

PETITION FOR AN ADJUSTED NEED DETERMINATION

Petition to Create an Adjusted Need Determination for One Unit of Fixed Cardiac Catheterization Equipment in Burke County in the *2023 State Medical Facilities Plan*

PETITIONER

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STATEMENT OF THE PROPOSED CHANGE

UNC Health Blue Ridge respectfully requests that the State Health Coordinating Council allocate one unit of fixed cardiac catheterization equipment for Burke County in the *2023 State Medical Facilities Plan (SMFP)*.

BACKGROUND

UNC Health Blue Ridge (“Blue Ridge”) is a comprehensive healthcare system, providing advanced healthcare and wellness services from nearly 50 locations across Burke, Caldwell, and McDowell counties. The system includes one hospital with two campuses (in Morganton and Valdese, both in Burke County), and employs over 120 primary care physicians, physician specialists, and extenders in the Blue Ridge medical group. Specific to cardiac catheterization services, while Blue Ridge regularly treats patients from across the three-county area and beyond, it recognizes that the service area in the *Proposed 2023 SMFP* is Burke County, per Table 17A-3, and is petitioning for a need determination for Burke County, in which Blue Ridge is the sole provider of those services.

Since October 2021, Blue Ridge has been managed by the UNC Health System. As such, UNC Health Blue Ridge is now associated with UNC Health’s enduring reputation for excellence and innovation in providing high quality healthcare services. As an example of the quality of care provided at Blue Ridge, in June 2022, the American Heart Association awarded Blue Ridge’s stroke program the *Get With The Guidelines®-Stroke Gold Plus* quality achievement award for its commitment to ensuring stroke patients receive the most appropriate treatment according to nationally recognized, research-based guidelines, ultimately leading to more lives saved and reduced disability. Specifically relating to the quality of cardiovascular services provided at UNC Health facilities, in 2021, eight UNC Health hospitals were recognized nationally by the American Heart Association for implementing quality improvement measures that ensure cardiovascular patients receive efficient and coordinated care, ultimately leading to more lives saved, shorter recovery times and fewer returns to the hospital. Blue Ridge expects its relationship with UNC

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Health to allow it to enhance the care provided to its patients, including its cardiac catheterization patients, subject to having long-term access to fixed cardiac catheterization equipment to serve those patients. For example, Blue Ridge's cardiologists, who are part of the employed group, will be learning from and utilizing protocols from UNC Health, as appropriate. Blue Ridge also recently began pursuing Level III Trauma status, which, when achieved, will increase the number of patients brought to the hospital for trauma and other life-threatening emergencies.

While the *Proposed 2023 SMFP* lists the cardiac catheterization unit at Blue Ridge as a "fixed" unit, it is actually a legacy or "grandfathered" unit that was previously mobile before being effectively permanently located inside the hospital (specifically, within UNC Health Blue Ridge – Morganton). 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 2023 SMFP*; however, Table 9U in the *2017 SMFP* and in earlier *SMFPs* lists Blue Ridge¹ in the mobile cardiac catheterization table but notes "see fixed" for reported volume.

This situation mirrors those of two other UNC Health Care facilities:

- Caldwell UNC Health Care ("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; and
- Pardee UNC Health Care ("Pardee"), which filed a petition for an adjusted need determination in the *2020 SMFP* for fixed cardiac catheterization equipment to replace its DLP Cardiac Partners-owned unit.

Both petitions, and their subsequent CONs, were approved. Given that Blue Ridge's situation is nearly identical to that of both Caldwell and Pardee, Blue Ridge is filing a similar petition, and hopes that it will be similarly well-received.

REASON FOR THE REQUESTED ADJUSTMENT

Similar to its sister facilities noted above, although Blue Ridge 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 Blue Ridge has successfully renewed its agreement with the vendor several times over the years, Blue Ridge believes that the risk of a change in the status of its contract has increased, for a few reasons.

First, the equipment was originally owned by MedCath, a cardiac care equipment and services provider; in 2011, however, that company's assets were acquired by DLP Cardiac Partners. Since

¹ Please note that prior to 2021, UNC Health Blue Ridge was managed by the Charlotte Mecklenburg Hospital Authority d/b/a Atrium Health, formerly known as Carolinas HealthCare System. As such, "UNC Health Blue Ridge" is named differently in all *SMFPs* prior to that of 2023. For example, in the above cited *SMFP (2017 SMFP)*, UNC Health Blue Ridge is classified as "Carolinas HealthCare System – Blue Ridge."

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the parent company for the equipment vendor also owns hospitals in western North Carolina and other parts of the state, Blue Ridge is now in the disadvantageous position of having its cardiac catheterization equipment subject to a contract with a competing organization. In particular, amongst several hospitals it owns in the state, DLP owns Frye Regional Medical Center (“Frye”) in Hickory, which is in Catawba County, contiguous to Burke County. Frye also provides diagnostic and interventional cardiac catheterization services.

Second, DLP Cardiac Partners and its parent company were acquired a few years ago by a private equity firm. That firm, Apollo Global Management, owns a broad portfolio of companies. The business model of private equity firms often involves acquiring distressed companies, increasing their value through cost-cutting or sale of profitable pieces of the business, then reselling the companies for a profit. To that end, subsequent to the initial acquisition by Apollo Global Management, last year (2021) it sold DLP to another Apollo fund for a \$1.6 billion profit². While this model may return value to the shareholders, it can result in much uncertainty for the companies owned by the firm. Blue Ridge expects DLP Cardiac Partners to continue honoring its current contract; however, given these circumstances, the future beyond that contract is less certain.

Third, while Blue Ridge currently performs interventional cardiac catheterization (PCI) procedures on an elective basis, it plans to expand its ability to perform emergent PCIs as well. The latter would treat ST-elevated myocardial infarctions (STEMIs), a type of heart attack that nearly always necessitates immediate intervention. In other words, these emergent procedures require an on-call cardiologist and appropriate catheterization equipment. Blue Ridge has already recruited an additional interventional cardiologist to help staff this program; this is a substantial investment, and a key step, in expanding the cardiology services available to residents of Burke County.

However, recruiting additional cardiologists to Blue Ridge will be more difficult without the assurance of permanent catheterization equipment. For example, Blue Ridge’s sister facility, Pardee, when initiating a similar emergent catheterization program while in a similar equipment situation to that of Blue Ridge (see above), found difficulty recruiting potential cardiologists to its facility due to the temporary nature of the contract for its catheterization equipment. It follows, then, that without the ability to own and permanently control the equipment used for this service, Blue Ridge’s ability to effectively initiate and sustain an emergent PCI service could be at significant risk.

This potential contract uncertainty could damage the stability and quality of Blue Ridge’s cardiac catheterization services, the volume of which has grown considerably over the previous three years (see Table 1, below).

² <https://www.bloomberg.com/news/articles/2021-07-29/apollo-books-1-6-billion-gain-selling-hospital-chain-to-itself>

Table 1: Cardiac Catheterization Volume Trend at UNC Health Blue Ridge

	2019	2020	2021	CAGR*
Diagnostic	402	386	526	14.4%
Interventional	134	136	130	-1.5%
Weighted Total	637	624	754	8.8%

Source: 2020-Proposed 2023 SMFPs

*Compound Annual Growth Rate

As shown, Blue Ridge’s historical overall cath volume has increased substantially, even prior to the pending initiation of emergent cath services. In addition, Blue Ridge has recently added cardiac CT capabilities to enhance its cardiac diagnostic services, which may increase the number of patients identified with cardiac blockages that could benefit from catheterizations. Without the means to own its own equipment, Blue Ridge’s ability to serve patients from Burke County and the surrounding area could be negatively impacted, potentially resulting in an interruption of service and a lack of access for patients in the area.

It is worth noting that in the Agency Reports³ on the similar petitions filed by Caldwell in 2017 and Pardee in 2019, the Agency recommended approval of both, noting for both petitions that each hospital had been performing more than 240 weighted procedures for a consistent time period. As shown in the table above, Blue Ridge easily exceeds this threshold.

As mentioned previously, Blue Ridge serves Burke County as well as the contiguous areas of Caldwell and McDowell counties. In addition to the utilization trend noted above, the demographic trends also support continued access for residents of the service area to cardiac catheterization services.

First, while total county population is projected to remain nearly flat from 2022 to 2027 (see Table 2, below), the total county population age 65 and older is projected to grow (see Table 3, also below). In other words, the overall ratio of those age 65 and older to the total population of Burke, Caldwell, and McDowell counties is increasing; by 2027, the age 65 and older population of the three counties is expected to account for 23.2 percent $(48,848/210,408) \times 100 = 23.2$) of the total population of the service area. This is significant, as older residents utilize healthcare services at a higher rate than those who are younger⁴.

³ https://www2.ncdhhs.gov/dhsr/mfp/pdf/2017/tec/0906_cce_caldwell_agencyrep.pdf,
https://info.ncdhhs.gov/dhsr/mfp/pdf/2019/tec/0904_cc_henderson_agencyrep.pdf.

⁴ National Center for Health Statistics available at <http://www.cdc.gov/nchs/data/nhsr/nhsr029.pdf> (Noting that in 2007, those aged 65 years and older accounted for just 13 percent of the U.S. population, but 37 percent of 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 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).

Table 2: 2022-2027 Population Growth

<i>County</i>	<i>2022 Population</i>	<i>2027 Population</i>	<i>CAGR</i>
Burke	86,355	86,578	0.1%
Caldwell	79,946	79,621	-0.1%
McDowell	44,207	44,207	0.0%
Total	210,508	210,406	0.0%

Source: NC Office of State Budget and Management, July 2022—July 2027 projections, accessed July 2022.

Table 3: 2022-2027 65 Years of Age and Older Growth

<i>County</i>	<i>2022 65 Years of Age and Older Population</i>	<i>2027 65 Years of Age and Older Population</i>	<i>CAGR</i>
Burke	18,763	20,353	1.6%
Caldwell	16,664	17,984	1.5%
McDowell	9,756	10,511	1.5%
Total	45,183	48,848	1.6%

Source: NC Office of State Budget and Management, July 2022—July 2027 projections, accessed July 2022.

Second, the percentage of populations of Burke, Caldwell, and McDowell counties age 65 and older, which already exceeds that of the state, is projected to continue doing so, as shown below.

Table 4: Burke, Caldwell, and McDowell Counties and North Carolina Percentage of Population Age 65 and Older⁵

	<i>2022</i>	<i>2027</i>
Burke County	21.7%	23.5%
Caldwell County	20.8%	22.6%
McDowell County	22.1%	23.8%
North Carolina	17.5%*	19.1%**

Source: NC Office of State Budget and Management, July 2022—July 2027 projections, accessed July 2022.

* Projected total population of North Carolina for 2022 is 10,631,667. Projected population Age 65 and older is 1,860,777. $1,860,777 / 10,631,667 = 17.5\%$

**Projected total population of North Carolina for 2027 is 11,184,448. Projected population Age 65 and older is 2,141,695. $2,141,695 / 11,184,448 = 19.1\%$

⁵ The figures in Table 4 were calculated by taking the projected 65 years of age and older population for each county and the state and dividing those figures by the respective total projected population of that given county or state, as listed on the NC Office of State Budget and Management, <https://www.osbm.nc.gov/media/2267/download?attachment> and <https://www.osbm.nc.gov/media/2258/download?attachment>.

Relatedly, the Agency Report approving Pardee’s 2019 petition cited amongst its approval factors the “growing senior citizen population” of Henderson County, the home of Pardee UNC Health Care⁶. Given that the service area of Blue Ridge is experiencing similar growth, Blue Ridge believes that its petition also warrants approval.

Lastly, the operational cost of providing cardiac catheterization services is substantially higher using a mobile vendor compared to equipment that Blue Ridge could own. If Blue Ridge owned and operated its own equipment, its staff would be directly employed by Blue Ridge, and the cost for using the equipment would not include a profit margin for the vendor. Similar to the analysis provided in the petitions from Caldwell and Pardee, Blue Ridge also analyzed the operational cost of providing the service using the vendor-owned equipment and estimates that the operational cost of providing the service with its own equipment would be significantly less.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

Without the approval of this petition, Blue Ridge will continue to work in good faith with DLP Cardiac Partners to provide cardiac catheterization services to residents of the service area. However, it will remain at-risk of the contract for the equipment ending and residents of Burke County and beyond being left without access to the service. Additionally, the operational cost of continuing to provide the service through the vendor will be materially more than the operational cost if Blue Ridge were to own the equipment.

ALTERNATIVES CONSIDERED

Blue Ridge does not believe there are many alternatives to an adjusted need determination to allow it to apply for an 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, at this time, to Burke County. Under the current methodology, since the *Proposed 2023 SMFP* shows the cardiac catheterization unit at Blue Ridge to be “fixed,” it will not generate a need for another unit of equipment until the current unit reaches 1,200 weighted procedures⁷. Even if Blue Ridge continues to expand its cardiac catheterization program using the vendor-owned equipment, it does not project reaching that volume of procedures for the foreseeable future. Thus, it will remain at-risk of the equipment being removed. Further, the *Proposed 2023 SMFP* does reflect a change in the methodology, but that change, even if ultimately approved, would effectively lower the volume threshold needed for a second cardiac catheterization laboratory, but still would not provide a pathway for Blue Ridge to acquire its own cardiac catheterization equipment.

The equipment provided by DLP Cardiac Partners is subject to few restrictions by the Certificate of Need Program. As such, Blue Ridge understands that there is little that the Division of Health

⁶ https://info.ncdhhs.gov/dhsr/mfp/pdf/2019/tec/0904_cc_henderson_agencyrep.pdf.

⁷ The *Proposed 2023 SMFP* includes a change to the methodology that would result in a need being triggered at 1,200 weighted procedures. If that change is not ultimately approved, the threshold would be 1,800 weighted procedures, based on the rounding rules that would apply.

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Service Regulation (DHSR) can do to assist it with this issue, apart from recommending approval of this petition to allow Blue Ridge to acquire its own cardiac catheterization equipment.

UNNECESSARY DUPLICATION

Blue Ridge does not believe that approval of this 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 Burke County or otherwise be limited in its ability to relocate or re-convert to mobile status. Thus, even if the petition is approved and Blue Ridge 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 equipment in Burke County, Blue Ridge would not be duplicating existing resources. Neither Blue Ridge nor DHSR can control the use or location of the equipment owned by DLP Cardiac Partners. Moreover, even if the vendor-owned equipment were to remain in Burke County, either as additional capacity at Blue Ridge or serving another provider, as explained above, it can be removed at any time, subject to contractual restrictions, and would not be owned or controlled by Blue Ridge. As such, it would not duplicate permanent, fixed equipment owned and operated at Blue Ridge.

BASIC PRINCIPLES

Safety and Quality

Blue Ridge’s cardiac catheterization program is focused on providing local access to safe, high-quality diagnostic and interventional services in Burke County. Patients benefit from cardiac cath services offered by a health system where emergency and specialized services can be readily available if needed immediately or promptly by patients undergoing cardiac cath services. Allowing Blue Ridge to have control over cardiac cath equipment used in its health system fosters more prompt services and a continuum of care for patients. The primary challenge to this goal is the lack of control Blue Ridge has over the equipment used to provide this service. Approval of this petition will allow Blue Ridge to fully control the service it provides to its patients, which will enhance the quality and safety of the service.

Access

Approval of this petition will improve access to cardiac catheterization services in two primary ways. First, it will provide permanent, locally owned equipment to serve patients in the service area. In Burke County, particularly, UNC Health Blue Ridge is the sole provider of cardiac catheterization services and is therefore an essential provider to that county’s larger community as well as patients from other counties that choose Blue Ridge for care. Second, Blue Ridge’s recent partnership with the greater UNC Health System – one of the premier providers of heart and vascular services in the state – allows it to utilize an expansive breadth of knowledge and services, cardiac catheterization services included.

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Value

The petition will enhance the value of the services offered at Blue Ridge by allowing the hospital to own its own cardiac catheterization equipment. Based on Blue Ridge's analysis, noted above, this change will reduce its cost for the service significantly, allowing it to reinvest the cost savings in other needed programs, including the significant amount of uncompensated care it provides each year. In its most recent community benefit report, UNC Health Blue Ridge's Community Benefit was more than \$82 million.

CONCLUSION

UNC Health Blue Ridge believes that the outcome sought by this petition is needed to ensure long-term access to diagnostic and interventional (including emergent) cardiac catheterization services in Burke County. Given the risks of continuing to offer the service under its current contractual arrangement with DLP Cardiac Partners, the growing demand for cardiac catheterization services, and the precedent of both Caldwell UNC Health Care's and Pardee UNC Health Care's similar petitions and subsequently approved CON applications to acquire their own fixed cardiac catheterization equipment, Blue Ridge believes it is necessary to obtain its own cardiac catheterization equipment, which can be achieved through the approval of this petition.