITION FOR AN ADJUSTED NEED DETERMINATION

Petition to Create an Adjusted Need Determination for One Unit of Cardiac Catheterization Equipment in Henderson County in the *2020 State Medical Facilities Plan*

PETITIONER

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STATEMENT OF THE PROPOSED CHANGE

Pardee UNC Health Care respectfully requests that the State Health Coordinating Council allocate one unit of fixed cardiac catheterization equipment to Henderson County in the *2020 State Medical Facilities Plan (SMFP)*.

BACKGROUND

Pardee UNC Health Care (Pardee) has been providing cardiac catheterization services since 2002. While the *Proposed 2020 SMFP* lists the cardiac catheterization unit at Pardee as a “fixed” unit, it is actually a “grandfathered” unit that was previously mobile before being located inside the hospital. As a “grandfathered” unit, owned by DLP Cardiac Partners (part of Duke LifePoint), the unit existed in the state prior to the addition of cardiac catheterization to the Certificate of Need statute in 1993, and can “toggle” between fixed and mobile status at will. This distinction is not noted in the *Proposed 2020 SMFP*; however, Table 9U in the *2017 SMFP* and in earlier *SMFPs* lists Pardee in the mobile cardiac catheterization table but notes “see fixed” for reported volume. This situation also existed until recently at another UNC Health Care facility, Caldwell Memorial Hospital (Caldwell), which filed a petition for an adjusted need determination in the *2018 SMFP* for fixed cardiac catheterization equipment to replace its DLP Cardiac Partners-owned unit. That petition was approved, and Caldwell subsequently submitted a Certificate of Need application for the unit, which was approved. Given its nearly identical situation, Pardee is filing a similar petition to that filed by Caldwell and hopes it also will be well-received.

REASON FOR THE REQUESTED ADJUSTMENT

Although Pardee has provided cardiac catheterization services using the equipment owned by DLP Cardiac Partners for many years, the availability of the equipment is subject to a time-limited service agreement contract with the vendor, which must be renewed periodically. While Pardee has successfully renewed its agreement with the vendor several times over the years, Pardee believes that the risk of a change in the status of its contract has increased in recent years, for a few reasons.

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First, the equipment was originally owned by a company called MedCath; however, that company and its assets were acquired by DLP Cardiac Partners. Since the parent company for the equipment vendor also owns hospitals in western North Carolina and other parts of the state, Pardee is now in the uncomfortable position of having its cardiac catheterization equipment subject to a contract with a competitor organization.

Second, DLP Cardiac Partners and its parent company were acquired last year by a private equity firm. That company, Apollo Global Management, owns a broad portfolio of companies. The business model of private equity firms includes acquiring distressed companies, increasing their value through cost-cutting or sale of profitable pieces of the business, then reselling the companies for a profit. While this model may return value to the shareholders, it can result in much uncertainty for the companies owned by the firm. Pardee expects that DLP Cardiac Partners will honor its current contract; however, the future beyond that point is less than certain given these circumstances.

Third, Pardee initiated interventional cardiac catheterization (PCI) procedures in 2017 through a part-time STEMI program, which provides emergency interventions for patients experiencing a life-threatening myocardial infarction with an ST-elevation. This program is provided in partnership with Mission Health, which provides emergency surgical back-up for patients presenting at Pardee. Since the start of the program, more than 100 patients have had their lives saved with this program. Given the need of the population of Henderson County for this service, Pardee plans to expand its STEMI program to be available on a full-time 24/7/365 basis. However, this service expansion requires the recruitment of additional interventional cardiologists to cover the round-the-clock call for emergent PCI procedures. The addition of cardiologists and the expansion of the STEMI program will also enable Pardee to develop an elective cardiac catheterization program, which will allow patients found to have a lesion needing intervention during a diagnostic catheterization to have the intervention immediately, rather than needing to be referred to another facility for a PCI. Pardee believes this program will greatly benefit the residents of Henderson County, but the recruitment of the additional cardiologists represents a substantial investment. Without the ability to own and permanently control the equipment used for this service, Pardee's investment would be at significant risk.

It should also be noted that recruiting the needed cardiologists to the community is more difficult given the ownership of the catheterization equipment. Although Pardee has had conversations with several potential cardiologists, each of them has expressed reluctance about relocating their families and their practices to Hendersonville because of the temporary nature of the contract for the catheterization equipment. Approval of this petition would allow Pardee to apply for a Certificate of Need to own its cardiac catheterization equipment, which would support its ability to bring needed cardiologists to the community for its patients.

As shown in the following table, while the cardiac catheterization volume has historically been low, with the commencement of the part-time STEMI program, volume has increased for diagnostic procedures as well as for interventions.

Table 1: Cardiac Catheterization Volume Trend at Pardee UNC Health Care

	2015	2016	2017	2018	CAGR*
Diagnostic	84	124	245	443	74.1%
Interventional	0	0	45	50	NA
Weighted Total	84	124	324	531	80.4%

*Compound Annual Growth Rate
 Source: 2016-Proposed 2020 SMFPs

While this growth trend is significant, Pardee believes the need in the community extends beyond just part-time emergency coverage and includes full-time STEMI coverage and the ability to provide elective PCI. Without the ability to own the equipment, Pardee will likely struggle to meet this need.

Pardee believes it is also important to note that in the Agency Report¹ on the similar petition filed by Caldwell Memorial Hospital (Caldwell) in 2017, the Agency recommended approval of the petition, noting that the hospital had been performing more than 240 weighted procedures annually for some time. Since initiation of its STEMI program, Pardee has also exceeded this threshold, and expects to continue doing so for as long as it has cardiac catheterization equipment. In fact, the weighted total procedures performed at Pardee in the first two years of its interventional program, 2017 and 2018, exceed the volume at Caldwell shown on the Agency report for 2013 and 2014. Caldwell’s robust and thriving program is clearly providing a needed service in its community; Pardee expects similar growth as its program matures, if not higher growth based on the larger population in Henderson County compared to Caldwell County².

In addition to the historical growth, Pardee expects a full-time STEMI and elective cardiac catheterization program to dramatically increase utilization, based on population growth and aging as well as other factors discussed below. The population of Henderson County is expected to grow at a higher rate than the state as a whole, as shown in the table below.

Table 2: Henderson County Projected Population Growth

	2019	2029	CAGR*
Henderson County	118,926	133,059	1.13%
North Carolina	10,524,548	11,728,282	1.09%

*Compound Annual Growth Rate
 Source: NC Office of State Budget and Management, December 2018 projections, accessed July 2019.

The population of Henderson County is also significantly older than the state as a whole. The 2019 projected median age for Henderson County is 47.9, while the statewide age is only 38.9³.

¹ https://www2.ncdhhs.gov/dhsr/mfp/pdf/2017/tec/0906_cce_caldwell_agencyrep.pdf

² Per the North Carolina Office of Budget and Management’s December 2018 projections, Caldwell County’s 2019 population is estimated to be 83,844 with a growth rate of 0.4 percent; Henderson County’s 2019 population is 118,926 with a growth rate of 1.1 percent.

³ NC Office of State Budget and Management, December 2018 projections, accessed July 2019.

This significant age difference is also shown by the percentage of the population age 65 and older, which already exceeds that of the state as a whole and is projected to continue doing so, as shown below.

**Table 3: Henderson County Percentage of Population
Age 65 and Older**

	2019	2029
Henderson County	26.9%	30.1%
North Carolina	16.5%	19.8%

*Compound Annual Growth Rate

Source: NC Office of State Budget and Management, December 2018 projections, accessed July 2019.

By 2029, nearly one-third of Henderson County residents are projected to be age 65 or older. This growing demographic of 65 and over will require increasing access to services in the future, including cardiac catheterizations, since older residents typically utilize healthcare services more frequently than younger residents⁴.

The cardiac catheterization unit at Pardee currently provides vital access to emergency interventions as well as diagnostic procedures for the residents of Henderson County. This access has recently become even more important due to road construction in the county. The North Carolina Department of Transportation began a project to widen a 22-mile stretch of Interstate 26 in Henderson and Buncombe counties earlier this year⁵. Like so many projects of its nature, the completion date is unknown, and although it will improve traffic in the area in the long-term, it will certainly create traffic issues for the foreseeable future. While this may be an inconvenience to travelers, it can create a life-threatening situation for residents in need of emergency services. EMS in Henderson, Polk and Transylvania counties are already strained with the growth in the area; this construction will further impede their ability to transport patients, particularly between Hendersonville and Asheville. Pardee believes that maintaining and expanding its interventional cardiac catheterization program is essential to provide timely access to care for residents of the area. Without approval of this petition, that access is ultimately not in Pardee's control.

Finally, the cost of providing the service is substantially higher using a mobile vendor compared to equipment that Pardee could own. If Pardee owned and operated its own equipment, the staff would be directly employed by Pardee and the cost for the equipment would not include a profit margin for the vendor. Based on discussions with equipment manufacturers, Pardee estimates that the cost of providing the service would be approximately one-half the current cost. As a county-owned, not-for-profit entity, it is important for Pardee to contain costs wherever possible.

⁴ National Center for Health Statistics (NCHS) available at <http://www.cdc.gov/nchs/data/nhsr/nhsr029.pdf> (noting that in 2007, those aged 65 years and over accounted for just 13 percent of the U.S. population, but 37 percent of the hospital discharges, and 43 percent of the days of care. In contrast, 15–44 year-olds comprised 42 percent of the population and 31 percent of the hospital discharges, but only 24 percent of the days of care. Children under age 15 years who made up 20 percent of the population, were only six percent of the hospitalizations and used only six percent of the days of care).

⁵ <https://www.ncdot.gov/projects/i-26-widening/Pages/default.aspx>

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Given the risks of continuing to offer the service under the current arrangements, the current and growing need for cardiac catheterization services and the precedent of Caldwell Memorial Hospital's experience in a similar situation, Pardee believes that it needs a way to obtain its own cardiac catheterization equipment, which can be achieved through the approval of this petition.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

Without approval of the petition, Pardee will continue to work in good faith with DLP Cardiac Partners to provide cardiac catheterization services in Henderson County. However, it will remain at risk of the contract for the equipment ending and the county being left without access to the service. Further, without a clear pathway to acquire its own equipment, Pardee is doubtful of its ability to recruit the cardiologists needed to expand its interventional cardiology program. In addition, the cost of providing the service will continue to be nearly twice the cost if Pardee owned the equipment.

ALTERNATIVES CONSIDERED

Pardee does not believe there are many alternatives to an adjusted need determination to allow it to apply for and acquire its own cardiac catheterization equipment. One potential alternative would be to petition for a methodology change; however, that would have a statewide impact for a need that is limited to Henderson County. Under the current methodology, since the *Proposed 2020 SMFP* shows the cardiac catheterization unit at Pardee to be "fixed," it will not generate a need for another unit of equipment until the current unit reaches 1,800 weighted procedures⁶. Even if Pardee is able to expand its interventional cardiology program using the vendor-owned equipment, it does not project to reach that volume of procedures for the foreseeable future. Thus, it will remain at risk of the equipment being removed.

The equipment provided by DLP Cardiac Partners is subject to few restrictions by Certificate of Need. As such, there is little that the Division of Health Service Regulation (DHSR) can do to assist Pardee with this issue, apart from recommending approval of this petition to allow Pardee to acquire its own cardiac catheterization equipment.

UNNECESSARY DUPLICATION

Pardee does not believe that approval of the petition will result in unnecessary duplication. Although the existing vendor-owned equipment is considered "fixed" by the methodology, it is not required to remain in Henderson County or otherwise be limited in its ability to relocate or re-convert to mobile status. Thus, even if the petition is approved and Pardee is ultimately approved to acquire its own cardiac catheterization equipment, it would operate fixed equipment that would be subject to Certificate of Need restrictions. Given that there is no similarly restricted

⁶ The methodology shows need at 1,200 weighted procedures performed on each existing fixed unit but does not round to a need for another unit of equipment until the incremental need is 0.5 or greater; therefore, the effective threshold to generate the need for another fixed catheterization laboratory is 1,800 (1,200 x 1.5) weighted procedures.

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equipment in Henderson County, Pardee would not be duplicating existing resources. Neither Pardee nor DHSR can control the disposition of the equipment owned by DLP Cardiac Partners.

BASIC PRINCIPLES

Safety and Quality

Pardee's cardiac catheterization program is focused on providing local access to safe, high quality diagnostic and interventional services in Henderson County. The primary challenge to this goal is the lack of control Pardee has over the equipment used to provide the service. Approval of the petition will allow it to fully control the service it provides to its patients, which will enhance the level of quality and safety for the service.

Access

Approval of the petition will improve access to cardiac catheterization services in several ways. First, it will provide permanent, locally-owned equipment to serve patients in Henderson County and the surrounding area. Next, it will enable Pardee to continue providing its part-time STEMI program, which saves the lives of patients with risk of death without immediate intervention. Finally, it will allow Pardee to provide a stable, ongoing program, which will enable it to recruit additional interventional cardiologists and expand to a full-time STEMI and elective PCI program. Without approval of this petition, patients are not likely to have access to these services in Henderson County.

Value

The petition will enhance the value of the services offered at Pardee by allowing the hospital to own its own cardiac catheterization equipment. Based on initial estimates from equipment manufacturers, this change will reduce Pardee's cost for the service by approximately one-half, allowing it to reinvest the cost savings in other needed programs, including the significant amount of uncompensated care it provides each year.

CONCLUSION

Pardee believes that the outcome sought by this petition is needed to ensure long term access to diagnostic and interventional cardiac catheterization services in Henderson County. Given the similarities in Pardee's situation with that of Caldwell Memorial Hospital, the approval of Caldwell's petition and the approval of Caldwell's CON application to acquire its own cardiac catheterization equipment to replace the equipment owned by DLP Cardiac Partners, merit approval of this petition.