



March 30, 2017

Transmitted via Electronic Mail

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Re: Certificate of Need Application filed by Blue Ridge HealthCare Hospitals, Inc. and Blue Ridge HealthCare Surgery Center, LLC
Project No. E-011298-17

Dear Ms. Frisone and Mr. Yakaboski:

The following comments are submitted on behalf of Catawba Valley Medical Center in response to a CON application filed by Blue Ridge HealthCare Hospitals, Inc. and Blue Ridge HealthCare Surgery Center, LLC to develop a free-standing ambulatory surgery center in Valdese, North Carolina (Burke County).

Overview

A Certificate of Need application was filed by Blue Ridge HealthCare Hospital, Inc. and Blue Ridge HealthCare Surgery Center, LLC for the March 1, 2017 review cycle to reorganize existing resources located on the campus of CHS Blue Ridge-Valdese, a licensed, general acute care hospital, into a free-standing licensed ambulatory surgery center in Burke County. At the completion of the project the applicant proposes the facility will continue to include four (4) operating rooms, two (2) endoscopy rooms, and one (1) procedure room.

The following comments will demonstrate that the application should not be approved as it fails to conform to all applicable review criteria as required by G.S. §131E-183.

CON Review Criterion 3

The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

The application does not conform to Criterion 3 for the following reasons.

- The project, as proposed, would create a new free-standing ambulatory surgery center located away from the greatest concentration of residents in Burke County.
- The projected project will likely hamper access to the new free-standing surgery center for traditionally underserved groups.

- The project would create an inadequate distribution of endoscopy rooms within Burke County.
- The project does nothing to reduce the current excess number of operating rooms located in Burke County as identified in the 2017 NC State Medical Facilities Plan.
- Projected volumes are not fully supported by the assumptions provided.

Geographic Accessibility

The applicants propose to convert four (4) existing hospital-based operating rooms, two (2) endoscopy rooms and one (1) procedure room at CHS Blue Ridge-Valdese into a free-standing ambulatory surgery center at its current location. As proposed, the project would result in the county’s only multi-specialty ambulatory surgery center in Burke County. However, the proposal fails to demonstrate that it will satisfy the needs of the majority of residents residing the primary service area. As the table below documents, the majority of Burke County’s population resides in the Morganton area, the location of CHS Blue Ridge - Grace. However, no free-standing ambulatory surgery operating rooms are proposed for Morganton. Instead, the applicant proposes the development of the county’s only multi-specialty ambulatory surgery center in Valdese.

Table 1

| County/Municipality | April 2010 | July 2015 | Net Chng | Percent Growth |
|---------------------|------------|-----------|----------|----------------|
| Burke County | 90,914 | 89,114 | -1,800 | -1.02 |
| Connelly Springs | 1,669 | 1,639 | -30 | -1.8 |
| Drexel | 1,858 | 1,842 | -16 | -0.86 |
| Glen Alpine | 1,517 | 1,535 | 18 | 1.19 |
| Hickory(Part) | 66 | 66 | 0 | 0 |
| Hildebran | 2,023 | 1,978 | -45 | -2.22 |
| Long View(Part) | 752 | 738 | -14 | -1.86 |
| Morganton | 16,918 | 16,716 | -202 | -1.19 |
| Rhodhiss(Part) | 700 | 723 | 23 | 3.29 |
| Rutherford College | 1,341 | 1,368 | 27 | 2.01 |
| Valdese | 4,490 | 4,442 | -48 | -1.07 |

Source: NC Office of State Budget and Management

As the above table illustrates, the greatest concentration of population in Burke County is in Morganton. At the completion of the proposed project, the majority of patients now receiving outpatient surgery services in Morganton will be forced to travel to Valdese to access free-standing ambulatory surgery operating rooms in Burke County. As a result, geographic accessibility to a licensed free-standing ambulatory surgery center will not be improved for the majority of Burke County residents.

Financial Accessibility for Ambulatory Surgical Cases

The applicants project the percent of outpatient surgical cases to be performed at Blue Ridge HealthCare Surgery Center (BRHCSC) by payer source on page 89 of the CON application. However, these projected percentages are significantly different than those provided for ambulatory surgical cases (excluding endoscopy cases) in the 2017 CHS Blue Ridge annual hospital license renewal application. As the table below illustrates, Medicare patients represented 41% of outpatient surgery cases at both Blue Ridge Hospitals for the year ending September 30, 2016. However, the percentage of Medicare patients is projected to represent only 32.7% of total outpatient surgery cases at the new ambulatory surgery center. A lower percentage of self-pay and charity care cases is also projected. However, the applicant did not support the difference between the payer sources for the existing hospital-based operating rooms and those projected for the proposed free-standing ambulatory surgery center. In addition, because the projected number of outpatient surgery cases is likely overstated for reasons described elsewhere in these comments, it would appear that the new ambulatory surgery center will serve a lower percentage of Medicare and self-pay/charity care patients than is presently the case at both Blue Ridge hospitals. If the volume of cases projected is not sufficiently supported, the lower percentages of Medicare and self-pay/charity cases are likely to result in a fewer number of patients served than is presently the case for the existing hospital-based operating rooms.

Table 2

| OP Surgery Cases | BR-Vald | BR-Morg | BRSC |
|----------------------|---------|---------|--------|
| SP/Charity | 4.1% | 4.1% | 3.3% |
| Medicare | 41.0% | 41.0% | 32.7% |
| Medicaid | 15.3% | 15.3% | 23.0% |
| Commercial Insurance | 1.1% | 1.1% | 35.7% |
| Managed Care | 34.4% | 34.4% | NR |
| Other | 4.1% | 4.1% | 5.2% |
| Total | 100.0% | 100.0% | 100.0% |

Source: Valdese and Morganton data excerpted from the Carolinas HealthCare System Blue Ridge 2017 NC Hospital License Renewal Application. BRSC data excerpted from page 89 of the application.

Financial access to BRSC will also be hampered because of its location in Valdese, not Morganton. Morganton has a significantly greater number of persons without health insurance coverage than does Valdese (2,595 vs. 324). Morganton has significantly more persons with public health insurance coverage (7,181 vs. 2,028). In addition, a greater percentage of persons are living below the poverty level in Morganton than in Valdese (19.9% as compared to 14.5%).

As Table 3 illustrates, locating the proposed project in the Morganton area would provide greater access to populations that are traditionally underserved for medical care. The Morganton area population is much more ethnically diverse than other areas of Burke County. This is important since many times minority populations are less likely to receive health care services at the same rate as other groups. Other indicators suggest that Morganton would offer a more favorable location to improve accessibility for underserved groups. It has a greater number of persons with no health insurance or public health insurance, a greater number of persons living below the poverty level and a greater number of persons over the age of 65 than other areas of the county. As a result, the proposal will not improve geographic or financial accessibility for the majority of Burke County residents.

Table 3

| | 2015 Percent Population White | 2015 Persons w/o Health Insurance | 2015 Persons with Public Hlth Insurance | 2015 Percent Persons Living Below Poverty | 2015 Number of Persons Living Below Poverty | 2015 Population 65+ |
|--------------------|--|--|--|--|--|---------------------------|
| Connelly Springs | 81.7% | 286 | 603 | 15.2% | 1,850 | 245 |
| Drexel | 84.5% | 212 | 606 | 23.1% | 1,730 | 483 |
| Glen Alpine | 81.2% | 189 | 540 | 12.8% | 1,510 | 252 |
| Hildebran | 92.8% | 350 | 993 | 28.0% | 2,173 | 409 |
| Morganton | 75.5% | 2,595 | 7,181 | 26.2% | 15,846 | 3,462 |
| Rutherford College | 99.7% | 183 | 457 | 9.1% | 1,417 | 234 |
| Valdese | 93.8% | 324 | 2,028 | 23.7% | 4,425 | 1,212 |

Source: <https://factfinder.census.gov> accessed 3/21/17.

Endoscopy Room Need

The application proposes to re-designate an existing endoscopy room currently available at CHS Blue Ridge-Grace to a procedure room, available for surgical and non-surgical procedures. As a result, at the conclusion of the project two endoscopy rooms will be available each in Morganton at Carolina Digestive Services and in Valdese at the new BRHSC. However, the assumptions used to project future utilization of the remaining endoscopy rooms in Burke County raise a number of questions. On page 27 of the application, projections are provided for the utilization of the existing endoscopy rooms at Carolina Digestive in Morganton. Those projections, based on internal data for calendar year 2013 through 2016, indicate that the volume of GI endoscopy procedures at Carolina Digestive grew by an annual rate of 5%. This growth rate for calendar years 2013 – 2016 is significantly different from the volume changes at Carolina Digestive Services reported on its annual license renewal applications. Those documents indicate that the number of procedures reported at Carolina Digestive actually fell by greater than 12% for a slightly different reporting period, October – September, between 2013 and 2016.

Table 4
Carolina Digestive Services
GI Endoscopy Procedures

| Reporting Period | GI Endoscopy Procedures | Chng from 2013-14 |
|---------------------|----------------------------|----------------------|
| 10/1/13-9/30/14 | 3,488 | |
| 10/1/14-9/30/15 | 3,046 | -12.7% |
| 10/1/15-9/30/16 | 3,060 | -12.3% |

Source: NC License Renewal Applications.

Such continued declines as those reported could threaten the ability of CDS to maintain the utilization threshold of 1,500 procedures/room/year.

Another question raised by the projected utilization of CDS involves the assumption that the volume of procedures would be reflective of Burke County's projected annual growth rate of its population at 0.1%. This is significantly below the annual growth rate of 5% provided in the CON application and may underestimate the number of GI endoscopy procedures to be performed. Should the number of GI endoscopies performed at CDS continue to grow at a rate of 5%, the volume could quickly exceed the capacity of the two existing rooms. This would force an increasing number of patients originating from Morganton area to seek care in Valdese. This could create additional hardships for patients with limited access to transportation services.

Projected Use Rate for Ambulatory Surgery

The application contains a detailed discussion supporting the contention that the use rate for outpatient surgery will increase as a result of a licensed ambulatory surgery center in Burke County. However, the applicants did not provide evidence supporting an increasing use rate for ambulatory surgery services. First, the number of operating rooms available to Burke County residents will remain unchanged as a result of this project, only a licensing designation will change. Secondly, the new ambulatory surgery center will be located in Valdese rather than in Morganton, the location of the greatest population concentration in Burke County. Uncertainties over future health insurance coverage are also likely to dampen the growth of outpatient surgery volume given the county's socio-economic indicators. Finally, the projected increase in the ambulatory surgery use rate is also highly dependent upon the successful recruitment of physicians to Burke County. Given the level of unmet need for physicians in the county, difficulties may continue to hamper recruitment efforts to this rural area.

Projected Utilization for Outpatient Operating Rooms

The applicant provides the projected utilization of the operating rooms at BRHCSC on page 43 and assumes that the volume of outpatient surgery cases will grow at 3.3% annually. This rate is based on the growth of cases at the Valdese facility between calendar years 2013 and 2016. However, as the same table illustrates, there was very little growth in the total volume of outpatient surgical cases at both CHS hospitals between 2014 and 2016, a CAGR of only 0.74%. Therefore, assuming an annual growth of outpatient surgery of 3.3% per year likely overstates the volume of surgical cases to be performed at BRHCSC.

The projected utilization of the operating rooms at the proposed BRHCSC also assumes that 80% of outpatient surgical cases that would otherwise be performed at the Morganton hospital will be shifted to the Valdese facility. However, the applicant provides no quantitative data to support this assumption. Neither does the applicant describe the impact of such a shift on the OR utilization at CHS Blue Ridge-Grace. Should, as assumed, 80% of CHSBR-Grace's outpatient surgery volume shift to the new surgery center at Valdese, the need for ORs at Morganton would fall from 4.3 to 3.0, significantly below the 10 ORs currently licensed to operate (9 shared and 1 inpatient OR) at CHS Blue Ridge-Grace.

As a result of these observations the applicant fails to sufficiently justify the need for the project described.

CON Review Criterion 3a

In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

As described in response to Criterion 3, the applicants failed to adequately demonstrate that the needs of the population of Burke County are best met by locating a new free-standing ambulatory surgery center in Valdese.

CON Review Criterion 4

Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

The application proposes to utilize existing OR and endoscopy resources at CHS Blue Ridge-Valdese. However, as described in response to Criterion 3, the application fails to demonstrate that the proposal represents the most effective alternative.

CON Review Criterion 5

Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

The application does not adequately support the projected utilization of the proposed BRHCSC. As a result, the financial projections are not fully supported.

CON Review Criterion 6

The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

The application describes plans to utilize the existing four (4) operating rooms located at the CHSBR-Valdese hospital. However, the proposal does nothing to reduce the excess number of operating rooms that presently exist in Burke County. In fact, an excess of operating rooms exists for all counties contained in the applicant's proposed service area. This application will result in a continued duplication of existing operating rooms in Burke and surrounding counties.

Table 5
Proposed 2017 SMFP Projected Operating Room Need for 2019

| Proposed Service Area Counties | Deficit/ Surplus (-) |
|-----------------------------------|-------------------------|
| Burke County | -4.13 |
| Caldwell County | -2.95 |
| Catawba County | -2.08* |
| McDowell County | -2.03 |
| Total SA | -11.19 |

*Note: OR need projections for Catawba County exclude 21 operating rooms at Frye Regional Medical Center due to chronic under utilization.

CON Review Criterion 7

The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

The application does not provide sufficient evidence of the availability of physicians necessary to generate the number of surgical cases projected in the application. On page 33 the applicant provides data from its physician need analysis showing a net need of 21 physicians, including four (4) general surgeons, three (3) gastroenterologists, three (3) orthopedic surgeons, two (2) urologists and one (1) otolaryngologist. Many of the physician specialties identified as needed are those instrumental to the success of this project and the feasibility of the projections provided. Given its rural location and lower-than-average economic conditions, recruiting these surgical specialties may be difficult. The inability to provide a number of surgeons sufficient to generate the surgical cases projected in the application creates serious questions regarding the financial feasibility of the project.

CON Review Criterion 8

The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

The application is heavily dependent upon the successful recruitment of surgeons to support the projections contained therein. Given past difficulties in recruiting and retaining physicians, it is unclear whether future efforts will yield results adequate to generate the number of cases projected in the application.

CON Review Criterion 9

An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

The application does not conform to Criterion 9 for the reasons provided in response to Criterion 3.

CON Review Criterion 12

Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

The application does not justify the need for the proposed project. As a result it does not conform to Criterion 12.

CON Review Criterion 13

The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- a. The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;*
- b. Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;*
- c. That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and*
- d. That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.*

As described in response to Criterion 3, the projected payer mix for the proposed BRHCSC is significantly lower for Medicare and self-pay/charity patients than the percentage currently treated at both hospital-based operating rooms. In addition, the percentage of Medicare and Medicaid patients projected to be served by the new free-standing GI endoscopy rooms in Valdese are significantly higher than the

percentage of Medicare and Medicaid patients treated at Carolina Diagnostic Services, PLLC which is owned by the same parent company, Blue Ridge Healthcare Systems, Inc. The applicant failed to provide an explanation of the difference between the two endoscopy facilities. This raises questions about the financial accessibility to endoscopy resources in future.

Table 6

| Payer Source | OP Surg | | | Endoscopy | |
|--------------|------------|------------|------------|------------|------------|
| | BR-Vald | BR-Morg | BRSC | CDS | BRSC |
| SP/Charity | 4.1% | 4.1% | 3.3% | 0.4% | 1.3% |
| Medicare | 41.0% | 41.0% | 32.7% | 36.6% | 51.6% |
| Medicaid | 15.3% | 15.3% | 23.0% | 7.1% | 16.3% |
| Comm Ins | 35.5% | 35.5% | 35.7% | 54.3% | 27.3% |
| Managed Care | incl above | incl above | incl above | incl above | incl above |
| Other | 4.1% | 4.1% | 5.2% | 1.5% | 3.5% |
| Total | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |

Source: Data for BRSC excerpted from CON application
 Remaining data excerpted from 2017 License Renewal Applications for CHS Blue Ridge and Carolinas Digestive Services

CON Review Criterion 14

The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

The application fails to justify the need for the project. As a result it does not conform to Criterion 14.

CON Review Criterion 18a

The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

The application does not conform to Criterion 18a for the following reasons.

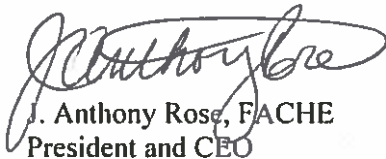
The application will not improve competition for ambulatory surgery services in Burke County. The only existing provider of ambulatory surgery services currently located in the applicant’s primary service area is CHS Blue Ridge. According to the application, Blue Ridge HealthCare Systems, Inc. will remain the parent company of both hospitals in Burke County, Carolinas Digestive Care, PLLC, as well as the proposed Blue Ridge Surgery Center. Therefore, the proposal does nothing to improve competition for health services in Burke County.

Summary

Based on the information provided in these comments, the CON application filed by Blue Ridge HealthCare Hospitals, Inc. and Blue Ridge HealthCare Surgery Center, LLC does not conform to all applicable review criteria and should not be approved. The deficiencies in the application that are noted in these comments are intended to apply to all relevant review criteria whether or not those deficiencies are expressly reiterated in the context of a specific criterion.

Thank you in advance for your consideration of these comments as you review the application.

Yours truly,



J. Anthony Rose, FACHE
President and CEO